



(51) International Patent Classification:

A61M 5/148 (2006.01) A61M 5/155 (2006.01)
A61M 5/145 (2006.01) A61M 31/00 (2006.01)

(21) International Application Number:

PCT/US2009/052056

(22) International Filing Date:

29 July 2009 (29.07.2009)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/084,570 29 July 2008 (29.07.2008) US

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(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, 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, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (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, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

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

(54) Title: INJECTION DEVICE WITH EXPANDABLE DRIVE FLUID CHAMBER

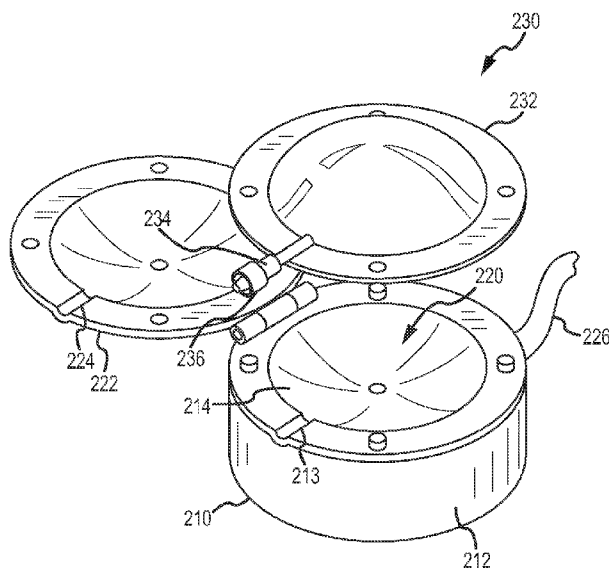


FIG.8

(57) Abstract: An injection device (210) having an expandable/contractable drive fluid chamber (216) is disclosed. A diaphragm (214) separates the drive fluid chamber (216) from a medical fluid chamber (220). A container (232) having a medical fluid (240) may be positioned in the medical fluid chamber (220). Directing a drive fluid (218) into the drive fluid chamber (216) results in medical fluid (240) being discharged from the injection device (210) by a resulting movement of the diaphragm (214).

INJECTION DEVICE WITH EXPANDABLE DRIVE FLUID CHAMBER

CROSS-REFERENCE TO RELATED APPLICATIONS

5 This patent application claims priority under 35 U.S.C. §119(e) to pending U.S. Provisional Patent Application Serial No. 61/084,570 entitled "INJECTION DEVICE WITH EXPANDABLE DRIVE FLUID CHAMBER" filed on July 29, 2008.

FIELD OF THE INVENTION

10 The present invention generally relates to injection systems and, more particularly, to the manner of applying a drive force to provide for a fluid discharge.

BACKGROUND

15 Various medical procedures require that one or more medical fluids be injected into a patient. For example, medical imaging procedures oftentimes involve the injection of contrast media into a patient, possibly along with saline and/or other fluids. Other medical procedures involve injecting one or more fluids into a patient for therapeutic purposes. Power injectors may be used for these types of applications.

A power injector generally includes what is commonly referred to as a powerhead. One or more syringes may be mounted to the powerhead in various manners (e.g., detachably; rear-loading; front-loading; side-loading).
20 Each syringe typically includes what may be characterized as a syringe plunger, piston, or the like. Each such syringe plunger is designed to interface with (e.g., contact and/or temporarily interconnect with) an appropriate syringe plunger driver that is incorporated into the powerhead, such that operation of the syringe plunger driver axially advances the associated syringe plunger inside and relative to a barrel of the syringe. One typical syringe plunger driver is in the form of a ram that is mounted on a threaded lead or drive screw. Rotation of the drive
25 screw in one rotational direction advances the associated ram in one axial direction, while rotation of the drive screw in the opposite rotational direction advances the associated ram in the opposite axial direction. The following describes alternative manners for providing powered injections of medical fluids.

SUMMARY

30 A first aspect of the present invention is generally directed to an injection device that includes a diaphragm that is disposed within an injector housing. A medical fluid chamber in which a medical fluid container may be positioned is disposed on a first side of this diaphragm, and a drive fluid chamber is disposed on a second side of this diaphragm. A drive fluid port is fluidly interconnected with the drive fluid chamber.

A number of feature refinements and additional features are applicable to the first aspect of the present
35 invention. These feature refinements and additional features may be used individually or in any combination. The following discussion is applicable to the first aspect, up to the start of the discussion of a second aspect of the present invention. The diaphragm may be characterized as movable, flexible, or both. The diaphragm may move in any appropriate manner. In one embodiment, the diaphragm is formed from an elastic material, in which case

the diaphragm may be moved by expanding (e.g., stretching, an elastic deformation) and contracting. The diaphragm may be characterized as being stretchable, contractable, flexible (e.g., capable of being flexed or undergoing flexure), pliable, deflectable, deformable, or any combination thereof. In one embodiment, part of the diaphragm (e.g., a perimeter portion) is maintained in a stationary or fixed position, while the remainder thereof is movable (e.g., via its elasticity or ability to stretch and contract). The diaphragm may elastically deflect into the medical fluid chamber in response to drive fluid being directed into the drive fluid chamber. The potential energy stored in the diaphragm during this deflection may be used to move the diaphragm in the direction of the drive fluid chamber (e.g., to discharge drive fluid out of the drive fluid chamber).

Any appropriate medical fluid may be contained within the container, for instance in the form of a liquid. Representative medical fluids include contrast media, saline, radiopharmaceuticals, therapeutic fluids, and the like. In one embodiment, the container is disposed in interfacing relation with the diaphragm. In any case, the container may be characterized as a deformable container, a flexible container, or the like. One or more sheets of material may be used to define the deformable container. Tubing may extend from the container, including prior to loading the same into the injection device. The container may also be mounted to a patient to transport the same from one location to another. In one embodiment, the container includes an armband. A patient may thereby "wear" the container, for instance when being transported to an imaging suite. Tubing extending from the container could also be fluidly connected with the patient at this time via an appropriate vasculature access device (e.g., a catheter).

Any appropriate drive fluid may be disposed within the drive fluid chamber, including a gas, liquid, or a combination thereof. In one embodiment, any medical fluid in the medical fluid chamber at all times remains fluidly isolated from any drive fluid in the drive fluid chamber. In one embodiment, the drive fluid chamber is defined at least in part by the injector housing and the diaphragm.

Drive fluid may be introduced into the drive fluid chamber via the drive fluid port to move the diaphragm, where this movement of the diaphragm may exert a compressive force on medical fluid in the medical fluid chamber to discharge the same from the injection device (e.g., by a compression or deformation of the container). Introducing drive fluid into the drive fluid chamber may increase the volume or expand the drive fluid chamber, which in turn may move the diaphragm. This movement of the diaphragm may exert a compressive force on medical fluid in the medical fluid chamber to discharge the same from the injection device, may reduce the volume of the medical fluid chamber, or both. The volumes of the medical fluid chamber and the drive fluid chamber may simultaneously change in opposite manners – one expands while the other contracts, and vice versa.

The injection device may include an access door. This access door may be movably interconnected with the injector housing in any appropriate manner. Opening the access door may allow a container having the medical fluid therein to be loaded in the medical fluid chamber of the injection device. Closing the access door may define an at least substantially enclosed space that coincides with the medical fluid chamber (e.g., the medical fluid chamber may be defined at least in part by the diaphragm and the access door).

An injection system may use the injection device described herein and a disposable, where this disposable includes a container and interconnected tubing. An appropriate connector may be positioned on a free

end of this tubing. As noted above, this container may be positioned within the medical fluid chamber of the injection device. Drive fluid may be introduced into the drive fluid chamber to expand the same, move the diaphragm, and compress the medical fluid chamber to in turn compress the container so as to discharge medical fluid from the container.

5 One embodiment of an imaging system uses the injection device described herein and an imaging table, where the injector housing may be positioned on this imaging table. Another embodiment of an imaging system uses the injection device described herein and an imaging unit, where this imaging unit includes a support rail, and where the injection device is detachably mounted on this support rail (e.g., suspended from the support rail).

Each such injection device may be used for any appropriate application where the delivery of one or more
10 medical fluids is desired, including without limitation any appropriate medical imaging application (e.g., computed tomography or CT imaging; magnetic resonance imaging or MRI; single photon emission computed tomography or SPECT imaging; positron emission tomography or PET imaging; X-ray imaging; angiographic imaging; optical imaging; ultrasound imaging) and/or any appropriate medical diagnostic and/or therapeutic application (e.g., injection of chemotherapy, pain management medication, etc.). Each such injection device may be used in
15 conjunction with any component or combination of components, such as an appropriate imaging system (e.g., a CT scanner). For instance, information could be conveyed between any such injection device and one or more other components (e.g., scan delay information, injection start signal, injection rate).

Any appropriate medical fluid may be discharged from a given injection device (e.g., contrast media, therapeutic fluids, radiopharmaceuticals, saline, and any combination thereof). In one embodiment, fluid
20 discharged from an injection device is directed into a conduit (e.g., medical tubing set), where this conduit is fluidly interconnected with the injection device in any appropriate manner and directs fluid to a desired location (e.g., to a catheter that is inserted into a patient, for instance for injection).

A second aspect of the present invention is directed to a method of injecting medical fluid into a patient using an injection device. This injection device includes a diaphragm, a first chamber (e.g., a medical fluid
25 chamber) on a first side of the diaphragm, and a second chamber (e.g., a drive fluid chamber) on an opposite, second side of the diaphragm. A deformable container includes a medical fluid and is loaded into the first chamber. A patient is fluidly interconnected with the deformable container. The deformable container is compressed by moving the diaphragm, which in turn discharges medical fluid from the deformable container and into the patient.

30 A number of feature refinements and additional features are applicable to the second aspect of the present invention. These feature refinements and additional features may be used individually or in any combination. The following discussion is applicable to at least the second aspect. The deformable container may be mounted onto a patient, and this mounting of the container onto the patient may occur in any appropriate manner. In one embodiment, the deformable container includes an armband such that the patient may "wear" the
35 deformable container. This may allow the patient to be "prepped" for an injection in one location (e.g., have a catheter or other access device inserted into a vein, where tubing fluidly interconnects the deformable container and catheter), where the patient may then be transported to another location for the actual injection and while

"wearing" the deformable container. A deformable container that has been mounted on the patient may be removed from the patient for loading into the injection device. Although, the patient may be fluidly interconnected with the deformable container prior to loading the deformable container into the injection device, such a fluid interconnection could be established after the container is loaded into the injection device.

5 The movement of the diaphragm that provides for discharge of medical fluid from the deformable container and into the patient is subject to a number of characterizations. One is that this movement of the diaphragm may entail the diaphragm being stretched (e.g., elastically). Another is that this movement of the diaphragm may entail the diaphragm being deformed. Yet another is that this movement of the diaphragm may be in the direction of the first chamber.

10 The compression of the deformable container may include (or may be in response to) an expansion of the second chamber. This expansion of the second chamber may be used to move the diaphragm, which in turn may provide for a contraction of the first chamber. The compression of the deformable container may be realized by increasing a volume of the second chamber and simultaneously decreasing a volume of the first chamber. In one embodiment, the compression of the deformable container is realized by directing a drive fluid into the second
15 chamber.

A number of feature refinements and additional features are separately applicable to each of the first and second aspects of the present invention. These feature refinements and additional features may be used individually or in any combination in relation to each of the first and second aspects. Initially, any feature of any of the various aspects of the present invention that is intended to be limited to a "singular" context or the like will be
20 clearly set forth herein by terms such as "only," "single," "limited to," or the like. Merely introducing a feature in accordance with commonly accepted antecedent basis practice does not limit the corresponding feature to the singular. Moreover, any failure to use phrases such as "at least one" also does not limit the corresponding feature to the singular. Use of the phrase "at least generally" or the like in relation to a particular feature encompasses the corresponding characteristic specified in relation to this feature and insubstantial variations thereof (e.g., indicating
25 that a syringe barrel is at least generally cylindrical encompasses the syringe barrel actually being cylindrical). Finally, a reference of a feature in conjunction with the phrase "in one embodiment" does not limit the use of the feature to a single embodiment.

BRIEF DESCRIPTION OF THE FIGURES

30 Figure 1 is a schematic of one embodiment of a power injector.

Figure 2A is a perspective view of one embodiment of a portable stand-mounted, dual-head power injector.

Figure 2B is an enlarged, partially exploded, perspective view of a powerhead used by the power injector of Figure 2A.

35 Figure 2C is a schematic of one embodiment of a syringe plunger drive assembly used by the power injector of Figure 2A.

Figure 3A is a perspective view of one embodiment of an injection system that utilizes a portable injection device having an expandable drive chamber to compress a container of the injection system for discharging fluid therefrom.

Figure 3B is a perspective view of a disposable that may be used by the injection system of Figure 3A.

5 Figure 4 is a perspective view of one embodiment of an injection system that utilizes a support-mounted injection device having an expandable drive chamber to compress a container of the injection system for discharging fluid therefrom.

10 Figure 5A is a perspective view of one embodiment of an injection system that utilizes a suspendable injection device having an expandable drive chamber to compress a container of the injection system for discharging fluid therefrom.

Figure 5B is a perspective view of one embodiment of an imaging system that utilizes the injection system of Figure 5A.

15 Figure 6 is a perspective view of one embodiment of an injection system that utilizes a stand-mounted injection device having an expandable drive chamber to compress a container of the injection system for discharging fluid therefrom.

Figure 7 is a perspective view of one embodiment of a base station having separate fluid loading and storage units for a portable injection device having an expandable drive chamber to compress a container of the injection system for discharging fluid therefrom.

20 Figure 8 is a perspective view of an injection device having an expandable drive chamber to compress a container for discharging fluid therefrom.

Figure 9A is a cross-sectional view of the injection device of Figure 8, prior to medical fluid having been loaded therein.

Figure 9B is a cross-sectional view of the injection device of Figure 8, with medical fluid having been loaded therein.

25 Figure 9C is a cross-sectional view of the injection device of Figure 8 as medical fluid is being discharged from the injection device by an expansion of the drive fluid chamber of the injection device.

Figure 10A is a perspective view of one embodiment of a strip or chain of the containers that may be used by the injection device of Figure 8.

30 Figure 10B is a perspective view of one embodiment of a strip or chain of a variation of the containers used by the injection device of Figure 8, and during the fabrication thereof.

DETAILED DESCRIPTION

Figure 1 presents a schematic of one embodiment of a power injector 10 having a powerhead 12. One or more graphical user interfaces or GUIs 11 may be associated with the powerhead 12. Each GUI 11: 1) may be of
35 any appropriate size, shape, configuration, and/or type; 2) may be operatively interconnected with the powerhead 12 in any appropriate manner; 3) may be disposed at any appropriate location; 4) may be configured to provide any of the following functions: controlling one or more aspects of the operation of the power injector 10;

inputting/editing one or more parameters associated with the operation of the power injector 10; and displaying appropriate information (e.g., associated with the operation of the power injector 10); or 5) any combination of the foregoing. Any appropriate number of GUIs 11 may be utilized. In one embodiment, the power injector 10 includes a GUI 11 that is incorporated by a console that is separate from but which communicates with the powerhead 12. In another embodiment, the power injector 10 includes a GUI 11 that is part of the powerhead 12. In yet another embodiment, the power injector 10 utilizes one GUI 11 on a separate console that communicates with the powerhead 12, and also utilizes another GUI 11 that is on the powerhead 12. Each GUI 11 could provide the same functionality or set of functionalities, or the GUIs 11 may differ in at least some respect in relation to their respective functionalities.

A syringe 28 may be installed on the powerhead 12 and, when installed, may be considered to be part of the power injector 10. Some injection procedures may result in a relatively high pressure being generated within the syringe 28. In this regard, it may be desirable to dispose the syringe 28 within a pressure jacket 26. The pressure jacket 26 is typically associated with the powerhead 12 in a manner that allows the syringe 28 to be disposed therein as a part of or after installing the syringe 28 on the powerhead 12. The same pressure jacket 26 will typically remain associated with the powerhead 12, as various syringes 28 are positioned within and removed from the pressure jacket 26 for multiple injection procedures. The power injector 10 may eliminate the pressure jacket 26 if the power injector 10 is configured/used for low-pressure injections and/or if the syringe(s) 28 to be utilized with the power injector 10 is (are) of sufficient durability to withstand high-pressure injections without the additional support provided by a pressure jacket 26. In any case, fluid discharged from the syringe 28 may be directed into a conduit 38 of any appropriate size, shape, configuration, and/or type, which may be fluidly interconnected with the syringe 28 in any appropriate manner, and which may direct fluid to any appropriate location (e.g., to a patient).

The powerhead 12 includes a syringe plunger drive assembly or syringe plunger driver 14 that interacts (e.g., interfaces) with the syringe 28 (e.g., a plunger 32 thereof) to discharge fluid from the syringe 28. This syringe plunger drive assembly 14 includes a drive source 16 (e.g., a motor of any appropriate size, shape, configuration, and/or type, optional gearing, and the like) that powers a drive output 18 (e.g., a rotatable drive screw). A ram 20 may be advanced along an appropriate path (e.g., axial) by the drive output 18. The ram 20 may include a coupler 22 for interacting or interfacing with a corresponding portion of the syringe 28 in a manner that will be discussed below.

The syringe 28 includes a plunger or piston 32 that is movably disposed within a syringe barrel 30 (e.g., for axial reciprocation along an axis coinciding with the double-headed arrow B). The plunger 32 may include a coupler 34. This syringe plunger coupler 34 may interact or interface with the ram coupler 22 to allow the syringe plunger drive assembly 14 to retract the syringe plunger 32 within the syringe barrel 30. The syringe plunger coupler 34 may be in the form of a shaft 36a that extends from a body of the syringe plunger 32, together with a head or button 36b. However, the syringe plunger coupler 34 may be of any appropriate size, shape, configuration, and/or type.

Generally, the syringe plunger drive assembly 14 of the power injector 10 may interact with the syringe plunger 32 of the syringe 28 in any appropriate manner (e.g., by mechanical contact; by an appropriate coupling (mechanical or otherwise)) so as to be able to move or advance the syringe plunger 32 (relative to the syringe barrel 30) in at least one direction (e.g., to discharge fluid from the corresponding syringe 28). That is, although
5 the syringe plunger drive assembly 14 may be capable of bi-directional motion (e.g., via operation of the same drive source 16), the power injector 10 may be configured such that the operation of the syringe plunger drive assembly 14 actually only moves each syringe plunger 32 being used by the power injector 10 in only one direction. However, the syringe plunger drive assembly 14 may be configured to interact with each syringe plunger 32 being used by the power injector 10 so as to be able to move each such syringe plunger 32 in each of two
10 different directions (e.g. in different directions along a common axial path).

Retraction of the syringe plunger 32 may be utilized to accommodate a loading of fluid into the syringe barrel 30 for a subsequent injection or discharge, may be utilized to actually draw fluid into the syringe barrel 30 for a subsequent injection or discharge, or for any other appropriate purpose. Certain configurations may not require that the syringe plunger drive assembly 14 be able to retract the syringe plunger 32, in which case the ram coupler
15 22 and syringe plunger coupler 34 may not be desired. In this case, the syringe plunger drive assembly 14 may be retracted for purposes of executing another fluid delivery operation (e.g., after another pre-filled syringe 28 has been installed). Even when a ram coupler 22 and syringe plunger coupler 34 are utilized, it may be such that these components may or may not be coupled when the ram 20 advances the syringe plunger 32 to discharge fluid from the syringe 28 (e.g., the ram 20 may simply "push on" the syringe plunger coupler 34 or directly on a proximal end
20 of the syringe plunger 32). Any single motion or combination of motions in any appropriate dimension or combination of dimensions may be utilized to dispose the ram coupler 22 and syringe plunger coupler 34 in a coupled state or condition, to dispose the ram coupler 22 and syringe plunger coupler 34 in an un-coupled state or condition, or both.

The syringe 28 may be installed on the powerhead 12 in any appropriate manner. For instance, the
25 syringe 28 could be configured to be installed directly on the powerhead 12. In the illustrated embodiment, a housing 24 is appropriately mounted on the powerhead 12 to provide an interface between the syringe 28 and the powerhead 12. This housing 24 may be in the form of an adapter to which one or more configurations of syringes 28 may be installed, and where at least one configuration for a syringe 28 could be installed directly on the powerhead 12 without using any such adapter. The housing 24 may also be in the form of a faceplate to which
30 one or more configurations of syringes 28 may be installed. In this case, it may be such that a faceplate is required to install a syringe 28 on the powerhead 12 – the syringe 28 could not be installed on the powerhead 12 without the faceplate. When a pressure jacket 26 is being used, it may be installed on the powerhead 12 in the various manners discussed herein in relation to the syringe 28, and the syringe 28 will then thereafter be installed in the pressure jacket 26.

35 The housing 24 may be mounted on and remain in a fixed position relative to the powerhead 12 when installing a syringe 28. Another option is to movably interconnect the housing 24 and the powerhead 12 to accommodate installing a syringe 28. For instance, the housing 24 may move within a plane that contains the

double-headed arrow A to provide one or more of coupled state or condition and an un-coupled state or condition between the ram coupler 22 and the syringe plunger coupler 34.

One particular power injector configuration is illustrated in Figure 2A, is identified by a reference numeral 40, and is at least generally in accordance with the power injector 10 of Figure 1. The power injector 40 includes a powerhead 50 that is mounted on a portable stand 48. Two syringes 86a, 86b for the power injector 40 are
5 mounted on the powerhead 50. Fluid may be discharged from the syringes 86a, 86b during operation of the power injector 40.

The portable stand 48 may be of any appropriate size, shape, configuration, and/or type. Wheels, rollers, casters, or the like may be utilized to make the stand 48 portable. The powerhead 50 could be maintained in a fixed position relative to the portable stand 48. However, it may be desirable to allow the position of the
10 powerhead 50 to be adjustable relative to the portable stand 48 in at least some manner. For instance, it may be desirable to have the powerhead 50 in one position relative to the portable stand 48 when loading fluid into one or more of the syringes 86a, 86b, and to have the powerhead 50 in a different position relative to the portable stand 48 for performance of an injection procedure. In this regard, the powerhead 50 may be movably interconnected
15 with the portable stand 48 in any appropriate manner (e.g., such that the powerhead 50 may be pivoted through at least a certain range of motion, and thereafter maintained in the desired position).

It should be appreciated that the powerhead 50 could be supported in any appropriate manner for providing fluid. For instance, instead of being mounted on a portable structure, the powerhead 50 could be interconnected with a support assembly, that in turn is mounted to an appropriate structure (e.g., ceiling, wall,
20 floor). Any support assembly for the powerhead 50 may be positionally adjustable in at least some respect (e.g., by having one or more support sections that may be repositioned relative to one or more other support sections), or may be maintained in a fixed position. Moreover, the powerhead 50 may be integrated with any such support assembly so as to either be maintained in a fixed position or so as to be adjustable relative the support assembly.

The powerhead 50 includes a graphical user interface or GUI 52. This GUI 52 may be configured to
25 provide one or any combination of the following functions: controlling one or more aspects of the operation of the power injector 40; inputting/editing one or more parameters associated with the operation of the power injector 40; and displaying appropriate information (e.g., associated with the operation of the power injector 40). The power injector 40 may also include a console 42 and powerpack 46 that each may be in communication with the powerhead 50 in any appropriate manner (e.g., via one or more cables), that may be placed on a table or mounted
30 on an electronics rack in an examination room or at any other appropriate location, or both. The powerpack 46 may include one or more of the following and in any appropriate combination: a power supply for the injector 40; interface circuitry for providing communication between the console 42 and powerhead 50; circuitry for permitting connection of the power injector 40 to remote units such as remote consoles, remote hand or foot control switches, or other original equipment manufacturer (OEM) remote control connections (e.g., to allow for the operation of
35 power injector 40 to be synchronized with the x-ray exposure of an imaging system); and any other appropriate componentry. The console 42 may include a touch screen display 44, which in turn may provide one or more of the following functions and in any appropriate combination: allowing an operator to remotely control one or more

aspects of the operation of the power injector 40; allowing an operator to enter/edit one or more parameters associated with the operation of the power injector 40; allowing an operator to specify and store programs for automated operation of the power injector 40 (which can later be automatically executed by the power injector 40 upon initiation by the operator); and displaying any appropriate information relation to the power injector 40 and including any aspect of its operation.

Various details regarding the integration of the syringes 86a, 86b with the powerhead 50 are presented in Figure 2B. Each of the syringes 86a, 86b includes the same general components. The syringe 86a includes plunger or piston 90a that is movably disposed within a syringe barrel 88a. Movement of the plunger 90a along an axis 100a (Figure 2A) via operation of the powerhead 50 will discharge fluid from within a syringe barrel 88a through a nozzle 89a of the syringe 86a. An appropriate conduit (not shown) will typically be fluidly interconnected with the nozzle 89a in any appropriate manner to direct fluid to a desired location (e.g., a patient). Similarly, the syringe 86b includes plunger or piston 90b that is movably disposed within a syringe barrel 88b. Movement of the plunger 90b along an axis 100b (Figure 2A) via operation of the powerhead 50 will discharge fluid from within the syringe barrel 88b through a nozzle 89b of the syringe 86b. An appropriate conduit (not shown) will typically be fluidly interconnected with the nozzle 89b in any appropriate manner to direct fluid to a desired location (e.g., a patient).

The syringe 86a is interconnected with the powerhead 50 via an intermediate faceplate 102a. This faceplate 102a includes a cradle 104 that supports at least part of the syringe barrel 88a, and which may provide/accommodate any additional functionality or combination of functionalities. A mounting 82a is disposed on and is fixed relative to the powerhead 50 for interfacing with the faceplate 102a. A ram coupler 76 of a ram 74 (Figure 2C), which are each part of a syringe plunger drive assembly or syringe plunger driver 56 (Figure 2C) for the syringe 86a, is positioned in proximity to the faceplate 102a when mounted on the powerhead 50. Details regarding the syringe plunger drive assembly 56 will be discussed in more detail below in relation to Figure 2C. Generally, the ram coupler 76 may be coupled with the syringe plunger 90a of the syringe 86a, and the ram coupler 76 and ram 74 (Figure 2C) may then be moved relative to the powerhead 50 to move the syringe plunger 90a along the axis 100a (Figure 2A). It may be such that the ram coupler 76 is engaged with, but not actually coupled to, the syringe plunger 90a when moving the syringe plunger 90a to discharge fluid through the nozzle 89a of the syringe 86a.

The faceplate 102a may be moved at least generally within a plane that is orthogonal to the axes 100a, 100b (associated with movement of the syringe plungers 90a, 90b, respectively, and illustrated in Figure 2A), both to mount the faceplate 102a on and remove the faceplate 102a from its mounting 82a on the powerhead 50. The faceplate 102a may be used to couple the syringe plunger 90a with its corresponding ram coupler 76 on the powerhead 50. In this regard, the faceplate 102a includes a pair of handles 106a. Generally and with the syringe 86a being initially positioned within the faceplate 102a, the handles 106a may be moved to in turn move/translate the syringe 86a at least generally within a plane that is orthogonal to the axes 100a, 100b (associated with movement of the syringe plungers 90a, 90b, respectively, and illustrated in Figure 2A). Moving the handles 106a to one position moves/translates the syringe 86a (relative to the faceplate 102a) in an at least generally downward

direction to couple its syringe plunger 90a with its corresponding ram coupler 76. Moving the handles 106a to another position moves/translates the syringe 86a (relative to the faceplate 102a) in an at least generally upward direction to uncouple its syringe plunger 90a from its corresponding ram coupler 76.

The syringe 86b is interconnected with the powerhead 50 via an intermediate faceplate 102b. A mounting
5 82b is disposed on and is fixed relative to the powerhead 50 for interfacing with the faceplate 102b. A ram coupler 76 of a ram 74 (Figure 2C), which are each part of a syringe plunger drive assembly 56 for the syringe 86b, is positioned in proximity to the faceplate 102b when mounted to the powerhead 50. Details regarding the syringe plunger drive assembly 56 again will be discussed in more detail below in relation to Figure 2C. Generally, the ram coupler 76 may be coupled with the syringe plunger 90b of the syringe 86b, and the ram coupler 76 and ram 74
10 (Figure 2C) may be moved relative to the powerhead 50 to move the syringe plunger 90b along the axis 100b (Figure 2A). It may be such that the ram coupler 76 is engaged with, but not actually coupled to, the syringe plunger 90b when moving the syringe plunger 90b to discharge fluid through the nozzle 89b of the syringe 86b.

The faceplate 102b may be moved at least generally within a plane that is orthogonal to the axes 100a, 100b (associated with movement of the syringe plungers 90a, 90b, respectively, and illustrated in Figure 2A), both
15 to mount the faceplate 102b on and remove the faceplate 102b from its mounting 82b on the powerhead 50. The faceplate 102b also may be used to couple the syringe plunger 90b with its corresponding ram coupler 76 on the powerhead 50. In this regard, the faceplate 102b may include a handle 106b. Generally and with the syringe 86b being initially positioned within the faceplate 102b, the syringe 86b may be rotated along its long axis 100b (Figure 2A) and relative to the faceplate 102b. This rotation may be realized by moving the handle 106b, by grasping and
20 turning the syringe 86b, or both. In any case, this rotation moves/translates both the syringe 86b and the faceplate 102b at least generally within a plane that is orthogonal to the axes 100a, 100b (associated with movement of the syringe plungers 90a, 90b, respectively, and illustrated in Figure 2A). Rotating the syringe 86b in one direction moves/translates the syringe 86b and faceplate 102b in an at least generally downward direction to couple the syringe plunger 90b with its corresponding ram coupler 76. Rotating the syringe 86b in the opposite direction
25 moves/translates the syringe 86b and faceplate 102b in an at least generally upward direction to uncouple its syringe plunger 90b from its corresponding ram coupler 76.

As illustrated in Figure 2B, the syringe plunger 90b includes a plunger body 92 and a syringe plunger coupler 94. This syringe plunger coupler 94 includes a shaft 98 that extends from the plunger body 92, along with
30 a head 96 that is spaced from the plunger body 92. Each of the ram couplers 76 includes a larger slot that is positioned behind a smaller slot on the face of the ram coupler 76. The head 96 of the syringe plunger coupler 94 may be positioned within the larger slot of the ram coupler 76, and the shaft 98 of the syringe plunger coupler 94 may extend through the smaller slot on the face of the ram coupler 76 when the syringe plunger 90b and its corresponding ram coupler 76 are in a coupled state or condition. The syringe plunger 90a may include a similar syringe plunger coupler 94 for interfacing with its corresponding ram coupler 76.

35 The powerhead 50 is utilized to discharge fluid from the syringes 86a, 86b in the case of the power injector 40. That is, the powerhead 50 provides the motive force to discharge fluid from each of the syringes 86a, 86b. One embodiment of what may be characterized as a syringe plunger drive assembly or syringe plunger driver

is illustrated in Figure 2C, is identified by reference numeral 56, and may be utilized by the powerhead 50 to discharge fluid from each of the syringes 86a, 86b. A separate syringe plunger drive assembly 56 may be incorporated into the powerhead 50 for each of the syringes 86a, 86b. In this regard and referring back to Figures 2A-B, the powerhead 50 may include hand-operated knobs 80a and 80b for use in separately controlling each of the syringe plunger drive assemblies 56.

Initially and in relation to the syringe plunger drive assembly 56 of Figure 2C, each of its individual components may be of any appropriate size, shape, configuration and/or type. The syringe plunger drive assembly 56 includes a motor 58, which has an output shaft 60. A drive gear 62 is mounted on and rotates with the output shaft 60 of the motor 58. The drive gear 62 is engaged or is at least engageable with a driven gear 64. This driven gear 64 is mounted on and rotates with a drive screw or shaft 66. The axis about which the drive screw 66 rotates is identified by reference numeral 68. One or more bearings 72 appropriately support the drive screw 66.

A carriage or ram 74 is movably mounted on the drive screw 66. Generally, rotation of the drive screw 66 in one direction axially advances the ram 74 along the drive screw 66 (and thereby along axis 68) in the direction of the corresponding syringe 86a/b, while rotation of the drive screw 66 in the opposite direction axially advances the ram 74 along the drive screw 66 (and thereby along axis 68) away from the corresponding syringe 86a/b. In this regard, the perimeter of at least part of the drive screw 66 includes helical threads 70 that interface with at least part of the ram 74. The ram 74 is also movably mounted within an appropriate bushing 78 that does not allow the ram 74 to rotate during a rotation of the drive screw 66. Therefore, the rotation of the drive screw 66 provides for an axial movement of the ram 74 in a direction determined by the rotational direction of the drive screw 66.

The ram 74 includes a coupler 76 that may be detachably coupled with a syringe plunger coupler 94 of the syringe plunger 90a/b of the corresponding syringe 86a/b. When the ram coupler 76 and syringe plunger coupler 94 are appropriately coupled, the syringe plunger 90a/b moves along with ram 74. Figure 2C illustrates a configuration where the syringe 86a/b may be moved along its corresponding axis 100a/b without being coupled to the ram 74. When the syringe 86a/b is moved along its corresponding axis 100a/b such that the head 96 of its syringe plunger 90a/b is aligned with the ram coupler 76, but with the axes 68 still in the offset configuration of Figure 2C, the syringe 86a/b may be translated within a plane that is orthogonal to the axis 68 along which the ram 74 moves. This establishes a coupled engagement between the ram coupler 76 and the syringe plunger coupler 96 in the above-noted manner.

The power injectors 10, 40 of Figures 1 and 2A-C each may be used for any appropriate application, including without limitation for medical imaging applications where fluid is injected into a subject (e.g., a patient). Representative medical imaging applications for the power injectors 10, 40 include without limitation computed tomography or CT imaging, magnetic resonance imaging or MRI, single photon emission computed tomography or SPECT imaging, positron emission tomography or PET imaging, X-ray imaging, angiographic imaging, optical imaging, and ultrasound imaging. The power injectors 10, 40 each could be used alone or in combination with one or more other components. The power injectors 10, 40 each may be operatively interconnected with one or more

components, for instance so that information may be conveyed between the power injector 10, 40 and one or more other components (e.g., scan delay information, injection start signal, injection rate).

Any number of syringes may be utilized by each of the power injectors 10, 40, including without limitation single-head configurations (for a single syringe) and dual-head configurations (for two syringes). In the case of a multiple syringe configuration, each power injector 10, 40 may discharge fluid from the various syringes in any appropriate manner and according to any timing sequence (e.g., sequential discharges from two or more syringes, simultaneous discharges from two or more syringes, or any combination thereof). Multiple syringes may discharge into a common conduit (e.g., for provision to a single injection site), or one syringe may discharge into one conduit (e.g., for provision to one injection site), while another syringe may discharge into a different conduit (e.g., for provision to a different injection site). Each such syringe utilized by each of the power injectors 10, 40 may include any appropriate fluid (e.g., a medical fluid), for instance contrast media, a radiopharmaceutical, saline, and any combination thereof. Each such syringe utilized by each of the power injectors 10, 40 may be installed in any appropriate manner (e.g., rear-loading configurations may be utilized; front-loading configurations may be utilized; side-loading configurations may be utilized).

Various embodiments of injection devices that may utilize an expandable and contractable drive fluid chamber to discharge fluid from a container are addressed below. Generally, a container may be positioned within the injection device. A drive fluid may be directed into the drive fluid chamber of the injection device to compress the container to discharge fluid therefrom. Although these injection devices may be used for any appropriate application, in one embodiment fluid that is discharged from the container in the noted manner is injected into a patient. A number of injection devices that may utilize the above-noted principles will first be addressed (Figures 3-7), followed by a representative configuration of an injection device with an expandable/contractable drive fluid chamber (Figures 8-9C) that may be utilized by each these injection devices.

One embodiment of injection system is illustrated in Figures 3A and 3B, and is identified by reference numeral 110. The injection system 110 includes an injection device 120 and a disposable 112. The injection device 120 may utilize an expandable/contractable drive fluid chamber for discharging fluid from the disposable 112 (e.g., Figure 8 discussed below). In this regard, the injection device 120 may utilize a movable diaphragm 124 that separates a container chamber 122 from a drive fluid chamber (not shown in Figure 3A). An access door 126 of the injection device 120 cooperates with the diaphragm 124 to define the noted container chamber 122 for the injection device 120.

A communication link 128 of any appropriate type (e.g., a cable, wireless-based) operatively interconnects the injection device 120 with a controller 130. This controller may be disposed at any appropriate location. In one embodiment, the injection device 120 includes what may be characterized as an on-board energy source and an on-board pressurizing unit for the drive fluid (e.g., a pump). In another embodiment, the injection device 120 may utilize a remote energy source, a remote pressurizing unit, or both. "Remote" in this context means spaced from the illustrated injection device 120.

The disposable 112 used by the injection system 110 includes a container 114 and tubing 116. This container 114 may be characterized as a flexible container 114 and/or as a deformable container 114. A

connector 118 of any appropriate type may be utilized to fluidly interconnect the disposable 112 with another component of the injection system 110 (e.g., additional tubing, a catheter), for instance to provide fluid discharged from the container 114 to a fluid target (e.g., for injection into a patient). Although the injection system 110 may be used for any appropriate application, in one embodiment the injection system 110 is utilized for an imaging operation.

The injection device 120 may be in the form of a small, hand-transportable structure. The reduced spaced required for the injection device 120 makes it particularly desirable for use in an imaging suite. Although the injection device 120 could occupy any appropriate location in an imaging suite, Figure 3A illustrates that the injection device 120 is small enough to be positioned on a table 138 without interfering with the patient and/or the imaging operation. Although the injection device 120 may be of any appropriate shape, in the illustrated embodiment it is a cylindrical structure.

Another embodiment of an injection system is illustrated in Figure 4, and is identified by reference numeral 140. The injection system 140 includes an injection device 142 and the above-noted disposable 112. The injection device 142 may utilize an expandable/contractable drive fluid chamber for discharging fluid from the disposable 112 (e.g., Figure 8 discussed below). In this regard, the injection device 142 may utilize a movable diaphragm 146, which may define the base of an access drawer 144 in which the container 114 of the disposable 112 may be positioned.

Figure 4 illustrates that the injection device 142 may be mounted on an appropriate support 148 (e.g., a ceiling-mounted or wall-mounted structure). However, the injection device 142 may be supported by any appropriate structure. In any case, the injection device 142 may include an on-board energy source, an on-board pressurizing unit for the drive fluid (e.g., a pump), and an on-board controller. In another embodiment, the injection device 142 may utilize a remote energy source, a remote pressurizing unit, a remote controller, or any combination thereof.

Although the injection system 140 may be used for any appropriate application, in one embodiment the injection system 140 is utilized for an imaging operation. In this regard, Figure 4 illustrates that an armband 119 may be used to temporarily mount the container 114 on a patient 150. This allows the disposable 112 to be fluidly interconnected with the patient 150 outside of the imaging suite, which may be beneficial in at least some instances. Note that the tubing 116 could of course be interconnected with a catheter that is inserted into the patient 150 prior to entering the imaging suite as well. Once in the imaging suite, the armband 119 may be removed from the patient 150 such that the container 114 may be positioned in the injection device 142. Moreover, the patient 150 may be placed in a desired position on an imaging table 138. Thereafter, the injection device 142 and an imaging unit 152 may be operated to acquire a desired image of the patient 150. It should be appreciated that the armband 119 could be utilized in each of the embodiments disclosed herein that use a disposable 112 or the like.

Another embodiment of an injection system is illustrated in Figures 5A and 5B, and is identified by reference numeral 160. The injection system 160 includes an injection device 162 and may also utilize the above-noted disposable 112. However, the disposable 112 is not shown in Figures 5A and 5B.

The injection device 162 may utilize an expandable/contractable drive fluid chamber for discharging fluid from the disposable 112 (e.g., Figure 8 discussed below). In one embodiment, the injection device 162 includes an on-board energy source, an on-board pressurizing unit for the drive fluid (e.g., a pump), and an on-board controller. In another embodiment, the injection device 162 may utilize a remote energy source, a remote
5 pressurizing unit, a remote controller, or any combination thereof.

Although the injection system 160 may be used for any appropriate application, in one embodiment the injection system 160 is utilized by an imaging system 168 for imaging operations. In this regard, the imaging unit 152 may include a support 154 in the form of a rail in the illustrated embodiment. The injection device 162 may include a handle or hanger 164 for supporting the injection device 162 from this support rail 154. However, the
10 injection device 162 may be supported by any appropriate structure.

Another embodiment of an injection system is illustrated in Figure 6, and is identified by reference numeral 170. The injection system 170 includes an injection device 172 and may also utilize the above-noted disposable 112. However, the disposable 112 is not shown in Figure 6.

The injection device 172 may utilize an expandable/contractable drive fluid chamber for discharging fluid
15 from the disposable 112 (e.g., Figure 8 discussed below). In the illustrated embodiment, the injection device 172 includes an on-board controller and an on-board pressurizing unit for the drive fluid (e.g., a pump) in the form of a base unit 174. Although the injection device 172 could also utilize an on-board energy source, in the illustrated embodiment a power cord 184 is used to provide power to each the injection device 172 and its base unit 174.

The base unit 174 of the injection device 172 may include a display 176, one or more indicators 178 to
20 provide feedback to operations personnel (e.g., a visual indication that an injection is underway), a control console 180 for inputting/editing one or more operational aspects of the injection device 172, one or more other appropriate components, or any combination thereof. In the illustrated embodiment, the injection device 172 and its base unit 174 are mounted on a portable stand 182. The injection device 172 may be rotated relative to this stand 182 and as indicated by the double-headed arrow 186. It may be desirable to rotate or pivot the injection device 172
25 between at least two general positions – an injection position and an air purging position.

Figure 7 illustrates one embodiment of a base station 190. The base station 190 includes a fluid-loading unit or side 192 and a storage unit or side 196. Generally, a disposable 112 may be loaded with an appropriate fluid by the fluid-loading unit 192 of the base station 190. In this regard, one or more containers 194 may be
utilized by the fluid-loading unit 192 to load fluid into the disposable 112.

A fluid-loaded disposable 112 may be stored in a drawer 198 on the storage side 196 of the base station
30 190. The storage side 196 also accommodates storage of an injection device 200 (e.g., in an appropriately sized, shaped, receptacle on the base station 190). The injection device 200 may include a handle 208 to facilitate removal of the injection device 200 from the base station 190, to facilitate hand-carrying of the injection device 200, to facilitate supporting the injection device 200 from an appropriate structure, or any combination thereof.

The injection device 200 may utilize an expandable/contractable drive fluid chamber for discharging fluid
35 from the disposable 112 (e.g., Figure 8 discussed below). In one embodiment, the injection device 200 includes an on-board energy source, an on-board pressurizing unit for the drive fluid (e.g., a pump), and an on-board

controller. In another embodiment, the injection device 200 may utilize a remote energy source, a remote pressurizing unit, a remote controller, or any combination thereof.

The injection device 200 includes a container chamber 202 in which the container 114 of the disposable 112 may be positioned on a movable diaphragm 203 of the injection device 200. This container chamber 202 may be collectively defined by the diaphragm 203 and an access door 204 of the injection device 200 when in its closed position (the access door 204 being in the open position in Figure 7). The tubing 116 of the disposable 112 will extend through a tubing slot or receiver 206 on the injection device 200 even when the access door 204 is closed, and then, for instance, to a patient.

One embodiment of an injection device is illustrated in Figures 8 and 9A-9C, and is identified by reference numeral 210. The injection device 210 includes a base or housing 212, a movable diaphragm 214, and an access door 222 that is movably interconnected with the base 212 in any appropriate manner. A drive fluid chamber 216 of the injection device 210 is defined by the base 212 and the movable diaphragm 214. An appropriate drive fluid 218 may be directed into the drive fluid chamber 216 through a drive fluid line 226 of any appropriate type. Where the drive fluid line 226 intersects with the drive fluid chamber 216 (e.g., to provide fluid access to the drive fluid chamber 216) may be characterized as a drive fluid port.

The injection device 210 further includes a medical fluid chamber 220 that is defined by the diaphragm 214 and the access door 222. A container 232 of a disposable 230 may be disposed within the container chamber 220 when the access door 222 of the injection device 210 is in its open position. A discharge port 234 of the container 232 may include any appropriate connector 236 for facilitating an interconnection with tubing 238 (Figures 9B and 9C). An appropriate medical fluid 240 may be contained within the container 232. In one embodiment, fluid from the container 232 is discharged through the discharge port 234, into the tubing 238, and is delivered to a patient for injection. The base 212 may include a tubing slot 213 and the access door 222 may include a tubing slot 224 to allow for a flow of medical fluid 240 out of the container 232 and into the noted tubing 238 (Figures 9B and 9C) even when the access door 222 is in its closed position (e.g., closing the access door 222 does not "pinch" the flowpath from the container 232).

Figures 9A-9C are representative illustrations that address various aspects of the operation of the injection device 210. Initially, a container 232 is not illustrated in Figures 9A-9C, but is in fact used. Figure 9A is a representative configuration for the injection device 210 when there is no medical fluid 240 in the medical fluid chamber 220 (e.g., prior to installing a container 232 in the injection device 210). The drive fluid 218 may therefore occupy a substantial entirety of an inner volume of the injection device 210 at this time.

Figure 9B is a representative configuration for the injection device 210 where a desired amount of medical fluid 240 is contained within the container chamber 220 and prior to an initial actuation of the injection device 210 (e.g., a "filled" condition for the container 232 in relation to the medical fluid 240). This may entail having directed medical fluid 240 into the medical fluid chamber 220 via tubing 238 (and into the container 232) and at least allowing the drive fluid 218 to exit the drive fluid chamber 216 through the drive fluid line 226. Compare the quantity of drive fluid 218 in Figure 9A (e.g., an "empty" configuration in relation to the medical fluid 240), to the quantity of drive fluid 218 in Figure 9B (e.g., a "full" configuration in relation to the medical fluid 240) – there is less

drive fluid 218 in the injection device 210 in the Figure 9B configuration compared to the Figure 9A configuration. Stated another way, the volume of the drive fluid chamber 216 is smaller in Figure 9B compared to Figure 9A, and the volume of the medical fluid chamber 220 is greater in Figure 9B compared to Figure 9A. This is due to movement of the diaphragm 214.

5 Figure 9C is a representative configuration for the injection device 210 during operation of the injection device 210. Note that drive fluid 218 is being directed into the drive fluid chamber 216, and that medical fluid 240 is being directed out of the injection device 210 through the tubing 238 (e.g., by a compression and/or deformation of the container 232). Note that the volume of the drive fluid chamber 216 is larger in Figure 9C compared to Figure 9B (but smaller than in Figure 9A), and that the volume of the medical fluid chamber 220 is smaller in Figure 10 9C compared to Figure 9B (but larger than in Figure 9A). Again, this is due to movement of the diaphragm 214.

The movement of the diaphragm 214 is subject to a number of characterizations. In one embodiment, the diaphragm 214 is formed from an elastic material, and it moves by stretching and contracting. The diaphragm 214 may also be characterized as flexible, pliable, deflectable, deformable, and expandable/contractable. In the illustrated embodiment, part of the diaphragm 214 (e.g., a perimeter portion thereof) is maintained in a stationary or fixed position, while the remainder thereof is movable (e.g., via its elasticity or ability to stretch and contract).

15 Figure 10A illustrates one embodiment of a strip or chain 250 of the above-noted containers 232. That is, a plurality of containers 232 could be simultaneously fabricated from a plurality of sheets of an appropriate material. Adjacent containers 232 in the strip or chain 250 may be physically separated from each other in any appropriate manner. Figure 10B illustrates another embodiment of a strip or chain 250' of the containers 232'. That is, a plurality of containers 232' could be simultaneously fabricated from a plurality of sheets of an appropriate material, for instance using one or more heat seals 254 or the like. Adjacent containers 232' in the strip or chain 20 250' may be physically separated from each other in any appropriate manner.

The foregoing description of the present invention has been presented for purposes of illustration and description. Furthermore, the description is not intended to limit the invention to the form disclosed herein. 25 Consequently, variations and modifications commensurate with the above teachings, and skill and knowledge of the relevant art, are within the scope of the present invention. The embodiments described hereinabove are further intended to explain best modes known of practicing the invention and to enable others skilled in the art to utilize the invention in such, or other embodiments and with various modifications required by the particular application(s) or use(s) of the present invention. It is intended that the appended claims be construed to include 30 alternative embodiments to the extent permitted by the prior art.

What is claimed:

1. An injection device, comprising:
 - an injector housing;
 - a flexible diaphragm disposed within said injector housing;
 - 5 a medical fluid chamber disposed on a first side of said diaphragm;
 - a deformable container disposed within said medical fluid chamber;
 - a drive fluid chamber disposed on a second side of said diaphragm; and
 - a drive fluid port fluidly interconnected with said drive fluid chamber.
2. The injection device of claim 1, wherein said diaphragm is able to flex in a direction of said
10 medical fluid chamber and is also able to flex in a direction of said drive fluid chamber.
3. The injection device of any of claims 1-2, wherein said diaphragm comprises an elastic material.
4. The injection device of any of claims 1-3, wherein said diaphragm comprises a stretchable material.
- 15 5. The injection device of any of claims 1-4, further comprising medical fluid within said deformable container.
6. The injection device of claim 5, wherein said medical fluid comprises a medical liquid.
7. The injection device of any of claims 5-6, wherein said medical fluid is contained within said deformable container prior to said deformable container being loaded into said medical fluid chamber.
- 20 8. The injection device of any of claims 1-7, further comprising a drive fluid disposed within said drive fluid chamber.
9. The injection device of claim 8, wherein said drive fluid comprises a liquid.
10. The injection device of claim 8, wherein said drive fluid comprises a gas.
11. The injection device of any of claims 1-10, wherein introducing drive fluid into said drive fluid
25 chamber moves said diaphragm to discharge medical fluid from said medical fluid chamber.
12. The injection device of any of claims 1-10, wherein introducing drive fluid into said drive fluid chamber moves said diaphragm to increase a volume of said drive fluid chamber and simultaneously decrease a volume of each of said deformable container and said medical fluid chamber.
13. The injection device of any of claims 1-6 and 8-12, wherein introducing medical fluid into
30 said deformable container, when disposed in said medical fluid chamber, moves said diaphragm to increase a volume of said medical fluid chamber and simultaneously decrease a volume of said drive fluid chamber.
14. The injection device of any of claims 1-13, further comprising an access door that is movably interconnected with said injector housing.
15. The injection device of claim 14, wherein said medical fluid chamber is defined at least in
35 part by said diaphragm and said access door.
16. The injection device of any of claims 1-15, wherein said drive fluid chamber is defined at least in part by said injector housing and said diaphragm.

17. The injection device of any of claims 1-16, wherein said injector housing is at least generally cylindrical.

18. The injection device of any of claims 1-17, further comprising a handle that in turn comprises a support aperture, wherein a support may be directed into said support aperture to suspend said injection device.

5 19. The injection device of any of claims 1-18, further comprising an armband interconnected with said deformable container.

20. The injection device of any of claims 1-19, wherein tubing is interconnected with said deformable container before being loaded into said injection device.

10 21. An imaging system comprising an imaging table and the injection device of any of claims 1-20, wherein said injector housing is positioned on said imaging table.

22. An imaging system comprising an imaging unit and the injection device of any of claims 1-20, wherein said imaging unit comprises a support rail, and wherein said injection device is detachably mounted on said support rail.

15 23. A method of using an injection device comprising a diaphragm, a first chamber on a first side of said diaphragm, and a second chamber on an opposite second side of said diaphragm, wherein said first and second chambers are separated by said diaphragm, the method comprising the steps of:

loading a deformable container into said first chamber, wherein said deformable container comprises medical fluid;

20 compressing said deformable container while the deformable container is in said first chamber, wherein said compressing step comprises moving said diaphragm; and

discharging said medical fluid from said deformable container in response to said compressing step.

24. The method of claim 23, further comprising the steps of:

mounting said deformable container on a patient; and

25 dismounting said the deformable container from said patient, wherein said loading step is executed after said dismounting step.

25. The method of claim 24, wherein said mounting step comprises using an armband.

26. The method of any of claims 24-25, wherein tubing extends from said deformable container at a time when each of said mounting and dismounting steps are executed.

30 27. The method of any of claims 23-26, wherein said moving step comprises stretching said diaphragm.

28. The method of any of claims 23-27, wherein said moving step comprises deforming said diaphragm.

29. The method of any of claims 23-28, wherein said compressing step comprises elastically deforming said diaphragm.

35 30. The method of any of claims 23-29, wherein said compressing step comprises stretching said diaphragm in a direction of said first chamber.

31. The method of any of claims 23-30, wherein said compressing step comprises:

expanding said second chamber;
executing said moving step in response to said expanding step; and
contracting said first chamber in response to said moving step.

32. The method of any of claims 23-31, wherein said compressing step comprises increasing a
5 volume of said second chamber and simultaneously decreasing a volume of said first chamber.

33. The method of any of claims 23-32, wherein said compressing step comprises directing
drive fluid into said second chamber.

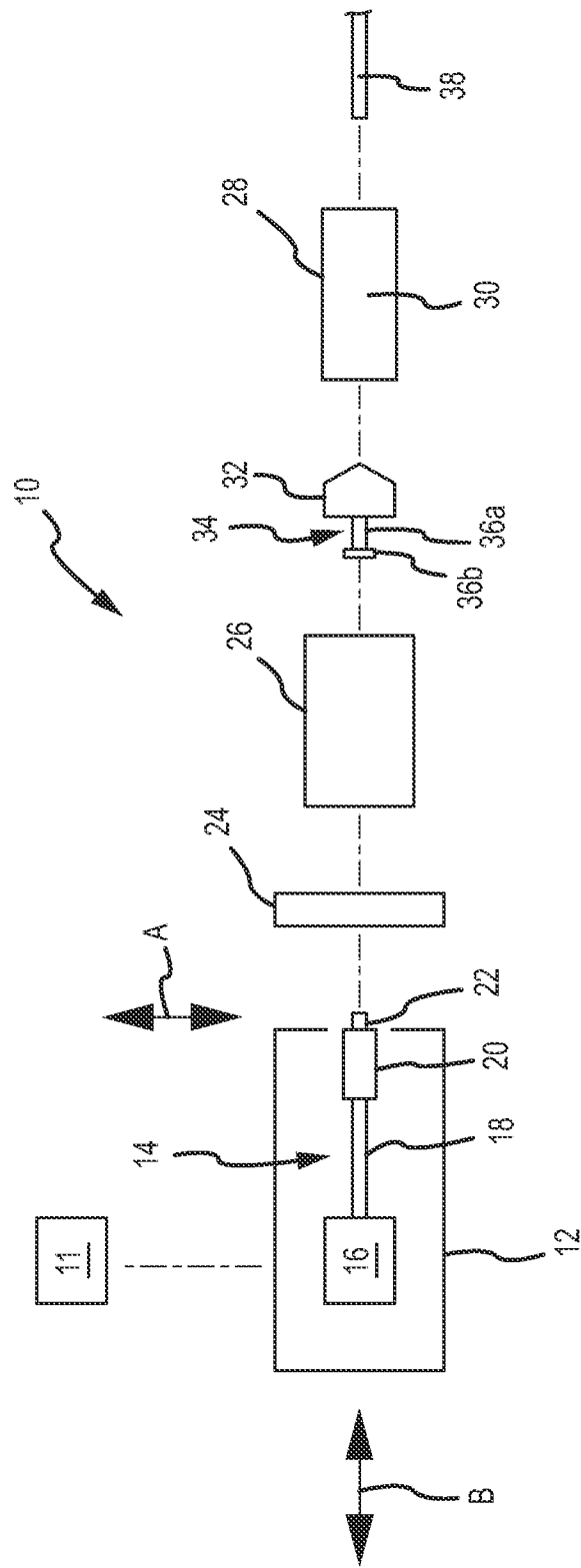


FIG.1

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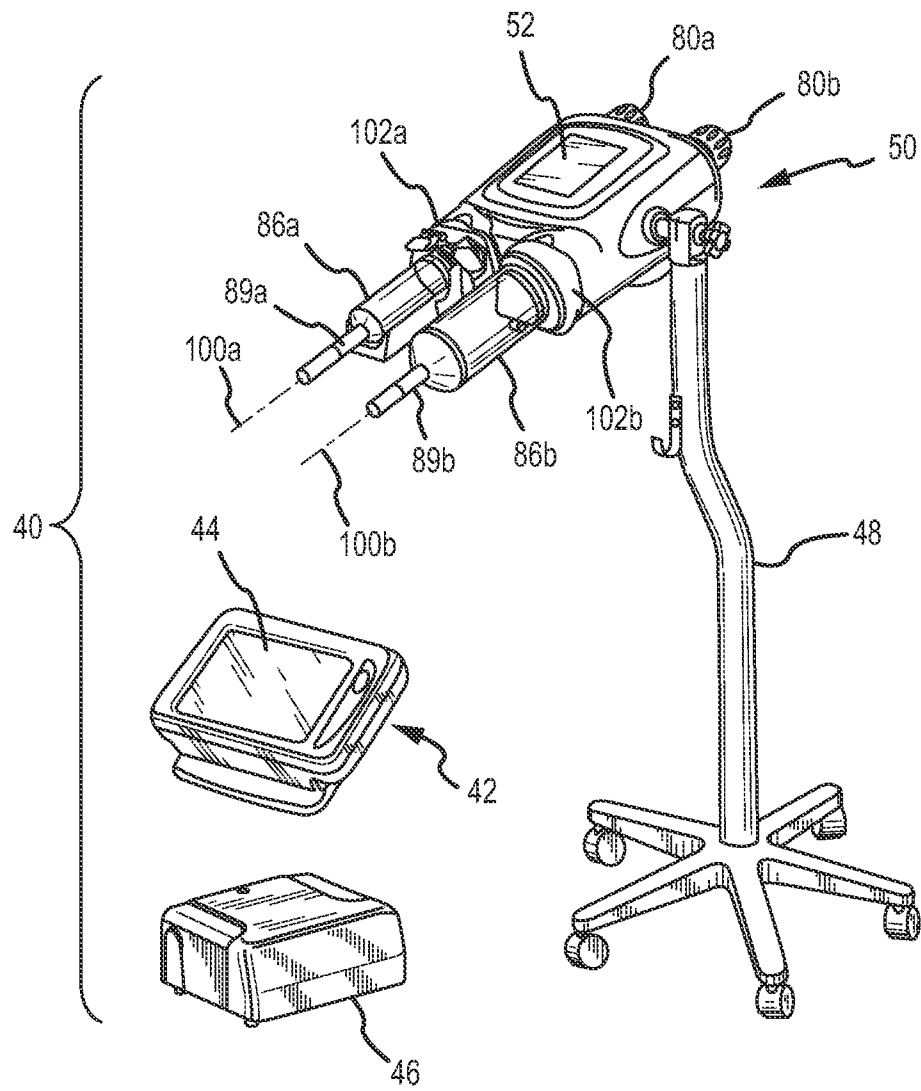


FIG.2A

3/13

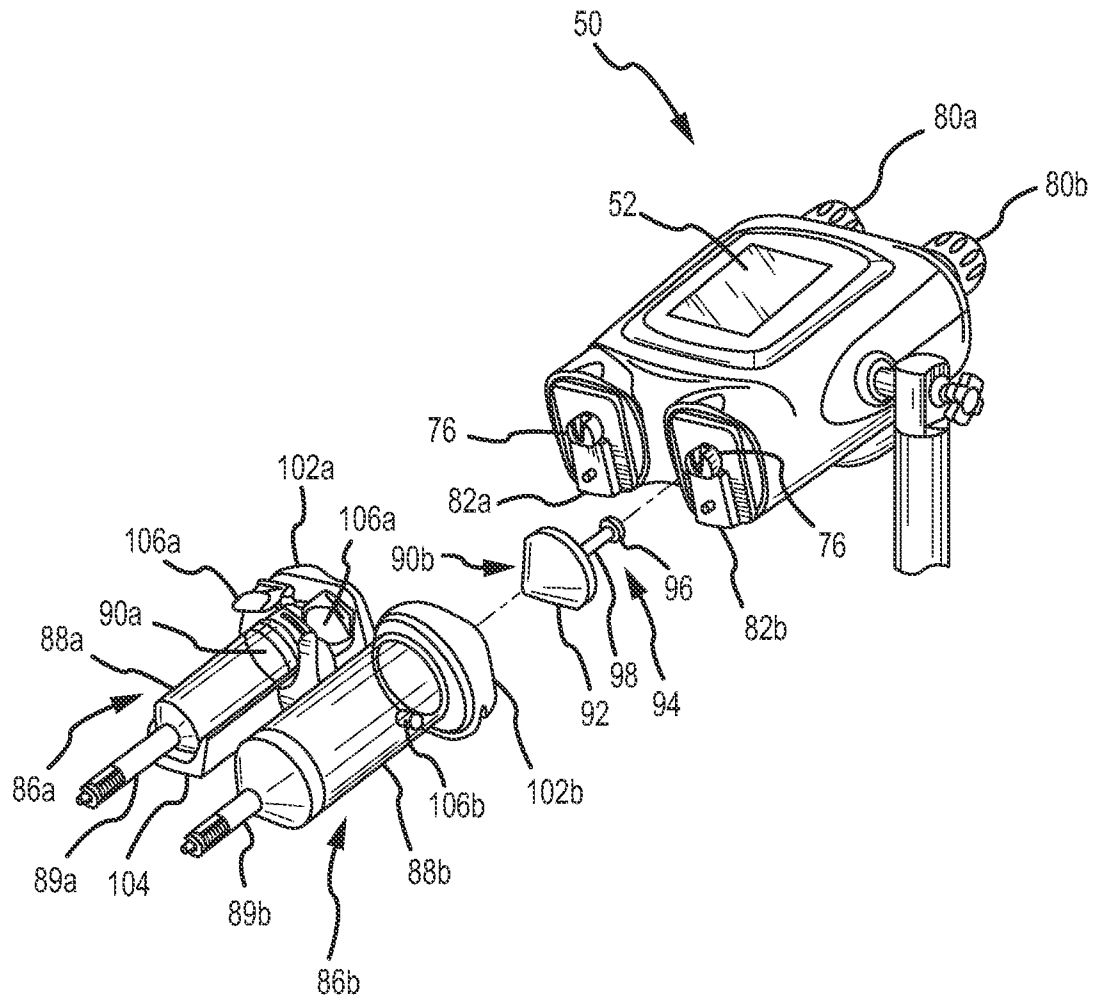


FIG.2B

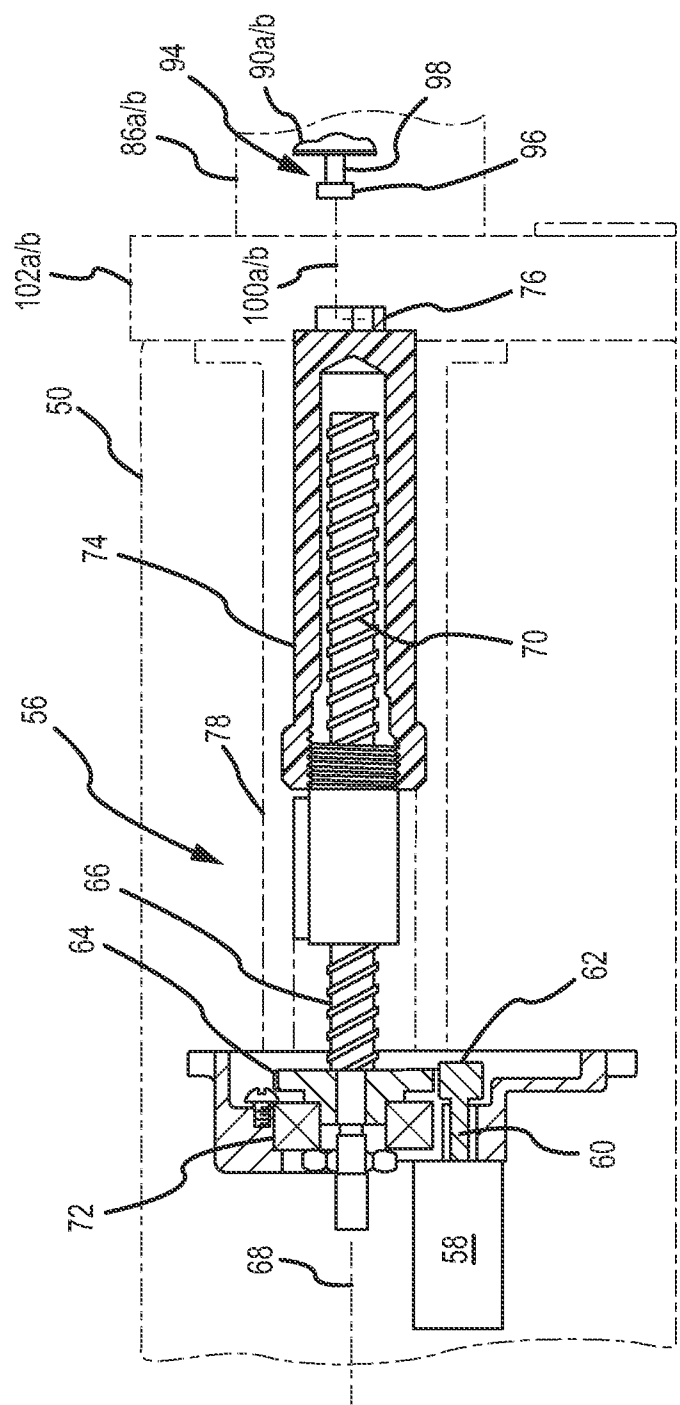


FIG. 2C

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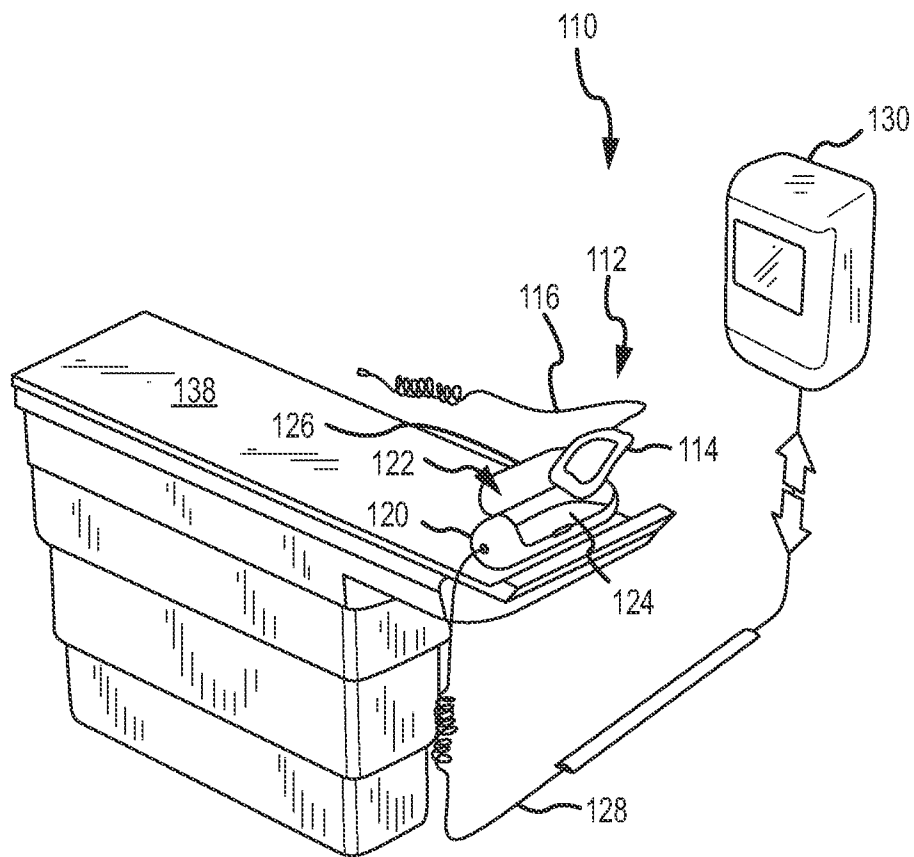


FIG.3A

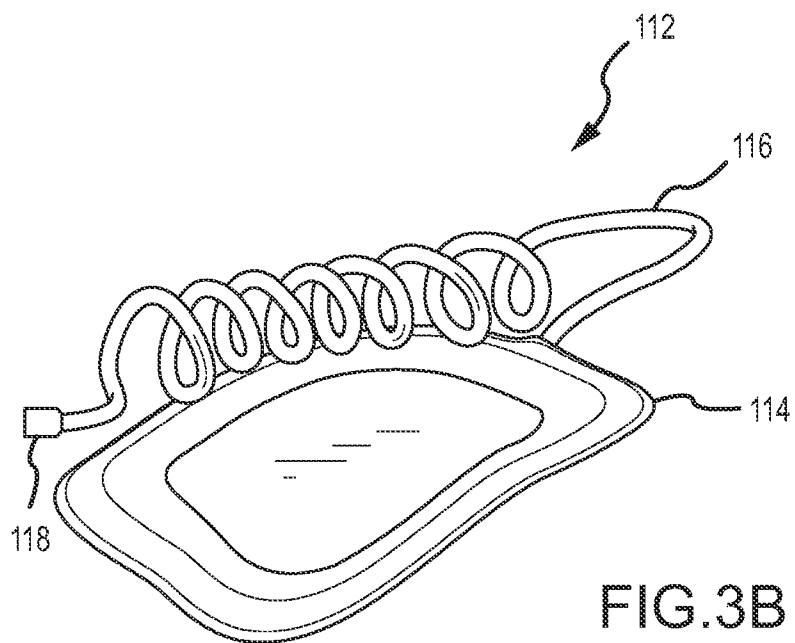


FIG.3B

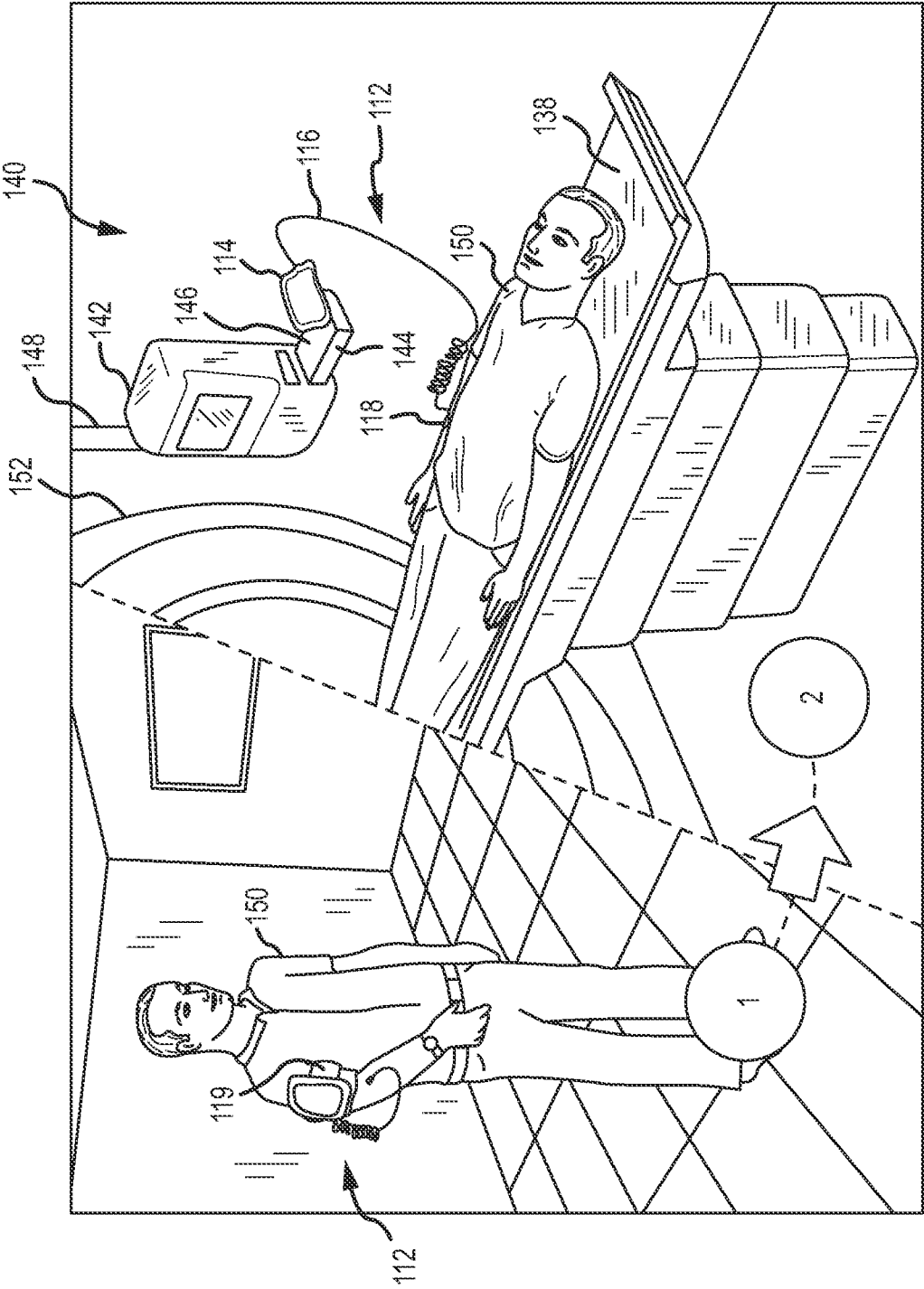


FIG.4

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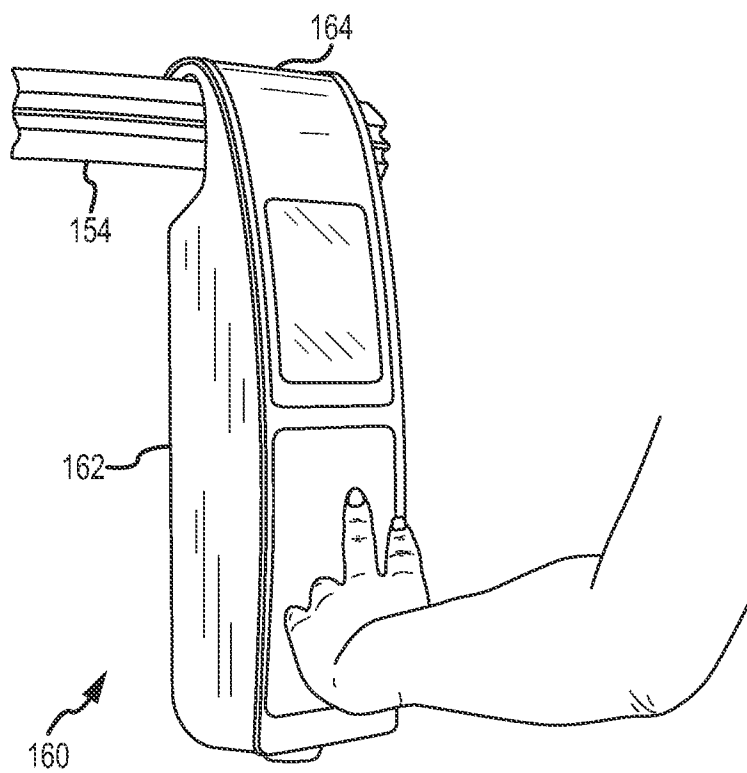


FIG. 5A

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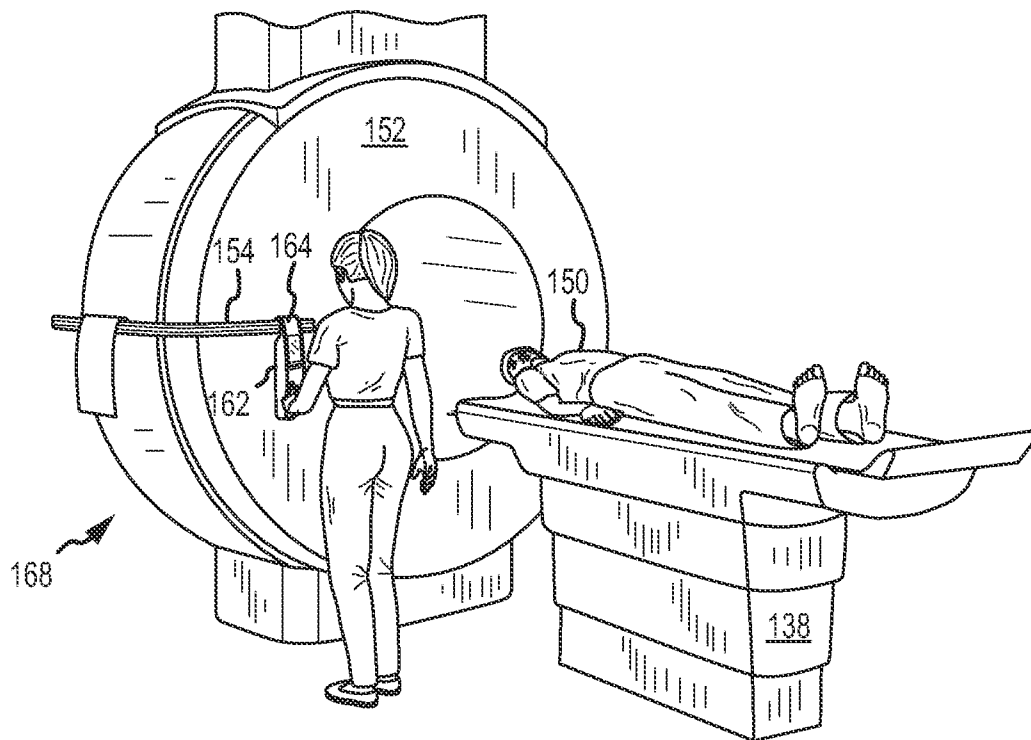


FIG.5B

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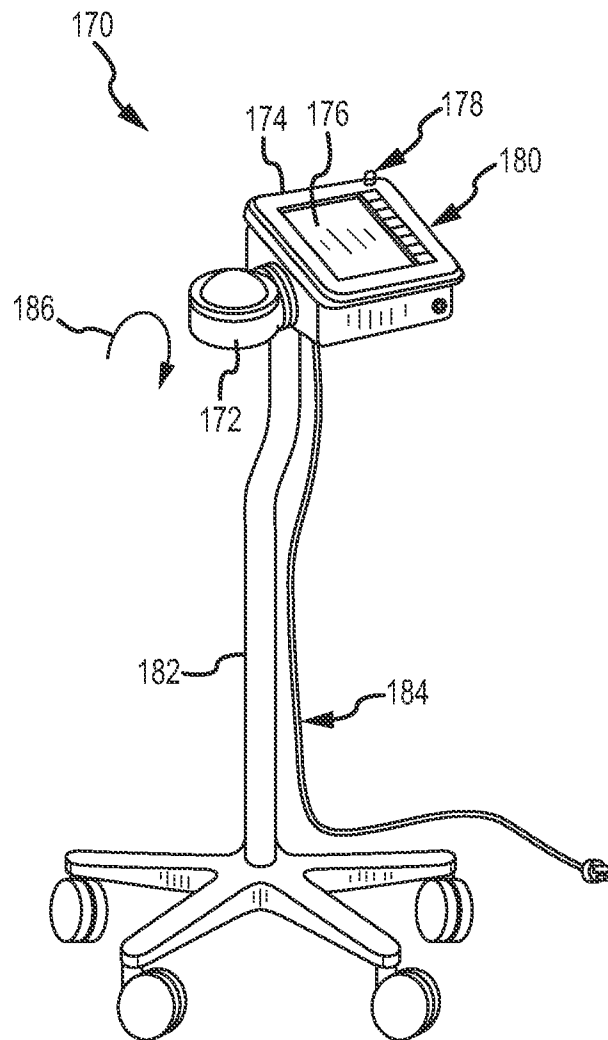


FIG.6

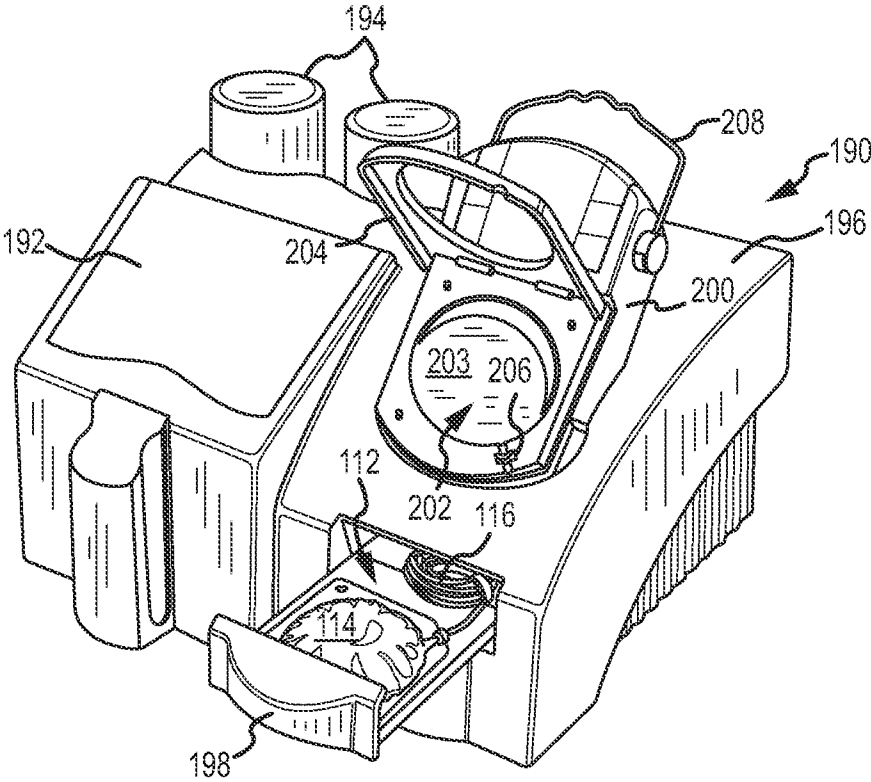


FIG.7

11/13

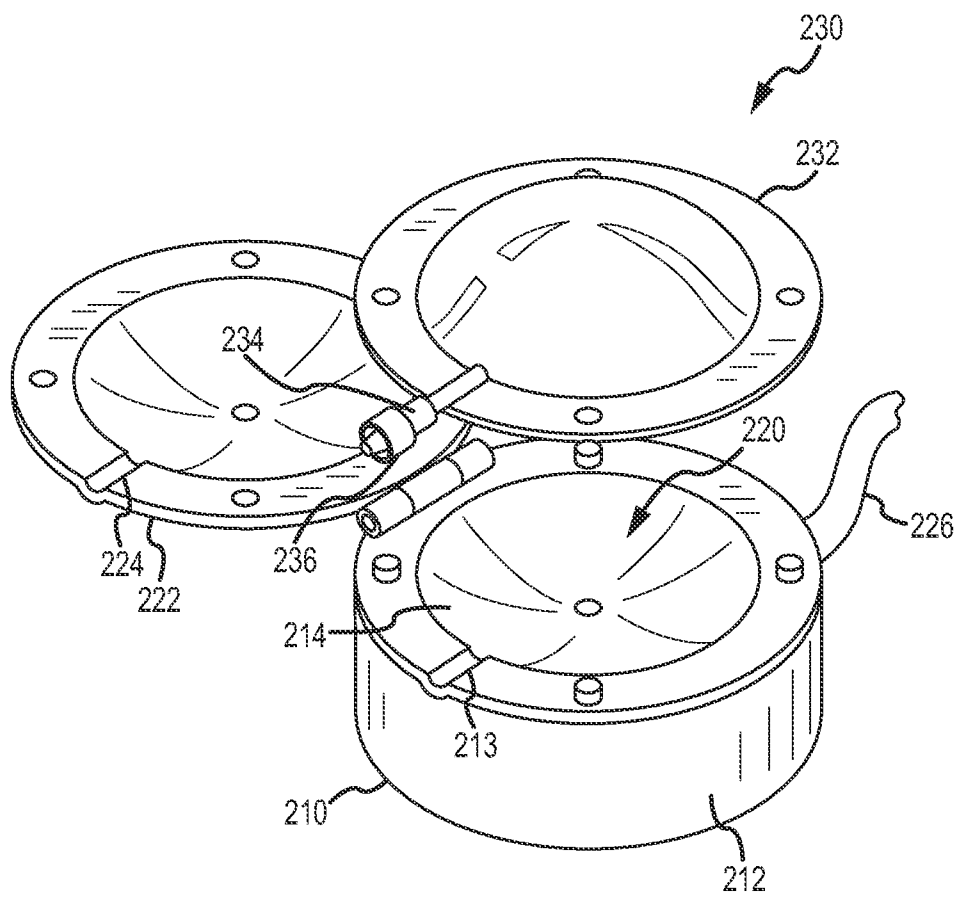


FIG.8

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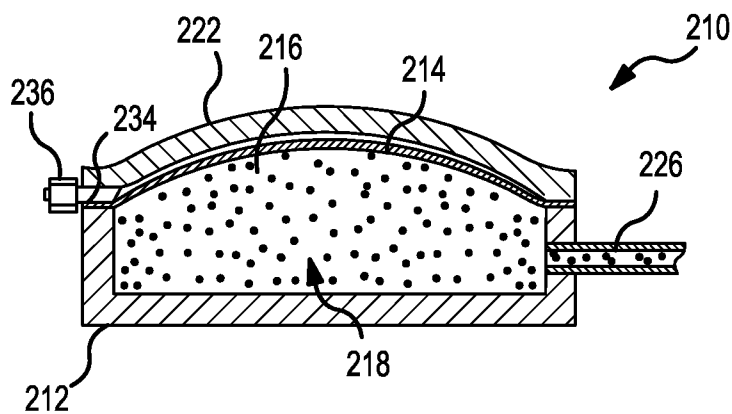


FIG. 9A

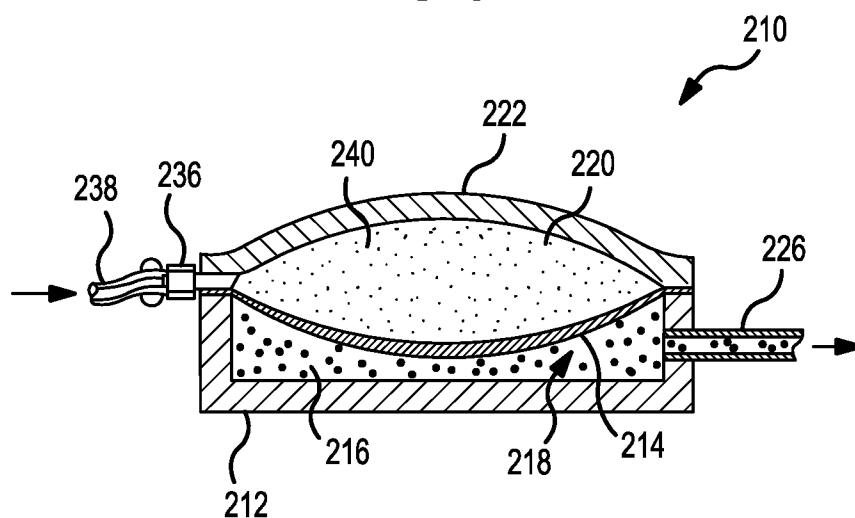


FIG. 9B

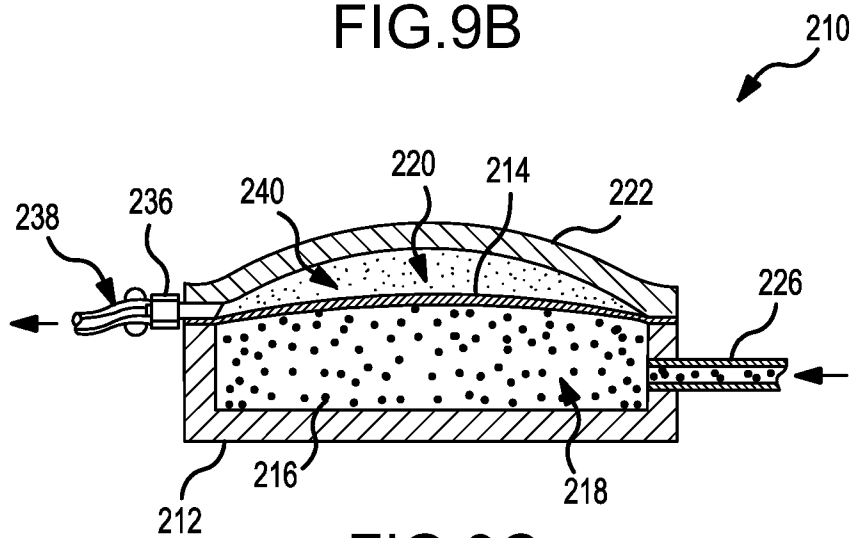
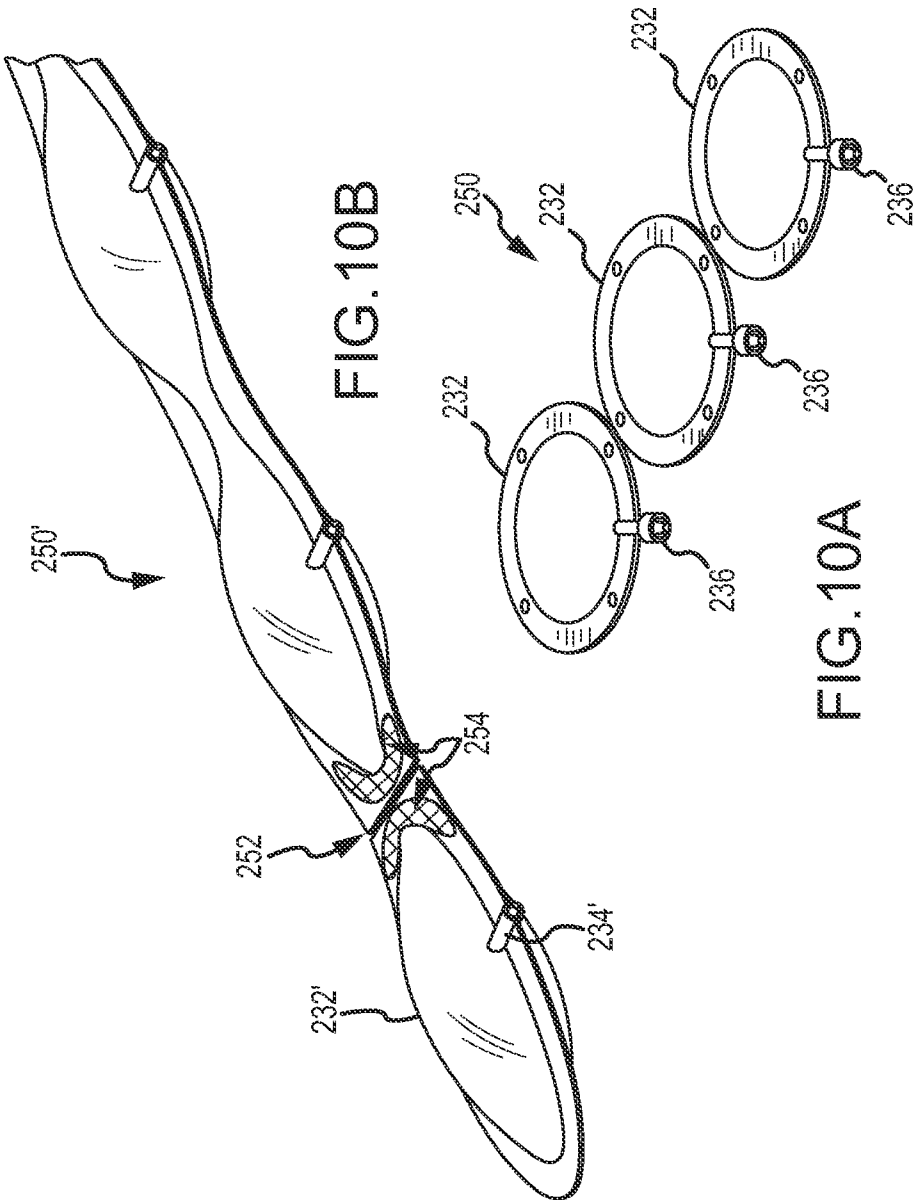


FIG. 9C



INTERNATIONAL SEARCH REPORT

International application No

PCT/US2009/052056

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M5/148 A61M5/145 A61M5/155 A61M31/00

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)

A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2005/011778 A (PRO MED MEDIZINISCHE PRODUKTIO [AT]; GALLNBOECK BERNHARD [AT]) 10 February 2005 (2005-02-10) the whole document	1-22
X	WO 97/05915 A (TILLANDER HANS [SE]) 20 February 1997 (1997-02-20) the whole document	1-22
X	DE 199 07 744 A1 (BACKES CLAUS H [DE]) 24 August 2000 (2000-08-24) abstract column 4, lines 7-35; figures 4,5	1-22
X	US 5 891 097 A (SAITO SATOSHI [JP] ET AL) 6 April 1999 (1999-04-06) the whole document	1-22
	-/--	

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"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

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"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

22 October 2009

Date of mailing of the international search report

02/11/2009

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Authorized officer

Nielsen, Michael

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2009/052056

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 106 374 A (APPERSON CURTIS R [US] ET AL) 21 April 1992 (1992-04-21) the whole document -----	1-22
X	EP 1 051 987 A (MEDICO S HIRATA INC [JP]) 15 November 2000 (2000-11-15) abstract paragraphs [0016] - [0022]; figures 1,2(a),2(b) -----	1-22
X	DE 196 17 248 A1 (VBM MEDIZINTECHNIK GMBH [DE]) 6 November 1997 (1997-11-06) the whole document -----	1-22
X	WO 95/01194 A (HERSKOWITZ GLENN [US]) 12 January 1995 (1995-01-12) the whole document -----	1-22

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/052056

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 23-33
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2009/052056

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2005011778 A	10-02-2005	AT 413649 B	15-04-2006
		AU 2004260548 A1	10-02-2005
		CA 2534379 A1	10-02-2005
		CN 1829546 A	06-09-2006
		EP 1651292 A1	03-05-2006
		JP 2007501083 T	25-01-2007
		KR 20060057580 A	26-05-2006
		NZ 544741 A	31-10-2008
		US 2006255063 A1	16-11-2006
WO 9705915 A	20-02-1997	AT 292486 T	15-04-2005
		AU 700259 B2	24-12-1998
		AU 6712196 A	05-03-1997
		CA 2228760 A1	20-02-1997
		DE 69634570 D1	12-05-2005
		DE 69634570 T2	16-02-2006
		EP 0850077 A1	01-07-1998
		ES 2240998 T3	16-10-2005
		JP 11510415 T	14-09-1999
		NO 980476 A	04-02-1998
		RU 2177806 C2	10-01-2002
		US 6406458 B1	18-06-2002
DE 19907744 A1	24-08-2000	NONE	
US 5891097 A	06-04-1999	JP 8058897 A	05-03-1996
US 5106374 A	21-04-1992	NONE	
EP 1051987 A	15-11-2000	JP 2000316970 A	21-11-2000
		US 6558346 B1	06-05-2003
DE 19617248 A1	06-11-1997	NONE	
WO 9501194 A	12-01-1995	AU 7203094 A	24-01-1995
		US 5348539 A	20-09-1994