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(54) **Title**: METHODS AND SYSTEM FOR FILLING IV BAGS WITH THERAPEUTIC FLUID

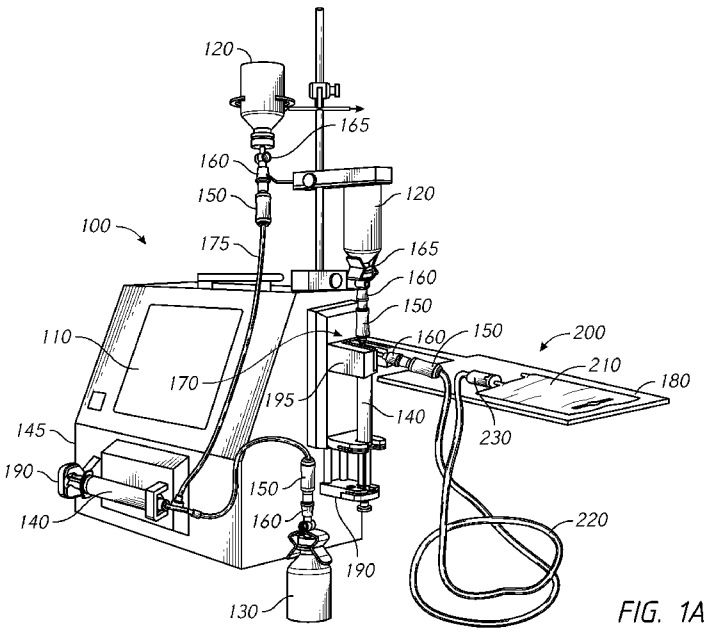


FIG. 1A

(57) **Abstract**: A. portable electronic fluid dispensing system can provide pre-filled, pre-primed IV bag assemblies comprising therapeutic fluids. The same fluid line and connector in the IV bag assembly can be used to fill the IV bag as is used to withdraw fluid from the IV bag and infuse such fluid into the patient. The connection points along the IV assembly, such as the connection between the IV bag and a drip chamber, or between an IV bag and tubing, or between a drip chamber and tubing, or between tubing and a closeable, reseable connector, can each be resistant to disconnection by a user. The healthcare practitioner at the patient care site is not required to attach any of these components to each other, and the healthcare practitioner at the patient care site is not required to introduce a spike into a spike port on the IV bag.

WO 2015/077184 A1

METHODS AND SYSTEMS FOR FILLING IV BAGS WITH THERAPEUTIC FLUID

RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 61/908,674, filed on November 25, 2013, and entitled "Method and Systems for Filling IV Bags with Therapeutic Fluid," the entire contents of which are incorporated by reference herein and made part of this specification.

BACKGROUND

Field

[0002] This invention relates generally to medical fluid systems, and specifically to systems for providing IV fluid to patients.

Related Art

[0003] In a typical hospital setting, when a patient is in need of intravenous fluid therapy, a healthcare practitioner: (i) obtains a pre-filled IV bag that has a large port with a flexible septum; (ii) wipes an antiseptic pad across the septum; and (iii) pierces the septum of the bag with a large, hollow spike. The septum forms a seal around the spike. The spike is connected to empty medical tubing, which in turn may be connected to a fluid connector.

[0004] The medical tubing is configured to convey medical fluid from the IV bag to the patient; however, before the tubing can be connected in fluid communication with the patient, it must be "primed" with liquid to avoid introducing air or vapors from the liquid into the patient's vasculature, which could be very harmful. To prime the tubing, the healthcare practitioner positions the IV bag at a higher location than the tubing, and sometimes squeezes the IV bag, permitting gravity and liquid pressure to drive the liquid in the IV bag downward in a column through the tubing, pushing the air and vapors in the tubing out the bottom end of the tubing. When the column of liquid reaches the bottom end of the tubing, a small amount of liquid is typically permitted to drip out of the end of the tubing, or out of the end of a connector attached to the end of the tubing, into a trashcan or sink, to ensure that no residual air or vapors remain in the fluid line.

[0005] The process of spiking the IV bag and priming the fluid line requires significant time and attention from the healthcare practitioner at the patient care site, and

also requires that multiple components be inventoried at the patient care site. In addition, there are many inherent disadvantages with the bag-spiking process. The tip of the spike is sharp and can inadvertently puncture the healthcare provider or patient. The spike or the septum of the spike port can carry microbes, if not properly disinfected, that may be introduced into the IV fluid when attached. The connection between the spike and spike port may leak if connected improperly. Also, the priming process can permit a small amount of vapors and liquid to escape, which can be dangerous, especially if the liquid is potential harmful, such as chemotherapy or immunosuppressive drugs.

[0006] Moreover, in many healthcare treatment settings, a large number of IV bags need to be filled with customized amounts and types of drugs on a daily basis for many different patients. If performed manually, this repetitive task is susceptible to mistakes by healthcare technicians. It can also continuously expose healthcare technicians to harmful medicinal vapors, and it can be a physically difficult chore for a healthcare technician, especially when using a large-diameter filling syringe in which the syringe plunger is especially wide and hard to push forward and back.

SUMMARY OF SOME EMBODIMENTS OF THE DISCLOSURE

[0007] In some embodiments, a portable electronic fluid dispensing system can provide pre-filled, pre-primed IV bag assemblies comprising therapeutic fluids in particular amounts and/or particular concentrations that are custom-made for a particular patient. The IV bag assembly in some embodiments can form a part of a substantially entirely closed fluid system. The same fluid line and connector in the IV bag assembly can be used to fill the IV bag as is used to withdraw fluid from the IV bag and infuse such fluid into the patient. The connection points along the IV assembly, such as the connection between the IV bag and a drip chamber, or between an IV bag and tubing, or between a drip chamber and tubing, or between tubing and a closeable, resealable connector, can each be resistant to disconnection by a user. In some embodiments, the healthcare practitioner at the patient care site is not required to attach any of these components to each other, and/or the healthcare practitioner at the patient care site is not required to introduce a spike into a spike port on the IV bag.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] Figure 1A is a perspective view of a portable electronic medical fluid dispensing system in fluid communication with an example of an IV assembly comprising an integral liquid delivery path;

[0009] Figure 1B is a perspective view of the electronic medical fluid dispensing system of Fig. 1A in fluid communication with another example of an IV assembly comprising an integral liquid delivery path;

[0010] Figure 2 is a top view of the IV assembly with an integral liquid delivery path as shown in Fig. 1;

[0011] Figure 3 is a cross-sectional view of two examples of male and female connectors among many types that can be used in one or more fluid delivery systems; and

[0012] Figure 4 shows a pre-filled, pre-primed IV assembly with an integral liquid delivery path in liquid communication with a patient.

DETAILED DESCRIPTION OF SOME EMBODIMENTS

[0013] The components, systems, assemblies, and methods that are illustrated or described in this specification are examples. Any component, structure, feature, or step illustrated or described in one embodiment can be used in additional to or instead of any component, structure, feature, or step illustrated or described in another embodiment. There is no component, structure, feature, or step in this specification that is essential or indispensable to the invention.

[0014] As shown in Figures 1A and 1B, an electronic fluid delivery system 100 can comprise an external housing 145 containing or supporting various internal components, such as a power regulator, a microprocessor, a drive motor, a driving mechanism (e.g., gearing), a memory, and communications hardware and software to enable electronic communication with a network or with one or more peripheral devices, such as a printer to produce a label or a report with information about a particular fluid delivery process that has been performed. The electronic fluid delivery system 100 can also comprise an electronic display and/or a user input system 110, one or more replaceable liquid source containers 120 filled with medical liquid (such as liquid medical vials as shown), one or more liquid pumps and/or liquid measurers 140 (such a syringe pump as shown), and/or one or more drive systems 190 functionally coupled to the liquid pumps and/or liquid measurers 140.

[0015] The electronic fluid delivery system 100 can be configured to receive one or more commands from a user through the user input system 100, or in some other way. The user command or commands can initiate a delivery of a particular type of one or more medications in a particular volume or concentration. Upon receiving a liquid delivery command, the electronic fluid delivery system 100 can cause the drive system 190 to actuate the liquid pump and/or measurer 140 to withdraw an amount of liquid from a liquid source container 120, move it through a fluid pathway or channel in the electronic fluid delivery system 100, and push it into a fluid destination container, such as an IV assembly 200, as shown. The fluid pathway or channel can comprise a number of different structures of the electronic fluid delivery system 100 through which liquid passes as it progresses from the liquid source container 120 to the fluid destination container 200.

[0016] An adapter, such as a vial adapter 165, as shown, can provide an interface between the liquid source container 120 and the fluid channel. The adapter can comprise a hollow spike (not shown) for penetrating a septum on a liquid vial to access the liquid contained in the vial. In some embodiments, a plurality of different liquid source containers 120, fluid channels, pumps, and/or liquid destination containers 130, 210 can be provided. In some embodiments, a plurality of different liquid source containers 120 with different medical fluids, such as different types of drugs, can be available to infuse in a specified combination into the same destination container 130, 210.

[0017] In some embodiments, a support 180 can be provided for supporting a liquid destination container. As illustrated, the support 180 can be oriented in a substantially horizontal position, but many other types of supports can be used, including substantially vertical supports such as hangers. The support 180 can provide a platform and/or a location to hold onto or secure an IV assembly 200 comprising an IV bag 210, a drip chamber 230, a tubing 220, and a fluid-line connector, such as a closeable male luer connector 150, as shown.

[0018] The IV assembly 200 can be removably attached to and/or in fluid communication with the fluid pathway or channel in the electronic fluid delivery system 100, which can include one or a plurality of an adapter, a pump, a connector (such as a resealable, needleless male or female luer connector 150, 160), tubing, and a removable, disposable fluid transfer cartridge 170. None of the foregoing components is essential or

indispensable; rather, various other types of components can be used instead of or in addition to those listed. For example, in some embodiments, an open-ended male or female fluid connector can be used instead of a resealable, needleless connector, especially in embodiments involving benign fluids with clamps or stop-cocks in the fluid line. Various components of the fluid channel in the electronic fluid delivery system 100 can be removed and replaced, such as the liquid source container 120, the IV assembly 200, the syringe pump 140, and the cartridge 170, which can each form a portion of the fluid channel when attached. Each of these components can form a repeatably resealable connection with the fluid channel, and when detached from the fluid channel, each of these components can comprise a sealed end that prevents conveyed or residual fluid from leaking out after disconnection. The resealable connections at each point of removable attachment in the fluid channel can be made using a series of male and female needleless luer connectors 150, 160.

[0019] The electronic fluid delivery system 100 can be positioned in a fume hood and the fluid transfer can be performed in the fume hood; however, in some embodiments, as shown, any fumes and fluid are maintained inside of a closed system, so it is not required to use the system 100 in a fume hood. In some embodiments, fluid progresses under the influence of back and forth motion of the fluid pump 140, in a substantially closed system from a liquid source container 120, through the fluid channel of the electronic fluid transfer cartridge 170, and to the fluid destination container 200, which substantially entirely prevents liquids and vapors from escaping during fluid transfer. As used herein, unless otherwise indicated, the terms "substantially entirely prevents," or "substantially entirely closed" or "substantially entirely closed system" and related or similar terms refer to processes and systems in which vapors and liquids are maintained inside a bounded region during normal usage and operating conditions to the degree that it is needed to avoid clinically significant adverse effects on healthcare practitioners or patients. Also, in some embodiments, each removable component (such as the cartridge 170, or the source container 120 and vial adapter 165, or the IV assembly 200) that temporarily forms part of, or that is temporarily attached to, the fluid channel in the electronic fluid transfer system 100 can separately form a resealable, substantially entirely closed fluid system within itself, which substantially entirely prevents liquids and vapors from escaping during fluid transfer, and which can dramatically lower or eliminate

the amount and frequency of exposure of healthcare practitioners to harmful liquids and vapors during preparation and transfer of harmful fluids.

[0020] The fluid transfer cartridge 170 can comprise a disposable portion of the fluid channel of the electronic fluid delivery system 100 that selectively directs fluid out of one or more fluid source containers 120 and into one or more fluid destination containers 210. The fluid transfer cartridge 170 may include one or more internal valves (not shown) to permit liquid to move in one direction away from a fluid source container 120 and toward a fluid destination container 210, while resisting unintended flow in an opposing direction. As illustrated, the fluid transfer cartridge 170 can comprise one or more closeable, resealable, needleless connectors, such as closeable male and female connectors 150, 160, that are configured to connect to other portions of the fluid channel within the electronic fluid delivery system, such as an adapter on the fluid source container 120 and a connector on the fluid destination container 210. The fluid transfer cartridge can be supported or held in place by a holder 195. As used in this specification, unless otherwise specified, the terms "connect," "attach," "hold," and related or similar terms are contemplated in a broad sense to refer to structures that are joined together, either directly or indirectly, to each other or to a common structure, and these terms can encompass parts that are either separable or integral with each other.

[0021] In some embodiments, as illustrated, the electronic fluid delivery system 100 can comprise multiple fluid pathways or channels for delivering different types of medicinal liquids. For example, a first pathway or channel can be configured to supply a first type of liquid (e.g., an inert or benign liquid such as water, saline solution, electrolyte liquid, or other diluent) from a first liquid source container 120, through a first fluid line 175, through a first pump or measurer 140, to a first fluid destination container 130, and a second pathway or channel can be configured to supply a second type of liquid (e.g., one or more drugs or combinations of drugs, such as a chemotherapy drug, an antibiotic, an immunosuppressive drug, and/or a pain management drug, etc.) from a second liquid source container 120, through a second fluid pathway to a second pump or measurer 140, to a second fluid destination container, such as the IV assembly 200. In some embodiments, both the first and second fluid pathways or channels can be used to fill the same fluid destination container, such as the IV assembly 200, either serially or in parallel, and/or through the same fluid port on the fluid destination container, or through multiple, different fluid ports on the same fluid destination container.

[0022] Referring to Figure 2, an example of a fluid destination container in the form of an IV assembly 200 is illustrated. Many other types or configurations of IV assemblies, and many other types or configurations of fluid destination containers, can be used in addition to or instead of the illustrated embodiment. Any reference in this specification to an IV bag or an IV assembly should be understood to also refer to and be applicable to any other type of fluid destination container, including but not limited to any bottle, vial, cartridge, syringe, chamber, bag, tank, or other enclosure. In its initial state, the IV assembly 200 comprises an empty, substantially flat IV bag 210 that can be formed in some embodiments by two layers of flexible plastic joined along substantially their entire peripheries, a long tubing 300, and a closeable needleless connector (if used), such as a closeable male luer connector 150, as illustrated. In some embodiments, as shown, the IV assembly 200 can comprise one or more additional fluid-line ports (if used), including one or more input or output ports, such as a needleless closeable female luer connector 160 and/or a pierceable septum connector 250, either or both of which can be configured to permit fluid to be added to or removed from the IV bag 210 by attaching another medical implement, such as a syringe or connector, to either or both of the input or output ports. The one or more additional fluid ports can be configured to permit filling of the IV assembly 200 with different types of liquids through different ports of the IV assembly 200. For example, a first type of fluid, such as one or more active or potentially harmful therapeutic fluids (e.g., chemotherapy drugs or immunosuppressive drugs), can be infused through a first port 160, and a second type of fluid, such as one or more inert or benign liquids (e.g., water, saline, or other diluent), can be infused through a second fluid pathway, such as the connector 150 and tubing 220. However, in some embodiments, all liquids can be passed into and out of the IV assembly 200 through a single fluid line and connector.

[0023] In some cases, if the fluids are passed through a single fluid line and connector, different types of fluids can be used to fill the IV assembly 200 in series (e.g., first the active drugs and/or potentially harmful drugs, and second the benign liquids such as water, saline, or other diluent). In some cases, if the fluids are passed through different fluid lines and connectors, different types of fluids can be used to fill the IV assembly 200 in parallel or generally simultaneously, and such an arrangement can in some embodiments accomplish the filling in a shorter amount of time. Further, in some cases, filling different drugs through different ports in the same IV assembly 200 can help to

achieve a more thorough mixing and generally uniform dilution and concentration of the liquids in the IV bag. Also, when the active or potentially harmful drugs are passed through the alternative or non-patient infusion line 160, 250, parallel infusion can help to avoid positioning harmful drugs in the leading fluid connector 150 or infusion fluid tubing 220 during transportation and initial opening of the fluid line in the IV assembly at the patient care site. In some embodiments, as shown, the IV assembly 200 can comprise a drip chamber 230 in the patient infusion fluid line.

[0024] In the illustrated embodiment, the drip chamber 230 is connected, or bonded directly, permanently, and irreversibly, to a bottom opening in the IV bag 210 at the IV bag-drip chamber bond 260, the long tubing 300 is connected, or bonded directly, permanently, and irreversibly, to a bottom opening in the drip chamber 230 at the drip chamber-tubing bond 290, and a needleless closeable connector, such as a closeable male luer connector 150 or a closeable female luer connector (not shown in Figure 2), is connected, or bonded directly, permanently, and irreversible to a bottom end of the long tubing 220 at the tubing-connector bond 300. In some embodiments, the long tubing 300 is connected, or bonded directly, permanently, and irreversibly, to a bottom opening in the IV bag 210, without a drip chamber 230. Either or both of the additional fluid-line ports can be bonded directly, permanently, and irreversibly to bottom openings in the IV bag 210 at the IV bag-pierceable septum connector bond 270 and/or at the IV bag-connector bond 280. The bonding at any of the bonding regions 260, 270, 280, 290, 300 can be accomplished in any suitable manner, such as using adhesive, solvent, ultrasonic welding, thermoforming, heat staking, one-way screwing attachment, snap-fit, interference fit, etc. In some embodiments, the permanence of these bonds helps to achieve a closed system and to diminish the risk of entry of microbes into the IV line and to diminish the risk of exposure of dangerous fluids or vapors to healthcare practitioners and patients. The permanence of these bonds can help to avoid inadvertent removal or pulling out of a fluid line (such as by tugging on a bag spike that has been inserted through a bag port). In some embodiments, one or more of the connection points between any of these components 210, 230, 220, 150 can comprise a rotating or swiveling connection to help avoid tangling or kinking of the tubing 220.

[0025] In some embodiments, the tubing 220 can be sufficiently long so as to extend comfortably, without creating a disruptive degree of fluid-line tension and without unduly constraining the patient's movement, from a typical position on or near the IV bag

210 in a hanging position on an IV pole (see Figure 4) or other holder to a region near a fluid pump or near a patient in a lying position on a standard hospital bed, such as at an attachment point with another fluid connector (e.g., a needleless closeable female luer connector 160), that is attached to a fluid line that extends into the patient. In some embodiments, the tubing is at least about 2 ½ feet (30 inches) long, or least about 3 feet (36 inches) long, or between about 2 ½ feet long and about 3 ½ feet long, or between about 30 inches long and about 100 inches long. In some embodiments, the tubing can be formed from an extruded, continuous, homogeneous material, with substantially the same thickness, durometer, flexibility, diameter, and/or tension strength from one end of the tubing to the other end of the tubing or from the connection point at the IV bag 210 or drip chamber 230 to the resealable connector 150.

[0026] As illustrated, in some embodiments, the fluid pathway within the IV assembly 200 is configured to be open and in continuous fluid communication from a location within the IV bag 210, through the drip chamber 230 and/or tubing 220, to the closeable connector 150, without any blockage, valve, obstruction and/or resistance to fluid flow. In some embodiments, the fluid pathway in the IV assembly 200 is integral: the connections between the components forming the fluid pathway within the IV assembly 200, from a location within the IV bag 210, through the drip chamber 230 and/or tubing 220, to the closeable connector 150, are configured to be permanent and/or to resist disconnection by a user at any point within the fluid delivery pathway within the IV assembly 200 from the IV bag 210 to the patient.

[0027] Figure 3 illustrates some examples of closeable or resealable needleless male and female luer connectors 150, 160 that can be used with the inventions disclosed in this specification. Many other types of connectors can be used, including open-ended connectors and/or non-standard connectors, in appropriate circumstances. In some embodiments, as illustrated, the connectors are standard IV medical luer connectors, e.g., compliant with the ISO 594 standard. Any reference in this specification to a male connector should be understood to be interchangeable with a female connector, and any reference in this specification to a female connector should be understood to be interchangeable with a male connector, with appropriate adjustments. In some embodiments, fluid connector adaptors can be used to make appropriate connections between fluid lines. For example, in a situation where two male fluid connectors must be joined to complete a fluid pathway, an adaptor comprising a pair of female fluid

connectors positioned in opposite directions on the fluid pathway and joined together with a fluid conduit or tubing can be attached to the male fluid connectors. In some embodiments, such an adaptor can be used, for example, to connect a cartridge 170 and an IV assembly 200 in which a male luer connector is positioned at the exit port of the cartridge 170 and a male luer connector is positioned on the end of the tubing 220 of the IV assembly 200.

[0028] A first connector 150 can be a closeable male luer connector that is configured to prevent fluid from escaping from or entering into the connector when it is not engaged with a corresponding female connector 160, but that allows fluid to flow when it is engaged with a corresponding female connector 160. In the embodiments shown, the first connector 150 is a version of the Spiros® closeable male connector manufactured by ICU Medical, Inc., of San Clemente, California. The first connector 150 can be configured to be attachable to a second connector 160, which is illustrated as a version of the Clave® closeable female connector, also manufactured by ICU Medical, Inc.

[0029] The first connector 150 can include a housing 398, a valve member 400, a resilient member 402, a sealing ring 404, an end cap 406, and an O-ring 407. The housing 398 can be generally tubular in shape, and can include a passageway 408 that extends axially through the housing. The housing 398 can include a male luer tip 410 that connects to the rest of the housing 398 at a base 412. The luer tip 410 can be generally tubular in shape, and the luer tip 410 can include a hole 414 at its end, providing access to the passageway 408. As illustrated, in some embodiments, connectors can be used to substantially entirely prevent fluid therein to leak, vaporize, or otherwise escape through apertures in the fluid pathway when the connectors are closed.

[0030] The luer tip 410 can be generally surrounded by a shroud 418 as illustrated. In some embodiments, the luer tip 410 extends a distance beyond the edge 420 of the shroud. The shroud 418 can include inner threads 422 on its interior surface. The inner threads 422 can be used for securing a female connector 160. The shroud can include an indented portion 424 that has a smaller outer diameter than the other portions of the housing. The indented portion 424 can be configured to engage a portion of the resilient member 402.

[0031] The housing 398 can be constructed from a variety of materials. The housing 398 can be constructed from a rigid material such as polycarbonate or other

polymeric materials. In some embodiments, the housing 398 can be constructed from a hydrophobic material such as Bayer Makrolon, or any other suitable material. In some embodiments, the housing 398 can be formed from a substantially transparent material.

[0032] The connector 150 can include a fluid passageway 440 extending axially from an opening formed in a base portion 444 and into a tube 446. In some embodiments, the passageway 440 can be wider in the base portion 444 than in the tube 446. In some embodiments, the tube 446 includes a narrowed tip 448. In some embodiments, the tip 448 can have a tapered outer surface. In some embodiments, the tip 448 can be made from a flexible or compressible material, such as silicone rubber, to facilitate formation of the fluid seal between the tip 448 and the shelf 416. In some embodiments, the tube can include one or more holes 450 for providing access to the fluid passageway 440. The holes 450 can be formed, for example, in the tip 448 of the tube 446.

[0033] In some embodiments, the valve member 400 can include two struts 452a, 452b extending out from the base 444 and positioned on either side of tube 446, so that an open space is defined on either side of the tube. In some embodiments, the tube 446 can extend axially past the ends of the struts 452a, 452b. The valve member 400 can be constructed from a variety of materials, such as polycarbonate or other polymeric materials. In some embodiments, the valve member 400 can be constructed from the same material as the housing 398. In some embodiments, the valve member 400 and housing 398 can be constructed from different materials. In some embodiments, the valve member 400 can be constructed from multiple materials or from multiple pieces. For example, the tip 448 can be constructed from a material that is more flexible than the remainder of the valve member 400. In some embodiments, the valve member 400 can be formed from a substantially opaque material.

[0034] The resilient member 402 can include a first ring and a second ring connected to each other by longitudinally extending elastic members (not shown). The elastic members can be made from an elastic material that exerts a restoring force when stretched, such as silicone. Thus, if the rings are pulled apart, the elastic members function to restore the rings to their relaxed configuration. In some embodiments, the rings are also constructed from an elastic material, such as the same material used to form the elastic members. In some embodiments, the second ring can have a greater diameter than the first ring. In some embodiments, the second ring can have a tapered outer surface so that the

end of the second ring that is closest to the first ring is wider than the end of the second ring that is furthest from the first ring.

[0035] The sealing ring 404 can be generally cylindrical in shape, and can have a bore extending axially therethrough. The sealing ring 404 can have a cylindrical body section and an O-ring located at one end of the body section 468. The sealing ring 404 can be constructed from a variety of materials. In some embodiments, the sealing ring 404 can be constructed from a deformable or elastic material such as a silicone rubber.

[0036] The end cap 406 can include a first end cap member 405 and a second end cap member 409. The second end cap member 409 can include an attachment portion, a plunger, and a disk portion located between the attachment portion and the plunger. The second end cap member 409 can have a fluid passageway axially positioned therein. In some embodiments, the plunger can be generally tubular in shape. In some embodiments, the outer surface of the plunger includes an indented region, which can be configured to receive the O-ring 407 therein.

[0037] The O-ring 407 can be constructed from an elastic material such as silicone rubber so that it can be stretched over the edge of the plunger and be seated in the indented region. In some embodiments, the O-ring can be constructed from the same material as the resilient member 402 and/or the sealing ring. In some embodiments, the O-ring can be sized so that when seated in the indented region, the thickest portion of the O-ring 407 extends radially outwardly a distance past the outer surface of the plunger.

[0038] The valve member 400 can be slidably inserted into the housing 398 so that the tube 446 enters the passageway 408. The narrowed tip 448 of the tube 446 can pass through the bore of the sealing ring 404 and into the male luer tip 410 until it abuts against the shelf 416. The tube 446 can have a width that substantially fills the bore 446 and presses against the O-ring 470 portion of the sealing ring 404 to form a fluid seal therebetween. The struts 452a, 452b can pass through holes in the housing 398, so that the struts 452a, 452b are positioned between the male luer tip 410 and the shroud 418.

[0039] The resilient member 402 can function to bias the valve member 400 against the housing 398. The first ring 460 can fit onto the lower portion 458 of the base 444 of the valve member 400, so that a surface of the ring 460 abuts against the protrusions 454. The second ring 462 can fit into the indented portion 424 of the housing. The elastic members can be positioned in channels.

[0040] The first connector 150 can be configured to engage a second connector 160. In some embodiments, the second connector 160 can be a closeable, resealable, needleless female connector, as illustrated. A variety of types of female connectors 332 can be used. The female connector 160 shown includes a housing 490, a spike 492, a base 494, and a resilient seal element 496. A fluid passageway 498 can pass through the base 494 and through the spike 492. The spike 492 can include one or more holes 500 providing fluid communication between the passageway 498 and the area outside the spike 492. The seal element 496 can be shaped and positioned to substantially surround the spike 492. The seal element 496 can include a closable aperture 502 or slit that can open to allow the tip of the spike 492 to pass through then end of the seal element 496 when the seal element 496 is compressed. The housing can include external threads 504 configured to engage the inner threads 422 on the housing 398 of the male connector 150. An end of the tubing 334 can be connected to the end of the female connector 160 by an adhesive, clamp, friction or pressure fitting, or other suitable manner to form a fluid tight connection.

[0041] In some embodiments, the housing 398, sealing ring 404, resilient member 402, valve member 400, and first end cap member 405 can rotate about the longitudinal axis with respect to the second end cap member 409. Thus, as the female connector 160 of the IV bag assembly is attached to the male connector 150, the female connector 160 can be held still while the housing 398 of the male connector 150 can rotate causing the threads 504, 422 to engage. Since the female connector 322 is not required to rotate during engagement and disengagement with the male connector 150, the tubing 334 can avoid being twisted or kinked and the user is not required to twist the IV bag to accommodate rotation of the female connector 322.

[0042] When not engaged with the female connector 160, the male connector 150 can be sealed. In some embodiments, fluid can enter the male connector 150 at the male connector 352 and pass through the passageway 478 of the end cap 406, through the passageway 440 of the valve member 400, through the holes 450, and into the portion of the passageway 408 of the male luer tip 410.

[0043] When the male connector 150 is engaged with the female connector 160, the external threads 504 of the female luer connector 332 can engage the inner threads 422 on the shroud 418, securing the female connector 160 to the male connector 150. The edge of the male luer tip 410 can press against and compress the resilient seal

element 496 so that the spike 492 passes through the aperture 502 until the holes 500 are exposed. The end of the housing 490 of the female luer connector 332 can enter the space between the male luer tip 410 and the shroud 418 until it contacts the struts 452a, 452b. As the female luer connector 332 further engages the male connector 150, it can push on the struts 452a, 452b causing the entire valve member 400 to retract. As the valve member 400 retracts, the elastic members 464a, 464b of the resilient member 402 stretch. When the valve member 400 retracts, the tip 448 disengages from the shelf 416, breaking the fluid seal and allowing fluid pass from the passageway 408 in the housing 398 of the male connector 150 to the passageway 498 in the female connector 160 via the holes 500. When engaged, the resilient seal element 496 exerts a restoring force toward the male connector 150 that presses the end of the seal element 496 against the end of the male luer tip 410, forming a fluid seal therebetween. Thus, the fluid can be kept isolated from the external environment while it is transferred from the male connector 150 to the female connector 160.

[0044] The female connector 160 can be disengaged from the male connector 150. The restoring force exerted by the resilient seal element 496 of the female connector 160 can cause it to return to its closed position, sealing off its passageway 498. The elastic members of the resilient member 402 can exert a restoring force on the valve member 400, causing the valve member 400 to return to its closed position with its tip 448 abutted against the shelf 416 as the female connector 160 is disengaged. Any suitable connection can be provided at the fluid line connection points illustrated and/or described in this specification, including but not limited to those illustrated and/or described in connection with Figure 3. Other connectors and/or other features of connectors can be used in addition to or instead of those illustrated and/or described in connection with Figure 3.

[0045] Returning to Figures 1A and 1B, some methods of filling a custom IV assembly 200 with a particular amount or concentration of a therapeutic fluid or fluids for the needs of a particular patient or patients can comprise one or more or any combination of the following steps:

[0046] (i) obtaining, or instructing a user to obtain, a request from a healthcare practitioner or from a computer system for a custom-filled IV bag or a plurality of IV bags, each with a particular drug or drugs, and/or a particular dose or concentration of a drug or drugs, for a particular patient or patients;

[0047] (ii) obtaining, or instructing a user to obtain, an integral IV assembly 200 with one or more permanent, pre-attached bonds along an internal fluid path from an IV bag 210 through a resealable needleless connector 150, the IV assembly initially being empty of liquid or not completely filled with liquid;

[0048] (iii) attaching, or instructing a user to attach, one or more fluid inlets in the IV assembly 200 to one or more fluid dispensing outlets in the electronic fluid dispensing system 100, such as attaching a connector (e.g., a resealable, needleless male connector 150) of the IV assembly 200 to at least a first fluid channel of an electronic fluid dispensing system 100, such as by way of a complimentary connector 160 (e.g., a resealable, needleless female connector 160) in a disposable fluid cartridge 170 of the electronic fluid dispensing system 100, or by way of a suitable fluid connection adaptor, in the event that the connectors are not capable of forming a fluid connection (such as when a male-to-male connection or a female-to-female connection needs to be made);

[0049] (iv) providing, or instructing a user to provide, one or more user commands to the electronic fluid dispensing system to enable the transfer of a specific amount and/or concentration of a liquid or liquids from one or more fluid source containers 120 to the IV bag 210, such as by first passing fluid from at least one fluid source container 120 through a combination of one or more of an adaptor 165, one or more connectors 150, 160, a fluid cartridge 170, a liquid pump and/or measurer 140, and/or one or more connectors 150, 160, to the IV assembly 200, then permitting the fluid to continue progressing into the connector 150 of the IV assembly 200, into the long tubing 220 of the IV assembly 200, through the drip chamber 230 (if included) of the IV assembly 200, and into the IV bag 210, until the desired amount and/or concentration of the drug or drugs is received in the IV bag 210 (as illustrated, for example, in Figure 1A), and/or providing one or more additional fluid filling lines in series or in parallel from the electronic fluid dispensing system 100 to the IV bag 210 (as illustrated, for example, in Figure 1B), in either manner in some embodiments filling the IV bag 210 and pre-priming the drip chamber 230, long tubing 220, and fluid connector 150, as part of the same step and/or at generally the same time as filling the IV bag 210;

[0050] (v) detaching, or instructing a user to detach, the IV assembly 200 from the electronic fluid dispensing system 100, such as by detaching the connector 150 of the IV assembly 200 from the corresponding portion of the fluid channel of the

electronic fluid dispensing system, and detaching any other fluid connections from any other fluid channels;

[0051] (vi) transporting, or instructing a user to transport, the custom-filled IV assembly 200 to a patient care site;

[0052] (vii) hanging or otherwise positioning, or instructing a user to hang or otherwise position, the IV bag 220 on an IV pole near a patient, such as by using a hanger 240 on the IV bag 220, or positioning the IV bag 220 on or in another type of holder; and/or

[0053] (iix) extending, or instructing a user to extend, the pre-primed long tubing 220 from the hanging IV bag to an infusion pump (not shown), which is in turn configured to pump fluid to a patient, or extending, or instructing a user to extend, the pre-primed long tubing 220 from the IV bag directly to an infusion site near a patient, and attaching the pre-primed, connector 150 of the IV assembly 200 to a complimentary connector 160 on a fluid line that leads into the fluid pump or directly into the patient's vasculature.

[0054] As illustrated in Figure 1B, in some embodiments in which the IV assembly includes multiple ports (also as shown in the example of Figure 2), the step of filling the IV assembly 200 can include multiple fluid connections between the electronic fluid dispensing system 100 and the IV bag 210. Different types of fluids can be infused through different ports. In some embodiments, to save time, different types of fluids can be infused in parallel, as illustrated in Figure 1B, generally simultaneously from the electronic fluid dispensing system 100 into the IV bag 210; however, in some embodiments, different fluids can be infused through different ports at different times.

[0055] All of the foregoing steps, or any combination of these steps, can be performed in some embodiments without requiring a healthcare practitioner to penetrate a spike-port on an IV bag with a hollow spike leading to a patient infusion line, and/or without requiring a healthcare practitioner to prime the fluid tubing, drip chamber (if used), and/or fluid connector (if used), of an IV assembly at or near the patient administration site and outside of a hazardous fume hood. As illustrated, in some embodiments, an IV bag can be provided without any spike-port at all or without any spike-port that has a septum configured to be pierced by a sharp spike. Rather, in some embodiments, the same fluid line in the IV assembly 200 can be used to fill the IV bag 210 with liquid in an upstream direction from the connector 150, through the long tubing

220 and drip chamber 230 (if used), to the IV bag 210, and then later to infuse the liquid from the IV bag 210 in a downstream direction through the same drip chamber 230 (if used), long tubing 220, and connector 150, to the patient injection site. The movement of liquid within the electronic fluid dispensing system 100 and/or the filling of the IV assembly 200 can be accomplished with any pump, such as a syringe pump or a peristaltic pump. In some embodiments, a syringe pump or a peristaltic pump is not used.

[0056] In some embodiments, during the IV assembly filling stage, after a desired quantity of therapeutic agent is delivered to the IV assembly 200, an additional volume of liquid, such as an inert or benign liquid, can be pushed through or made to "chase" the drug through the lower fluid pathway of the IV assembly 200, such as through the bottom connector 150, the tubing 520, the drip chamber 530 (if used), and/or into the IV bag 210, so as to flush or move any potentially harmful liquid or vapors an effective distance into the IV assembly 200 and away from persons who are transporting, storing, and/or administering the therapeutic liquid to a patient.

[0057] Figure 4 illustrates an example of a pre-primed IV assembly 500 at a patient care site that has been filled using some type of an electronic fluid dispensing system, such as the electronic fluid dispensing system of Figures 1A and 1B. The IV bag 510 of the IV assembly 500 is hung with a hanger 540 on an IV pole 550. The liquid 505 containing one or more therapeutic agents, such as antibiotics, pain management medication, chemotherapy, and/or immunosuppressive drugs, in the IV bag 510 moves under the influence of gravity from an exit location at the bottom of the IV bag 510, into the drip chamber 530 (if used), into the long tube 520, through the connectors 150,160, through the patient catheter 560, and into the patient 570. In some embodiments, the one or more therapeutic agents in the IV bag 510 move from the IV bag 510, into the drip chamber (530) if used, into the long tube 520, through the end connector on the IV assembly 500 if used, and into an input connector 160 (not shown) on an IV pump assembly (not shown). In the illustrated embodiment, the distance or length of the pre-primed fluid path of the IV assembly 500, from the exit location on the IV bag 510 to the resealable connector 160 on the patient catheter 560, is at least about 2 ½ feet and/or less than or equal to about 3 ½ feet, which is sufficiently long to provide a comfortable attachment distance between the IV bag 510 and the patient when the patient is in a generally flat position on a hospital bed or when the patient is sitting in a chair with a

generally horizontally extended arm. Many other types, configurations, and lengths of tubing can be used.

THE FOLLOWING IS CLAIMED:

1. A method of pre-filling custom IV bags, the method comprising:

obtaining an electronic fluid transfer system configured to receive instructions from a user regarding an amount of fluid to be transferred from one or more source containers into an IV bag;

obtaining a pre-assembled IV assembly comprising an IV bag, a tubing permanently bonded to the IV assembly in fluid communication with the IV bag, without requiring a user to attach the tubing to the IV assembly, and a connector permanently bonded to the tubing, without requiring a user to attach the closeable connector to the tubing, the connector comprising an open position and a closed position for providing a selectively accessible closed fluid system, and the tubing being sufficiently long to be configured to extend from a hanging position on a pole stand to a connector attached to a patient or to an infusion pump;

connecting the connector of the IV assembly to the electronic fluid transfer system, placing the IV assembly in fluid communication with the electronic fluid transfer system;

transferring fluid from one or more source containers in the electronic fluid transfer system, through the connector, then through the tubing, then into the IV bag, to produce a pre-primed IV assembly with fluid extending from the connector through the tubing and into the IV bag.

2. The method of claim 1, wherein the pre-assembled IV assembly further comprises a drip chamber permanently bonded to the IV bag and to the tubing.

3. The method of Claim 2, wherein the step of transferring fluid from one or more source containers in the electronic fluid transfer system comprises transferring fluid through the closeable connector, then through the tubing, then through the drip chamber, then into the IV bag.

4. A method of enabling a user to provide a pre-primed IV assembly filled with therapeutic medical fluid to a patient, the method comprising:

providing to the user an IV assembly comprising:

an empty IV bag with an outlet on a lower side;

a tubing with an upper end and a lower end, the tubing being permanently attached in fluid communication with the IV bag, the tubing being sufficiently long to be capable of extending from the outlet on the lower side of the IV bag

when the IV assembly is attached to a pole stand to an access point in an IV tube attached to the arm of a patient in a lying position; and

a closeable male luer connector with a first end and a second end, the first end of the closeable male luer connector being permanently attached in fluid communication with the tubing, the closeable male luer connector comprising an open position and a closed position for sealing fluid within the IV assembly; and

instructing the user to connect the IV assembly to an electronic system for filling IV bags, enabling the user to attach the closeable male luer connector to the electronic system and to fill the IV bag by pushing fluid up through the closeable male luer connector, through the tubing, through the drip chamber, and into the IV bag, without requiring the user to assemble or attach any of the IV bag, drip chamber, tubing, or closeable male luer connector to each other, to provide a closed, primed IV assembly that is ready to connect to an access point in an IV tube attached to a patient.

5. The method of Claim 4, in which the IV bag further comprises at least one access port for permitting additional fluid to be introduced into the IV bag or for permitting at least a portion of fluid that is introduced into the IV bag to be removed.

6. The method of Claim 5, in which the IV bag comprises at least two access ports.

7. The method of Claim 6, in which one of the access ports is a closeable female luer connector and one of the access ports comprises a pierceable septum accessible by a needle.

8. The method of Claim 4, in which none of the drip chamber, tubing, or closeable male luer connector comprises or is attached to a bag spike for piercing a septum on the IV bag for accessing the interior of the IV bag.

9. The method of Claim 4, in which the closeable male luer connector comprises a male end that includes an interior closure element that is flush with the male end in the closed position.

10. An IV bag assembly configured to be pre-primed by an electronic fluid delivery system, the IV bag assembly comprising:

an IV bag configured to contain therapeutic fluid;

a drip chamber configured to contain therapeutic fluid, the drip chamber being irreversibly attached to the IV bag;

a tubing irreversibly attached to the drip chamber, the tubing comprising a first end and a second end, the tubing being sufficiently long to be configured to extend from a hanging position on an IV pole to a patient vascular access site or to an infusion pump, the tubing being formed of a continuous, homogeneous material with substantially the same diameter and durometer from the first end to the second end of the tubing, and the tubing being filled with therapeutic fluid from the first end to the second end; and

a closeable male connector irreversibly attached to the second end of the tubing, the closeable male connector configured to be filled with therapeutic fluid;

wherein the IV bag assembly does not include a bag spike, is not configured to receive a bag spike, and is not assembled by piercing the IV bag with a bag spike.

11. A system of delivering therapeutic fluids comprising the IV bag assembly of Claim 10 and an IV pole or an infusion pump.

12. A system of delivering therapeutic fluids comprising the IV bag assembly of claim 10 and a patient vascular access site attached to a patient.

13. The pre-primed IV bag assembly of Claim 10, further comprising a closeable female luer connector permanently attached directly to the IV bag.

14. The pre-primed IV bag assembly of Claim 10, further comprising an infusion point comprising a pierceable septum.

15. The pre-primed IV bag assembly of Claim 10, wherein the tubing is at least about 30 inches long.

16. The pre-primed IV bag assembly of Claim 15, wherein the tubing is about 36 inches long.

17. A method of using the IV bag assembly of Claim 10 comprising the step of filling the IV bag assembly with therapeutic fluid.

18. The method of Claim 17, wherein the step of filling the IV bag assembly is accomplished with an electronic fluid dispensing device.

19. A method of providing therapeutic fluids to a patient comprising:

obtaining an empty, pre-assembled IV assembly comprising: (i) an IV bag; (ii) a drip chamber permanently bonded to the IV bag; (iii) a tubing permanently bonded to the drip chamber, the tubing being sufficiently long to extend from the drip chamber in a hanging position to a patient during use; and (iv) a connector permanently bonded to the tubing, wherein the IV assembly is not assembled by penetrating the IV bag with a bag spike;

attaching the empty IV assembly to an electronic fluid transfer system;

using the electronic fluid transfer system to transfer a first fluid from a source container through the connector, through the tubing, through the drip chamber, and into an opening in the IV bag, thereby priming the tubing and the closeable male connector during filling of the IV assembly;

conveying the IV assembly to a patient;

attaching the IV assembly to an IV pole or infusion pump;

connecting the connector to a needleless female connector access site that is in fluid communication with the patient's vasculature.

20. The method of Claim 19, wherein the connector is a closeable connector.

21. The method of Claim 20, wherein the connector is a resealable connector.

22. The method of Claim 21, wherein the connector is a needleless connector.

23. The method of Claim 22, wherein the connector is a male connector.

24. The method of Claim 23, wherein the connector is a luer connector.

25. The method of Claim 19, further comprising using the electronic fluid transfer system to transfer additional fluid from an additional source container into the IV assembly.

26. The method of Claim 25, wherein the additional fluid is different from the first fluid.

27. The method of Claim 26, wherein the additional fluid is infused through a second opening in the IV bag than the first fluid.

28. The method of Claim 27, wherein the additional fluid is a dangerous fluid.

29. The method of Claim 28, wherein the additional fluid is one or more chemotherapy drugs.

30. The method of Claim 28, wherein the additional fluid is one or more immunosuppressive drugs.

31. The method of Claim 27, wherein the additional fluid is infused at generally about the same time as the first fluid.

32. The method of Claim 27, wherein the second opening comprises a closeable connector.

33. The method of Claim 32, wherein the closeable connector is a resealable connector.

34. The method of Claim 33, wherein the resealable connector is a needleless connector.

35. The method of Claim 34, wherein the needleless connector is a female connector.

36. The method of Claim 35, wherein the female connector is a luer connector.

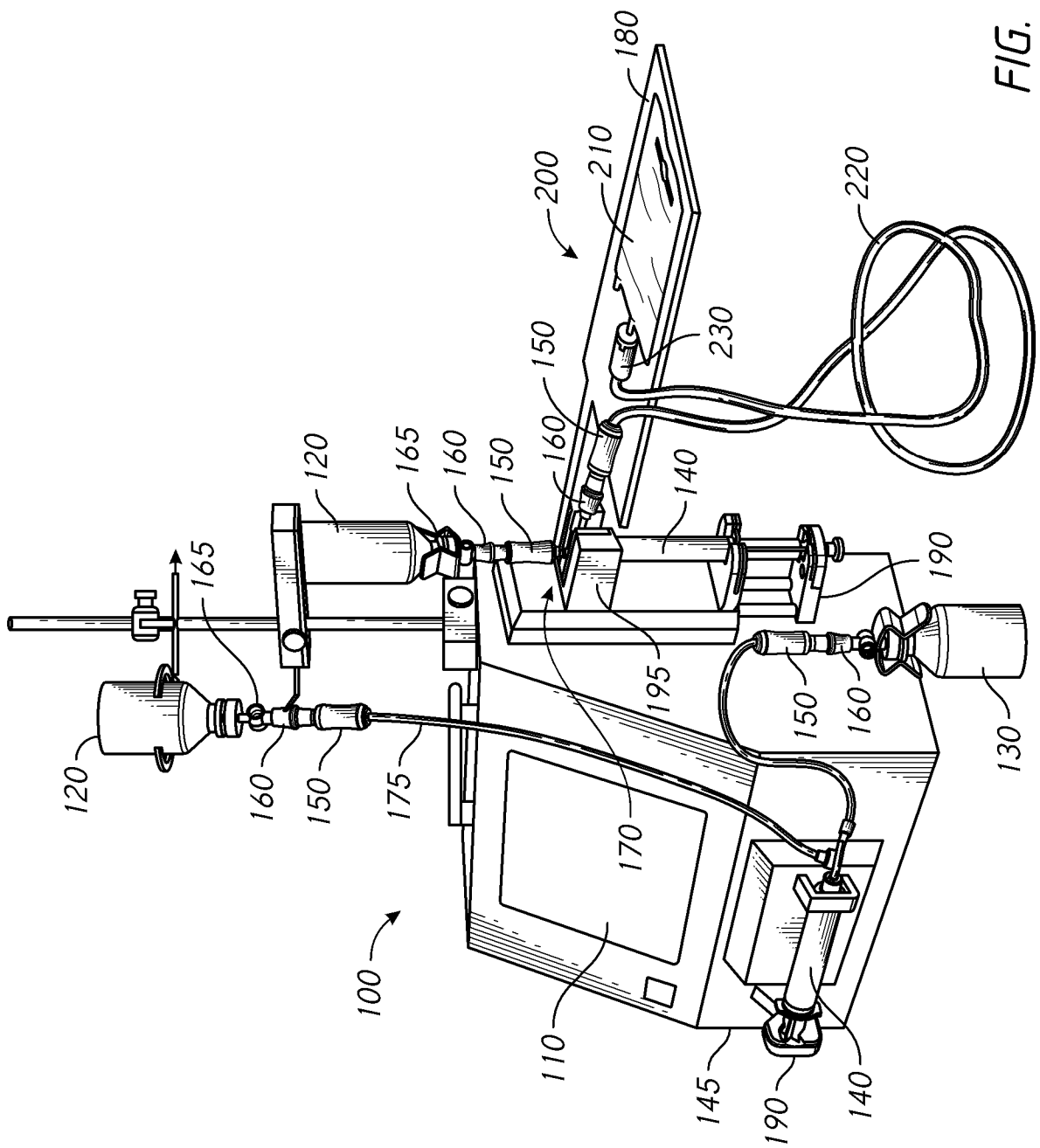

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FIG. 1A

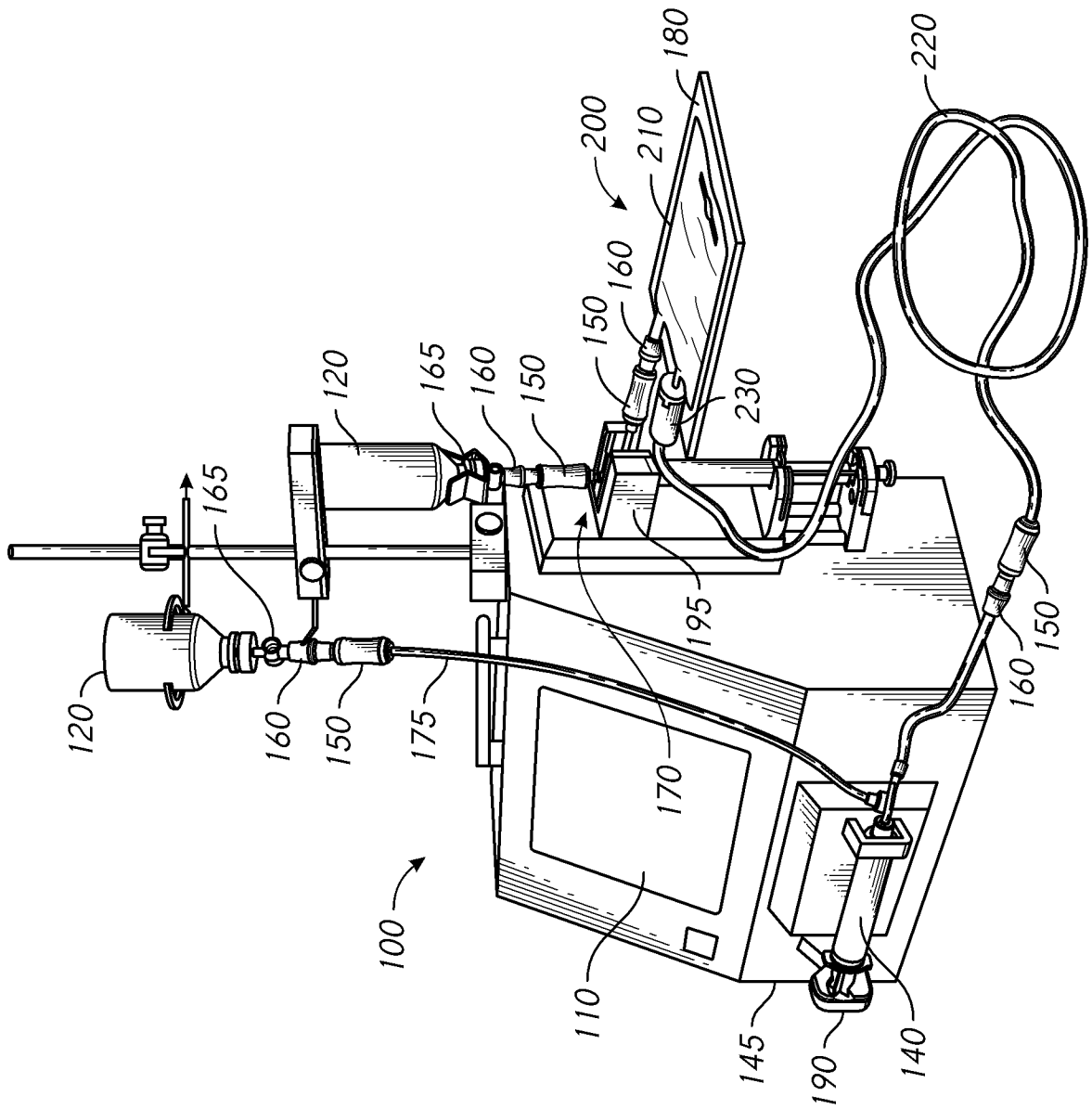

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FIG. 1B

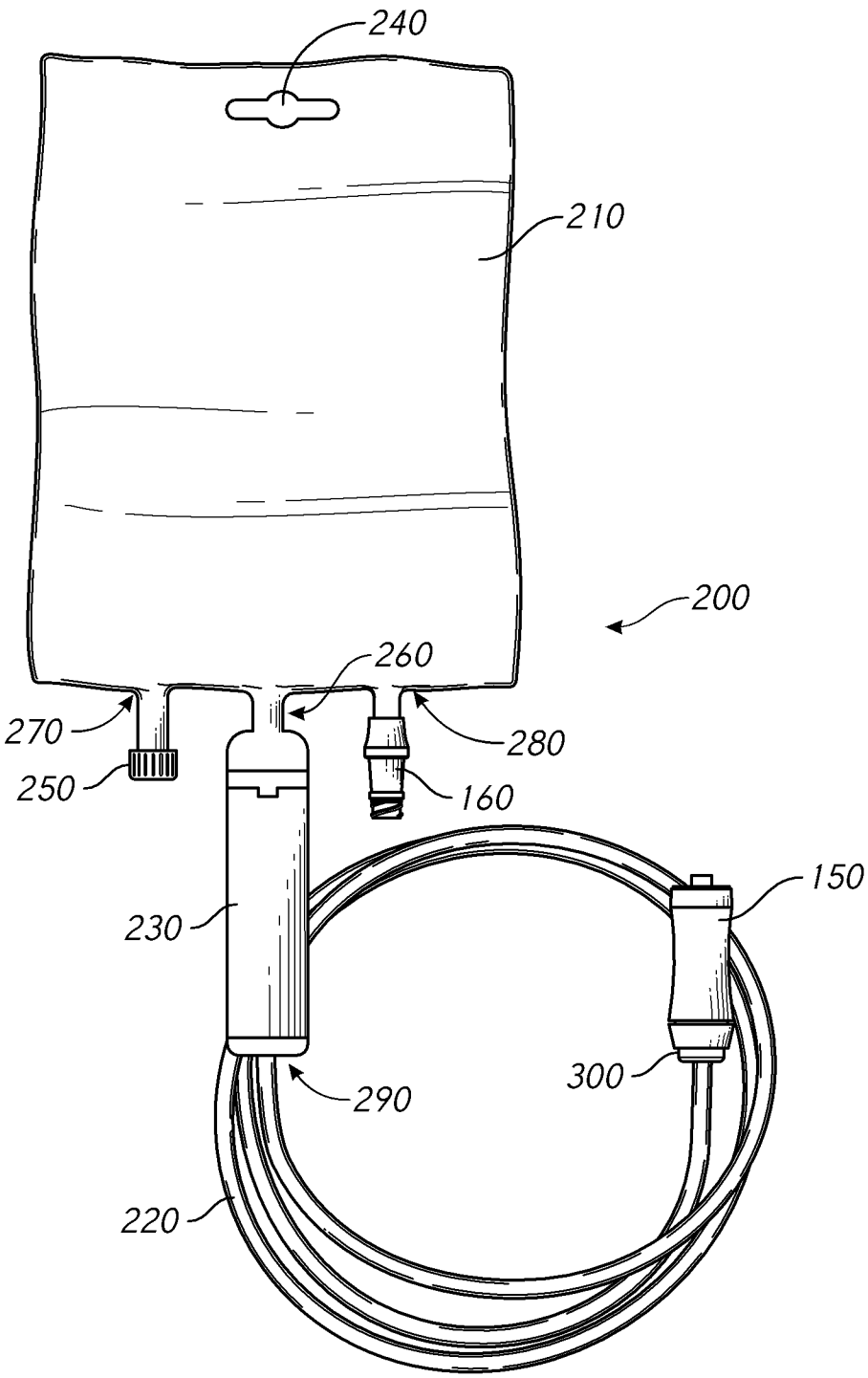


FIG. 2

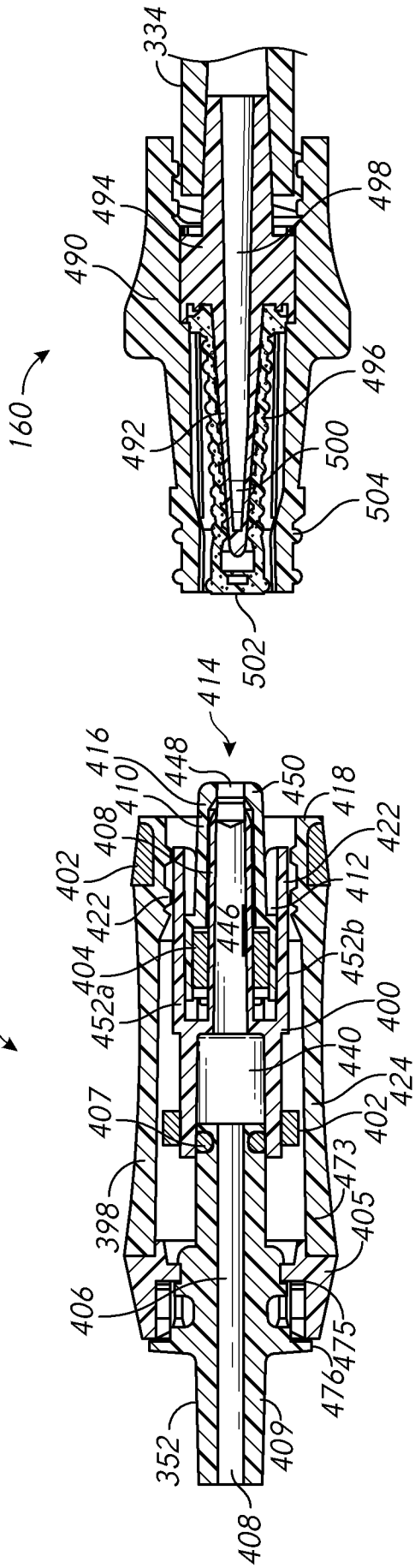

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FIG. 3

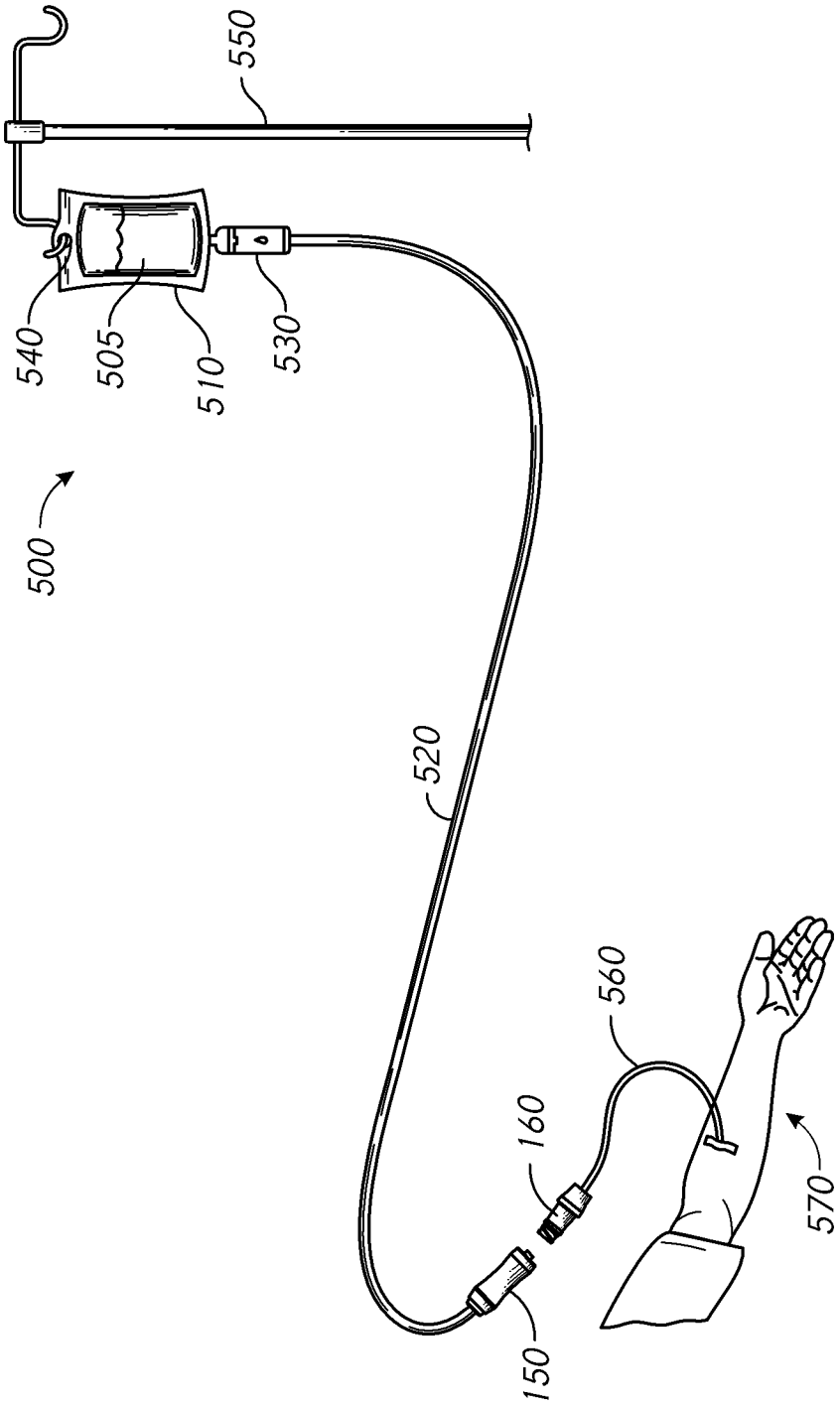


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/065972

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61J 1/20 (2015.01)
CPC - A61J 1/20 (2015.01)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61J 1/00, 1/10, 1/14, 1/20 (2015.01)
CPC - A61J 1/00, 1/10, 1/14, 1/20, 1/2093, 1/2096, 1/22 (2015.01) (keyword delimited)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC -137/561R; 604/403, 406, 408, 416

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase, Google Patents, Google.
Search terms used: IV bag, filling, mixing, system, luer connector, drip chamber, user instructions

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	WO 2013/096911 A1 (ICU MEDICAL INC) 27 June 2013 (27.06.2013) entire document	1-3 ----- 10-36
Y	US 2012/0041391 A1 (FANGROW et al) 16 February 2012 (16.02.2012) entire document	10-36
A	US 2011/0062703 A1 (LOPEZ et al) 17 March 2011 (17.03.2011) entire document	1-36
A	US 6,221,041 B1 (RUSSO) 24 April 2001 (24.04.2001) entire document	1-36
A	US 5,807,312 A (DZWONKIEWICZ) 15 September 1998 (15.09.1998) entire document	1-36

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 January 2015	24 FEB 2015
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)