(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
28 March 2013 (28.03.2013)

WIPO | PCT

(10) International Publication Number
WO 2013/043868 A1

(51) International Patent Classification:
A61M 5/142 (2006.01) *F04B 19/04* (2006.01)
A61M 5/145 (2006.01) *F16K 11/02* (2006.01)
F04B 15/00 (2006.01)

(21) International Application Number:
PCT/US2012/056328

(22) International Filing Date:
20 September 2012 (20.09.2012)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/537,371 21 September 2011 (21.09.2011) US

(71) Applicant: **MEDRAD, INC.** [US/US]; One Medrad Drive, Indianola, PA 15051 (US).

(72) Inventors: **CAPONE, Christopher, D.**; 3606 Windsor Court, Pittsburg, PA 15238 (US). **SEMAN, Richard, A.**; 249 Apple Hill Drive, Delmont, PA 15626 (US). **HAURY, John, A.**; 2514 Nicholson Road, Sewickley, PA 15143 (US). **PREM, Edward, K.**; 4027 Gwynedd Drive, Allison Park, PA 15101 (US). **BISEGNA, Joseph, E.**; 63 Overlook Place, Cheswick, PA 15024 (US). **HELLER, Ronald**; 1751 Mountain View Drive, Monroeville, PA 15146 (US). **WILLIAMS, Glen, P.**; 213 Sycamore Ridge Drive, Springdale, PA 15144 (US). **MATOR, Joseph, C.**; 221 Guyasuta Road, Pittsburgh, PA 15215 (US). **BAZALA, Jason, L.**; 201 Christine Drive, Irwin, PA 15642 (US).

(74) Agents: **DENESVICH, Jill** et al.; MEDRAD, INC., One Medrad Drive, Indianola, PA 15051 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

[Continued on next page]

(54) Title: CONTINUOUS MULTI-FLUID DELIVERY SYSTEM AND METHOD

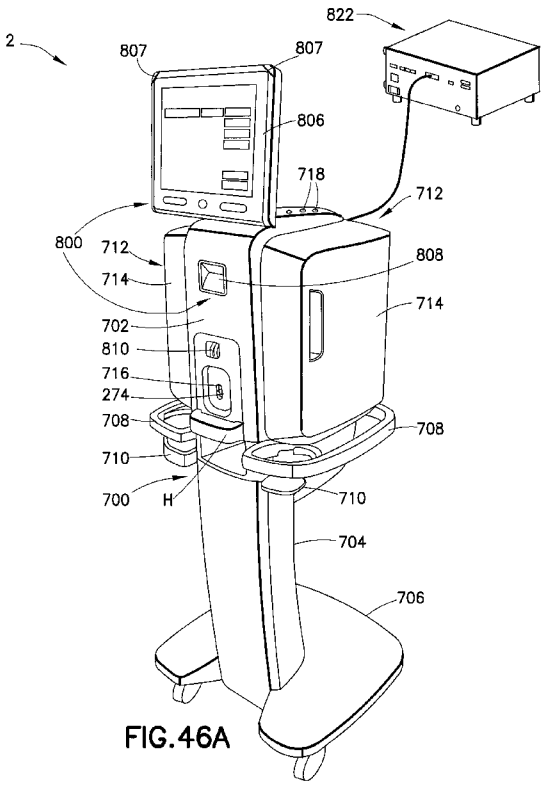

FIG.46A

(57) Abstract: A fluid pump device is operable by a drive and actuating system. The fluid pump device includes a pump manifold, a plurality of pump cylinders, a plunger reciprocally operable in each of the pump cylinders, and at least one inlet selector valve. The pump cylinders may extend proximally from the pump manifold and are in selective fluid communication with the pump manifold via, for example, respective inlet and outlet check valves. The plungers are reciprocally operable within the pump cylinders and are independently and reciprocally operable by respective piston linear actuators provided in the drive and actuating system. The inlet selector valve is used to establish selective fluid communication between one or more fluid source containers and the pump manifold to control fluid flow into the pump manifold. The inlet selector valve may be located laterally outboard of the pump cylinders and extend generally parallel to the pump cylinders.

WO 2013/043868 A1

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

CONTINUOUS MULTI-FLUID DELIVERY SYSTEM AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of United States Provisional Application No. 61/537,371, filed September 21, 2011 and entitled "Continuous Multi-Fluid Delivery System and Method", and which is incorporated herein in its entirety.

BACKGROUND OF THE INVENTION

Field of the Invention

[0002] The invention described herein is directed to a fluid delivery system comprising a fluid pump device and an associated drive and actuating system for continuous multi-fluid delivery applications in medical diagnostic and therapeutic procedures wherein one or more fluids are infused/injected into a patient.

Description of Related Art

[0003] In the medical field, fluid delivery devices used to provide fluids to patients are generally well-known and exist in many different forms. A system commonly used for this purpose is a gravity-feed system wherein a fluid containing bag is supported above the level of the patient's body and wherein the flow rate to the patient is controlled by the gross pressure of a clamp upon the flexible tube extending between the bag and the patient. It will be readily understood that the flow rate of fluid through the tube is a function of the amount of constriction of the tube. Manually operated devices are known in the medical field for delivery of fluid under pressure to a patient. Examples of such manually-operated pumping devices are known from United States Patent Nos. 3,464,359 to King et al.; 2,062,285 to Bergman; and 1,748,810 to Wandel, as examples.

[0004] Syringe-based infusion pumps and peristaltic pumps have also been used in the medical field for delivering fluids to patients under pressure and provide more precise control over the flow rate and volumetric delivery of fluids to patients. An example of a syringe pump adapted to deliver fluid to a patient is described in United States Patent No. 5,529,463 to Layer et al., which discloses a multi-syringe pump for this purpose. A peristaltic pump system suitable for delivering a constant flow of fluid under pressure to a patient is described in United States Patent Nos. 6,558,125 and 6,488,660, both to Futterknecht.

[0005] There are a number of medical procedures which require the delivery of fluids to a patient in a precisely controlled manner. One such application involves the delivery of contrast media fluid to a patient during a diagnostic computed tomography (CT) scan to

provide enhanced x-ray images. Traditionally, such contrast media fluid has been delivered to the patient using a syringe-based injection system. Such injection systems require the contrast media fluid to be transferred from its original container to a disposable syringe. The injection system then pressurizes the fluid within the syringe to deliver the fluid to the patient at a controlled flow rate, precisely when needed. Some syringe-based injection systems are capable of accommodating two separate syringes to facilitate sequential or simultaneous delivery of two different types of fluid.

[0006] One limitation of a syringe-based fluid injection system is the need to refill and replace the disposable syringes prior to each patient procedure. United States Patent No. 5,806,519 to Evans, III et al. describes a fluid delivery system which could be used to deliver fluid to multiple patients in succession without the need to refill and replace syringes for each patient. Another fluid delivery system that purports to overcome this limitation is disclosed in United States Patent Nos. 6,558,125 and 6,488,660 (Futterknecht). These latter patents disclose a fluid delivery system that utilizes a peristaltic pump to deliver fluid directly from contrast media bottles to the patient. While this system eliminates the need to replace disposable syringes after each patient, the use of a roller-type peristaltic pump inherently limits the pressure capability of the system to approximately 200 psi. Unfortunately, many CT procedures and virtually all angiographic procedures require fluid to be delivered at higher pressures.

[0007] In order to provide more precise control of flow rates and volumetric delivery of fluids to patients, positive displacement pump platforms have been developed in the medical field. These devices eliminate the use of syringes and provide increased pressure ranges over peristaltic pumps. One such positive displacement pump device is disclosed in United States Patent Nos. 5,196,197 and 6,197,000 to Reilly et al., which describe a system for the continuous delivery of contrast media fluid to a patient that uses a cam-driven multi-piston pump. Such a pump is capable of delivering fluids at relatively high pressures in a controlled manner. Another example of a positive displacement pump platform intended for use in delivering fluid to a patient undergoing a medical procedure is disclosed in International Publication No. WO 2006/056828, which discloses a volumetric pump with reciprocating and rotating pistons that are adapted to deliver a controlled and continuous flow rate of fluid during a medical procedure. Japanese Publication Nos. JP 61-42199 and JP 61-4220, both assigned to Nemoto Kiyourindou KK, disclose another multi-piston cylinder pump which enables the controlled and continuous delivery of fluids during a medical procedure.

[0008] There are several disadvantages present in positive displacement pump platforms known in the medical field for fluid delivery to a patient. One disadvantage is that these pump platforms are, typically, limited to pumping a single fluid type. Many medical procedures, such as CT procedures, often involve the use of a combination of contrast media fluid and saline delivered precisely to the region of interest within a patient's body. For example, after an initial injection of contrast media fluid is performed, a bolus of saline fluid may be administered to move the contrast fluid into the region of interest. In order to have the capability of delivering two or more different types of fluids, an external selection valve (such as a stopcock) must be added upstream of the pump inlet to allow the fluid delivery system to select from one of the two available fluid sources or possibly both if a mixing device is also provided. If two interconnected pumps are present in the fluid delivery system, the system may be capable of delivering a controlled mixture of two fluids. However, each of the two pumps must be independently controlled to provide the required flow rate of its respective fluid type. Downstream mixing devices may also be used in such a two-pump system.

SUMMARY OF THE INVENTION

[0009] This disclosure presents exemplary embodiments of a fluid pump device for association with a drive and actuating system, exemplary embodiments of the drive and actuating system, and exemplary embodiments of a fluid delivery system comprising the drive and actuating system and fluid pump device, as well as methods of assembling the fluid pump device and methods of operating one or more embodiments of the fluid pump device, drive and actuating system, and fluid delivery system. In one embodiment, a fluid pump device comprises a plurality of pump cylinders, a plunger reciprocally operable within each of the pump cylinders, and an inlet selector valve to establish selective fluid communication between at least one fluid source and the pump cylinders. The inlet selector valve may be located laterally outboard of the pump cylinders.

[0010] The inlet selector valve may be oriented generally parallel to the pump cylinders. The fluid pump device may further comprise a pump manifold controlling fluid communication to the pump cylinders, and the inlet selector valve controls fluid communication with the at least one fluid source to control fluid flow into the pump manifold. The pump manifold comprises an inlet manifold channel and an outlet manifold channel, and further comprises an outlet selector valve in fluid communication with the outlet manifold channel to control fluid flow from the pump manifold. The outlet selector valve

comprises an outlet selector valve cylinder having a valve stem disposed therein, and wherein the outlet selector valve comprises a patient outlet port and a waste outlet port. The outlet selector valve stem defines a flow passage to establish selective fluid communication with the patient outlet port or the waste outlet port. The outlet selector valve stem may define a tapered end. The pump manifold may comprise an inlet manifold channel and an outlet manifold channel, and the pump cylinders may each comprise at least one inlet opening for fluid communication with the inlet manifold channel and at least one outlet opening for fluid communication with the outlet manifold channel. The pump cylinders may be in selective fluid communication with the inlet manifold channel and the outlet manifold channel via respective inlet check valves and outlet check valves. The at least one outlet opening may be positioned at a high point in each of the pump cylinders for air bubble egress.

[0011] The inlet selector valve may comprise an inlet selector valve cylinder having a valve stem disposed therein, the valve stem defining an axial passage and a plurality of radial inlet ports connected to the axial passage. The radial inlet ports may be disposed at different angular orientations around the valve stem. The radial inlet ports may alternatively be disposed at different angular orientations around the valve stem and at different axial locations along the valve stem. A saline manifold may be in selective fluid communication with the pump cylinders via the inlet selector valve to establish selective fluid communication between a saline fluid source and the pump cylinders. The saline manifold may extend across the plurality of pump cylinders.

[0012] In another embodiment, the fluid pump device may comprise a plurality of pump cylinders, a plunger reciprocally operable within each of the pump cylinders, and an inlet selector valve to establish selective fluid communication between at least one fluid source and the pump cylinders. The inlet selector valve may be located laterally outboard of the pump cylinders, and identifying indicia may be provided on the fluid pump device and encoded with identifying information for the fluid pump device.

[0013] The inlet selector valve may comprise an inlet selector valve cylinder having a valve stem disposed therein, the valve stem defining an axial passage and plurality of radial inlet ports connected to the axial passage, and the identifying information comprising at least an initial angular orientation of the valve stem in the inlet selector valve cylinder or a representation thereof. The radial inlet ports may be disposed at different angular orientations around the valve stem. Alternatively, the radial inlet ports may be disposed at different angular orientations around the valve stem and at different axial locations along the valve

stem. The inlet selector valve cylinder may be oriented generally parallel to the pump cylinders.

[0014] The identifying indicia may be an optically encoded transparent member. The identifying indicia may be disposed on one of the pump cylinders. The inlet selector valve may comprise an inlet selector valve cylinder having a valve stem disposed therein, and the identifying information may comprise at least an initial angular orientation of the valve stem in the inlet selector valve cylinder or a representation thereof. The valve stem may comprise a plurality of radial inlet ports disposed at different angular orientations around the valve stem. Alternatively, the valve stem may comprise a plurality of radial inlet ports disposed at different angular orientations around the valve stem and at different axial locations along the valve stem. The inlet selector valve cylinder may be oriented generally parallel to the pump cylinders. The inlet selector valve cylinder may comprise multiple inlet ports for connection to multiple fluid sources.

[0015] The identifying information may comprise at least one of a pump configuration/type number, a manufacturing batch number, a pump type identifier, a pump sequential identification number, or any combination thereof.

[0016] In yet another embodiment, the fluid pump device comprises a plurality of pump cylinders, a plunger reciprocally operable within each of the pump cylinders, each plunger comprising a piston interface member extending proximally therefrom that is split into at least two parts that are compressible towards one another, and an inlet selector valve to establish selective fluid communication between at least one fluid source and the pump cylinders. The inlet selector valve located may be laterally outboard of the pump cylinders.

[0017] The plungers may each comprise a distal end disc and a proximal end disc. The plungers may be reciprocally operable in the respective pump cylinders such that the distal end disc of each plunger is operable within a pumping zone of the pump cylinders and the proximal end disc is operable within an isolation zone of the pump cylinders. A seal may be provided at least circumferentially about each of the distal end disc and the proximal end disc.

[0018] A radial lip may be provided on each of the at least two parts of the piston interface member to interface with a drive piston. A support member may be coaxially disposed in the piston interface member. The radial lip on each of the at least two parts of the piston interface member may interface with a receiving groove defined in a socket in a drive piston. The piston interface member may be generally cylindrical shaped and the at least two parts may define at least two arcuate segments.

[0019] In another embodiment, a fluid delivery system is provided including a fluid pump device comprising a plurality of pump cylinders, a plunger reciprocally operable within each of the pump cylinders, and an inlet selector valve to establish selective fluid communication between at least one fluid source container and the pump cylinders, the inlet selector valve located laterally outboard of the pump cylinders. A drive and actuating system independently and reciprocally operates the plungers in the pump cylinders.

[0020] The inlet selector valve may be oriented generally parallel to the pump cylinders.

[0021] A pump manifold may control fluid communication to the pump cylinders, and the inlet selector valve may control fluid communication with the at least one fluid source to control fluid flow into the pump manifold. The pump manifold may comprise an inlet manifold channel and an outlet manifold channel, and the pump cylinders may each comprise at least one inlet opening for fluid communication with the inlet manifold channel and at least one outlet opening for fluid communication with the outlet manifold channel. The pump cylinders may be in selective fluid communication with the inlet manifold channel and the outlet manifold channel via respective inlet check valves and outlet check valves. The at least one outlet opening may be positioned at a high point in each of the pump cylinders for air bubble egress.

[0022] The inlet selector valve may comprise an inlet selector valve cylinder having a valve stem disposed therein, and the valve stem may define an axial passage and a plurality of radial inlet ports connected to the axial passage. The radial inlet ports may be disposed at different angular orientations around the valve stem. The valve stem may alternatively comprise a plurality of radial inlet ports disposed at different angular orientations around the valve stem and at different axial locations along the valve stem.

[0023] A saline manifold may be in selective fluid communication with the pump cylinders via the inlet selector valve to establish selective fluid communication between a saline fluid source and the pump cylinders. The saline manifold may extend across the plurality of pump cylinders. The inlet selector valve may be operable by the drive and actuating system independently of the plungers.

[0024] Identifying indicia may be provided on the fluid pump device and encoded with identifying information for the fluid pump device. The inlet selector valve may comprise an inlet selector valve cylinder having a valve stem disposed therein, and the identifying information may comprise at least an initial angular orientation of the valve stem in the inlet selector valve cylinder or a representation thereof. The valve stem may comprise a plurality of radial inlet ports. The radial inlet ports may be disposed at different angular orientations

around the valve stem. Alternatively, the radial inlet ports may be disposed at different angular orientations around the valve stem and at different axial locations along the valve stem. The inlet selector valve cylinder may be oriented generally parallel to the pump cylinders.

[0025] The identifying indicia may be an optically encoded transparent member. The identifying indicia may be disposed on one of the pump cylinders.

[0026] Each of the plungers may comprise a piston interface member extending proximally therefrom, and the piston interface member may be split into at least two parts that are compressible towards one another. The plungers may each comprise a distal end disc and a proximal end disc. The plungers may be reciprocally operable in the respective pump cylinders such that the distal end disc of each of the plungers is operable within a pumping zone of the pump cylinders and the proximal end disc is operable within an isolation zone of the pump cylinders. A seal may be provided at least circumferentially about each of the distal end disc and the proximal end disc. A radial lip may be provided on each of the at least two parts of the piston interface member to interface with a drive piston of the drive and actuating system. A support member may be coaxially disposed in the piston interface member.

[0027] A drive and actuating system may be provided for operating the fluid pump device. The drive and actuating system includes an extendable and retractable pump drawer to accept the fluid pump device, with the fluid pump device comprising a plurality of pump cylinders and a plunger reciprocally operable within each of the pump cylinders. Drive pistons are provided and adapted for mechanical connection to the plungers, respectively, to independently and reciprocally operate the plungers in the pump cylinders. Piston linear actuators are respectively coupled to the drive pistons, and drive motors are operatively coupled to the piston linear actuators, respectively, to provide motive forces to the piston linear actuators to independently and reciprocally operate the plungers.

[0028] The fluid pump device may further comprise an inlet selector valve to establish selective fluid communication between at least one fluid source container and the pump cylinders, and the inlet selector valve may be located laterally outboard of the pump cylinders.

[0029] An inlet selector valve actuator may be provided adapted for mechanical connection to the inlet selector valve to control operation of the inlet selector valve to establish the selective fluid communication between the at least one fluid source container and the pump cylinders.

[0030] A pump manifold may control fluid communication to the pump cylinders, and a pump clamping mechanism may be operable to secure the fluid pump device in the pump drawer and apply a compressive force to the pump manifold when the fluid pump device is loaded in the pump drawer. The pump clamping mechanism may comprise a clamping block to engage the pump manifold when the fluid pump device is loaded in the pump drawer. The clamping block may be operated by a clamp actuating mechanism to engage and disengage the clamping block with the pump manifold. The pump manifold may comprise a pressure sensing port with a pressure sensing diaphragm, and the drive and actuating system may further comprise a pressure measuring mechanism adapted to interface with the pressure sensing port. The operation of the clamp actuating mechanism to engage the clamping block with the pump manifold may concurrently cause the pressure measuring mechanism to operatively interface with the pressure sensing diaphragm. The drive and actuating system may further comprise a pressure measuring mechanism adapted to interface with the pressure sensing port.

[0031] The pump manifold may comprise an inlet manifold channel and an outlet manifold channel, and an outlet selector valve may be in fluid communication with the outlet manifold channel to control fluid flow from the pump manifold. The drive and actuating system may further comprise an outlet selector valve actuator to control operation of the outlet selector valve.

[0032] The plungers of the fluid pump device may each comprise a piston interface member split into at least two parts that are compressible towards one another to enable the mechanical connection with the respective drive pistons. A radial lip may be provided on each of the at least two parts to interface with the respective drive pistons. A support member may be coaxially disposed in the piston interface member. Further, a radial lip may be provided on each of the at least two parts of the respective piston interface members to interface with a receiving groove in a socket in the corresponding drive pistons of the drive and actuating system.

[0033] Another embodiment is directed to a method of interfacing a fluid pump device with a drive and actuating system of a fluid delivery system. The fluid pump device generally comprises a plurality of pump cylinders, and a plunger reciprocally operable within each of the pump cylinders, each of the plungers comprising a piston interface member extending proximally therefrom. The piston interface member is split into at least two parts that are compressible towards one another. The plungers are interfaced with respective drive pistons of the drive and actuating system, such that the at least two parts of each of the piston

interface members compress towards one another to enable mechanical engagement with the respective drive pistons. The drive pistons independently and reciprocally operate the plungers in the respective pump cylinders.

[0034] The fluid pump device may further comprise an inlet selector valve to establish selective fluid communication between at least one fluid source container and the pump cylinders, with the inlet selector valve located laterally outboard of the pump cylinders.

[0035] The plungers may each comprise a distal end disc and a proximal end disc. The plungers may be reciprocally operable in the respective pump cylinders such that the distal end disc of each of the plungers is operable within a pumping zone of the pump cylinders and the proximal end disc is operable within an isolation zone of the pump cylinders. A seal may be provided at least circumferentially about each of the distal end disc and the proximal end disc. A radial lip may be provided on each of the at least two parts of the respective piston interface members to interface with a receiving groove in a socket in the respective drive pistons of the drive and actuating system. A support member may be coaxially disposed in the piston interface member. In an alternative configuration, a radial lip may be provided on each of the at least two parts of the piston interface members, and the respective drive pistons may each comprise a distal end socket defining a receiving groove, such that the step of interfacing the plungers with the respective drive pistons comprises receiving the piston interface members into the distal end socket in the respective drive pistons and engaging the radial lip on the at least two parts with the receiving groove in the distal end socket in each of the respective drive pistons.

[0036] Another embodiment is directed to a method of assembling a fluid pump device, comprising providing a pump body having a plurality of pump cylinders and at least one inlet selector valve cylinder located laterally outboard of the pump cylinders, inserting an inlet selector valve body comprising a valve stem into the inlet selector valve cylinder such that the valve stem is in a predetermined angular orientation in the inlet selector valve cylinder, and inserting respective plungers into the pump cylinders.

[0037] The pump body may further comprise a saline manifold extending across the pump cylinders and defining at least one saline channel, and the method may further comprise installing a saline manifold cap onto the pump body to enclose the at least one saline channel.

[0038] The pump body may comprise a front plate and the pump cylinders may extend proximally from the front plate, and the method may further comprise installing a pump manifold plate onto the front plate to form a pump manifold. At least one check valve may be captured between the manifold plate and the front plate during the step of installing the

manifold plate onto the front plate to form the pump manifold. The front plate may comprise at least one inlet manifold channel defined by at least one channel member, and the method may further comprise installing an inlet manifold cap on the at least one channel member to enclose the at least one inlet manifold channel. The manifold plate may comprise an outlet selector valve cylinder, and the method may further comprise inserting an outlet selector valve body comprising a valve stem into the outlet selector valve cylinder. The outlet selector valve cylinder may comprise a patient outlet port and a waste outlet port and the valve stem of the outlet selector valve body defines a flow passage, and the step of inserting the outlet selector valve body into the outlet selector valve cylinder may comprise aligning the flow passage to be in fluid communication with the waste outlet port. The step of inserting the outlet selector valve body into the outlet selector valve cylinder may be preceded by spraying lubricant onto the interior wall surface of the outlet selector valve cylinder.

[0039] The method may further comprise spraying lubricant onto the interior wall surface of the pump cylinders and onto the interior surface of the at least one inlet selector valve cylinders prior to the steps of inserting the inlet selector valve body into the inlet selector valve cylinder and inserting the respective plungers into the pump cylinders.

[0040] The steps of inserting the inlet selector valve body into the inlet selector valve cylinder and inserting the respective plungers into the pump cylinders can occur concurrently.

[0041] The predetermined angular orientation of the valve stem of the inlet selector valve body may be encoded in identifying indicia provided on the pump body, and the identifying indicia may be a bar code.

[0042] The method may further comprise generating an inlet selector valve position number and encoding the inlet selector valve position number as identifying indicia provided on the pump body. The inlet selector valve position number may correspond to the predetermined angular orientation of the valve stem of the inlet selector valve body in the inlet selector valve cylinder. The method may further comprise etching the identifying indicia on one of the pump cylinders.

[0043] Further details and advantages of the various embodiments described in detail herein will become clear upon reviewing the following detailed description of the various embodiments in conjunction with the accompanying drawing figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0044] **FIG. 1** is a schematic view of a fluid delivery system for continuous multi-fluid delivery applications.

[0045] **FIG. 2** is a front perspective view of a fluid pump device for use in the fluid delivery system shown in **FIG. 1**.

[0046] **FIG. 3** is a rear perspective view of the fluid pump device shown in **FIG. 2**.

[0047] **FIG. 4** is a bottom perspective view of the fluid pump device shown in **FIG. 2**.

[0048] **FIG. 5A** is a bottom view of the fluid pump device shown in **FIG. 2**.

[0049] **FIG. 5B** is a detail view of detail **5B** in **FIG. 5A**.

[0050] **FIG. 6** is an exploded perspective view of the fluid pump device shown in **FIG. 2**.

[0051] **FIG. 7** is a front perspective view of a pump body of the fluid pump device shown in **FIG. 2**.

[0052] **FIG. 8** is a rear perspective view of the pump body shown in **FIG. 7**.

[0053] **FIG. 9** is a rear view of a pump cylinder of the pump body shown in **FIG. 7**.

[0054] **FIG. 10** is a cross-sectional view of the fluid pump device taken along line **10-10** in **FIG. 2** and with a plunger of the fluid pump device removed for clarity.

[0055] **FIG. 11** is a rear perspective view of a plunger for the fluid pump device shown in **FIG. 2**.

[0056] **FIG. 12** is a cross-sectional view taken along line **12-12** in **FIG. 11**.

[0057] **FIG. 13** is a cross-sectional perspective view of a distal portion of a drive piston adapted to capture and actuate the plunger shown in **FIG. 11**.

[0058] **FIG. 14** is a cross-sectional perspective view showing engagement of the drive piston shown in **FIG. 13** with the plunger shown in **FIG. 11**.

[0059] **FIG. 15** is a perspective view of the fluid pump device showing inlet manifold caps exploded from the fluid pump device.

[0060] **FIG. 16** is a perspective view of a right front portion of a pump manifold plate adapted for association with the pump body shown in **FIG. 7**.

[0061] **FIG. 17** is a rear perspective view of the pump manifold plate supporting inlet and outlet check valves of the fluid pump device.

[0062] **FIG. 18** is a rear perspective view of a right portion of a pump manifold plate adapted for association with the pump body shown in **FIG. 7**.

[0063] **FIG. 19** is a longitudinal cross-sectional and perspective view of a portion of the pump manifold plate adapted for association with the pump body shown in **FIG. 7**.

[0064] **FIG. 20** is a cross-sectional perspective view of a portion of the fluid pump device shown in **FIG. 2** showing operation of an inlet check valve of the fluid pump device.

[0065] **FIG. 21** is a cross-sectional perspective view of a portion of the fluid pump device shown in **FIG. 2** showing operation of an outlet check valve of the fluid pump device.

[0066] **FIG. 22** is a cross-sectional perspective view taken along line **22-22** in **FIG. 17**.

[0067] **FIG. 23** is a cross-sectional perspective view taken along line **23-23** in **FIG. 3**.

[0068] **FIG. 24A** is an isometric perspective view of an outlet selector valve body used in the fluid pump device shown in **FIG. 2**.

[0069] **FIG. 24B** is a cross-sectional perspective view taken along line **24B-24B** in **FIG. 24A**.

[0070] **FIGS. 25A-25Q** illustrate additional embodiments of the outlet selector valve wherein the outlet selector valve body is embodiment with different sealing arrangements.

[0071] **FIG. 26** is an isometric perspective view of a swabable valve for use in association with the outlet selector valve shown in **FIG. 24**.

[0072] **FIG. 27** is a cross-sectional perspective view taken along line **27-27** in **FIG. 3**.

[0073] **FIG. 28A** is an isometric front perspective view of an inlet selector valve stem used in the fluid pump device shown in **FIG. 2**.

[0074] **FIG. 28B** is an isometric rear perspective view of the inlet selector valve stem used in the fluid pump device shown in **FIG. 2**.

[0075] **FIGS. 28C-28D** are isometric perspective view of the inlet selector valve stem shown in **FIGS. 28A-28B** and further comprising a first exemplary sealing arrangement.

[0076] **FIGS. 28E-28F** are isometric perspective view of the inlet selector valve stem shown in **FIGS. 28A-28B** and further comprising a second exemplary sealing arrangement.

[0077] **FIG. 29A-29H** are schematic cross-sectional views of the inlet selector valve showing exemplary operation thereof.

[0078] **FIG. 30** is a cross-sectional perspective view taken along line **30-30** in **FIG. 3**.

[0079] **FIG. 31** is a cross-sectional perspective view of one of the pump cylinders of the fluid pump device of **FIG. 2** showing a forward-most position of the plunger disposed in the right inboard pump cylinder.

[0080] **FIG. 32** is a horizontal cross-sectional and perspective view of a right side portion of the fluid pump device shown in **FIG. 2** to show inflow from a first fluid source container associated with the fluid pump device.

[0081] **FIG. 33** is a horizontal cross-sectional and perspective view of a right side portion of the fluid pump device shown in **FIG. 2** to show inflow from a second fluid source container associated with the fluid pump device.

[0082] **FIG. 34** is a horizontal cross-sectional and perspective view of a right side portion of the fluid pump device shown in **FIG. 2** to show inflow from a right side saline source associated with the fluid pump device.

[0083] **FIG. 35** is a horizontal cross-sectional and perspective view of a right side portion of the fluid pump device shown in **FIG. 2** to show inflow from a left side saline source associated with the fluid pump device.

[0084] **FIG. 36** is an enlarged view of the cross-sectional perspective view shown in **FIG. 35**.

[0085] **FIG. 37** is a cross-sectional perspective view taken through a pump cylinder of the fluid pump device shown in **FIG. 2**, and showing an inlet check valve and an outlet check valve of the fluid pump device.

[0086] **FIG. 38** is a cross-sectional and perspective view that is an enlargement of a portion of the view shown in **FIG. 37**.

[0087] **FIG. 39** is a cross-sectional perspective view taken through the same pump cylinder shown in **FIG. 37**, and showing fluid flow in an outlet manifold channel of the fluid pump device.

[0088] **FIG. 40** is a schematic view showing the fluid pump device of **FIG. 2** with a first or basic embodiment of a fluid supply set associated with the fluid pump device.

[0089] **FIG. 41** is a schematic view showing the fluid pump device of **FIG. 2** with a second or high-use embodiment of the fluid supply set associated with the fluid pump device.

[0090] **FIG. 42** is a schematic view showing the fluid pump device of **FIG. 2** with a third or limited-use embodiment of the fluid supply set associated with the fluid pump device.

[0091] **FIG. 43** is a schematic view showing the fluid pump device of **FIG. 2** with a fourth and additional limited-use embodiment of the fluid supply set associated with the fluid pump device that may be used with single-patient fluid source containers.

[0092] **FIG. 44** is a perspective view of an exemplary patient supply set for use with the fluid pump device shown in **FIG. 2**.

[0093] **FIG. 45** is a schematic view showing the fluid pump device with the second or high-use embodiment of the fluid supply set as shown in **FIG. 41**, and further showing a waste collection system associated with the fluid pump device.

[0094] **FIG. 46A** is a perspective view of the fluid delivery system for continuous multi-fluid delivery applications embodied as a mobile system.

[0095] **FIG. 46B** is a schematic view of the fluid delivery system of **FIG. 46A** shown interfacing with external devices including a remotely located display, computed tomography scanner, and a computer network as examples.

[0096] **FIG. 47** is a schematic representation of a drive and actuating system for the fluid delivery system shown in **FIG. 46A**, and further showing features of a control system for the fluid delivery system.

[0097] **FIG. 48** is a top perspective of the drive and actuating system for the fluid delivery system shown in **FIG. 46A**, with a pump drawer in a closed position.

[0098] **FIG. 49** is a top perspective view of the drive and actuating system for the fluid delivery system shown in **FIG. 46A**, with the pump drawer in an open position.

[0099] **FIG. 50** is a side perspective view of the drive and actuating system for the fluid delivery system shown in **FIG. 46A**, with the pump drawer in the open position.

[00100] **FIG. 51** is a side view of the drive and actuating system for the fluid delivery system shown in **FIG. 46A**, with the pump drawer in the closed position.

[00101] **FIG. 52** is a top view of the drive and actuating system for the fluid delivery system shown in **FIG. 46A**, with the pump drawer in the closed position.

[00102] **FIG. 53** is a cross-sectional view of the drive and actuating system for the fluid delivery system shown in **FIG. 46A**, taken along line **53-53** in **FIG. 52**.

[00103] **FIG. 54** is a cross-sectional view of the drive and actuating system for the fluid delivery system shown in **FIG. 46A**, taken along line **54-54** in **FIG. 52**.

[00104] **FIG. 55** is a top perspective view of a rear portion of the drive and actuating system for the fluid delivery system shown in **FIG. 46A**.

[00105] **FIG. 56** is a front perspective view of the drive and actuating system for the fluid delivery system shown in **FIG. 46A**, with the pump drawer in the closed position.

[00106] **FIG. 57** is a top perspective view of a front portion of the drive and actuating system for the fluid delivery system shown in **FIG. 46A**.

[00107] **FIG. 58** is a cross-sectional view of the drive and actuating system for the fluid delivery system shown in **FIG. 46A**, taken along line **58-58** in **FIG. 52**.

[00108] **FIG. 59** is a top view of a pressure measurement mechanism for the fluid delivery system shown in **FIG. 46A**.

[00109] **FIG. 60** is a perspective view of a fluid handling compartment provided in the mobile fluid delivery system shown in **FIG. 46A**.

[00110] **FIG. 61** is a velocity vs. time graph illustrating velocity profiles under typical operating conditions for a two (2) plunger – pump cylinder arrangement.

[00111] **FIG. 62** is a flow rate vs. time graph corresponding to the two (2) plunger – pump cylinder arrangement of **FIG. 61**.

[00112] **FIG. 63** is a perspective view of a drive piston incorporating a force transducer for use in detecting an under volume condition during the course of a fluid injection.

[00113] **FIG. 64** is a force vs. displacement graph illustrating a potential use of the drive piston shown in **FIG. 63**.

[00114] **FIG. 65** is a velocity vs. time graph illustrating velocity profiles during a slight under volume operating condition for a second plunger – cylinder combination in a two (2) plunger – pump cylinder arrangement.

[00115] **FIG. 66** is a flow rate vs. time graph showing the combined output flow rate for the two (2) plunger – cylinder arrangement of **FIG. 65**.

[00116] **FIG. 67** is a flow rate vs. time graph showing the combined output flow rate for a two (2) plunger – cylinder arrangement in which the second plunger – cylinder combination experiences a severe under volume operating condition.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[00117] For purposes of the description hereinafter, spatial orientation terms, as used, shall relate to the referenced embodiment as it is oriented in the accompanying drawing figures or otherwise described in the following detailed description. However, it is to be understood that the embodiments described hereinafter may assume many alternative variations and configurations. It is also to be understood that the specific components, devices, features, and operational sequences illustrated in the accompanying drawing figures and described herein are simply exemplary and should not be considered as limiting.

[00118] Referring initially to **FIGS. 1-6**, a fluid pump device **10**, generally provided in the form of a disposable pump cassette, is shown. While fluid pump device or pump cassette **10** (hereinafter referred to as "pump **10**") is intended as a disposable component, the pump **10** is intended for multiple uses prior to disposal. Such multiple uses may be for multiple patients or for a multiple and discrete number of uses in medical diagnostic and therapeutic procedures which may involve a single or multiple patients. The pump **10** is adapted to interface with a drive and actuating system **400** that accepts, drives, and actuates various components on the pump **10**. The drive and actuating system **400** is described herein in connection with **FIGS. 46-60**. A control system **800** is also provided to control operation of the various components of the drive and actuating system **800**, as described herein in connection with **FIGS. 46-60**.

[00119] The pump **10** may be considered to have a front or distal side **12**, a rear or proximal side **14**, a right side **16** as viewed looking from the front or distal side **12** toward the

rear or proximal side **14**, and a left side **18** as viewed looking from the front or distal side **12** toward the rear or proximal side **14**. Generally, as shown schematically in **FIG. 1**, the pump **10** may be part of a fluid delivery system **2** which includes the drive and actuating system **400**, discussed herein. The pump **10** generally comprises a fluid supply section **20**, a pump metering and pressurizing section **22**, and a pump outlet section **24**. The fluid supply section **20** includes one or more fluid source containers **30** containing various fluids to be supplied to the pump **10**, and a fluid supply set **32** (see **FIGS. 40-43** discussed herein) that conducts the one or more fluids to the pump **10**. Various versions and embodiments of the fluid supply set **32** may be associated with the pump **10** to meet different patient and/or procedural needs, as described herein. Each of the various versions and embodiments of the fluid supply set **32** comprises one or more fluid supply tubes **34** each having one end connected to the pump **10** and the opposing end connected to a spike **36** used to access a fluid source container **30**.

[00120] The pump outlet section **24** includes a disposable single-use or single-patient supply set **40** (hereinafter "patient supply set **40**"; see **FIG. 44** discussed herein) comprising medical tubing having opposed free ends each having a fluid connector **42** used to make a fluid connection, such as to a catheter inserted into a patient to convey a desired fluid or mixture of fluids to a desired location within a patient's body. At least one of the fluid connectors **42** may include a check valve (not shown) to prevent reverse flow from the patient. Additionally, the pump outlet section **24** comprises a waste collection system **44** that is associated with the pump **10** to collect and store waste fluids. The waste collection system **44** generally comprises a waste collection tube set **46** connected to a waste collection container **48**, as shown in **FIG. 45** discussed further herein. The waste collection tube set **46** is adapted to make a fluid connection with the pump **10**.

[00121] The pump **10** forms a part of the pump metering and pressurizing section **22**. The pump **10** generally comprises a pump manifold **80**, a pump body **100**, a plurality of independently operable plungers **200** operatively associated with the pump body **100**, a pump manifold plate **230** which is joined to the pump body **100** to form the pump manifold **80**, an outlet selector valve **280** associated with the pump body **100** for controlling fluid delivery or output from the pump **10**, and a plurality of inlet selector valves **300** associated with the pump body **100** for controlling fluid flow to the pump body **100**. In operation, the pump **10** is typically interfaced with multiple and different fluids contained in the fluid source containers **30**, and is actuated or operated by the drive and actuating system **400** to select a fluid type from the several fluid source containers **30** and continuously deliver fluids, either individually or as a fluid mixture, to the patient. The pump **10**, under the directed operation of

the drive and actuating system **400**, draws in fluid directly from the fluid source containers **30** and accurately meters the appropriate volumes and specified fluid flow rates and infusion time to the patient via the patient supply set **40** (shown in **FIG. 44**). As noted in the foregoing, various fluid supply sets **32** may be associated with the pump **10** to meet different patient and/or procedural needs, and these various versions or embodiments are detailed further herein in connection with **FIGS. 40-43**.

[00122] The drive and actuating system **400** which operates the pump **10** pressurizes the fluid dispensed from the pump **10** to the patient supply set **40** sufficiently to overcome any resistance through the patient supply set **40** and the catheter connected thereto so that accurate fluid volume and pressure are delivered to the desired treatment or diagnostic location within the patient's body. Fluid flow from the pump **10** is delivered substantially continuously to the patient via an indwelling catheter and may be a single fluid, or multiple fluids delivered substantially simultaneously that are combined into a mixture of any desired proportions and delivered as a single stream via the outlet selector valve **280**.

[00123] Referring additionally to **FIGS. 7-10**, the pump body **100** is typically formed as an integral or singular body formed from polycarbonate and like polymeric materials via an injection molding process. The pump body **100** comprises a front or distal plate **102** and a plurality of pump cylinders **104** extending proximally from the front plate **102**. In the illustrated embodiment, a total of four (4) pump cylinders **104** are provided in the pump **10**, with the two (2) right side pump cylinders **104** providing one fluid circuit and the two (2) left side pump cylinders **104** providing a second fluid circuit, as described in further detail herein. While of four (4) pump cylinders **104** are provided in the pump **10**, the pump **10** may be "scalable" to include additional pairs of pump cylinders **104** or may be provided with just two (2) tandem pump cylinders **104**. While the pump cylinders **104** are preferred to have a cylindrical shape, they may also have other symmetrical or non-symmetrical cross-sectional shapes (such as D-shaped) in vertical or transverse cross-section. Each pump cylinder **104** defines a pump chamber **106** and accepts a plunger **200** which is reciprocally operable within the pump cylinder **104**. The plungers **200** are independently operable by the drive and actuating system **400**. The respective pump cylinders **104** each have an interior wall or surface **108** that defines the pump chamber **106**. The pump cylinders **104** each have a generally enclosed front or distal end wall **110** formed by the front plate **102** and an open rear or proximal end **112**.

[00124] Additionally, the pump body **100** comprises a plurality of inlet selector valve cylinders **114** that extend proximally from the front plate **102** laterally outboard of the two (2)

outer pump cylinders **104**. Each inlet selector valve cylinder **114** defines a cylindrical chamber **116** that accepts an inlet selector valve **300** which is rotationally operable within the inlet selector valve cylinder **114**. The drive and actuating system **400** also independently operates the respective inlet selector valves **300** disposed within the inlet selector valve cylinders **114**. In the illustrated embodiment, two (2) inlet selector valve cylinders **114** are provided in pump **10** to respectively control inflow to the two (2) "right side" pump cylinders **104** providing one fluid circuit and the two (2) "left side" pump cylinders **104** providing the second fluid circuit in pump **10**. The respective inlet selector valve cylinders **114** have a front or distal end opening **118** formed in the front plate **102** and a rear or proximal end opening **120** to accept the inlet selector valve **300**.

[00125] Each inlet selector valve cylinder **114** comprises, in the illustrated embodiment, a pair of inlet ports **122**, **124** for use in connecting the pump **10** to two (2) fluid sources of diagnostic or therapeutic (*e.g.*, pharmaceutical) fluids, such as imaging contrast media, to be received in the pump chambers **106** of the pump cylinders **104**. Further, each inlet selector valve cylinder **114** comprises, in the illustrated embodiment, an additional rear or proximal inlet port **126** for use in connecting the pump **10** to, typically, a source of flushing or diluting fluid such as saline. As such, the rearmost inlet port **126** is referred to hereinafter as a "saline port **126**", while inlet ports **122**, **124** are referred to hereinafter as "first and second inlet ports **122**, **124**", respectively. The inlet ports **122**, **124**, **126** are axially spaced along the inlet selector valve cylinder **114**, with the first inlet port **122** located near the front plate **102** and the saline port **126** located near the rear or proximal end opening **120** of the inlet selector valve cylinder **114**. The saline port **126** is located at a lower level than the first and second inlet ports **122**, **124**, and connects to a saline manifold located on the underside of the pump body **100**, as described herein. Accordingly, the saline port **126** is located at a lower level and opens into the inlet selector valve cylinder **114** and the saline manifold **130** to access one of two (2) saline channels in the saline manifold **130**, as described herein, rather than intersecting or directly opposing the valve body of the inlet selector valve **300** as in the case of the first and second inlet ports **122**, **124**. The first and second inlet ports **122**, **124** and the saline ports **126** on the inlet selector valve cylinders **114** may be formed with luer-type connector tips or barbed connection tips, and like fluid connections arrangements, for making either removable or permanent fluid connections to the fluid supply tubes **34** used to connect the pump **10** to the one or more fluid source containers **30** that provide therapeutic or diagnostic (*e.g.*, pharmaceutical) fluids or saline to the pump **10**.

[00126] The illustrated embodiment of the pump **10** is shown for exemplary purposes with six (6) supply ports, three (3) on each of the right and left sides **16**, **18** of the pump **10**. These supply ports include the two (2) right side inlet ports **122**, **124** and the right side saline port **126** on the pump body **100** and the two (2) left side inlet ports **122**, **124** and the left side saline port **126** on the pump body **100**. However, this specific configuration is illustrated for expediency in explaining the various components, features, and desirable operational characteristics of the pump **10** and should be considered as non-limiting. Accordingly, the pump **10** may comprise a fewer or a greater number of ports **122**, **124**, **126** on each side **16**, **18**, as desired.

[00127] The saline port **126** on the respective inlet selector valve cylinders **114** is in fluid communication with a saline manifold **130** that extends across the underside of the pump body **100** and across the pump cylinders **104**. The saline manifold **130** is oriented generally parallel to the front plate **102**. The saline manifold **130** is typically adapted to be placed in fluid communication via the two (2) saline ports **126** to two (2) sources of saline **S1**, **S2** contained in two (2) respective fluid source containers **30**. The saline manifold **130** is bifurcated into two (2) saline channels **132**, **134**. The respective inlet selector valves **300** are configured so that saline may be drawn from either of the sources of **S1**, **S2** in the saline fluid source containers **30** via the saline channels **132**, **134**, even though the saline fluid source container **30** may be physically on the opposite side of the pump **10** from the inlet selector valve **300**, as described further herein. In the illustrated embodiment of the pump **10**, the forward or distal or "first" saline channel **132** of the saline manifold **130** is supplied by the saline source **S2** in the fluid source container **30** connected to the saline port **126** located on the right side inlet selector valve cylinder **114**, and the rear or proximal or "second" saline channel **134** of the saline manifold **130** is supplied by the saline source **S1** in the fluid source container **30** connected to the saline port **126** located on the left side inlet selector valve cylinder **114**. The shape of the saline channels **132**, **134** may be formed with smooth interior surfaces and curvatures to minimize the potential for trapped air and pressure drop (*e.g.*, flow restriction) through each saline channel **132**, **134**. A saline manifold cap **136** encloses the saline channels **132**, **134** and may be secured in place on the saline manifold **130** formed on the underside of the pump body **100** via medical grade adhesive, solvent bonding, laser and ultrasonic welding, and like joining techniques.

[00128] As the forward saline channel **132** is connected to the right saline source **S2** and the rear saline channel **134** is connected to the left saline source **S1**, it is desirable to purge air using saline from the left saline source **S1** as this is the rearmost saline channel. By using the

rearmost saline channel **134** connected to the left saline source **S1** for fluid priming operations, the fluid passages in the pump **10** may be primed from rear to front with saline, and air is purged forward from the rear of each of the inlet selector valves **300**. This result occurs because there are no other ports "behind" the rearmost saline channel **134**. For example, it would not be possible to purge all of the air from the inlet selector valves **300** if one of the inlet ports **122**, **124** was used to supply a priming fluid. This is because there would be a "dead space" in the inlet selector valve **300** behind the two (2) front inlet ports **122**, **124** through which no fluid would flow. Any air in this portion of the inlet selector valve **300** would remain after priming.

[00129] A front or distal side **140** of the front plate **102** defines a plurality of inlet openings **142**, one for each of the pump cylinders **104**. The inlet openings **142** are provided in the distal end wall **110** of each of the pump cylinders **104**. The inlet openings **142** permit fluid to enter the pump chamber **106** of the respective pump cylinders **104**. The inlet openings **142** are spaced apart on the front plate **102** to respectively coincide with the pump chambers **106** of the respective pump cylinders **104**. Accordingly, four (4) spaced inlet openings **142** are provided in the illustrated embodiment, one for each pump cylinder **104**, and are positioned to be near the bottom center of each of the pump cylinders **104**, as shown in **FIG. 9**. An inlet check valve support structure **144** is provided in each of the inlet openings **142** and is desirably recessed within each of the inlet openings **142** for supporting an inlet check valve **194**. The inlet check valves **194** are flexible polymeric, typically polyurethane, disks that regulate the fluid flow into each pump cylinder **104**. The inlet check valve support structure **144** comprises a central hub **146** and one or more prongs **148** extending radially outward from the central hub **146**. A total of three (3) prongs **148** is present in the inlet check valve support structure **144** in the illustrated embodiment. The central hub **146** desirably includes a centrally-located preload pin **150** that allows a preload force to be applied to the inlet check valve **194** to ensure that the inlet check valve **194** closes when there is no pressure gradient present across the inlet check valve **194**. The preload force is not set too high so as to overly increase the "cracking" or opening pressure of the inlet check valve **194** as this would undesirably cause a higher pressure drop across the check valve **194**. The preload pins **150** also help to counteract the effects of long-term storage, which could cause the inlet check valves **194** to develop a compression set over time. The front or distal end openings **118** in the front plate **102** leading to the inlet selector valve cylinders **114** are circumferentially bordered by one or more concentric ribs or rims **152** formed on the front side **140** of the front plate **102** and which extend around the front or distal end openings **118**.

[00130] The front side **140** of the front plate **102** further defines an elongated recess **154** extending across the front side **140** above the elevational location of the inlet openings **142**, but still coinciding with the pump chambers **106** of the respective pump cylinders **104**. The elongated recess **154** is bordered by a perimetrical recess **156** so that a sealing element, such as an elongated O-ring or gasket or like sealing element, may be placed in the perimetrical recess **156** and form a fluid sealing border about the elongated recess **154**. A plurality of recessed areas **158** is defined in the elongated recess **154** and is spaced apart in the elongated recess **154** to coincide, respectively, with the pump chamber **106** defined by the pump cylinders **104**. Accordingly, a total of four (4) recessed areas **158** is provided in the illustrated embodiment. Each recessed area **158** typically defines at least one top or air egress opening **160** in the distal end wall **110** of each of the pump cylinders **104**, and is desirably positioned to be near the top center of each of the pump cylinders **104**, as shown in **FIG. 9**, for providing an egress opening for air bubbles in the pump chambers **106** of the respective pump cylinders **104**. Each of the recessed areas **158** further defines one or more outlet openings **162** in the front plate **102**, typically on either side of the top air egress opening **160**, and in the distal end wall **110** of each of the pump cylinders **104** to permit fluid to exit the respective pump cylinders **104**. It is also noted that the upper surface or leg of the elongated recess **154** is substantially flat and horizontal and its centerline is raised slightly above the recessed areas **158** which allows any air that is present in the elongated recess **154** to be ejected upward through the outlet selector valve **280**.

[00131] In summary, each pump cylinder **104** has an inlet opening **142** in fluid communication with its pump chamber **106** and one or more outlet openings **162** in fluid communication with its pump chamber **106**, with the one or more outlet openings **162** defined in one of the recessed areas **158** in the elongated recess **154** defined in the front side **140** of the front plate **102**. Referring next to **FIG. 10**, the pump cylinder **104** generally has a working or pumping region or zone identified by arrow **164** in the pump chamber **106** and an isolation region or zone identified by arrow **166** in the pump chamber **106**. The plunger **200** is removed in the view of **FIG. 10** for clarity.

[00132] A plate support structure or groove **168** may be provided on at least one of the pump cylinders **104**, such as provided on a top or upper facing side of one of the outboard pump cylinders **104**. The plate support structure **168** supports a pump indicator plate **170** which is encoded with identifying information regarding the pump **10** to enable the control system **800** which controls operation of the drive and actuating system **400** to determine, for example, the configuration of the pump **10**. The configuration of the pump **10** is dependent,

typically, on the type or configuration of the fluid supply set **32** as manufactured or associated with the pump **10** and used to meet different patient and/or procedural needs.

[00133] The configuration of the pump **10** may also, or alternatively, be encoded into identifying indicia **172**, such as bar code indicia as shown in **FIG. 2**, that is affixed on or etched into a top or upper facing side of one of the pump cylinders **104**, such as affixed on or etched into the opposite outboard pump cylinder **104** from the pump cylinder **104** carrying the pump indicator plate **170**. It will be understood that the pump indicator plate **170** and identifying indicia **172** may be located on any suitable surface or location on the pump body **100** or on the pump manifold plate **230**. The identifying indicia **172** may also be a suitable RFID (radio frequency identification device) tag, as shown in **FIG. 3**, as a suitable arrangement for storing pertinent information about the pump **10**. The identifying indicia **172** is scanned prior to installation of the pump **10** in association with the drive and actuating system **400** to determine the configuration of the pump **10**, and other identifying information. The pump indicator plate **170** and/or the identifying indicia **172** may contain additional pertinent information, such as pump serial number, manufacturing identification number, use-by date, manufacturing lot code/batch number, initial angular orientation of the inlet selector valves **300** in their respective inlet selector valve cylinders **114** on the pump body **100**, cryptographic hash code to confirm validity of information, and like information. More limited information may be carried by the pump indicator plate **170** than the identifying indicia **172**, with the identifying indicia **172** typically including all of the foregoing information. Thus, the pump indicator plate **170** may alternatively be encoded with only limited information, such as pump type information to identify the specific configuration of the pump **10** as shown, for example, in **FIGS. 40-43** discussed herein. Moreover, if the identifying indicia **172** is an RFID (radio frequency identification device) tag, the RFID tag or device can store the same information listed above, such as: pump type/configuration, pump serial number, manufacturing identification number, use-by date, manufacturing lot code/batch number, and initial angular orientation of the inlet selector valves **300** in their respective inlet selector valve cylinders **114** on the pump body **100**. Because RFID tags can have read/write capability, the RFID tag could also store information on how many times the "tagged" pump **10** has been used, the volume of pumped fluid, peak pressure, and like operational information. The RFID tag may be located on any suitable surface of the pump **10** and can be read and written to by an antenna in close proximity to the pump **10**, such as associated with the drive and actuating system **400**.

[00134] The pump indicator plate **170** is typically provided as an optically encoded transparent polymeric member that fits within and is secured by the plate support structure **168**. The indicator plate **170** provides a length of material disposed along at least a portion of the wall. The length of material propogates electromagnetic energy therethrough. The length of material may include at least two indicators or grooves **174**, each of the grooves being located at a different predetermined longitudinal position along the length of material and each of the grooves being positioned to longitudinally align with a sensor when a barrel, such as one of the pump cylinders **104**, is engaged with the drive and actuating system **400** and thereby attached to the fluid injector portion of the fluid delivery system **2**. The pump indicator plate **170** comprises a series of grooves **174** that permits at least the configuration of the pump **10** to be optically read or verified after installation in association with the drive and actuating system **400**. Thus, the drive and actuating system **400** may include an optical detector and like technology and the pump indicator plate **170** may be provided and encoded with information in accordance with the disclosures of United States Patent Nos. 7,018,363 and 7,462,166, both to Cowan et al., which disclose optical technology for determining configuration, including size of a fluid pumping component mounted to a power fluid injector and are incorporated herein by reference in their entirety for these and any other pertinent applications. The foregoing Cowan patents are generally directed to syringes and like pump devices such that the optical technology therein may be applied to the pump cylinders **104** of the pump **10**. The pump cylinders **104** are analogous and operable generally in the same manner as cylindrical syringe bodies and like pump devices as disclosed in the foregoing Cowan patents. Thus, the optical technology described in the foregoing Cowan patents may be applied to the pump cylinders **104** whereby the pump indicator plate **170** is provided with the optical technology detailed in these patents or the pump cylinders **104** are marked or otherwise identified in the various manners and embodiments disclosed in these patents. The pump indicator plate **170** is provided as an exemplary element for applying the indentifying indicia **172** to the pump **10** and should not be deemed limiting as this application expressly includes application of the optical technology found in the foregoing Cowan patents to the pump **10** generally and the pump body **100** in particular. The pump body **100** may be opaque to absorb laser light during a laser welding process during assembly of the pump **10**, but the opaque pump body **100** also helps with optical sensor performance in the optical reading of the information contained in the grooves **174** in the pump indicator plate **170**. Additionally, the plate support structure **168** may be adapted for a snap-lock fit with the pump indicator plate **170**. The plate support structure **168** may comprise a recessed groove **176** in the pump

cylinder **104** for accepting the pump indicator plate **170**, and a pair of flanges **178** for restraining the pump indicator plate **170** in the groove **176**. Further, the snap-lock fit may be provided by a snap-lock tab **180** formed within the groove **176** in the pump cylinder **104** and a corresponding mating recess (not shown) defined in the underside of the pump indicator plate **170**.

[00135] Referring further to **FIGS. 11-14**, as noted previously, a plunger **200** is reciprocally operable within each of the pump cylinders **104** and is independently controlled by the drive and actuating system **400**. Each plunger **200** comprises a rigid plunger body **202** that is injection molded from polycarbonate and like polymeric materials. The plunger body **202** may be a unitary, solid body formed to include a series of wall segments **204** that extend between a front or distal end disc **206** and a rear or proximal end disc **208**. The rear or proximal end disc **208** is formed with a piston interface member or device **210** which is adapted to interface with an independent drive piston **50** associated with the drive and actuating system **400** for the pump **10**. The piston interface member **210** is split into at least two (2) parts or halves to form opposing halves or legs **212** that may compress towards one another, or radially inward toward a central longitudinal axis of the plunger **200**, to be received in a distal end recess or socket **52** in the drive piston **50**. Additionally, the piston interface member **210** comprises a circumferential radial lip or rim **214**, which is provided on each of the interface halves or legs **212**, to engage a corresponding groove or recess **53** defined proximally inward from radial lip or rim **54** provided in the distal end socket **52** in the drive piston **50**. The engaging lips or rims **54**, **214** secure the engagement between the plunger **200** and drive piston **50**. Thus, the rear or proximal end disc **208** of each plunger body **202** includes several features that allow the plunger **200** to "snap" into the distal end socket **52** in the actuating drive piston **50**. A desirable result of the foregoing "snap-fit" connection is that it is non-orientation specific and the drive piston **50** may engage the plunger **200** in any radial orientation of the plunger **200**. Moreover, it will be understood that the piston interface member **210** may be split into a plurality of portions or parts **212** that may compress inwardly toward a central longitudinal axis of the plunger **200**. Additionally, the piston interface member **210** may be generally cylindrical shaped and, as such, the plurality of portions or parts may be formed as arcuate sections or segments.

[00136] Once the plunger **200** is "snapped" into place in association with the drive piston **50**, the drive piston **50** can move the plunger **200** in a reciprocal manner in the associated pump cylinder **104**. When the plunger **200** is pressurizing fluid in the pump chamber **106** of the pump cylinder **104** by moving forward or distally in the pump cylinder **104**, a central ring

or cylinder support member **216** extending proximally from the rear or proximal end disc **208** seats against a flat interior end or bottom **56** of the distal end socket **52** in the actuating drive piston **50**, thereby transferring the compressive axial load to the drive piston **50**. The support member **216** coaxially disposed in the piston interface member **212**. When the pump **10** is to be removed from the drive and actuating system **400**, the drive piston **50** is retracted rearward or proximally until the rear or proximal end disc **208** of the plunger body **202** contacts a stationary projection. Further retraction of the drive piston **50** disengages the snap-fit interface between the piston interface member **210** and the drive piston **50**.

[00137] Each plunger **200** comprises two (2) over-molded seals, a front or distal end lip seal **218** provided circumferentially about and on the front side of the front or distal end disc **206**, and a rear or proximal bead seal **220** provided circumferentially about the rear or proximal end disc **208**. The front end disc **206** with over-molded lip seal **218** is used to seal liquid within the pumping zone **164** of the pump cylinder **104**, and the rear end disc **208** with over-molded bead seal **220** is used to prevent wetted portions of the interior wall **108** of the pump cylinder **104** from being exposed to the ambient environment. The seals **218**, **220** may be made of polyurethane and like polymeric materials. The front lip seal **218** is desirably adapted to withstand fluid pressure of at least 400 psi and, desirably, at least 500 psi and is desirably hydraulically energized by fluid pressure. Accordingly, higher pressures result in greater sealing force. The rear bead seal **220** typically seals against dust and particulates that may be pulled into the open rear or proximal end **112** of the pump cylinder **104**, and is actuated by compression within the isolation zone **166** of the pump cylinder **104**. Seal runners **222** may extend from the front lip seal **218** to the rear bead seal **220** along two (2) or more or all of the wall segments **204**. In the illustrated embodiment, seal runners **222** extend along two (2) of the wall segments **204** located on opposite lateral sides of the plunger body **202**. The seal runners **222** are typically formed during the over-molding process used to form the front lip seal **218** and the rear bead seal **220** on the front and rear end discs **206**, **208**, respectively. The "flat" front of the front end disc **206** is desirable for minimizing residual fluid volume in the pump chamber **106** of the pump cylinder **104**, helps to eject air bubbles from the pump chamber **106** during fluid priming of the pump **10** and, further, helps clean the pump chamber **106** during flushing procedures.

[00138] It is noted that the retaining force of the snap-fit connection between the drive piston **50** and the plunger **200** is significantly greater than the expected retraction force to be applied to the plunger **200**. The expected retraction force is the sum of the vacuum/suction force on the plunger **200** during filling of the pump cylinder **104** and the friction between the

foregoing plunger seals **218**, **220** and the interior wall **108** of the pump cylinder **104**. If snap-fit retention force is too low, the plunger **200** could disconnect prematurely from the drive piston **50** during use.

[00139] Referring additionally to **FIGS. 15-19**, the pump **10**, as noted previously, comprises a pump manifold **80** that is formed by the connection or joining of the pump manifold plate **230** with the pump body **100**. The pump manifold **80** is generally formed by assembling the pump manifold plate **230** to front plate **102** of the pump body **100**. The pump manifold plate **230** (hereinafter "manifold plate **230**") comprises a front or distal side **232** and a rear or proximal side **234**. The manifold plate **230** is generally shaped to correspond to the shape of the front plate **102** of the pump body **100** and is joined with the front plate **102** so that the rear side **234** of the manifold plate **230** is in engagement with the front side **140** of the front plate **102**. The front side **232** of the manifold plate **230** includes right and left inlet manifold channels **236** provided on lateral right and left halves of the manifold plate **230**. The inlet manifold channels **236** generally extend longitudinally along the front side **232** of the manifold plate **230**. The two inlet manifold channels **236** correspond, respectively, to the two (2) right side pump cylinders **104** and the two (2) left side pump cylinders **104** of the pump body **100**. As noted previously, in the illustrated embodiment, a total of four (4) pump cylinders **104** is provided in pump **10**, with the two (2) "right" side pump cylinders **104** providing one fluid circuit and the two (2) "left" side pump cylinders **104** providing a second fluid circuit. The "right" inlet manifold channel **236** corresponds to the two (2) "right" side pump cylinders **104**, and the "left" inlet manifold channel **236** corresponds to the two (2) "left" side pump cylinders **104**. Alignment slots or holes **237** may be provided in the manifold plate **230** to facilitate loading of the pump **10** in association with the drive and actuating system **400**, which is described herein.

[00140] Each of the right and left inlet manifold channels **236** is defined by a raised channel member or flange wall **238** provided on the front side **232** of the manifold plate **230**. The manifold plate **230** defines a lateral opening **240** in each of the inlet manifold channels **236** that coincides with the distal or front end opening **118** in the front plate **102** of the pump body **100** which leads to the inlet selector valve cylinder **114**. Accordingly, each lateral opening **240** registers with a corresponding front end opening **118** to place the "right" and "left" inlet selector valves **300** in fluid communication with the corresponding "right" and "left" inlet manifold channels **236**, respectively. Additionally, the manifold plate **230** defines two (2) sets of inlet openings **242** in each of the right and left inlet manifold channels **236** that correspond to the inlet openings **142** in the front plate **102** of the pump body **100**. As noted

previously, the inlet openings **142** are spaced apart on the front plate **102** to respectively coincide with the pump chambers **106** of the respective pump cylinders **104**, and the inlet openings **142** are positioned to be near the bottom center of each of the pump cylinders **104**, as shown in **FIG. 9**. The respective sets of inlet openings **242** are, desirably, a plurality of openings **242** arranged in a predetermined pattern, such as a circular pattern, and enable fluid communication with the inlet openings **142** in the front plate **102** of the pump body **100**. However, the two (2) sets of inlet openings **242** in each inlet manifold channel **236** may alternatively be provided as two (2) singular large openings in the respective inlet manifold channels **236**. The illustrated circular arrangement of the inlet openings **242** desirably includes at least one inlet opening **242** located at a "high" point, such as near to the top part of the channel member **238** defining the inlet manifold channel **236**. This "high point" inlet opening **242** minimizes the potential for air bubbles to become trapped within the inlet manifold channels **236** because any air present in the inlet manifold channels **236** is pulled into the pump cylinders **104** during the initial fluid priming process for the pump **10**. The number and size of inlet openings **242** may be selected to minimize pressure drop across the underlying inlet check valves **194** during filling of the pump cylinders **104**, while minimizing the potential for high pressures in the pump cylinders **104** which could cause the polymeric material of the inlet check valves **194** to "extrude" into the inlet openings **242** under high pressure.

[00141] The rear or proximal side **234** of the manifold plate **230** also defines an elongated outlet manifold channel or recess **244** extending across the rear side **234** above the elevational location of the sets of inlet openings **242** in the manifold plate **230**, but still coinciding with or corresponding to the pump chambers **106** of the respective pump cylinders **104**. The outlet manifold channel **244** generally corresponds to the elongated recess **154** defined in the front side **140** of the front plate **102** of the pump body **100**. The elongated recess **154** is sized larger than the outlet manifold channel **244** and is bordered by the perimetrical recess **156**, as described previously, so that an elongated O-ring or gasket and the like, may be placed in the perimetrical recess **156** and form a fluid sealing border around the outlet manifold channel **244** when the manifold plate **230** is joined to the front plate **102** of the pump body **100** to form the pump manifold **80**. In a variation of the foregoing sealing arrangement, a weld joint, typically a laser weld, occupies the location of the perimetrical recess **156** and the sealing O-ring or gasket is not required, and this embodiment or variation is illustrated in the accompanying figures. The elongated recess **154** also forms the back wall of the outlet

manifold channel **244** when the manifold plate **230** is joined to the front plate **102** of the pump body **100**.

[00142] The outlet manifold channel **244** is used to place the respective pump cylinders **104** in fluid communication with the outlet selector valve **280** on the manifold plate **230**. A plurality of outlet check valve receiving recesses **246** is defined as part of the outlet manifold channel **244**. The outlet check valve receiving recesses **246** are spaced apart in the outlet manifold channel **244**. Each of the receiving recesses **246** accommodates an outlet check valve **196**. Thus, an outlet check valve receiving recess **246** is provided for each of the pump cylinders **104** of the pump body **100** so that an outlet check valve **196** opposes each of the respective sets of air egress openings **160** and outlet openings **162** in the front plate **102** of the pump body **100**. The outlet check valve receiving recesses **246** are located directly above the sets of inlet openings **242** defined in the manifold plate **230**, respectively. Each of the outlet check valve receiving recesses **246** further includes a centrally located preload pin **250** that allows a preload force to be applied to the outlet check valve **196** to ensure that the outlet check valve **196** closes when there is no pressure gradient present across the outlet check valve **196**. The outlet check valves **196** are flexible polymeric discs, typically polyurethane discs, which regulate the fluid flow from each pump cylinder **104**. Thus, the outlet check valves **196** are located within the respective outlet check valve receiving recesses **246** in the outlet manifold channel **244**, with each of the outlet check valves **196** associated, respectively, with a corresponding set of outlet openings **162** and top openings **160** in the front plate **102** leading to the pump chambers **106** of the pump cylinders **104**.

[00143] The rear or proximal side **234** of the manifold plate **230** further comprises dish-shaped areas or recesses **252** opposite the inlet openings **142** in the front plate **102** leading to the pump chambers **106** of the pump cylinders **104**. The dish-shaped areas or recesses **252** form valve seats for the respective inlet check valves **194**. As shown, for example, in **FIG. 7**, the perimetrical recess **156**, which extends around the elongated recess **154** defined in the front side **140** of the front plate **102** of the pump body **100**, also extends around or borders each of the inlet openings **142**. Thus, the inlet openings **142** may be sealed by the same sealing element, such as an O-ring, gasket, or weld, disposed about the elongated recess **154**, to form a fluid sealing border around the respective dish-shaped recessed areas **252**. The sealing element (*e.g.*, O-ring, gasket, or weld) forms a fluid sealing border around the outlet manifold channel **244** and the respective dish-shaped recessed areas **252** when the manifold plate **230** is joined to the front plate **102** of the pump body **100** to form the pump manifold

80. As noted previously, a welded joint, a laser or ultrasonic weld, is preferred in the location of the perimetrical recess **156** in the accompanying figures.

[00144] As described previously, the inlet check valves **194** are held in place in the opposing inlet openings **142** by the respective inlet check valve support structure **144** provided on the front plate **102** of the pump body **100**. One or more receiving slots **254** may further be provided in the rear side **234** of the manifold plate **230** and located at spaced circumferential locations around the dish-shaped recesses **252**. The one or more receiving slots **254** are adapted to receive corresponding tabs **256** extending from the radial prongs **148** of the inlet check valve support structures **144** provided on the opposing front plate **102** of the pump body **100**, thereby securing the inlet check valves **194** opposite the dish-shaped recesses **252** formed in the rear or proximal side **234** of the manifold plate **230**. A further purpose of the tabs **256** is to maintain the inlet check valves **194** centered relative to the inlet openings **142**. Generally, it is desirable to provide some clearance between the disc edge of the inlet check valves **194** and the wall of the inlet openings **142** to permit fluid to flow past the inlet check valves **194** when opened. The three small tabs **256** keep the inlet check valves **194** centered during operation while leaving most of their circumference free from contact with the wall of the inlet openings **142**.

[00145] The front side **232** of the manifold plate **230** comprises an outer circumferential flange or channel **258** which forms a border around the front side **232** of the manifold plate **230**, and a series of stiffening ribs **260**. The outer flange **258** and stiffening ribs **260** stiffen or provide rigidity to the pump manifold **80** without increasing the thickness of the molded polymeric material forming the pump body **100** and the manifold plate **230**. Additionally, the outer flange **258** and the stiffening ribs **260** transfer the clamping force that is applied by the drive and actuating system **400** to the welded joints that are subjected to high stress, as described herein. Moreover, the outer flange **258** and stiffening ribs **260** may also be used for orienting and positioning the pump **10** in association with the drive and actuating system **400** used to operate the pump **10** so that the drive and actuating system **400** may operate the respective drive pistons **50** to capture and independently operate the respective plungers **200** disposed within the pump cylinders **104**. The stiffening ribs **260** may be located on the face of the front side **232** of the manifold plate **230**, or be formed as part of the outer flange **258** on the front side **232** of the manifold plate **230**. A pair of positioning or stiffening tabs **261** may be provided on each of the respective channel members **238** defining the inlet manifold channels **236**, and disposed generally between the two (2) circular sets of inlet openings **242** in inlet manifold channels **236**. The stiffening tabs **261** help to prevent deflection of the ends

of the pump cylinders **104** when they are subjected to internal fluid pressure, for example, on the order of at least 400 psi and, often, at least 500 psi and greater. Manifold caps **262** are provided for each of the right and left inlet manifold channels **236** and are secured to the respective channel members **238** defining the inlet manifold channels **236** via an ultrasonic or laser welding process and like joining techniques.

[00146] The manifold plate **230** is joined to the front side **140** of the front plate **102** of the pump body **100** via a laser welding process and like joining process. This laser welding process secures the manifold plate **230** to the front plate **102** of the pump body **100** and forms a hermetic seal around the fluid paths defined between the manifold plate **230** and the front plate **102**. As a result of this laser welding process, the respective sets of inlet openings **242** in the manifold plate **230** are placed in correspondence with the respective inlet openings **142** in the front plate **102** of the pump body **100** to provide fluid communication (across the separating inlet check valves **194**) between the right and left inlet manifold channels **236** and the two (2) right and the two (2) left pump cylinders **104**, respectively. Further, the laser welding process secures the inlet check valves **194** in association with the respective dish-shaped recesses **252** which form the valve seats for the inlet check valves **194**. The inlet check valves **194** are held in place in the inlet openings **142** by the respective inlet check valve support structures **144**, as mentioned previously. Additionally, the laser welding process secures the engaging tabs **256** associated with the radial prongs **148** of the inlet check valve support structures **144** in their corresponding receiving slots **254** in the rear proximal side **234** of the manifold plate **230**, thereby further securing and aligning the inlet check valves **194** in the dish-shaped recesses **252** forming the valve seats for the inlet check valves **194**. Moreover, the laser welding process places the outlet manifold channel **244** in fluid communication (across the separating outlet check valves **196**) with the respective sets of outlet openings **162** and top openings **160** in the front plate **102** to permit fluid to exit the pump chambers **106** of the respective pump cylinders **104** and enter the outlet manifold channel **244**. The outlet check valves **196** are similarly secured and aligned in the outlet check valve receiving recesses **246** in the outlet manifold channel **244** and opposite the plurality of recessed areas **158** defined in the elongated recess **154** on the front side **140** of the front plate **100** during the laser welding process. The plurality of recessed areas **158** forms the valve seats for the respective outlet check valves **196** in a similar manner to the way the dish-shaped recesses **252** form valve seats for the inlet check valves **194**. Furthermore, the laser welding process provides a weld joint in the perimetrical recess **156**, described previously, which forms a fluid sealing border around the outlet manifold channel **244** and the respective

dish-shaped recessed areas **252** when the manifold plate **230** is joined to the front plate **102** of the pump body **100**.

[00147] Referring further to **FIGS. 20-21**, in operation, when the pressure in the inlet manifold channels **236** is greater than the pressure within the associated pump cylinders **104**, the inlet check valves **194** deform to allow fluid flow, designated by arrows F_1, into the pump chamber **106** of the associated pump cylinders **104**. When the pressure within the pump cylinders **104** is greater than the pressure within the associated inlet manifold channels **236**, the inlet check valves **194** are pressed against the dish-shaped recesses **252** formed in the rear or proximal side **234** of the manifold plate **230**, and prevent fluid flow out of the pump cylinders **104** into the corresponding inlet manifold channel **236**. Similarly, when pressure within the pump cylinders **104** is greater than pressure in the outlet manifold channel **244**, the outlet check valves **196** associated with the pump cylinders **104** deform to allow fluid flow, as designated by arrows F_2, from the pump cylinder **104**. When the pressure in the outlet manifold channel **244** is greater, the outlet check valves **196** associated with the pump cylinders **104** are pressed into the respective recessed areas **158** defined in the elongated recess **154** on the front side **140** of the front plate **102** to seal the respective sets of outlet openings **162** and top openings **160** in the front plate **102** leading to the pump chambers **106** of the pump cylinders **104** and prevent fluid flow from the outlet manifold channel **244** into the pump cylinders **104**.

[00148] Referring additionally to **FIGS. 22-26**, the manifold plate **230** further comprises an outlet selector valve cylinder **264** extending upward from a top portion of the manifold plate **230** and, in particular, upward from the outer flange **258** which forms a border around the front side **232** of the manifold plate **230**. The outlet selector valve cylinder **264** defines a valve bore **266** to accept the body of the outlet selector valve **280** therein. The valve bore **266** and a connecting passage **268** thereto are desirably located above the outlet manifold channel **244**, permitting any air that is initially trapped in the outlet manifold channel **244** to rise up into the connecting passage **268** and valve bore **266** during the fluid priming process.

[00149] The outlet selector valve **280** controls fluid delivery or output from the pump **10**. The valve bore **266** is in fluid communication with the outlet manifold channel **244** via the connecting passage **268**. The outlet selector valve cylinder **264** further defines a pair of outlet ports **270**, **272**, including a patient outlet port **270** that accepts a swabable valve **274** and a waste outlet port **272**. The swabable valve **274** may be secured within the patient outlet port **270** via medical grade adhesive, solvent bonding, laser and ultrasonic welding, and like joining techniques. As an alternative, the patient port **270** may be overmolded around the

stem of the swabable valve **274**, which eliminates the need for adhesive, solvents, or welding. The swabable valve **274** is generally used to connect the patient supply set **40** to the patient outlet port **270**. Because the valve is swabable, multiple connections may be made without compromising the connection. A self-sealing silicone stem (not shown) in the swabable valve **274** also prevents fluid drips when the patient supply set **40** is removed.

[00150] The outlet selector valve **280** comprises a unitary outlet selector valve body **282** with an actuator interface head **284** and a depending valve stem **286** that terminates in a rounded or tapered bottom edge or end **288**. Suitable material choices for the outlet selector valve body **282 i**nclude, but are not limited to: polyethylene (plain and fiber reinforced), polypropylene, nylon (including fiber reinforced), Ultem® PEI (polyetherimide), polycarbonate (plain and with silicone or siloxane), and like materials. The valve stem **286** defines a 90° flow passage **290** which tapers smoothly to the bottom edge or end **288** of the valve stem **286**. The "bell" shape of the flow passage **290** which tapers to the rounded bottom end **288** of the valve stem **286** minimizes the potential for air bubbles to become trapped below the valve stem **286**. The flow passage terminates **290** at one side of the valve stem **286** to define an outlet port **291** for fluid communication with the patient outlet port **270** and the waste outlet port **272**. The actuator interface head **284** of the outlet selector valve body **282** is adapted to interface with a valve actuator, described herein, associated with the drive and actuating system **400** which operates the pump **10**. The valve actuator controls operation of the outlet selector valve **280** to place the valve stem **286** in orientations at least to: (1) place the flow passage **290** in fluid communication with the patient outlet port **270** and, thus, in fluid communication with the connecting passage **268** leading to the outlet manifold channel **244**; (2) place the flow passage **290** in fluid communication with the waste outlet port **272** and, thus, in fluid communication with the connecting passage **268** leading to the outlet manifold channel **244**; and (3) place the flow passage **290** in a shut-off position or "off" position where the flow passage **290** is not aligned with either the patient outlet port **270** or the waste outlet port **272**, thereby preventing fluid flow from the outlet manifold channel **244** to either outlet port **270**, **272**.

[00151] The actuator interface head **284** is generally T-shaped and comprises, for example, two (2) outwardly extending tabs **292** and a recessed area **294** for engagement with the valve actuator associated with the drive and actuating system **400**, detailed hereinw. The T-shape of the actuator interface head **284** allows the outlet selector valve body **282** to slide into engagement with the valve actuator and also "keys" the outlet selector valve body **282** so that it may be engaged by the valve actuator in only one particular orientation. This interface

between the actuator interface head **284** and the valve actuator of the drive and actuating system **400** also prevents the outlet selector valve body **282** from being ejected upward from the outlet selector valve cylinder **264** on the manifold plate **230** under high operating pressure.

[00152] Additionally, the outlet selector valve **280** comprises a rear or proximal pressure sensing port **296** defined in the outlet selector valve cylinder **264** supporting the outlet selector valve body **282** that supports a pressure sensing diaphragm **298**, which interfaces with the drive and actuating system **400** so that fluid pressure in the valve bore **266** may be measured. The pressure sensing diaphragm **298** is a thin polyurethane (and like polymeric materials) diaphragm that is used to measure the fluid pressure in the outlet manifold channel **244**. The pressure sensing diaphragm **298** is desirably overmolded into the pressure sensing port **296** and seals the port **296** while transferring the fluid pressure within the pressure sensing port **296** to its exterior surface. The pressure sensing diaphragm **298** allows the pressure in the outlet manifold channel **244**, which is connected to the valve bore **266** via the connecting passage **268**, to be measured at any time, not just when injecting fluid into a patient. As one example, during fluid priming or flushing operations, the control system **800** can monitor the pressure in the outlet manifold channel **244** and determine if the waste collection tube set **46** is blocked or kinked. A load cell or like device, provided as part of the drive and actuating system **400**, interfaces with the diaphragm **298** to measure the fluid pressure through the diaphragm **298**, as described herein in connection with the drive and actuating system **400**.

[00153] As noted previously, the waste collection system **44** is connected to the waste outlet port **272** on the outlet selector valve cylinder **264** on the manifold plate **230** and is used to collect and store waste fluids. In particular, the waste collection tube set **46** is connected to the waste outlet port **272** to conduct waste fluids to the waste collection container **48** when the outlet selector valve **280** is actuated to place the flow passage **290** in fluid communication with the waste outlet port **272**.

[00154] **FIGS. 25A-25Q** illustrate additional embodiments of the outlet selector valve body **282**, wherein the outlet selector valve body **282** is embodied with different sealing arrangements. In a first such example shown in **FIGS. 25A-25C**, a lip seal arrangement **1200** is provided which comprising compliant overmolded lips seals formed, for example, of thermoplastic material such as TPU (thermoplastic polyurethane), on the rigid valve stem **286**. The compliant seals allow the valve stem **286** to be sealed in the valve bore **266** of the outlet selector valve cylinder **264** on the manifold plate **230**. The valve stem **286** may be a

rigid polycarbonate stem having the attached flexible thermoplastic lip seal arrangement **1200**. The lip seal arrangement **1200** comprises a lower lip seal **1202** that provides a compliant seal between a lower portion of the valve stem **286** and the valve bore **266** and centers the valve stem **286** within the valve bore **266**. Additionally, the lip seal arrangement **1200** comprises an upper lip seal **1204** that prevents ingress of foreign particles into the valve bore **266** and prevents fluid from exiting the valve bore **266** if any of the other lip seals leak. Further, the lip seal arrangement **1200** comprises a port lip seal **1206** that surrounds the outlet port **291** defined by the flow passage **290** on the sidewall of the valve stem **286** and provides a compliant seal between the sidewall of the valve stem **286** and the valve bore **266** of the outlet selector valve cylinder **264** on the manifold plate **230**. Moreover, the lip seal arrangement **1200** comprises an isolation seal **1208** that is located on the valve stem **286** at a position approximately 180° opposite from the port lip seal **1206**. The isolation seal **1208** is used to isolate the patient outlet port **270** from the waste outlet port **272** when the valve stem **286** is in the "off" position, wherein each of these ports are isolated from one another and the flow passage **290**. The geometry of the lip seals **1202**, **1204**, **1206** provide a higher level of sealing force when high pressure fluid is in contact with the seals (*e.g.*, the seals are hydraulically energized).

[00155] The flow passage **290** has an inlet at the bottom of the valve stem **286** and is always connected to the outlet manifold channel **244**, as described previously The outlet port **291** is located on the sidewall of the valve stem **286** and may be rotated to direct flow to either the patient outlet port **270** or the waste outlet port **272**. The shape of the flow passage **290** minimizes the potential for trapping air bubbles, as described previously. Additionally, as the outlet port **291** is at a higher elevation than the inlet to the flow passage **290**, there is a natural tendency for air bubbles to rise to the selected outlet port, the patient outlet port **270** or the waste outlet port **272**, and be ejected typically from the outlet selector valve **280** via the waste outlet port **272**.

[00156] The diameter of the lip seals **1202**, **1204**, **1206** is slightly larger than the diameter of the valve bore **266** so that when the valve stem **286** is assembled into the valve bore **266**, the lip seals **1202**, **1204**, **1206** are slightly compressed against the wall of the valve bore **266**. At low fluid pressures, the initial compression from the assembly process is sufficient to seal against low fluid pressures and, because the seals are compliant and easily deformed, the sealing force (and frictional torque) between the valve stem **286** and the valve bore **266** of the outlet selector valve cylinder **264** is low. At high fluid pressures, the lip seals **1202**, **1204**, **1206** become "hydraulically energized." The hydraulic pressure of the fluid against the lip

seals **1202**, **1204**, **1206** creates an additional sealing force. This additional force presses the lip seals **1202**, **1204**, **1206** more firmly against the outlet selector valve cylinder **264** as the pressure increases, and higher pressures result in greater sealing forces without requiring a large degree of initial compression.

[00157] When the valve stem **286** is positioned so that the flow passage **290** is in fluid connection with the patient outlet port **270**, the lower lip seal **1202** prevents high pressure fluid from entering the annular space around the valve stem **286**. The port lip seal **1206** directs fluid from the center of the flow passage **290** to the patient outlet port **270** and prevents high pressure fluid from entering the annular space around the valve stem **286**. Because there is no port in the outlet selector valve cylinder **264** that is directly across from the patient outlet port **270**, the isolation seal **1208** is not required when the valve stem **286** is in this position. As fluid is ejected through the outlet port **291**, there is a hydraulic reaction force that tends to push the valve stem **286** away from the patient outlet port **270**. Rigid support pads **1210** may be provided on the side of the valve stem **286** to resist this reaction force and prevent the lower lip seal **1202** from being deformed excessively. Under normal operating conditions, the upper lip seal **1204** is used to keep the valve stem **286** centered in the valve bore **266**, and prevents fluid egress if one of the other lip seals leaks.

[00158] When the valve stem **286** is positioned so that the flow passage **290** is in fluid connection with the waste outlet port **272**, the lower lip seal **1202** prevents low pressure fluid from entering the annular space around the valve stem **286**. The port lip seal **1206** directs fluid from the center of the flow passage **290** to the waste outlet port **272** and prevents low pressure fluid from entering the annular space around the valve stem **286**. Because there is no port in the outlet selector valve cylinder **264** that is directly across from the waste outlet port **272**, the isolation seal **1208** is not required when the valve stem **286** is in this position. The patient outlet port **270** is connected to the annular space around the valve stem **286** and, because this annular space is not connected to any other port at this time, the patient outlet port **270** remains isolated from all other ports. Under normal operating conditions, the upper lip seal **1204** is used to keep the valve stem **286** centered in the valve bore **266**, and prevents fluid egress if one of the other lip seals leaks.

[00159] In a second sealing example shown in **FIG. 25D**, the valve stem **286** is formed with a thin cylindrical wall **1212** and an elastomeric core **1214** is disposed in the thin-walled cylindrical valve stem **286**. The open center of the valve stem **286** is filled with a compliant elastomeric core **1214** made from materials such TPU (thermoplastic urethane) or silicone rubber, and defines the flow passage **290** to provide a defined fluid pathway through the

valve stem **286**. The thin cylindrical sidewall **1212** defines an aperture **1216** connected to the outlet port **291** of the flow passage **290**. The upper portion of the valve body **282** maintains the features described previously for interfacing with the drive and actuating system **400**. The thin cylindrical wall **1212** of the valve stem **286** and forming the lower portion of the valve body **282** may be easily deformed to allow the outside diameter of the valve stem **286** to conform to and seal against the valve bore **266** of the outlet selector valve cylinder **264**. The elastomeric core **1214** defines the flow passage **290**, which serves to direct fluid from the inlet thereto to the outlet port **291** connected to the aperture **1216** in the valve stem **286**, and the flow passage **290** maintains the features described previously for minimizing the potential for trapped air and stagnant regions in the flow path. The elastomeric core **1214** is generally soft and compliant enough that it does not significantly stiffen the cylindrical wall or walls **1212** of the valve stem **286**. When the valve stem **286** is subjected to internal pressure, the cylindrical sidewall **1212** of the valve stem **286** expands outward to increase the sealing force between the outer diameter of the valve stem **286** and the valve bore **266**.

[00160] In a third sealing example shown **in FIGS. 25E-25G**, a sealing arrangement **1220** similar to sealing arrangement **1200** described previously is provided but now comprises a plurality of o-ring seals on the valve stem **286**, which is a rigid polycarbonate stem and has the same general structure as described previously in connection with **FIGS. 24A-24B** and **FIGS. 25A-25C**. In one embodiment of the sealing arrangement **1220**, four (4) o-ring seals **1222-1228** are installed in grooves molded in the valve stem **286**. A first o-ring seal **1222** provides a compliant seal between the lower portion of the valve stem **286** and the valve bore **266** and centers the valve stem **286** within the valve bore **266**. A second o-ring seal **1224** prevents the ingress of foreign particles into the valve bore **266** and prevents fluid from exiting the valve bore **266** if any of the other seals leak. A third o-ring seal **1226** surrounds the outlet port **291** in the sidewall of the valve stem **286** and provides a compliant seal between the valve stem **286** and valve bore **266** of the outlet selector valve cylinder **264**. A fourth isolation o-ring seal **1228** is located on the valve stem approximately 180° opposite from the third o-ring seal **1226** surrounding the outlet port **291**. The isolation o-ring seal **1228** is used to isolate the patient outlet port **270** from the waste outlet port **272** when the valve stem **286** is in the "off" position. The o-ring seals **1222-1228** may be made of any type of suitable elastomeric material including polyurethane, silicone or EPDM.

[00161] In a hybrid embodiment shown in **FIGS. 25H-25I**, the valve stem **286**, as shown in **FIG. 25D** having a thin cylindrical wall **1212** and an elastomeric core **1214** disposed in the thin-walled cylindrical valve stem **286**, is combined with a sealing o-ring **1230** disposed in a

groove in or seated against a ledge **1232** defined by the upper portion of the valve stem **286**. The o-ring **1230** may be made of silicone rubber, polyurethane, EPDM or other suitable elastomer. Any fluid that may leak between the valve stem **286** and the outlet selector valve cylinder **264** is prevented from leaking outside of the outlet selector valve cylinder **264** by the upper o-ring **1230** at the top of the valve stem **286**.

[00162] In another sealing arrangement **1234** as shown in **FIGS. 25J-25L**, the valve stem **286** is segmented to define a plurality of finger elements **1236** with spaces **1238** in-between, and the valve stem **286** is enclosed by a cooperating sleeve element **1240**. Each finger element **1236** acts like a cantilevered leaf spring that is biased to expand outward against the wall of the valve bore **266**. The finger elements **1236** may be molded in a cylindrical configuration, as shown, or may be molded in a conical formation such that the finger elements **1236** compress inward to initially install the valve stem **286** into the valve bore **266**. In either configuration, the finger elements **1236** provide a radial outward force against the valve bore **266** to improve sealing.

[00163] The sleeve element **1240** serves as the sealing surface against the wall of the valve bore **266** and may be made of TPU and other suitable elastomeric materials. The sleeve element **1240** comprises internal, axially-extending radial ridges **1242** that are trapped in the spaces **1238** in-between the finger elements **1236**, forcing the finger elements apart **1236** and radially-outward. The sleeve element **1240** further defines the upper end of the flow passage **290** and corresponding apertures **1246**, **1248** are defined in the valve stem **286** and the sleeve element **1240**, respectively, to define the outlet port **291** of the flow passage **290**. In use with low fluid pressures, the spring action of the finger elements **1236** presses the sleeve element **1240** radially outward until it is sealed against the wall of the valve bore **266**. The radial ridges **1242** that are trapped in the spaces **1238** in-between the finger elements **1236** may also help to force the finger elements **1236** circumferentially apart, increasing the sealing force. In use with high fluid pressures, fluid pressure inside of the flow passage **290** in the valve stem **286** also helps to generate a radial-outward force on the finger elements **1236** and the sleeve element **1240**, increasing the sealing force against the wall of the valve bore **266**.

[00164] In another sealing arrangement **1250** as shown in **FIGS. 25M-25N**, the valve body **282** is of composite form, namely having an upper portion **1252** formed of a stiff polycarbonate material or like material, and a compliant lower portion **1254** formed of TPU or other suitable elastomeric materials. The lower portion **1254** generally forms the valve stem **286** while the upper portion **1252** defines the features described previously for interfacing with the drive and actuating system **400**. The lower portion **1254** generally

forming the valve stem **286** has integral upper and lower sealing beads **1256**, **1258** to seal against the wall of the valve bore **266** and another sealing bead **1260** to form a seal about the outlet port **291** of the flow passage **290** to create sufficient sealing force around this port. The material used for the lower portion **1254** generally forming the valve stem **286** may have a higher durometer (and higher stiffness) than the material used for the various fluid seals in the preceding sealing arrangements described in connection with **FIGS. 25A-25L**.

[00165] In yet another sealing arrangement **1270** as shown in **FIGS. 25O-25Q**, a sleeve or liner **1272** formed of compliant sealing material is seated within the valve bore **266** of the outlet selector valve cylinder **264** instead of on the valve stem **286**. The valve body **282** has the same general configuration as described previously in connection with **FIGS. 24A-24B**, with the addition of an upper ridge or ledge or sealing bead **1274** formed below the actuator interface head **284** and an exterior raised bead **1276** around the outlet port **291** of the flow passage **290** in the valve stem **286** to ensure suitable sealing characteristics in the valve bore **266**. The valve body **282** may be made of a rigid material such as polycarbonate. The elastomeric sleeve or liner **1272** may be made of TPU or a similar elastomer. The liner **1272** defines an upper recessed area **1278** to receive the ridge or ledge and/or sealing bead **1274** provided on the valve stem **286**, and defines respective side apertures **1280** to provide fluid communication with the outlet port **291** of the flow passage **290** in the valve stem **286**, and the patient outlet port **270** and the waste outlet port **272**. The liner **1272** may include one or more axial recessed areas **1282** to prevent contact with the exterior raised bead **1276** around the outlet port **291** of the flow passage **290**, and this axial recessed area **1282** is a suitable location to orient the raised bead **1276** during shipment or storage of the pump device **10**. By placing the raised bead **1276** in the recessed area **1282** during shipping and storage, the liner **1272** is less likely to experience compression set or creep which could cause a reduction in sealing characteristics. It may also be desirable to integrate the pressure sensing diaphragm **298** as part of the liner **1272** to consolidate components.

[00166] Referring further to **FIGS. 27-29**, as noted in the foregoing, an inlet selector valve **300** is provided in each of the inlet selector valve cylinders **114**. Each inlet selector valve cylinder **114** defines a cylindrical chamber **116** that accepts the inlet selector valve **300** which is rotationally operable within the inlet selector valve cylinder **114**. The drive and actuating system **400** which operates the pump **10** also desirably includes separate valve actuators that operate the respective inlet selector valves **300**. The respective inlet selector valves **300** each comprise an inlet selector valve body **302** with an actuator interface head **304** and an elongated and hollow valve stem **306** that terminates in a distal edge or end **308** which abuts

(or is disposed in proximity to) the front plate **102** and extends about the front or distal end opening **118** formed in the front plate **102**. The valve stem **306** defines an axial bore or passage **310**. The actuator interface head **304** of the inlet selector valve body **302** is adapted to interface with an inlet selector valve actuator, described herein, associated with the drive and actuating system **400**. The actuator interface head **304** may be generally round or circular in shape and comprises a proximally extending tab **312**, or a plurality of such tabs **312**, and an interface engagement member **314** formed internally within the actuator interface head **304**. The proximally extending tab **312** and internal engagement member **314** form interfacing features for engagement with the inlet selector valve actuator associated with the drive and actuating system **400**. For safety purposes, it is desirable for the valve stem **306** to be engaged to the drive and actuating system **400** in one particular angular orientation. If the valve stem **306** can be installed in more than one angular orientation, it could be possible to deliver the wrong type of fluid, as described further herein.

[00167] The valve stem **306** defines a series of radial inlet openings or ports **320** that connect to the central or axial passage **310**. The radial inlet openings or ports **320** are located at different angular locations around the valve stem **306** and at different axial locations along the valve stem **306**. The radial inlet openings or ports **320** include a first inlet port **322** for placing the first inlet port **122** on the receiving inlet selector valve cylinder **114** in fluid communication with the axial passage **310** in the valve stem **306**, a second inlet port **324** for placing the second inlet port **124** on the receiving inlet selector valve cylinder **114** in fluid communication with the axial passage **310** in the valve stem **306**, and third and fourth inlet ports **326**, **328** positioned to allow fluid communication between either of the saline channels **132**, **134** of the saline manifold **130** and the axial passage **310** in the valve stem **306**. The respective inlet ports **322**, **324**, **326**, **328** are defined at different angular locations around the valve stem **306** and are positioned at spaced axial locations along the valve stem **306** so that, at most, only one of these inlet ports **322-328** permits fluid communication with the axial passage **310** in the valve stem **306** at any given time, and thereby permit fluid flow into the valve stem **306** from the first inlet port **122**, second inlet ports **124**, or one of the saline channels **132**, **134**. In particular, the respective inlet ports **322-328** are defined at different angular locations around the valve stem **306** and spaced axial locations along the valve stem **306** so that only one of the first and second inlet ports **122**, **124** and the saline channels **132**, **134** of the saline manifold **130** is in fluid communication with the axial bore or passage **310** in the valve stem **306** at any given time. Accordingly, if the first inlet port **322** is in fluid communication with the first inlet port **122**, the second inlet port **124** is blocked by the valve

stem **306** to fluid flow, as are both of the saline channels **132**, **134** of the saline manifold **130**. Similarly, if the second inlet port **324** is in fluid communication with the second inlet port **124**, the first inlet port **122** is blocked by the valve stem **306** to fluid flow, as are both of the saline channels **132**, **134** of the saline manifold **130**. If the third inlet port **326** is aligned with the first or forward saline channel **132**, the first and second inlet ports **122**, **124** are blocked to fluid flow by the valve stem **306**, as is the second or rearmost saline channel **134**. Further, if the fourth inlet port **328** is aligned with the second or rearmost saline channel **134**, the first and second inlet ports **122**, **124** are blocked to fluid flow by the valve stem **306**, as is the first or forward saline channel **132**.

[00168] In the depicted arrangement, the inlet ports **322-328** are axially spaced along the valve stem **306**, with the first inlet port **322** located near the distal end **308** of the valve stem **306** and the last or fourth inlet port **328** located near the actuator interface head **304**. As explained previously, the foregoing axial order of the ports **122-126** and corresponding ports **322-328** is desirable for air management issues. In particular, in the pump **10** in the accompanying figures, the "left" saline source **S1** is connected to the left saline port **126** so that the rearmost saline channel **134** is filled first with saline for priming purposes. The rearmost or fourth inlet port **334** in the valve stem **306** is located in the rearmost position to establish fluid communication with the rearmost saline channel **134** to allow the entire inlet selector valve **300** to be primed with saline from the far rear or proximal end. If this "saline" port was located in any other "forward" position, it would not be possible to remove all of the air from the length of the inlet selector valve **300** as air would be trapped behind this position. It is noted that the distance from the saline inlet port **328** and the proximal or rear end of axial passage **310** adjacent the actuator interface head **304** is minimized as much as possible to limit the potential for air bubbles to be trapped behind this inlet port **328** and the end of the axial passage **310**.

[00169] Referring specifically to **FIGS. 28C-28D**, the inlet selector valve **300** may be provided with a sealing arrangement **1300** on the valve stem **306**. The sealing arrangement **1300** uses a series of elastomeric seals, which are similar to o-rings, to seal the valve stem **306** in the inlet selector valve cylinder **114**. Each of the four inlet ports **322-328** is sealed in two (2) ways according the illustrated embodiment. First, a circular sealing bead **1302** is provided around each of the inlet ports **322-328** in the valve stem **306**, and this seal prevents any fluid that may be in the central or axial passage **310** of the valve stem **306** from moving into the space between the valve stem **306** and the inlet selector valve cylinder **114**. Secondly, two (2) circumferential sealing rings **1304**, **1306** are axially located on either side of each

inlet port **322-328**, and are used to isolate the inlet ports **322-328** in the inlet selector valve cylinder **114**. These circumferential seal rings **1304**, **1306** prevent fluids connected to the first inlet port **122**, second inlet port **124**, or one of the saline channels **132**, **134** from mixing with one another in the inlet selector valve cylinder **114**. Each of the foregoing seals **1302**, **1304**, **1306** is made of TPU (thermoplastic polyurethane) or like elastomers and is attached to the rigid valve stem **306** during an overmolding process. The valve stem **306** may be made of polycarbonate and like materials. Each seal **1302**, **1304**, **1306** has a "D-shaped" cross-section which seals against the inlet selector valve cylinder **114**.

[00170] Referring to **FIGS. 28E-28F**, the inlet selector valve **300** may be provided with an alternative sealing arrangement **1310** on the valve stem **306**. In this embodiment, a soft (TPU - thermoplastic polyurethane, or like material) sleeve **1312** is overmolded onto the rigid valve stem **306**, which may be polycarbonate to provide rigidity and torsional stiffness to the valve stem **306**. The overmolded sleeve **1312** provides a compliant surface to allow the valve stem **306** to seal against the against the inlet selector valve cylinder **114**. The compliant surface allows the valve stem **306** to fully seal against the interior wall of the inlet selector valve cylinder **114** even if surface imperfections are present in either component.

[00171] With the foregoing radial and axial locations for the inlet ports **322-328**, the inlet selector valve actuators, described herein, of the drive and actuating system **400** control operation of the right and left inlet selector valves **300** to place the valve stem **306** in an orientation to: (1) connect the first inlet port **322** with the first inlet port **122** to provide fluid communication between a first source of therapeutic or diagnostic (*e.g.*, pharmaceutical) fluid **A1**, **B1** contained in a connected fluid source container **30** and the corresponding inlet manifold channel **236**, while the second inlet port **124** and both of the saline channels **132**, **134** of the saline manifold **130** are blocked to fluid flow by the valve stem **306**; (2) connect the second inlet port **324** with the second inlet port **124** to provide fluid communication between a second source of therapeutic or diagnostic (*e.g.*, pharmaceutical) fluid **A2**, **B2** contained in a connected fluid source container **30** and the corresponding inlet manifold channel **236**, while the first inlet port **122** and both of the saline channels **132**, **134** of the saline manifold **130** are blocked to fluid flow by the valve stem **306**; (3) connect the third inlet port **326** with the first or forward saline channel **132** of the saline manifold **130** to connect the third inlet port **326** with the first or forward saline channel **132** of the saline manifold **130** via saline port **332** (**FIG. 5B**) to provide fluid communication between a second source of saline **S2** contained in a connected fluid source container **30** and the corresponding inlet manifold channel **236**, while the first and second inlet ports **122**, **124** and

the second or rear saline channel **134** of the saline manifold **130** are blocked to fluid flow by the valve stem **306**; (4) connect the fourth inlet port **328** with the second or rearmost saline channel **134** of the saline manifold **130** via saline port **334** (**FIG. 5B**) to provide fluid communication between a first source of saline **S1** contained in a connected fluid source container **30** and the corresponding inlet manifold channel **236**, while the first and second inlet ports **122**, **124** and the first or forward saline channel **132** of the saline manifold **130** are blocked to fluid flow by the valve stem **306**; and (5) an "OFF" position wherein the valve stem **306** is in a position to block each of the first and second inlet ports **122**, **124** and the first and second saline channels **132**, **134**, thereby preventing fluid flow from the various external fluid sources contained in the fluid source containers **30** to the corresponding inlet manifold channel **236**. Thus, at least a total of five (5) different operational states are present for each of these inlet selector valves **300** in the embodiment of the pump **10** found in the accompanying figures. However, this embodiment should not be considered limiting as additional inlet ports (not shown) may be provided on the respective inlet selector valve cylinders **114**, with corresponding inlet ports (not shown) being provided in the valve stem **306** of the respective inlet selector valves **300** to accommodate additional connected fluid sources as desired.

[00172] Referring specifically to **FIGS. 5A** and **5B**, it will be understood that the saline manifold **130** is formed to extend across the pump cylinders **104** and has opposing ends that connect to the respective inlet selector valve cylinders **114**. With this construction, the saline channels **132**, **134** extend the length between the two (2) outboard inlet selector valve cylinders **114**. Saline ports **332**, **334** are defined in the bottom of each of the inlet selector valve cylinders **114** to connect the inlet selector valve cylinders **114** to the saline channels **132**, **134**. The first or forward saline ports **332** connect the inlet selector valve cylinders **114** to the first or forward saline channel **132** and the second or rear saline ports **334** connect the inlet selector valve cylinders **114** to the second or rear saline channel **134**. Accordingly, when the valve stem **306** of the actuated inlet selector valve **300** is rotated to connect the third inlet or "saline" port **326** with the first or forward saline channel **132** of the saline manifold **130**, the third inlet "saline" port **326** is actually aligned with the first or forward saline port **332** in the inlet selector valve cylinder **114**. Additionally, when the valve stem **306** of the actuated inlet selector valve **300** is rotated to connect the fourth inlet "saline" port **328** with the second or rear saline channel **134** of the saline manifold **130**, the fourth inlet or "saline" port **328** is actually aligned with the second or rear saline port **334** in the inlet selector valve cylinder **114**.

[00173] In the exemplary configuration of the pump **10** depicted in the accompanying figures, the left side inlet ports **122**, **124** may be connected, respectively, to two (2) different sources of therapeutic or diagnostic (*e.g.*, pharmaceutical) fluids, **A1**, **A2**, to be received in the two (2) left pump cylinders **104**, and the left side saline port **126** may be connected to a first source of saline, designated as "**S1**". Fluid "**A1**" provided in one of the fluid source containers **30** may be connected to first inlet port **122** and fluid "**A2**" provided in one of the fluid source containers **30** may be connected to the second inlet port **124**, or vice versa, on the left side **18** of the pump **10**. Likewise, the right side inlet ports **122**, **124** may be connected, respectively, to two (2) different sources of therapeutic or diagnostic (*e.g.*, pharmaceutical) fluid, **B1**, **B2** to be received in the two (2) right pump cylinders **104**, and the right side saline port **126** may be connected to the second source of saline, designated as "**S2**". The two (2)-channel saline manifold **130** permits saline from either saline source **S1**, **S2** to be pulled into either of the inlet selector valves **300** during operation of the pump **10**. Fluid "**B1**" provided in one of the fluid source containers **30** may be connected to first inlet port **122** and fluid "**B2**" provided in one of the fluid source containers **30** may be connected to the second inlet port **124**, or vice versa, on the right side **16** of the pump **10**. Further, fluids **A1**, **A2** may be connected to the right side inlet ports **122**, **124** in any desired pairing, and the fluids **B1**, **B2** may be connected to the left side inlet ports **122**, **124** in any desired pairing as an alternative configuration for the pump **10**. Accordingly, for exemplary purposes only in this disclosure, fluid flow of the fluids **A1**, **A2** contained in the fluid source containers **30** is controlled by the left side inlet selector valve **300** and fluid flow of the fluids **B1**, **B2** contained in the fluid source containers **30** is controlled by the right side inlet selector valve **300**. As noted previously, the respective inlet selector valves **300** may draw saline from either of the saline channels **132**, **134** of the saline manifold **130**. Hence, the respective inlet selector valves **300** may draw from either saline source **S1**, **S2**. Accordingly, each "half" of the pump **10** has a single inlet selector valve **300** that allows selection from several fluid sources that are to be fed into the two (2) associated pump cylinders **104**. Thus, control of fluids to the two (2) left side pump cylinders **104** is provided by the left side inlet selector valve **300** and control of fluids to the two (2) right side pump cylinders **104** is provided by the right side inlet selector valve **300**.

[00174] The initial angular orientation of the valve stem **306** of the inlet selector valves **300** may be preset by the manufacturer and this orientation may be encoded into the pump indicator plate **170** and/or into identifying indicia **172** on the pump body **100**, described previously. The control system **800** can thereby determine the initial or preset angular

orientation of the valve stem **306** and operate the drive and actuating system **400** accordingly. If the angular orientation of the valve stem **306** is not needed for control by the control system **800** (such as if a read-write RFID tag is used for the identifying indicia **172**) the valve stem **306** of the inlet selector valves **300** may have any suitable initial angular orientation such as the "OFF" position outlined previously. Once associated with the drive and actuating system **400**, the respective plungers **200** may be driven forward into the pumping zone **164** of the pump chambers **106** until the distal end of the plunger **200** contacts the distal end wall **110** of the pump cylinder **104**. Priming of the various fluid pathways in the pump **10** may be then be conducted.

[00175] The storage/isolation zone **166** has a larger diameter than the primary working/pumping zone **164** in each of the pump cylinders **104** to allow the forward or distal end lip seal **218** to reside in an uncompressed state within the large diameter storage/isolation zone **166** during storage. If this seal **218** was stored in the working/pumping zone **164**, there is the possibility that the seal **218**, over time, could "creep" or "relax" or take a compression set to the point that it would no longer be adequately squeezed/compressed during use, preventing it from sealing appropriately.

[00176] Referring further to **FIGS. 30-36**, general operation of one of the "primed" pump cylinders **104** in the pump **10** will now be provided with reference primarily to the right outboard pump cylinder **104** of the pump body **100** as shown in **FIGS. 32-36**. Initially, as shown by the horizontal cross-sectional view of the pump **10** shown in **FIG. 30**, the respective plungers **200** are located in the isolation zone **166** in the pump chamber **106** of the respective pump cylinders **104**, and the inlet selector valves **300** are in the "OFF" position. Assuming priming of the fluid pathways in the pump **10** has been completed, the right side selector valve **300** may be actuated to, for example, place the valve stem **306** in an angular orientation in the inlet selector valve cylinder **114** to permit fluid communication between the first inlet port **322** in the valve stem **306** and the first inlet port **122** on the right inlet selector valve cylinder **114**, as shown in **FIG. 32**. Retraction of the plunger **200** in the pump chamber **106** of the right outboard pump cylinder **104** results in fluid **B1** in the connected fluid source container **30** being drawn through the axial passage **310** in the valve stem **306** and into the right side inlet manifold channel **236** to act upon the underlying inlet check valve **194** and open the inlet check valve **194** (see also the previous discussion of **FIG. 20**). The fluid flow acts upon the inlet check valve **194** supported by the inlet check valve support structure **144** in the inlet opening **142** and opens the inlet check valve **194** so that fluid **B1** may pass through the inlet opening **142** and enter the pump chamber **106** of the pump cylinder **104**.

The inlet check valve **194** regulates the fluid flow into the pump chamber **106** of the pump cylinder **104**. The fluid flow of fluid **B1** is identified by arrow A_1 in **FIG. 32**.

[00177] Next, if desired, a second therapeutic or diagnostic (*e.g.*, pharmaceutical) fluid may be drawn into the pump chamber **106** of the right outboard pump cylinder **104** to be mixed with the fluid **B1** present in the pump chamber **106**. If so, the right side selector valve **300** may be actuated to place the valve stem **306** in an angular orientation in the inlet selector valve cylinder **114** to permit fluid communication between the second inlet port **324** in the valve stem **306** and the second inlet port **124** on the inlet selector valve cylinder **114**, as shown in **FIG. 33**. Additional retraction of the plunger **200** in the pump chamber **106** of the right outboard pump cylinder **104** results in fluid **B2** in the connected fluid source container **30** being drawn through the axial passage **310** in the valve stem **306** and into the right side inlet manifold channel **236** to act upon the underlying inlet check valve **194** and open the inlet check valve **194** (see also the previous discussion of **FIG. 20**). The fluid flow acts upon the inlet check valve **194** supported by the inlet check valve support structure **144** in the inlet opening **142** and opens the inlet check valve **194** so that the fluid **B2** may pass through the inlet opening **142** and enter the pump chamber **106** of the pump cylinder **104**. The inlet check valve **194** regulates the fluid flow into the pump chamber **106** of the pump cylinder **104**. The fluid flow of fluid **B2** is identified by arrow A_2 in **FIG. 33**. In the scenario presented in the foregoing, it is assumed that fluid **B1** is different from fluid **B2**, but these fluids may also be the same medical fluid as well. This example is provided to illustrate mixing of fluids in the respective pump chambers **106** of the pump cylinders **104**, if so desired, and with appropriate safety protocols in the control system **800** relating to the mixing of fluids. As an alternative, if the fluids **B1**, **B2** are the same fluid, the fluid delivery system **2** may deliver fluid continuously from the fluid source container **30** holding fluid **B1** until this container is exhausted, and the system **2** may then switch to the "backup" fluid source container **30** holding fluid **B2**.

[00178] Further, if desired, saline from the saline sources **S1**, **S2** contained in the connected saline fluid source containers **30** provided on opposite sides of the pump **10** may be drawn into the pump chamber **106** of the right outboard pump cylinder **104** to be mixed with the fluids **B1**, **B2** present in the pump chamber **106**. The rights side inlet selector valve **300** may be operated to draw from either saline source **S1**, **S2**. In a desirable operational practice, mixing saline **S1**, **S2** with fluids **B1** and/or **B2** can occur by delivering saline with the two (2) pump cylinders **104** on one side of the pump **10** and delivering the diagnostic or therapeutic (*e.g.*, pharmaceutical) fluids **B1**, **B2** with the two (2) pump cylinders **104** on the

other side of the pump **10**. In the present example, if it is desired, for example, to next mix in saline **S2**, the right side selector valve **300** may be actuated to place the valve stem **306** in an angular orientation to permit fluid communication between the third inlet port **326** in the valve stem **306** and the saline port **332** in the inlet selector valve cylinder **114** which connects to the first or forward saline channel **132** of the saline manifold **130**, as shown in **FIG. 34**. Further retraction of the plunger **200** in the pump chamber **106** of the right outboard pump cylinder **104** results in saline **S2** in the connected fluid source container **30** being drawn from the saline channel **132** through the saline port **332** in the inlet selector valve cylinder **114** into the axial passage **310** in the valve stem **306** and into the right side inlet manifold channel **236** to act upon and open the underlying inlet check valve **194** (see also the previous discussion of **FIG. 20**). The fluid flow acts upon the inlet check valve **194** supported by the inlet check valve support structure **144** in the inlet opening **142** and opens the inlet check valve **194** so that the saline **S2** may pass through the inlet opening **142** and enter the pump chamber **106** of the pump cylinder **104**. The inlet check valve **194** regulates the fluid flow into the pump chamber **106** of the pump cylinder **104**. The fluid flow of saline **S2** is identified by arrow **A_3** in **FIG. 34**.

[00179] Moreover, if saline **S1** is also desired to be mixed into the fluids **B1**, **B2** and saline **S2** now present in the pump chamber **106** of the pump cylinder **104**, the right side selector valve **300** may be actuated to place the valve stem **306** in an angular orientation to permit fluid communication between the fourth inlet port **328** in the valve stem **306** and the saline port **334** in the inlet selector valve cylinder **114** which connects to the second or rearmost saline channel **134** of the saline manifold **130**, as shown in **FIGS. 35-36**. Further retraction of the plunger **200** in the pump chamber **106** of the right outboard pump cylinder **104** results in saline **S1** in the connected fluid source container **30** being drawn from the saline channel **134** through the saline port **334** in the inlet selector valve cylinder **114** into the axial passage **310** in the valve stem **306** and into the right side inlet manifold channel **236** to act upon and open the underlying inlet check valve **194** (see also the previous discussion of **FIG. 20**). The fluid flow acts upon the inlet check valve **194** supported by the inlet check valve support structure **144** in the inlet opening **142** and opens the inlet check valve **194** so that the saline **S1** may pass through the inlet opening **142** and enter the pump chamber **106** of the pump cylinder **104**. The inlet check valve **194** regulates the fluid flow into the pump chamber **106** of the pump cylinder **104**. The fluid flow of saline **S1** is identified by arrow **A_4** in **FIGS. 35-36**.

[00180] As will be clear from the foregoing, retraction of the plungers **200** in the pump chambers **106** of the respective pump cylinders **104** results in fluid being drawn into the

corresponding inlet manifold channel **236** to act upon the inlet check valves **194**. The fluid flow acts upon the inlet check valves **194** and the inlet check valves **194** regulate the fluid flow into the pump chambers **106** of the pump cylinders **104**. When the pressure in the inlet manifold channel **236** is greater than the pressure within the pump chambers **106** of the pump cylinders **104**, such as when the plungers **200** are retracted in the pump cylinders **104**, the inlet check valves **194** deform to allow fluid flow into the pump chambers **106**. When the pressure within the pump chambers **106** of the pump cylinders **104** is greater than the pressure within the inlet manifold channel **236**, such as when the plungers **200** are moving forward or distally within the pump cylinders **104**, the inlet check valves **194** are pressed against the check valve recesses **252** formed in the rear or proximal side **234** of the manifold plate **230**, and prevent fluid flow out of the pump cylinders **104** into the corresponding inlet manifold channel **236**.

[00181] As fluid enters the pump chamber **106** of the pump cylinder **104** via the inlet opening **142** as the plunger **200** is retracted within the pump cylinder **104**, the fluid enters the front pumping zone **164** of the pump cylinder **104**. The rear isolation zone **166** of the pump cylinder **104** is present for sterility purposes, as described previously. The inner diameter of the pump cylinder **104** in the area of pumping zone **164** is desirably slightly smaller than the inner diameter of the pump cylinder **104** in the area of the isolation zone **166**. The larger inner diameter of the pump cylinder **104** in the area of the isolation zone **166** serves as a storage location for the plunger **200** prior to use and prevents the front lip seal **218** from being compressed and permanently deformed during long-term storage. This storage configuration is shown in **FIG. 30**, discussed previously. During use, the front lip seal **218** remains within the front pumping zone **164** of the pump cylinder **104** and the rear bead seal **220** remains in the rear isolation zone **166**. Since the two (2) seals **218**, **220** do not contact the same surfaces, the potential for contamination from the ambient environment is reduced.

[00182] For each of the inlet selector valves **300**, the rearmost saline port **334** on the inlet selector valve cylinder **114** is located near the rear or proximal end opening **120** and, accordingly, located near the proximal end of the axial passage **310** in the valve stem **306** of the inlet selector valve body **302** to allow substantially the entire valve **300** to be primed using saline. During priming, air is pushed by the priming saline from the rear of the selector valve **300** down the length of the axial passage **310** in the valve stem **306** and into the associated inlet manifold channel **236** and into the pump chambers **106** of the associated pump cylinders **104**. Desirably, the axial passage **310** in the valve stem **306** is generally horizontal rather than oriented at an angle or having a slope, which enhances air bubble

removal. However, if desired, the axial passage **310** in the valve stem **306** may generally slope upward toward the corresponding inlet manifold channel **236** to aid in air removal from the valve stem **306**. The inlet selector valve cylinder **114** and valve stem **306** of the inlet selector valve **300** are also generally parallel to the corresponding pump cylinders **106**. As a result of the foregoing arrangement and priming sequence, stagnation regions or "dead areas" are minimized in the inlet selector valve cylinder **114** and in the axial passage **310** in the valve stem **306**, minimizing the potential for trapped air bubbles. Saline **S1** or saline **S2** contained in the fluid source containers **30** may be used for priming of the pump **10** with fluid. As saline is much less expensive than most therapeutic or diagnostic (*e.g.*, pharmaceutical) fluids, it is preferred for priming operations for the pump **10**. After a fluid injection or infusing procedure involving a therapeutic or diagnostic (*e.g.*, pharmaceutical) fluid has occurred, it may be desirable to flush the contents of the pump chambers **106** of the pump cylinders **104** from the pump **10**, and the saline **S1**, **S2** in the connected fluid source containers **30** may be used for this purpose. This "saline" flushing step also desirably flushes residual fluids in the flow paths upstream and downstream from the pump cylinders **104**.

[00183] Referring to **FIGS. 29A – 29H**, the inlet ports **322-328** in the valve stem **306** of the inlet selector valves **300** are desirably placed at respective angular locations to minimize "cross-over" of unprimed inlet ports **122**, **124** or an unprimed port **332**, **334** connected to the saline manifold **130**. In practice, the rearmost saline port **334** is primed first with saline as the first installed fluid source container **30** is a saline fluid source container **30** that is installed in the left rear position on the pump **10**, and minimization of "cross over" is primarily a concern with respect to inlet **122**, **124** and saline port **332**. Crossing over an unprimed port can undesirably introduce air into the axial passage **310** in the valve stem **306** of the selector valve **300**. Accordingly, the rearmost saline channel **134** of the saline manifold **130** is supplied by the saline source **S1** connected to the saline port **126** located on the left side **18** of the pump **10** and delivers saline to rearmost inlet port **328** on both the left and right inlet selector valves **300**. Next, the forward saline channel **132** is supplied by the saline source **S2** connected to the saline port **126** located on the right side **16** of the pump **10** and delivers fluid to the next-to-rearmost inlet port **326** on both the left and right inlet selector valves **300**. The inlet ports **322-328** are located so that the valve stem **306** may be moved from a position permitting fluid communication between the rearmost inlet port **328** and the saline port **334** to the saline channel **134** connected to the left side saline fluid source containers **30** containing saline "**S1**" and the "OFF" position of the valve stem **306**, without any of the remaining inlet ports **322-326** crossing over any of the inlet ports **122**, **124** of the inlet selector valve cylinder

114 or the forward saline port **332** leading to the saline channel **132** of the saline manifold **130**. Accordingly, the valve stem **306** may be rotated from any inlet port **122**, **124** with an installed or connected fluid source and any saline port **332**, **334** with an installed or connected saline source **S1**, **S2** to any other such port with an installed or connected fluid source without crossing over an unprimed inlet port. **FIGS. 29A-29H** show several exemplary scenarios showing how the angular positioning of the inlet ports **322-328** prevents "cross-over" of unprimed fluid ports.

[00184] In **FIG. 29A**, the valve stem **306** of the inlet selector valve **300** is shown at an "OFF" position and a saline fluid source container **30** containing saline **S1** has been installed, primed, and is ready for use as the first "saline" port **S1**. As shown in **FIG. 29B**, the valve stem **306** may be rotated between the OFF position and the first saline port **S1** without having to pass over any unprimed ports, such as ports **A1**, **A2**, or **S2**, as discussed herein. If the valve stem **306** passes over an unprimed port, it is possible for air to be introduced into the axial passage **310** in the valve stem **306** of the inlet selector valve **300**. This air could eventually be delivered to the patient outlet port **270** and to the patient unless the fluid injection is aborted by the control system **800**. As shown by **FIGS. 29A-29B**, the first saline port **S1** is always desired to be the first primed port because if the second saline port **S2** was primed before the first saline port **S1**, the valve stem **306** would be forced to pass over the unprimed first saline port **S1**.

[00185] **FIGS. 29C** and **29D** show the inlet selector valve **300** after the first saline port **S1** and a first "contrast" port **A1** have been installed, primed, and are ready for use. Again, in this situation, the valve stem **306** may be freely rotated from the first saline port **S1**, past the OFF position, and to the first contrast port **A1** without having to pass over any unprimed ports, such as ports **A2** or **S2**. Again, if the second "contrast" port **A2** had been primed with fluid before the first contrast port **A1**, the valve stem **306** of the inlet selector valve **300** would have to pass over the unprimed first contrast port **A1**. For this reason, the fluid source containers **30** should be loaded in a specific order as outlined herein. In brief, the first saline source **S1** should be installed before the second saline source **S2**, the first "medical" fluid source **A1** should be installed before the second such source **A2**, etc.

[00186] **FIGS. 29E** and **29F** show the inlet selector valve **300** after the fluid source container **30** containing the first contrast source **A1** has run empty and the fluid source container **30** containing the second contrast source **A2** has been installed. When the fluid source container **30** containing the first contrast source **A1** runs empty, an air detector (described herein) associated with the connected fluid supply tube **34** alerts the control

system **800**, which actuates the drive and actuating system **400** to stop using the fluid source container **30** before any air can be drawn into the inlet selector valve **300**. Thus, the fluid supply tube **34** connected to the fluid source container **30** containing the first contrast source **A1** remains primed even though the fluid source container **30** is now empty. The valve stem **306** may be moved from the first saline port **S1**, past the OFF position, past the still-primed first contrast port **A1**, and to the second, primed contrast port **A2** without having to pass over an unprimed port, such as the second saline port **S2**. Even though the fluid supply container **30** connected to the first contrast port **A1** is now empty, the valve stem **306** can still pass over this port because the connected fluid supply tube **34** remains primed with fluid.

[00187] **FIGS. 29G** and **29H** show the inlet selector valve **300** after the fluid source containers **30** containing the first saline source **S1** and the first contrast port **A1** have run empty and the fluid source container **30** containing the second saline source **S2** has been installed. Again, in a similar manner to the foregoing, the first saline port **S1** and the first contrast port **A1** remain primed even though their respective fluid source containers **30** have run empty. If the valve stem **306** is initially located at the second saline port **S2**, it may be safely moved past the first saline port **S1**, the OFF position, and the first contrast port **A1** ports to access the second contrast port **A2**.

[00188] As will be clear from all the foregoing, fluid as selected by the inlet selector valve **300** enters the associated inlet manifold channel **236** via the corresponding or registering openings **118**, **240** in the front plate **102** of the pump body **100** and in the manifold plate **230**. The left and right inlet manifold channels **236** are located low across the manifold plate **230** below the outlet manifold channel **244** to allow trapped air to rise upward and into the pump chambers **106** of the respective pump cylinders **104** during saline priming. The inlet manifold channels **236** are also formed with smooth interior surfaces and curvatures to avoid "dead ends" to minimize the potential for trapped air bubbles and to allow fluids to be easily flushed from the pump **10**. Moreover, the width and height of the inlet manifold channels **236** are sized and shaped to minimize the pressure drop (*e.g.*, flow restriction) while keeping the total enclosed volume to a minimum to minimize the volume of fluid required to prime the pump **10**. Fluid from the inlet selector valve **300** is available to either or both of the pump cylinders **104** on the same side of the pump **10**.

[00189] Referring further to **FIGS. 37-39**, during the forward or distal movement of the plunger **200** in the pump chamber **106** of the pump cylinder **104**, pressure within the pump chamber **106** of the pump cylinder **104** is greater than the pressure in the outlet manifold channel **244**, and the outlet check valve **196** associated with the pump cylinder **104** deforms

to allow fluid flow from the pump cylinder **104**. Accordingly, in the example described previously, the pump chamber **106** of the right outboard pump cylinder **104** contains a fluid mixture comprising diagnostic or therapeutic (*e.g.*, pharmaceutical) fluids **B1**, **B2** and saline **S1**, **S2**. As the plunger **200** in the right outboard pump cylinder **104** is moved forward or distally in the pump cylinder **104**, pressure within the pump chamber **106** is greater than the pressure in the outlet manifold channel **244** and the outlet check valve **196** associated with the right outboard pump cylinder **104** deforms to allow a fluid flow of the fluid mixture comprising fluids **B1**, **B2** and saline **S1**, **S2** to exit the right outboard pump cylinder **104** via the air egress opening **160** and outlet openings **162** present in the distal end wall **110** of the pump cylinders **104**, and enter the outlet manifold channel **244**. The fluid flow of the fluid mixture comprising fluids **B1**, **B2** and saline **S1**, **S2** from the pump chamber **106** to the outlet manifold channel **244** is identified by arrow A_5 in **FIGS. 38-39**. The outlet manifold channel **244** collects the fluid ejected from each of the four (4) pump cylinders **104** and directs the combined fluid flow via the connecting passage **268** leading to the outlet selector valve **280** and the flow passage **290** therein. Accordingly, in the foregoing example, the fluid flow of the fluid mixture comprising fluids **B1**, **B2** and saline **S1**, **S2** is delivered under pressure into the outlet manifold channel **244** and enters the connecting passage **268** leading to the flow passage **290** in the outlet selector valve **280**. The outlet selector valve **280** may selectively direct the fluid mixture to the patient outlet port **270** having the patient supply set **40** connected thereto, or to the waste outlet port **272** having the waste collection system **44** connected thereto.

[00190] Conversely, when the pressure in the outlet manifold channel **244** is greater, such as when the plunger **200** is retracted in the pump cylinder **104**, the outlet check valve **196** associated with the pump cylinder **104** is pressed into the recessed area **158** defined in the elongated recess **154** on the front side **140** of the front plate **102** to seal the outlet openings **162** and top opening **160** in the front plate **102** leading to the pump chamber **106** of the pump cylinder **104** and prevents fluid flow from the outlet manifold channel **244** into the pump cylinder **104**. This result occurs for each of the outlet check valves **196** to prevent fluid flow from the respective pump cylinders **104** when the corresponding plunger **200** is retracted in the pump chamber **106** of the pump cylinder **104**.

[00191] The outlet check valves **196** regulate the fluid flow from each pump cylinder **104**. Because pressure restrictions are not a significant concern on the outlet side of the pump **10**, the one or more outlet openings **162** and the top opening **160** to each of the pump cylinders **104** may be small in comparison to the inlet openings **142** to the pump cylinders **104** to

reduce the pressure stresses on the corresponding outlet check valves **196**. Additionally, the preload pins **250** in the outlet check valve receiving recesses **246** located in outlet manifold channel **244** apply a relatively high force to the outlet check valves **196**, which causes the valves **196** to have a relatively high cracking pressure and help prevent free-flow due to gravity from the fluid source containers **30** to the outlet selector valve **280**. The compression of the preload pins **250** and the thickness of the polymeric discs comprising the outlet check valves **196** may be optimized to prevent free-flow due to gravity from the fluid source containers **30** to the outlet selector valve **280**. The preload pins **250** apply a biasing or preload force to the polymeric discs comprising the outlet check valves **196** so that a certain minimum fluid pressure, often termed "cracking pressure", is required to cause the polymeric disc to initially open. Generally, the fluid source containers **30** as associated with the pump **10** are located at a higher elevation than the location where the patient supply set **40** connects to the pump **10**, namely, the patient outlet port **270**. Accordingly, there is a possibility that fluid could flow under gravity alone from the fluid source container(s) **30** to the patient when the pump **10** is not operating. To prevent this situation, the preload on the outlet check valves **196** may be made high enough that their cracking pressure is greater than this head pressure.

[00192] The outlet manifold channel **244** collects the fluid ejected from each of the four (4) pump cylinders **104** and directs the combined fluid flow to the outlet selector valve **280**. The outlet selector valve **280** allows the fluid output to be directed to either patient outlet port **270** having the patient supply set **40** connected thereto, or to the waste outlet port **272** having the waste collection system **44** connected thereto. As noted previously, the valve stem **286** may be rotated to one of three (3) possible positions, including: (1) placing the flow passage **290** in fluid communication with the patient outlet port **270**; (2) placing the flow passage **290** in fluid communication with the waste outlet port **272**; and (3) placing the flow passage **290** in a shut-off position wherein flow to either the patient outlet port **270** or the waste outlet port **272** is prevented.

[00193] As noted previously, the manifold plate **230** is laser welded to the front plate **102** of the pump body **100** to secure these two components together and form a hermetic seal around critical fluid path areas. Because the outlet manifold channel **244** is generally under high pressure, for example, at least 400 psi and, often, at least 500 psi and greater, the welded seam in the perimetrical recess **156** around the outlet manifold channel **244** may not be fully capable of repeatedly withstanding the high stresses while maintaining a hermetic seal. To reduce the stress on this particular welded joint, the drive and actuating system **400** includes a spring-loaded clamp (described herein) to apply several hundred pounds of force to the rear

side of the front plate **102** of the pump body **100** and allows the pump **10** to withstand fluid pressure of at least 400 psi and, desirably, at least 500 psi and greater. This clamping force likewise prevents separation of the laser weld joint or joints between the front plate **102** of the pump body **100** and the manifold plate **230**.

[00194] As previously noted, various versions and embodiments of the fluid supply set **32** may be associated with the pump **10** to meet different patient and/or procedural needs, as described herein. The combination of the pump **10** and a specific configuration of the fluid supply set **32** forms the multi-use or multi-patient disposable set for the fluid delivery system or unit **2**. Referring further to **FIGS. 40-43**, each of the various versions and embodiments of the fluid supply set **32** comprises one or more fluid supply tubes **34** each having one end connected to the pump **10** and the opposing end connected to a spike **36** used to access a fluid source container **30**. In certain variations or configurations, the fluid supply set **32** may allow the fluid source containers **30** to be replaced without contamination of the pump **10**.

[00195] A "basic" embodiment of the fluid supply set **32** is shown in **FIG. 40**. The basic fluid supply set **32** comprises six (6) fluid supply tubes **34** which connect six (6) fluid source containers **30** to the six (6) inlet ports **122**, **124**, **126** on the inlet selector valve cylinders **114** on the pump body **100**. The basic configuration is for a typical end user performing, for example, 8-12 procedures per day and be may be used, for example, on up to about 15 patients. In this configuration, two (2) contrast fluid source containers **30** containing contrast fluids **A1**, **A2**, for example, the same type or brand of contrast fluid, may be connected to the first and second inlet ports **122**, **124** on the left side inlet selector valve cylinder **114**, and two (2) contrast fluid source containers **30** containing contrast fluids **B1**, **B2**, for example, the same type or brand of contrast fluid but different from contrast fluids **A1**, **A2**, may be connected to the first and second inlet ports **122**, **124** on the right side inlet selector valve cylinder **114**. However, if desired, the same type of fluid may be present in all four (4) of the foregoing installed fluid source containers **30**. Fluid source containers **30** containing saline **S1**, **S2** are connected to the saline ports **126** on each of the inlet selector valve cylinders **114** in the manner discussed previously. The basic fluid supply set **32** typically has permanently attached spikes **36** on the free end of each of the fluid supply tubes **34**, and the other end of each of the fluid supply tubes **34** is permanently connected to the respective inlet ports **122**, **124**, **126**. However, one or more of the spikes **36** may be replaceable spikes if so desired. For example, replaceable spikes **36** may be provided for accessing the saline fluid source containers **30** containing saline **S1**, **S2**. Once the fluid source container **30** attached to each spike **36** is empty, that particular fluid supply tube **34** and the associated inlet port **122**, **124**,

126 should no longer be used because of the contamination risk involved in changing out a fluid source container **30**.

[00196] In **FIG. 41**, a "high-use" fluid supply set **32** is shown and differs only from the basic configuration in that all the spikes **36** are replaceable. A swabable valve **70** may be provided on the free end of the fluid supply tubes **32** for connection to the spikes **36**. In this variation, one fluid source container **30** may be attached to each spike **36** and, once empty, the empty container **30** and used spike **36** may be removed and discarded. The permanently attached swabable valve **70** may then be cleaned and a new spike **36** attached to the valve **70**. Multiple fluid source containers **30** may be installed on a given fluid supply set **32** as long as the spike **36** is replaced with each new container **30** and the corresponding swabable valves **70** are cleaned appropriately.

[00197] In **FIG. 42**, another variation of the fluid supply set **32** is shown and intended for limited use with only a few patients, such as may occur on a weekend. This variation of the fluid supply set **32** may be used, for example, on up to about five (5) patients and has a single fluid source container **30** containing a desired therapeutic or diagnostic (e.g., pharmaceutical) fluid connected to one of the first inlet ports **122** on the left or right side inlet selector valve cylinders **114**. A saline fluid source container **30** containing saline is connected to the saline port **126** on the same inlet selector valve cylinder **114**. The spikes **36** are shown permanently attached to fluid supply tubes **34** so once a fluid source container **30** is empty, that particular fluid supply tube **34** and inlet port **122**, **126** should no longer be used. However, swabable valves **70** may also be used in the manner shown in **FIG. 41**.

[00198] In **FIG. 43**, a further variation of the fluid supply set **32** is shown and is intended for use with small, single-patient fluid source containers **30**. This variation is intended to be used, for example, for up to about 15 patients. In this variation, a first type of therapeutic or diagnostic (*e.g.*, pharmaceutical) fluid **A1** in a fluid source container **30** is connected to the first inlet port **122** on one of the inlet selector valve cylinders **114**, and a second type of therapeutic or diagnostic (*e.g.*, pharmaceutical) fluid **B1** is connected to the first inlet port **122** on the other inlet selector valve cylinder **114**. Saline **S1** in a fluid source container **30** is connected to the saline port **126** on one of the inlet selector valve cylinders **114**. In this variation, swabable valves **70** are provided on the free ends of the fluid supply tubes **32** for connection to replaceable spikes **36**. Accordingly, once the fluid source container **30** attached to the respective spikes **36** is empty, the empty container **30** and used spike **36** may be removed and discarded. The permanently attached swabable valve **70** may then be cleaned

and a new spike **36** may be attached to the valve **70**, along with a new fluid source container **30**.

[00199] As shown in **FIG. 44**, the single-patient supply set **40** generally comprises medical tubing having opposed free ends each with a fluid connector **42**. The patient-end fluid connector **42** is used to make a fluid connection to a catheter inserted into a patient to convey a desired fluid or mixture of fluids to a desired location within the patient's body. The patient-end fluid connector **42** may include a check valve (not shown) to prevent reverse flow from the patient. The other free end fluid connector **42** is connected to the patient outlet port **272** on the outlet selector valve cylinder **264** on the manifold plate **230**.

[00200] Further, **FIG. 45** shows the waste collection system **44** associated with a pump **10** having a "high-use" fluid supply set **32**. As described previously, the waste collection system **44** generally comprises a waste collection tube set **46** connected to a waste collection container **48** used to collect and store waste fluids. The waste collection tube set **46** is adapted to make a fluid connection with the pump **10**. In particular, the waste collection system **44** is connected to the waste outlet port **272** on the outlet selector valve cylinder **264** on the manifold plate **230**, as noted previously, and the waste collection tube set **46** conducts waste fluids to the waste collection container **48** when the outlet selector valve **280** is actuated to place the flow passage **290** in fluid communication with the waste outlet port **272**. A check valve (not shown) may be incorporated into the fluid connector on the waste collection tube set **46** which prevents accidental reverse flow from the waste collection container **48** into the pump **10**. Additionally, if the waste collection container **48** is removed and replaced with a new waste collection container **48**, the check valve prevents the contents of the full waste collection container **48** from being ejected during handling.

[00201] As noted in the foregoing, the fluid delivery system **2** comprises a drive and actuating system **400** that interfaces with the pump **10** to provide the motive forces for operating the various components of the pump **10**. Referring next to **FIGS. 46-60**, details of the drive and actuating system **400** will be described. The drive and actuating system **400** is supported by a mobile support or superstructure **700** that also supports a fluid management system **720** for supporting, maintaining, and monitoring the various diagnostic or therapeutic (*e.g.*, pharmaceutical) fluids to be associated with the pump **10**. Particularly, the fluid management system **720** provides air management functions for the fluid delivery system **2**, as described herein in connection with **FIG. 60**. The mobile support or superstructure **700** permits the fluid delivery system **2** to be a mobile system for applications in various medical environments, such as medical imaging suites that utilize a computed tomography (CT)

scanner, as an example. As a result, the fluid delivery system **2** may be positioned in close proximity to the patient during a fluid injection and scanning procedure and a "short" patient supply set **40** may be used. Additionally, depending upon the type of procedure being performed, it may be desirable to place the fluid delivery system **2** either in front of the CT scanner gantry or behind the gantry. This placement is typically determined by whether the scan is being performed with the patient's hands/arms above their head for chest and abdominal scans, or at their sides for head and neck scans. Further, the system **2** may easily be moved out of the way to permit the patient to be placed on or removed from the bed of the CT scanner. Furthermore, the fluid delivery system **2** includes a control system **800**, as noted previously, for coordinating and controlling operation of the various components and functions of the drive and actuating system **400** and fluid management system **720**, each supported on the mobile support **700**.

[00202] **FIG. 47** is a block schematic representation of the drive and actuating system **400** of the fluid delivery system **2**. Generally, the drive and actuating system **400** comprises a movable pump drawer section **402** that is extendable and retractable on the mobile support **700** to allow loading/unloading of the pump **10** into/from the pump drawer **402**. The drive and actuating system **400** also comprises a drive section **440** that generates the motive forces for reciprocal operation of the pistons **50** operating the respective plungers **200** and rotational operation of the inlet selector valves **300**. Additionally, the drive and actuating system **400** comprises a drive interface section **460** that translates and/or transmits the motive forces from the drive section **440** to the pistons **50** and inlet selector valves **300**. Further, the drive and actuating system **400** comprises a pump clamping section **520**, also referred to herein as a pump clamping mechanism **520**, that secures the pump **10** in association with the drive and actuating system **400**. Furthermore, the drive and actuating system **400** comprises an outlet selector valve actuating section **580** that operates the outlet selector valve **280** on the pump **10**. The drive and actuating system **400** desirably further supports several components of the control system **800**, including a drive control board **802** that is electronically connected and interfaced with the control system **800** to enable the control system to control operation of the drive section **440**, and a sensor control board **804** used to collect sensor information from various sensors in the drive and actuating system **400** and relay this electronic information to the control system **800** to enable the control system **800** to control operation of the drive section **440**, drive interface section **460**, pump clamping mechanism **520**, and outlet selector valve actuating section **580**. Each of the foregoing sections is described hereinafter in connection with **FIGS. 46-60**.

[00203] The pump drawer **402** is generally extendable and retractable from the mobile support **700** and comprises a drive and actuating support structure **420** that mounts and supports the various components of the drive section **440**, drive interface section **460**, pump clamping section **520**, and outlet selector valve actuating section **580**. The pump drawer **402** includes a handle housing portion **404** and a waste collection compartment **406** to accommodate the waste collection container **48** and at least portions of the associated waste collection tubing set **46**, which were described previously. The handle housing portion **404** is supported by a composite drawer support structure **408** that is mechanically affixed to a drawer shelf plate **410**. The handle housing portion **404** is mounted to the drawer support structure **408** so that the handle housing portion **404** forms a portion of the cosmetic outer face of the pump drawer **402**.

[00204] A pump cradle **412** is fixedly mounted on the top side of the drawer shelf plate **410** to support and maintain the pump **10** on the drawer shelf plate **410**. The pump cradle **412** is preformed to the shape of the pump **10** to secure the pump **10** in the pump drawer **402** and comprises preformed cradle appendages **414** to interface with the fluid supply tubes **34** of the various embodiments of the fluid supply sets **32** described previously. The cradle appendages **414** are formed for easy loading of the pump **10** in the pump drawer **402**. The handle housing portion **404** may be a singular component or a composite structure, as indicated above, that includes a reinforcing and locking support plate **416** sandwiched between two face plates **418**. A drawer handle **H** is formed integrally on the outside face of the handle housing portion **404** to enable a user to slidably operate the pump drawer **402**. The waste collection compartment **406** may be detachably suspended from lateral sides of the drawer shelf plate **410**. The locking support plate **416** may be made of metal such as stainless steel or another metal suitable for applications in medical environments, and the face plates **418** may be polymeric covering face plates that have suitability for improving the ornamental or cosmetic exterior appearance of the pump drawer **402**.

[00205] The drive and actuating support structure **420** comprises a rear support plate **422** that supports a top, distally-extending support plate **424** and a bottom, distally-extending support plate **426**. The drawer shelf plate **410** of the pump drawer **402** is journalled for slideable movement relative to the bottom support plate **426** by a pair of mounting flanges **428** mounted on opposing sides of the top side of the bottom support plate **426**. A drive enclosure or housing **430** may be secured to the bottom support plate **426** to enclose a region forward or distal of the rear support plate **422** and below the bottom support plate **426**. The drive enclosure **430** encloses the various drive motors of the drive section of the drive and

actuating system **400** as well as the drive control board **802**, as described herein. A base plate **432** may be connected to or extend from the lower end of the rear support plate **422** to support the drive control board **802**, and support rods may extend from the drive control board **802** to the bottom support plate **426** for rigidity purposes. An intermediate support plate **434** is located on top of the bottom support plate **426** and forward of the rear support plate **422** to support the drive pistons **50** and actuator components used to operate the inlet selector valves **300**, as described hereinafter. Several support openings **436** are provided in the intermediate support plate **434** for the drive pistons **50** and the actuator components used to operate the inlet selector valves **300**. Support elements **438** are provided in each of the support openings **436** in the intermediate support plate **434** to support the drive pistons **50** and actuator components used to operate the inlet selector valves **300**. These support elements **438** may be bushings in the case of the drive pistons **50** and support ball bearings in the case of the actuator components.

[00206] As noted in the foregoing, the drawer shelf plate **410** of the pump drawer **402** is journalled for slideable movement relative to the bottom support plate **426** by a pair of mounting flanges **428** mounted on opposing sides of the top side of the bottom support plate **426**. This slideable movement permits the pump drawer **402** to move from a closed position in which the pump drawer **402** is received within the mobile support **700** to an extended position outward from the mobile support **700** to permit a user to load a pump **10** into the pump cradle **412**. The handle **H** on the handle housing portion **404** is used by the user to extend and close the pump drawer **402**. The sliding movement of the drawer shelf plate **410** enables the handle housing portion **404** and the waste collection compartment **406** depending from the drawer shelf plate **410** to be moved together as a singular unit from the closed or retracted position of the pump drawer **402** to the extended or loading position of the pump drawer **402**. The pair of mounting flanges **428** mounted on opposing sides of the top side of the bottom support plate **426** support the drawer shelf plate **410** in both the extended or loading position of the pump drawer **402** and the closed or retracted position of the pump drawer **402** and an extension limiter may be provided so that the drawer shelf plate **410** cannot be extended to a point where the pump drawer **402** disengages entirely from the mounting flanges **428**. As described further herein, a locking connection may be provided between the locking support plate **416** and the drive and actuating support structure **420** to lock the pump drawer **402** in the closed position so that the pump **10** is secured during operation of the fluid delivery system **2**.

[00207] The drive section **440** comprises, in the present embodiment, four (4) piston actuator drive motors **442**, such as servomotors and the like, that provide the motive forces which drive four (4) respective piston linear actuators **462** that individually operate the drive pistons **50**. Additionally, the drive section **440** comprises a pair of inlet selector valve actuator drive motors **444**, such as stepper motors and the like, that provide the motive forces which drive a pair of inlet selector valve actuators **464** that independently operate the respective inlet selector valves **300**, as also described herein. The piston drive motors **442** are mounted to the front or distal facing side of the rear support plate **422** beneath the bottom support plate **426** and each have a drive shaft **446** extending through an opening in the rear support plate **422** to output motive forces to the piston linear actuators **462**. Likewise, the respective inlet selector valve drive motors **444** are mounted to the front or distal facing side of the rear support plate **422** beneath the bottom support plate **426** and each have a drive shaft **448** extending through an opening in the rear support plate **422** to provide motive forces to the inlet selector valve actuators **464**. The respective drive motors **442**, **444** are electronically controlled by the control system **800** via respective electronic connections **450** with the drive control board **802**. A drive pulley **452** is mounted to the drive shaft **446** of each of the piston drive motors **442** and, likewise, a drive pulley **454** is mounted to the drive shaft **448** of each of the inlet selector valve drive motors **444**. As will be appreciated from the foregoing, a piston drive motor **442** is provided for each of the drive pistons **50** and an inlet selector valve drive motor **444** is provided for each of the inlet selector valves **300** based on the pump **10** comprising four (4) separate pump cylinders **104** and two (2) separate inlet selector valves **300**. However, as noted previously, this exemplary configuration should not be deemed limiting as other configurations with a fewer or increased number of pump cylinders **104** and inlet selector valves **300** may be desirable for the fluid delivery system **2**.

[00208] As mentioned in the foregoing, a locking connection is desirably provided between the locking support plate **416** and the drive and actuating support structure **420** to lock the pump drawer **402** in the closed position so that the pump **10** may be secured during operation of the fluid delivery system **2** or at other suitable times. This locking connection may be provided by a series of locking teeth **456** on the upper end or edge of the locking support plate **416** that engages a corresponding series of locking slots **458** provided in a front or distal end **508** of the opposing top support plate **424**. The locking slots **458** may define a generally L-shaped configuration to receive the locking teeth **456**. The locking support plate **416** is sandwiched and supported between the two opposing face plates **418** so as to be capable of limited lateral, side-to-side movement between the face plates **418**. This limited

lateral, side-to-side movement enables the locking teeth **456**, after having engaged the L-shaped locking slots **458**, to be placed into the transversely extending or "dog leg" of the locking slots **458** from a longitudinal or entry leg of the locking slots **458** by limited lateral movement of the locking support plate **416**. The movement of the locking teeth **456** into the transversely extending portion or "dog leg" of the locking slots **458** places the pump drawer **402** into a locked position or state. A similar set of "lower" locking teeth (not shown) to the "upper" locking teeth **456** may be provided on the bottom of the locking support plate **416** to engage similar "lower" locking slots (not shown) to the "upper" locking slots **458** provided in the bottom support plate **426**.

[00209] The locking slots **458** generally oppose the locking teeth **456** so that when the pump drawer **402** is moved by the user to the closed or retracted position, the locking teeth **456** are automatically engaged in the longitudinal or entry legs of the locking slots **458**. A lock actuator (not shown), such a cam mechanism, may be provided to actuate the locking support plate **416** between the foregoing locked position (*e.g.*, in which the locking teeth **456** engage a transversely extending portion of the locking slots **458**) and the release or unlocked position in which the locking teeth **456** are aligned with the longitudinal or entry leg of the locking slots **458** that are aligned with the locking teeth **456**. A drawer closed sensor **818** is provided on the top support plate **424** to determine the presence of the locking teeth **456** in the locking slots **458**. The drawer closed sensor **818** is electronically coupled to the sensor control board **804** and, thereby, the control system **800** can determine when the locking teeth **456** are engaged in the locking slots **458** and whether the lock actuator should be actuated to move the locking support plate **416** laterally into a locking engagement with the transversely extending portion of the locking slots **458** so the locking support is locked with the top and bottom support plates **424**, **426**, or unlocked from the top and bottom support plates **424**, **426** so that the pump drawer **402** may be opened for loading or removal of the pump **10**.

[00210] As noted in the foregoing, a lock actuator (not shown), such as a cam mechanism, may be associated with the locking support plate **416** to move the locking support plate **416** between the locked and unlocked positions. The cam mechanism may be operated or actuated by extension and retraction of one of the two (2) inboard piston linear actuators **462**, described herein, and, typically, the left inboard piston linear actuator **462** in the embodiment of the drive and actuating system **400** shown in **FIGS. 47-59**. The operation of the left inboard piston linear actuator **462** moves the cam mechanism to move the locking support plate **416** between the locked and unlocked positions, which locks and unlocks the pump drawer **402**. For example, retraction of one of the inboard piston linear actuators **462**,

typically, the left inboard piston linear actuator **462**, moves the cam mechanism to move the locking support plate **416** laterally to the unlocked position, which unlocks the pump drawer **402**. The pump drawer **402** has right and left sides corresponding to the right and left sides **16**, **18** of the pump **10**. The user may then open the pump drawer **402** and insert the pump **10** into the pump drawer **402**. The user may then close the pump drawer **402**. Once the pump drawer **402** is closed, the control system **800** is so alerted by the drawer closed sensor **818**, as noted in the foregoing, and may actuate the left inboard piston linear actuator **462** to move the locking support plate **416** to lock the pump drawer **402**. In particular, the control system **800** detects that the pump drawer **402** is closed via the drawer closed sensor **818** and operates the drive motor **442** associated with the left inboard piston linear actuator **462** to move the left inboard piston linear actuator **462** slightly forward to actuate the cam mechanism to move the locking support plate **416** laterally to the locked position. The control system **800** confirms that the pump drawer **402** has been locked with a drawer locked sensor **820** provided on the top support plate **424** which may detect the shifted lateral position of the locking support plate **416**. It will be appreciated that a manually-actuated locking device may be provided in place of the foregoing automated lock actuator or may be provided as an augmentation to the automated lock actuator, and have a handle or other suitable manual actuator on the exterior of the mobile support **700** for operation by the user or operator. The drawer locked sensor **820** may be used as a safety device in that, if this sensor is not tripped to indicate that the pump drawer **402** is closed, no drive motion will be permitted by the control system **800** in order to prevent possible user injury.

[00211] The drive interface section **460** is provided to convert the rotary output of the drive shafts **446** of the piston drive motors **442** into reciprocal translational motion of the drive pistons **50** and, further, transfer and translate the rotary output of the drive shafts **448** of the inlet selector valve drive motors **444** into corresponding and controlled rotational movement of the inlet selector valve actuators **464**, which control the angular positioning of the respective inlet selector valves **300** and, hence, the operational state of the inlet selector valves **300**. In one exemplary embodiment, the drive interface section **460** comprises four (4) piston linear actuators **462** in the form of ball screw linear actuators that convert the rotational drive output of the drive shafts **446** of the piston drive motors **442** into reciprocal translational movement of the pistons **50** so that the pistons **50** may reciprocally and independently operate the plungers **200** in the respective pump cylinders **104**. In the illustrated embodiment, each ball screw-type piston linear actuator **462** comprises a ball screw shaft **466** rotationally journalled in a ball screw nut **468** by threaded engagement as is

well-known in the mechanical arts. Each ball screw nut **468** is fixedly mounted to an individual slide block **470** and may be mounted for guided sliding reciprocal movement on a support platform **472** disposed between the mounting flanges **428** on the top side of the top support plate **424** of the drive and actuating support structure **420**.

[00212] The ball screw shafts **466** each have a proximal portion **474** extending through a corresponding mounting opening **476** in the rear supporting plate **422**. The proximal portion **474** of each ball screw shaft **466** is rotationally supported in the receiving mounting opening **476** by a suitable rotational, thrust support bearing **478**. A support plate **480** is provided on the distal or front side of the rear support plate **422** to restrain the bearings **478** in the respective mounting openings **476**. As will be understood from the view in **FIG. 53**, the respective pistons **50** each have a proximal end **58** and define a central or axial bore **60** opening externally at the proximal end **58**. The proximal end **58** of each of the pistons **50** may have a lip or flange **62** for mounting the proximal end **58**, in any desirable manner, to a corresponding slide block **470** so that reciprocal movement of the individual slide blocks **470** results in concurrently reciprocal movement of the connected drive piston **50**. The proximal portion **474** of each of the ball screw shafts **466** has an actuator pulley **482** mounted thereto, and a timing belt **484** is reeved about the drive pulley **452** on the drive shaft **446** of the corresponding piston drive motor **442** and the actuator pulley **482** to rotationally interface the drive shaft **446** and the ball screw shaft **466**. The pulleys **452**, **482** and timing belt **484** permit the driving rotational movement of the associated drive shaft **446** to be imparted to the ball screw shaft **466** as will be understood to those skilled in the mechanical arts. As the ball screw shaft **466** rotates clockwise or counterclockwise, the ball screw nut **468** converts this rotational motion to linear reciprocal motion of the associated slide block **470** and, hence, linear motion of the connected drive piston **50**. The drive pistons **50** are supported in the respective support openings **436** in the intermediate support plate **434** by the support elements **438**, namely bushings, in the respective support openings **436** to support the linear reciprocal movement of the drive pistons **50** in the support openings **436**.

[00213] The respective inlet selector valve actuators **464** are rotational motion actuators adapted to transfer and translate the rotary output of the drive shafts **448** of the inlet selector valve drive motors **444** into corresponding and controlled rotational movement of the inlet selector valve actuators **464** which control the angular positioning of the respective inlet selector valves **300** and, hence, the operational state of the inlet selector valves **300**. The respective inlet selector valve actuators **464** comprise a selector rod **486** having a distal or actuator end **488** adapted to interface with the actuator interface head **304** on the inlet selector

valve body **302** of the corresponding inlet selector valves **300**, and a proximal end **490** extending through one of the respective mounting openings **476** in the rear supporting plate **422**. The selector rods **486** are rotationally supported in the respective mounting openings **476** by a suitable rotational support bearing **492** and restrained in the respective mounting openings **476** by the same support plate **480**, noted previously, used to secure the rotational, thrust support bearings **478** supporting the proximal portion **474** of the ball screw shafts **466** in the respective mounting openings **476** in the rear supporting plate **422**. An electro-mechanical angular position sensor **494**, such as a rotary encoder, is mechanically coupled to the proximal end **490** of each selector rod **486**. The angular position sensor **494** is electronically linked to the control system **800** via an electronic link or connection **496** to the sensor control board **804**. The angular position sensors **494** are operable to determine the specific angular orientation of the valve stem **306** of the inlet selector valve body **302** of the associated inlet selector valve **300**, which is relayed to the control system **800** via the sensor control board **804**. Accordingly, by controlled operation of the inlet selector valve drive motors **444** by the control system **800**, the associated inlet selector valve **300** may be angularly positioned to one of the several operating positions discussed previously.

[00214] The distal end **488** of each of the selector rods **486** may be configured with engagement or interface elements **498** to interface with corresponding engagement components or structures on the actuator interface head **304** of the inlet selector valve body **302** of the selector valves **300**. As discussed previously, these corresponding engagement components or structures include the proximal tab **312** and interface engagement member **314** formed on the actuator interface head **304**. As mentioned previously, for safety purposes, it is desirable for the valve stem **306** to be engaged to the drive and actuating system **400** in only one particular angular orientation. Thus, the foregoing features on the actuator interface head **304** preferably require the valve stem **306** to be in one particular orientation for engagement with the engagement or interface elements **498** and this information may be encoded into the pump indicator plate **170** and/or into identifying indicia **172** on the pump body **100**, described previously. The control system **800** can thereby determine the initial or preset angular orientation of the valve stem **306** in the inlet selector valve cylinder **114** and operate the inlet selector valve actuators **464** to engage the valve stem **306** in the right angular orientation. If the valve stem **306** can be engaged in more than one angular orientation, the wrong type of fluid could possibly be delivered to the patient. The wrong type of fluid could be delivered because, with more than one angular engagement orientation, there would no longer be a uniquely-predefined relationship between the angular position sensor **494** and the actual

position of the valve stem **306** of the inlet selector valve **300**, and the control system **800** could cause the inlet selector valve **300** to be oriented in an unintended position whereby an unintended fluid is delivered by the pump **10**.

[00215] The respective selector rods **486** are supported in the support openings **436** in the intermediate support plate **434** to permit free rotational movement of the selector rods **486**. As noted previously, a support element **438**, such as a bushing, is provided in each of the support openings **436** in the intermediate support plate **434** that support the linear reciprocal movement of the drive pistons **50**. In the case of the selector rods **486**, the support elements **438** are support ball bearings that facilitate the rotational motion of the respective pair of selector rods **486**. The proximal end **490** of each of the respective selector rods **486** has an actuator pulley **500** mounted thereto, and a timing belt **502** is reeved about the drive pulley **454** on the drive shaft **448** of the driving inlet selector valve drive motor **444** and the actuator pulley **500** to rotationally interface the drive shaft **448** and the selector rod **486**. The pulleys **454**, **500** and timing belt **502** permit the driving rotational movement of the associated drive shaft **448** to be transferred and imparted to the associated selector rod **486**. As the drive shaft **448** rotates clockwise or counterclockwise, the pulleys **454**, **500** and timing belt **502** transmit the rotary motion to the selector rod **486** so that the corresponding inlet selector valve **300** may be angularly positioned to one of the several operating positions discussed previously, or any angular position programmed into the control system **800**. The pulleys **454**, **500** and timing belt **502** permit controlled rotational movement of the drive shaft **448** to be transferred and imparted to the associated selector rod **486**, while the angular position sensor **494** continuously monitors the angular position of the selector rod **486** and, hence, enables the control system **800** to determine and control the specific angular orientation of the valve stem **306** of the inlet selector valve body **302** of the associated inlet selector valve **300**. The actuator pulley **500** on the proximal end **490** of each of the respective selector rods **486** may be secured to the selector rod **486** via a suitable mechanical fastener arrangement and the respective angular position sensors **494** may be supported for mechanical connection to the proximal end **490** of the respective selector rods **486** by a support bracket mounted to the rear or proximal side of the rear support plate **422**. The respective slide blocks **470**, discussed previously, also each define a tapered top end portion **504**, the use of which is discussed herein.

[00216] As noted previously, the pump clamping section or mechanism **520** of the drive and actuating system **400** secures the pump **10** in association with the drive and actuating system **400**. The top support plate **424** generally defines a proximally extending portion or

slot **512** extending rearward or proximally from the front or distal end **508** of the top support plate **424**. The proximally extending slot **512** includes opposed interior ledges **514** along the walls of the proximal slot **512** which support certain components of the pump clamping section or mechanism **520**, as described herein. A series of elongated apertures **516** are also provided in the top support plate **424** forward or distal of the proximal end of top support plate **424** to allow the top end portions **504** of the slide blocks **470** to project upward through the top support plate **424** and, additionally, for guiding the sliding reciprocal movement of the slide blocks **470** relative to the upper support plate **424**. Accordingly, a total of four (4) elongated apertures **516** are provided in the top support plate **424** forward or distal of the proximal end of the top support plate **424**, one for each of the four (4) slide blocks **470** in the illustrated embodiment of the fluid delivery system **2**. Additionally, a pair of actuator apertures **518** is provided in the top support plate **424** distal or forward of the slide block apertures **516**, for purposes described herein.

[00217] The pump clamping section or mechanism **520** generally comprises a clamping block **522** having a front or distal end **524** and a rear or proximal end **526**. A pair of guide rods **528** extends proximally or rearward from the clamping block **522**. The guide rods **528** are opposed, respectively, by a corresponding pair of distally-extending guide rods **530** mounted to the front or distal side of the rear support plate **422**. A pair of preloaded clamping springs **532** is mounted on the two opposing pairs of guide rods **528**, **530** to apply a biasing force to the clamping block **522** in the direction of the pump drawer **402** and, particularly, the drawer support structure **408** of the pump drawer **402**. The clamping block **522** is vertically supported by a series of spaced, C-shaped support appendages **534** that extend upward from the clamping block **522** to engage the opposed ledges **514** along the walls of the proximal slot **512** in the top support plate **424** so that the clamping block **522** is supported to depend below the top support plate **424**. In the illustrated embodiment, a total of four (4) support appendages **534** are provided, including two (2) forward or distal support appendages **534** and two (2) rear or proximal support appendages **534**. The body of the clamping block **522** is positioned below the top support plate **424** and the top support plate **424** restrains the clamping block **522** against upward movement, while the engagement of the clamping block support appendages **534** with the opposed ledges **514** along the walls of the proximal slot **512** in the top support plate **424** permits forward and rearward movement in the proximal slot **512** in the top support plate **424**.

[00218] Generally, in use, when a pump **10** is loaded into the pump cradle **412** in the pump drawer **402**, as described previously, the clamping block **522** is used to exert a compressive

force on the pump manifold **80** and, in particular, the rear or proximal side of the front plate **102** of the pump body **100**. This compressive force is applied to the sealing element (*e.g.*, O-ring, gasket, or weld, typically a laser weld) located in the perimetrical recess **156** around the respective dish-shaped recessed areas **252** and around the outlet manifold channel **244**. The compressive force seals the sealing element (*e.g.*, O-ring, gasket, or laser or ultrasonic weld) in the perimetrical recess **156** and permits the pump manifold **80** to withstand higher pressures. As noted previously, a laser weld joint typically occupies the location of the perimetrical recess **156** in the accompanying figures, but an O-ring, gasket or like element may alternatively be provided in this location, if desired. The compressive force of the clamping block **522** similarly secures the sealing element, whether provided as a weld joint, O-ring, gasket, etc., to enable the pump manifold **80** to withstand higher operating pressures. Another feature of the pump clamping mechanism **520**, and the clamping block **522** in particular, is to assist in preventing the pump **10** from moving when in use. When the respective plungers **200** are retracted in the pump cylinders **104**, there is both a frictional force due to the friction between the plunger seals **218**, **220** on the respective plungers **200** and the interior wall **108** of the pump cylinders **104**, and a vacuum force due to the vacuum in the pump cylinders **104** during filling (*e.g.*, retraction or withdrawal of the plungers **200** in the pump cylinders **104**.) These frictional and vacuum forces "pull" the entire pump body **100** rearwards in the pump cradle **412**. The pump clamping mechanism **520** acts against these frictional and vacuum forces to help hold the pump **10** in place.

[00219] The outer flange **258** and stiffening ribs **260** on the front face or side **232** of the manifold plate **230** transfer the clamping force applied by the clamping block **522** to the laser welded joint, O-ring, or gasket in the perimetrical recess **156** that is subjected to relatively high fluid pressure and stress, as well as to the other laser weld joint or joints between the manifold plate **230** and the front or distal plate **102** of the pump body **100**. Additionally, the manifold caps **262** enclosing the respective right and left inlet manifold channels **236** and the stiffening ribs **260** on the front face or side **232** of the manifold plate **230** all lie substantially in the same plane so that the clamping force applied by the clamping block **522** to the manifold **80** does not deflect the front plate **102** of the pump body **100** and manifold plate **230** unevenly and/or in such a way as to damage the various laser weld joints between the manifold plate **230** and the front or distal plate **102** of the pump body **100** and, particularly, the laser weld joint in the perimetrical recess **156** that is subjected to relatively high fluid pressure and stress. This front "planar" configuration allows the clamping block **522** to prevent of the foregoing features from deflecting when subjected to high loads. Without the

clamping force applied by the clamping block **522**, the various laser welded joints and molded features of the pump body **100** and manifold plate **230** would likely have to be much stronger and stiffer.

[00220] The clamping block **522** further comprises a pair of actuator blocks **536** that extend upward through the respective lateral apertures **518** in the top support plate **424**. The lateral actuator block apertures **518** are slightly larger and longer than the actuator blocks **536** to permit limited movement, in a forward or rearward direction, by the actuator blocks **536** in the actuator block apertures **518**. Such movement is provided to enable a small retraction of the clamping block **522** in the proximal slot **512** in the top support plate **424** and toward the rear support plate **422** to permit loading and unloading of the pump **10** from the pump cradle **412** without having to manually retract the clamping block **522** and compress the clamping springs **532**. The clamping block **522** further defines a forward lip or flange **538** provided on a top side or surface of the clamping block **522**.

[00221] A clamp actuating mechanism **540** is provided to enable a small retraction of the clamping block **522** in the proximal slot **512** in the top support plate **424** and toward the rear support plate **422** to permit loading and unloading of the pump **10** from the pump cradle **412**. The clamp actuating mechanism **540** is adapted to retract the clamping block **522** from engagement with the front plate **102** of the pump body **100** of the pump **10** without manual manipulation of the clamping bock **522**. The clamp actuating mechanism **540** comprises, for example, a pair of pivoting cam arms **542** that are pivotally connected by pivot pins **544** to the top support plate **424**. The cam arms **542** are pivotally connected to the top side of the top support plate **424** outboard of the actuator blocks **536** to interface with the actuator blocks **536**. The cam arms **542** comprise a first or hook end **546** that is in operative engagement with the respective actuator blocks **536** that extend upward through the respective actuator block openings **518** in the top support plate **424**. The opposing second ends of the cam arms **542** are formed as cam ends **548** which contact the top end portions **504** of the slide blocks **470** of the two (2) outer or outboard slide blocks **470** that project upward through the two (2) outer or outboard slide block apertures **516** in the top support plate **424**. The top end portions **504** of at least these two (2) outer or outboard slide blocks **470** comprise a tapered cam surface **550** opposing the cam ends **548** of the cam arms **542** so that rearward movement of the two (2) outer or outboard slide blocks **470** induces an outward pivotal movement of the cam arms **542** about their respective pivot pins **544**. In particular, when it is desired to load or unload a disposable pump **10** from the pump cradle **412** in the pump drawer **402**, the piston linear actuators **462** associated with the two (2) outer slide blocks **470** may be driven so that the

slide blocks **470** move proximally or rearward in their slide block aperture **518** toward the rear support plate **422**. This proximal or rearward movement causes the tapered cam surface **550** on the top end portions **504** of the two (2) outer slide blocks **470** to contact the cam end **548** on each of the cam arms **542** and pivot the cam arms **542** about pivot pins **544**. The cam ends **548** on the cam arms **542** pivot laterally outward toward the lateral outer sides of the top support plate **424** while the hook ends **546** of the cam arms **542** move the respective actuator blocks **536**, extending upward from the clamping block **522**, slightly rearward or proximally in their respective actuator block openings **518** in the top support plate **524** and toward the rear support plate **422** thereby slightly compressing the associated clamping springs **532**. As the actuator blocks **536** move rearward or proximally, the clamping block **522** is removed from contacting compressive engagement with the pump **10** and, in particular, from compressive engagement with the rear or proximal side of the front plate **102** of the pump body **100** of the pump **10**. The pump **10** may then be removed from the pump cradle **412** in the pump drawer **402** without hindrance from the clamping block **522** and replaced with a new pump **10**. Once a new pump **10** is placed in the pump cradle **412** and the pump drawer **402** is closed and locked, as described in the foregoing, the piston linear actuators **462** associated with the two (2) outer slide blocks **470** may be driven so that the slide blocks **470** move distally or forward in their slide block apertures **518** and enabling the clamping block **522** to compressively engage the rear or proximal side of the front plate **102** of the pump body **100** of the replacement pump **10**.

[00222] The pump clamping section or mechanism **520** further comprises a pressure measurement mechanism **552** for interfacing with the outlet selector valve **280** and, in particular, the rear or proximal pressure sensing port **296** defined in the outlet selector valve cylinder **264** on the manifold plate **230**. The pressure measurement mechanism **552** comprises a hollow support block or housing **554** seated on a top face of the clamping block **522**. The support block or housing **554** defines an interior chamber **556** that supports a pressure sensor interface pin **558** and a pressure measurement load cell **560** operatively engaged with the pressure sensor interface pin **558**. The support block or housing **554** comprises a front or distal end **562** defining a cylindrical front or distal port **564** defining a through bore through which the pressure sensor interface pin **558** projects so as to extend outward from the front port **564** to contact the pressure sensing diaphragm **298** in the rear or proximal pressure sensing port **296** in the outlet selector valve cylinder **264** on the manifold plate **230**. The distal end **562** of the support block **554** is in contact or seats against the top lip or flange **538** on the clamping block **522**. The front port **564** is adapted to engage the rear or

proximal pressure sensing port **296**. The pressure measurement load cell **560** is in operative engagement with the pressure sensor interface pin **558** so that fluid pressure changes as exerted on the pressure sensing diaphragm **298** in the rear or proximal pressure sensing port **296**, which reflects the fluid pressure changes in the outlet manifold channel **244,** are transmitted to the pressure measurement load cell **560**. The pressure measurement load cell **560** converts movement of the pressure sensing diaphragm **298** into an electronic signal that is transmitted to the sensor control board **804** via an electronic link or connection **566**. The sensor control board **804** continuously relays this pressure information to the control system **800** so that fluid pressure within the outlet manifold channel **244** may be measured and tracked. This measurement enables the control system **800** to ascertain the fluid pressure in the patient outlet port **270** or the waste outlet port **272** depending on the rotational position of the outlet selector valve **280**.

[00223] The pressure measurement load cell **560** is preloaded by a preload spring **568** which is supported at one end on a spring guide **570** extending rearward or proximally from the rear side of the support block or housing **554**, and has a second end secured to a spring support **572** secured to the two (2) rearmost (*e.g.*, proximal) support appendages **534** extending upward from the clamping block **522**. A cover **574** may be provided to enclose the interior chamber **556** in the support block **554**. The support block **554** may be secured against upward movement in the proximally extending slot **512** in the top support plate **424** by a suitable restricting connection with the opposed ledges **514** along the walls of the proximal slot **512** or suitable connection with the clamping block **522** itself. The preload spring **568** provides sufficient preloading to the pressure measurement load cell **560** and further ensures that the front port **564** on the front or distal end **562** of the support block **554** remains operatively seated or engaged in the rear or proximal pressure sensing port **296** in the outlet selector valve cylinder **264** on the manifold plate **230** when the pump **10** is in operation and under pressure. The operative engagement between the front port **564** and the pressure sensing port **296** maintains operative contact or interface between the pressure sensor interface pin **558**, which projects outward or distally from the front port **564**, and the pressure sensing diaphragm **298** in the pressure sensing port **296** in the outlet selector valve cylinder **264**. Although many pressure sensing devices are available that use a diaphragm and load cell to measure pressure, in the present embodiment, since the pressure sensing diaphragm **298** is located in the disposable pump **10** and the pressure measurement load cell **560** and pressure sensor interface pin **558** are located in the reusable drive and actuating system **400**, a more robust and sensitive load cell may be used for the pressure measurement load cell **560**. This

arrangement allows the fluid-contacting diaphragm **298** to be replaced frequently for sterility purposes, while permitting the use of a high-precision load cell for the pressure measurement load cell **560**.

[00224] From the foregoing, it will be understood that the clamp actuating mechanism **540**, which retracts the clamping block **522** from compressive engagement with the front plate **102** of the pump body **100**, as described in the foregoing, also affects operation of the foregoing pressure measurement mechanism **552**. For example, if a pump **10** is loaded in the pump cradle **412** in the pump drawer **402** and it is desired to remove the existing pump **10**, the piston linear actuators **462** associated with the two (2) outer or outboard slide blocks **470** may be operated so that the slide blocks **470** move proximally or rearward in their respective slide block apertures **518** toward the rear support plate **422**, which concurrently moves the clamping block **522** proximally or rearward via the clamp actuating mechanism **540** as discussed in the foregoing. This movement disengages the clamping block **522** from contact with the front plate **102** of the pump body **100** of the pump **10**. As the support block **554** is supported by the clamping block **522**, forward or rearward movement of the clamping block **522** likewise moves the pressure measurement mechanism **552** in its entirety. Accordingly, as the clamp actuating mechanism **540** retracts the clamping block **522** in the manner described previously, the pressure measurement mechanism **552** is likewise retracted and the front port **564** on the front or distal end **562** of the support block **554** is likewise disengaged from the rear or proximal pressure sensing port **296** in the outlet selector valve cylinder **264** on the manifold plate **230**, and the pressure sensor interface pin **558** is removed from operative contact with the pressure sensing diaphragm **298** in the pressure sensing port **296**. Upon loading of a new pump **10** in the pump drawer **402**, the piston linear actuators **462** associated with the two (2) outer or outboard slide blocks **470** may be driven so that the slide blocks **470** move distally or forward in their respective slide block apertures **518** and enable the clamping block **522** to compressively engage the rear or proximal side of the front plate **102** of the pump body **100** of the replacement pump **10**. This distal or forward movement of the clamping block **522** likewise places the front port **564** on the front or distal end **562** of the support block **554** in engagement with the rear or proximal pressure sensing port **296** in the outlet selector valve cylinder **264** on the manifold plate **230**, and the pressure sensor interface pin **558** is placed in operative contact or engagement with the pressure sensing diaphragm **298** in the pressure sensing port **296** in the outlet selector valve cylinder **264**. As noted previously, the preload spring **568** provides sufficient preloading to the pressure measurement load cell **560** and further ensures that the front port **564** on the front or distal end **562** of the

support block **554** remains operatively seated or engaged in the rear or proximal pressure sensing port **296** in the outlet selector valve cylinder **264** on the manifold plate **230** when the pump **10** is in operation and under pressure.

[00225] In operation, fluid pressure transmitted through the pressure sensing diaphragm **298** applies a representative force to the pressure measurement load cell **560**, which converts the pressure-dependent force to an electronic signal that can be used by the control system **800**. The force applied to the pressure sensor interface pin **558** is substantially proportional to the fluid pressure and the cross-sectional area of the pressure sensing diaphragm **298**. Since the cross-sectional area of the pressure sensing diaphragm **298** remains substantially constant, the output of the pressure measurement load cell **560** is generally proportional to the fluid pressure. Features may be provided between the front port **564** on the front or distal end **562** of the support block **554** and the rear or proximal pressure sensing port **296** in the outlet selector valve cylinder **264** to ensure proper alignment between the pressure measurement load cell **560** and the disposable pump **10**. The elastomeric pressure sensing diaphragm **298** is desirably formed during a secondary molding operation that occurs after the manifold plate **230** is molded.

[00226] The outlet selector valve actuating section **580** is disposed on top of the top support plate **424** that supports the various components of the outlet selector valve actuating section **580**. The outlet selector valve actuating section **580** provides the drive and mechanical interfacing components for operating the outlet selector valve **280**. The outlet selector valve actuating section **580** comprises a support platform **582** disposed and supported on the top side of the top support plate **424**. The support platform **582** extends across the proximal slot **512** in the top support plate **424**. The outlet selector valve actuating section **580** further comprises an outlet selector valve actuator **584** driven by an outlet selector valve drive motor **600**. The outlet selector valve actuator **584** comprises an actuator element **586** comprising an upper or top end **588** and a lower or bottom end **590**. The top end **588** of the actuator element **586** is rotationally supported by suitable rotational support bearings **592** in an actuator enclosure housing **594** supported on the support platform **582**. The rotational support bearing **592** in the actuator enclosure **594** vertically and rotationally supports the upper or top end **588** of the actuator element **586**. An electro-mechanical angular position sensor **596**, such as a rotary encoder, is mechanically coupled to the upper or top end **588** of the actuator element **586**. The angular position sensor **596** is electronically linked to the control system **800** via an electronic link or connection **598** to the sensor control board **804**. The angular position sensor **596** is operable to determine the specific angular orientation of

the valve stem **286** of the outlet selector valve body **282** of the outlet selector valve **280**, which is relayed to the control system **800** via the sensor control board **804**. From the foregoing, it will be understood that the control system **800** receives signal information from the angular position sensor **596** associated with the actuator element **586** and may operate the drive motor **600** to set the angular orientation of the valve stem **286** of the outlet selector valve body **282** of the outlet selector valve **280** in any one of the operating states discussed previously, or any desired angular position in the outlet selector valve cylinder **264** on the manifold plate **230**.

[00227] The outlet selector valve drive motor **600** is likewise supported by the support platform **582** adjacent the outlet sector valve actuator **584**. The outlet selector valve drive motor **600** has an output drive shaft **602** that extends through the support platform **582**. A drive pulley **604** is mounted on the drive shaft **602** below the support platform **582** and an actuator pulley **606** is mounted to the lower or bottom end **590** of the actuator element **586**. A timing belt **608** is reeved about the drive pulley **604** on the drive shaft **602** and the actuator pulley **604** mounted to the lower or bottom end **590** of the actuator element **586** to rotationally interface the drive shaft **602** and the actuator element **586** so that rotation of the drive shaft **602** imparts corresponding rotary motion to the actuator element **586**. The outlet selector valve drive motor **600** may be a servomotor or stepper motor that is electronically linked to the sensor control board **804** via an electronic link or connection **610** so that the control system **800** may control operation of the drive motor **600** and, hence, control operation of the outlet selector valve actuator **584**. The sensor control board **804** provides power to the drive motor **600** via the electronic link or connection **610**. Accordingly, by controlled operation of the outlet selector valve drive motor **600**, the outlet selector valve **280** may be angularly positioned to one of the desired operating positions discussed previously, or any desired angular position, and the angular position of the valve stem **286** of the outlet selector valve **280** is monitored by the angular position sensor **596** coupled to the top end **588** of the actuator element **586** and linked to the control system **800** via the sensor control board **804**.

[00228] The lower or bottom end **590** of the actuator element **586** is formed with an actuator head **612** that defines a U-shaped pocket **614** for receiving the actuator interface head **284** at the top end of the valve stem **286** of the outlet selector valve body **282** of the outlet selector valve **280**. As noted previously, the actuator interface head **284** is generally T-shaped and comprises two (2) outwardly extending tabs **292**. The U-shaped pocket **614** accommodates the T-shaped interface head **284** with the outward extending tabs **292** seating

against the face of the actuator head **612**. The T-shape of the actuator interface head **284** allows the outlet selector valve body **282** to slide into engagement with the pocket **614** in the actuator head **612** and "keys" the outlet selector valve body **282** so that it may be engaged by the actuator head **612** in only one particular orientation. The interface between the actuator interface head **284** and the actuator head **612** also prevents the outlet selector valve body **282** from being ejected upward from the outlet selector valve cylinder **264** on the manifold plate **230** under high pressure as the actuator element **586** is limited in the vertical direction by the rotation support bearings **592** in the actuator enclosure **594**. The actuator element **586** is desirably vertically positioned above the clamping block **522** and the pressure measurement mechanism **552** so that when the pump **10** is loaded into the pump cradle **412** in the pump drawer **402**, the actuator interface head **284** at the top end of the valve stem **286** of the outlet selector valve body **282** of the outlet selector valve **280** is diametrically opposed to the U-shaped pocket **614** in the actuator head **612**. Accordingly, as the pump drawer **402** is closed, the U-shaped pocket **614** automatically receives the T-shaped actuator interface head **284**.

[00229] A main power supply coupling **620** may be mounted on the base plate **432** and the rear support plate **422**. The power supply coupling **620** provides power to the drive control board **802** and the sensor control board **804**, and suitable power supply cabling **622** from the drive control board **802** provides power to the various piston drive motors **442** and inlet selector valve drive motors **444** in the drive section **440**. The base plate **432** includes an electronic connection port **624** for electronically connecting the drive control board **802** to the control system **800**. The sensor control board **804** may likewise be electronically connected to the electronic connection port **624** for electronically connecting the sensor control board **804** to the control system **800**.

[00230] A power and signal coupling **620** may be connected to the drive control board **802** and the sensor control board **804**. The power and signal coupling **620** provides power to the sensor control board **804**, and transfers control signals between the drive control board **802** and the sensor control board **804**. Suitable power supply cabling **622** from the drive control board **802** provides power to the various piston drive motors **442** and inlet selector valve drive motors **444** in the drive section **440**. The drive control board **802** may include an electronic connection port **624** for electronically connecting the drive control board **802** to the control system **800**. The sensor control board **804** may likewise be electronically connected to the control system **800** via the power and signal coupling **620** and electronic connection port **624**. The drive control board **802** is supported by the base plate **432** extending rearward from the rear support plate **422**.

[00231] As noted in the foregoing, the drive and actuating system **400** and, desirably, the control system **800** are supported and contained by the mobile support **700**. The mobile support **700** generally comprises a support housing **702** vertically supported by a support pedestal or column **704** connected to a wheeled base **706**. The wheeled base **706** permits the mobile support **700** to be movable within a hospital or like medical facility. The pedestal **704** may include a handle structure **708** for moving the mobile support **700**. Bottle or container supports **710** may be provided on lateral sides of the pedestal **704** for stably supporting bottles or containers, such as the fluid source containers **30** discussed previously, during spiking operations. The bottle or container supports **710** allow bottles or containers to be spiked and to be maintained in an upright posture during spiking at a location near the pump drawer **402** since the fluid supply tubes **34** of the various embodiments of the fluid supply sets **32** are typically permanently affixed to the pump **10**. Additionally, the support housing **702** may comprise two (2) lateral fluid handling compartments **712**, as shown in **FIG. 60**, which are supported within respective lateral compartment doors **714** that close against and form part of the support housing **702** of the mobile support **700**. These lateral fluid handling compartments **712** house components of the fluid management system **720** and, thus, the lateral fluid handling compartments **712** support and maintain the various diagnostic or therapeutic (*e.g.*, pharmaceutical) fluids to be associated with the pump **10**. The mobile support **700** also supports components of the control system **800**, as shown in **FIG. 46A**. While the details of the control system **800** are provided herein, **FIG. 46A** shows certain components of the control system **800** supported on the support housing **702** including a local user interface display **806**, typically a touch screen, a packaging reader **808** such as bar code or RFID tag reader, and a patient outlet air detector **810** which interfaces with and accepts the medical tubing of the patient supply set **40**. A patient outlet port opening **716** is further provided in the support housing **702** to provide an egress opening for the swabable valve **274** seated in the patient outlet port **270** on the outlet selector valve cylinder **264** on the manifold plate **230**. Further, the handle housing portion **404** and waste collection compartment **406** of the pump drawer **402** are accessible from the front of the support housing **702** and are formed to blend cosmetically as part of the support housing **702**. If desired, the support housing **702** may be detachable from the pedestal **704** and may include overhead mounting points **718** on a top or upper face for mounting the support housing **702** to an overhead support system (not shown). The support housing **702** and support pedestal **704** together may have any suitable ornamental appearance.

[00232] As shown in **FIG. 60**, each fluid handling compartment **712** encloses a fluid management system **720**. In particular, the fluid management system **720** comprises identical fluid handling arrangements, one in each fluid handling compartment **712**. Each fluid handling arrangement comprises a saline container support or hanger **724** supporting a saline fluid source container **30** such as a saline bag, and a pair of fluid container supports **726** for supporting one of the fluid source containers **30**, discussed previously, in an inverted fluid delivery orientation. Any type of support or hanger may be provided for supports or hangers **724**, **726**, such as those described in U.S. Patent No. 7,240,882 to Degentesh, et al. incorporated herein by reference for this purpose.

[00233] Upper and lower indicator lights **728**, **730** are provided in the interior of the fluid handling compartment **712**, above and below each of the saline container support **724** and the respective fluid container supports **726**. The upper and lower indicator lights **728**, **730** may be controlled by the control system **800** to alert the operator via visual means (and potentially augmented by auditory or other means) as to the location in the respective fluid handling compartments **712** where the fluid source containers **30** should be placed for an injection procedure. The indicator lights **728**, **730** may be color coded to correspond to a specific fluid. For example, the indicator lights **728**, **730** associated with the saline support **724** may be blue, while the indicator lights **728**, **730** for the fluid container supports **726** in the left fluid handling compartment **712** are green, and the indicator lights **728**, **730** for the fluid container supports **726** in the right fluid handling compartment **712** are purple, as examples. Additionally, a pump connection status bar **732** is provided in the interior of each of the fluid handling compartments **712** in a lower corner and contains three (3) indicator lights, designated as **732a**, **732b**, **732c** in **FIG. 60**. These indicator lights **732a**, **732b**, **732c** correspond, respectively, to the three (3) pairs of indicator lights **728**, **730** and, ideally, have the same color-coding as the corresponding indicator lights **728**, **730**. Accordingly, indicator light **732a** may be blue to correspond to the indicator lights **728**, **730** associated with the saline support **724**, and indicator light **732b** may be green to correspond to the indicator lights **728**, **730** associated with the "center" or "middle" fluid container supports **726** in the left fluid handling compartment **712**, etc.

[00234] As described in detail herein, when a new fluid source container **30** is installed in a fluid handling compartment **712**, the control system **800** causes all three (3) indicator lights **728**, **730**, **732** for that source location to flash or blink together. The indicator lights **728**, **730** respectively show the user where to place the fluid source container **30** and which associated air detector (as described herein) is active for that fluid source container **30**. The lower

indicator light **730** also shows the user which of the three (3) fluid supply tubes **34** on that side of the pump **10** should be used to connect to the fluid source container **30**. Once the fluid source container **30** is installed and successfully primed, all three indicator lights **728**, **730**, **732** change from flashing or blinking to solid "on". This indicates that the fluid source container **30** is "active" and available for use if desired. Once the fluid source container **30** has been depleted, the control system **800** turns all three (3) indicator lights **728**, **730**, **732** "off" to show that the fluid source container **30** is no longer available. If the "open life" of the fluid source container **30** expires or if the user indicates that the fluid source container **30** should no longer be used, the indicator lights **728**, **730**, **732** are turned "off". The indicator lights **728**, **730**, **732** are not typically used during a fluid injection as they are typically closed behind the lateral compartment doors **714** during fluid injections.

[00235] As was described previously, each pump **10** in the illustrated embodiment comprises a pump body **100** with three (3) inlet ports **122**, **124**, **126** on each lateral side, including two (2) fluid inlet ports **122**, **124** and a single saline inlet port **126**. To accommodate this embodiment of the pump **10**, each fluid handling compartment **712** is adapted to support three (3) fluid containers **30** to be associated with the inlet ports **122-126** on the lateral sides of the pump body **100**. However, this configuration of the pump **10**, as noted previously, is merely exemplary and should not be considered limiting. The pump **10** and the foregoing corresponding configuration of the respective fluid handling compartments **712** should not be considered as exclusive and the pump **10** and the respective fluid handling compartments **712** may be expanded to include additional fluids (*e.g.*, four (4) or more fluids), or fewer fluids (*e.g.*, less than three (3) fluids). However, the arrangement of two (2) fluid handling compartments **712**, each supporting up to three (3) fluid source containers **30**, is desirably effective for interfacing with the pump **10**.

[00236] The respective fluid handling compartments **712** also each support a series of fluid inlet air detectors **812**, **814**, **816** for the fluid supply tubes **34** used to conduct fluids from the respective fluid source containers **30**. The inlet air detectors are respectively associated with the saline container support **724** and the respective fluid container supports **726** in the fluid handling compartments **712**. The air detectors **812-816** and the patient outlet air detector **810**, discussed previously, provide air bubble detection information to the control system **800** for operational control of the fluid delivery system **2**. The various air detectors **810-816** may be conventional optical or ultrasonic air detectors as are well known in the medical field, and are discussed further herein.

[00237] Further, it is often desirable to maintain the fluid contained in the various fluid source containers **30** in each fluid handling compartment **712** in a warmed state for the comfort of the patient and other purposes. For example, in the case of contrast media used in radiographic imaging procedures, increasing the temperature of the contrast media also has the desirable effect of reducing the viscosity of the contrast media for easier injection into the patient, among other advantages. Accordingly, each fluid handling compartment **712** is warmed by a convective heating system **734**. The convective heating system **734** may include devices or components (not shown) that may intake air through an intake vent **736** in each fluid handling compartment **712**, warm the air across a heating system, such as simple electrical resistance coils, and return the heated air into the interior of the fluid handling compartment **712** via an air outlet vent **738**.

[00238] During a fluid injection, one or more indicator lights **807** on the user interface display **806** may be turned on by the control system **800** to show which fluids are being injected. For example, the indicator lights **807** may be two (2) multi-color indicator lights located in the top left and right corners of the user interface display **806**. The indicator lights **807** may be either flashing or solid "on" and may emit white, blue, green, purple, etc. light depending on the fluid being injected. For example, if saline is being injected into the patient, the indicator lights **807** may be blue based on the color convention discussed previously in connection with the indicator lights **728**, **730**, **732** in the fluid handling compartments **712**. Both indicator lights **807** desirably always display the same state (flashing or solid "on" and the same color). Additional and larger indicator lights (not shown) may be placed on the user interface display **806** or on the support housing **702** and may be sized so that a user is able to see these indicator lights from anywhere in the room where the fluid delivery system **2** is located. These "larger" indicator lights (not shown) desirably indicate when the fluid delivery system **2** is armed and during a fluid injection, and may show which type of fluid is currently being injected. For example, if saline is being injected, these larger indicator lights can flash blue, and if contrast from the left fluid handing compartment **712** is being injected, the larger indicator lights can flash green.

[00239] Turning next to operational aspects of the fluid delivery system **2**, it will be understood that numerous steps are undertaken during "normal" or "typical" setup and operation of the system **2**. The following discussion outlines a series of steps that typically occur during normal setup and operation of the fluid delivery system **2**. The following operational discussion is intended as exemplary and non-limiting, and generally outlines the steps and procedures for normal or typical setup and operation from which one skilled in the

art may operate the fluid delivery system **2**. Operation of the fluid delivery system **2** may be considered to be divided into a number of different procedures or steps such as installing a pump **10**, priming the pump **10** and associated inlet fluid handling components, priming the outlet patient supply set **40**, etc. Relevant procedures and steps are described hereinafter for installing a pump **10**, priming the pump **10** and associated inlet fluid handling components, and priming the outlet patient supply set **40**. Reference continues to **FIGS. 1-60** hereinafter.

[00240] Initially, the control system **800** of the fluid delivery system **2** is turned "ON" and provided with power, which boots up all processors, sensors, such as the angular position sensors **494**, **596**, drawer closed sensor **818**, and drawer locked sensor **820**, as examples, and the user interface display **806**. The foregoing listing is not intended to be exhaustive. It will be appreciated that the control system **800** comprises a system controller or computer **822** with appropriate software for controlling operation of the fluid delivery system **2** and this controlling computer may physically reside on-board the mobile support **700**, or be located at some external location, such as in a control room, and interface via a hardwired connection or wireless connection, as desired, with the electronic components associated with the support housing **702**, such as the drive control board **802** and sensor control board **804**, sensors, such as the angular position sensors **494**, **596**, drawer closed sensor **818**, and drawer locked sensor **820**, as examples, and the user interface display **806**. While the microprocessor and like components for controlling the various components of the drive and actuating system **400** may reside entirely with the system controller **822**, these control components may be distributed between the system control computer **822** and the drive control board **802** and sensor control board **804** as desired by one skilled in the computer field. The system controller **822** may interface via wired or wireless connections with external devices such as a computer network **900** (via an Ethernet connection), a CT scanner **902**, a remotely located display **904**, such as a touch screen, and like external devices, as shown in **FIG. 46B**. Further, it will be appreciated by one skilled in the computer field that all of the processing, data storage, and other computer-implemented tasks described herein may be performed by the control system **800**, the system controller **822** or any other device with such capabilities that is in communication with the control system **800** and/or the system controller **822**. Such a device may be in communication with the control system **800** and system controller **822** via a computer network **900** or any other means for wired or wireless data communication.

[00241] Safety tests and internal self tests are performed on various parts of the control system **800**, such as the air detectors **812-816**, the optical sensor or like detector (not shown) used to read the pump indicator plate **170**, and the user interface display **806**, and other

various sensors physically included in the drive and actuating system **400**, such as the drawer closed sensor **818**, drawer locked sensor **820**, angular position sensors **494**, **596**, pressure measurement mechanism **552** (*e.g.*, strain gauge/load cell **560**), etc. The control system **800** includes an optical sensor or like detector (not shown) associated with the drive and actuating system **400** used to read the pump indicator plate **170** to confirm that no pump **10** is currently installed in the pump drawer **402**. If the control system **800** is recovering from a power failure or other unusual event and a pump **10** is already associated with the drive and actuating system **400**, a more complex recovery sequence may be executed by the system controller **822**. The piston drive motors **442** for the four (4) piston linear actuators **462** are "homed" by moving them until a "home sensor" **824** for each actuator **462** is tripped thereby resetting their positions to zero. Each home sensor **824** is electronically connected with the sensor control board **804** as best shown in **FIGS. 54** and **58**. The inlet selector valve drive motors **444** for the respective inlet selector valve actuators **464** and the outlet selector valve drive motor **600** for the outlet selector valve actuator **584** are moved to their "home" positions by using the angular position sensors **494**, **596** associated with each actuator **464**, **584**. It is now possible for a user to begin using the fluid delivery system **2**.

[00242] Before an injection procedure may be performed, several setup steps are typically required including, but not limited to: (1) installing a pump **10** and priming the same with saline **S1**, **S2**; (2) installing the fluid source containers **30** having sufficient volume of saline **S1**, **S2** and therapeutic or diagnostic (*e.g.*, pharmaceutical) fluids **A1**, **A2** and **B1**, **B2**, to support the desired patient protocol, which also may be termed a fluid injection procedure; (3) installing a patient supply set **40** to the pump **10** and priming the same with saline **S1**, **S2**; (4) programming a patient protocol or selecting a patient protocol from protocol storage in the system controller **822** and which is accepted by the control system **800** as "valid"; and (5) assuring that there is sufficient free space in the waste collection container **48** to accept any waste fluid that may be generated during the fluid injection procedure. It will be understood that the foregoing steps do not have to be performed in the order listed, but some steps may depend on the successful completion of a previous step. For example, it is possible for the user to enter a patient protocol first and then subsequently install the fluid source containers **30** but it is not possible to install the fluid source containers **30** or attach a patient supply set **40** until the pump **10** is installed in association with the drive and actuating system **400**. The foregoing steps are described in greater detail herein.

[00243] Initially, it is desirable to install a pump **10** in association with the drive and actuating system **400**. The user interface display **806** typically displays a "Home Screen".

The user first opens the packaging containing a pump **10** and removes the pump **10** from the packaging. The user scans or otherwise reads the identifying indicia **172**, such as a bar code or RFID tag, using the packaging reader **808** on the mobile support **700**. As an alternative, the user may use the user interface display **806** to indicate that a new pump **10** is being installed and can manually enter the barcode digits and like information read from the identifying indicia **172**. If the packaging reader **808** is equipped to read an RFID tag, the information contained thereby may be read by the packaging reader **808**. An RFID tag reader may also, or alternatively, be present within the drive and actuating system **400** so that the RFID tag as the identifying indicia **172** may be "read" when the pump **10** is installed in the drive and actuating system **400**. In this situation, the pump **10** is installed in the pump drawer **402**, and when the pump drawer **402** is closed and locked the RFID tag reader "reads" the information container in the RFID tag identifying indicia **172** and may further "write" to the RFID tag identifying indicia **172**, as discussed previously. The foregoing "internal" RFID tag reader may take the place of the optical sensor or like detector (not shown) used to read the pump indicator plate **170**.

[00244] The control system **800** now automatically switches the user interface display **806** to a "Pump Installation Dialog Screen". The system controller **822** decodes the information contained in the identifying indicia **172** from the packaging reader **808** and indentifies one or more of the: pump type/configuration, pump serial number, pump manufacturing identification number, use-by date, manufacturing lot code/batch number, and initial angular position (*e.g.*, inlet selector valve position code) of the inlet selector valves **300**. The system controller **822** desirably checks the pump serial number against an internal database. If the pump serial number is already in an internal database of "used pumps", the control system **800** generates a message on the user interface display **806** to indicate that pump **10** cannot be used. The control system **800** uses the inlet selector valve position code to determine the initial angular position of the inlet selector valves **300** which informs the system controller **822** as to the initial or "preset" angular orientation of the valve stem **306** of the inlet selector valve body **302** and, hence, the initial angular positions of the inlet ports **322**-**328** in the valve stem **306**. From the initial angular orientation of the valve stem **306** of the inlet selector valve body **302** for the respective inlet selector valves **300**, the system controller **822** positions the respective inlet selector valve actuators **464** to correctly match the angular orientation of the inlet selector valves **300**. The outlet selector valve actuator **584** operates the outlet selector valve **280** to place the outlet selector valve body **282** in a "waste" position in which the flow passage **290** in the outlet selector valve body **282** of the outlet selector valve **280** is placed in

fluid communication with the waste outlet port **272** on the outlet selector valve cylinder **264** on the manifold plate **230**. The piston drive motors **442** for the four (4) piston linear actuators **462** move the respective piston linear actuators **462** to their fully retracted (rearmost) position. The piston linear actuators **462** generally operate behind the normal working or pumping zone **164** of the pump cylinders **104** before the plungers **200** are connected thereto and then may operate in the normal working or pumping zone **164** of the pump cylinders **104** after the plungers **200** are connected thereto. The retraction of the two (2) outboard piston linear actuators **462** compresses the clamping springs **532** and withdraws the clamping block **522** to permit pump installation, in the manner described previously hereinabove.

[00245] As noted in the foregoing, retraction of one of the inboard piston linear actuators **462**, namely the left inboard piston linear actuator **462** in the description provided in the foregoing, moves a lock actuator (not shown), such as a cam mechanism, to move the locking support plate **416** to the unlocked position, which unlocks the pump drawer **402**. The user then opens the pump drawer **402** in the front of support housing **702**, inserts the pump **10** into pump drawer **402**, and places it in the pump cradle **412**. The attached waste collection system **44** is placed in the waste collection compartment **406**. The user then closes the pump drawer **402**. Once closed, the control system **800** desirably locks the pump drawer **402**. The control system **800** detects that the pump drawer **402** is closed via the drawer closed sensor **818** and operates the drive motor **442** associated with the left inboard piston linear actuator **462** to move the left inboard piston linear actuator **462** slightly forward to actuate the lock actuator to move the locking support plate **416** to the locked position. The control system **800** confirms that the pump drawer **402** has been locked with the drawer locked sensor **820**.

[00246] The control system **800** then operates the drive motors **442** for the two (2) outboard piston linear actuators **462** to move these actuators forward slightly to release the clamping springs **532**, permitting the clamping block **522** to apply a compressive force to the rear of the front plate **102** of the pump body **100** and clamp the pump **10** in place in the pump cradle **412**. When the clamping springs **532** apply compressive force to the pump **10**, the pressure measurement mechanism **552** is automatically engaged with the pressure sensing diaphragm **298** in the pressure sensing port **296** in the outlet selector valve cylinder **264** on the manifold plate **230**, and the optical sensor or detector (not shown) used to read the pump indicator plate **170** on the pump body **100** also engages or interfaces with the pump **10**. The control system **800** uses the optical sensor or detector (not shown) to read the groove pattern of the pump indicator plate **170** and confirms that this pattern matches at least the pump type encoded in the barcode or RFID tag forming the identifying indicia **172**. The strain

gauge/load cell **560** of the pressure measurement mechanism **552** is "zeroed", meaning that the current sensor value is recorded as a zero pressure value.

[00247] Additionally, all four (4) piston linear actuators **462** are "calibrated" to the pump **10**. In this calibration step, the pistons **50** are advanced to contact the rear face of their respective plungers **200**. The piston linear actuators **462** push the plungers **200** from the rear "assembly" or isolation zone **166** into the forward "working" or "pumping" zone **164** of the respective pump cylinders **104**. The piston linear actuators **462** continue to push the plungers **200** into the pump chambers **106** of the pump cylinders **104**. As the front or distal end disc **206** on each plunger **200** contacts the distal end **108** of the pump cylinder **104** formed by the front plate **102** of the pump body **100**, the respective pistons **50** "snap" onto the respective plungers **200** via the snap-fit connection described previously. At this point, the electrical current in the associated drive motor **442** will increase significantly (*e.g.*, "spike"). The control system **800** detects each current "spike" via the respective electronic connections **450** between the drive motors **442** and the drive control board **802**. The control system **800** stops the respective drive motors **442**, moves the piston linear actuators **462** rearward slightly, and then sets a "zero volume position" for each pump cylinder **104**. The left and right inlet selector valves **300** are moved to their "OFF" positions. The user may open the lateral compartment doors **714** at this time, or these doors **714** may be opened earlier in the foregoing process. Saline fluid source containers **30** may be installed in the lateral fluid handling compartments **712** and the saline priming process may now begin. The foregoing presupposes that the pump drawer **402** is locked and the pump **10** is held in place by the clamp actuating mechanism **540**.

[00248] The user typically scans a barcode and like indicia on the saline fluid source container/bag **30** using the packaging reader **808** on the mobile support **700**. Alternatively, the user may use the user interface display **806** to manually indicate that a new saline fluid source container **30** is being installed and specify the type and container size. The control system **800** identifies the type and size of the saline source **S1** that is being installed and displays the information on the user interface display **806**. The control system **800** indicates on the user interface display **806** that the saline fluid source container **30** is to be installed in the left side fluid handling compartment **712**, as viewed from the front of the mobile support **700** (*e.g.*, the view of **FIG. 60**) so that the left side of the pump **10** is supplied by the first saline fluid source container **30**. The control system **800** causes the upper and lower indicator lights **728**, **730** associated with the saline support **724** in the left fluid handling compartment **712** to flash, blink, or otherwise visually indicate to the user as to where the saline fluid

source container **30** should be installed. An additional lower indicator light **730** may be provided adjacent the rearmost saline air detector **816** and can flash, blink, or otherwise visually indicate that this rearmost saline air detector **816** is used for the fluid supply tube **34** connected to the spike **36** used to access the saline fluid source container **30**. Depending on the configuration of the fluid supply set **32** provided with the pump **10**, as shown in **FIGS. 40-43** discussed previously, the user may be required to clean a swabable valve **70** associated with the fluid supply tube **34** and connect a spike **36** thereto to access the saline fluid source container **30**. However, the relevant point is that the rearmost fluid supply tube **34** associated with the rearmost saline inlet port **126** on the left side **18** of the pump body **100** of the pump **10** is connected to the first saline fluid source container **30** that is loaded into the left fluid handling compartment **712**. The user also inserts the fluid supply tube **34** into the air detector **816**, and the flashing lower indicator light **730** near the air detector **816** guides the user in associating the fluid supply tube **34** with the correct "saline" air detector **816**. The control system **800** detects that the fluid supply tube **34** is installed in the air detector **816** and enables a "Prime" button on the user interface display **806** which may be disabled or "grayed out" prior to the foregoing installation of the fluid supply tube **34** with the air detector **816**.

[00249] The user may then press the "Prime" button and the fluid supply tube **34**, inlet selector valves **300**, and inlet manifold channels **236** are primed with saline. The outlet selector valve **280** is rotated to the waste position (if not already in position), as described previously, and the left and right inlet selector valves **300** are moved from the "OFF" position to a "left saline source" or "**S1**" position to allow fluid communication between the rear saline channel **134** of the saline manifold **130** and the rearmost saline port **334** in the valve stem **306** of the inlet selector valve body **302** of both inlet selector valves **300**. All four (4) plungers **200** are retracted substantially simultaneously to pull air/saline from the left saline fluid source container **30** into the rear saline channel **134** of the saline manifold **130** via the left saline inlet port **126** on the left side inlet selector valve cylinder **114** of the pump body **100**. The plungers **200** are retracted to deliver up to a predetermined or preset priming volume of air/saline into the pump chambers **106**. The pump cylinders **104** on the left side **18** of the pump body **100** draw air/saline from the left saline fluid source container **30**, through the fluid supply tube **34**, through the left inlet selector valve **300** and left inlet manifold channel **236**, and into the two (2) left pump cylinders **104**. The pump cylinders **104** on the right side **16** of the pump **10** draw air/saline from the left saline fluid source container **30**, through the fluid supply tube **34**, across the rear saline channel **134**, through the right inlet selector valve **300** and right inlet manifold channel **236**, and into the two (2) right pump

cylinders **104**. At this point all four (4) pump cylinders **104** contain a mixture of air and saline. All four (4) plungers **200** are then advanced substantially simultaneously to eject the air/saline mixture into the waste collection container **48**. As this mixture is ejected, the pressure sensor output signal from the pressure measurement mechanism **552** is monitored. If the pressure exceeds a predetermined limit, indicating a blockage in the waste collection tube set **46**, the priming process is halted.

[00250] If, in the foregoing process, the final extracted volume (X ml) of air and saline from the left saline fluid source container **30** contains less than a predetermined volume of air (Y ml), as determined by the system controller **822** based on sensed air detection information from the left saline air detector **816**, priming of the fluid supply tube **34** is considered complete (*e.g.*, X>Y). If more than a predetermined maximum volume of air (Y ml) was determined by the system controller **822** based on sensed air detection information from the left saline air detector **816**, the user is prompted via the user interface display **806** to repeat the foregoing priming process. The control system **800** may also query the user via the user interface display **806** to visually confirm that the fluid supply tube **34** is free of air and that the priming process is complete. If the user sees air in the fluid supply tube **34**, the user may initiate a repeat of the priming process using the user interface display **806**. In other words, in this saline priming process, a predetermined volume of air and saline (X ml) is extracted from the left saline source container **30** and at least a minimum volume (*e.g.*, X ml – Y ml) has to be free of air to consider this priming process complete. The system controller **822** is programmed in advance with information (X ml and Y ml) that a certain minimum or predetermined volume of saline must be drawn from the left saline fluid source container **30** in order to prime the downstream volume of the fluid supply tube **34**, inlet selector valves **300**, and inlet manifold channels **236**, and can cause the drive pistons **50** to withdraw the plungers **200** a predetermined distance or "stroke" in the pump cylinders **104** to ensure that the predetermined minimum volume of saline is present for the priming of the fluid supply tube **34**. If for any reason the left saline air detector **816** registers the presence of air after the forward or priming stroke of the respective pistons **50**, the system controller **822** will require a repeat of the foregoing priming process.

[00251] The control system **800** also initiates clearing or purging of air from the outlet manifold channel **244**. In this procedure, all four (4) plungers **200** are retracted substantially simultaneously to pull fluid from the left saline fluid source container **30** into the pump **10** up to a predetermined flushing volume. All four (4) plungers **200** are then advanced to eject the saline in the pump cylinders **104** into the waste collection container **48**, clearing the outlet

manifold channel **244** of air in the process. The pump **10** and the fluid path including the fluid supply tube **34** to the left saline fluid source container **30** are now primed with saline and the control system **800** records the installation time of the left saline fluid source container **30**. This recorded information may be displayed for the user on the user interface display **806** or may be automatically or manually viewed at a later point in time, if desired. The control system **800** may also provide and initialize a countdown timer that may be viewed at any time on the user interface display **806** to see the remaining "open life" of the saline in the left saline fluid source container **30** based on manufacturer's information and/or other guidelines for the permitted "open life" of the fluid. The control system **800** also may display expiration warnings on the user interface display **806** when there is less than a predetermined amount of remaining "open life" and when the remaining "open life" has reached zero. Further, the control system **800** moves the inlet selector valves **300** to their "OFF" positions and moves the outlet selector valve **280** to the "OFF" position. The control system **800** then changes the indicator lights **728**, **730** associated with the left saline fluid source container **30** and the saline air detector **816** from flashing to solid, as an example, to indicate that the fluid source container **30** has been installed, primed, and ready for use. If desired, the control system **800** may now prime the patient supply set **40** and perform a saline-only injection.

[00252] The user may next install a fluid source container **30** containing a therapeutic or diagnostic (*e.g.*, pharmaceutical) fluid, such as a contrast bottle. The user typically scans a barcode and like indicia on the fluid source container **30**, which is assumed to be contrast media in the present example, using the packaging reader **808** on the mobile support **700**. Alternatively the user may use the user interface display **806** to manually indicate that a new contrast fluid source container **30** is being installed and specify the type of contrast, concentration, and container size. If it is not already being displayed on the user interface display **806**, the control system **800** next displays a fluid loading screen on the user interface display **806**. The control system **800** uses the information from the barcode or like indicia such as an RFID tag in conjunction with an internal database and identifies, for example, the contrast type, iodine concentration, and size of the contrast fluid source container **30** that is to be installed and displays the information on the user interface display **806**. The control system **800** indicates on the user interface display **806** that the contrast fluid source container **30** is to be installed in the first or default position "**L1**" in the left side fluid handling compartment **712** on the mobile support **700**. Alternatively, the user may use the user interface display **806** to override this default location and indicate that the contrast fluid source container **30** is being installed in the right side fluid handling compartment **712**. This

alternative location may be provided as some users may have a preference to always install the same type of contrast or other fluid on the same side of the mobile support **700**. This override option allows users to install any type of therapeutic or diagnostic (*e.g.*, pharmaceutical) fluid first but still have each type of fluid located in its preferred location. Nonetheless, even with this override option, the first "contrast" fluid source container **30** is installed in the first position "**L1**" or "**R1**" in either fluid handling compartment **712** reserved for a therapeutic or diagnostic (*e.g.*, pharmaceutical) fluid, and this position is immediately adjacent the saline support **724** in the fluid handling compartment shown in **FIG. 60**.

[00253] The control system **800** again flashes the upper and lower indicator lights **728**, **730** that are associated with the selected fluid container support **726** to indicate where the contrast fluid source container **30** should be installed and where the associated fluid supply tube **34** should be used. The user typically removes a protective cap from the top of the contrast fluid source container **30** and cleans the rubber septum. The user may place the contrast fluid source container **30** in the bottle or container support **710** provided on the chosen lateral side of the pedestal **704**. The user then makes a fluid connection between the selected "center" fluid supply tube **34** associated with the "center" inlet port **124** on the pump body **100** of the pump **10** and the contrast fluid source container **30** using the spike **36**. Depending on the configuration of the fluid supply set **32** provided with the pump **10**, as shown in **FIGS. 40-43** discussed previously, the user may be required to clean a swabable valve **70** associated with the fluid supply tube **34** and connect a spike **36** thereto to access the contrast fluid source container **30**. The user then inverts the contrast fluid source container **30** and inserts the container **30** into the first or "center" fluid container support **726**. The "center" fluid supply tube **34** associated with the second or "center" inlet port **124** on the pump body **100** of the pump **10** is now connected to the contrast fluid source container **30** hanging in the center or middle location in the fluid handling compartment **712**. In the present example, it may be assumed that the "center" fluid supply tube **34** associated with the second or "center" inlet port **124** on the pump body **100** of the pump **10** is now connected to the contrast fluid source container **30** hanging in the left fluid handling compartment **712**. The upper and lower indicator lights **728**, **730** associated with the first or center fluid container support **726** remain flashing to guide the user in installing the contrast fluid source container **30** with the correct middle support **726** and, further, guide the user in associating the fluid supply tube **34** with the center or middle air detector **814**. The control system **800** detects when the fluid supply tube **34** is installed in the center or middle air detector **814** and enables the "Prime" button on the user interface display **806**.

[00254] Next, the user presses the "Prime" button on the user interface display **806** to begin the priming process. The outlet selector valve **280** is rotated to the "waste" position (if not already in position), and the left inlet selector valve **300**, based on the foregoing example of locating the contrast fluid source container **30** in the "**L1**" position in the left side fluid handling compartment **712**, is moved from the "OFF" position to a "first" fluid position. In this position, the valve stem **306** of the inlet selector valve body **302** of the left inlet selector valve **300** is rotated by the associated inlet selector valve actuator **464** to permit fluid communication between the second inlet port **324** and the second inlet port **124** on the inlet selector valve cylinder **114** of the pump body **100**. Fluid communication is thereby established between the contrast fluid source container **30** and the axial passage **310** in the valve stem **306**. One or both of the plungers **200** in the left two (2) pump cylinders **104** of the pump body **100** are retracted to pull air/fluid from the contrast fluid source container **30** into the pump **10** up to a predetermined or preprogrammed priming volume. If the predetermined priming volume may be achieved using one (1) plunger **200**, only one of the two (2) plungers in the left two (2) pump cylinders **104** is actuated. If the predetermined priming volume cannot be achieved with one (1) plunger **200**, both left plungers **200** are actuated. The pump cylinder or cylinders **104** on the left side **18** of the pump **10** draw air/fluid from the contrast fluid source container **30**, through the fluid supply tube **34** connected to the second inlet port **124** on the inlet selector valve cylinder **114** of the pump body **100**, through the left inlet selector valve **300** and left inlet manifold channel **236**, and into the left pump cylinder or cylinders **104**. At this point, one or both of the two (2) left pump cylinders **104** contain a mixture of air and contrast, and one or both of the two (2) left plungers **200** are advanced, substantially simultaneously, to eject the air/contrast mixture into the waste collection container **48**. As this mixture is ejected, the pressure sensor output signal from the pressure measurement mechanism **552** is monitored. If the pressure exceeds a predetermined limit, indicating a blockage in the waste collection tube set **46**, the priming process is halted.

[00255] If, in the foregoing process, the final extracted volume (X ml) of air and contrast fluid from the left contrast fluid source container **30** contains less than a predetermined volume of air (Y ml), as determined by the system controller **822** based on sensed air detection information from the associated air detector **814**, priming of the fluid supply tube **34** is considered complete. If more than a predetermined volume of air (Y ml) was detected by the system controller **822** based on sensed air detection information from the associated air detector **814**, the user is prompted via the user interface display **806** to repeat the foregoing priming process. The control system **800** may also query the user via the user interface

display **806** to visually confirm that the fluid supply tube **34** is free of air and that the priming process is complete. If the user sees air in the fluid supply tube **34**, the user may initiate a repeat of the priming process using the user interface display **806**. In other words, in the contrast priming process, a predetermined volume of air and contrast fluid (X ml) is extracted from the left saline source container **30** and at least a minimum volume (*e.g.*, X ml – Y ml) has to be free of air to consider this priming process complete. The system controller **822** is programmed in advance with information (*e.g.*, X ml and Y ml) that a certain or predetermined volume of fluid must be drawn from the installed contrast fluid source container **30** in order to prime the volume of the fluid supply tube **34**, and can cause the drive pistons **50** to withdraw the plungers **200** a predetermined distance or "stroke" in the pump cylinders **104** to ensure that the predetermined minimum volume of fluid is present for the priming of the fluid supply tube **34**. If for any reason the associated air detector **814** registers the presence of air after the forward or priming stroke of the respective pistons **50**, the system controller **822** will require a repeat of the foregoing priming process.

[00256] Additionally, the control system **800** ideally initiates the clearing of air and contrast from the left inlet selector valve **300** and left inlet manifold channel **236**, since it is undesirable to leave contrast in the inlet selector valve **300** or inlet manifold channel **236** as the next injection may use this side of the pump **10** to deliver saline instead of contrast. The left inlet selector valve **300** is moved to the "left saline source" or "**S1**" position described previously, and the plungers **200** in the two (2) left pump cylinders **104** are retracted substantially simultaneously to pull saline from the left saline fluid source container **30** and into the pump **10** through the fluid path described previously up to a predetermined flushing volume. At this point, both left pump cylinders **104** contain a mixture of air, the contrast that was previously present in the left inlet selector valve **300** and the left inlet manifold channel **236**, and now saline. Both plungers **200** are then advanced substantially simultaneously to eject the air/contrast/saline mixture into the waste collection container **48**. As this mixture is ejected, the pressure sensor output signal from the pressure measurement mechanism **552** is monitored. If the pressure exceeds a predetermined limit, indicating a blockage in the waste collection tube set **46**, the priming process is halted.

[00257] The control system **800** also initiates clearing or purging of air and residual contrast from the outlet manifold channel **244**. In this procedure, all four (4) plungers **200** are retracted substantially simultaneously to pull saline from the left saline fluid source container **30** into the pump **10** up to a predetermined flushing volume. All four (4) plungers **200** are then advanced to eject the saline in the pump cylinders **104** into the waste collection

container **48**, clearing the outlet manifold channel **244** of air and residual contrast in the process. As this mixture is ejected, the pressure sensor output signal from the pressure measurement mechanism **552** is monitored. If the pressure exceeds a predetermined limit, indicating a blockage in the waste collection tube set **46**, the priming process is halted. All four (4) plungers **200** are used for this step, not just the left two (2) plungers **200**, because if only the two (2) left plungers **200** are used, residual contrast may be pushed from the two (2) left pump cylinders **104** into the inactive right half of the outlet manifold channel **244**. Moving all four (4) plungers **200** forces saline from all four (4) pump cylinders **104** at once, driving any residual contrast or air to the waste collection container **48**.

[00258] The fluid supply tube **34** to the left or first contrast fluid source container **30** at position "**L1**" is primed with contrast and the control system **800** records the installation time of the left contrast fluid source container **30**. This recorded information may be displayed for the user on the user interface display **806** or may be viewed automatically or manually at a later point in time, if desired. The control system **800** may also initialize a countdown timer that may be viewed at any time on the user interface display **806** to see the remaining "open life" of the contrast in the left contrast fluid source container **30** based on manufacturer's information or other guidelines for the permitted "open life" of the fluid. The control system **800** may also display expiration warnings on the user interface display **806** when there is less than a predetermined amount of remaining "open life" and when the remaining "open life" has reached zero.

[00259] The control system **800** then moves both inlet selector valves **300** and the outlet selector valve **280** to their "OFF" positions. The control system **800** further changes the upper and lower indicator lights **728**, **730** associated with the center or middle fluid container support **726** from flashing to solid, as an example, to indicate that the left contrast fluid source container **30** has been installed, primed, and is ready for use. The user may elect to close the left compartment door **714** to enclose the left fluid handling compartment **712** with the support housing **702**. Further, if the convective heating system **734** has been enabled, the control system **800** may engage the heating system **734** to heat the two (2) installed fluid source containers **30**. Typically, the heating system **734** heats the air inside of the fluid handling compartment **712** to 40° C and the air inside of the fluid handling compartment **712** is circulated continuously around all of the fluid source containers **30** to warm the fluids. This heating system **734** also heats any fluid source containers **30** that may have been placed in the various supports/hangers **724**, **726** even if they are not installed and primed. When the compartment door **712** is in the closed position, the temperature of the air inside of the fluid

handling compartment **712** may be displayed on the user interface display **806** and is continuously monitored by the control system **800**. If desired, the fluid delivery system **2** may now be used to perform patient injections using contrast and/or saline, or additional fluid source containers **30** may be installed.

[00260] If it is desired to load additional fluid source containers **30**, these containers **30** may be installed whenever the fluid delivery system **2** is not performing a fluid injection. For example, additional fluid source containers **30** may be installed prior to performing any fluid injection, or may be installed after some fluid injections have been performed but before the existing fluid source containers **30** are empty. If an additional saline fluid source container **30** is installed in the "right saline source" position or "**S2**" position in the right fluid handling compartment **712**, the foregoing procedure followed to install the "left saline source" or "**S1**" position is essentially repeated with the right saline fluid source container **30**, and both "sides" of the pump **10** are still used during this second saline priming process since the "right saline source" or "**S2**" must be used to prime both inlet selector valves **300** and the saline channel **132** of the saline manifold **130** for right saline fluid source container **30**. If an additional contrast fluid source container **30** is installed, the foregoing process for installing the contrast fluid source container **30** in the first or default position "**L1**" in the left side fluid handling compartment **712** on the mobile support **700** is followed for installing a second contrast fluid source container **30** in the first or default position "**R1**" in the right side fluid handling compartment **712** on the mobile support **700**.

[00261] In the foregoing example of the fluid delivery system **2** comprising the pump **10**, drive and actuating system **400**, mobile support **700**, and control system **800**, there may be several limitations on where contrast fluid source containers **30** may be installed. The first contrast fluid source container **30** is installed in the first or default position "**L1**" of the left fluid handling compartment **712**. If a second contrast fluid source container **30** is to be installed and contains a different type and/or concentration of contrast than the first contrast fluid source container **30**, this second contrast fluid source container **30** is installed in the opposite side "**R1**" position of the right fluid handling compartment **712**. In many operation scenarios, all contrast sources in a given fluid handling compartment **712** are of the same type and concentration (but bottle size may vary). Thus, if the second contrast fluid source container **30** is of the same type and concentration as the first, it is typically installed in the second position "**L2**" of the left fluid handling compartment **712**. It is possible, and may be desirable, to install the same type and concentration of contrast in both fluid handling compartments **712** and this has the advantage of providing a greater volume of available

contrast. Accordingly, for each fluid handling compartment **712**, it is not permissible, according to the foregoing exemplary implementation of the fluid delivery system **2** comprising saline and contrast fluids, to install contrast in the "**L2**" or "**R2**" position unless the same type and concentration of contrast has previously been installed in the "**L1**" or "**R2**" positions. As noted previously, if desired, the same type of fluid may be present in all four (4) installed fluid source containers **30** in locations **L1**, **L2** and **R1**, **R2**.

[00262] Once both compartment doors **714** are closed to enclose the fluid handling compartments **712** within the support housing **702** and the convective heating system **734** is enabled, the control system **800** may engage the heating system **734** to heat any installed fluid source containers **30**. Typically, the heating system **734** heats the air inside of the fluid handling compartment **712** to 40° C and the air inside of the fluid handling compartment **712** is circulated continuously around all of the installed or stored fluid source containers **30** to warm the fluids. When the compartment doors **714** are in the closed position, the temperature of the air inside of the respective fluid handling compartments **712** may be displayed on the user interface display **806**, as noted previously.

[00263] Typically, the user will specify a patient protocol that is used to perform a fluid injection. This protocol may be specified before, during, or after the process of installing a pump **10** and the fluid source containers **30**. The patient protocol programming may occur concurrently with the installation of the pump **10** or fluid priming processes if the patient protocol is programmed using a remote display screen **904** as shown in **FIG. 46B**, which may be located in, for example, a control room. The local user interface display **806** is desirably available for installation of the pump **10** and the foregoing fluid priming processes. There may be several different options available for patient protocol entry including, but not limited to: (1) manually programming the patient protocol, specifying the relevant parameters for each phase (fluid type, flow rate, volume, etc.); (2) recalling a previously stored patient protocol from the memory of the control system **800** (or the system controller **822**) and the recalled protocol may be used as is or modified by the user before use; and (3) using installed software to have the control system **800** generate a recommended protocol based on the patient's height, weight, type of scan, type of contrast being used, etc. Such system installed software may be adopted from United States Patent No. 5,687,208, incorporated herein by reference, or adopted from one or more of United States Patent Application Publication Nos.: 2007/0282263; 2008/0097197; 2010/0030073; 2010/0113887; and 2010/0204572, also each incorporated herein by reference. If all of the parameters of the entered patient protocol are

acceptable, the control system **800** accepts the patient protocol and allows the user to return to the "Home Screen".

[00264] Next, the user may elect to install and prime a patient supply set **40**. The user first cleans the swabable valve **274** located in the patient outlet port **270** on the outlet selector valve cylinder **264** on the manifold plate **230**. The user typically scans a barcode and like indicia on the packaging containing the patient supply set **40** using the packaging reader **808** on the mobile support **700**. As an alternative, the user may use the user interface display **806** to indicate that a patient supply set **40** is being installed and then manually enter the indicia information. The control system **800** next automatically displays a "Patient Supply Set" installation screen on the user interface display **806**. The system controller **822** decodes the indicia information and indentifies the type/configuration, serial number, manufacturing lot number, etc. of the patient supply set **40**. The system controller **822** may check the serial number against an internal database. If the serial number is already in the internal database of "used" patient supply sets **40**, the system controller **822** generates an error message on the user interface display **806** to indicate that the patient supply set **40** cannot be used. Otherwise, the patient supply set **40** installation process continues.

[00265] The user opens the packaging and removes the patient supply set **40**. An indicator LED or other similar lighted device (not shown) may be provided on the patient outlet air detector **810**, and may be flashed to remind the user to install the tubing of the patient supply set **40** in the air detector **810**. The user attaches the patient supply set **40** to the swabable valve **274**. The connector ends **42** of the patient supply set **40** may be color-coded different colors, with one of the colors matching the color of the swabable valve **274** to guide the user in proper connections for the patient supply set **40**. If it is not already accomplished, the user installs the tubing of the patient supply set **40** in the air detector **810**. The control system **800** desirably detects the presence of the patient supply set **40** in the patient outlet air detector **810** and confirms that the tubing does not contain fluid. If the tubing does contain fluid, the control system **800** may be programmed to assume that the user has accidentally re-installed a used patient supply set **40**, issues a warning, and requires removal of the patient supply set **40** before proceeding further.

[00266] Next, the control system **800** displays the priming controls on the user interface display **806** for priming the patient supply set **40**. The user holds the free end of the patient supply set **40** over a suitable collection container, and presses the "Prime" button on the user interface display **806**. The control system rotates the outlet selector valve from "OFF" to "Patient" to align the flow passage **290** in the valve stem **286** of the outlet selector valve body

282 of the outlet selector valve **280** with the patient outlet port **270** on the outlet selector valve cylinder **264** on the manifold plate **230**. The control system **800** also rotates the right inlet selector valve **300** from "OFF" to permit fluid communication between the saline port **332**, **334** active for saline supply, namely the right saline source "**S2**" in the foregoing example. One of the two (2) plungers **200** on the right side **16** of the pump **10** is retracted, drawing saline into the pump cylinder **104**, and the plunger **200** is pushed forward to eject the saline through the outlet manifold channel **244** and into the patient supply set **40**. As the saline is ejected, the pressure sensor output signal from the pressure measurement mechanism **552** is monitored. If the pressure exceeds a predetermined limit, indicating a blockage, the priming process is halted. As the saline is ejected, the control system **800** monitors the output air detector signal from the patient outlet air detector **810**. The final ejected air and liquid volume (*e.g.*, "X ml") is monitored and must contain less than a predetermined volume of air (*e.g.*, "Y ml"). The exact prime volumes (*e.g.*, X ml, Y ml) depend on the specific configuration of patient supply set **40** (*e.g.*, diameter, length, etc.). The user may be prompted to visually confirm that the entire patient supply set **40** has been primed and confirm the priming by pressing a button on the user interface display **806**. The user may optionally press a "Small Prime" button on the user interface display **806** to deliver a small amount of additional priming fluid. This option may only appear on the user interface display **806** after the foregoing standard or "full" priming process has been completed. The control system **800** rotates the outlet selector valve **280** from "Patient" back to "OFF", and rotates the right inlet selector valve **300** back to "OFF". The free "patient" end of the patient supply set **40** is secured until the patient is ready for a fluid injection.

[00267] Once the patient supply set **40** is primed, the fluid delivery system **2** may be used in a fluid injection procedure. The user attaches the free or "patient" end of the primed patient supply set **40** to a catheter inserted into the patient. Once all of the patient protocol criteria to perform a patient injection have been met, as described previously, the control system **800** enables an "Arm" button on the "Home Screen", which was previously "grayed-out" and inoperable. Once the "Arm" button is pressed, the control system **800** may perform several final checks, including, but not limited to: (1) confirming that the entered patient protocol is valid; (2) confirming that a sufficient volume of each fluid type has been loaded to execute the patient protocol; in making this determination, the control system **800** may also consider the amount of saline that will be required to flush the pump **10** after the fluid injection; (3) confirming that there is sufficient capacity in the waste collection container **48** to flush the pump **10** after the fluid injection; (4) performing a series of safety checks to ensure that all

sensors and like electronic elements of the fluid delivery system **2** are operating properly; and (5) locking out certain capabilities, such as preventing the addition of additional fluid sources, and preventing the patient protocol from being changed, edited, etc.

[00268] If all of the final checks are successfully performed, the control system **800** indicates that it is in an armed state and enables a "Start" button, which the user presses to execute the programmed patient protocol. The user interface display **806** is updated to indicate that the fluid delivery system **2** is injecting fluid. The outlet selector valve **280** is moved from the "OFF" position to the "Patient" position, and one or both of the inlet selector valves **300** are moved from the "OFF" position to enable fluid communication to the appropriate fluid source container(s) **30**. Which inlet selector valves **300** are moved depends upon the specific patient protocol and whether one or two types of fluid are required.

[00269] If it is assumed that two fluids, contrast and saline as in the foregoing example, are to be injected, one plunger **200** on each half of the pump **10** is retracted to fill with fluid. The distance that each plunger **200** is retracted varies with the specific patient protocol. The filling time is minimal and may be on the order of about 2.50 seconds, which includes the time required for the outlet and inlet selector valves **280**, **300** to open. One or both of the retracted plungers **200** now moves forward to eject fluid, which is dependent on the specific parameters of the patient protocol. While the initial plungers **200** are ejecting fluid, the "second" or "tandem" plungers **200** in each half of the pump **10** begin to retract and fill their pump cylinders **104** with fluid. This filling process is completed before the moving or ejecting plungers **200** reach the end of their pumping strokes. The two (2) plungers **200** in each half of the pump **10** continue to alternate back and forth in tandem as the fluid injection progresses.

[00270] The overall speed of the plungers **200** in each half of the pump **10** may be independently adjusted upward and downward throughout the fluid injection, as required, to meet the desired flow rate for each patient protocol phase. For many phases, the plungers **200** on one side of the pump **10** may be halted if that side of the pump **10** is not required to deliver fluid during a protocol phase. Throughout the fluid injection procedure, the pressure sensor output signal from the pressure measurement mechanism **552** is monitored by the control system **800**. If the outlet pressure in the pressure sensing port **296** begins to near a predefined set point, 300 psi as an example, the velocity of all of the plungers **200** is reduced until the pressure is remains below the defined limit. The velocity of the plungers **200** is dynamically controlled by the control system **800** so that the predefined pressure set point is

not exceeded. If the control system **800** is unable to maintain the sensed pressure below a predetermined safe limit, the fluid injection is aborted.

[00271] Additionally, throughout the fluid injection, the patient outlet air detector **810** is monitored, and this information is combined with information about the prevailing flow rate and fluid pressure to calculate the volume of air that has been detected. When one or more air bubbles with a total predetermined volume have been detected, the control system **800** may be programmed to abort the fluid injection. In other words, once a predetermined total "allowable" volume of air has been detected as having passed through the patient outlet air detector **810**, the control system **800** is operable to abort the fluid injection. Further, throughout the fluid injection, the control system **800** monitors the "inlet" air detectors **812-816**. Any air output signals of inactive fluid source containers **30** (those not currently being used to fill the pump **10**) are ignored, while the air output signals from the "inlet" air detectors **812-816** associated with the active fluid source containers **30** are combined with information on the prevailing filling flow rate to calculate the total volume of air that has been detected (if any). When one or more air bubbles with a total predetermined "allowable" volume have been detected in a given fluid supply tube **34**, the control system **800** typically performs one of two actions. First, if a second fluid source container **30** of the same fluid type has been installed and primed, the control system **800** can automatically rotate the appropriate inlet selector valve **300** to access this secondary source. Second, if a second fluid source container **30** of the same fluid type is not available, the control system **800** aborts the fluid injection.

[00272] After execution of the programmed patient protocol is completed, the control system **800** moves the inlet selector valves **300** to their "OFF" positions. The control system **800** continues to monitor the pressure in the pressure sensing port **296** and, once the pressure has dropped to nearly zero, the outlet selector valve **280** is moved from "Patient" to "OFF". If the pressure does not dissipate within a predetermined period of time, the outlet selector valve **280** is moved from "Patient" to "Waste" to permit the pressure to dissipate, and then the outlet selector valve **280** is moved to the "OFF" position. The control system **800** indicates to the user via, for example, the user interface display **806** that the fluid injection is complete and summary information on the completed fluid injection may be presented on the user interface display **806**. The user may indicate if another fluid injection is desired for the same patient. In this case, the user programs or selects the desired patient protocol and "arms" the fluid delivery system **2** for the next fluid injection. The control system **800** can

track the total volume of each fluid delivered to a patient. If the user specifies a new patient, then these totals are cleared and the pump **10** is flushed.

[00273] The control system **800** next typically automatically performs a flushing process to remove residual contrast from the inlet selector valve **300** and the inlet manifold channel **236** that delivered the contrast in the fluid injection procedure. For this flushing procedure, the outlet selector valve **280** is moved to the "waste" position. The inlet selector valve **300** that was used to deliver contrast during the fluid injection is moved to the saline port **332**, **334** for the active saline fluid source container **30**. Saline is pulled into one of the pump cylinders **104** on the side **16**, **18** of the pump **10** that previously delivered contrast, clearing the inlet selector valve **300** of residual contrast, and drawing the contrast into the pump cylinder **104**. The saline and contrast mixture is then ejected from the pump cylinder **104** into the waste collection container **48**. There are several possible flush options available including, but not limited to, flushing after each fluid injection, flushing after each patient is completed, and flushing whenever the there is a switch from using one type of fluid such as contrast to another (*e.g.*, when switching from contrast A to contrast B or vice versa).

[00274] The control system **800** next typically automatically performs a flushing process to remove residual contrast from the pump cylinders **104**. The plungers **200** are retracted simultaneously for both of the pump cylinders **104** on the side **16**, **18** of the pump **10** that previously delivered contrast, pulling saline into the pump cylinders **104**. Both plungers **200** are then advanced substantially simultaneously to eject the saline and contrast mixture from the pump cylinders **104** into the waste collection container **48**. This flushing process may be repeated as necessary to remove residual contrast from the pump cylinders **104**.

[00275] Further, the control system **800** performs a flushing process to remove residual contrast from the outlet manifold channel **244**. In this procedure, all four (4) plungers **200** are retracted substantially simultaneously, pulling saline into the pump cylinders **104**. Next, all four (4) plungers **200** are advanced substantially simultaneously to eject fluid from the pump cylinders **104** into the waste collection container **48**. The user may now disconnect the patient supply set **40** from the patient catheter, disconnect the patient supply set **40** from the swabable valve **274** in the patient outlet port **270**, and discard the patient supply set **40** as medical waste.

[00276] Moreover, the user may also want to remove the pump **10** from the drive and actuating system 400. As the final fluid injection ends, all four (4) plungers **200** are fully inserted into their corresponding pump cylinder **104**. The control system **800** may indicate to the user that the pump **10** has expired due to the number of patients processed, use time

expiration, or a total maximum number of fluid source containers **30** have been installed, or the user may have simply decided that no further procedures are going to be done. The user indicates on the user interface display **806** that the pump **10** is to be removed. The control system **800** ensures that the pump cylinders **104** are empty of fluid and the inlet selector valves **300** and the outlet selector valves **280** are in their "off" positions. The control system **800** retracts all four (4) piston linear actuators **462**, either together or one at a time, to their rear-most positions of the normal working stroke. At this point, the plungers **200** remain attached to the drive pistons **50** associated with the piston linear actuators **462** and are pulled back as well. The control system **800** retracts each piston linear actuator **462**, for example, one at a time, and the plungers **200** attached to the drive pistons **50** until the rear or proximal end disc **208** on each plunger **200** contacts a stripper pin (not shown) or like structure that is provided in the drive and actuating system **400**. The striper pin prevents the plunger **200** from moving backwards any further. As the piston linear actuator **462** continues to move rearward, the plunger **200** is stripped-off the drive piston **50**. The plunger **200** remains in place in the pump cylinder **104** as the piston linear actuator **462** continues to retract. The foregoing process is repeated for the remaining plungers **200**.

[00277] In a fluid injection procedure, a fluid source container **30** may often be fully consumed. Thus, it is desirable to replace the spent fluid source container **30** with a new container **30**. In certain of the configurations of the pump **10** shown in **FIGS. 40-43**, it is not advisable or allowable to replace a fluid source container **30**. For example, if a fluid spike **36** is permanently attached to the fluid supply tube **34**, the spike **36** cannot safely be used more than once. If the spike **36** is removable, the used spike **36** may be removed, along with the used fluid source container **30**, and discarded. The swabable valve **70** may then be cleaned and a new spike **36** installed. A new fluid source container **30** of the same fluid type and concentration may then be installed in the same location. Based on the type or configuration of the pump **10**, from the pump indicator plate **170** and/or identifying indicia **172**, the control system **800** detects which spikes **36** are permanently attached and which are replaceable. The control system **800** may be configured to not permit the user to install a replacement source in a location with a permanently attached spike **36**. Additionally, the control system **800** may not permit the user to install a different type of therapeutic or diagnostic (*e.g.*, pharmaceutical) fluid, for example, a different type or concentration of contrast. The replacement fluid source container **30** is to be of the same type and concentration as that which was previously installed in the location.

[00278] As mentioned in the foregoing, fluid source containers **30** may be replaced whenever the fluid delivery system **2** is not performing a fluid injection. Fluid source containers **30** may also be replaced or added whenever the control system **800** is in a programmed hold phase during a fluid injection. A programmed hold phase temporarily suspends the fluid injection process until the user presses the "Start" button to resume the fluid injection. If a saline fluid source container **30** is replaced, the foregoing saline priming sequence is essentially repeated with the new saline fluid source container **30**, and both fluid circuits on the two (2) sides **16**, **18** of the pump **10** are used during this saline priming process since the new saline fluid source container **30** is used to prime both inlet selector valves **300** and the saline channels **132**, **134** and any air that is introduced to the pump **10** is removed. If a replacement contrast fluid source container **30** is installed, the foregoing "contrast" priming sequence is essentially repeated for the appropriate location and appropriate side of the pump **10**. While the foregoing discussion was related to saline and contrast fluids as the applicable fluids for use in the pump **10**, this specific combination should not be considered limiting. While saline may likely be needed for any fluid injection procedure, the foregoing example using contrast media is intended to be exemplary and any therapeutic or diagnostic (*e.g.*, pharmaceutical) fluid may take the place of contrast media typically used in medical imaging procedures.

[00279] The control system **800** also allows the user to set an adjustable pressure limit. The pressure limit is typically used to ensure that the fluid pressure delivered to the attached catheter remains below the catheter manufacturer's specified maximum pressure rating. The pressure presented to the catheter is largely dependent on the flow rate of the fluid delivered by the fluid delivery system **2**. The control system **800** uses the pressure sensor output signal from the pressure measurement mechanism **552** to dynamically reduce the flow rate of the injected fluid as required to ensure the specified pressure limit is not exceeded. The pressure measurement mechanism **552** may also be used to compensate for flow-rate fluctuations that can occur with the multi-stroke plunger - pump cylinder configuration of the pump **10**.

[00280] As represented in the accompanying figures, the pump **10** uses two (2) tandem piston operated plungers **200** to deliver a substantially constant flow of fluid from one or more connected fluid source containers **30** to a patient. As shown in **FIGS. 61-62**, under typical operating conditions, in a tandem plunger **200** – pump cylinder **104** arrangement, as a first plunger **200** begins to decelerate at the end of its pumping or ejection stroke, the second plunger **200** accelerates to reach its target velocity. This is shown in **FIG. 61** with the velocity profile of the first plunger **200** – pump cylinder **104** identified by reference character

"**P1**" and the velocity profile of the staggered or second plunger **200** – pump cylinder **104** identified by reference character "**P2**". The resulting combined output flow rate from the pump **10** is shown in **FIG. 62** and is substantially continuous. The output flow rate is proportional to the sum of the velocities of the two (2) plungers **200** or, more precisely, the sum of the absolute values of the velocities of the two (2) plungers **200**. Therefore, as one plunger **200** – pump cylinder **104** ("**P1**") ejects fluid to the patient, the adjacent plunger **200** - pump cylinder **104** ("**P2**") fills with fluid from the same fluid source container **30**. During a brief transition period, the nearly-empty ejecting plunger **200** – pump cylinder **104** decelerates and the newly-filled plunger **200** – pump cylinder **104** accelerates and begins ejecting fluid. By controlling the acceleration and deceleration of the plungers **200**, a nearly constant net outlet flow-rate is achieved, as shown in **FIG. 62**. However, due, in part, to pressure-dependent compliances in the fluid delivery system **2**, the accelerating plunger **200** does not deliver fluid immediately and a brief fluctuation in flow rate can occur during the transition period. Since the ejection delay of the accelerating plunger **200** is dependent on the instantaneous outlet pressure of the pump **10** as measured in the pressure sensing port **296** of the outlet selector valve cylinder **264** on the manifold plate **230**, the control system **800** can use the pressure sensor output signal from the pressure measurement mechanism **552** to monitor the pump outlet pressure in the pressure sensing port **296**, which is in fluid communication via the connecting passage **268** with the outlet manifold channel **244**, and dynamically advance the timing of the accelerating plunger **200** as required to minimize the flow-rate fluctuation. The control system **800** may be programmed to predict the amount of fluctuation that will most likely occur, based on prevailing conditions, and take corrective action before the fluctuation occurs.

[00281] The pressure measurement mechanism **552** can also be used to detect incomplete filling of the pump cylinders **104** of the pump **10**. If the pump cylinders **104** are not completely filled, the patient may not receive the prescribed volume of fluid in the patient protocol. Some conditions that can cause insufficient filling of the pump cylinders **104** include clogged air vents, occluded spikes, and pinched fluid supply tubes **34**. If a pump cylinder **104** is not completely full when its plunger **200** begins ejecting fluid, no fluid will be delivered from the pump cylinder **104** until the "under volume" is displaced by the plunger **200**. With no fluid being delivered during this period, the outlet pressure of the pump **10** drops. By monitoring the pump outlet pressure in the pressure sensing port **296** via the pressure measurement mechanism **552**, the control system **800** can detect the characteristic pressure drop associated with an under-filled pump cylinder **104** and abort the fluid injection

procedure, or initiate compensating measures. Various techniques for identifying and accounting for an under-volume situation or condition are described in further detail herein.

[00282] As each pump **10** is disposable and may be used for multi-patient use over an extended period of time, such as 24 hours, it is desirable to minimize the amount of residual contrast media that remains in the pump **10** after each patient procedure if contrast media is the therapeutic or diagnostic (*e.g.*, pharmaceutical) fluid(s) that is to be utilized in the fluid delivery system **2**. Residual contrast that is left in the pump **10** has several disadvantages. If contrast is left in the pump **10** for an extended period of time, it is possible for the contrast to crystallize and form iodine salt crystals inside of the fluid conducting passages. This crystallization can result because contrast is a saturated salt solution and even a small amount of water loss may cause crystallization to begin. Additionally, because the pump **10** may be used with more than one type of contrast, it may be desirable to prevent the two types of contrast from mixing. If a small amount of residual contrast of a first type is left in the fluid conducting passages of the pump **10**, it may react with contrast of a second type in an undesirable manner. Further, as the pump **10** may be used with more than one type of contrast, it is desirable to minimize the amount of residual contrast of a first type if the subsequent patient injection will use contrast of a different type, as this will minimize the amount of contrast of the first type that the second or subsequent patient receives.

[00283] To achieve the foregoing minimization of residual contrast, the control system **800** may perform a number of steps to minimize the amount of residual contrast that remains in the pump **10** after a fluid injection. For example, the control system **800** may automatically add a final saline flush phase at the end of each patient protocol. This final saline flush phase helps to clear the outlet manifold channel **244** and outlet selector valve **280** of residual contrast. If the user has already programmed a saline flush at the end of the programmed patient protocol, the control system **800** does not need to add an "automatic" saline flush phase. Additionally, at the end of each patient protocol, the control system **800** may end the fluid injection process with all of the plungers **200** in their forward-most positions within the respective pump cylinders **104** (*e.g.*, with empty pump cylinders **104**). This forward-most positioning of the plungers **200** in the pump cylinders **104** minimizes the fluid volume that remains in the pump **10** at the end of a fluid injection.

[00284] After a patient protocol is completed, the control system **800** may also automatically load and execute a pre-defined "Pump Flushing Protocol". This flushing protocol may be designed and optimized to remove as much residual contrast as practical without creating a burdensome volume of waste fluid for the waste collection container **48**. In

this flushing protocol, the control system **800** first clears contrast from the inlet selector valve **300** and inlet manifold channel **236** from the fluid circuit on the side **16**, **18** of the pump **10** that was recently used to deliver contrast. To achieve the desired flushing, the "contrast" inlet selector valve **300** is moved to achieve fluid connection with the current or active saline fluid source container **30**, **S1** or **S2**, and the outlet selector valve **280** is moved to the "Waste" position. Both plungers **200** from the "contrast" fluid circuit on the "contrast" side **16**, **18** of the pump **10** are retracted substantially simultaneously to pull saline from the current or active saline fluid source container **30** into the pump **10**. Both plungers **200** are then advanced substantially simultaneously to eject the contrast/saline mixture into the waste collection container **48**. As this mixture is ejected, the pressure sensor output signal from the pressure measurement mechanism **552** is monitored. If the pressure exceeds a predetermined limit, indicating a blockage in the waste collection tube set **46**, the flushing process is halted.

[00285] Next, the control system **800** clears residual contrast from the outlet manifold channel **244**. The inlet selector valves **300** are both moved to achieve fluid connection with the current or active saline fluid source container **30**, **S1** or **S2**. All four (4) plungers **200** are retracted substantially simultaneously to pull fluid from the current or active saline fluid source container **30** into the pump **10**. All four (4) plungers **200** are then advanced to eject the saline in the pump cylinders **104** into the waste collection container **48**, clearing the outlet manifold channel **244** of contrast in the process. As this mixture is ejected, the pressure sensor output signal from the pressure measurement mechanism **552** is monitored. If the pressure exceeds a predetermined limit, indicating a blockage in the waste collection tube set **46**, the flushing process is halted. All four (4) plungers **200** are used for this step, not just the two (2) plungers **200** on the "contrast" fluid circuit on the "contrast" side **16**, **18** of the pump **10** because, if only the two (2) "contrast" plungers **200** are used, residual contrast may be pushed from the contrast-containing pump cylinders **104** into the inactive half of the outlet manifold channel **244**. Moving all four (4) plungers **200** substantially simultaneously forces saline from all four (4) pump cylinders at once, driving any residual contrast to the waste collection container **48** which flushes everything substantially simultaneously. The control system **800** then returns both inlet selector valves **300** and the outlet selector valve **280** to their "OFF" positions.

[00286] In addition to the foregoing control features provided by the control system **800**, there are several physical features of the fluid delivery system **2** which assist in minimizing residual contrast and flushing. For example, the pump cylinders **104** permit virtually all of the fluid in the pump cylinders **104** to be ejected. The front or distal end disc **206** on each plunger

200 closely matches the internal shape of the distal end **110** of the pump cylinders **104**. Additionally, the inlet and outlet check valves **194**, **196** are recessed into the front side **140** of the front end plate **102** on the pump body **100**, permitting the plungers **200** to be fully inserted into the respective pump cylinders **104**. As noted previously, the pump **10** may draw saline from either side **16**, **18** of the pump **10** for flushing operations, and the saline manifold **130** with two (2) saline channels **132**, **134** allows both pairs of pump cylinders **104** to access either saline fluid source container **30**, regardless of its physical location. Moreover, the saline supply ports **332**, **334** are located at the rear of each inlet selector valve **300** to permit the entire valve stem **306** to be flushed of contrast. Further, the drive and actuating system **400** includes a drive motor **600**, such as a stepper motor, for automated control of the outlet selector valve **280**, permitting the flushing process to occur without user intervention. Furthermore, the fluid delivery system **2** includes a waste collection container **48** to allow the flushing process to occur without user intervention. Without the waste collection container **48**, the patient supply set **40** would have to be manually directed to a suitable waste receptacle for the flushing fluid. The volume of the patient supply set **40** may also be minimized to reduce the amount of saline flush that must be administered to the patient at the end of a fluid injection.

[00287] While it is known in syringe-based power injector systems to store patient protocols in system memory for later use, these stored protocols typically indicate whether a given protocol phase required contrast, saline, or a mixture of contrast and saline. When these "legacy" syringe-based power injector systems stored a patient protocol, they typically did not store any information to indicate what specific type of contrast was used in the stored patient protocol. The user often manually recorded which type of contrast was used for each stored patient protocol. The control system **800** automatically stores different fluid type information with each saved patient protocol. When a stored patient protocol is retrieved from system memory, the type, for example contrast brand and concentration, which was stored with the patient protocol is displayed on the user interface display **806**. If, for example, the contrast type that was stored with the patient protocol is currently installed on the fluid delivery system **2**, the control system **800** adjusts the patient protocol, if necessary, to correspond to the current configuration of fluid source containers **30**, even if the current configuration differs from the configuration as originally presented in the stored patient protocol. For example, if a patient protocol was written which specified the use of "Contrast A", which was, at the time the protocol was written, in the fluid circuit on the left side **16** of the pump **10** and, at a later date, the same patient protocol is recalled but "Contrast A" has

been installed in the fluid circuit on the right side **18** of the pump **10** and designated as "Contrast B", the control system **800** can automatically adjust the patient protocol to replace all of the "Contrast A" references with "Contrast B" references.

[00288] In another instance, if, for example, the fluid type that was stored with the patient protocol is not currently installed on the fluid delivery system **2**, the control system **800** can recommend to the user the type of fluid, typically the type of contrast, that should be installed and recommend an installation location, if one is available. The user may be given the option to substitute one of the currently installed fluid types for the fluid type that was originally specified for the patient protocol. Moreover, the control system **800** can be configured to display by default only those stored patient protocols that use the currently loaded fluid types. Further, a "show all" option may be provided to view the remaining patient protocols on the user interface display **806** that use other types of fluids.

[00289] As noted previously, when a fluid source container **30** is installed, the control system **800** typically notes the installation time and can track the remaining "open life" of the installed fluid source container **30** based on the manufacturer's instructions or other guidelines for use, as described previously. Once a fluid source container **30** is installed and primed, the control system **800** can (but is not limited to): (1) record the installation time; (2) use manufacturer's information or other guidelines for the fluid to look up, for example in an internal database, the recommended or permitted open life for the fluid; (3) track the remaining open life for the fluid and display the remaining open life for each fluid source container **30** on the user interface display **806**; (4) provide an alert to the user on the user interface display **806** when there is less than a predetermined amount of time remaining in the open life of the fluid; (5) notify the user on the user interface display **806** once the remaining open life has expired and optionally provide the user the option of continuing to use the fluid source container **30** or disabling the fluid source container **30**; and (6) automatically switch to another fluid source container **30** if another fluid source container **30** of the same fluid type and concentration has already been installed.

[00290] As also described previously, when a new fluid source container **30** is installed on the fluid delivery system **2**, the control system **800** recommends, typically via the user interface display **806**, a specific location where the fluid source container **30** should be installed. This recommendation is determined by the location and types of existing fluid source containers **30** that have already been installed, the type of new fluid that is being installed, and prior programming of how the fluid delivery system **2** is typically used. For example, when installing a saline fluid source container **30**, if no saline sources have yet been

installed, the control system **800** indicates that the first saline source container **30** is to be installed in the left side fluid handling compartment **712** in the rearmost "**S1**" location provided by the saline support or hanger **724**, as the physical geometry of the pump **10** indicates that saline be installed in this position to support initial priming and flushing procedures. If two (2) saline fluid source containers **30** are currently installed, the control system **800** indicates that there are currently no available open locations to install additional saline. Depending on the configuration of the pump **10** as determined from the associated fluid supply set **32**, the user may elect to remove and replace one of the existing saline fluid source containers **30**. Alternatively, if one (1) of the two (2) saline fluid source containers **30** is empty, the control system **800** recommends the empty location for installation of the new saline source. The recommended location is indicated by flashing or blinking the upper and lower indicator lights **728**, **730** associated with the saline support or hanger **724**, and this recommended location may also be graphically indicated on the user interface display **806**.

[00291] When installing contrast, if no contrast fluid source containers **30** are installed, the control system **800** indicates, typically via the user interface display **806**, that the contrast fluid source container **30** is to be installed in the first or default "**L1**" position in the left side fluid handling compartment **712**. The upper and lower indicator lights **728**, **730** associated with the recommended "**L1**" position, flash or blink to indicate the recommended installation location. If contrast of the same type and concentration has already been installed, the control system **800** recommends, typically via the user interface display **806**, that the new fluid source container **30** be installed in the same fluid handling compartment **712** as the previous container **30** of the same type. Alternatively, if there is an empty fluid source container **30** in the selected fluid handling compartment **712**, the control system **800** recommends, typically via the user interface display **806**, this location for installation of the new fluid source container **30**. If two (2) contrast fluid source containers **30** are currently installed in the selected fluid handling compartment **712**, the control system **800** indicates, typically via the user interface display **806**, that there are currently no available open locations to install additional fluid source containers **30**. Depending on the configuration of the pump **10** as determined from the associated fluid supply set **32**, the user may elect to remove and replace one of the existing contrast fluid source containers **30** or install the contrast in the other fluid handling compartment **712**. If the new fluid source container **30** contains a different type or concentration than the original fluid source container **30**, then several options are available. For example, if contrast fluid source containers **30** have not yet been installed in one of the fluid handling compartments **712**, the control system **800** recommends, typically via the user

interface display **806**, installing the new fluid source container in the "**L1**" or "**R1**" positions in the "unused" fluid handling compartment **712**. If contrast fluid source containers **30** have already been installed in both fluid handling compartments **712**, the control system **800** indicates that it is not possible to install the new contrast fluid source container **30**. Thus, if four (4) fluid source containers **30** are already installed, no new containers **30** may be installed, and if one (1) of the four (4) positions is empty and the new contrast type scanned by the user matches the contrast type already installed on that half of the fluid delivery system **2**, the user is permitted to install the new fluid source container **30**.

[00292] Because the fluid delivery system **2** may comprise a pump **10** having several different configurations based on the associated fluid supply set **32**, the control system **800** can identify the type of pump **10** that is being used and appropriately limit the fluid delivery system **2** to avoid potential safety issues, particularly for multi-patient use situations. Various configurations or versions of the pump **10** are shown in **FIGS. 40-43**, which comprise different configurations or versions of the associated fluid supply set **32**. There are several types of limits that may be imposed based on the type or configuration of the pump **10** that is installed. In one limitation, the total volume of fluid may be limited based on the type or configuration of the pump **10** and, thus limit the total volume delivered to each patient. This total volume limitation helps ensure that components of the disposable pump **10** are not subjected to excess levels of wear. For example, the distal end lip seal **218** and/or rear or proximal bead seal **220** of the plungers **200** of the pump **10** are subjected to wear and fatigue, respectively, that is roughly proportional to the volume of fluid delivered, and limiting the total volume delivered can help to ensure that excess wear/fatigue levels are not reached that cause failure of the foregoing seals **218**, **220**. It may be desirable to manufacture the pump **10** with different types of materials, perhaps more robust materials, so that the pump **10** may support a greater number of patient procedures or a greater volume of fluid.

[00293] Additionally, the control system **800** may limit the number of patients that may be connected to a given disposable pump **10**. For example, the control system **800** may limit the total number of patients that may be used with each configuration of the pump **10** (see **FIGS. 40-43** described previously). This limitation may be set to ensure that components of the disposable pump **10** are not subjected to excess levels of wear. For example, components of the pump **10**, such as the outlet selector valve **280**, inlet selector valves **300**, and the swabable valves **70** are subjected to wear that is roughly proportional to the number of fluid injection procedures that are conducted, and limiting the total number of patients for a given pump **10** can help to ensure that excess wear/fatigue levels are not reached. The risk of external

contamination also increases with the number of fluid connections that are made. Again, it may be desirable to manufacture the pump **10** with different types of materials, perhaps more robust materials, so that the pump **10** may support a greater number of patient procedures or a greater volume of fluid.

[00294] The control system **800** may also limit the total number of fluid connections made with the pump **10**. As discussed previously in connection with the configurations of the pump **10** shown in **FIGS. 40-43**, some of the associated fluid supply sets **32** have permanently attached spikes **36** that can only be safely used with a single fluid container. Once a fluid source container **30** is installed on a permanently attached spike **36**, no additional fluid source containers **30** may be installed on that spike **36**. Because the permanent spikes **36** are only designed for one use, re-using a spike **36** with a second fluid source container **30** could possibly introduce contamination into the fluid path. When a pump **10** is installed, the control system **800** identifies the configuration of the pump **10** via the pump indicator plate **170** and/or the identifying indicia **172**. If the installed pump **10** has permanently attached spikes **36**, the control system **800** may be programmed to permit the user to install one fluid source container **30** at each location with a permanently attached spike **36**, and if the user tries to install a second fluid source container **30** on a permanently attached spike **36**, the control system **800** may be programmed to not permit the second container **30** to be primed and used. As a comparison, configurations of the pump **10** that have swabable valves **70** may have the associated spikes **36** removed and replaced with new spikes **36**. Replaceable spikes **36** allow fluid source containers **30** to be removed and safely replaced with new fluid source containers **30** and replacement spikes **36** for sterility purposes. The control system **800** can also impose a practical limit on the number of replacement fluid source containers **30** that may be installed when a spike **36** is replaced with each new fluid source container **30** to limit the potential wear and potential contamination of the swabable valves **70**.

[00295] Further, the control system **800** may limit the total "open life" of the pump **10**. The "open life" or permitted use limit of the pump **10** may be pre-limited by the programming of the control system **800** to ensure sterility during use. While the configurations of the pump **10** (see **FIGS. 40-43**) are expected to have a certain minimum "open life", for example 24 hours, it is also possible and desirable to develop additional configurations that would have a longer open life. For example, it may be possible to modify the materials used in the pump **10**, such as by including silver ions, to help the internal fluid passages of the pump **10** to remain sufficiently sterile over a longer period of time.

[00296] Moreover, the control system **800** may limit use of the pump **10** based on the patient supply set **40** that is installed on the pump **10**. To prevent cross-contamination between patients, it is desirable for the control system **800** to require that the patient supply set **40** be replaced after each patient. For example, the control system **800** can monitor the status of the patient outlet air detector **810** to determine if the patient supply set **40** has been replaced after each patient. If the patient supply set **40** is properly replaced, the control system **800** can infer, based on the status of the patient outlet air detector **810**, that a new and unused patient supply set **40** has been installed. The patient outlet air detector **810**, as well as the inlet air detectors **812-816** each typically include a tubing latch to hold the tubing of the patient supply set **40** or the fluid supply tubes **34**. Electronic signals regarding the status of this latch (*e.g.*, closed or open) and whether fluid is detected in the tubing loaded therein can be used by the control system **800** to determine whether the status of the patient supply set **40** or the fluid supply tubes **34**. In the case of the patient supply set **40**, it is desirable to know that a new and unused patient supply set **40** has been installed and primed. For example, the control system **800** may be programmed to confirm that a sequence of events has occurred that indicates that the patient supply set **40** has been replaced. For example, this sequence may include, but is not limited to: (1) determining that the latch is closed and fluid is detected in the tubing; (2) determining when an injection has ended and prompting the user to replace the patient supply set **40**; (3) determining that the latch is open and air is detected in the tubing; (4) determining that the latch is closed and air is detected in the tubing; (5) determining that the sequence for priming the patient supply set **40** has been accomplished; and (6) determining that the latch is closed and fluid is present in the tubing. Failure to detect the foregoing states or steps from the patient outlet air detector **810** may indicate that the patient supply set **40** has not been replaced. For example, if a tubing latch on the patient outlet air detector **810** is opened and closed, but the new tubing is filled with fluid prior to priming, it may be inferred that the user has removed and re-installed the used patient supply set **40** in the patient outlet air detector **810**. Alternatively, a "tubing present sensor" may be used in place of a latch which allows the control system **800** to determine whether the air detector **810** has tubing installed. The inlet air detectors **812**, **814**, **816** may have latches or could utilize either molded detents or spring clips to hold tubing in place. In the present embodiment, the **812**, **814**, **816** have small spring-loaded pins (not shown) that allow the control system **800** to determine if tubing has been installed in a particular inlet air detector **812**, **814**, **816**.

[00297] In a variation of the use limitation for the patient supply set **40**, the total "open life" of the patient supply set **40** may be used to limit use of the pump **10**. As with the pump **10**, each patient supply set **40** has a manufacturer's recommended predetermined safe "open life". Beyond this "open life", it may no longer be possible to assure sufficient sterility for patient use. The control system **800** can determine when a particular patient supply set **40** has been installed and track its remaining safe "open life". Again, it may be desirable to provide the patient supply set **40** made from materials suitable for extending "open life", such as using silver ion impregnated polymeric material. Additionally, it may be possible to limit use of the pump **10** based on performance limits of the patient supply set **40**. While one specific and non-limiting embodiment of the patient supply set **40** is shown in **FIG. 44**, discussed previously, several different types or embodiments of the patient supply set **40** may be provided based on desired performance characteristics, which may be encoded in a bar code or like indicia on the packing of the patient supply set **40** and/or on the patient supply set **40** itself. Upon identifying the type or configuration of the patient supply set **40**, the control system **800** can adjust performance limits accordingly. For example, the patient supply set **40** may be provided in varying lengths. As such, because the tubing volume varies with length, the control system **800** may adjust the required priming volume and initial fluid delivery delay adjustment based on the tubing length. Alternatively, the patient supply set **40** may have varying constructions, and various types of the patient supply set **40** may have different pressure ratings and the like. If some of the configurations or types of the patient supply set **40** are stronger and less compliant than others, the control system **800** can permit these "reinforced" patient supply sets **40** to operate at higher delivery pressures. Further, a patient supply set **40** with a smaller diameter bore could be provided for low flow rate procedures to provide improved flexibility, reduce the amount of flush that must be delivered to the patient at the end of each fluid injection to clear the patient supply set **40**, and provide a faster response time at the beginning of each fluid injection, since the smaller tube volume means less time is required for the fluid to reach a patient.

[00298] In known syringe-based power injector systems, the user is often able to set a pressure limit for the system. During the patient procedure, the system controller monitors the pressure in the syringe and limits the delivered flow rate to ensure that the pressure in the syringe does not exceed the programmed pressure limit. A limitation of this approach is that the pressure limit generally must be set according to the pressure rating of the patient's catheter. For example, if the catheter has a maximum pressure rating of 300 psi, the user configures the system to limit the pressure in the syringe to 300 psi. While this strategy

prevents the catheter from being over pressurized, it also limits system performance since the actual pressure at the catheter is typically much lower than the catheter's pressure rating. The cause of this discrepancy is due to the frictional losses that occur in the tubing that connects the syringe to the catheter. At high flow rates with high viscosity fluids, the pressure drop in the tubing may be more than 100 psi. Because the system measures and regulates pressure at the syringe, this has the effect of reducing the available pressure at the catheter.

[00299] The present fluid delivery system **2** provides an improved approach. In operation, the control system **800** measures the pressure in the pressure sensing port **296** in the outlet selector valve cylinder **264** on the manifold plate **230** which supports the outlet selector valve body **282** of the outlet selector valve **280**. Using knowledge of the instantaneous flow rate and properties of the fluid that is being delivered, such as viscosity and density, the control system **800** can estimate the pressure drop that will occur in the patient supply set **40**. The estimate may either be performed with analytically derived equations based on fluid mechanics or by extrapolating from empirically derived laboratory data. The control system **800** estimates the pressure at the catheter hub by subtracting the estimated pressure drop from measured pressure. The estimated pressure at the catheter is used as an input to the control system **800**. If the current flow rate is at the targeted/programmed flow rate and the estimated catheter pressure is at or below a predefined pressure limit, the flow rate is the targeted/programmed flow rate. If the estimated catheter pressure is greater than the predefined pressure limit, the actual flow rate is decreased from the targeted flow rate using a control algorithm, such as a Proportional–Integral–Derivative ("PID") control algorithm which is programmed into the control system **800**, such as into the system controller **822**. If the estimated catheter pressure is less than the predefined limit and the current flow rate is below the target flow rate, the current flow rate is increased using a control algorithm, such as the PID control algorithm. The control algorithm dynamically adjusts to changes in the flow rate and the transition of fluid types and resulting change in viscosity and density within the patient supply set **40**. By correcting for frictional losses in the patient supply set **40**, the foregoing approach maximizes the flow rate delivered by the fluid delivery system **2**.

[00300] As described in the foregoing, the disposable pump **10** typically has a total "open life" in which the safety and sterility of the pump **10** can be reasonably assured. Accordingly, since the safety and sterility of the pump **10** can only be assured for a limited period of time after installation, the pump **10** may incorporate features to ensure that the pump **10** is not used beyond its safe life as recommended by the manufacturer or by other guidelines. For example, the control system **800** may be programmed to not permit a used pump **10** to be

reinstalled after its total "open life" has expired. The control system **800** can track and record the pump serial number of each pump **10** that is installed in the drive and actuating system **400** and prevent the user from reinstalling the same pump **10** at a later date. One method for preventing such inappropriate and potentially harmful reuse is to position the inlet selector valves **300** to guard against the possibility that a used pump **10** may be installed at a later time in the same fluid delivery system **2** or another such system **2**.

[00301] For example, when a pump **10** is assembled and manufactured, desirably in an automated assembly and manufacturing process, a random valve position number between **1** and **N** (inclusive) may be selected, with "**N**" representing the **N** possible combinations of the angular positions of the valve stem **306** of the inlet selector valves **300**. Each inlet selector valve **300** may be assembled in any one of $\sqrt{N}$ possible angular positions, yielding $\sqrt{N} \times \sqrt{N} = N$ possible positions for the combination of the left and right inlet selector valves **300**. The automated manufacturing process combines the randomly selected valve position number, the sequential pump serial number, the manufacturing batch/lot number and other data, such as the product expiration date, manufactured date, etc., and generates an encoded or encrypted data string. This data string is printed on the pump body **100**, desirably as both a human-readable string and as a machine-readable barcode or like machine-readable indicia, as the identifying indicia **172** and/or as part of the pump indicator plate **170**. A manufacturing station in the process reads the identifying indicia **172** and/or the pump indicator plate **170** on each assembled pump **10**, extracts the valve position code, and inserts the left and right valve stems **306** of the inlet selector valves **300** into the respective left and right inlet selector valve cylinders **114** on the pump body **100** in the specified angular orientations. The pump **10** may then be packaged, sterilized, and shipped to an end user.

[00302] When a user installs a pump **10** in the drive and actuating system **400**, the user opens the package and scans the identifying indicia **172** on the pump body **100** using the packaging reader **808** on the mobile support **700**. Alternatively, the user may manually enter the character string located on the identifying indicia **172** on the pump body **100** using the user interface display **806**. The system controller **822** receives the information contained in the identifying indicia **172** and extracts the pump serial number and valve position code, and other relevant information as described previously. If the pump serial number corresponds to the serial number of a pump that was previously used in this particular fluid delivery system **2**, the control system **800**, typically the system controller **822**, rejects the pump **10** and generates a message to the user. If the pump **10** has not been previously used in this fluid delivery system **2**, the system controller **822** rotates the left and right inlet selector valve

actuators **464** to correspond to the angular positions of the valve stem **306** of the inlet selector valve body **302** of the inlet selector valves **300** indicated by the valve position code. The user may then insert the pump **10** into the drive and actuating system **400** since the orientation of the inlet selector valves **300** will now match that of inlet selector valve actuators **464** and the pump **10** will fit into the pump cradle **412** in the drive and actuating system **400** and the pump drawer **402** may be properly closed and locked.

[00303] When a user wants to remove a "used" pump **10** from the pump drawer **402**, the user indicates, via the user interface display **806**, that he/she wishes to remove the pump **10**. The control system **800** actuates the left and right inlet selector valve actuators **464** to position the valve stem **306** of the inlet selector valves **300** to their "OFF" positions. This "OFF" position may be provided so that it does not correspond to any of the possible initial angular orientations of the valve stems **306** of the inlet selector valves **300** for a "new" pump **10**. The user then removes and properly discards the "used" pump **10**.

[00304] When a user attempts to re-install a "used" pump in a different fluid delivery system **2**, the user scans the identifying indicia **172** on the pump body **100** of the "used" pump **10** using the packaging reader **808** on the mobile support **700**. The system controller **822** receives the information contained in the identifying indicia **172** and extracts the pump serial number and valve position code, and other information as described previously. Since the pump serial number does not correspond to a pump serial number of a pump **10** that was previously used in this specific fluid delivery system **2**, the system controller **822** "accepts" the pump **10**. The system controller **822** rotates the left and right inlet selector valve actuators **464** to correspond to the angular positions of the valve stem **306** of the inlet selector valve body **302** of the inlet selector valves **300** indicated by the valve position code for a "new" pump **10**, as indicated by the valve position code derived from the identifying indicia **172**. If the user attempts to load the pump **10** into the drive and actuating system **400**, the drive and actuating system **400** will not physically "accept" the pump **10** because the valve stems **306** of the respective inlet selector valves **300** are set to their "OFF" positions, and this positioning does not match that of the left and right inlet selector valve actuators **464**, which have been set to positions corresponding to the encoded angular positions indicated by the "read" valve position code, and the pump drawer **402** cannot be fully closed by the user.

[00305] In the foregoing, while a bar code was generally described as one possible implementation for the identifying indicia **172** on the pump body **100**, this may be replaced by a writeable RFID tag on the pump body **100** in the same location, if desired. If a rewriteable RFID is used, the RFID tag can track the uses by decrementing or incrementing a

count after each use until a maximum number has been reached or the counter reaches zero. As alternatives, the counter may be decremented/incremented after each patient procedure until a maximum number has been reached or the counter reaches zero. When the counter reaches a maximum or zero, the pump **10** cannot be used again as this "prior-use" information is locally stored on the pump **10**. As noted in the foregoing, once the pump **10** is installed into a fluid delivery system **2**, the control system **800** initiates a timer to limit the total amount of time the pump **10** may be exposed to the operational environment. When this timer expires, the control system **800** can prevent further patient procedures from being initiated with that pump **10**. A display of the pump time remaining and uses may be displayed to the user on the user interface display **806**.

[00306] In known syringe-based power injector systems, conventional optical and ultrasonic air detection devices are typically used to detect the presence of air in medical tubing sets. These sensors are generally only able to detect the presence or absence of air within their detection field and they are not able to measure the quantity of air that has been detected. As a result, when a conventional air detector indicates the presence of air, the injector system typically halts the injection process, regardless of the volume of air involved. In the present fluid delivery system **2**, while conventional optical or ultrasonic air detectors may be used for air detectors **810-816**, these air detectors **810-816**, in conjunction with other elements of the fluid delivery system **2**, can be used to measure and track the amount of air that has been observed passing through the patient supply set **40** and the fluid supply tubes **34** of the various fluid supply sets **32** that may be associated with the pump **10**. By measuring the quantity of air that has passed through the various medical tubes in the fluid delivery system **2**, the control system **800** can operate the fluid delivery system **2** to provide enhanced performance.

[00307] For example, during most venous computed tomography (CT) injections, a very small amount of injected air can be tolerated without adverse effects. In many situations, the harm of aborting a fluid injection due to the detection of a small amount of air may be more detrimental than the potential harm of actually injecting a small amount of air into a patient. In these instances, it is often preferable to continue with the fluid injection instead of aborting the fluid injection if the volume of air may be measured and is determined to be small. This behavior helps reduce the number of "nuisance alarms". It also enables the control system **800** to confirm priming by assuring that the fluid volume necessary to prime the tubing downstream from the air detector(s) **810-816** has passed free of an unacceptable amount of air.

[00308] During a fluid injection procedure, the system controller **822** of the control system **800** may monitor several different "air detection channels" and track the cumulative volume of air that has been detected in each channel. Several input parameters or signals may be used by the system controller **822** in the calculation process, including, but not limited to: (1) the six (6) total air detector signals from the respective inlet air detectors **812-816** in the two (2) lateral fluid handling compartments **712** indicating the presence of air in the respective fluid supply tubes **34** connected to the pump **10**; (2) the two (2) angular position signals from angular position sensors **494** associated with the two (2) inlet selector valves **300** and which are connected to the sensor control board **804**; (3) the motor direction of the four (4) piston drive motors **442** that provide the motive forces for operating the respective piston linear actuators **462**; and (4) a motor encoder count as determined by a drive motor encoder **826** associated with each of the four (4) piston drive motors **442** that records an encoder count each time the piston drive motor **442** advances or retracts, for example, advances or retracts a distance equivalent to 0.075 μL of displacement of the plungers **200** in the respective pump cylinders **104** of the pump body **100** of the pump **10**.

[00309] In the foregoing, if a particular inlet selector valve **300** is in the "OFF" position, it may be assumed that this valve **300** cannot be contributing to an increase in the cumulative volume of measured air. Additionally, in the foregoing, the direction of one or more of the piston drive motors **442** may be assessed and, for example, if a particular piston drive motor **442** is moving forward, then the signal from the associated drive motor encoder **826** is not considered in the calculation process for measuring air that is being drawn into the pump **10**, since this particular piston drive motor **442** is operating the associated piston linear actuator **462** to move the plunger **200** to eject fluid from the pump cylinder **104** and, hence, is moving in the "wrong" direction.

[00310] In the calculation process for monitoring the several different "air detection channels", the foregoing electronic signal inputs to the system controller **822** of the control system **800** are used. In the calculation process for each of the "air detection channels", if an inlet air detector **812-816** indicates the presence of air in one of the fluid supply tubes **34** connected to the pump **10**, and if the left inlet selector valve **300** is in the required angular position, and if the right inlet selector valve **300** is in the required position, and if one of the monitored piston drive motors **442** is moving in the "correct" direction, a cumulative volume of air counted in the system controller **822** for that specifically monitored "air detection channel" is incremented by a predetermined volume, such as 0.075 μL, for each encoder pulse that is detected with the corresponding piston drive motor **442**. Once the cumulative

volume of air for a given "air detection channel" has reached or exceeded a predetermined threshold, the control system **800** can command the inlet selector valve **300** to connect the pump **10** to a secondary fluid source container **30** containing fluid of the same type and concentration, if one exists and is available, or abort the fluid injection if no secondary source is available. If no backup fluid source container **30** exists, then the fluid injection cannot be completed since there is insufficient fluid volume available. The foregoing cumulative air detection procedure may be used to confirm that the fluid supply tubes **34** are properly primed when a new fluid source container **30** is installed. During the initial portion of the fluid priming process, the control system **800** can reset the predetermined threshold after the initial air present in the fluid supply tube(s) **34** has been cleared. If the predetermined threshold is exceeded during the remaining bolus of the fluid priming process, the control system **800** can require the priming operation to be repeated. Another approach to the foregoing is to count encoder pulses without air and stop when they exceed the required prime bolus.

[00311] In summary, in the foregoing, the control system **800** typically selects one of the inlet selector valves **300** for examination. The control system **800** then only needs to monitor the inlet air detector **812-816** associated with the active fluid source container **30** (e.g., **S1/S2**, **L1/R1** or **L2/R2**) associated with the selected inlet selector valve **300**. Next, when air is detected, the encoder counts of the two (2) drive motors **442** associated with the selected inlet selector valve **300** (*e.g.*, signal inputs from the two (2) drive motor encoders **826** connected with the two (2) drive motors **442**) are added to the "running" air total if the drive motors **442** are moving in the "correct" withdrawing or retracting direction. Once the total of encoder pulses exceeds a predetermined limit (*e.g.*, equivalent to a predetermined air volume), the system controller **822** sends a command to switch to a backup fluid source container **30**. If no such source is available, the fluid injection is terminated.

[00312] The process for monitoring the patient outlet air detector **810**, which tracks the volume of air that is being delivered via the patient supply set **40**, is generally similar to the foregoing process used for the inlet air detectors **812-816**, with certain differences. These differences include: (1) the fact that there is only one air detector **810** of interest, so only one "air detection channel" is monitored; (2) only encoder counts/pulses from those piston drive motors **442** causing the connected plunger **200** to eject fluid from the associated pump cylinder **104** are of interest and assessed by the system controller **822**, with electronic signals from any other piston drive motor **442** being ignored; and (3) because of the significant pressures in the patient supply set **40**, which can be 400-500 psi and greater, the calculation

for the cumulative volume of air should be adjusted for the prevailing fluid pressure. In this latter instance, if, for example, the fluid pressure is 147 psig, the actual air bubble size will be about 1/10th of the air bubble size at atmospheric pressure. Once the permitted predetermined threshold for permitted cumulative air volume has been reached, the fluid injection is aborted by the system controller **822**.

[00313] In known syringe-based power injector systems, the syringe is filled by the user in advance of a patient procedure. During the filling operation, the user confirms that the syringe has been properly filled to the correct volume and does not contain air. Because the present fluid delivery system **2** has, in a desirable embodiment, two (2) tandem plunger **200** – pump cylinder **104** arrangements that deliver fluid continuously, the pump chambers **106** of the pump cylinders **104** are automatically filled immediately before each delivery stroke of the plunger **200**. The continuous fluid delivery system **2** comprises certain safeguards to ensure that the proper type of fluid and volume is delivered for each delivery stroke of the plungers **200** in the respective pump cylinders **104**. These certain safeguards may include, but are not limited to, monitoring of the piston drive motors **442** that provide the motive forces to the respective piston linear actuators **462** that operate the plungers **200** to confirm that each of the piston linear actuators **462** have moved the appropriate distance to deliver the requested volume.

[00314] As noted previously, it is desirable, in the present continuous fluid delivery system **2**, to detect any "under volume" conditions. In an under volume condition, a restriction in the fluid supply path, for example, in the spikes **36**, fluid supply tubes **34**, pump inlet selector valves **300**, inlet check valves **194**, etc. can prevent one or more of the pump cylinders **104** from filling completely. The drive and actuating system **400** can still draw the plungers **200** back through the appropriate stroke, but the restriction can prevent the pump cylinder or cylinders **104** from filling completely with fluid in the allotted "fill" time. Instead, in this situation, the pump cylinder **104** typically contains a mixture of fluid and vapor (under vacuum) at the end of the filling operation. When the associated plunger **200** is advanced to eject fluid from the pump cylinder **104**, the vapor bubble collapses as the volume in the pump cylinder **104** is reduced and, eventually, any liquid present in the pump cylinder **104** is ejected. However, the requested volume of liquid is not delivered in the ejection or forward stroke of the plunger **200** in the pump cylinder **104**. This under volume condition may not be detected by the patient outlet air detector **810** as the pump cylinder **104** does not contain air and no air will be present for detection by the air detector **810**. Any vapor bubbles in the pump cylinder **104** collapse and revert back to liquid form before being ejected from the

pump cylinder **104**. To guard against this "under volume" condition, various techniques for identifying and accounting for an under-volume situation or condition may be incorporated into the control system **800**. Typically, the control system **800**, typically the system controller **822**, includes an "under volume detection algorithm" to detect under volume conditions and alert the user. The algorithm may be programmed so that, if the under volume condition is severe enough, the control system **800** may abort the fluid injection.

[00315] The under volume detection algorithm may be based one or more methods that may be used to detect an under volume condition during the course of a fluid injection. Referring to **FIGS. 63-64**, one such detection scheme can be to include an integral force transducer **828** as part of the drive piston **50**, as shown in **FIG. 63**. For example, this force transducer **828** could be a strain gauge that has been incorporated into the distal portion of the drive piston **50** that interfaces with the plunger **200**. The force transducer **828** is capable of measuring the linear force that is applied to the corresponding plunger **200** during operation. In "normal" or "typical" operation, the plunger **200** is retracted by the associated piston linear actuator **462** to fill the corresponding pump cylinder **104** as described previously. Once the pump cylinder **104** is filled with fluid, the drive piston **50** is advanced to eject the fluid. As the ejecting or pumping stroke begins, the control system **800** monitors the output of the force transducer **828**. If the pump cylinder **104** is properly filled with fluid, the force will immediately begin to ramp upward as shown by curve "**C1**" in **FIG. 64**, which is a force vs. displacement graph. Any compliance in the drive and actuating system **400** and/or the pump **10** may cause the force to gradually rise upward (as shown) until the pressure in the pump cylinder **104** matches the pressure in the outlet manifold channel **244**. The force of the piston linear actuator **462** typically remains constant for the remainder of the ejection stroke.

[00316] If a restriction exists, as described in the foregoing, the pump cylinder **104** likely contains a mixture of liquid and vapor at the end of the filling cycle. As the plunger **200** is advanced to eject fluid from the pump cylinder **104**, the force transducer **828** indicates that little or no force is being applied to the plunger **200** as shown by curve "**C2**" in **FIG. 63**. This lack of force is because the plunger **200** is initially compressing the vapor bubble, which requires little or no applied force. Once the vapor bubble is fully compressed and the pump cylinder **104** contains only liquid, the force applied to the plunger **200** begins to rise, as shown by curve **C2**. Again, any compliance in the drive and actuating system **400** and/or the pump **10** may cause the force to gradually rise upward (as shown) until the pressure in the pump cylinder **104** matches the pressure in the outlet manifold channel **244**. The degree of under volume generally corresponds to that portion of the pump cylinder **104** that has not

been properly filled with fluid, and may be estimated by measuring the distance that the plunger **200** moves before the force of the piston linear actuator **462** begins to rise. For example, if the plunger **200** moves approximately 25% of the total ejection stroke before the force begins to rise, it may be inferred that only about three-fourths (3/4) of the requested volume was actually loaded in the pump chamber **106**.

[00317] The under volume detection algorithm may also include a motor current detection scheme in place of or as an augmentation to the foregoing force transducer **828** arrangement to detect an under volume condition during the course of a fluid injection. In this detection scheme, the force transducer **828** is not required for each piston linear actuator **462**. Instead, the control system **800**, namely the system controller **822**, monitors the current drawn by each of the piston drive motors **442** for the respective piston linear actuators **462** as each plunger **200** is advanced within its pump cylinder **104**. The current drawn by each piston drive motor **442** is proportional to both the torque that the piston drive motor **442** develops and the linear force that is applied to the associated plunger **200**. The under volume detection algorithm may use this motor current information to determine an under volume condition. An advantage of the foregoing motor current detection scheme is that the multiple force transducers **828** which are integrated into the drive pistons **50**, as described in the foregoing, can be eliminated, if desired.

[00318] Further, the under volume detection algorithm may also include a pressure waveform analysis detection scheme in place of or as an augmentation to the foregoing motor current detection scheme and/or the foregoing force transducer **828** arrangement to detect an under volume condition during the course of a fluid injection. The pressure waveform analysis detection scheme may be used to detect an under volume condition by continuously analyzing the pressure in the pressure sensing port **296** and, therefore, the outlet manifold channel **244** using the pressure sensor output signal from the pressure measurement mechanism **552**, and the system controller **822** looks for trends or changes in the output pressure.

[00319] Referring again to **FIGS. 61-62** and further to **FIGS. 65-67**, the pressure waveform analysis detection scheme may be explained with an example. In this example, it is assumed that only two (2) plungers **200** are being used to deliver fluid. As shown in **FIGS. 61-62**, described previously, under typical operating conditions, in a two (2) plunger **200** – pump cylinder **104** arrangement, as a first plunger **200** begins to decelerate at the end of its pumping or ejection stroke, the second plunger **200** accelerates to reach its target velocity. This operational state is shown in **FIGS. 61-62**, with the velocity profile of the first plunger

200 – pump cylinder **104** identified by reference character "**P1**", and the velocity profile of the staggered or second plunger **200** – pump cylinder **104** identified by reference character "**P2**". The resulting combined output flow rate from the pump **10** is shown in **FIG. 62** and is substantially continuous. The output flow rate is proportional to the sum of the velocities of the two plungers **200** or, more precisely, the sum of the absolute values of the velocities of the two plungers **200**.

[00320] Next, a pump **10** with an under volume condition is considered with reference to **FIGS. 65-67**. In this situation, it may be assumed that the "first" plunger **200** – pump cylinder **104** ("**P1**") has completely filled as expected but the "second" plunger **200** – pump cylinder **104** ("**P2**") has not filled completely because of a restriction. In the present example, the degree of under volume is relatively small and only a few milliliters, perhaps 10%-20% of the volume of the pump cylinder **104**. Because of the under volume condition, the output flow rate of the second plunger **200** – pump cylinder **104** ("**P2**") is not proportional to plunger velocity. In **FIG. 65**, the velocity profile of the second plunger **200** – pump cylinder **104** ("**P2**") will be as desired, but the output flow rate from the pump cylinder **104** lags behind the plunger velocity as shown with the dashed line in **FIG. 65**. This lag is present because no fluid is ejected from the pump cylinder **104** until the vapor bubble has been fully compressed and the pressure in the pump cylinder **104** exceeds the pressure in the outlet manifold channel **244**. **FIG. 66** shows the combined output flow rate for the two plunger **200** – pump cylinder **104** arrangements from **FIG. 65**, and there is a pronounced "dip" or "sag" in the flow rate profile. The corresponding pressure profile in the outlet manifold channel **244**, as measured by the pressure measurement mechanism **552** via the pressure sensing port **296**, is very similar in shape to the flow rate profile shown in **FIG. 66**. **FIG. 67** shows the combined output flow rate for a pump **10** in which the second plunger **200** – pump cylinder **104** ("**P2**") has experienced a severe under volume condition. In this case, the second plunger **200** – pump cylinder **104** ("**P2**") has been filled to, perhaps, only 60%-70% of full capacity, and the corresponding flow rate and pressure profile "dips" or "sags" are very significant and pronounced.

[00321] The foregoing pressure waveform analysis detection method has the advantages that no additional sensors or transducers are needed in the drive and actuating system **400** beyond those present for normal operation, as described in the foregoing. The calculations to be carried out by the under volume detection algorithm programmed into the system controller **822** are well within the skill of one skilled in the computer arts, and do not have to be performed at an extremely high update rate. A possible disadvantage of the pressure

waveform analysis method is that it may be challenging to detect certain types of under volume conditions, such as at extremely low flow rates when sufficient pressure is not present in the outlet manifold channel **244**, or when a fluid mixture operation, for example a mixture of saline and contrast, is being conducted and there may not be a large enough pressure deviation for reliable under volume detection. For example, if saline constitutes 10% of the current phase, it may not be possible to detect an under volume condition in one or more of the "saline" pump cylinders **104** because the "contrast" pump cylinders **104** may be generating the vast majority of the output flow rate and pressure. Further, under volume detection may not be possible for ejection phases that start near a point in the programmed patient protocol where the flow rate is required to change. For example, if the programmed flow rate drops, the control system **800** can expect a sudden decrease in outlet pressure since the overall flow rate of the pump **10** is being intentionally decreased. It may be difficult to distinguish an unexpected drop in outlet pressure due to an under volume condition from an expected drop in pressure due to an intentional programmed change in the flow rate.

[00322] While several assembly steps for assembly the pump **10** have been described in the foregoing, this disclosure now provides further information on the assembly of the pump **10** for us in the fluid delivery system **2**. The following discussion is intended as exemplary and non-limiting as to an assembly for process for constructing the disposable pump **10**.

[00323] Before beginning assembly of a "batch" or "run" of pumps **10**, the operator enters a manufacturing batch number and pump type number into a manufacturing process control computer in a production facility. If the pump sequential identification numbering does not begin with 00001, the starting number is also be specified. The manufacturing process control computer assigns a unique, sequential identification to each pump **10**. This number typically begins with 00001 for the first pump **10** of the batch and is incremented by 1 for each subsequent pump **10**. Next, the saline manifold cap **136** is installed over the saline manifold channels **132**, **134** and is welded, typically laser welded, to the pump body **100**. The inlet and outlet check valves **194**, **196** are placed in their respective recesses, described previously. The front manifold plate **230** may then be installed onto the pump body **100**, capturing the check valves **194**, **196** between these two components. The front manifold plate **230** is then welded, typically laser welded, to the pump body **100**. An inlet manifold cap **262** is installed onto each of the two channel members **238** forming the respective inlet manifold channels **236**.

[00324] The manufacturing process control computer next selects an inlet selector valve position number for each pump **10** and this number may be assigned sequentially starting with 01 for the first pump **10** in the batch and incrementing by one (1) for each subsequent

pump **10**. Once a maximum permitted value has been reached, for example 36, the counter is reset back to a value of 01 for the next or 37th pump **10**. Alternatively, the manufacturing process control computer may randomly select a number between 01 and a maximum permitted value, for example **36**, for the initial angular position of the valve stem **306** of the inlet selector valves **300**, instead of sequentially assigning values. The designated inlet selector valve position number is combined with the uniquely-assigned serial number along with other information as desired, such as the manufacturing lot code and pump type/configuration identifier. This combined data is then encoded into a 14-character string. The 14-character data string is used, for example, to create the identifying indicia **172**, such as a barcode label, that can be laser-etched directly onto the pump **10**, as described previously in this disclosure. The encoded data string is used to generate a corresponding machine-readable barcode matrix, as an example, and the label desirably also contains the same information in human-readable alphanumeric characters. A mist of silicone lubricant may be sprayed onto the interior wall surface of the pump cylinders **104**, onto the interior surface of the inlet selector valve cylinders **114**, and onto the interior surface of the outlet selector valve cylinder **264** on the manifold plate **230**. Next, at a valve insertion assembly station of the manufacturing facility, the manufacturing process equipment reads the identifying indicia **172**, such as a barcode label, on the pump body **100**, the encoded information is decoded using a decoding algorithm, and the inlet selector valve position number is extracted. The extracted inlet selector valve position number is used in conjunction with a look-up table to determine the assembled positions of the left and right inlet selector valves **300**. For example, if the extracted inlet selector valve position number was 19/36, the valve stem **306** of the left inlet selector valve **300** may be placed in one predetermined position, such as angular position "4" which corresponds to a specific angular orientation of the valve stem **306** in the left inlet selector valve cylinder **114**, and the valve stem **306** of the right inlet selector valve **300** may be placed in another predetermined position, such as angular position "1" which corresponds to a specific angular orientation of the valve stem **306** in the right inlet selector valve cylinder **114**. Next, the two (2) valve stems **306** and four (4) plungers **200** are loaded into an automated insertion fixture, which uses servomotors to adjust the angular orientation of the left and right valve stems **306** to match the angular positions indicated by the extracted inlet selector valve position number. The automated insertion fixture concurrently inserts both valve stems **306** and all four (4) plungers **200** into the respective inlet selector valve cylinders **114** and pump cylinders **104** on the pump body **100**. It will be appreciated that the valve stems **306** and the plungers **200** may be inserted into the respective inlet selector valve

cylinders **114** and pump cylinders **104** on the pump body **100** in a two or more step process, for example, one at a time.

[00325] Additionally, for the outlet selector valve **280**, the valve stem **286** of the outlet selector valve body **282** is inserted into the outlet selector valve cylinder **264** on the manifold plate **230**. Prior to insertion, the angular orientation of the valve stem **286** is adjusted to ensure that the flow passage **290** is aligned or in fluid communication with the waste outlet port **272** on the outlet selector valve cylinder **264**. Next, the fluid supply tubes **34** are attached to the inlet ports **122**, **124**, **126** on the inlet selector valve cylinders **114** via, for example, integral barbs on the inlet ports **122**, **124**, **126**. Next, the pump indicator plate **170** is installed into the recessed groove **176** on the outside of one of the pump cylinders **104**. The indicator plate **170**, as described previously, contains grooves **174** which indicate at least the specific pump configuration of the pump **10** based on the associated fluid supply set **32** for the pump **10**. The groove pattern **174** in the pump indicator plate **170** matches the configuration of the pump **10** and its associated fluid supply tubes **34** (see **FIGS. 40-43**). The waste collection tube set **46** with attached waste collection container **48** is attached to the waste outlet port **272** on the outlet selector valve cylinder **264** on the manifold plate **230**.

[00326] While embodiments of a fluid delivery system including a fluid pumping device, optionally provided as a disposable pump cassette, and methods of assembling and use and operation thereof were provided in the foregoing description, those skilled in the art may make modifications and alterations to these embodiments without departing from the scope and spirit of the invention. Accordingly, the foregoing description is intended to be illustrative rather than restrictive. The invention described hereinabove is defined by the appended claims and all changes to the invention that fall within the meaning and the range of equivalency of the claims are to be embraced within their scope.

THE INVENTION CLAIMED IS:

1. A fluid delivery system, comprising:

a fluid pump device, comprising:

a plurality of pump cylinders;

a plunger reciprocally operable within each of the pump cylinders; and

an inlet selector valve to establish selective fluid communication between at least one fluid source container and the pump cylinders, the inlet selector valve located laterally outboard of the pump cylinders; and

a drive and actuating system to independently and reciprocally operate the plungers in the pump cylinders.

2. The fluid delivery system as claimed in Claim 1, wherein the inlet selector valve is oriented generally parallel to the pump cylinders.

3. The fluid delivery system as claimed in Claim 1, further comprising a pump manifold controlling fluid communication to the pump cylinders, and wherein the inlet selector valve controls fluid communication with the at least one fluid source to control fluid flow into the pump manifold.

4. The fluid delivery system as claimed in Claim 3, wherein the pump manifold comprises an inlet manifold channel and an outlet manifold channel, and wherein the pump cylinders each comprise at least one inlet opening for fluid communication with the inlet manifold channel and at least one outlet opening for fluid communication with the outlet manifold channel.

5. The fluid delivery system as claimed in Claim 4, wherein the pump cylinders are in selective fluid communication with the inlet manifold channel and the outlet manifold channel via respective inlet check valves and outlet check valves.

6. The fluid delivery system as claimed in Claim 5, wherein the at least one outlet opening is positioned at a high point in each of the pump cylinders for air bubble egress.

7. The fluid delivery system as claimed in Claim 1, wherein the inlet selector valve comprises an inlet selector valve cylinder having a valve stem disposed therein, the valve stem defining an axial passage and a plurality of radial inlet ports connected to the axial passage.

8. The fluid delivery system as claimed in Claim 7, wherein the radial inlet ports are disposed at different angular orientations around the valve stem.

9. The fluid delivery system as claimed in Claim 7, wherein the valve stem comprises a plurality of radial inlet ports disposed at different angular orientations around the valve stem and at different axial locations along the valve stem.

10. The fluid delivery system as claimed in Claim 1, further comprising a saline manifold in selective fluid communication with the pump cylinders via the inlet selector valve to establish selective fluid communication between a saline fluid source and the pump cylinders.

11. The fluid delivery system as claimed in Claim 10, wherein the saline manifold extends across the plurality of pump cylinders.

12. The fluid delivery system as claimed in Claim 1, wherein the inlet selector valve is operable by the drive and actuating system independently of the plungers.

13. The fluid delivery system as claimed in Claim 1, further comprising identifying indicia on the fluid pump device and encoded with identifying information for the fluid pump device.

14. The fluid delivery system as claimed in Claim 13, wherein the inlet selector valve comprises an inlet selector valve cylinder having a valve stem disposed therein, the identifying information comprising at least an initial angular orientation of the valve stem in the inlet selector valve cylinder or a representation thereof.

15. The fluid delivery system as claimed in Claim 14, wherein the valve stem comprises a plurality of radial inlet ports.

16. The fluid delivery system as claimed in Claim 15, wherein the radial inlet ports are disposed at different angular orientations around the valve stem.

17. The fluid delivery system as claimed in Claim 15, wherein the radial inlet ports are disposed at different angular orientations around the valve stem and at different axial locations along the valve stem.

18. The fluid delivery system as claimed in Claim 14, wherein the inlet selector valve cylinder is oriented generally parallel to the pump cylinders.

19. The fluid delivery system as claimed in Claim 13, wherein the identifying indicia is an optically encoded transparent member.

20. The fluid delivery system as claimed in Claim 13, wherein the identifying indicia is disposed on one of the pump cylinders.

21. The fluid delivery system as claimed in Claim 1, wherein each of the plungers comprises a piston interface member extending proximally therefrom, and wherein the piston interface member is split into at least two parts that are compressible towards one another.

22. The fluid delivery system as claimed in Claim 21, wherein the plungers each comprise a distal end disc and a proximal end disc.

23. The fluid delivery system as claimed in Claim 22, wherein the plungers are reciprocally operable in the respective pump cylinders such that the distal end disc of each of the plungers is operable within a pumping zone of the pump cylinders and the proximal end disc is operable within an isolation zone of the pump cylinders.

24. The fluid delivery system as claimed in Claim 22, further comprising a seal provided at least circumferentially about each of the distal end disc and the proximal end disc.

25. The fluid delivery system as claimed in Claim 21, further comprising a radial lip on each of the at least two parts to interface with a drive piston of the drive and actuating system.

26. The fluid delivery system as claimed in Claim 21, further comprising a support member coaxially disposed in the piston interface member.

27. A drive and actuating system for operating a fluid pump device, comprising:

an extendable and retractable pump drawer to accept the fluid pump device, the fluid pump device comprising a plurality of pump cylinders and a plunger reciprocally operable within each of the pump cylinders;

drive pistons adapted for mechanical connection to the plungers, respectively, to independently and reciprocally operate the plungers in the pump cylinders;

piston linear actuators respectively coupled to the drive pistons; and

drive motors operatively coupled to the piston linear actuators, respectively, to provide motive forces to the piston linear actuators to independently and reciprocally operate the plungers.

28. The drive and actuating system as claimed in Claim 27, wherein the fluid pump device further comprises an inlet selector valve to establish selective fluid communication between at least one fluid source container and the pump cylinders, and wherein the inlet selector valve is located laterally outboard of the pump cylinders.

29. The drive and actuating system as claimed in Claim 28, further comprising an inlet selector valve actuator adapted for mechanical connection to the inlet selector valve to control operation of the inlet selector valve to establish the selective fluid communication between the at least one fluid source container and the pump cylinders.

30. The drive and actuating system as claimed in Claim 27, further comprising a pump manifold controlling fluid communication to the pump cylinders, and a pump clamping mechanism operable to secure the fluid pump device in the pump drawer and apply a compressive force to the pump manifold when the fluid pump device is loaded in the pump drawer.

31. The drive and actuating system as claimed in Claim 30, wherein the pump clamping mechanism comprises a clamping block to engage the pump manifold when the fluid pump device is loaded in the pump drawer.

32. The drive and actuating system as claimed in Claim 31, wherein the clamping block is operated by a clamp actuating mechanism to engage and disengage the clamping block with the pump manifold.

33. The drive and actuating system as claimed in Claim 32, wherein the pump manifold comprises a pressure sensing port with a pressure sensing diaphragm, and wherein the drive and actuating system further comprises a pressure measuring mechanism adapted to interface with the pressure sensing port.

34. The drive and actuating system as claimed in Claim 33, wherein operation of the clamp actuating mechanism to engage the clamping block with the pump manifold concurrently causes the pressure measuring mechanism to operatively interface with the pressure sensing diaphragm.

35. The drive and actuating system as claimed in Claim 27, further comprising a pump manifold controlling fluid communication to the pump cylinders, and wherein the pump manifold comprises a pressure sensing port comprising a pressure sensing diaphragm, and wherein the drive and actuating system further comprises a pressure measuring mechanism adapted to interface with the pressure sensing port.

36. The drive and actuating system as claimed in Claim 27, further comprising a pump manifold controlling fluid communication to the pump cylinders, the pump manifold comprising an inlet manifold channel and an outlet manifold channel, and further comprising an outlet selector valve in fluid communication with the outlet manifold channel to control fluid flow from the pump manifold.

37. The drive and actuating system as claimed in Claim 36, wherein the drive and actuating system further comprises an outlet selector valve actuator to control operation of the outlet selector valve.

38. The drive and actuating system as claimed in Claim 27, wherein the plungers each comprise a piston interface member split into at least two parts that are compressible towards one another to enable the mechanical connection with the respective drive pistons.

39. The drive and actuating system as claimed in Claim 38, further comprising a radial lip on each of the at least two parts to interface with the respective drive pistons.

40. The drive and actuating system as claimed in Claim 38, further comprising a support member coaxially disposed in the piston interface member.

41. The drive and actuating system as claimed in Claim 38, further comprising a radial lip on each of the at least two parts of the respective piston interface members to interface with a receiving groove in a socket in the corresponding drive pistons of the drive and actuating system.

42. A method of interfacing a fluid pump device with a drive and actuating system of a fluid delivery system, comprising:

providing the fluid pump device, comprising:

a plurality of pump cylinders; and

a plunger reciprocally operable within each of the pump cylinders, each of the plungers comprising a piston interface member extending proximally therefrom, and wherein the piston interface member is split into at least two parts that are compressible towards one another; and

interfacing the plungers with respective drive pistons of the drive and actuating system, such that the at least two parts of each of the piston interface members compress towards one another to enable mechanical engagement with the respective drive pistons.

43. A method as claimed in Claim 42, wherein the drive pistons independently and reciprocally operate the plungers in the respective pump cylinders.

44. The method as claimed in Claim 42, wherein the fluid pump device further comprises an inlet selector valve to establish selective fluid communication between at least one fluid source container and the pump cylinders, the inlet selector valve located laterally outboard of the pump cylinders.

45. A method as claimed in Claim 42, wherein the plungers each comprise a distal end disc and a proximal end disc.

46. The method claimed in Claim 45, wherein the plungers are reciprocally operable in the respective pump cylinders such that the distal end disc of each of the plungers is operable within a pumping zone of the pump cylinders and the proximal end disc is operable within an isolation zone of the pump cylinders.

47. The method as claimed in Claim 45, further comprising a seal provided at least circumferentially about each of the distal end disc and the proximal end disc.

48. The method as claimed in Claim 42, further comprising a radial lip on each of the at least two parts of the respective piston interface members to interface with a receiving groove in a socket in the respective drive pistons of the drive and actuating system.

49. The method as claimed in Claim 42, further comprising a support member coaxially disposed in the piston interface member.

50. The method as claimed in Claim 42, further comprising a radial lip on each of the at least two parts of the piston interface members, and the respective drive pistons each comprising a distal end socket defining a receiving groove, such that the step of interfacing the plungers with the respective drive pistons comprises receiving the piston interface members into the distal end socket in the respective drive pistons and engaging the radial lip on the at least two parts with the receiving groove in the distal end socket in each of the respective drive pistons.

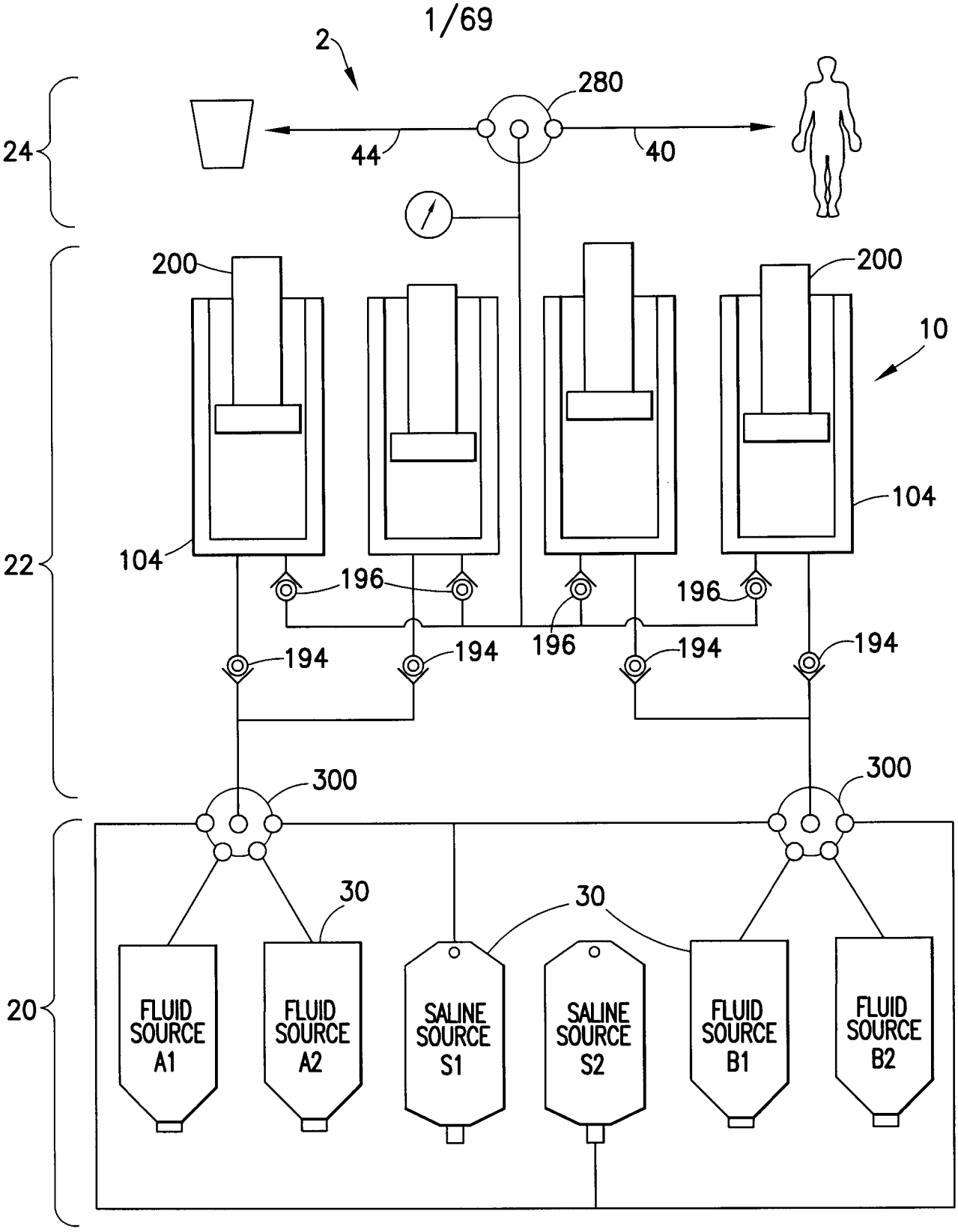
2
280
24
44
40
200
200
10
104
104
22
196
196
196
194
194
194
194
300
300
30
30
20
FLUID SOURCE A1
FLUID SOURCE A2
SALINE SOURCE S1
SALINE SOURCE S2
FLUID SOURCE B1
FLUID SOURCE B2

FIG. 1

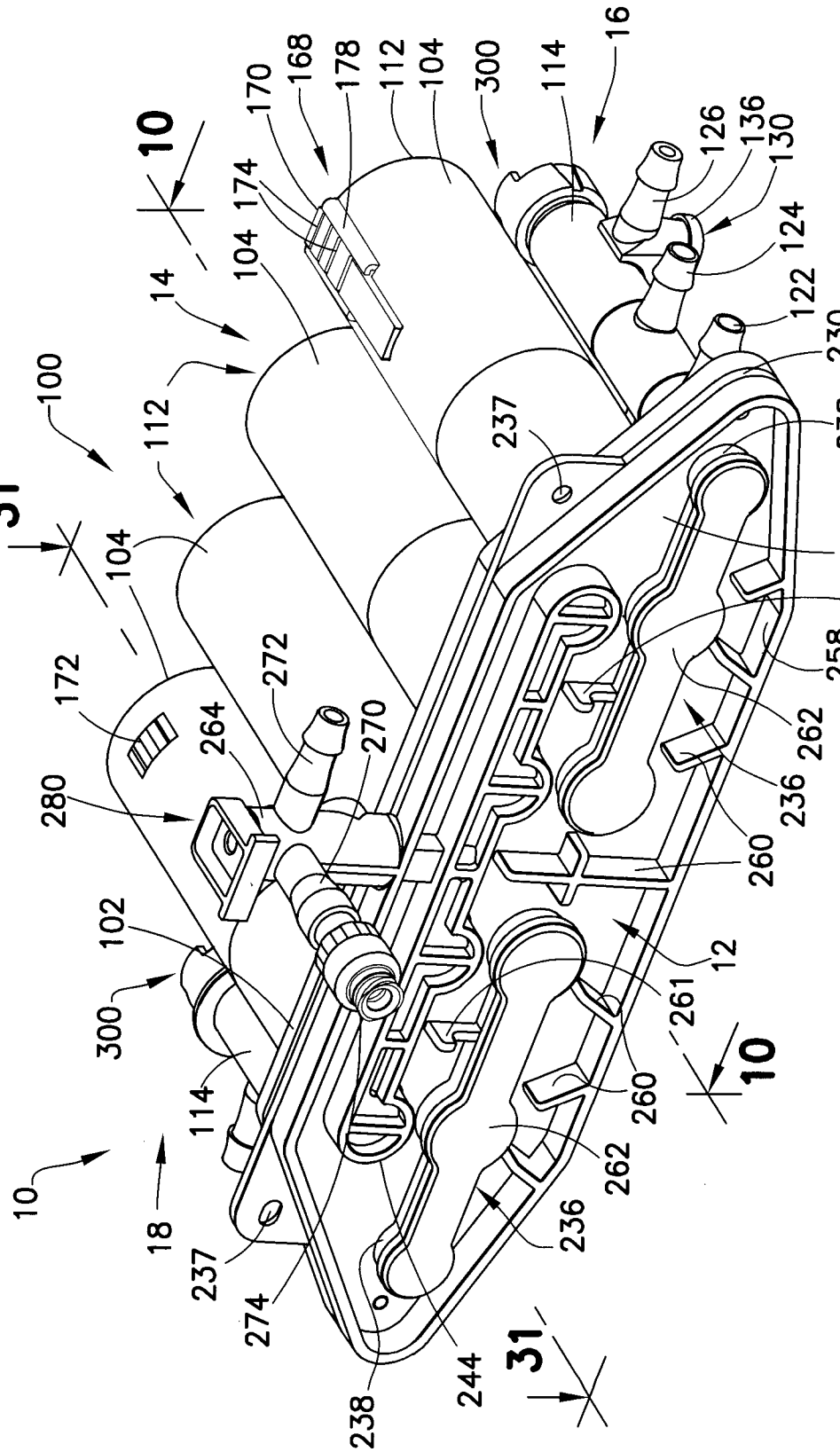
10
14
16
18
31
100
102
104
112
114
122
124
126
130
136
168
170
172
174
178
230
232
236
237
238
244
258
260
261
262
264
270
272
274
280
300

FIG.2

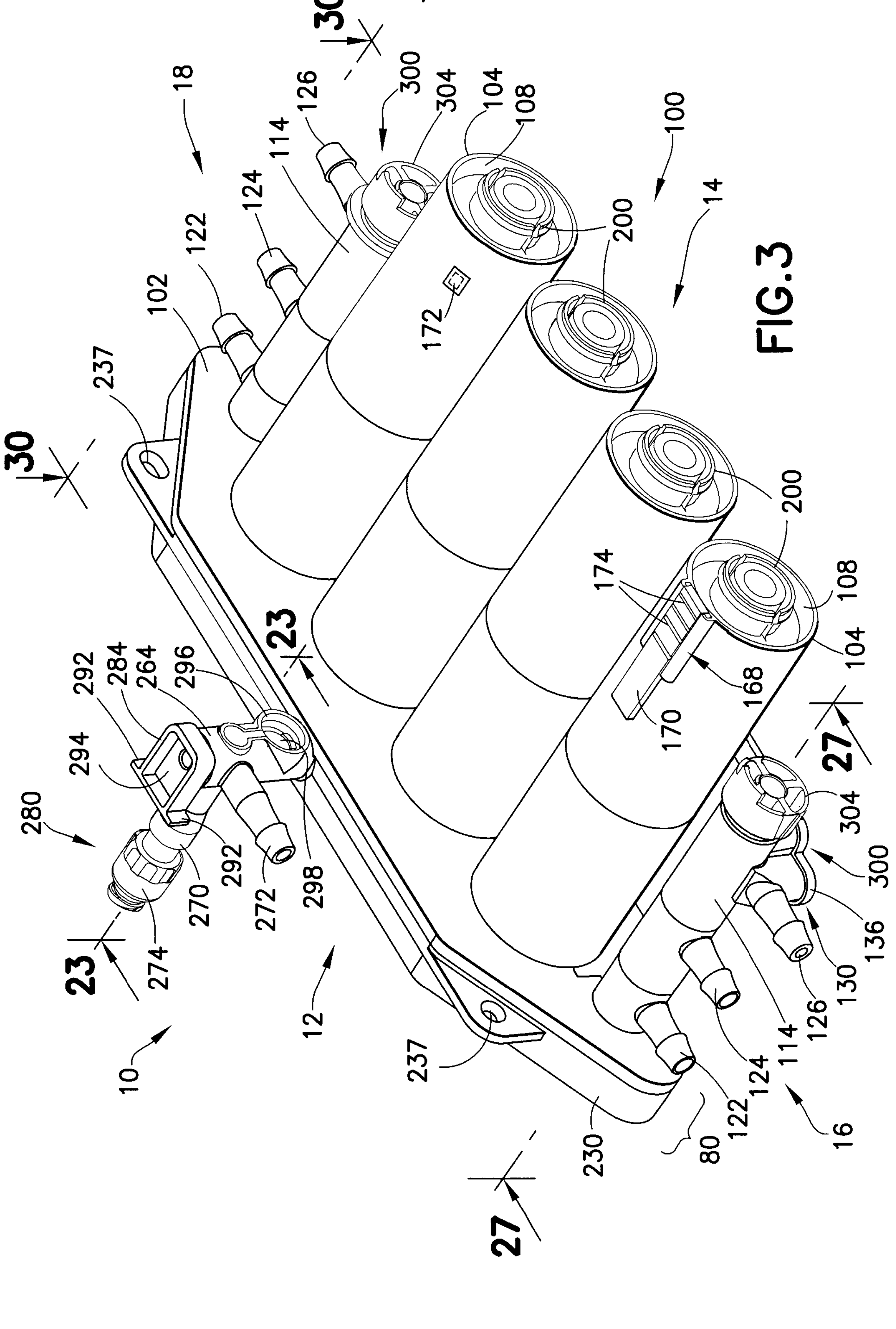
30
30
18
126
300
304
104
108
100
114
124
122
102
237
14
200
200
172
200
200
174
108
104
168
170
23
23
292
284
264
296
294
280
292
270
272
298
274
27
27
304
300
136
130
126
124
114
122
12
10
237
230
80
16

FIG.3

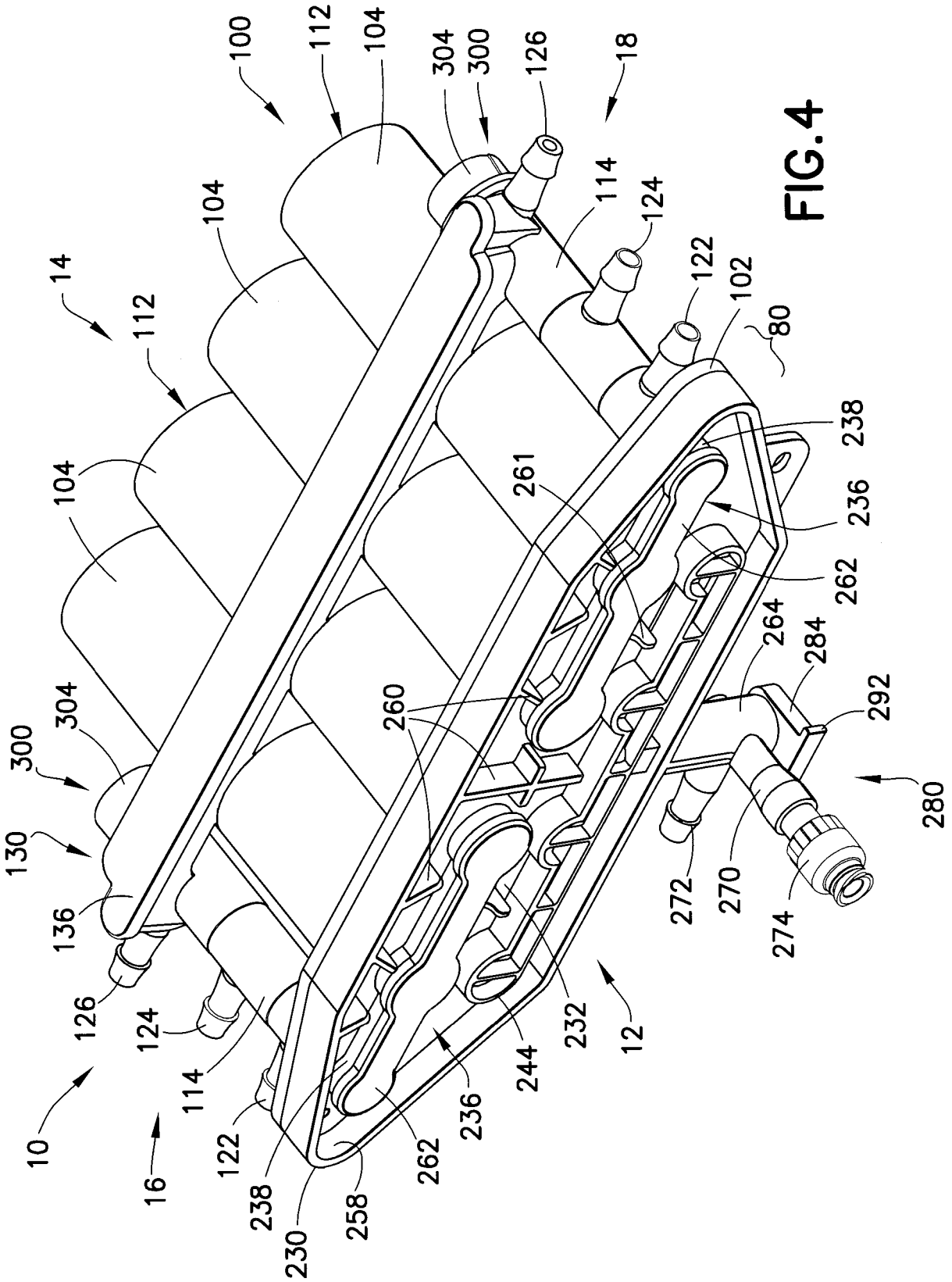
100
112
104
304
300
126
18
104
114
124
14
112
122
102
80
104
238
261
236
262
264
284
292
304
260
300
280
130
136
272
270
274
126
124
114
232
12
10
244
236
16
122
262
238
258
230

FIG.4

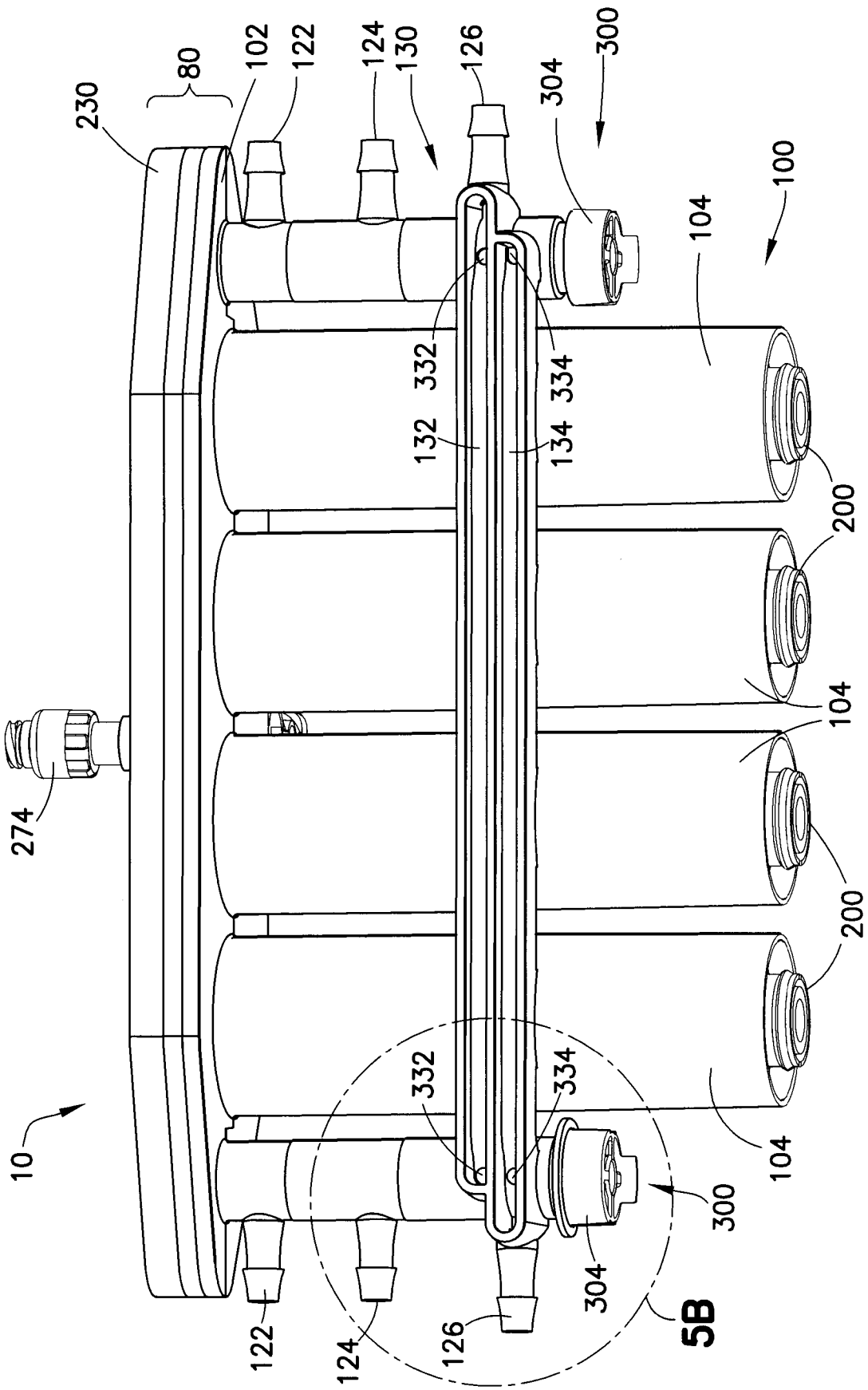
230
80
102
122
124
130
126
304
300
100
104
332
334
132
134
200
274
10
5B

FIG.5A

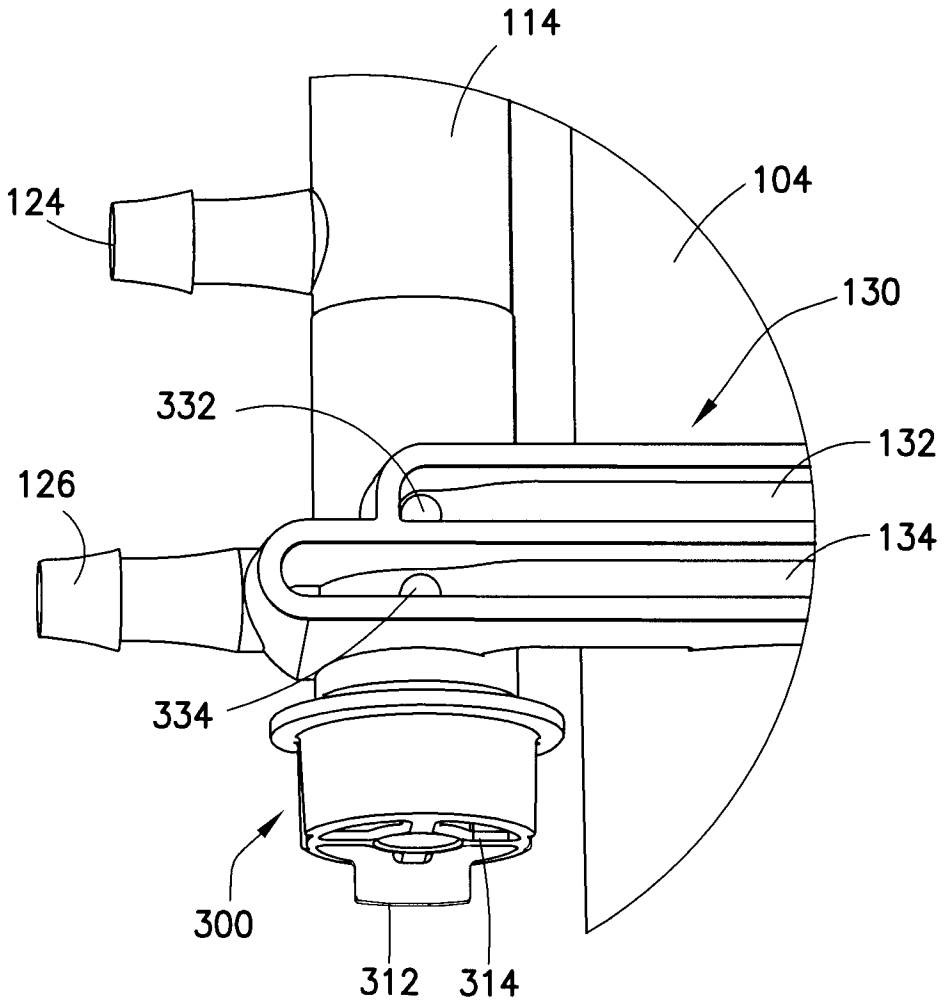

FIG.5B

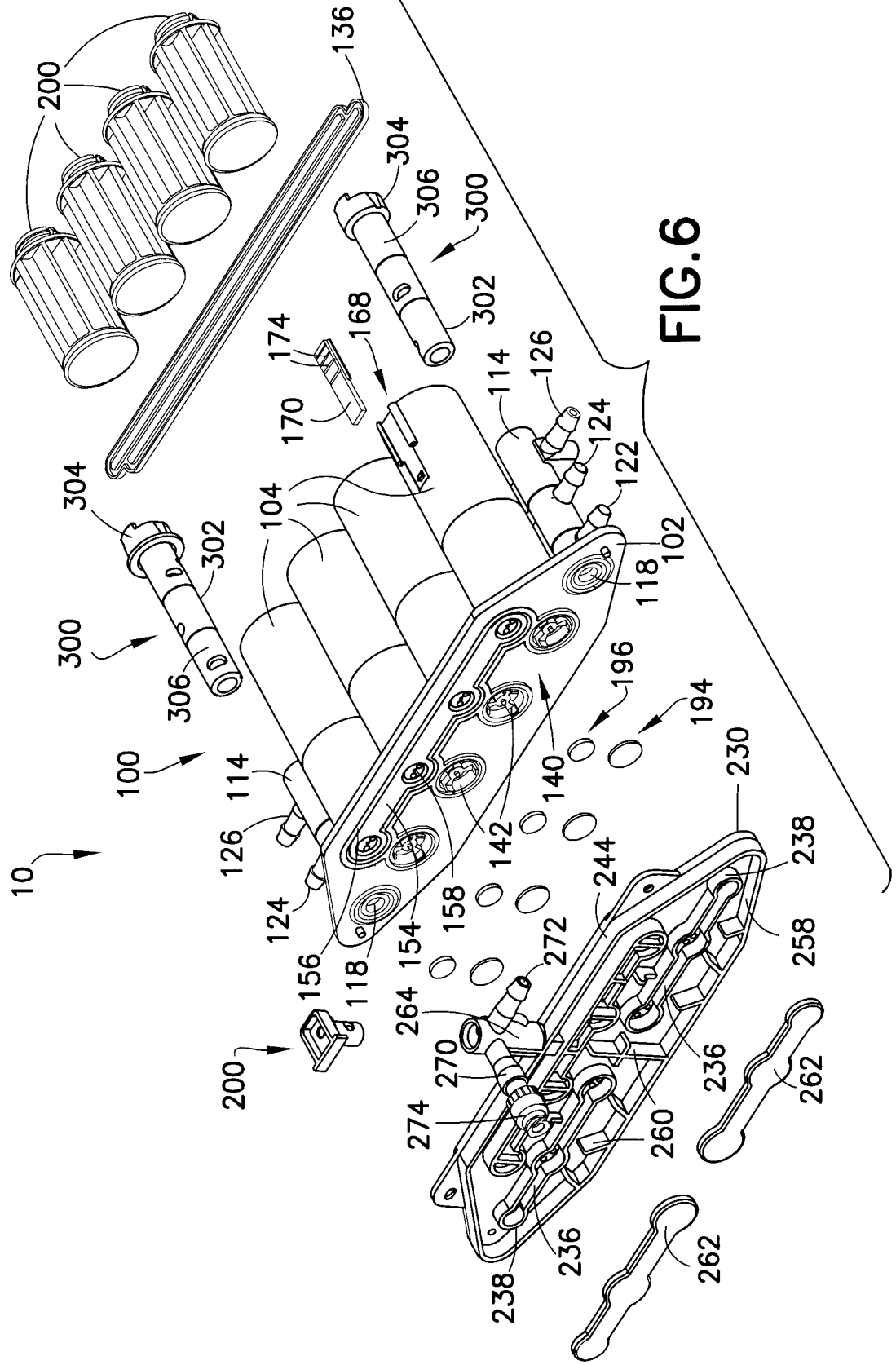
10
100
200
300
302
304
306
102
104
114
118
122
124
126
136
140
142
154
156
158
168
170
174
194
196
230
236
238
244
258
260
262
264
270
272
274

FIG.6

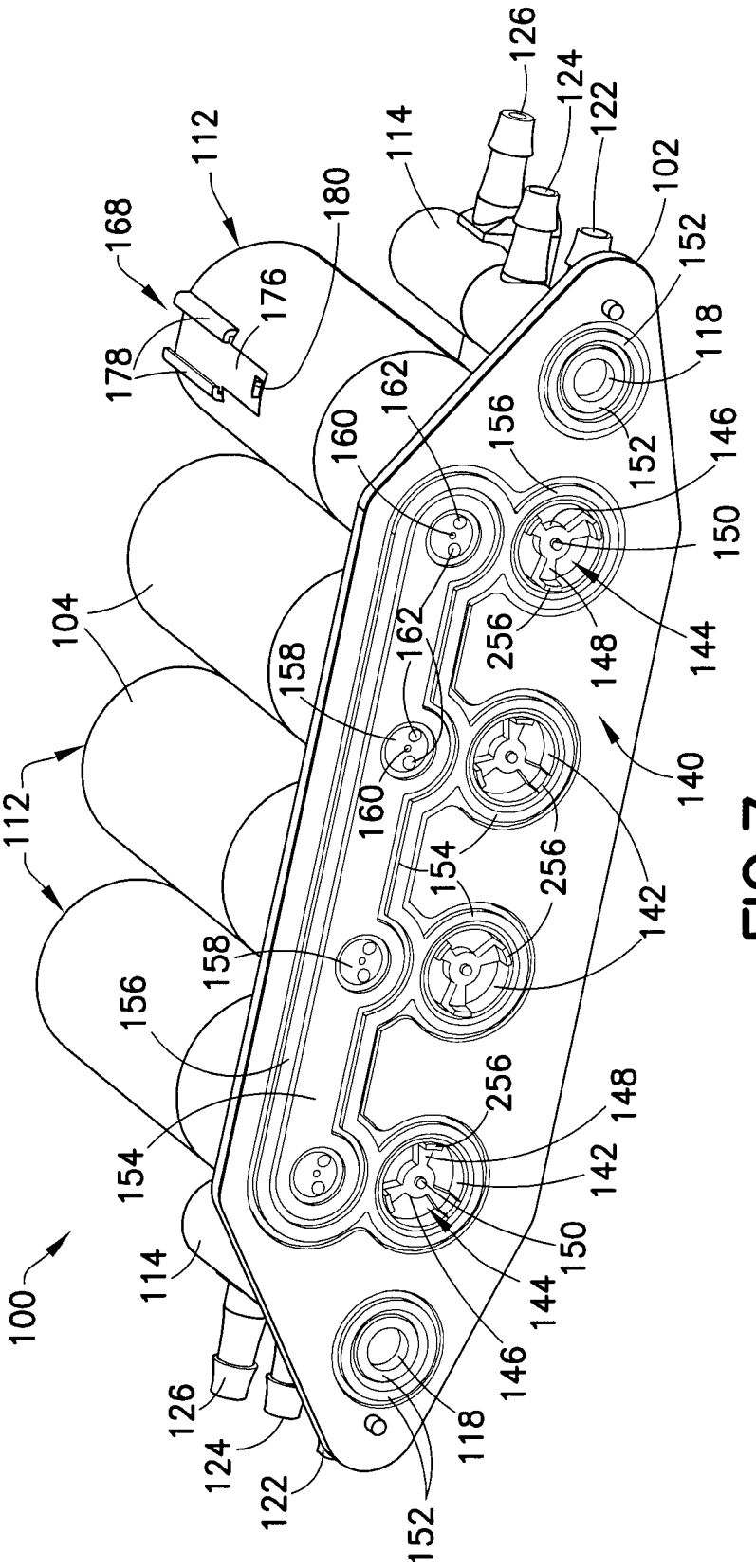
100
102
104
112
114
118
122
124
126
140
142
144
146
148
150
152
154
156
158
160
162
168
176
178
180
256

FIG.7

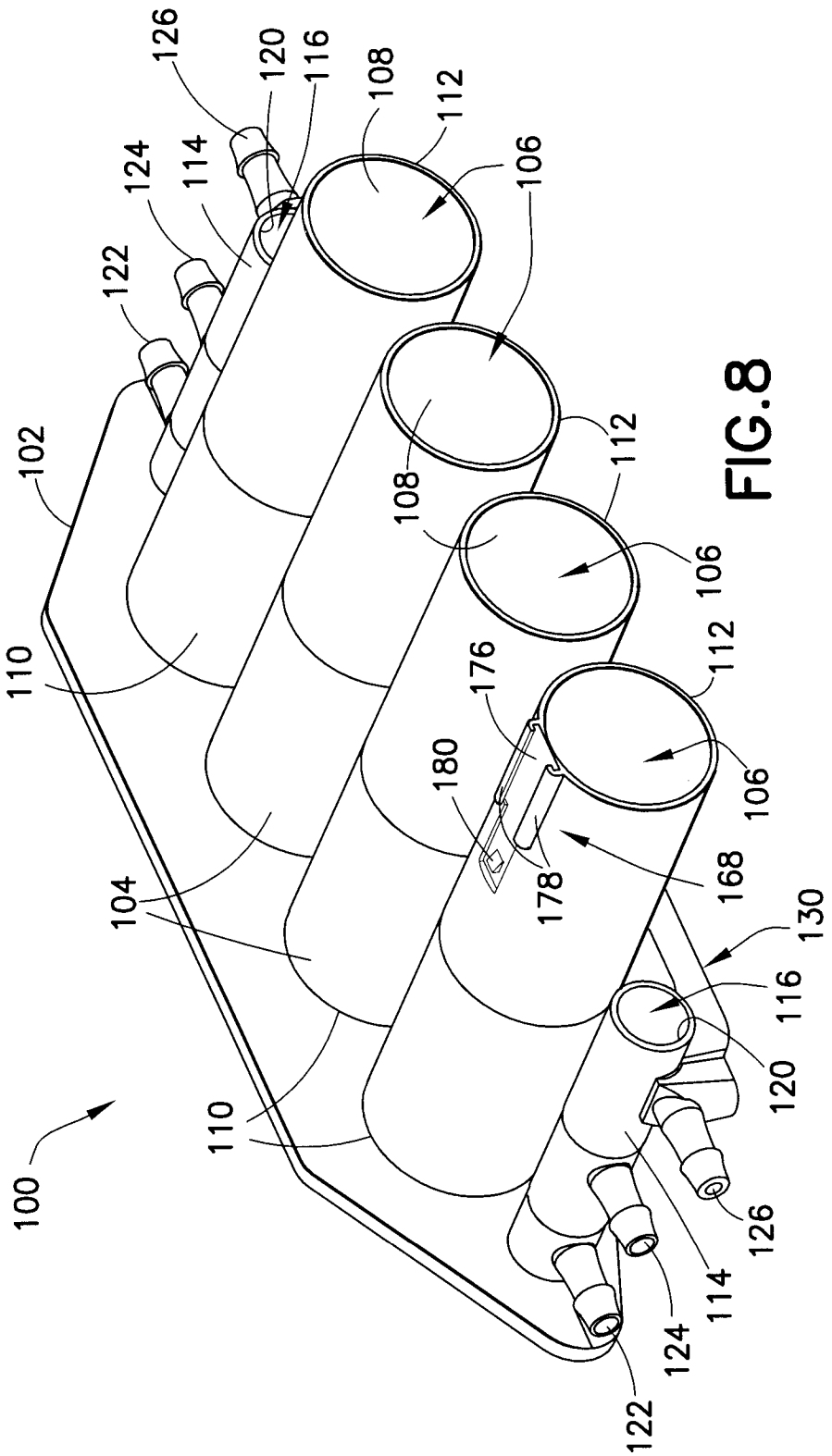
126
120
116
108
112
106
124
114
122
102
108
112
106
110
176
112
180
106
178
168
104
130
116
110
120
100
126
114
124
122

FIG.8

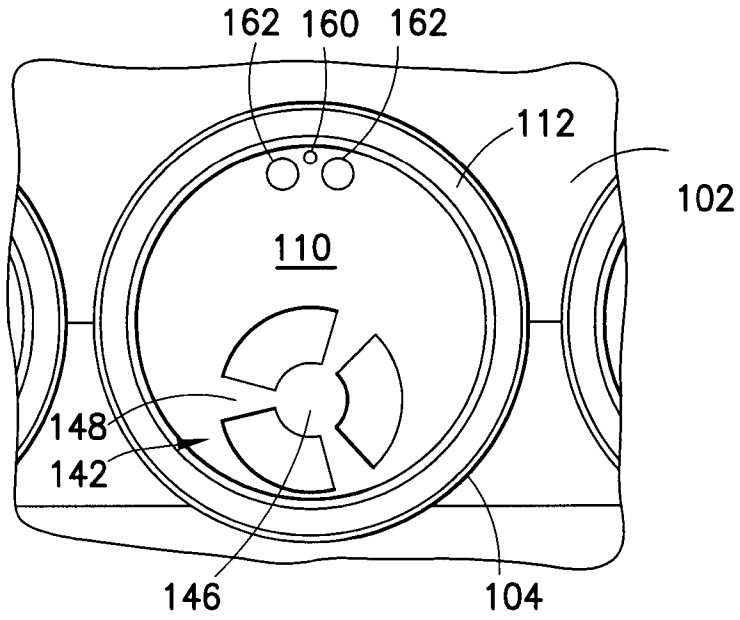
162
160
162
112
102
110
148
142
146
104

FIG.9

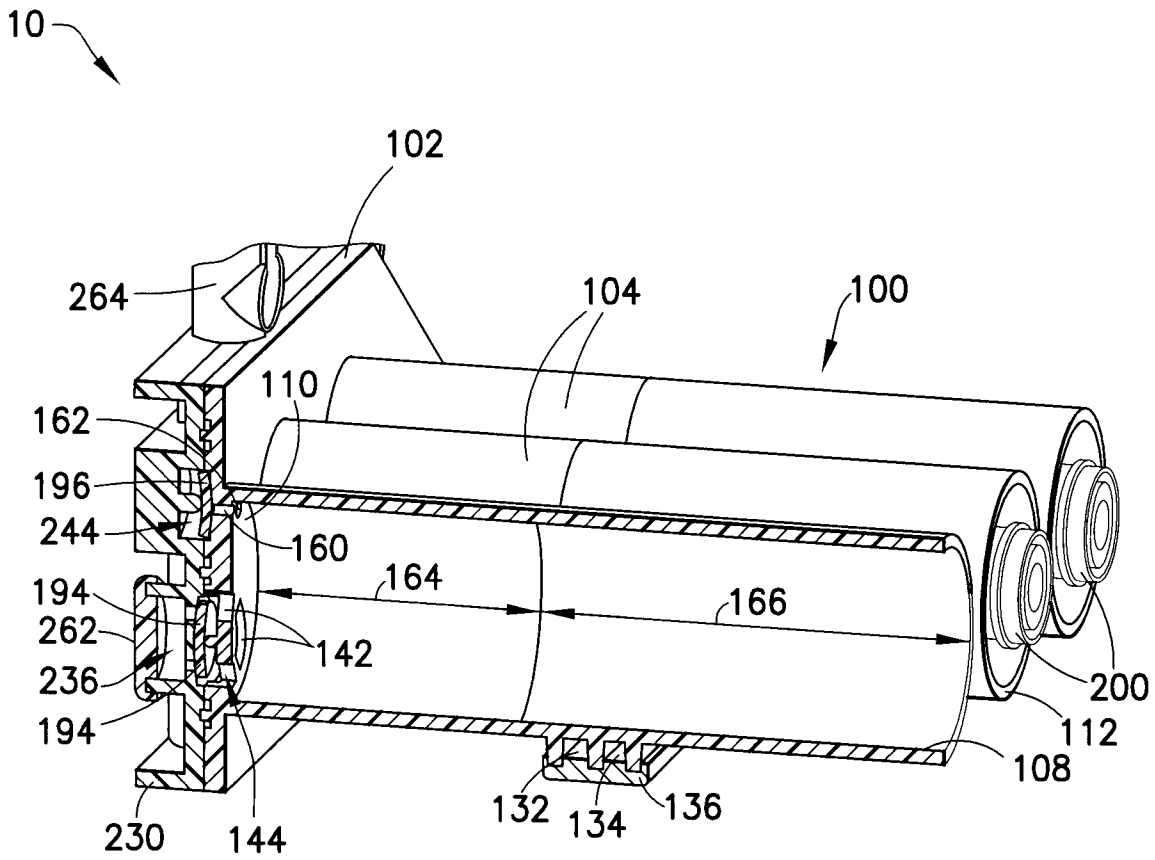
10
102
264
104
100
110
162
196
244
160
164
166
194
262
142
236
194
200
112
108
230
144
132
134
136

FIG.10

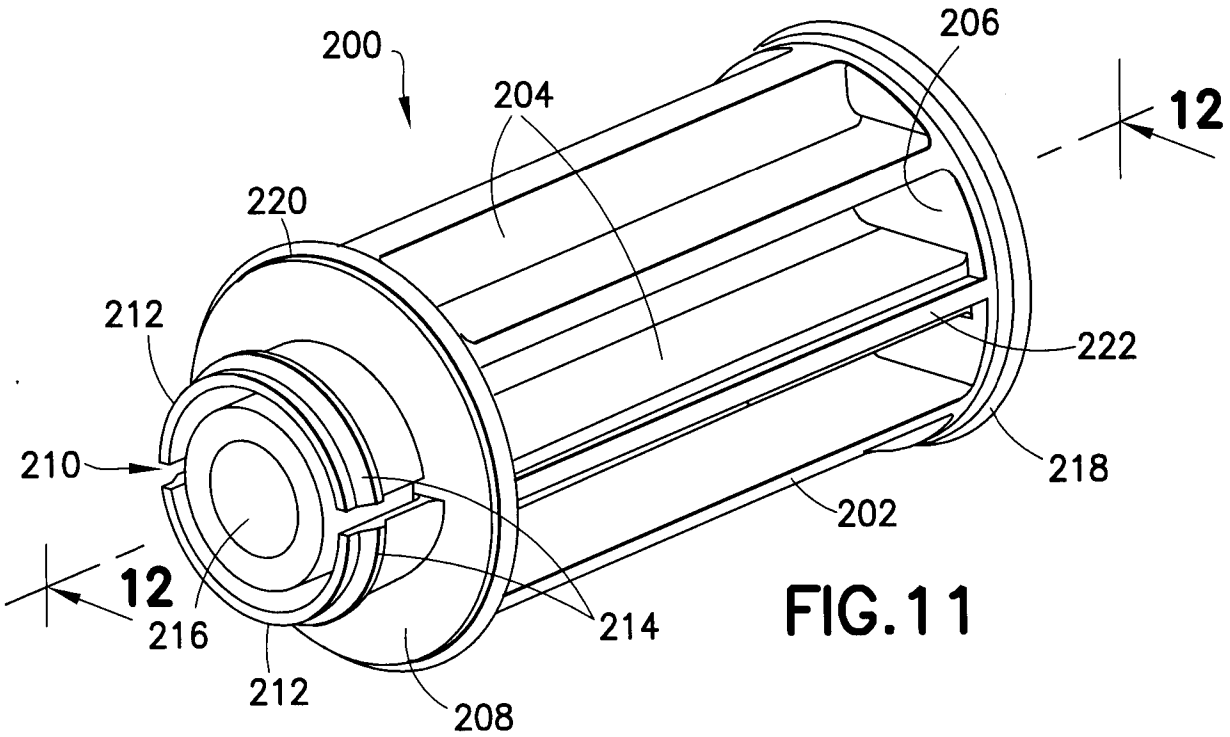
200
204
206
12
220
212
222
210
218
202
12
216
214
212
208

FIG.11

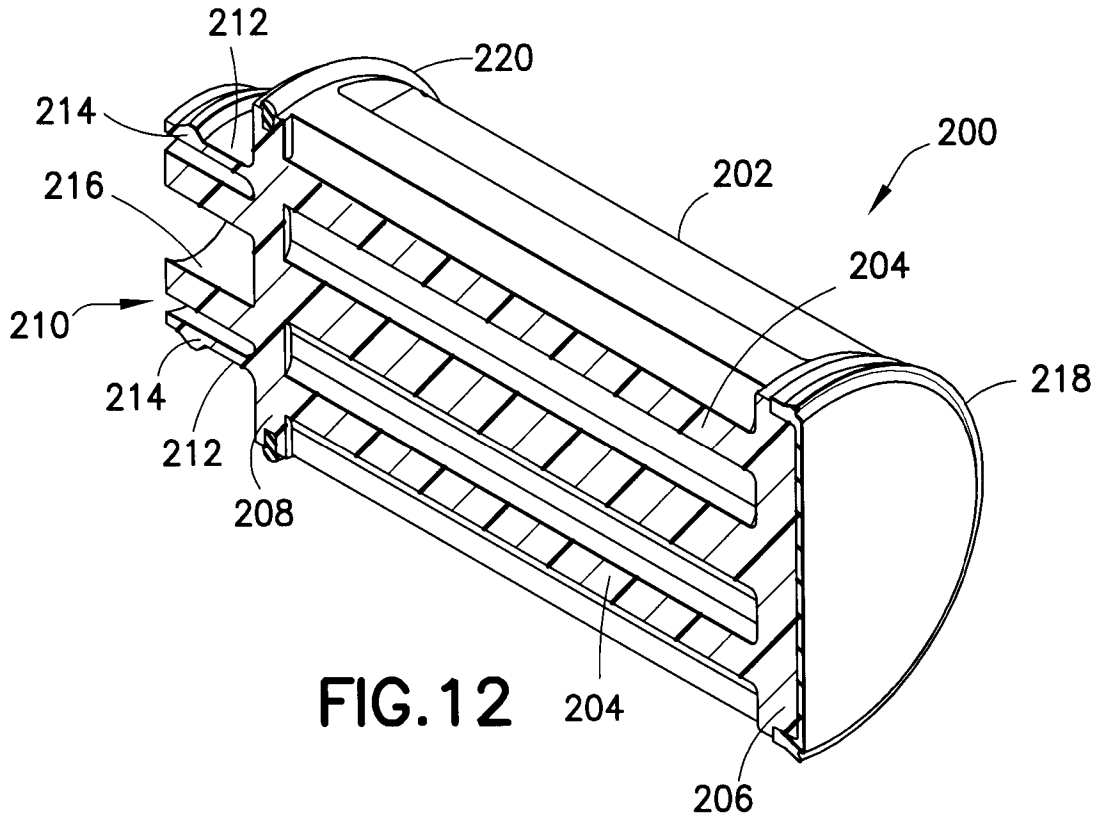
212
220
214
200
202
216
204
210
218
214
212
208
204
206

FIG.12

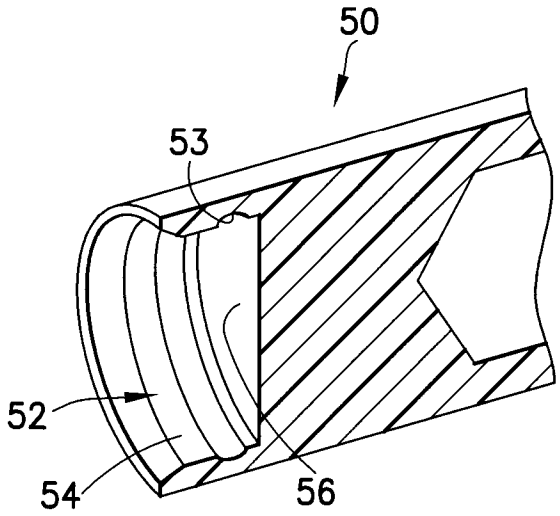

FIG. 13

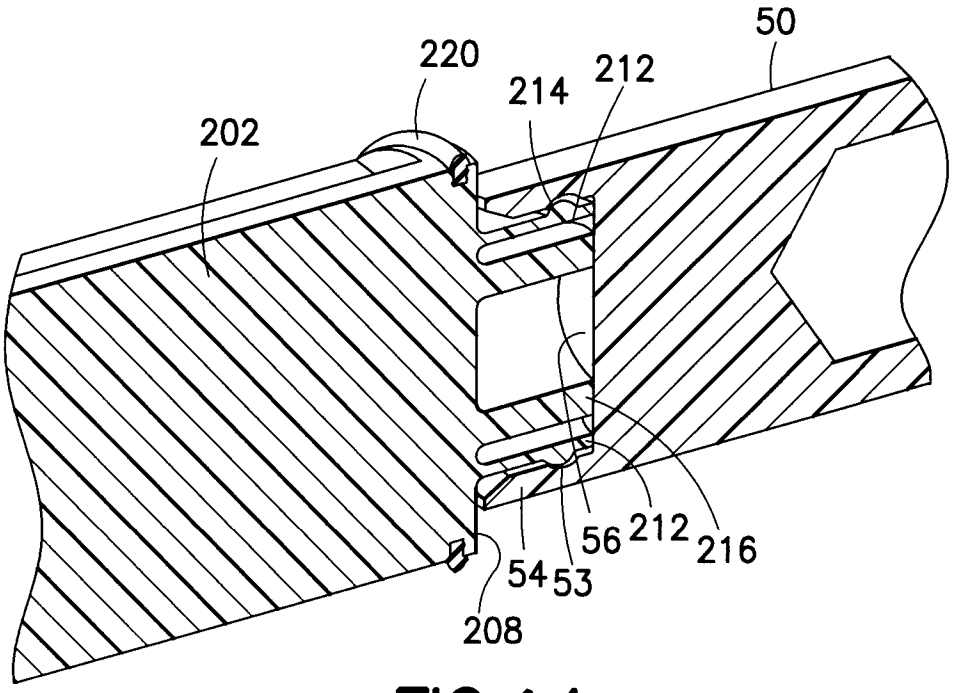

FIG. 14

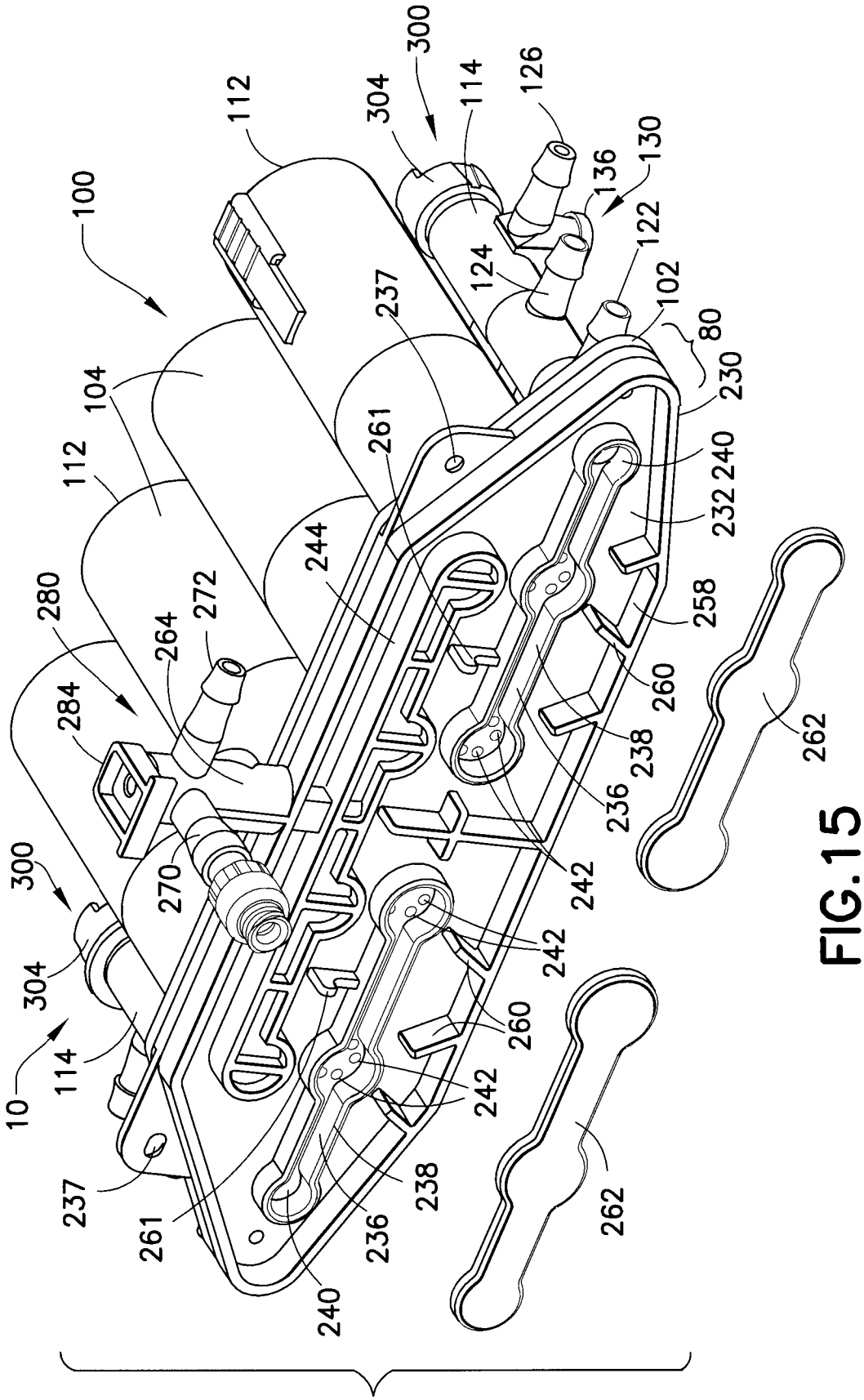
100
112
300
304
114
126
130
136
122
124
102
80
230
237
104
261
240
232
244
258
280
272
264
284
260
238
236
262
270
242
10

FIG.15

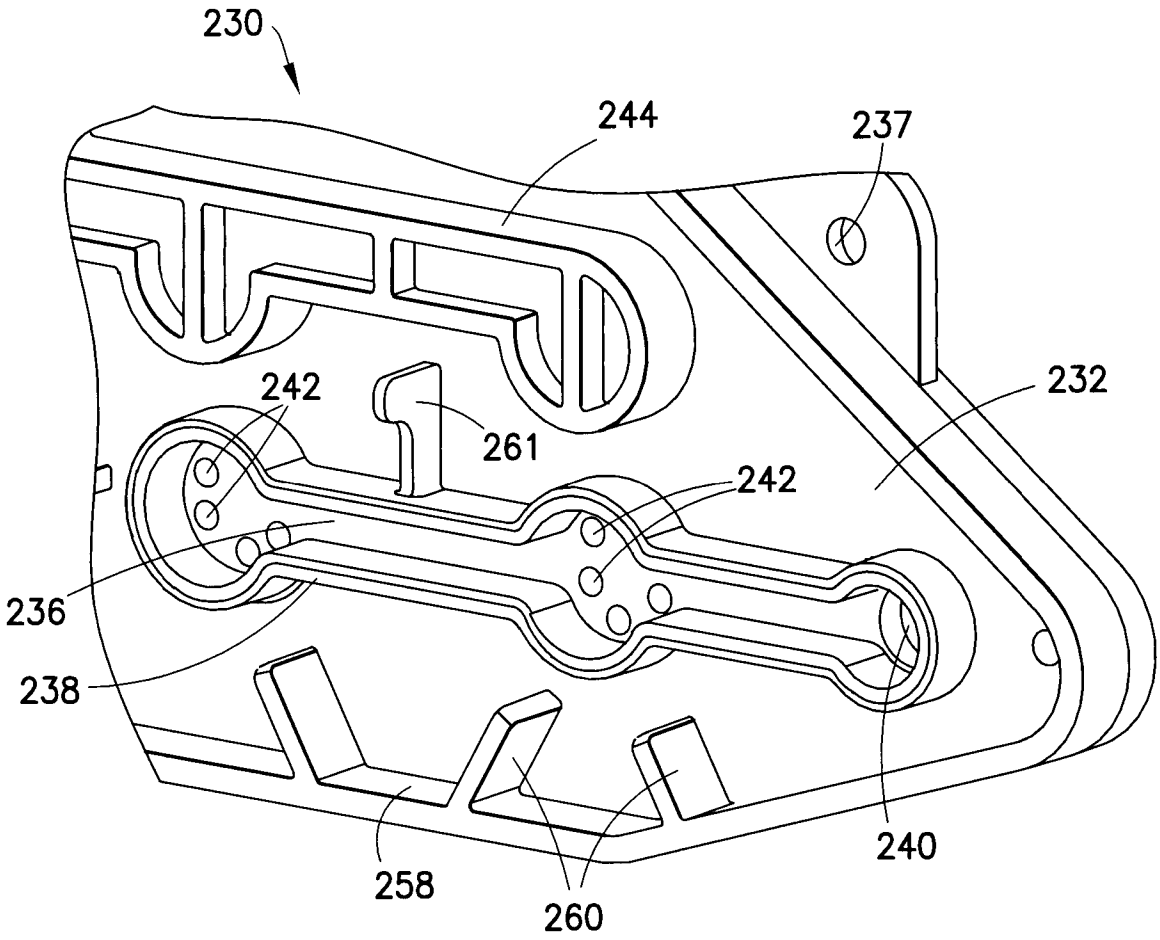

FIG. 16

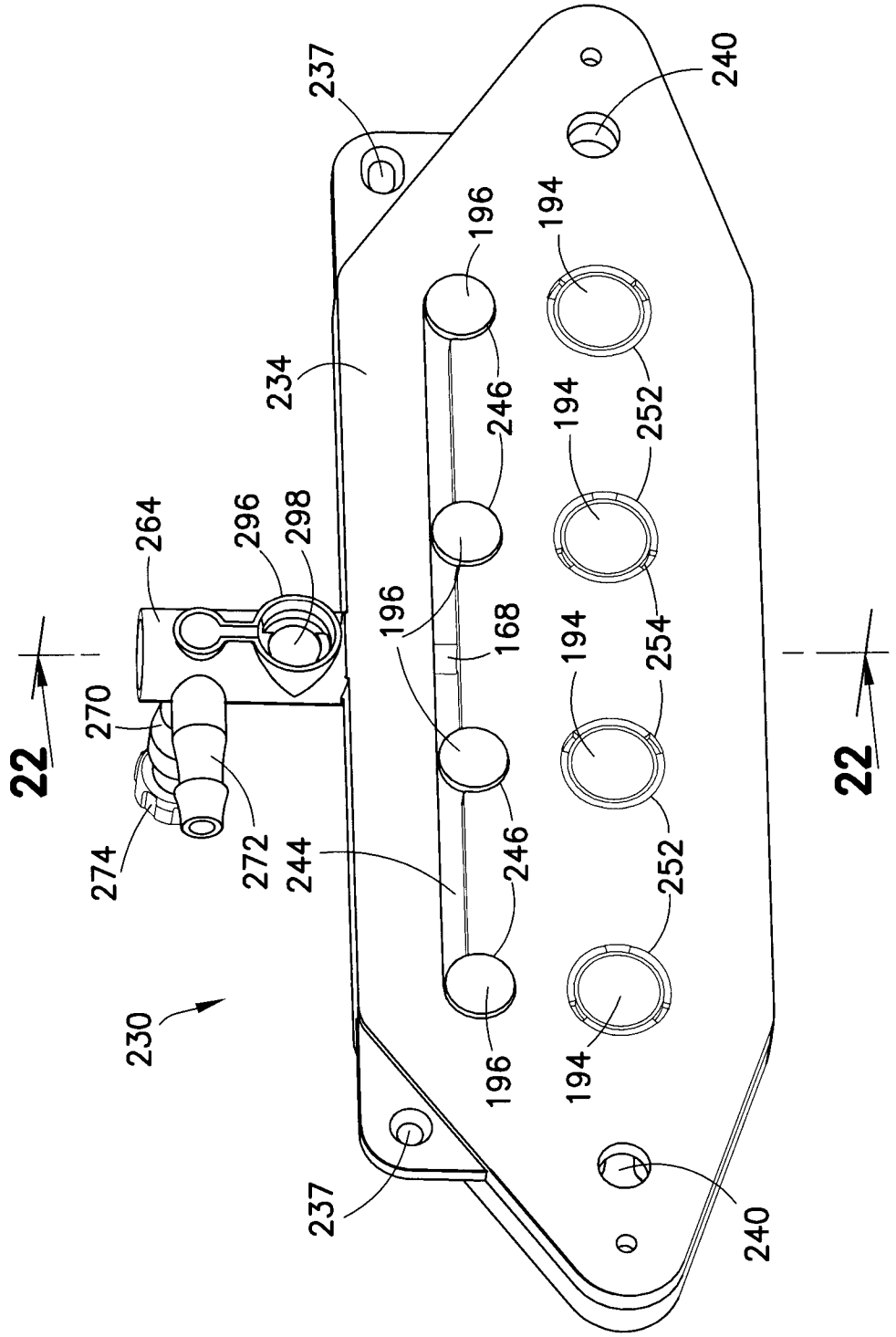
237
240
196
194
234
246
194
252
264
296
298
196
168
194
254
270
22
22
274
272
244
246
252
230
196
194
237
240

FIG.17

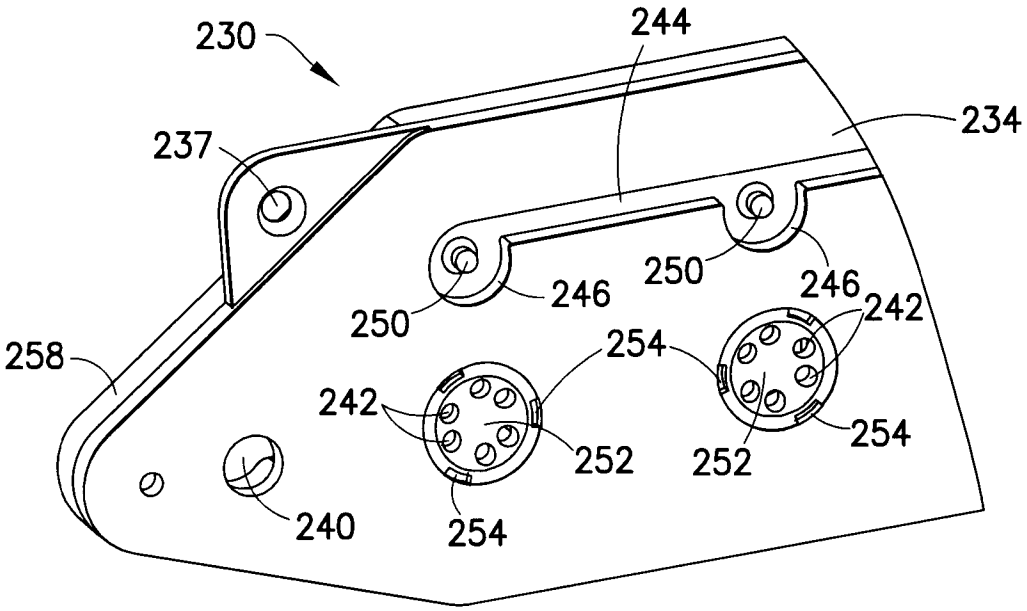
230
244
234
237
250
246
250
246
242
258
254
242
252
252
254
254
240

FIG.18

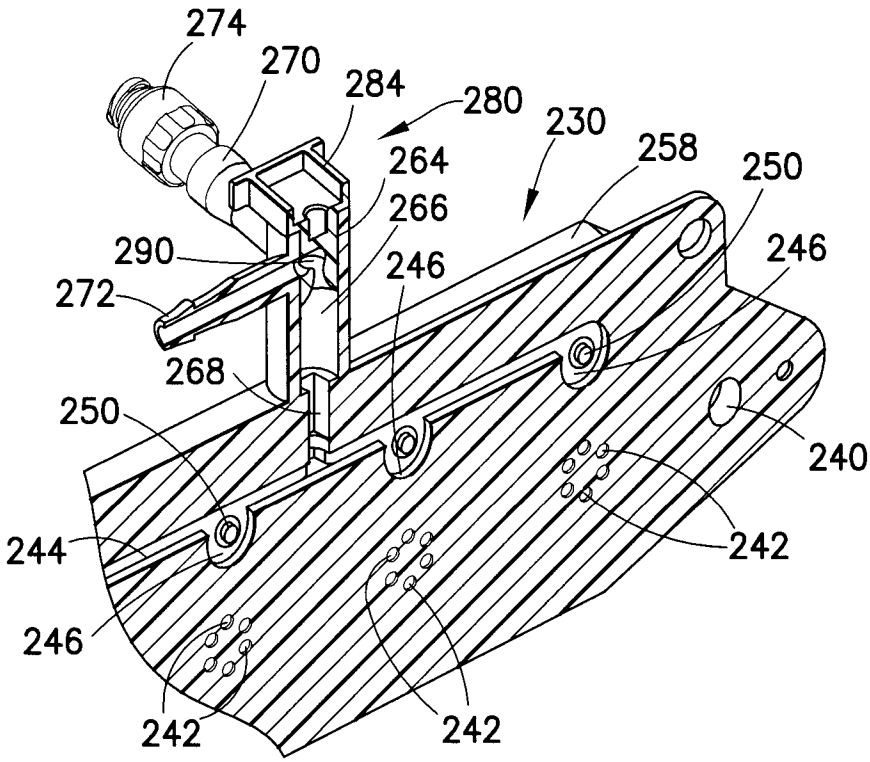
274
270
284
280
230
258
250
264
266
246
290
246
272
268
250
240
244
242
246
242
242

FIG.19

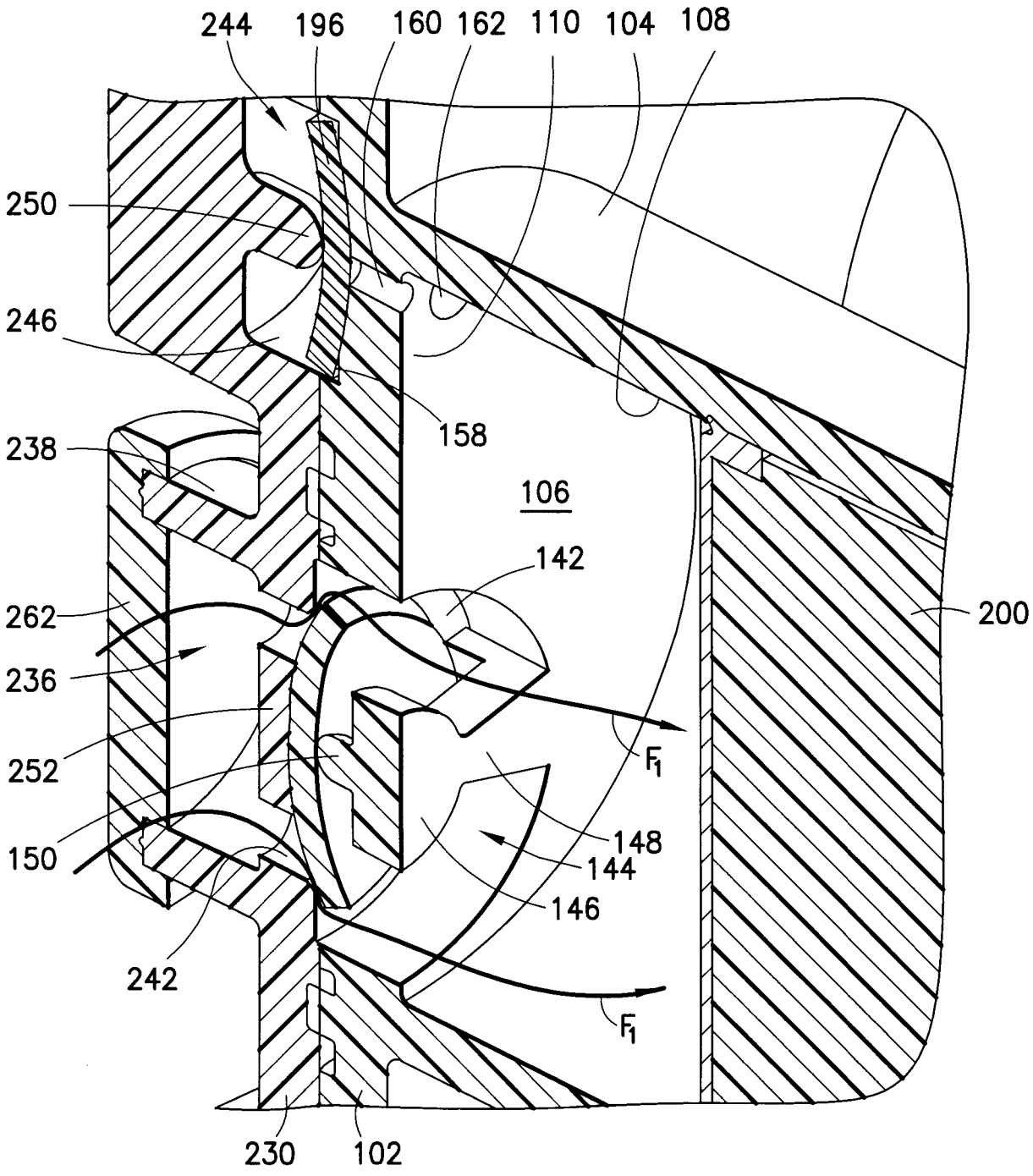
244
196
160
162
110
104
108
250
246
158
238
106
142
262
200
236
252
F_1
148
150
144
146
242
F_1
230
102

FIG.20

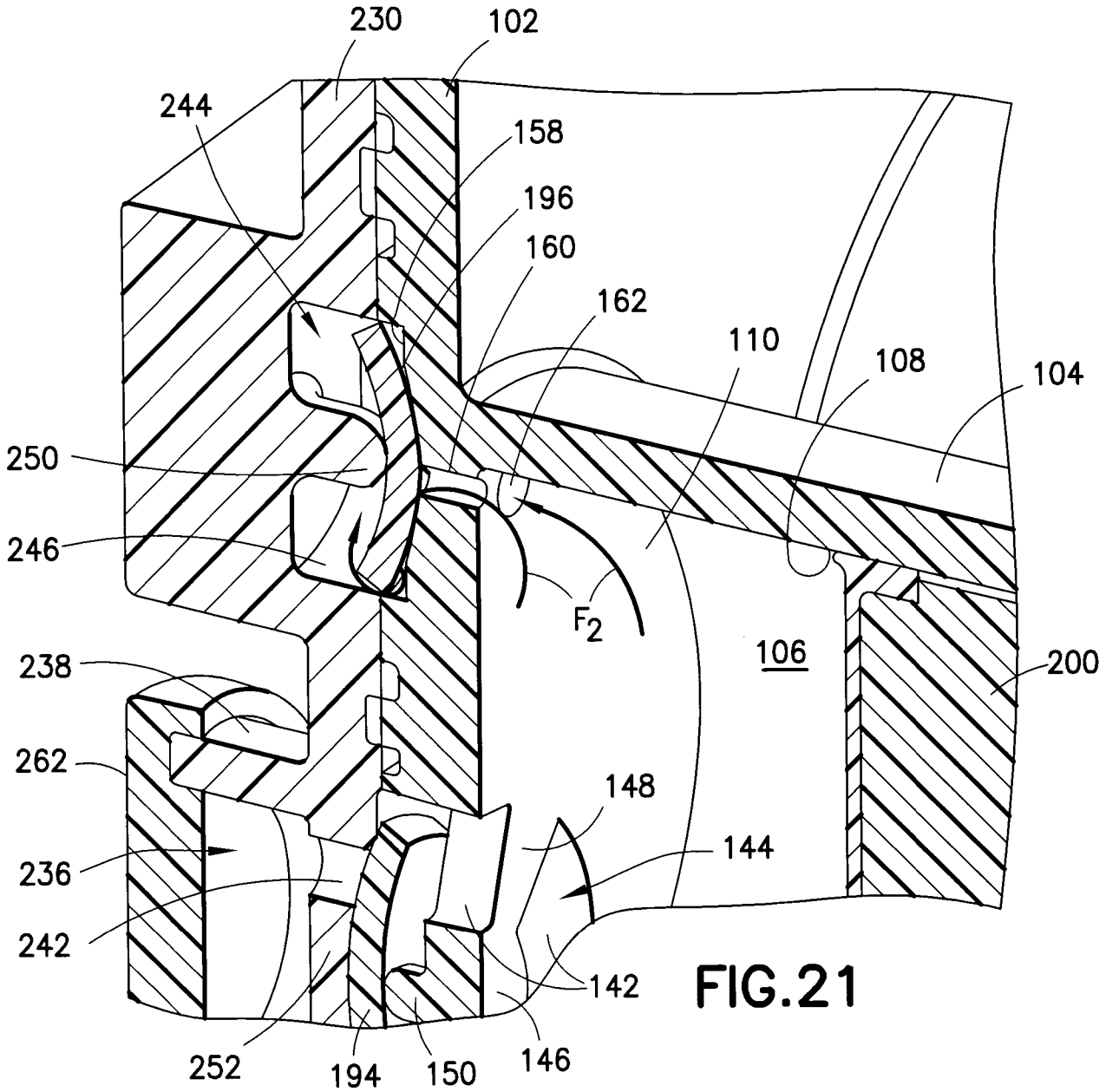
230
102
244
158
196
160
162
110
108
104
250
246
F_2
106
200
238
262
148
144
236
242
142
252
194
150
146

FIG.21

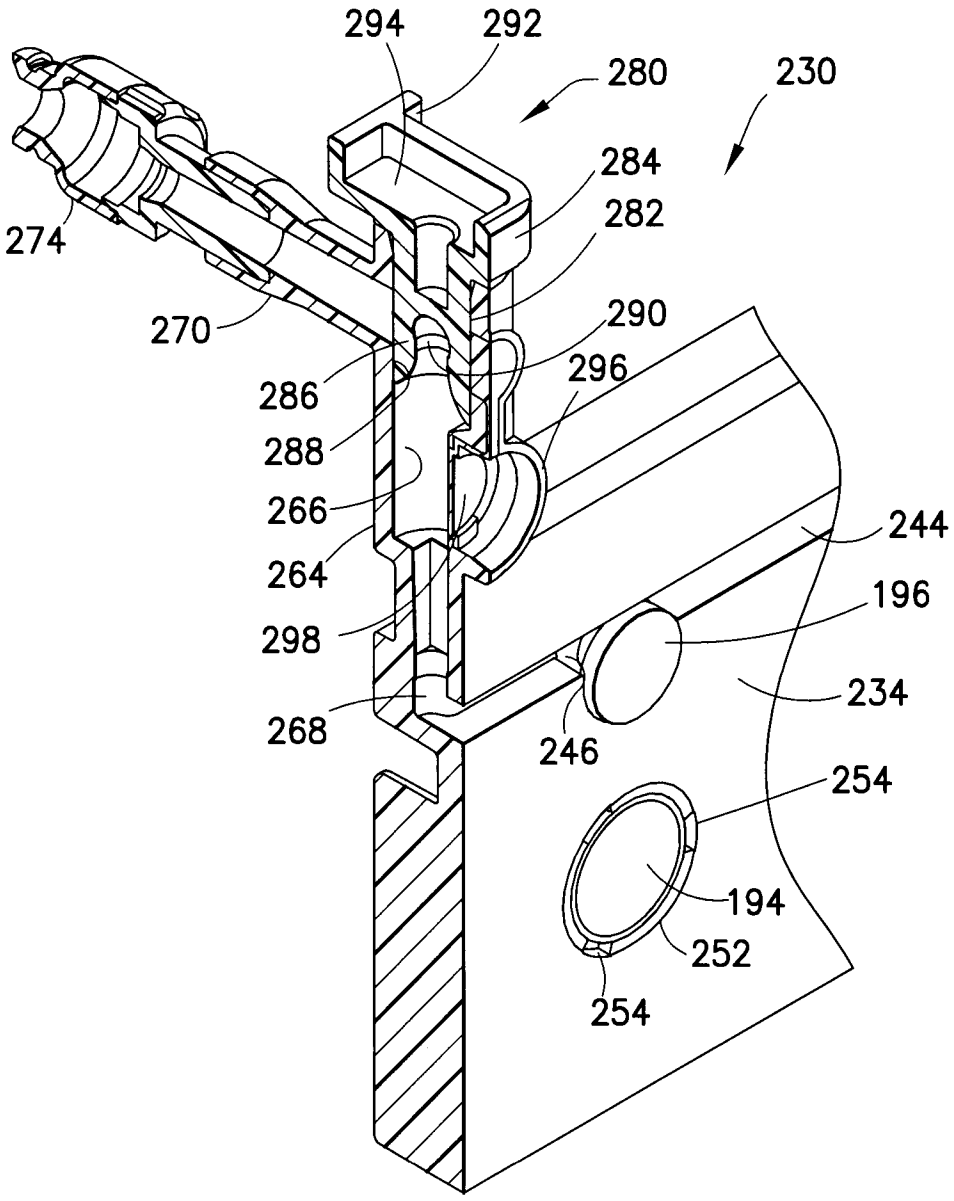
294
292
280
230
284
282
274
290
270
296
286
288
266
244
264
196
298
234
268
246
254
194
252
254

FIG.22

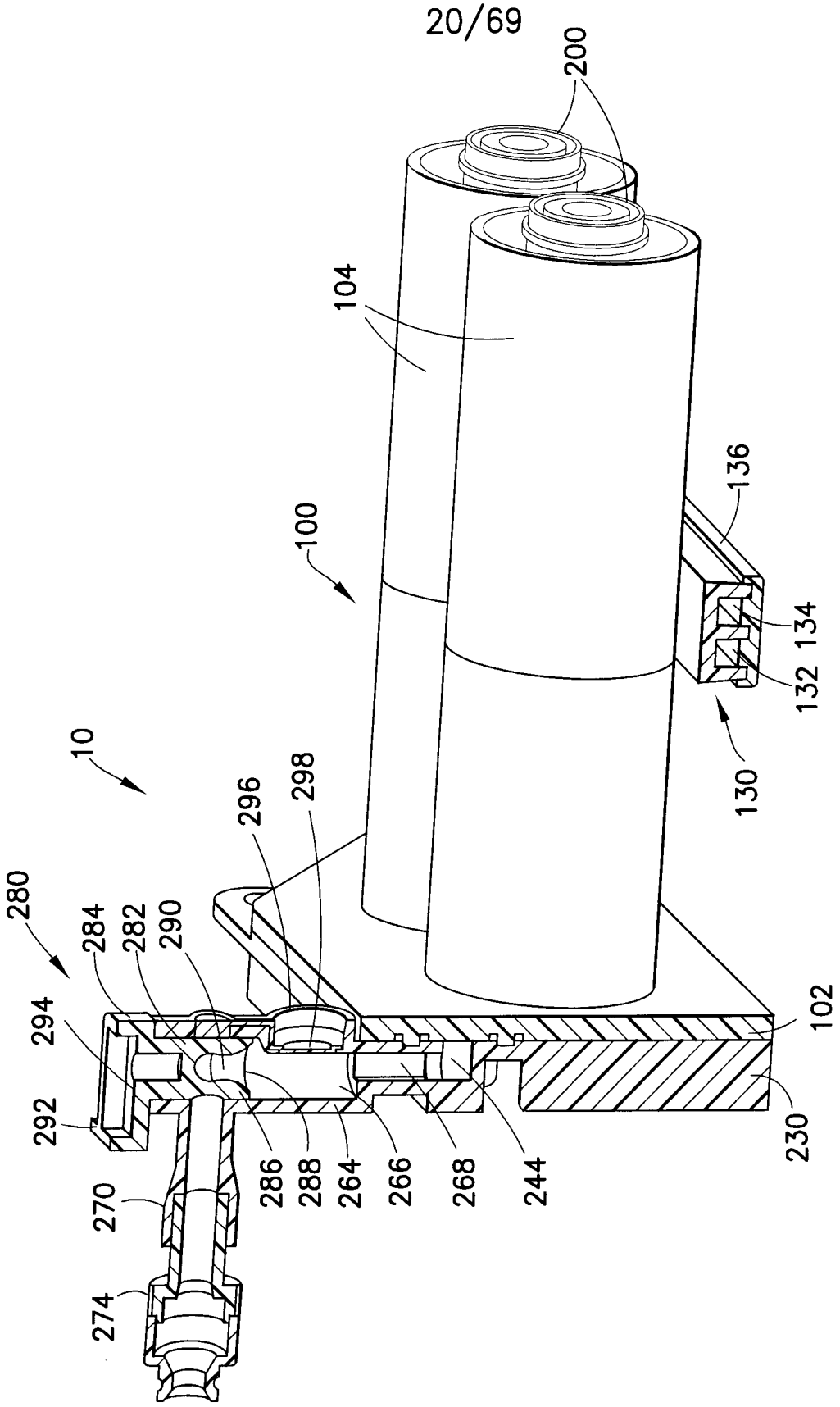
200
104
100
136
134
132
130
10
296
298
280
284
282
290
294
292
102
230
286
288
264
266
268
244
270
274

FIG.23

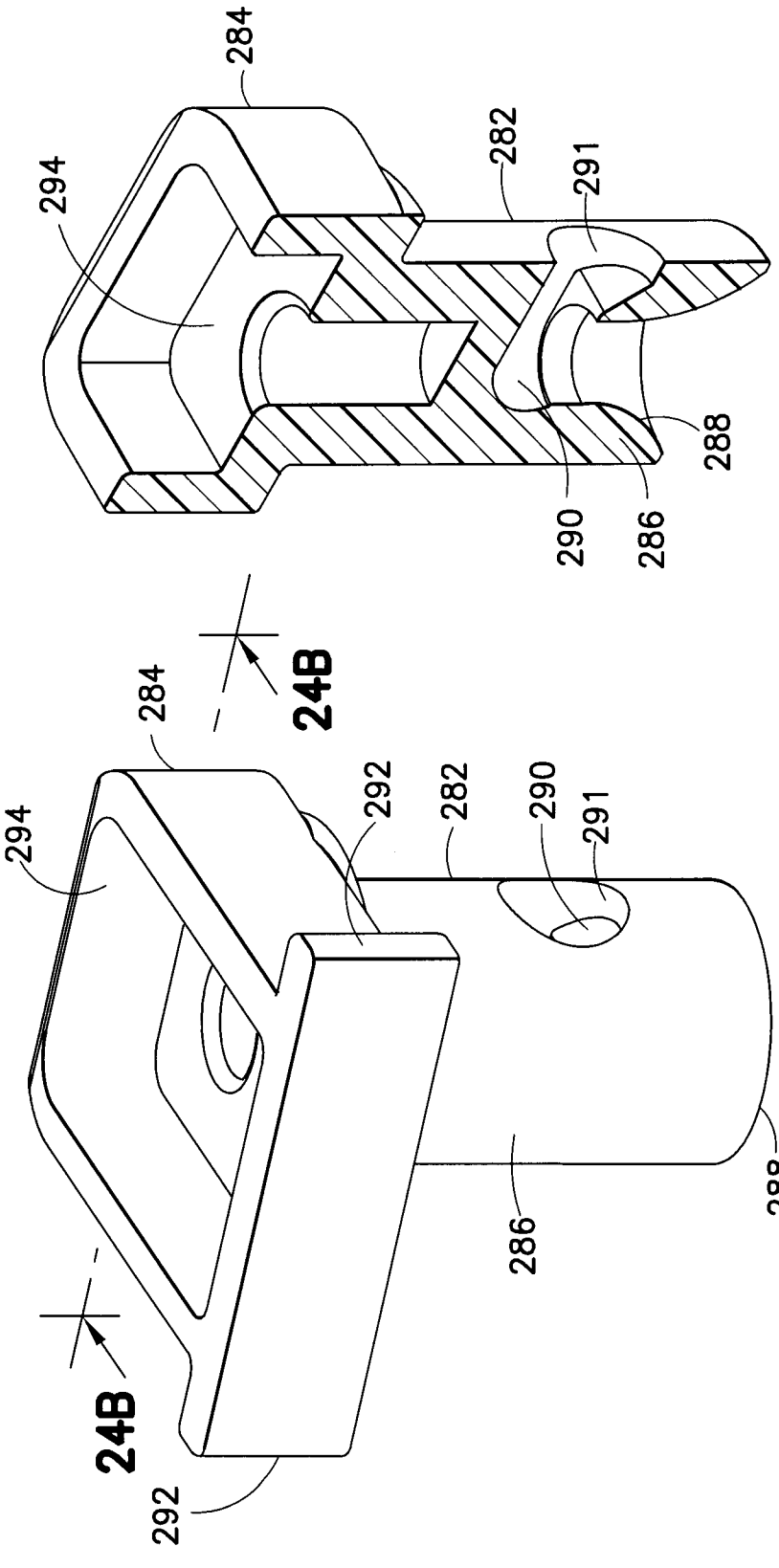

FIG.24B

FIG.24A

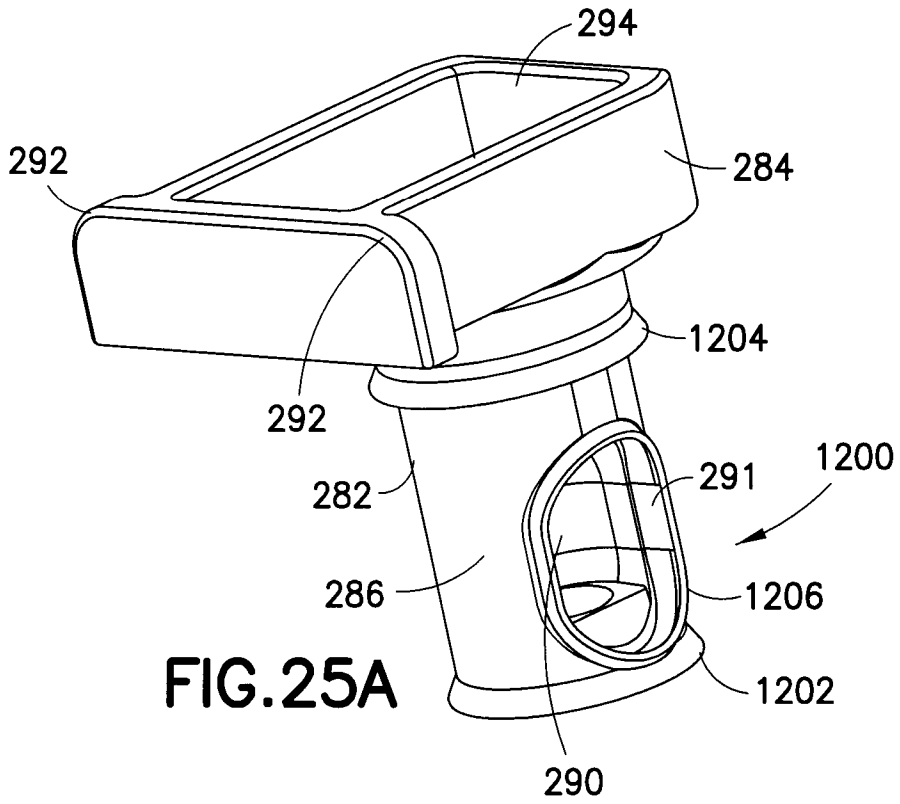

FIG.25A

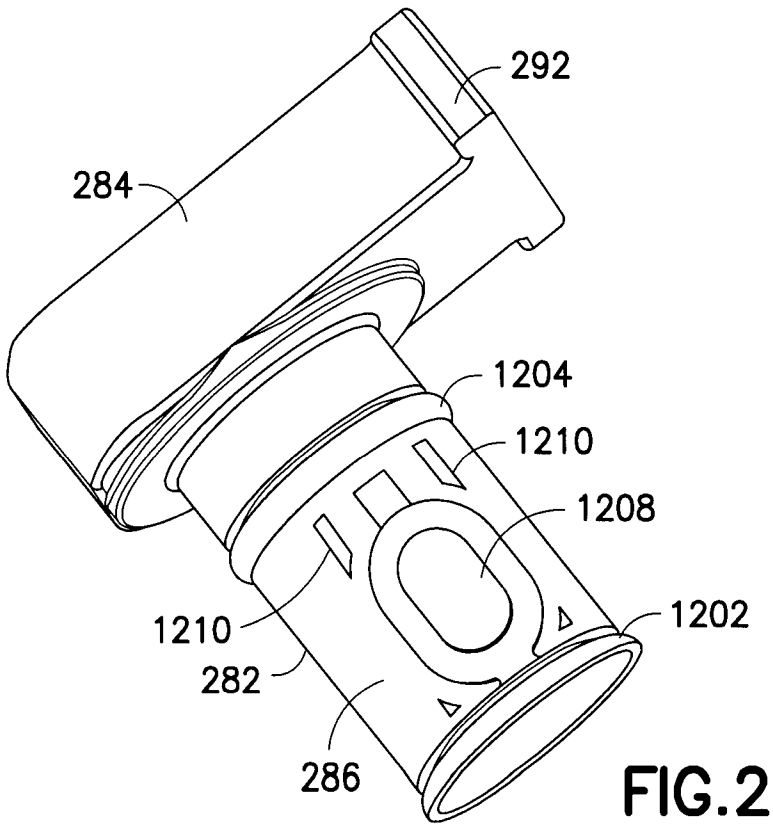

FIG.25B

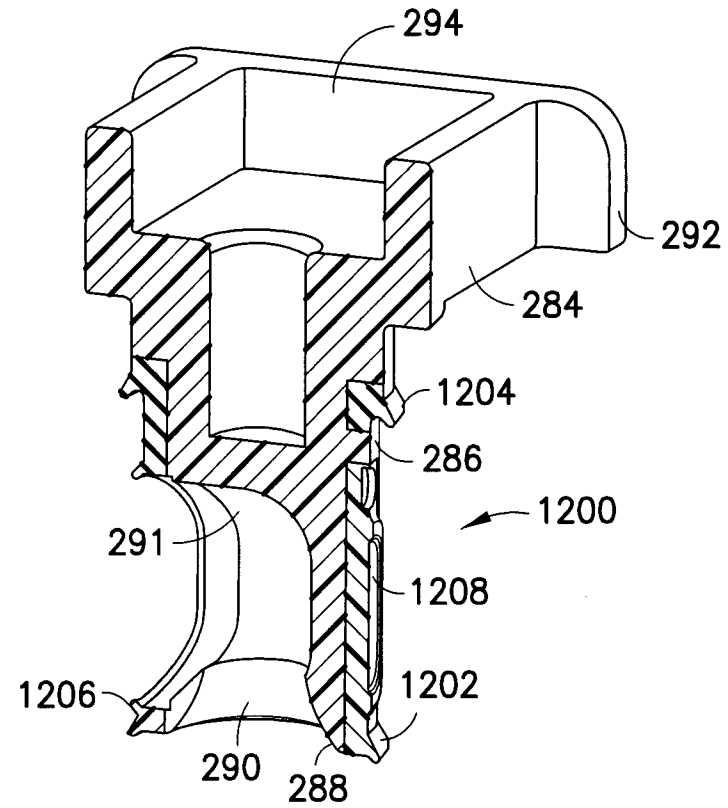

FIG.25C

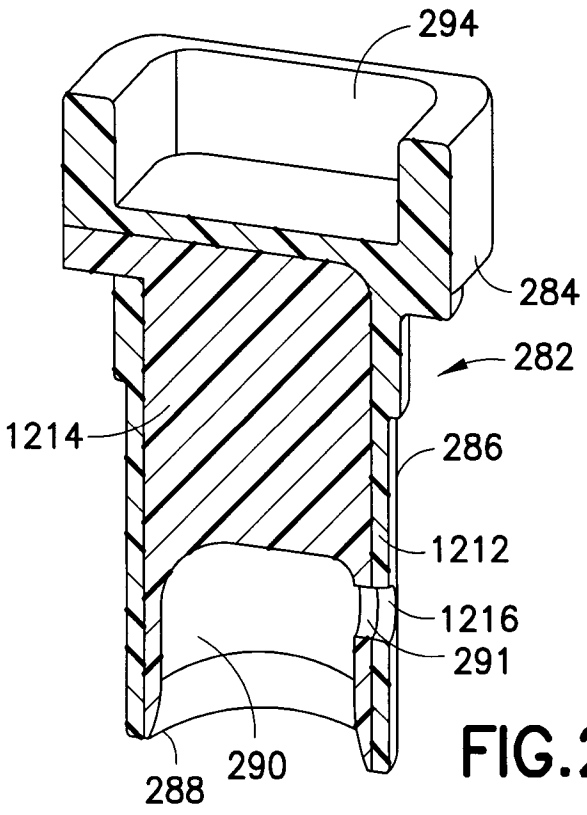

FIG.25D

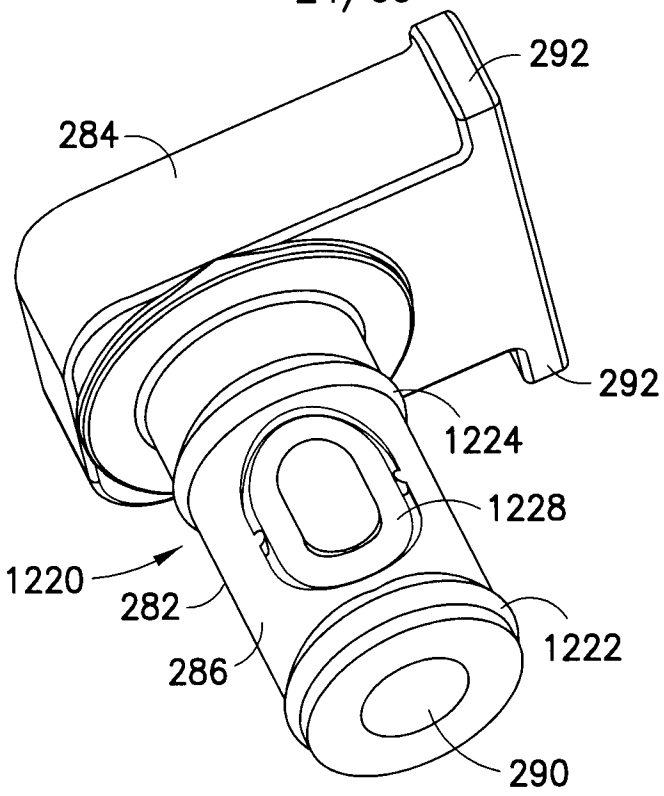

FIG.25E

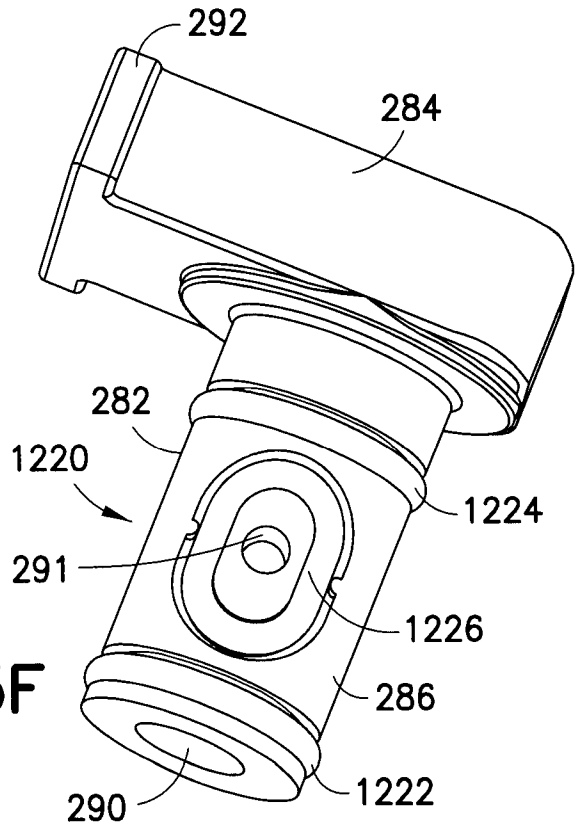

FIG.25F

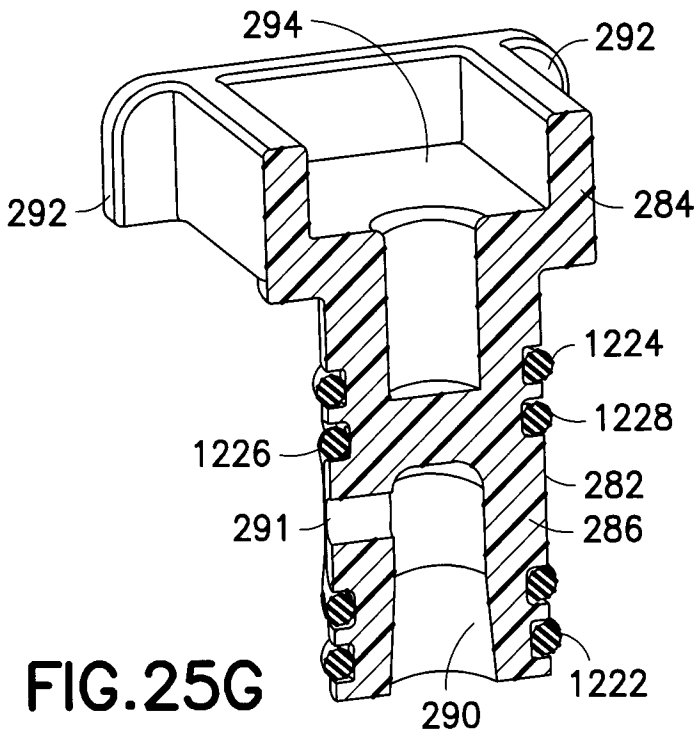

FIG.25G

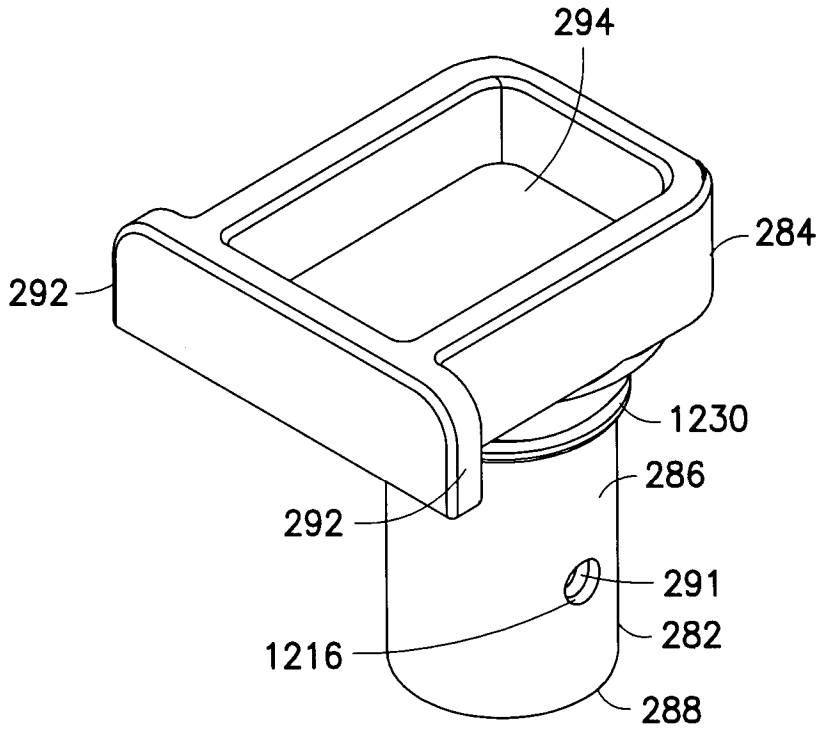

FIG.25H

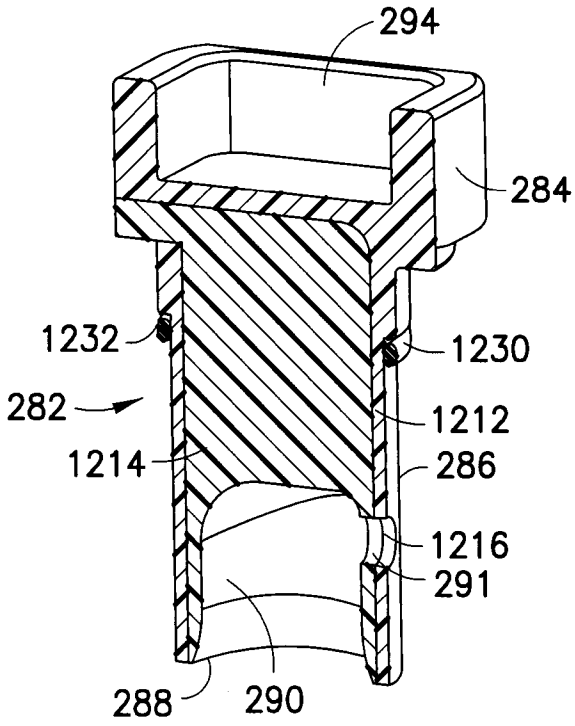

FIG.25I

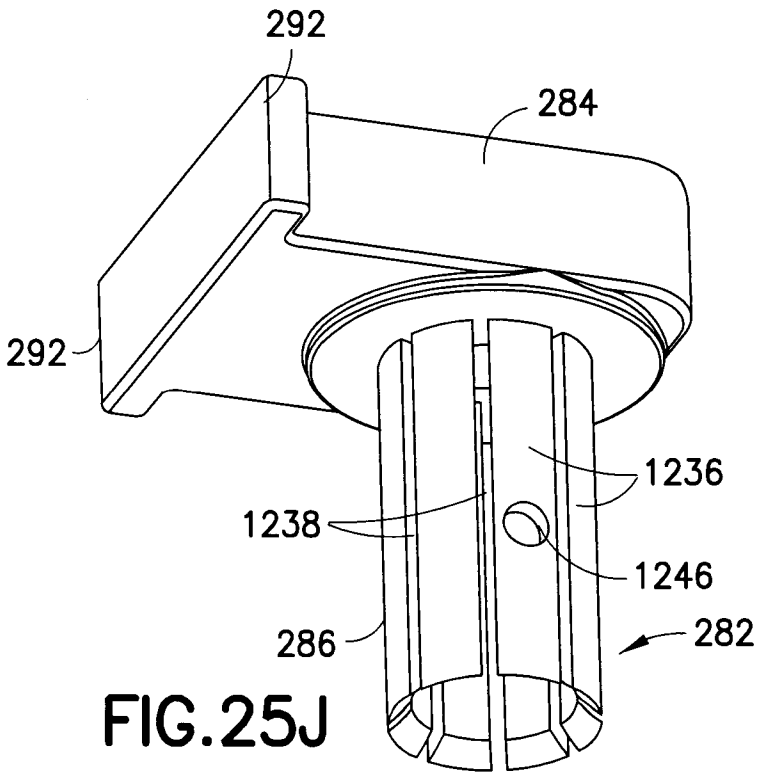

FIG.25J

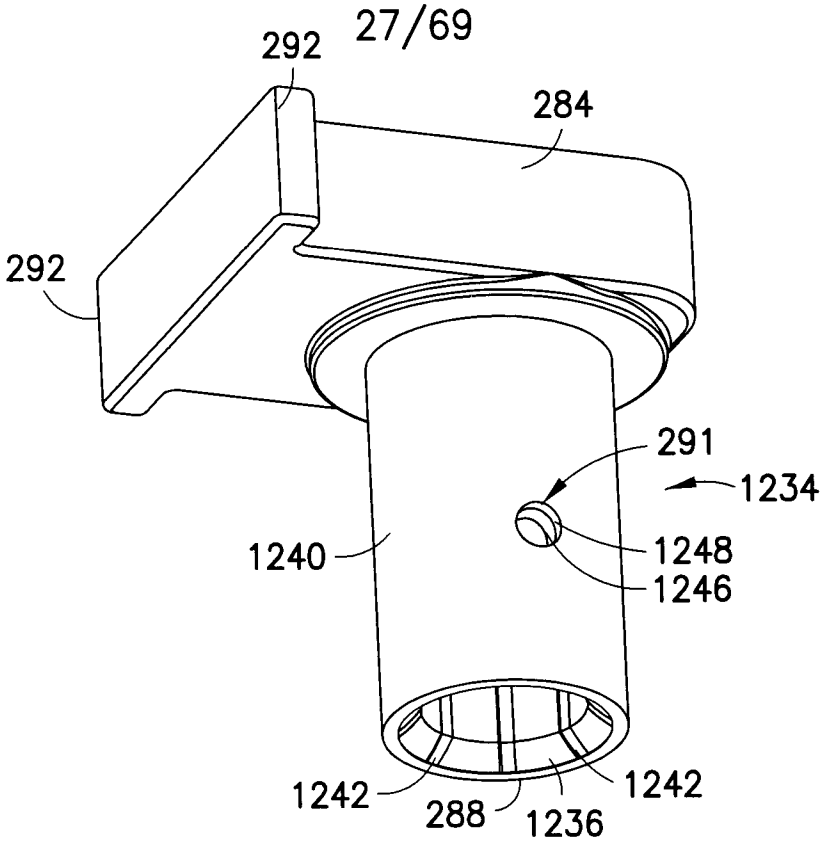

FIG.25K

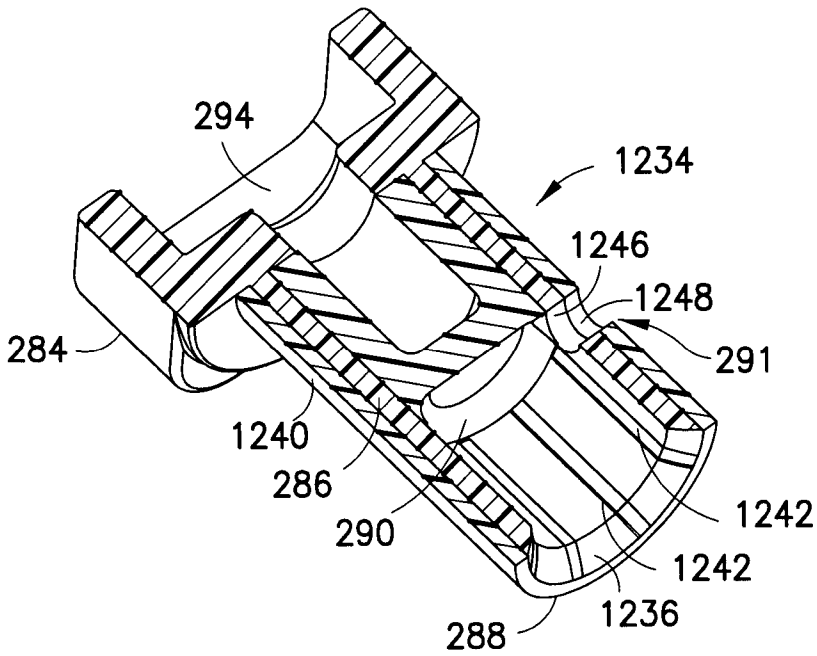

FIG.25L

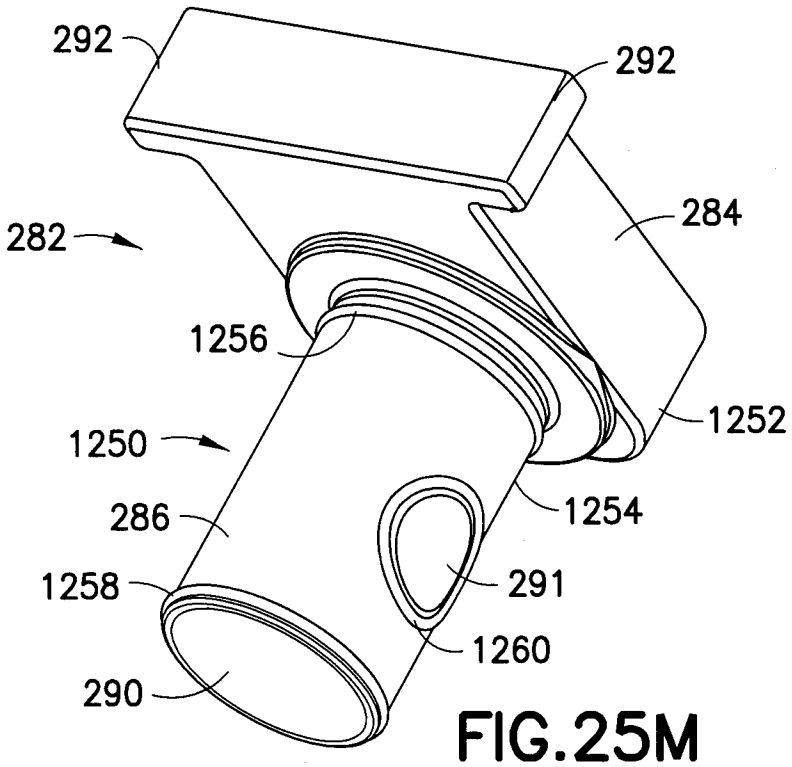

FIG.25M

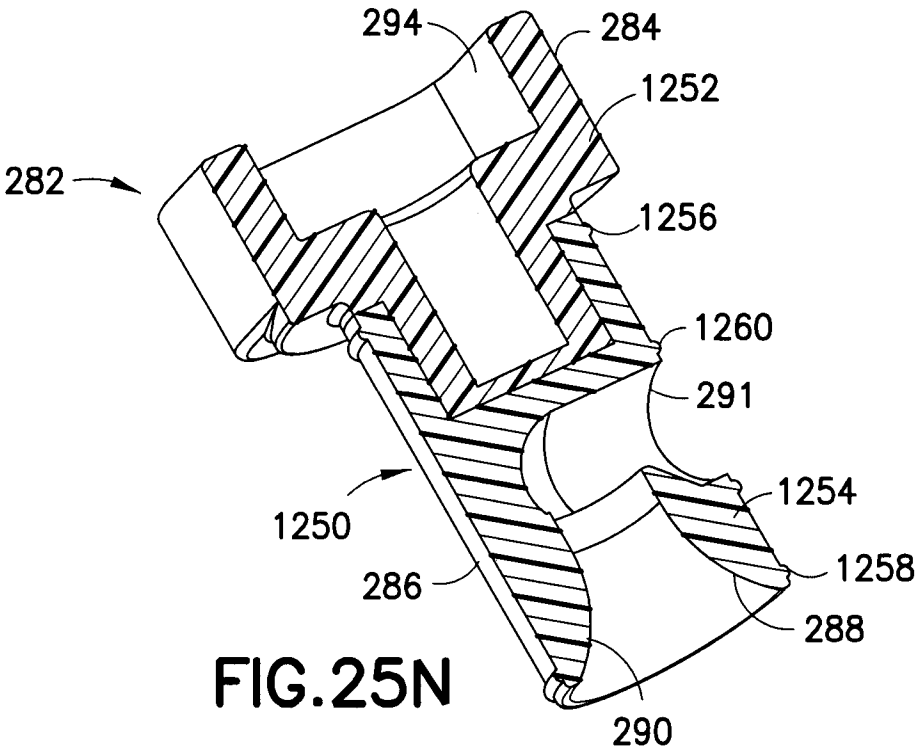

FIG.25N

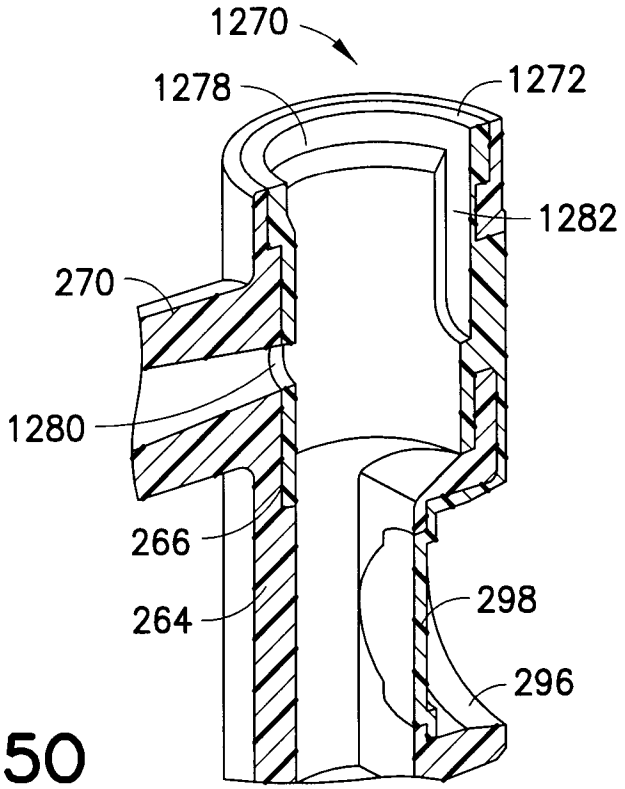

FIG.25O

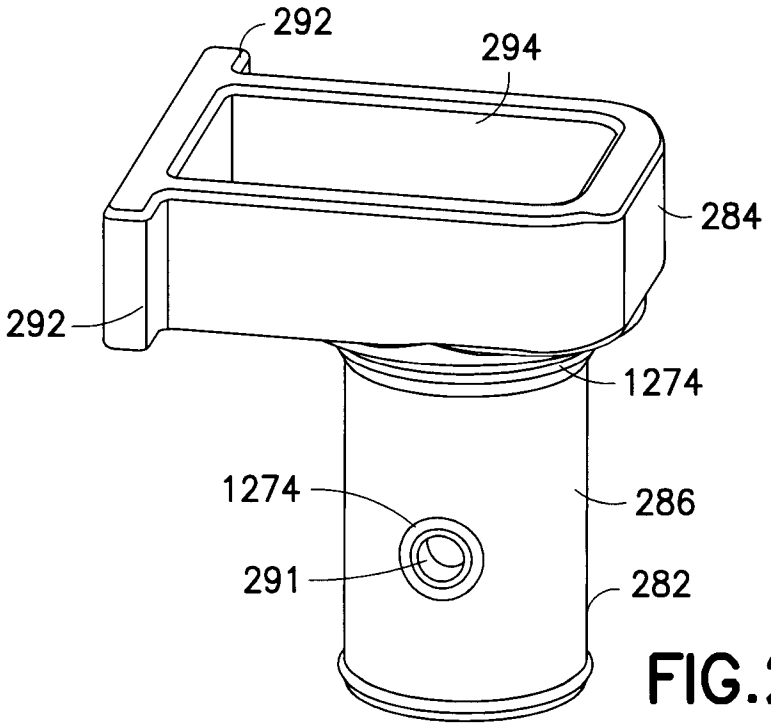

FIG.25P

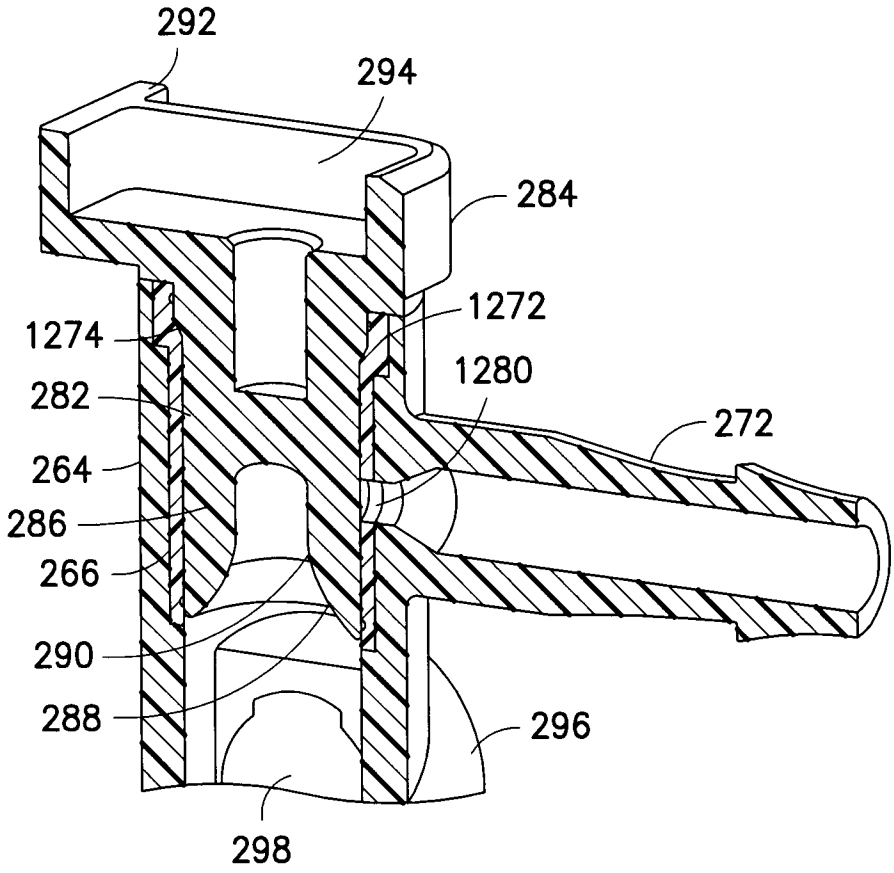

FIG.25Q

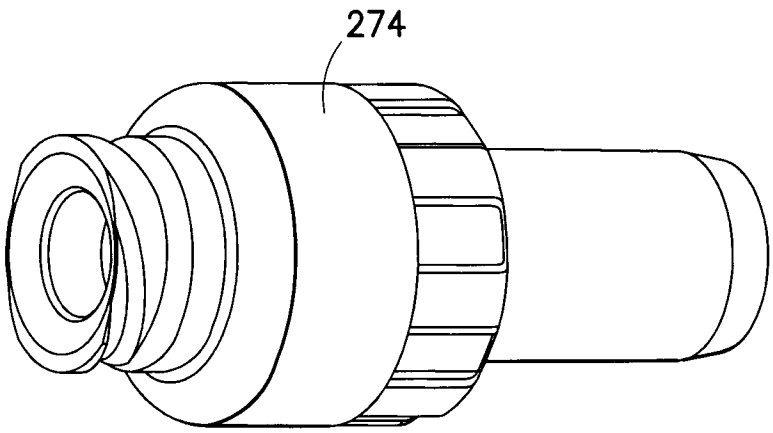

FIG.26

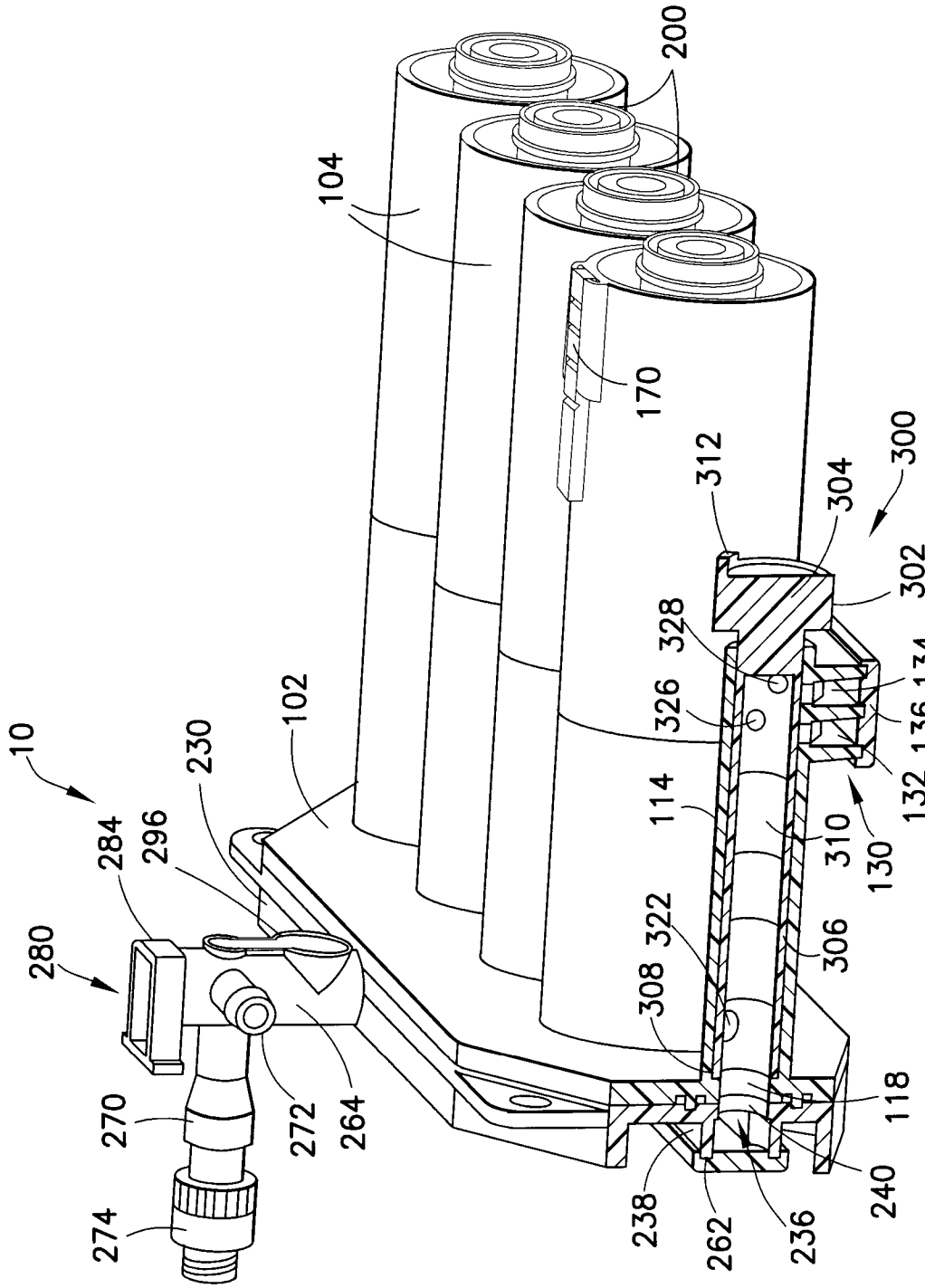
200
104
170
312
304
300
302
328
134
326
136
102
230
132
10
114
310
130
284
296
280
322
306
308
270
272
264
118
274
238
262
236
240

FIG.27

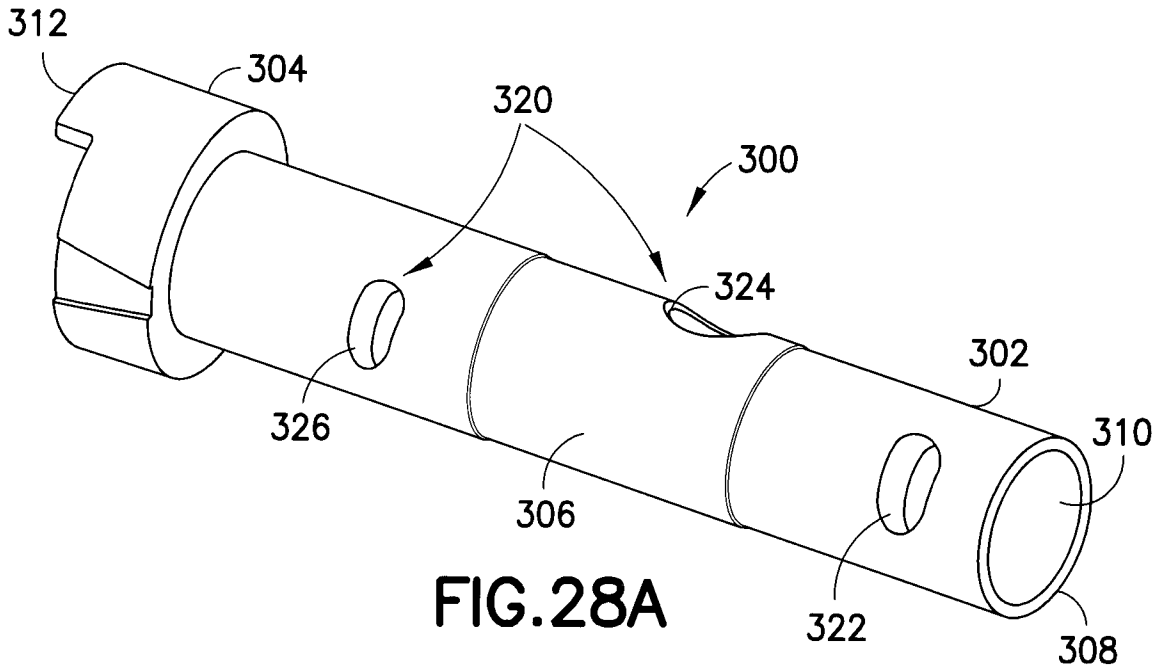

FIG.28A

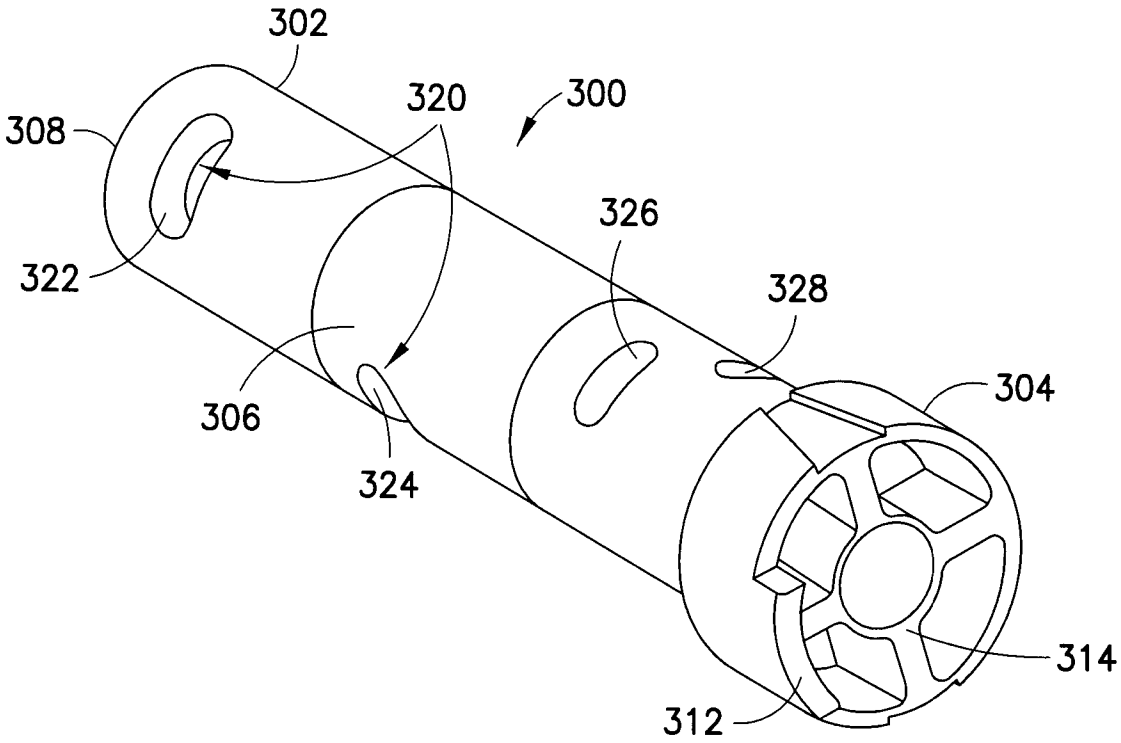

FIG.28B

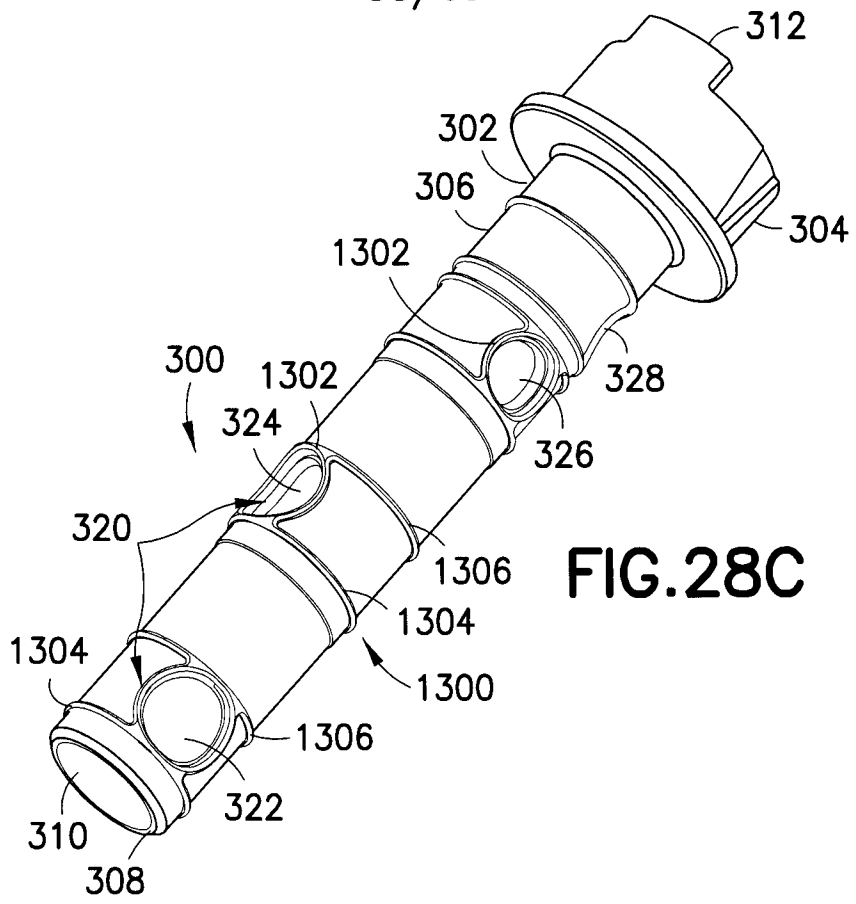

FIG.28C

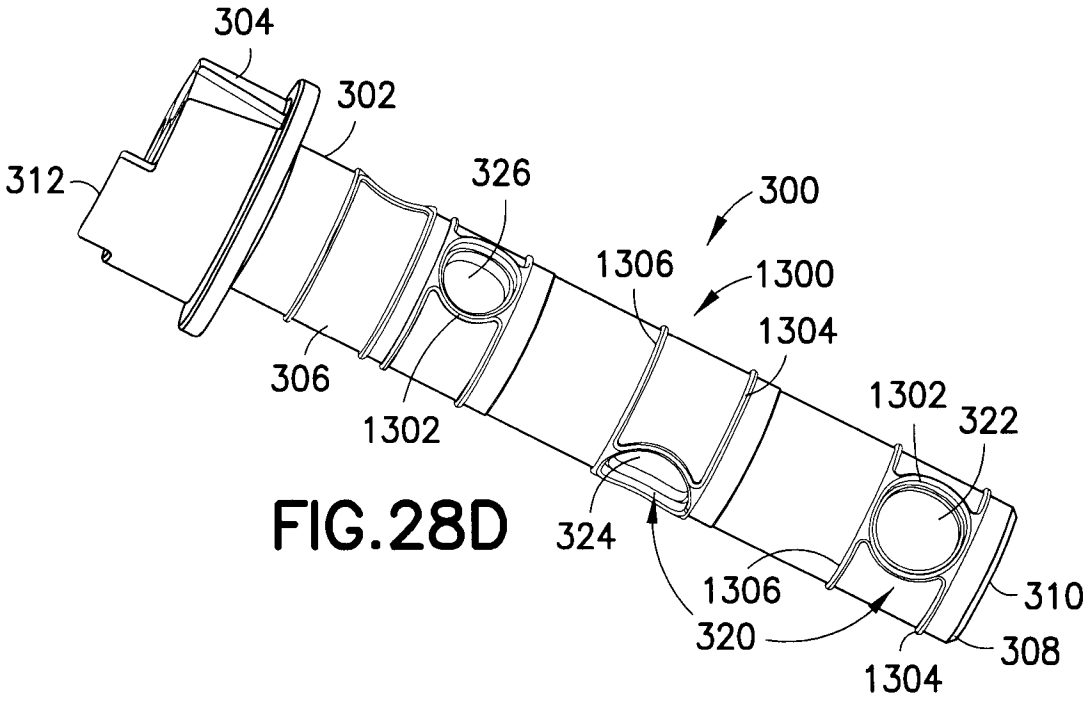

FIG.28D

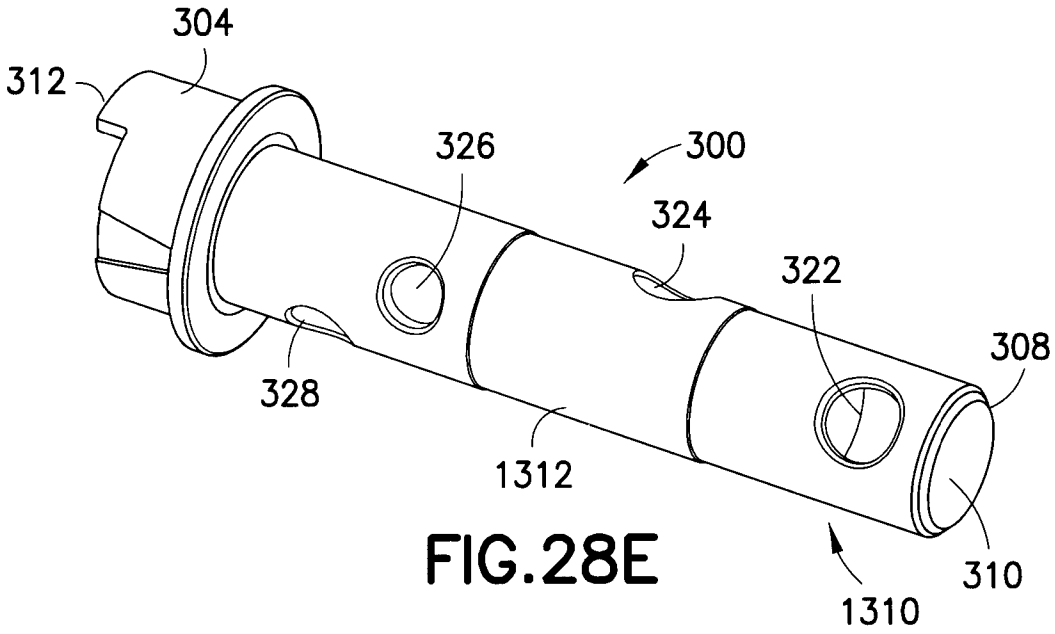

FIG.28E

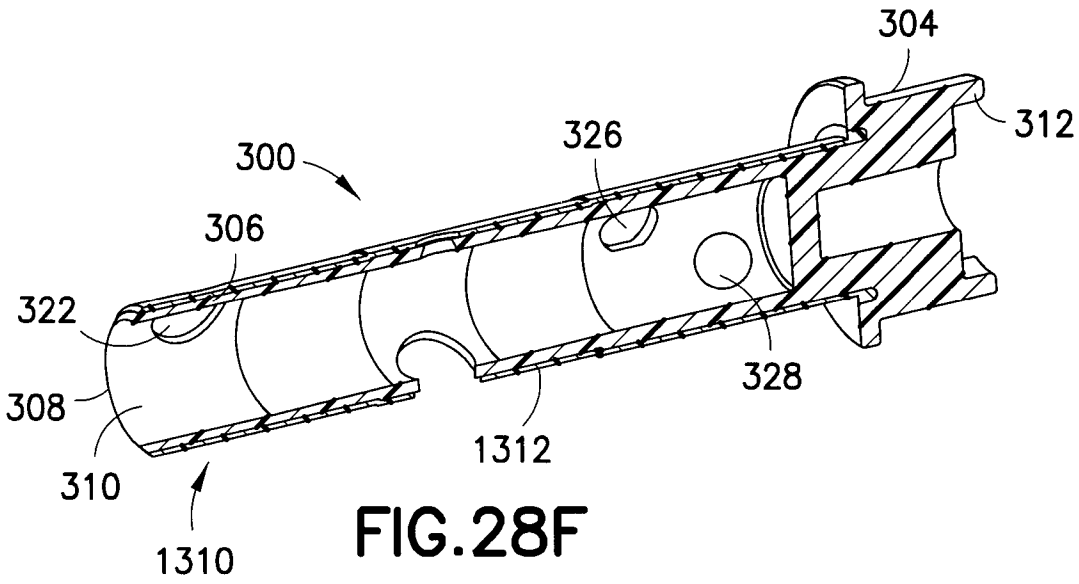

FIG.28F

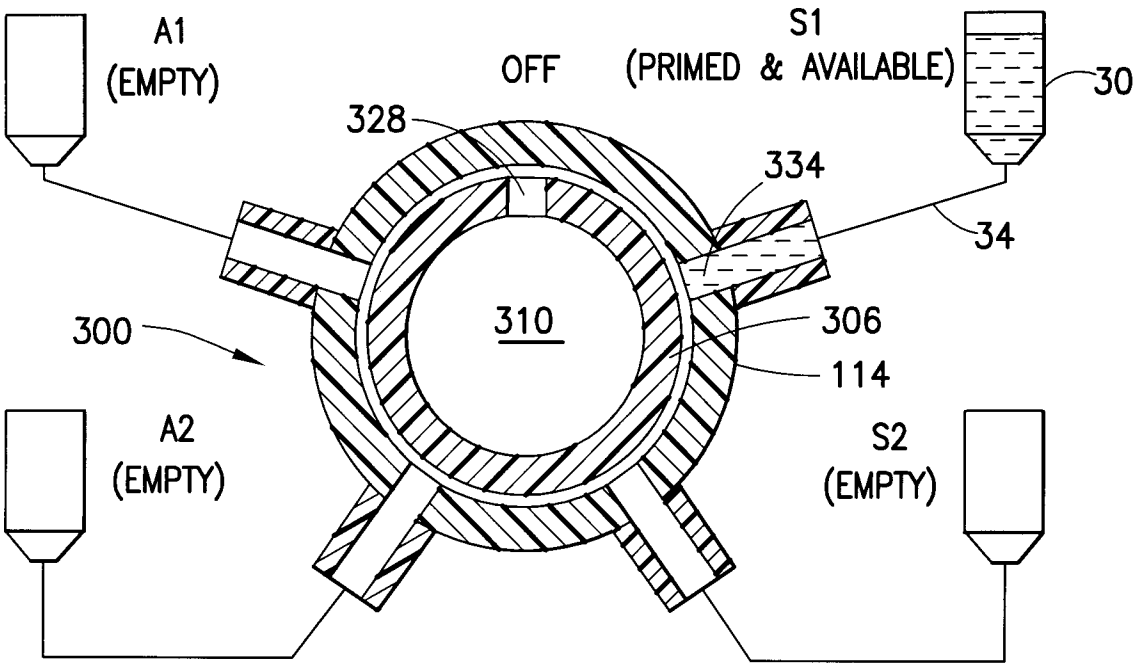

FIG.29A

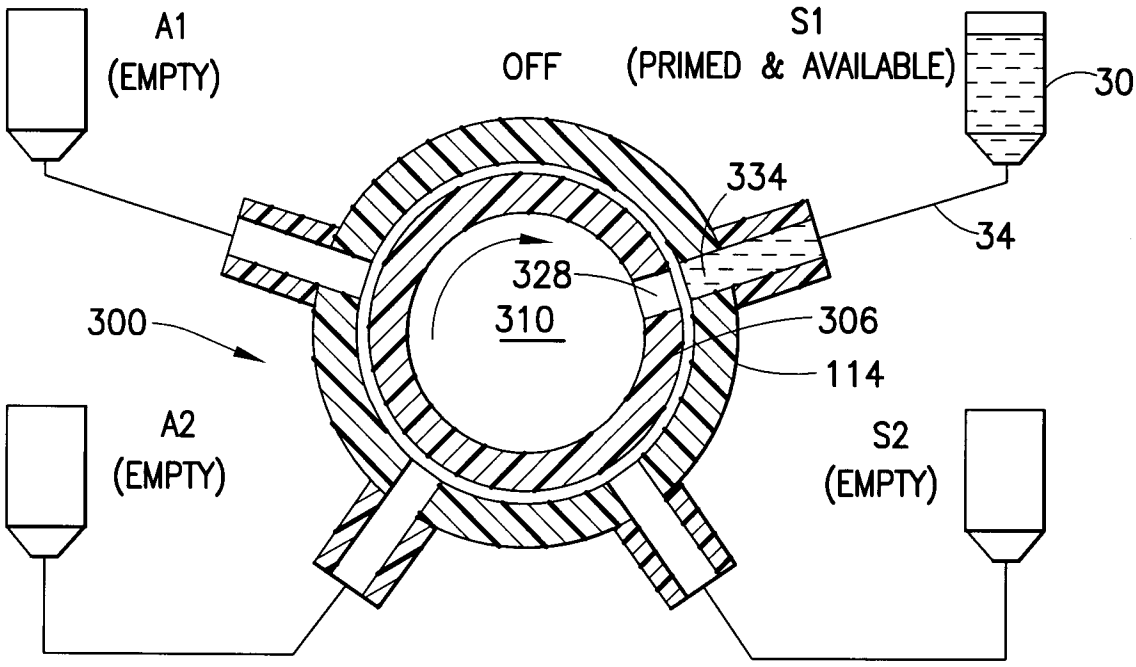

FIG.29B

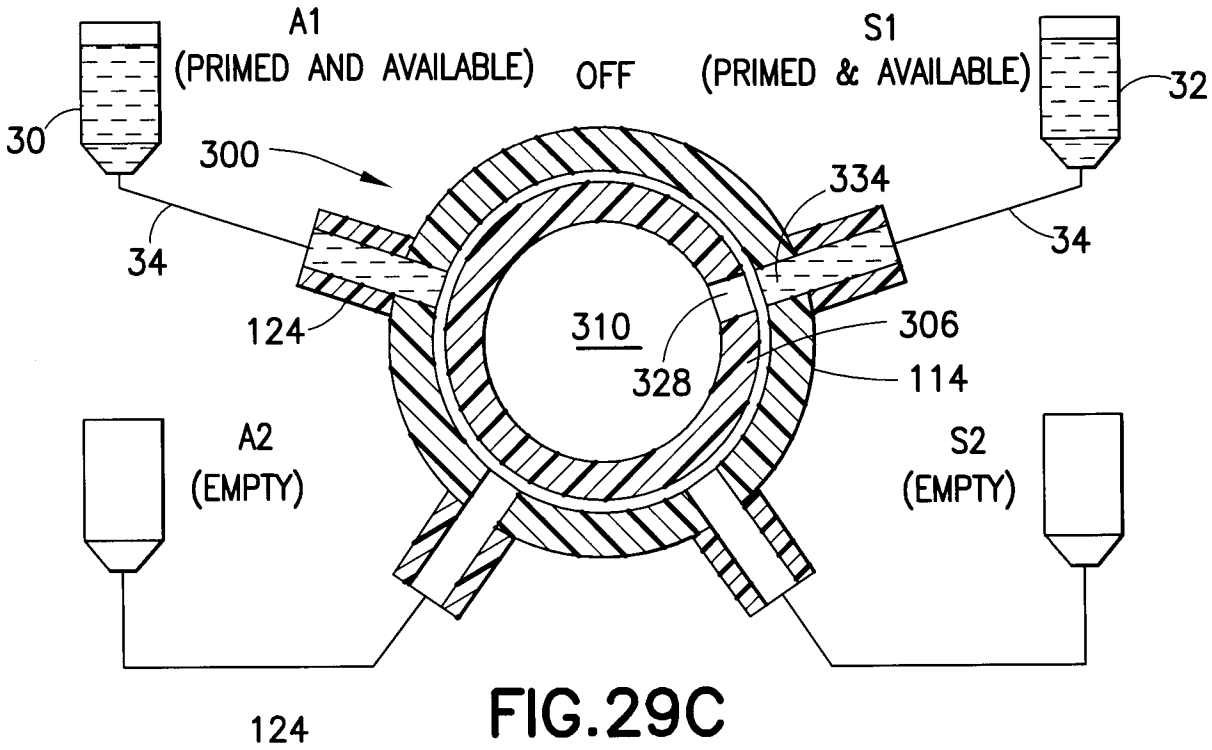

FIG.29C

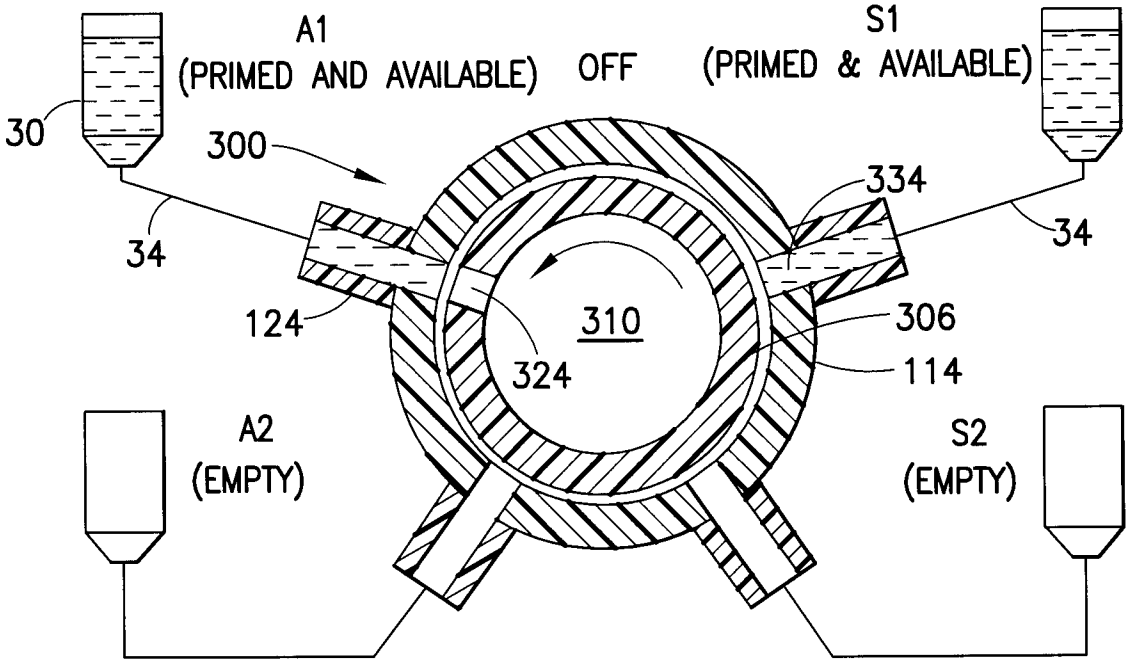

FIG.29D

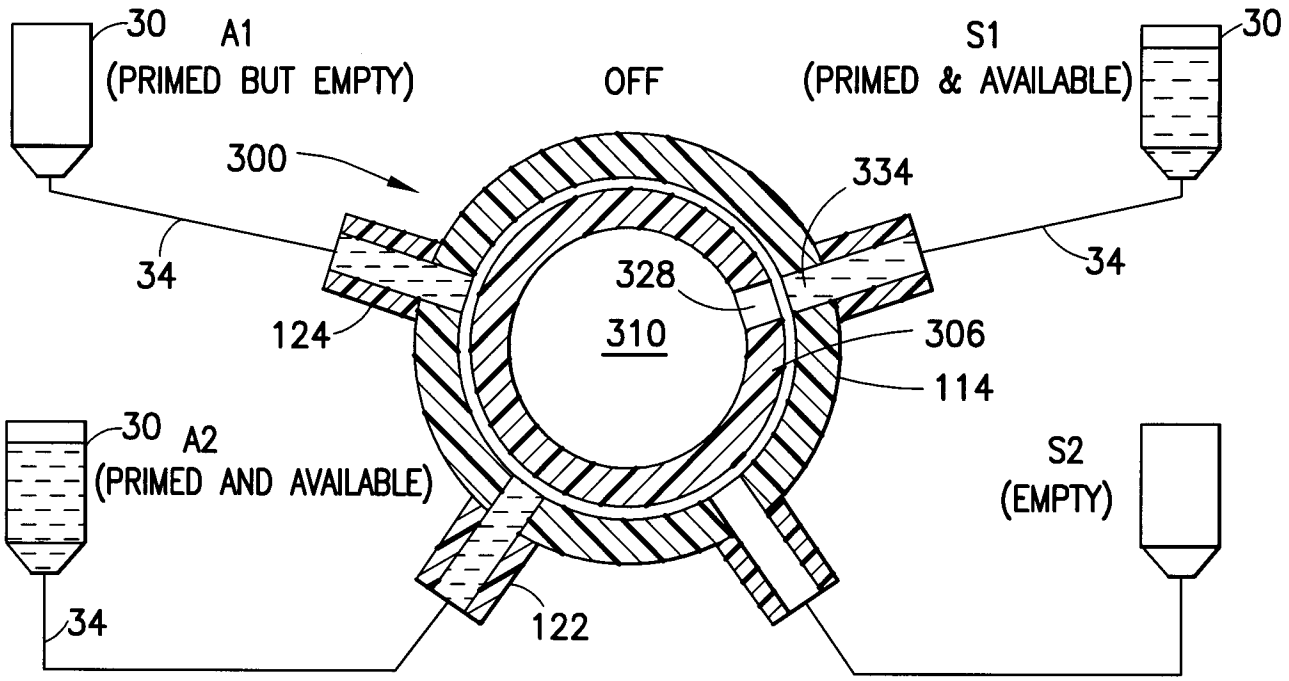

FIG.29E

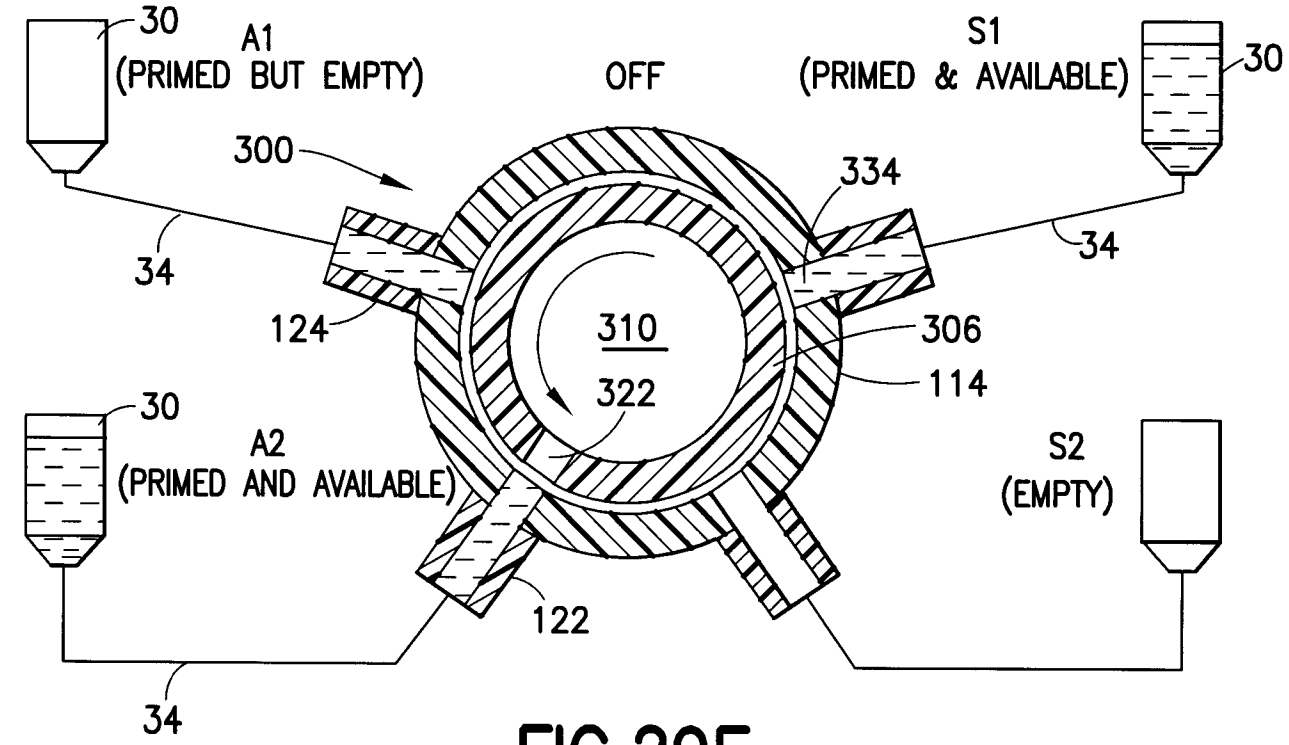

FIG.29F

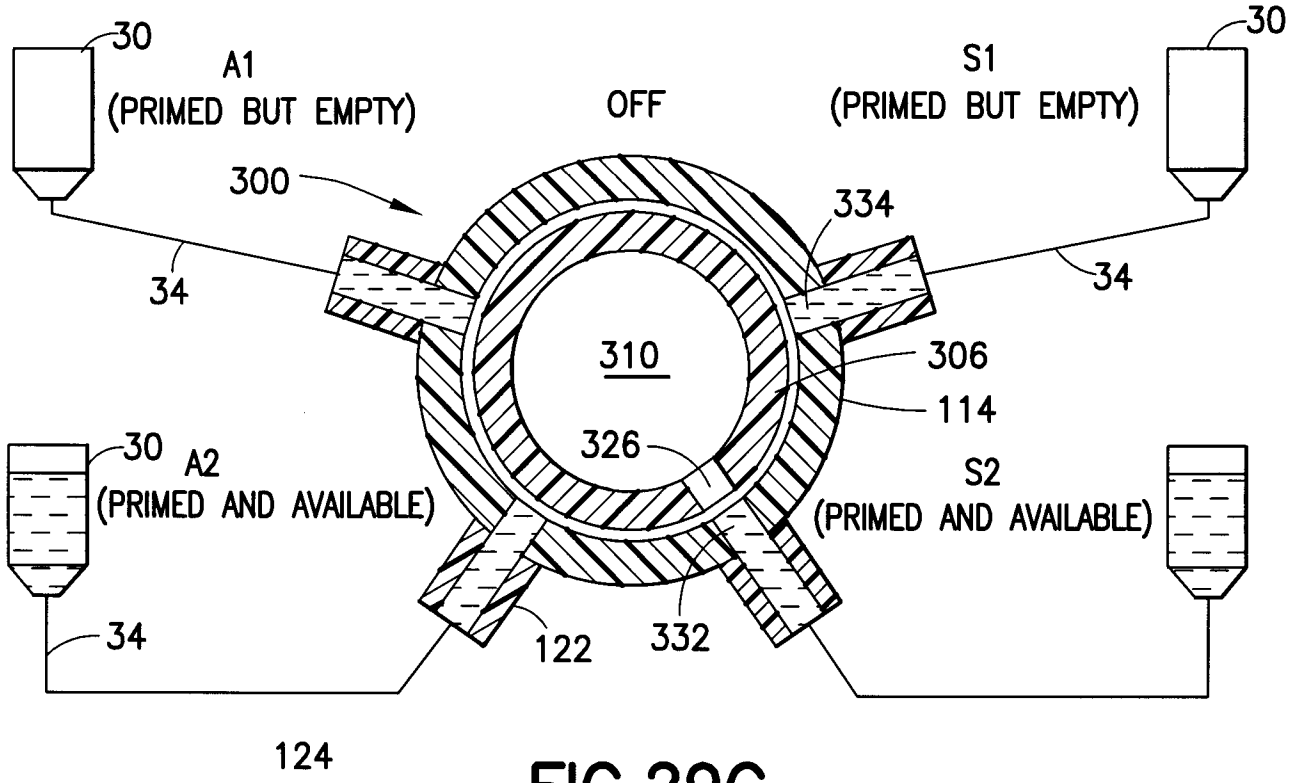

FIG.29G

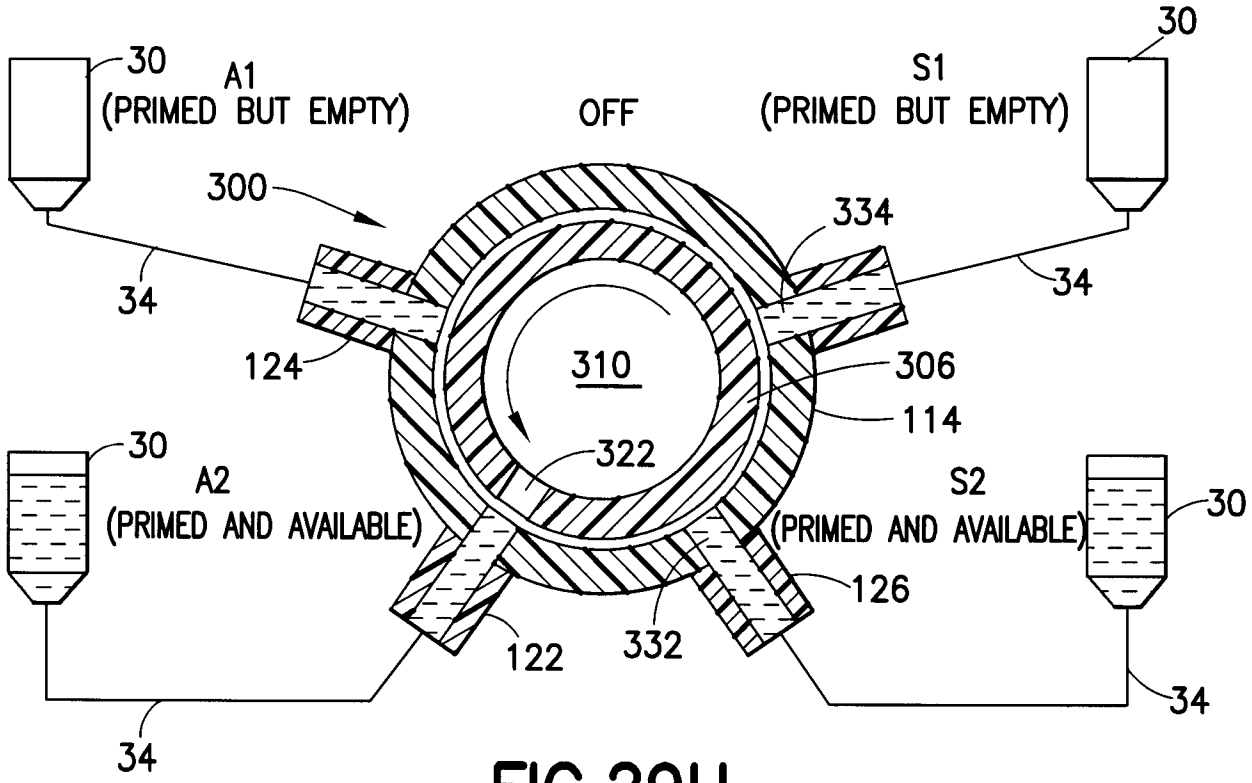

FIG.29H

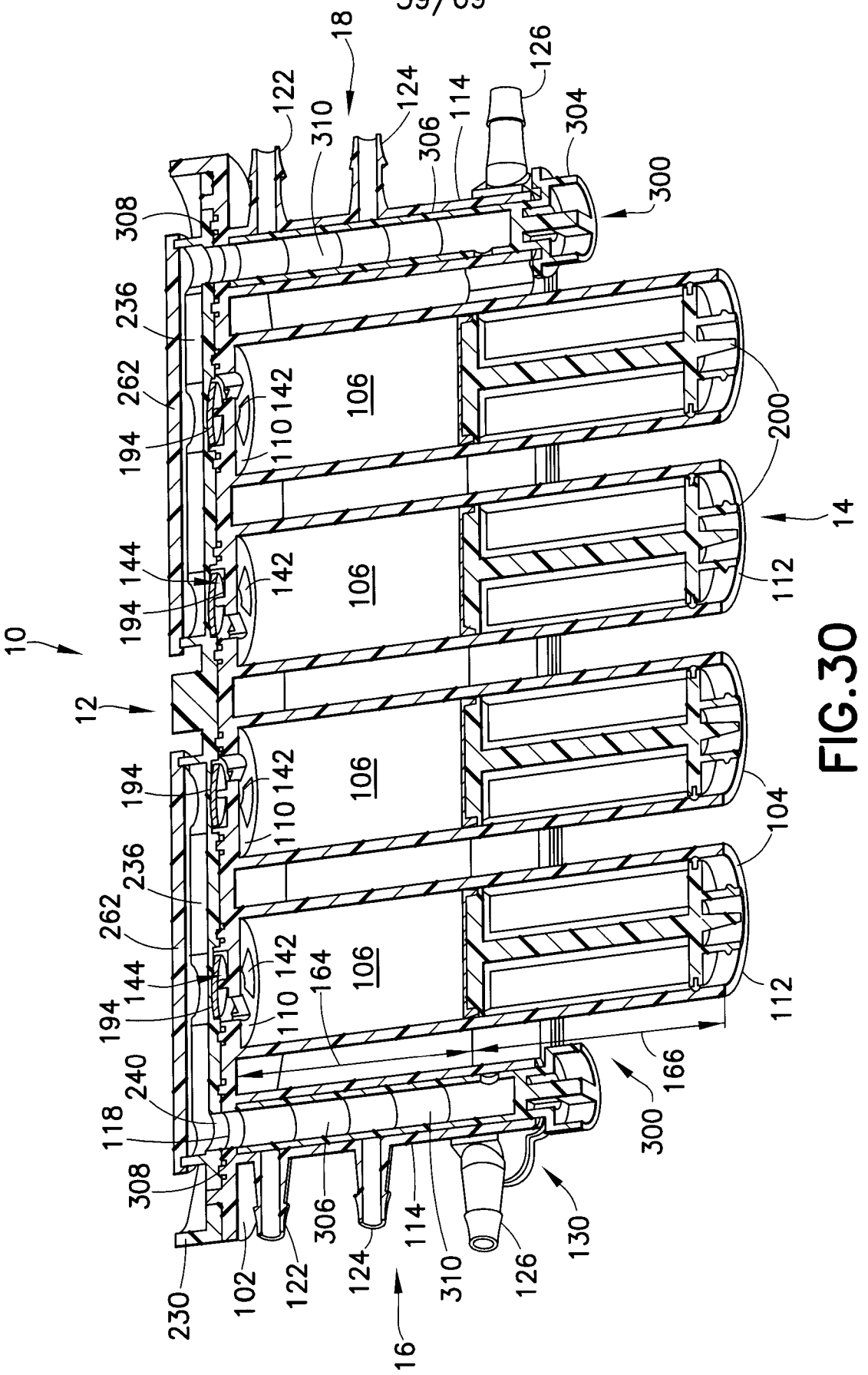
10
12
14
16
18
102
104
106
110
112
114
118
122
124
126
130
142
144
164
166
194
200
230
236
240
262
300
304
306
308
310

FIG.30

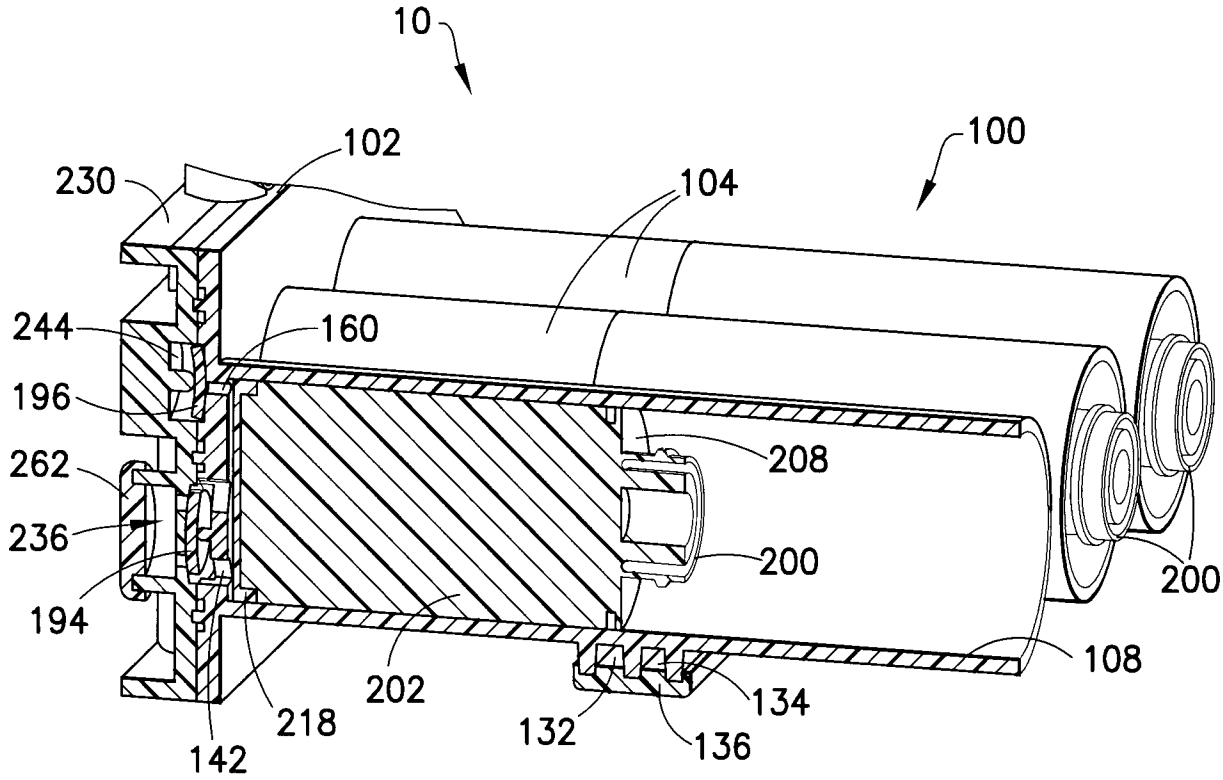
10
100
102
230
104
244
160
196
208
262
200
236
200
194
108
202
134
218
132
142
136

FIG.31

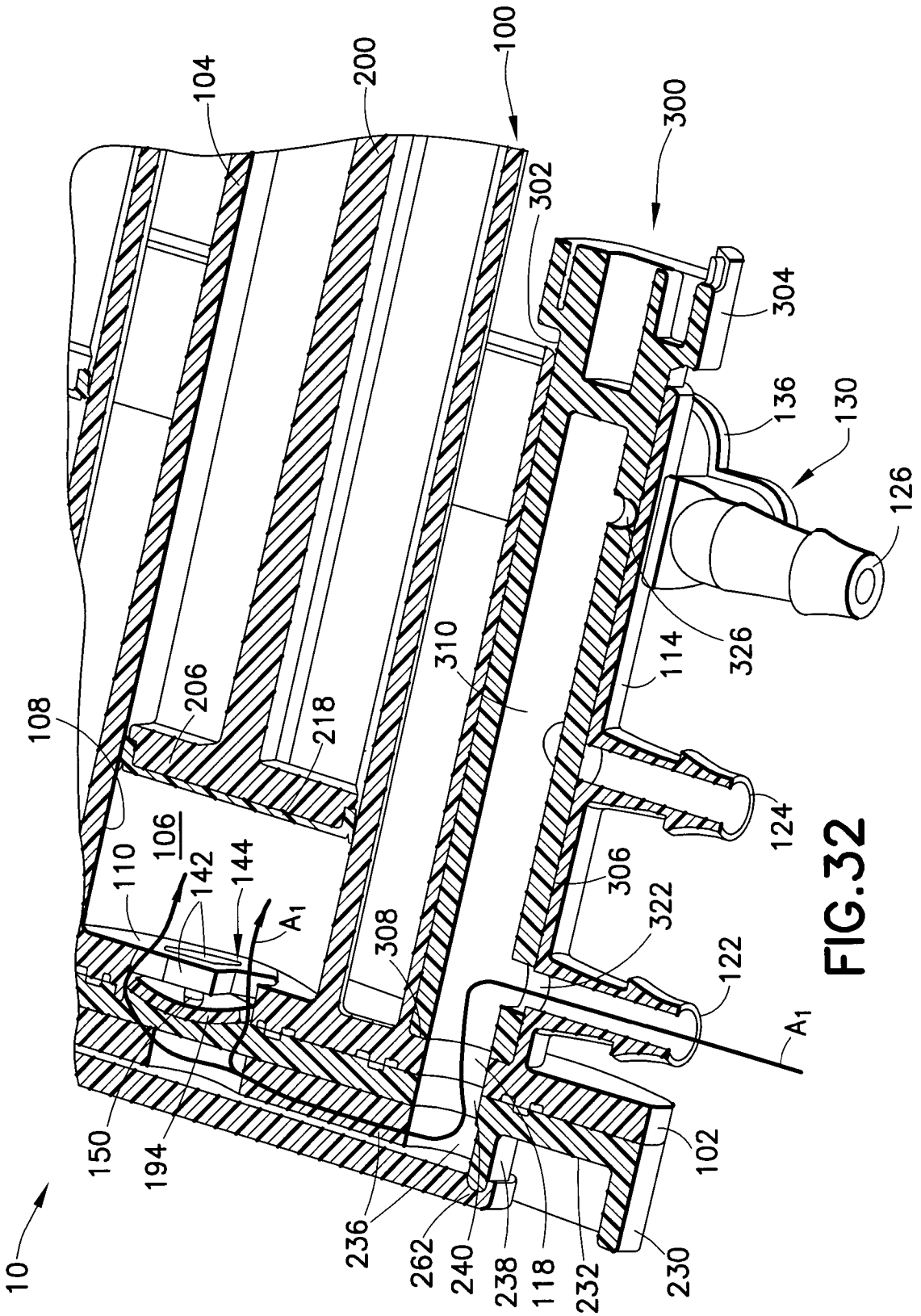
10
104
200
100
300
302
304
136
130
126
326
114
310
108
206
218
106
110
142
144
A_1
308
306
322
122
124
150
194
236
262
240
238
118
232
230
102

FIG.32

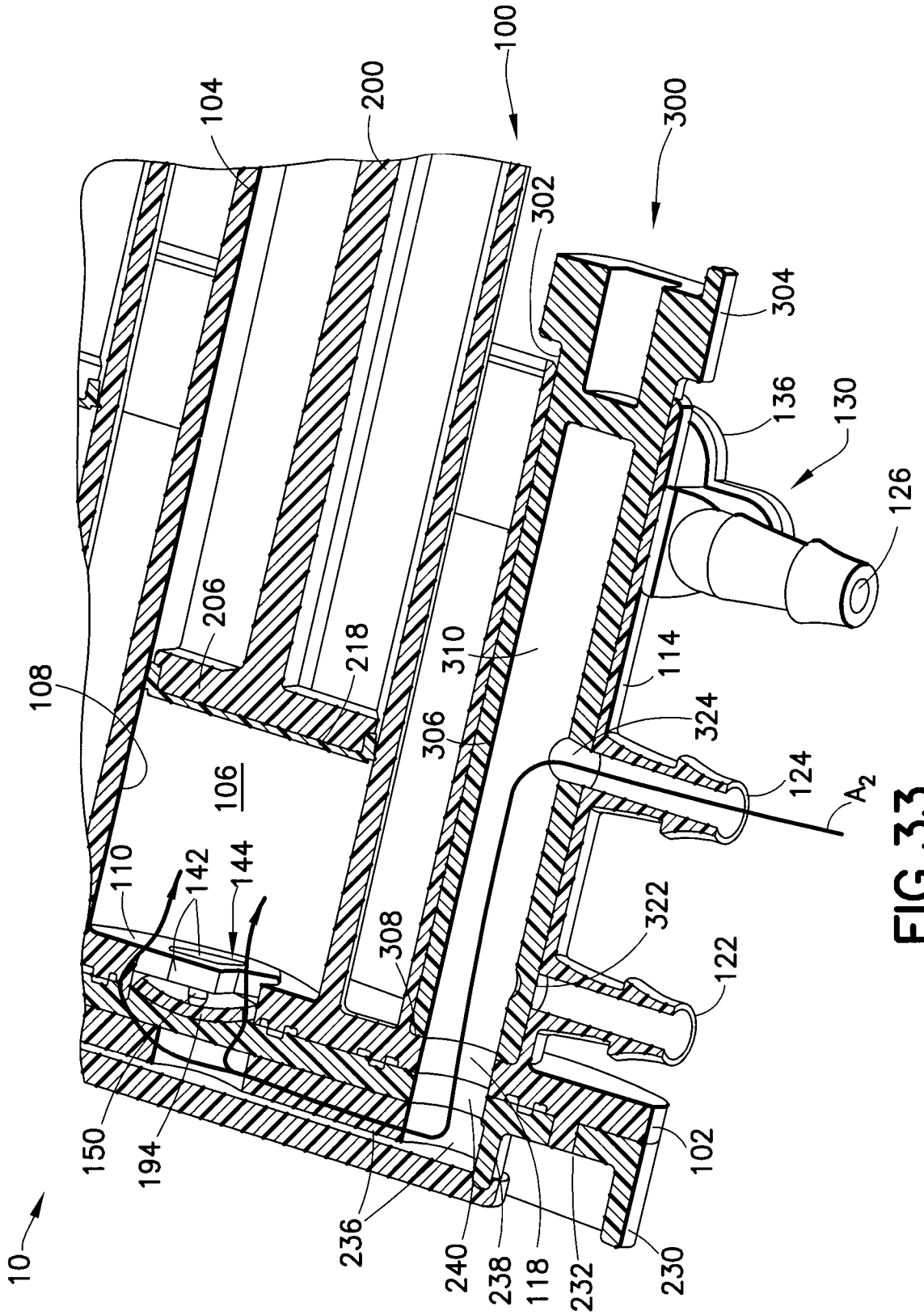
100
104
200
300
302
304
136
130
126
206
218
310
114
108
324
306
124
A_2
106
110
142
144
322
308
122
150
194
102
236
240
238
118
232
230
10

FIG.33

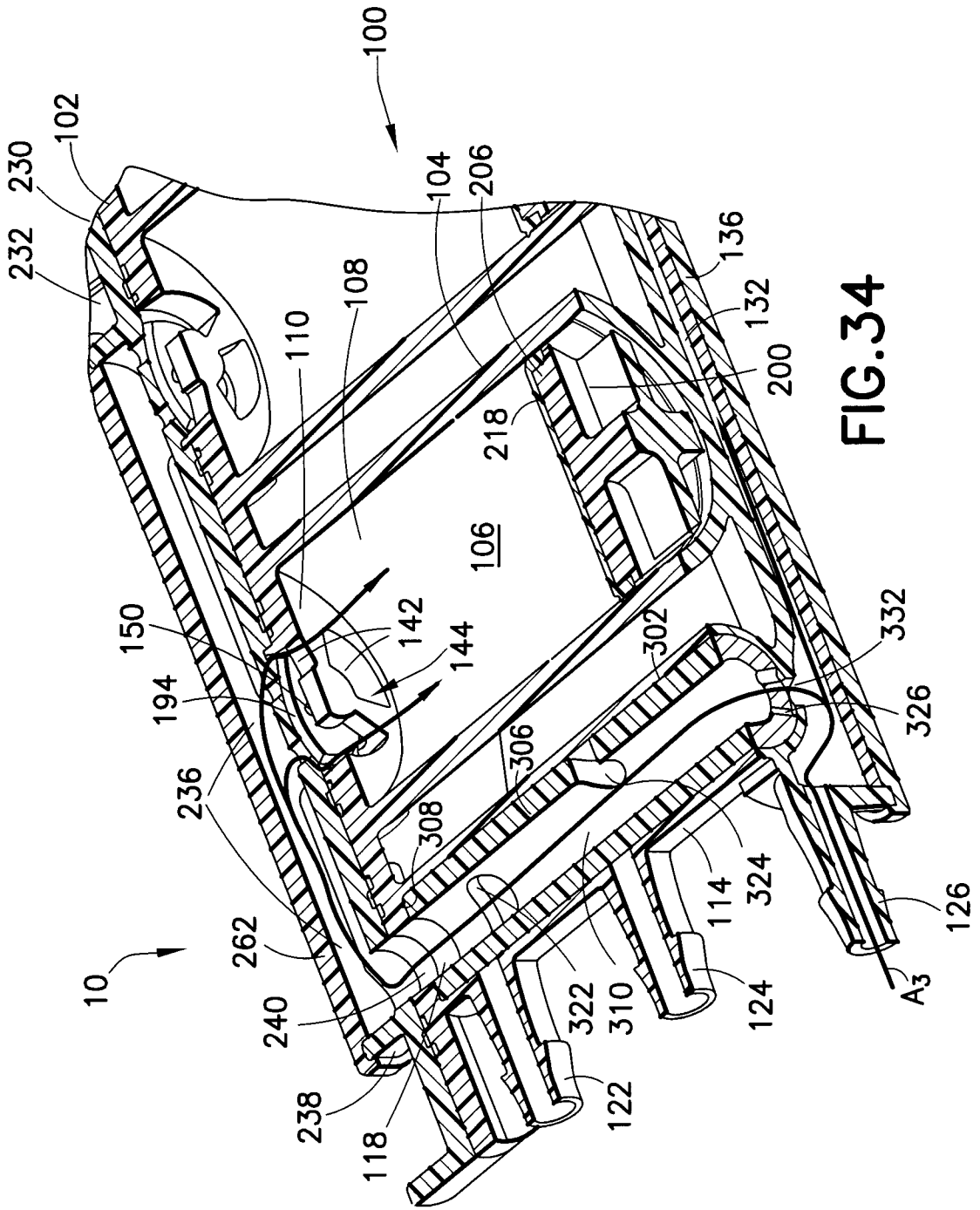
100
102
230
232
104
206
136
132
108
110
200
218
106
142
144
150
194
236
302
332
326
306
308
262
240
238
118
322
310
122
114
324
124
126
10
A3

FIG.34

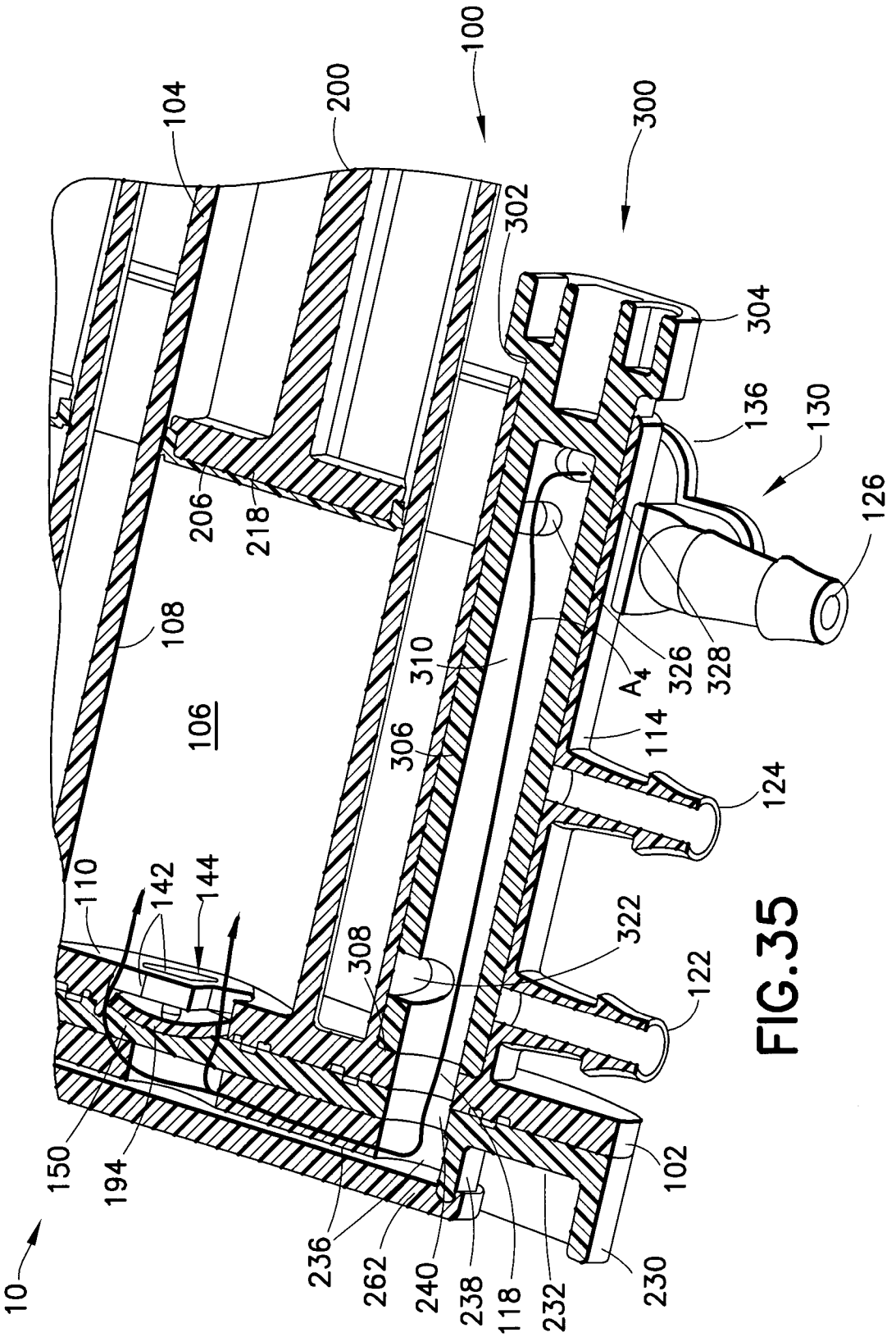
100
104
200
300
302
304
136
130
126
206
218
108
106
310
A_4
326
328
114
306
124
110
142
144
308
322
122
150
194
102
236
262
240
238
118
232
230
10

FIG.35

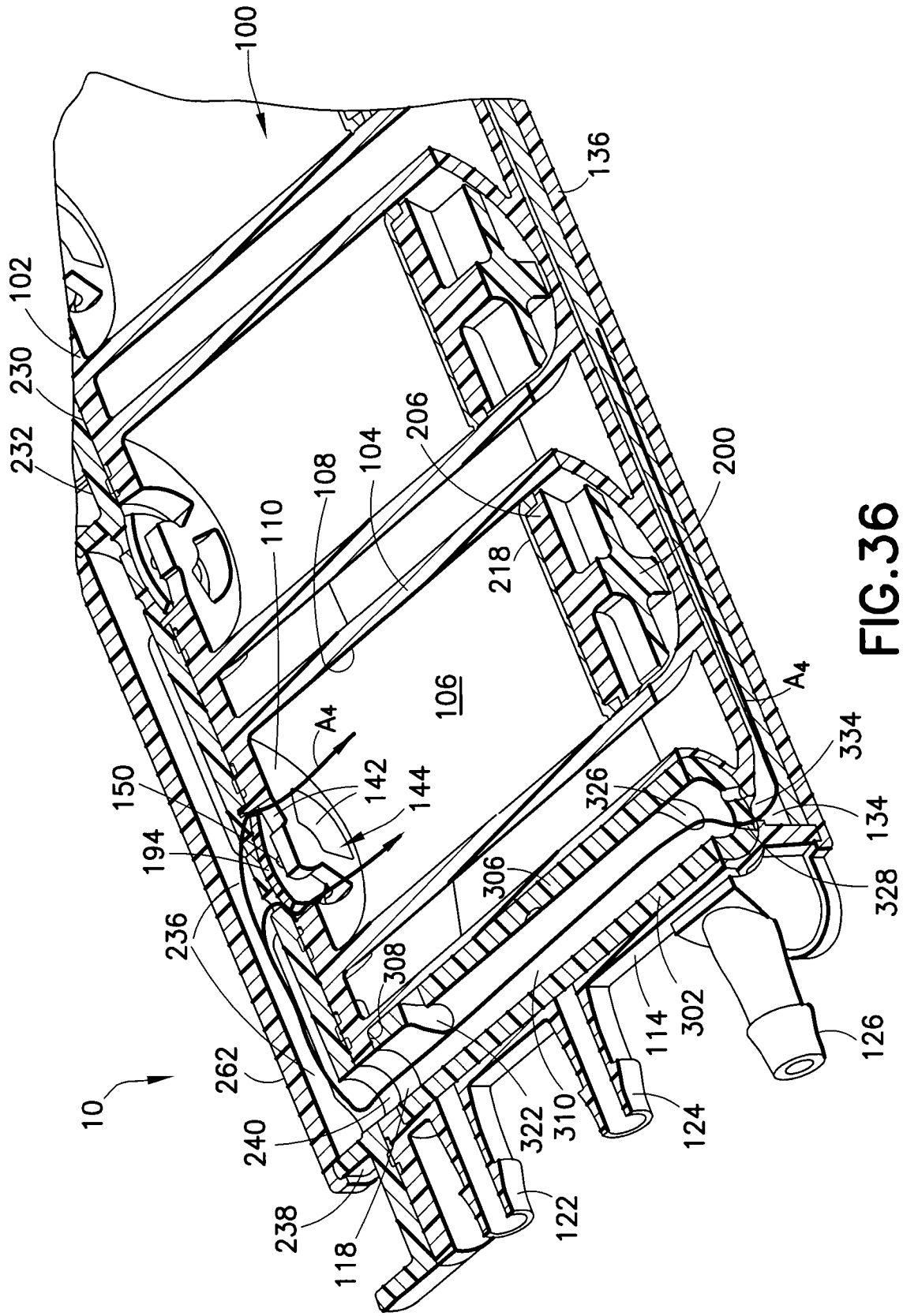
100
136
102
230
232
206
104
108
110
200
218
106
A4
A4
150
142
144
194
326
334
134
306
328
236
308
262
114
302
126
10
240
322
310
124
238
122
118

FIG.36

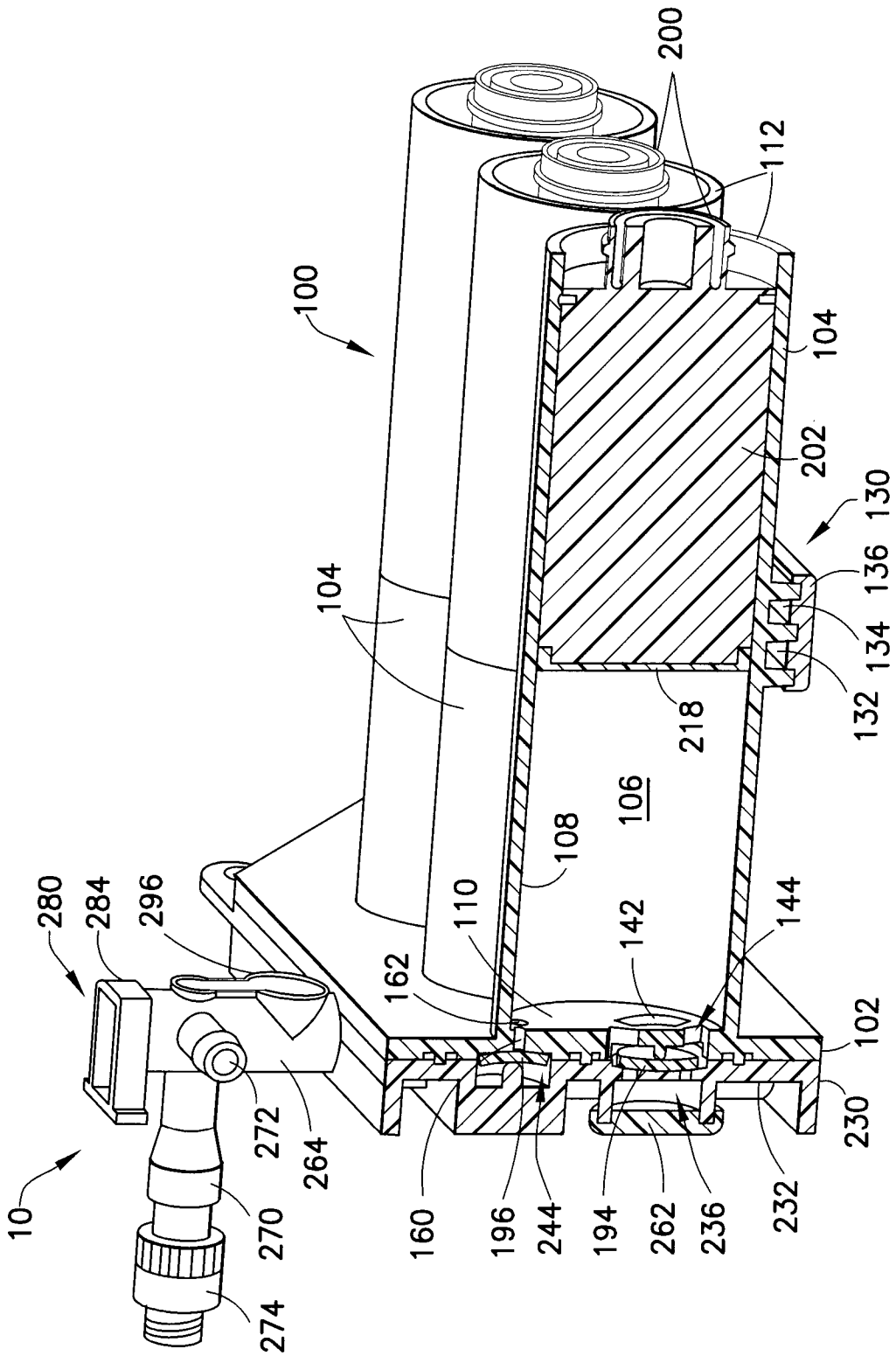
200
112
100
104
202
130
136
134
132
104
218
106
108
110
162
142
144
102
230
232
280
284
296
272
264
270
274
10
160
196
244
194
262
236

FIG.37

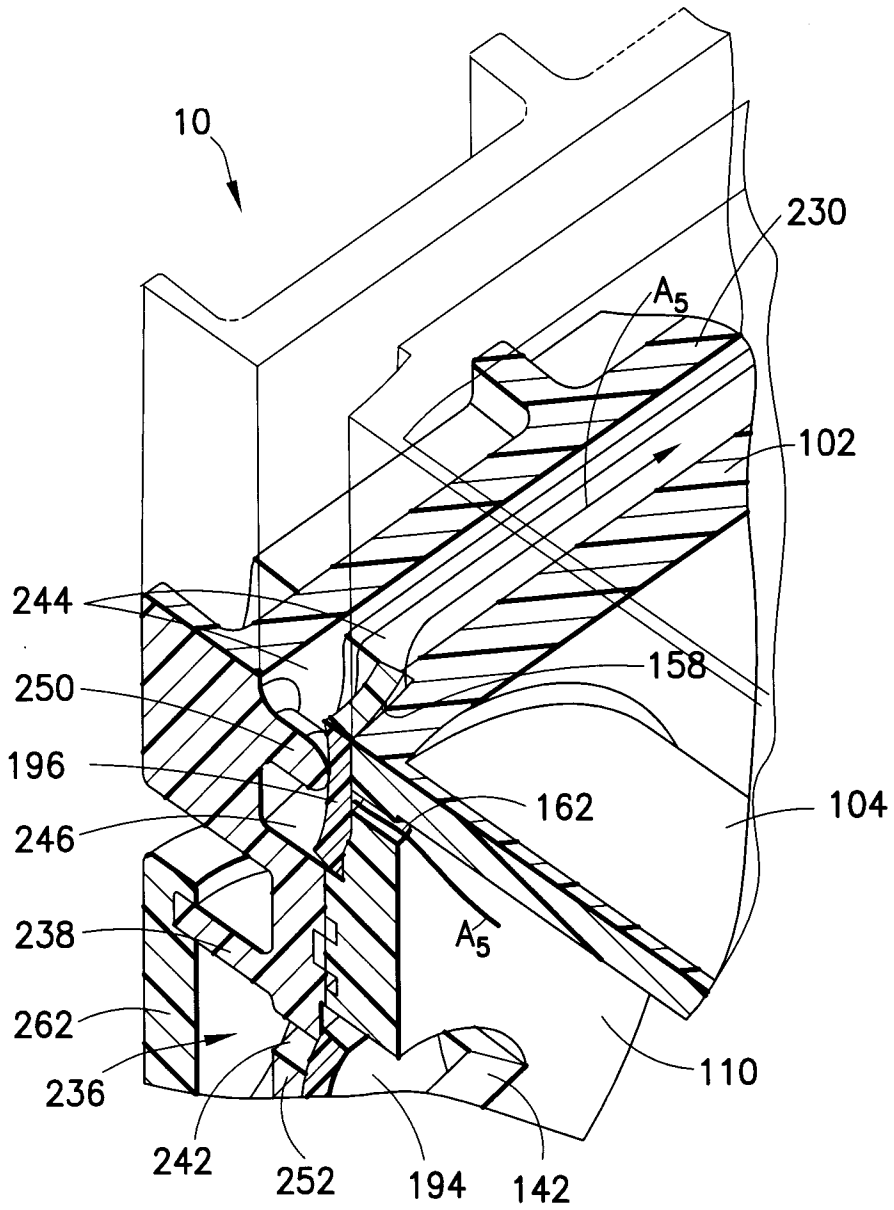
10
230
A_5
102
244
158
250
196
162
104
246
238
A_5
262
110
236
242
252
194
142

FIG.38

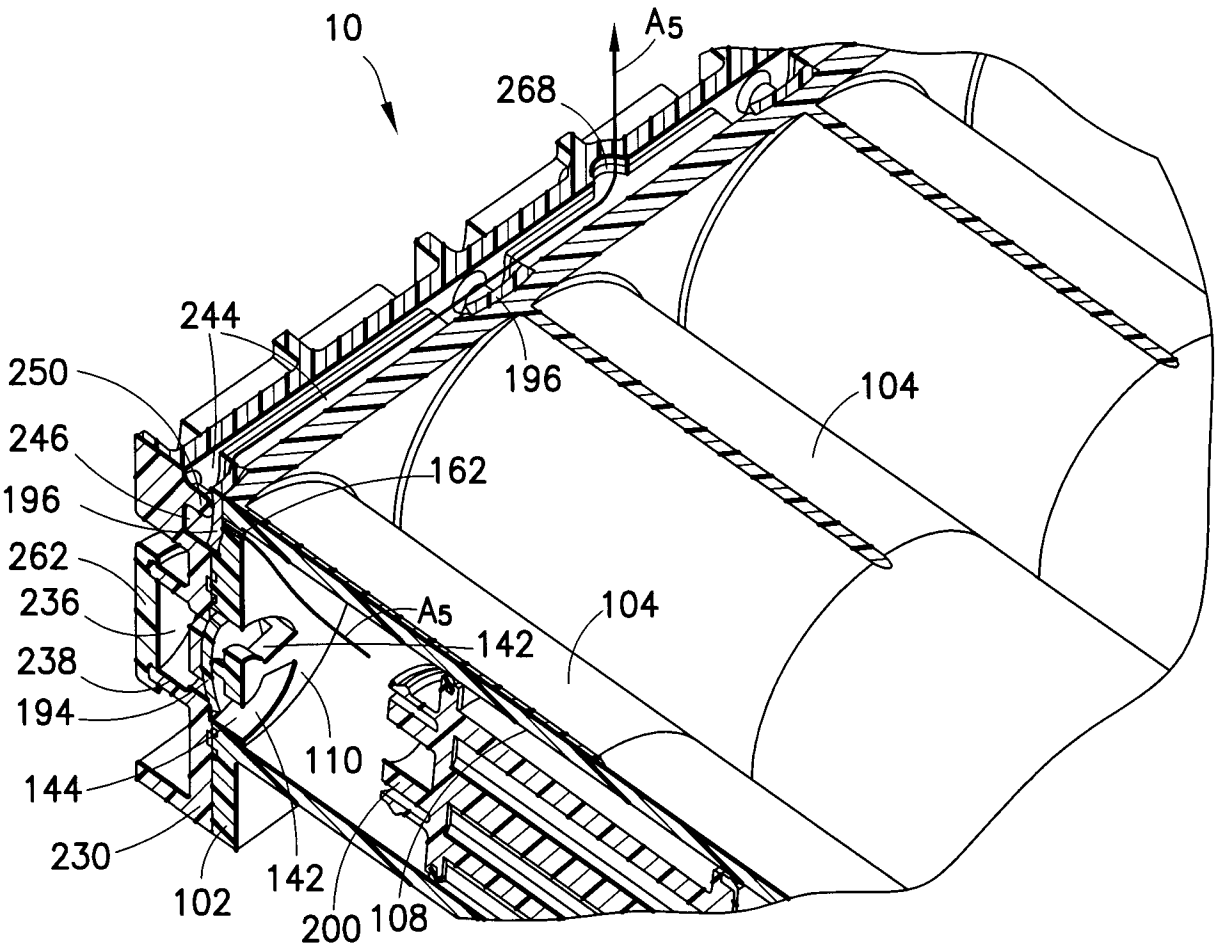
10
A5
268
244
250
246
196
262
236
238
194
144
230
102
142
200
108
110
196
162
104
A5
142
104

FIG.39

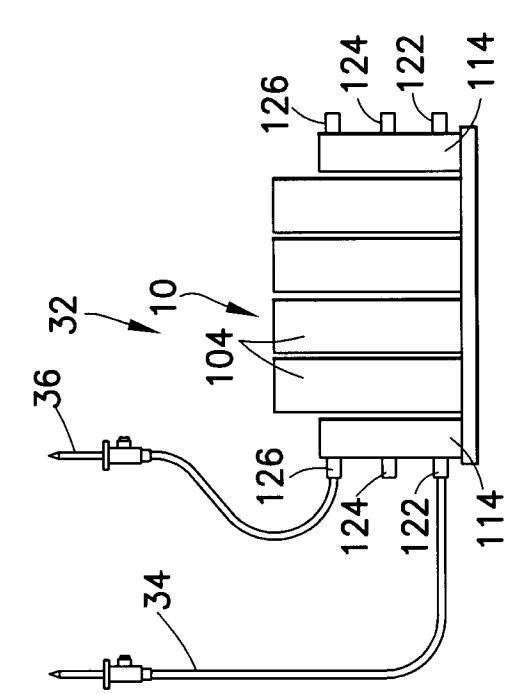

FIG.42

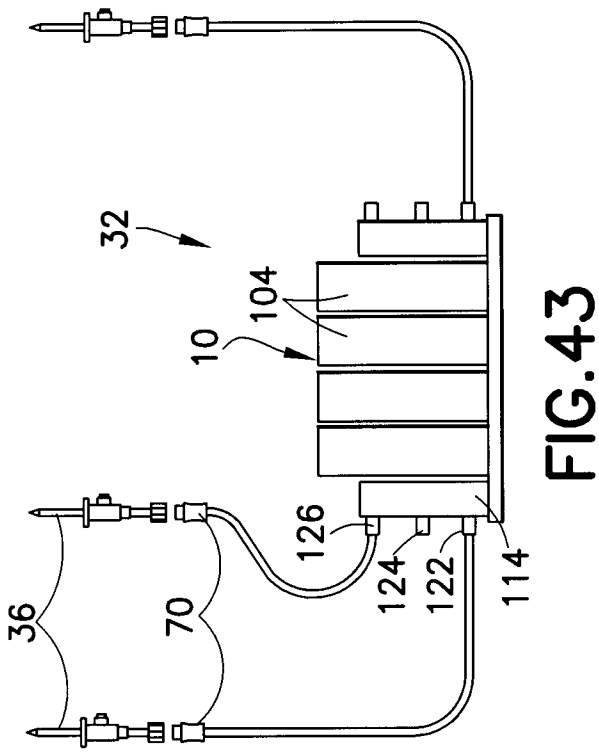

FIG.43

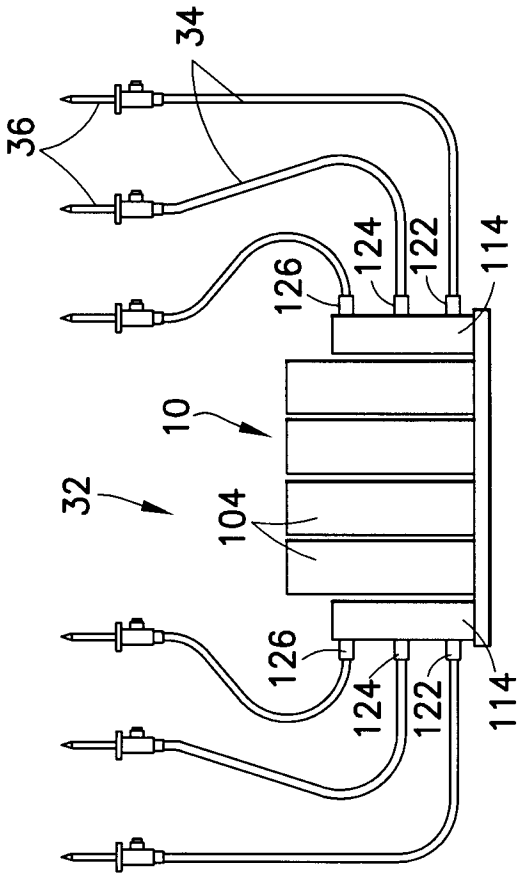

FIG.40

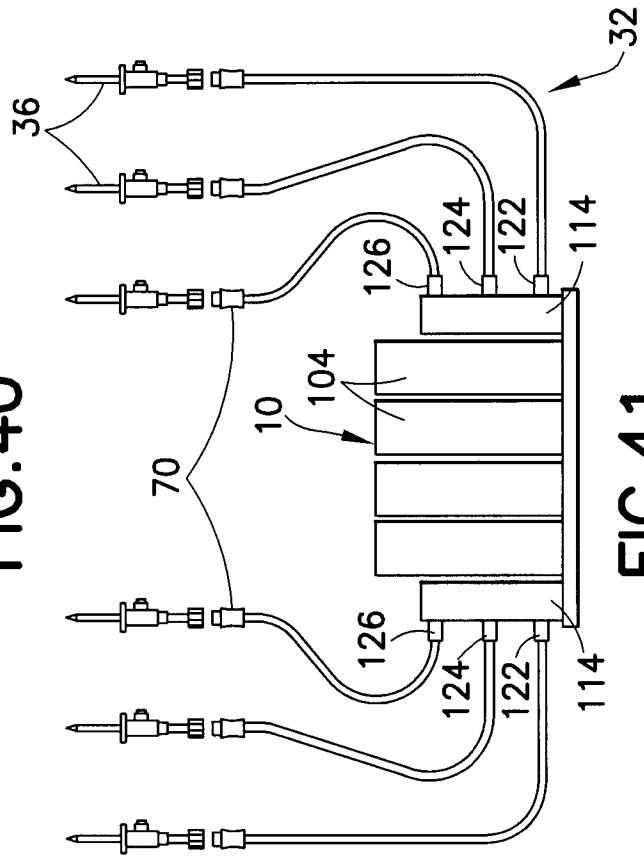

FIG.41

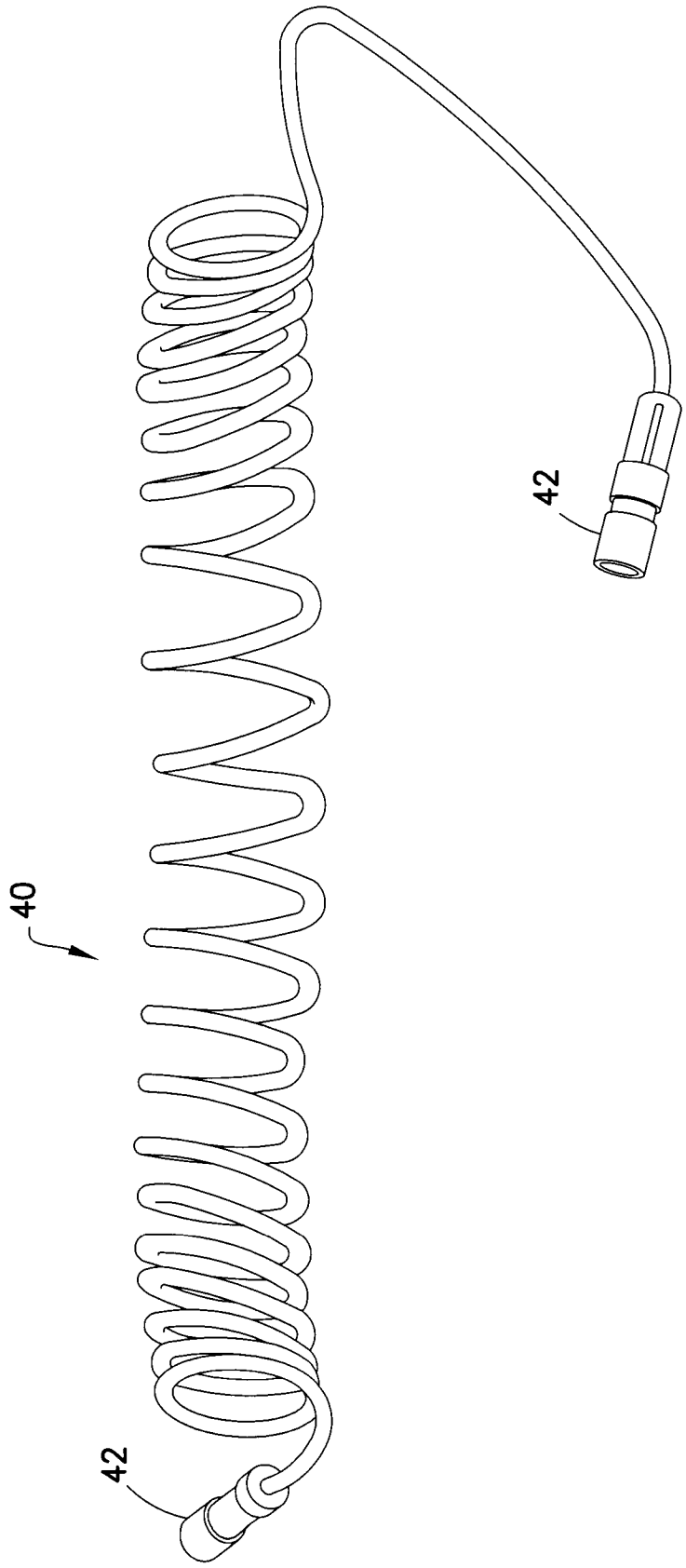

FIG.44

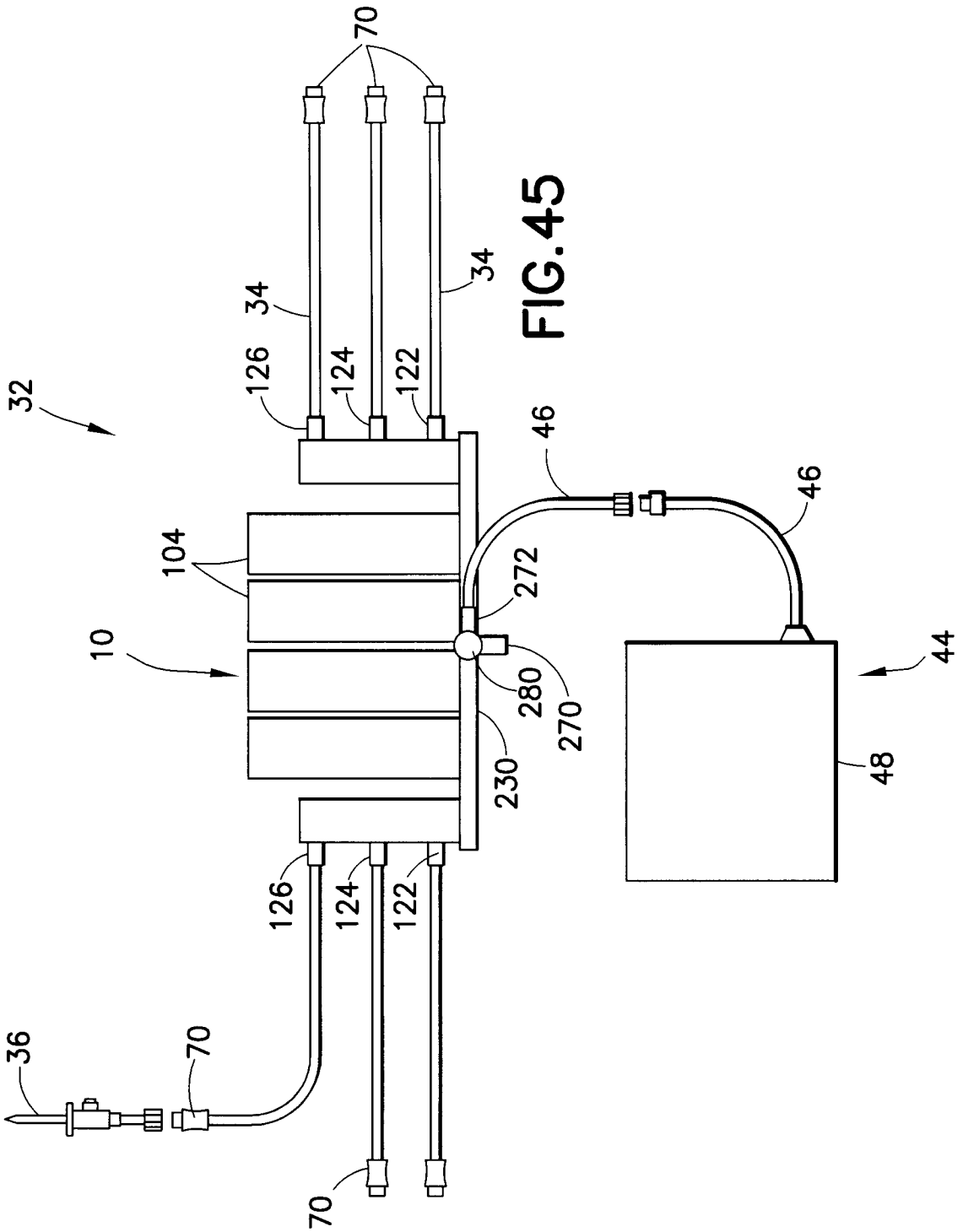
70
34
34
126
124
122
32
46
46
104
272
10
44
280
270
230
48
126
124
122
36
70
70

FIG.45

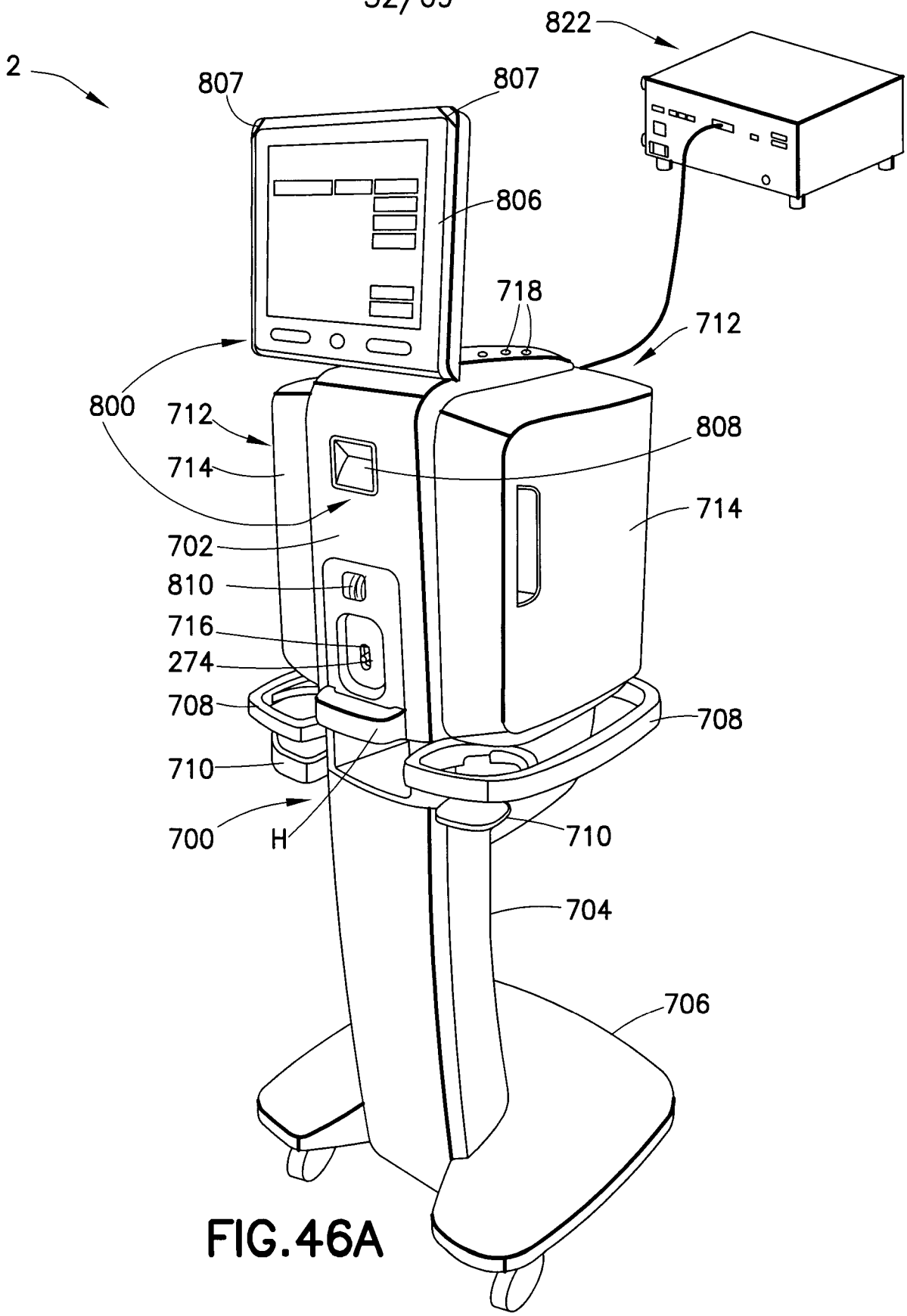
2
822
807
807
806
718
712
800
712
808
714
714
702
810
716
274
708
708
710
700
H
710
704
706

FIG.46A

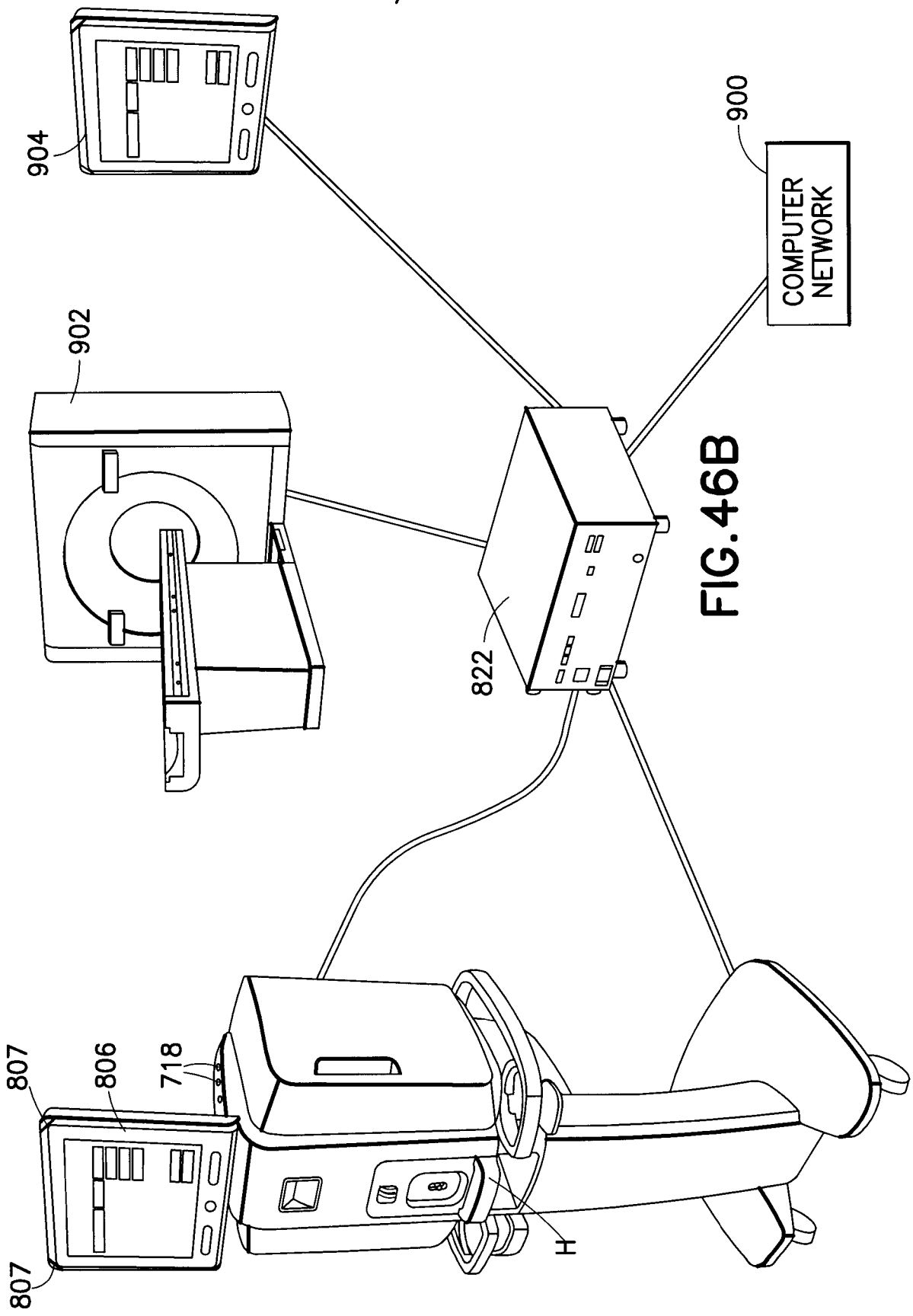

FIG.46B

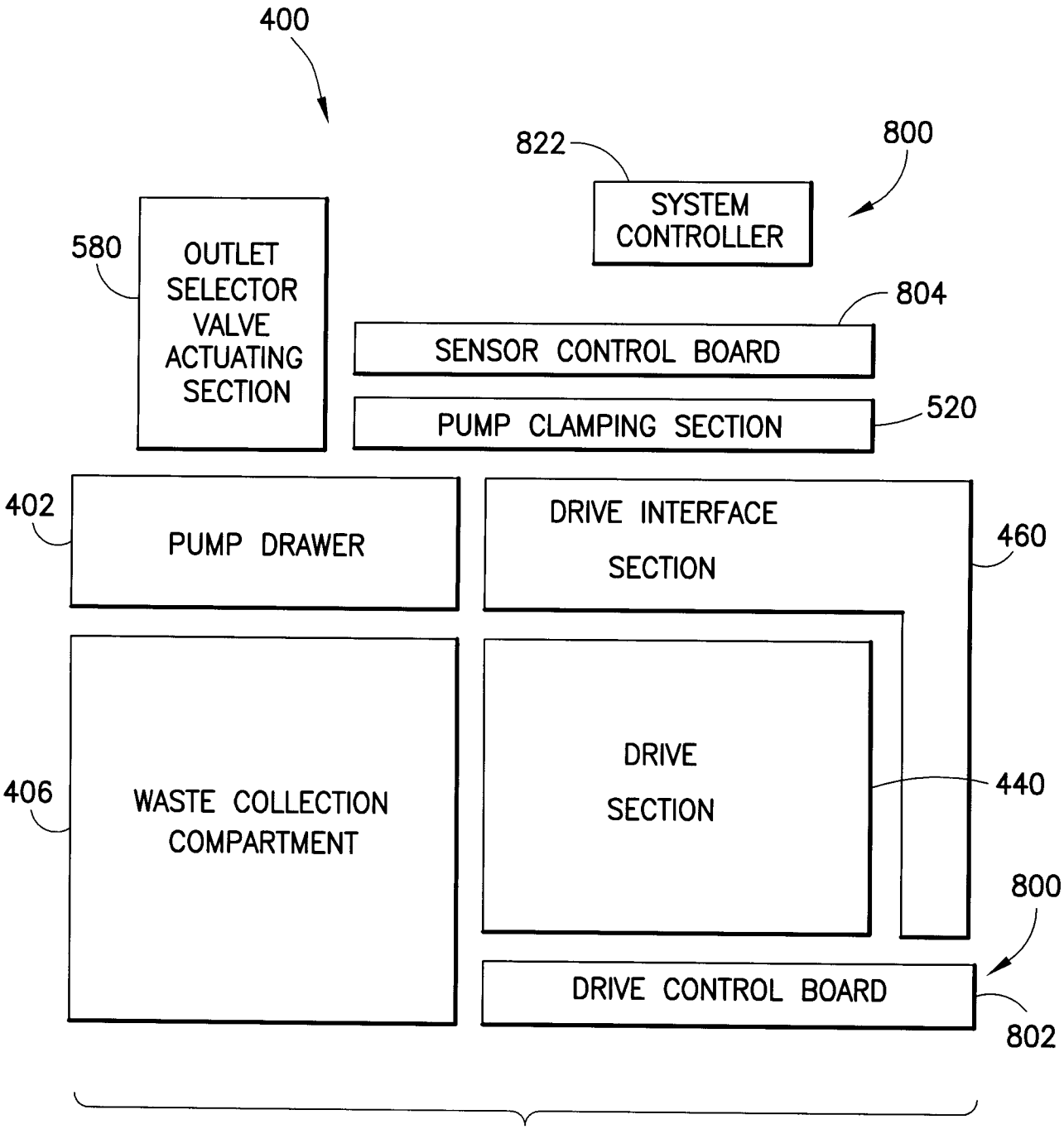
400
822
800
SYSTEM CONTROLLER
580
OUTLET SELECTOR VALVE ACTUATING SECTION
804
SENSOR CONTROL BOARD
PUMP CLAMPING SECTION
520
402
PUMP DRAWER
DRIVE INTERFACE SECTION
460
406
WASTE COLLECTION COMPARTMENT
DRIVE SECTION
440
800
DRIVE CONTROL BOARD
802

FIG.47

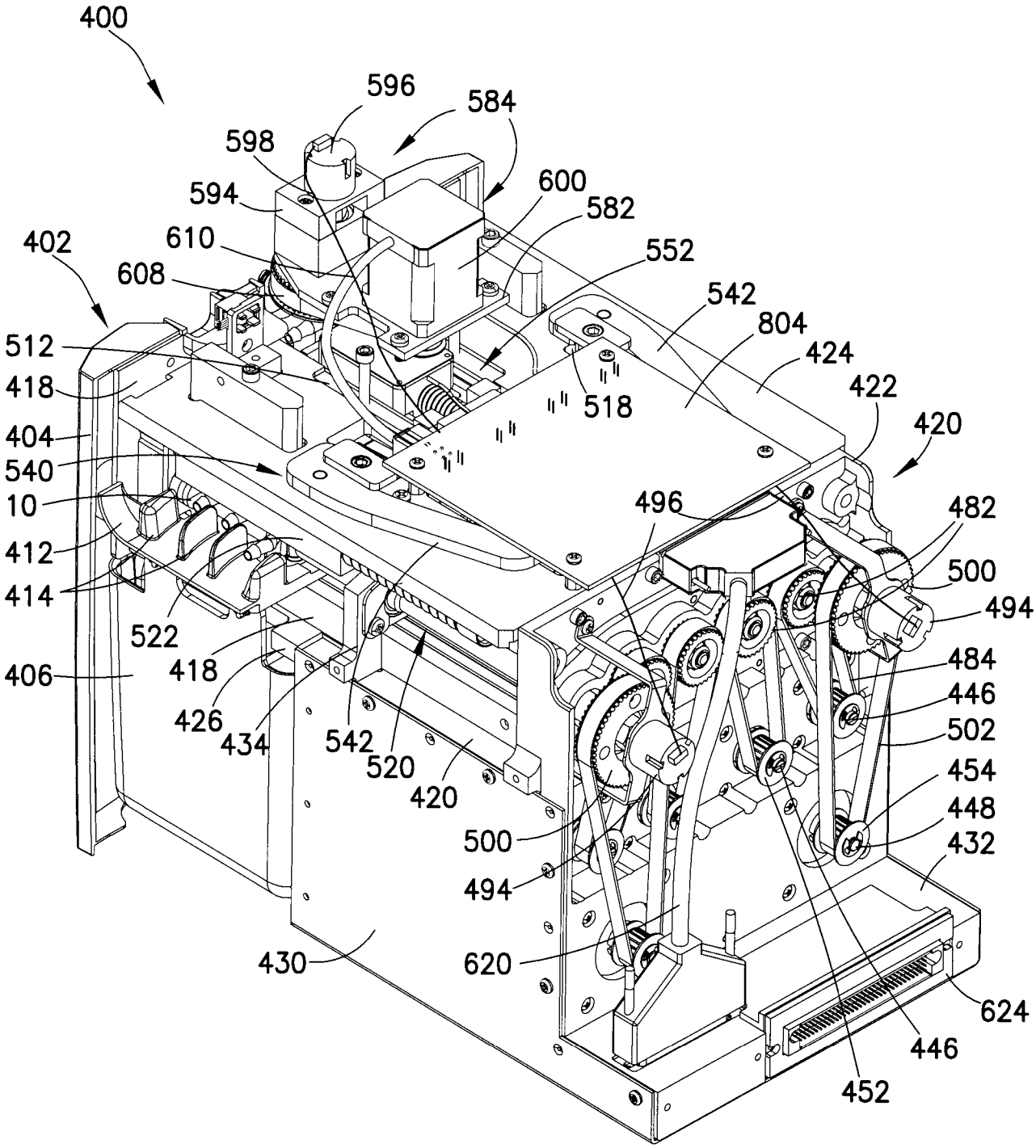
400
596
584
598
600
594
582
610
552
402
608
542
804
512
424
418
422
518
404
420
540
496
482
10
500
412
494
414
484
522
446
418
502
406
426
454
434
542
520
448
420
432
500
494
430
620
624
446
452

FIG.48

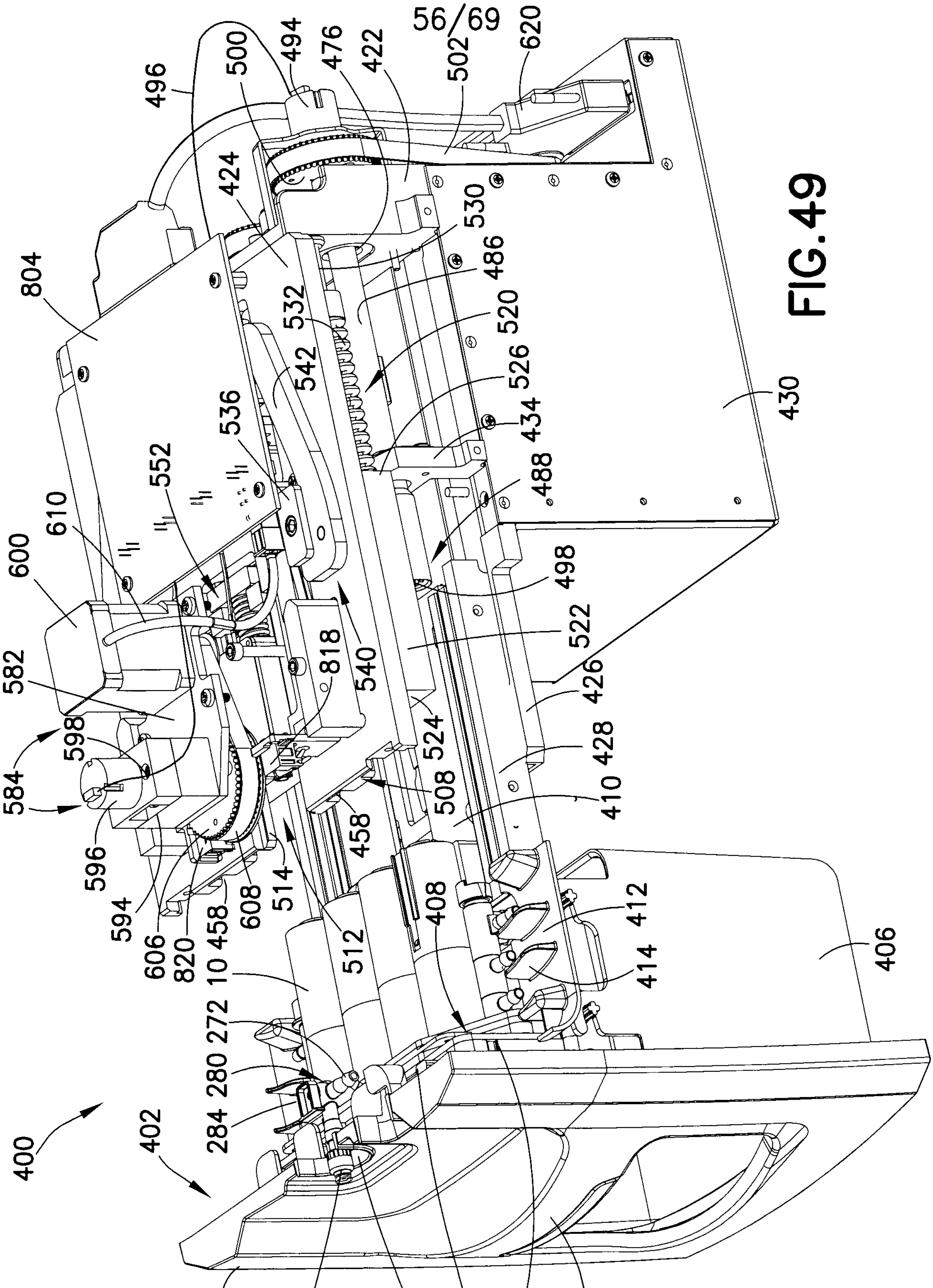
400
402
404
274
716
456
418
H
284
280
272
10
458
820
606
594
596
584
598
582
600
610
552
536
542
532
804
424
496
500
494
476
422
56/69
502
620
530
486
520
526
434
488
498
522
426
428
410
508
524
540
818
608
514
512
458
408
412
414
406
430

FIG.49

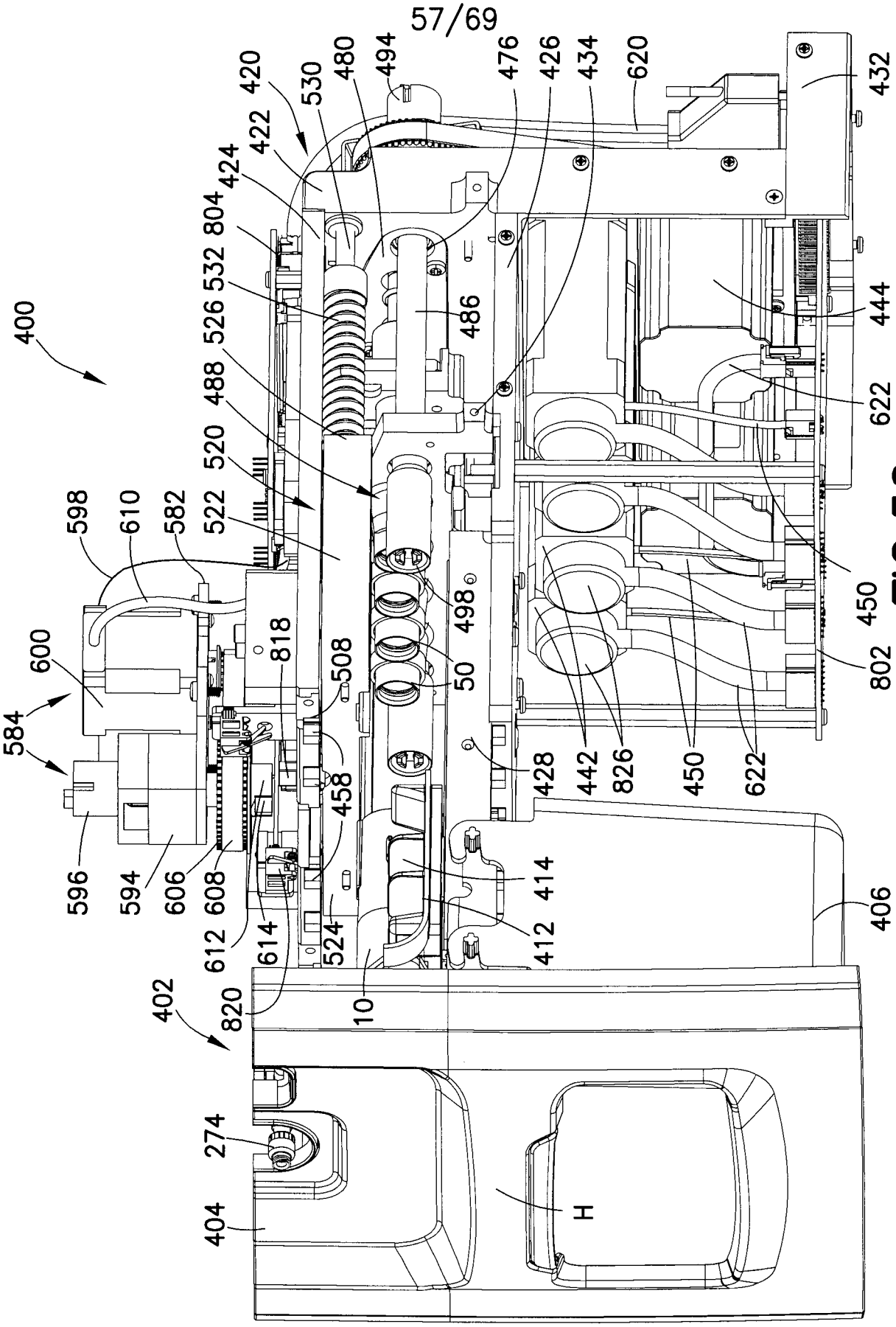
400
420
422
424
804
532
526
488
520
522
598
610
582
600
584
596
594
606
608
612
614
524
458
818
508
498
50
530
480
494
476
426
434
620
432
444
622
450
802
428
442
826
450
622
414
412
406
402
820
10
274
404
H

FIG.50

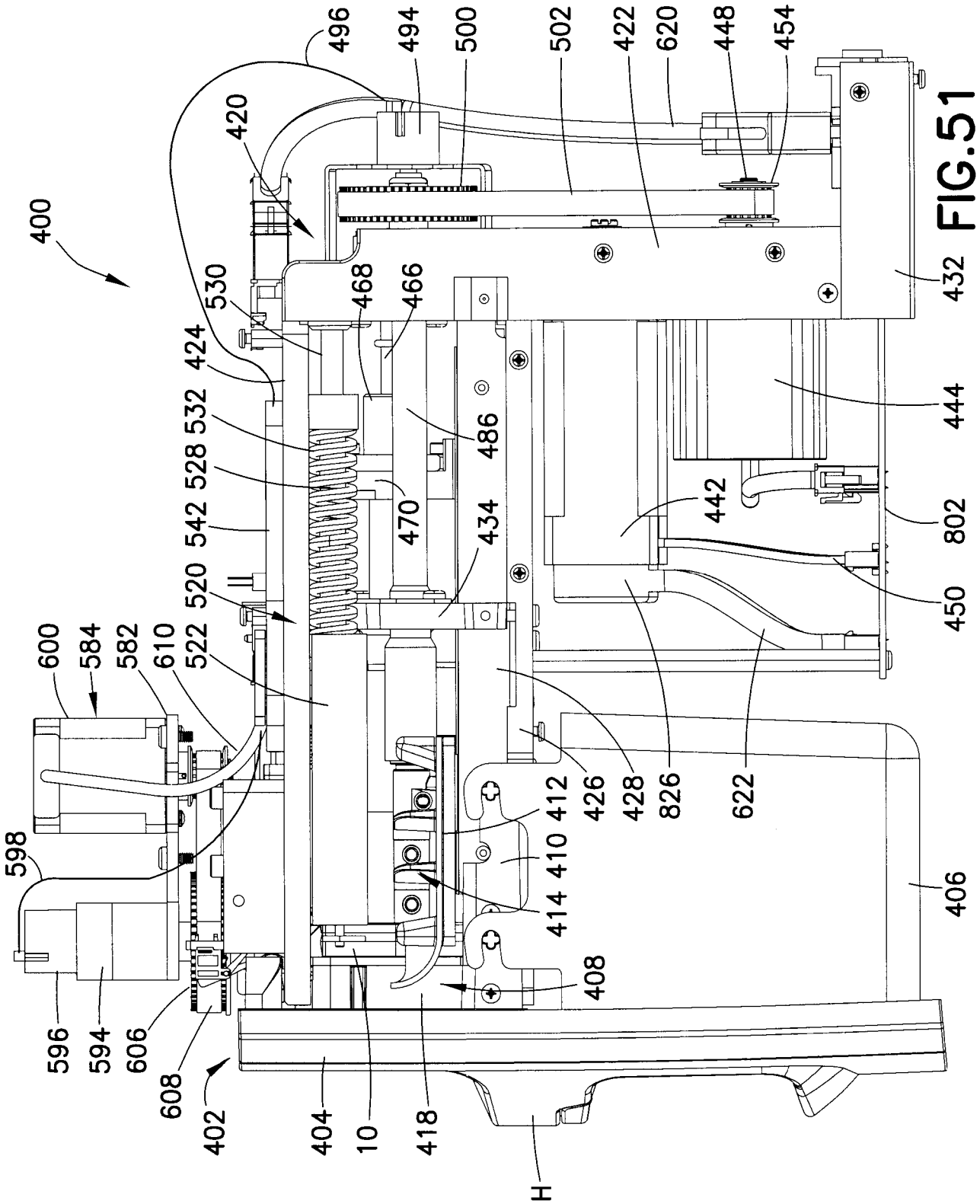
400
496
494
500
502
422
620
448
454
420
530
468
466
424
532
528
542
520
522
610
582
584
600
598
596
594
606
608
402
404
10
418
H
486
470
434
442
444
802
450
432
826
622
428
426
412
410
414
408
406

FIG.51

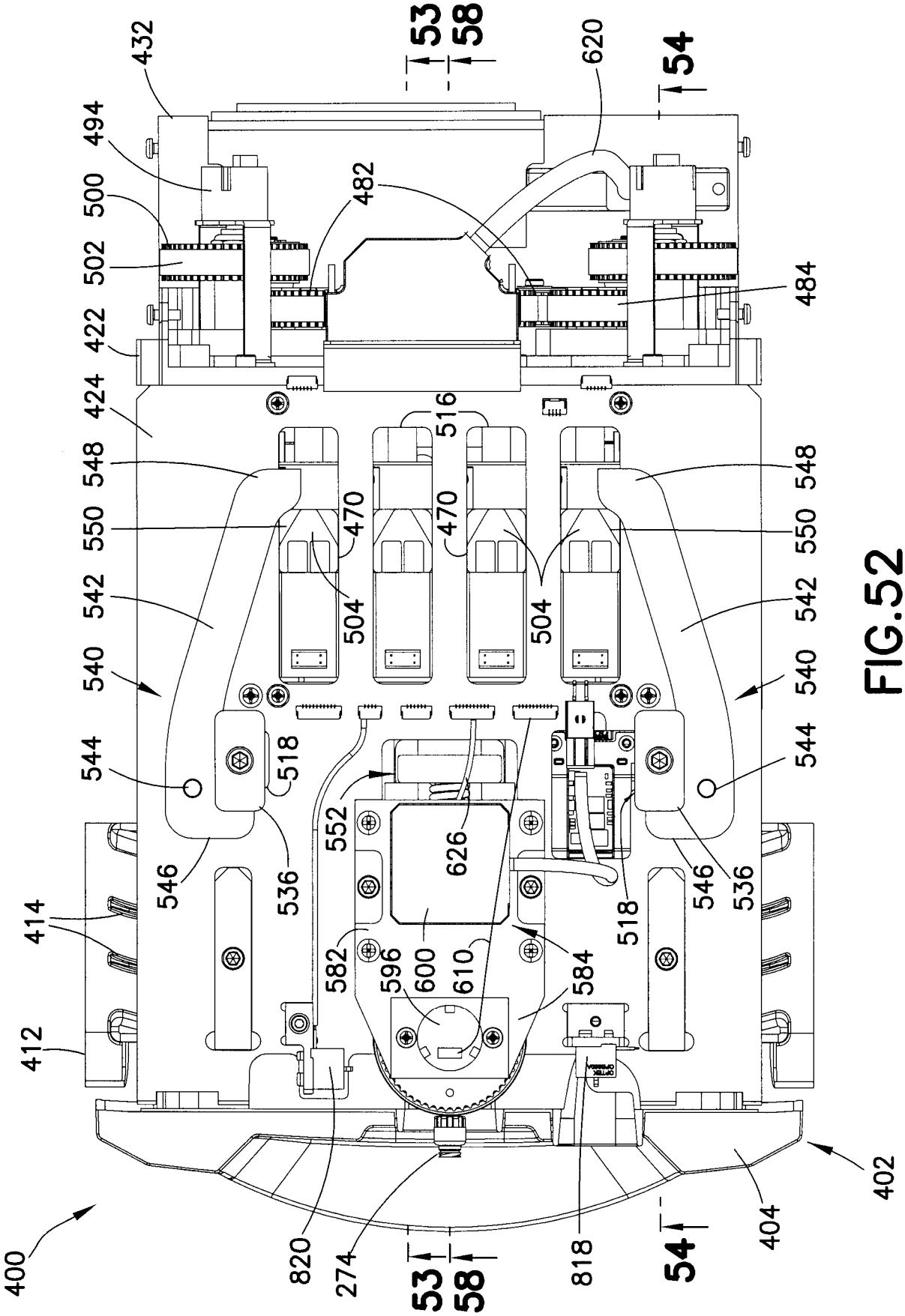
53
58
54
432
620
494
500
502
422
424
482
484
516
548
550
542
540
544
470
504
518
552
626
546
536
414
412
582
596
600
610
584
400
820
274
818
404
402

FIG.52

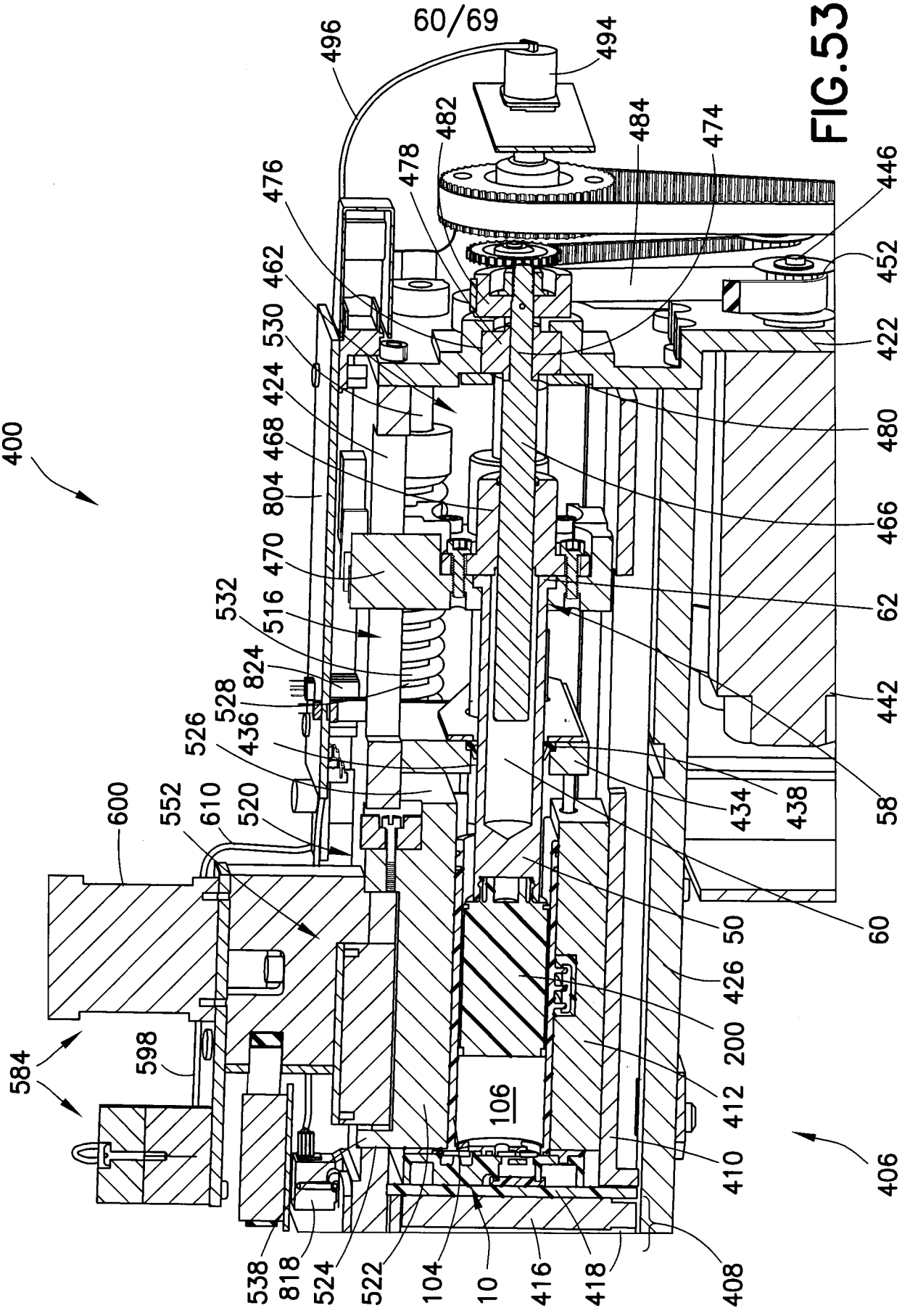
400
496
494
482
484
474
478
476
462
530
424
468
804
470
516
532
824
528
436
526
552
610
520
600
598
584
446
452
422
480
466
62
442
58
434
438
60
50
426
200
412
410
406
408
538
818
524
522
104
10
416
418
106

FIG.53

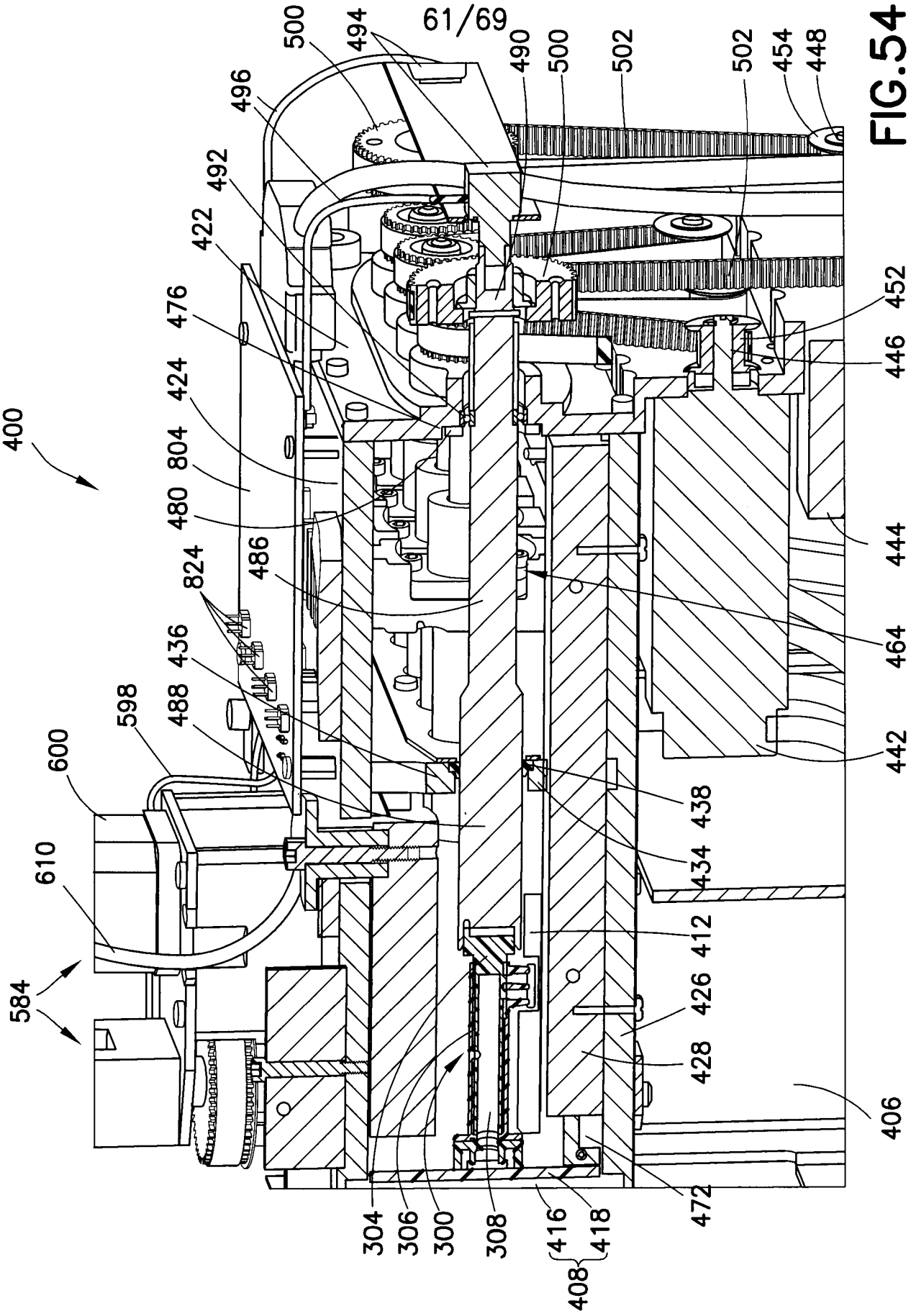
400
584
610
600
598
488
436
824
486
480
804
424
476
422
492
496
500
494
490
500
502
502
454
448
452
446
444
464
442
438
434
412
426
428
406
472
304
306
300
308
416
418
408

FIG.54

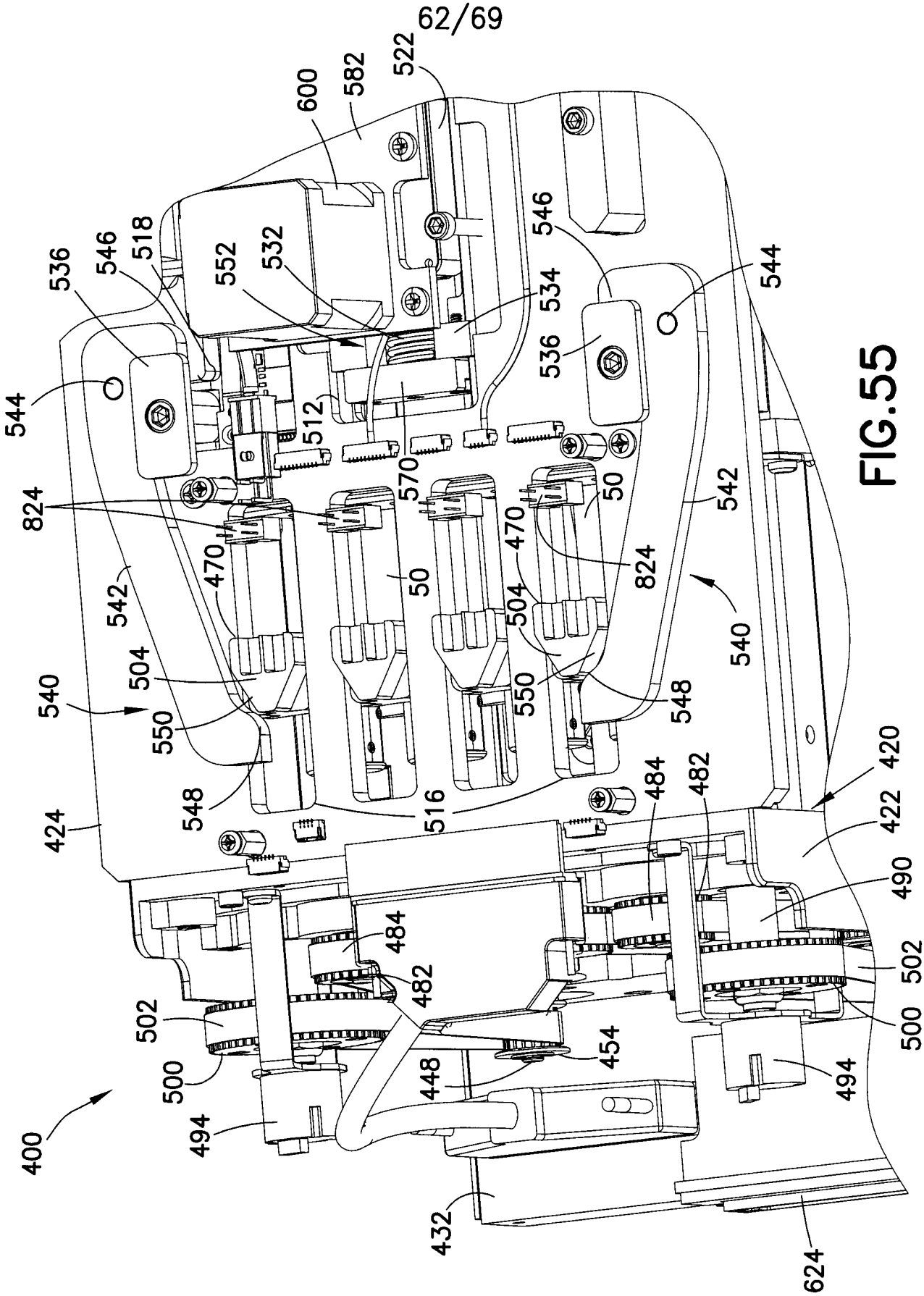
400
424
432
448
454
470
482
484
494
500
502
504
512
516
518
522
532
534
536
540
542
544
546
548
550
552
570
582
600
624
824
50
420
422
490

FIG.55

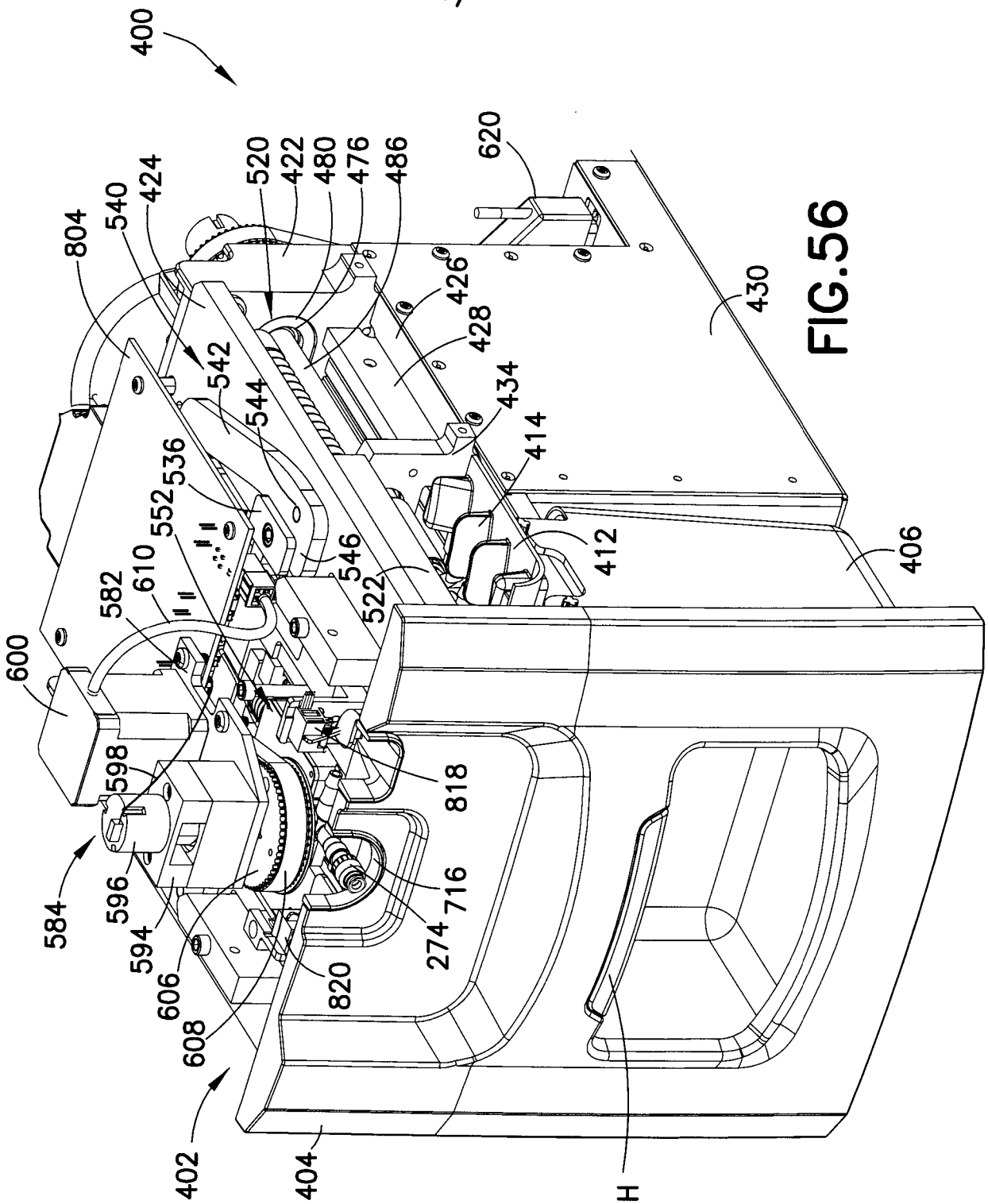
400
620
520
422
480
476
486
424
540
804
426
428
430
542
544
434
414
536
552
546
412
406
610
582
522
600
598
818
584
596
716
594
274
606
820
608
402
404
H

FIG.56

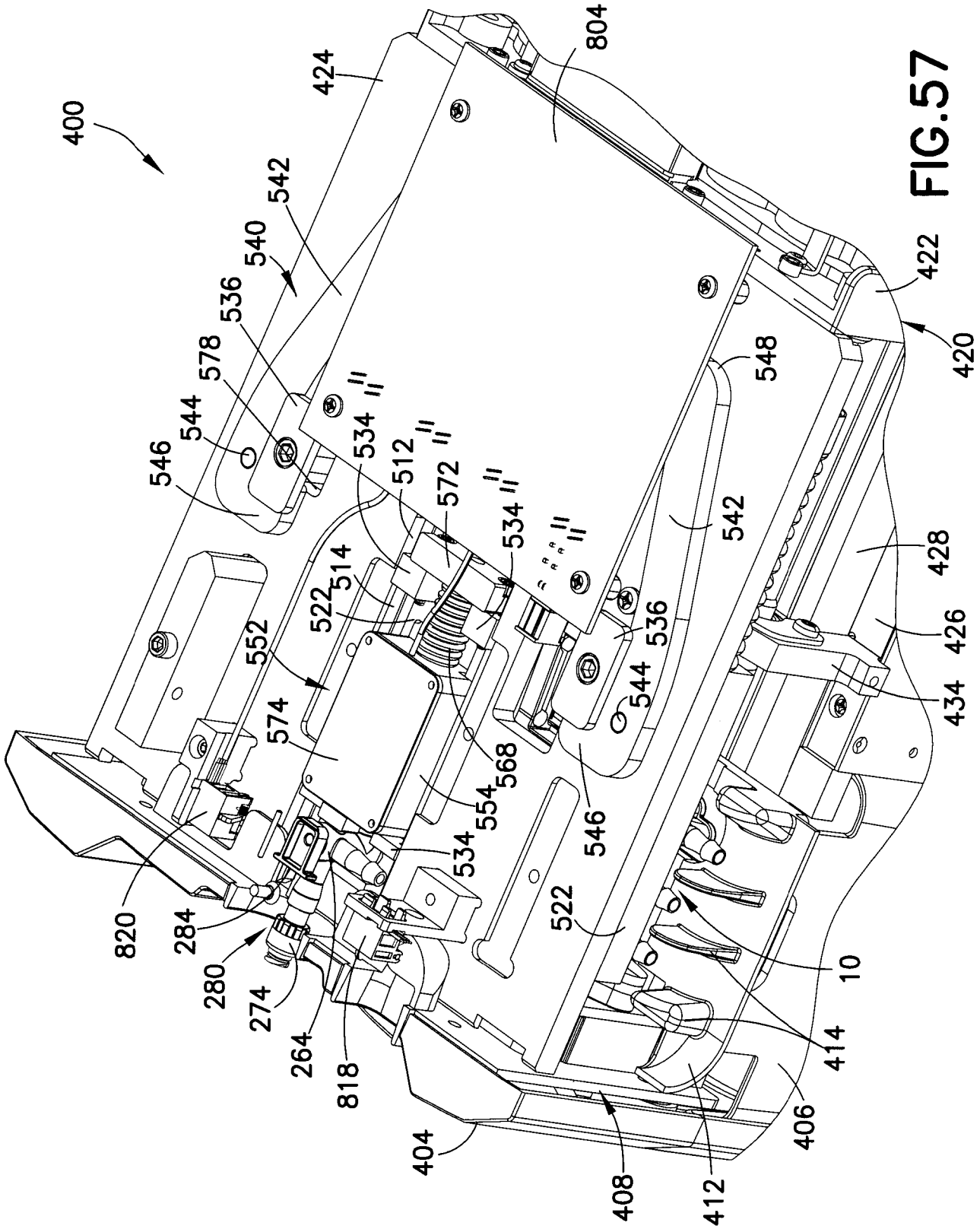
400
424
804
542
540
536
578
544
546
534
512
572
514
522
552
574
568
554
820
284
280
274
264
818
404
408
412
406
414
10
422
420
548
428
426
434

FIG.57

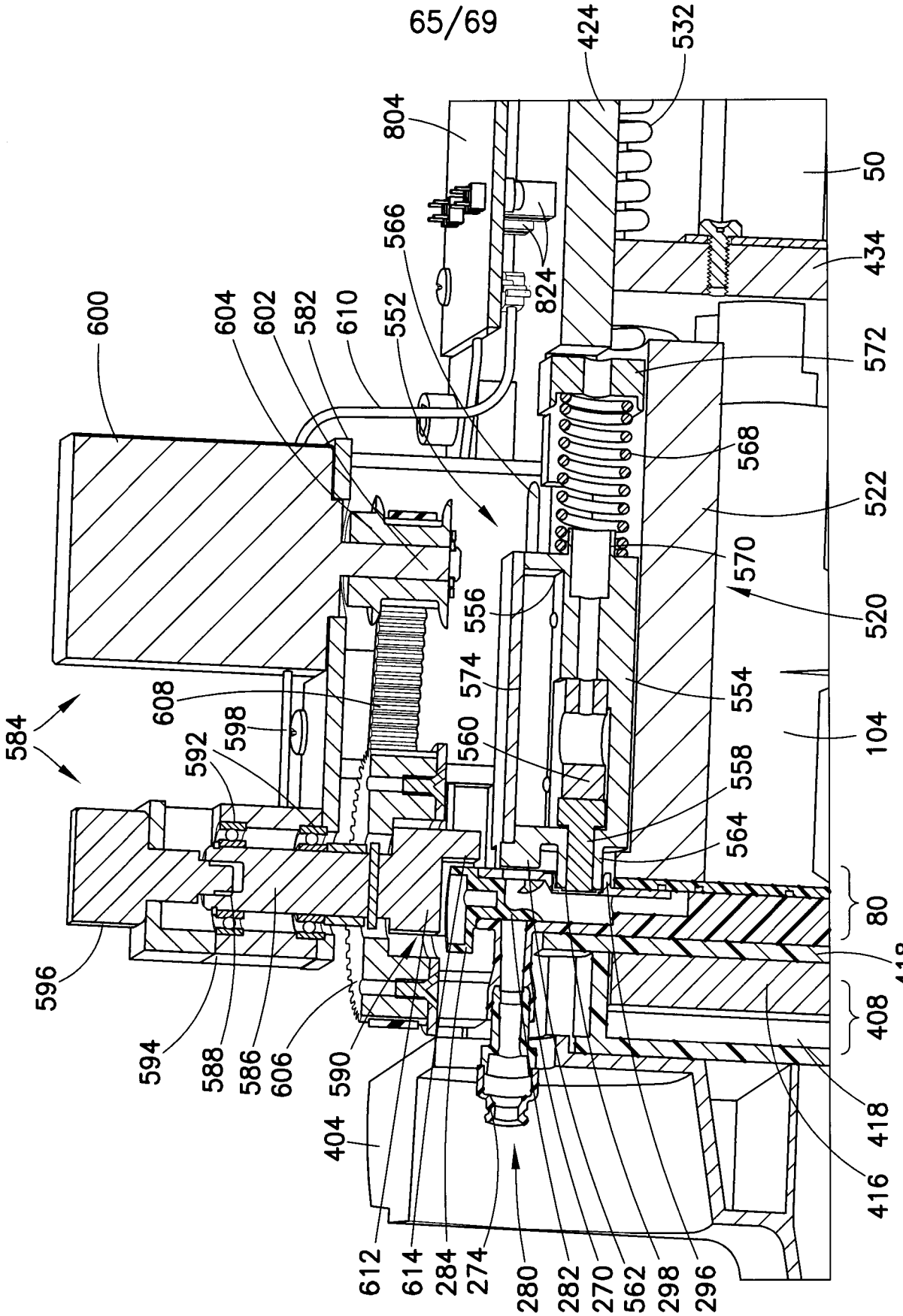
424
532
804
50
566
824
434
552
610
582
602
604
600
572
568
522
570
520
556
574
554
608
598
592
560
104
558
564
584
80
596
418
408
594
588
586
606
590
404
418
416
612
614
284
274
280
282
270
562
298
296

FIG.58

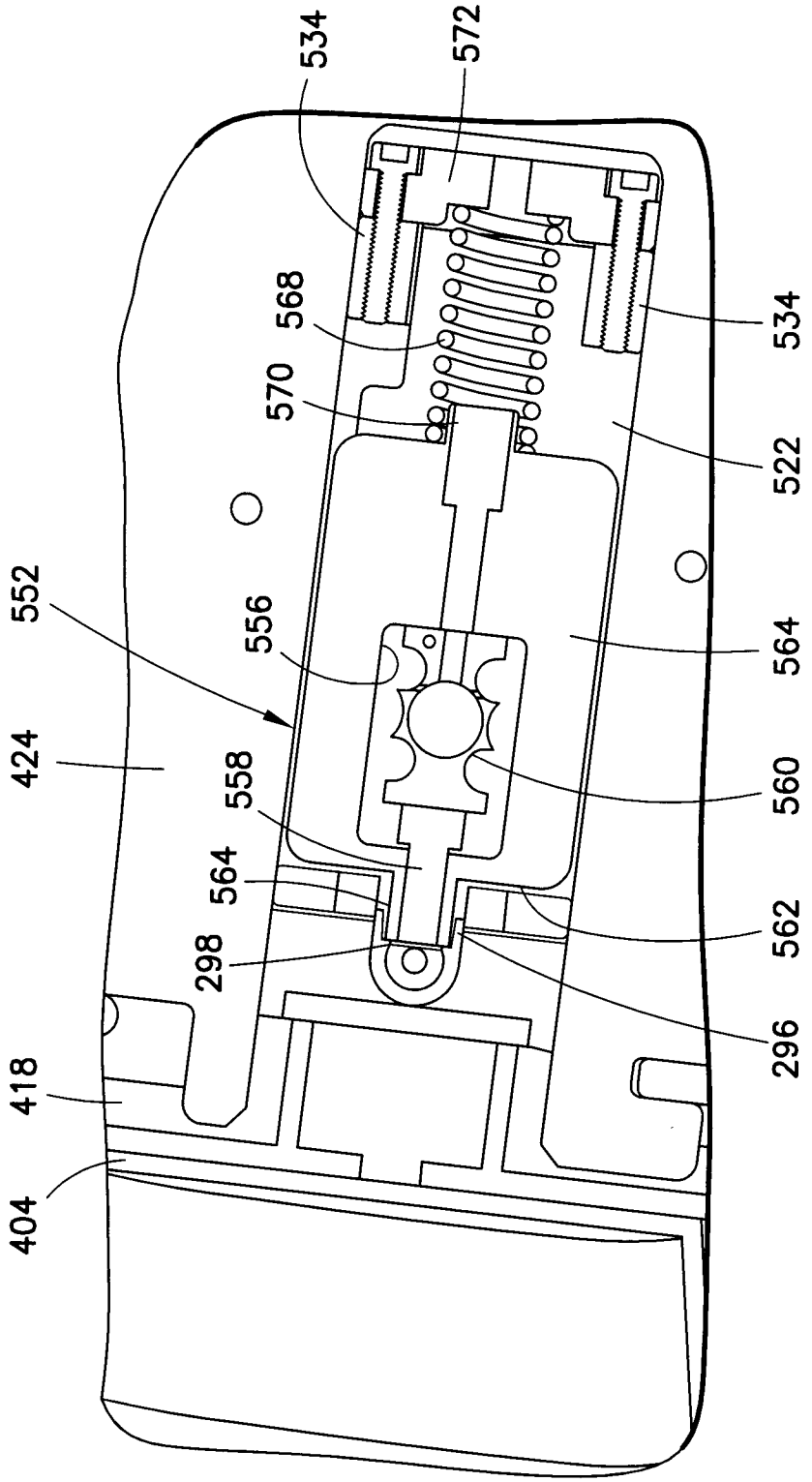
534
572
568
570
534
522
552
556
564
424
558
560
564
562
298
296
418
404

FIG.59

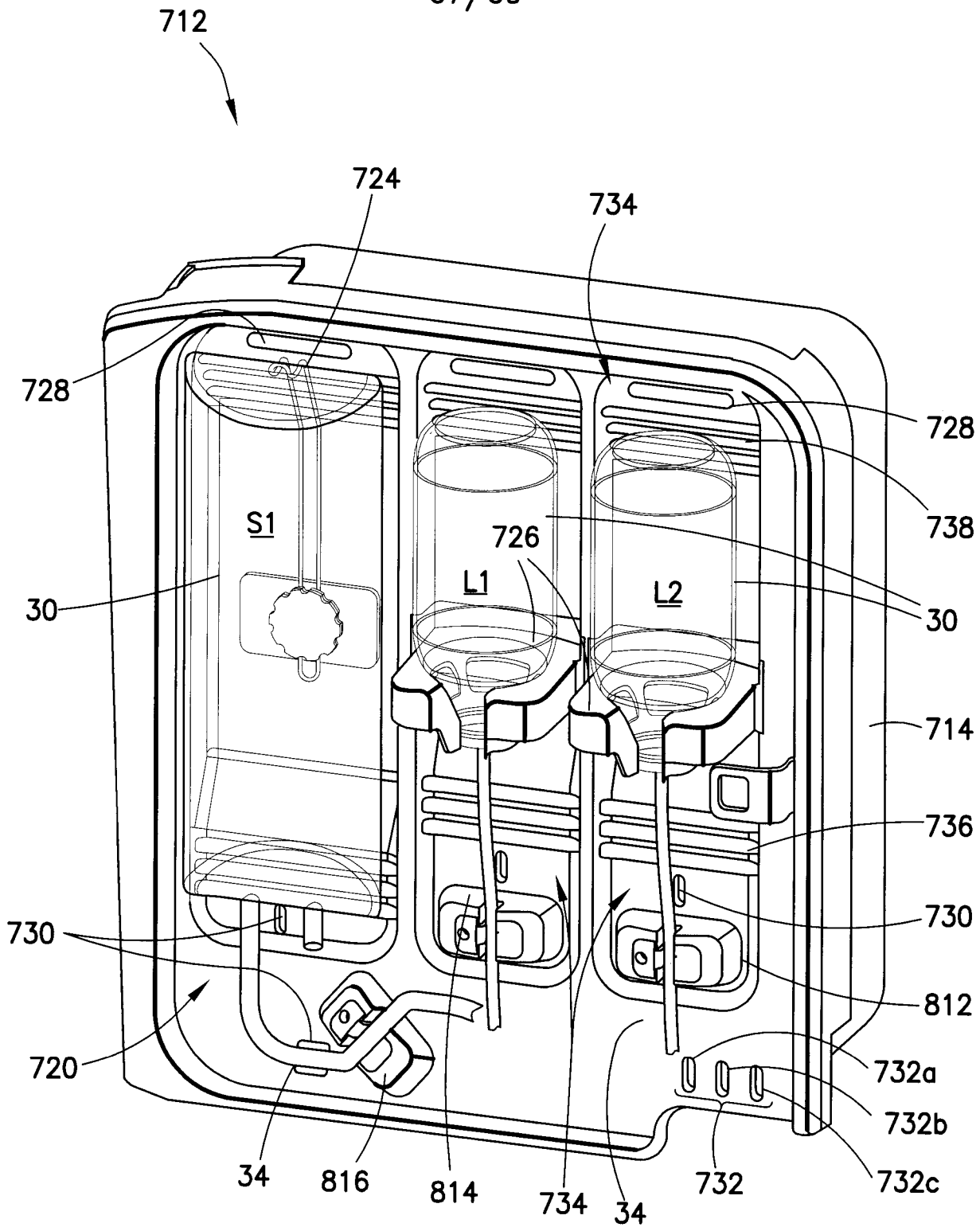
712
724
734
728
728
738
S1
726
L1
L2
30
30
714
736
730
730
812
720
732a
732b
732c
34
816
814
734
34
732

FIG.60

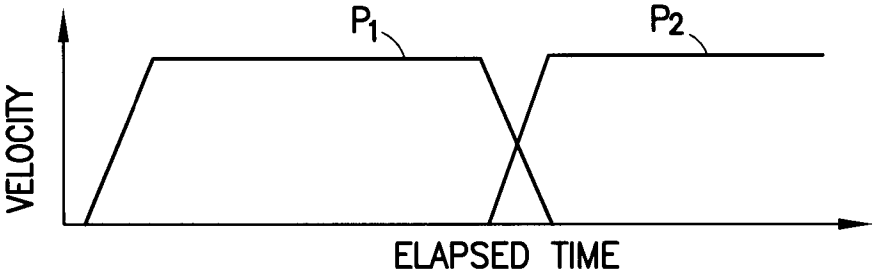

FIG.61

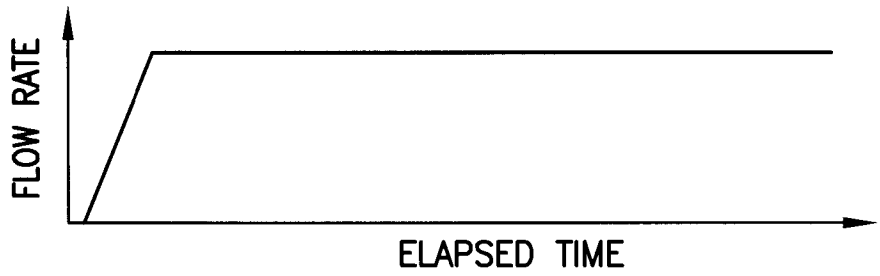

FIG.62

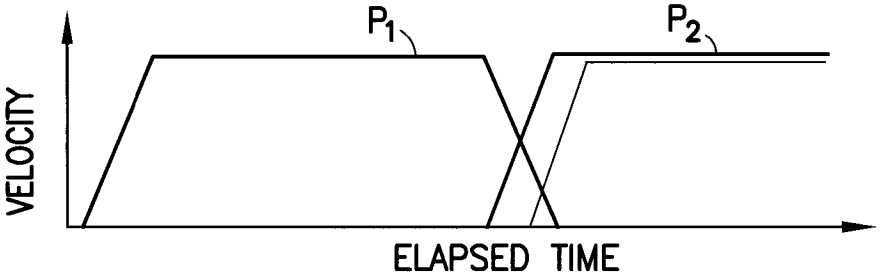

FIG.65

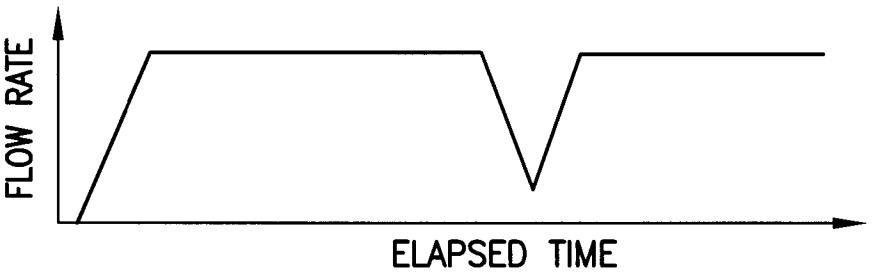

FIG.66

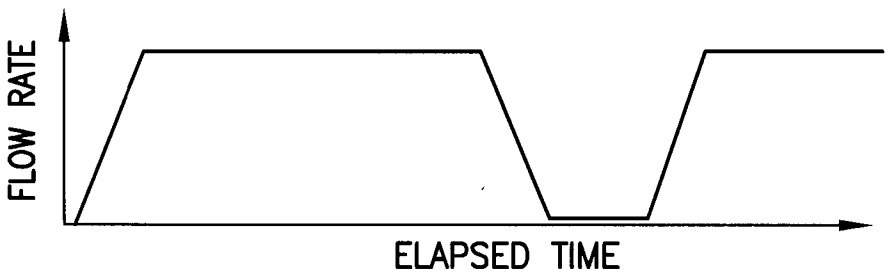

FIG.67

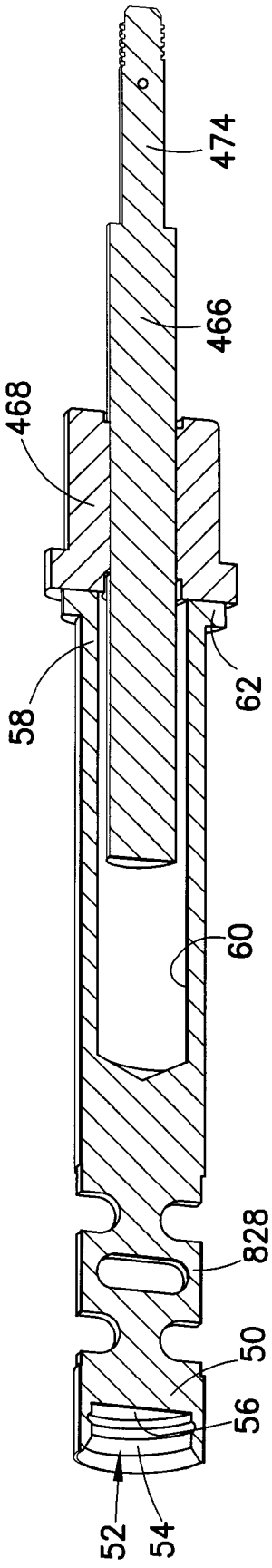

FIG.63

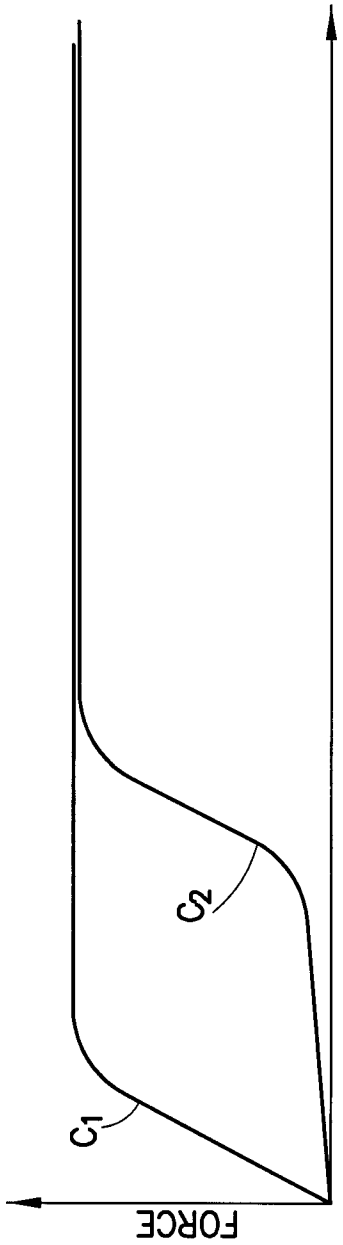

FIG.64

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 12/56328

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 5/142, 5/145; F04B 15/00, 19/04; F16K 11/02 (2012.01)
USPC - 417/442
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) - A61M 5/142, 145; F04B 15/00, 19/04; F16K 11/02 (2012.01)
USPC - 417/442

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 137/597, 625, 625.4, 625.42; 417/338, 426, 427, 478, 485, 521, 522, 523, 524, 536, 538 (text search - see terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST(USPT,PGPB,EPAB,JPAB); PatBase; Google Scholar; Google Patents
Search Terms: select, valve, pump, plunger, manifold, selector, cylinder, indicia, drawer, clamp, piston, disc, radial, lip,... etc.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2011/0200456 A1 (Patzer) 18 August 2011 (18.08.2011), fig 10A, 16, 17 and 18A, para [0060], [0068], [0080]-[0084], [0088] and [0091]-[0092]	1-4 and 10-12 --- 5-9 and 13-50
Y	US 2010/0298699 A1 (Reilly et al.) 25 November 2010 (25.11.2010), fig 3, para [0046]	5 and 6
Y	US 4,469,121 A (Moen) 04 September 1984 (04.09.1984), fig 1 and 2, col 3, ln 11-22	7-9 and 15-17
Y	US 6,436,072 B1 (Kullas et al.) 20 August 2002 (20.08.2002), col 3, ln 1-18	13-20
Y	US 2008/0034959 A1 (Vu) 14 February 2008 (14.02.2008), fig 1, 2 and 3, para [0025]-[0026]	21-50
Y	US 6,197,000 B1 (Reilly et al.) 06 March 2001 (06.03.2001), fig 2B, col 5, ln 52-57	21-26 and 38-50
Y	US 5,362,291 A (Williamson, IV) 08 November 1994 (08.11.1994), fig 3 and 11, col 4, ln 50-55, col 6, ln 16-42	27-41
Y	US 2004/0074281 A1 (Lobdell et al.) 22 April 2004 (22.04.2004), fig 1, para [0015]	33-35

☐ 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
26 November 2012 (26.11.2012)	13 DEC 2012
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: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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