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Orr

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(54) **MEDICAL FLUID PUMPING SYSTEM HAVING BACKFLOW PREVENTION**

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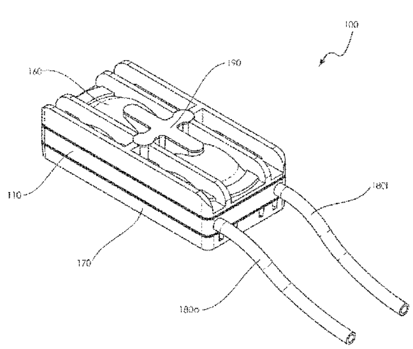
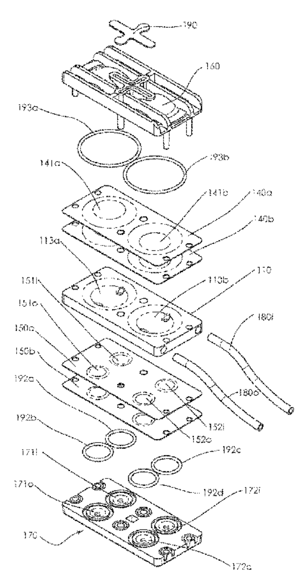
(57) **ABSTRACT**

A medical fluid pumping system includes a medical fluid pump for pumping a process fluid and a medical fluid chassis operable with the medical fluid pump. The medical fluid pump includes a first pump chamber, a first inlet valve chamber including a first inlet valve diaphragm, a first outlet valve chamber, a second pump chamber, a second inlet valve chamber including a second inlet valve diaphragm, and a second outlet valve chamber. The medical fluid chassis includes a motive fluid source providing motive fluid at a motive fluid pressure. The first and second inlet valve diaphragms are configured to actuate from an open to a closed position at a pressure less than the motive fluid pressure to mitigate process fluid backflow through the first and second inlet valves.

19 Claims, 25 Drawing Sheets





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continuation of application No. 14/558,021, filed on Dec. 2, 2014, now Pat. No. 10,670,005, which is a continuation of application No. 13/472,099, filed on May 15, 2012, now Pat. No. 8,932,032, which is a continuation of application No. 11/945,177, filed on Nov. 26, 2007, now Pat. No. 8,197,231, which is a continuation-in-part of application No. 11/484,061, filed on Jul. 11, 2006, now Pat. No. 7,717,682.

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See application file for complete search history.

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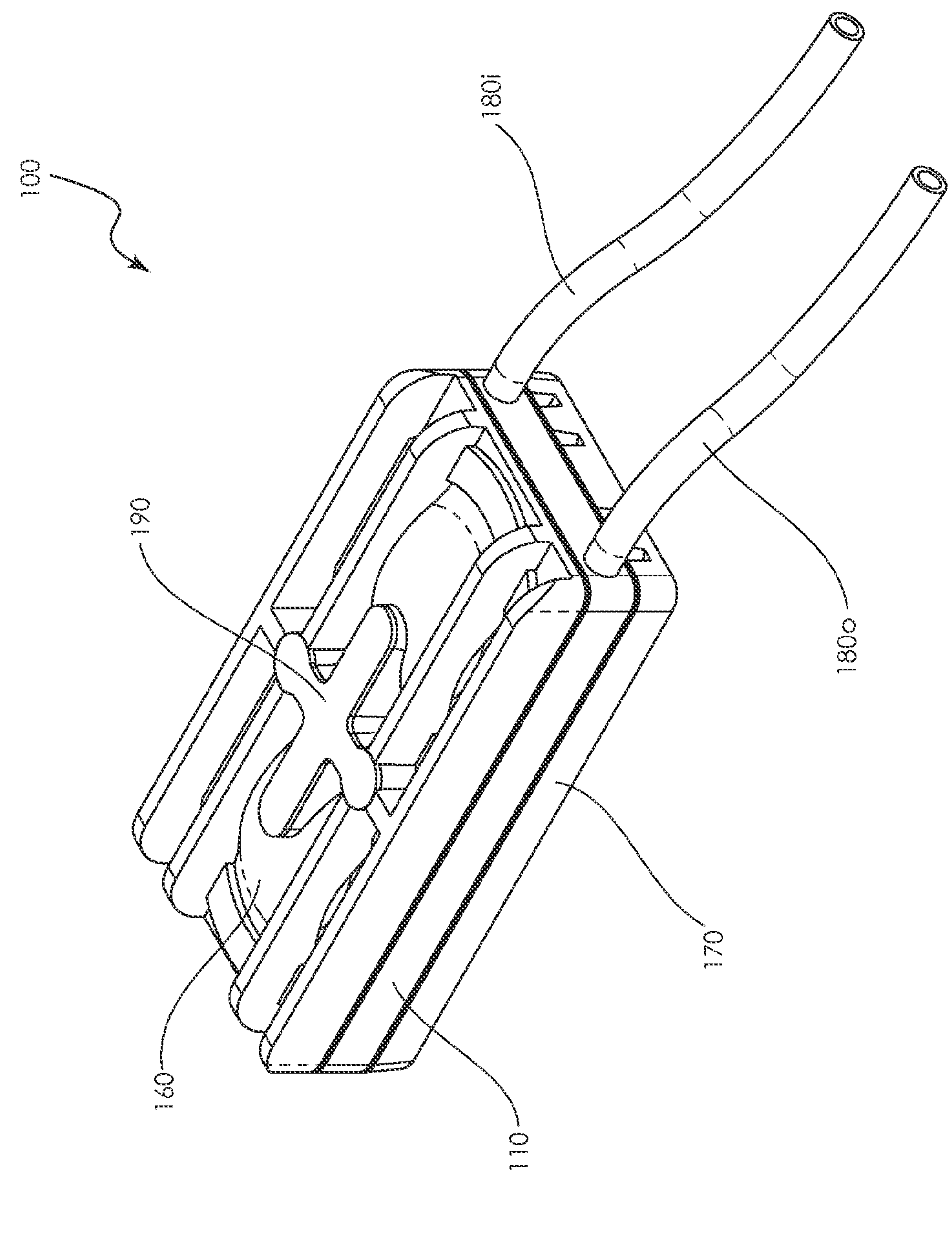

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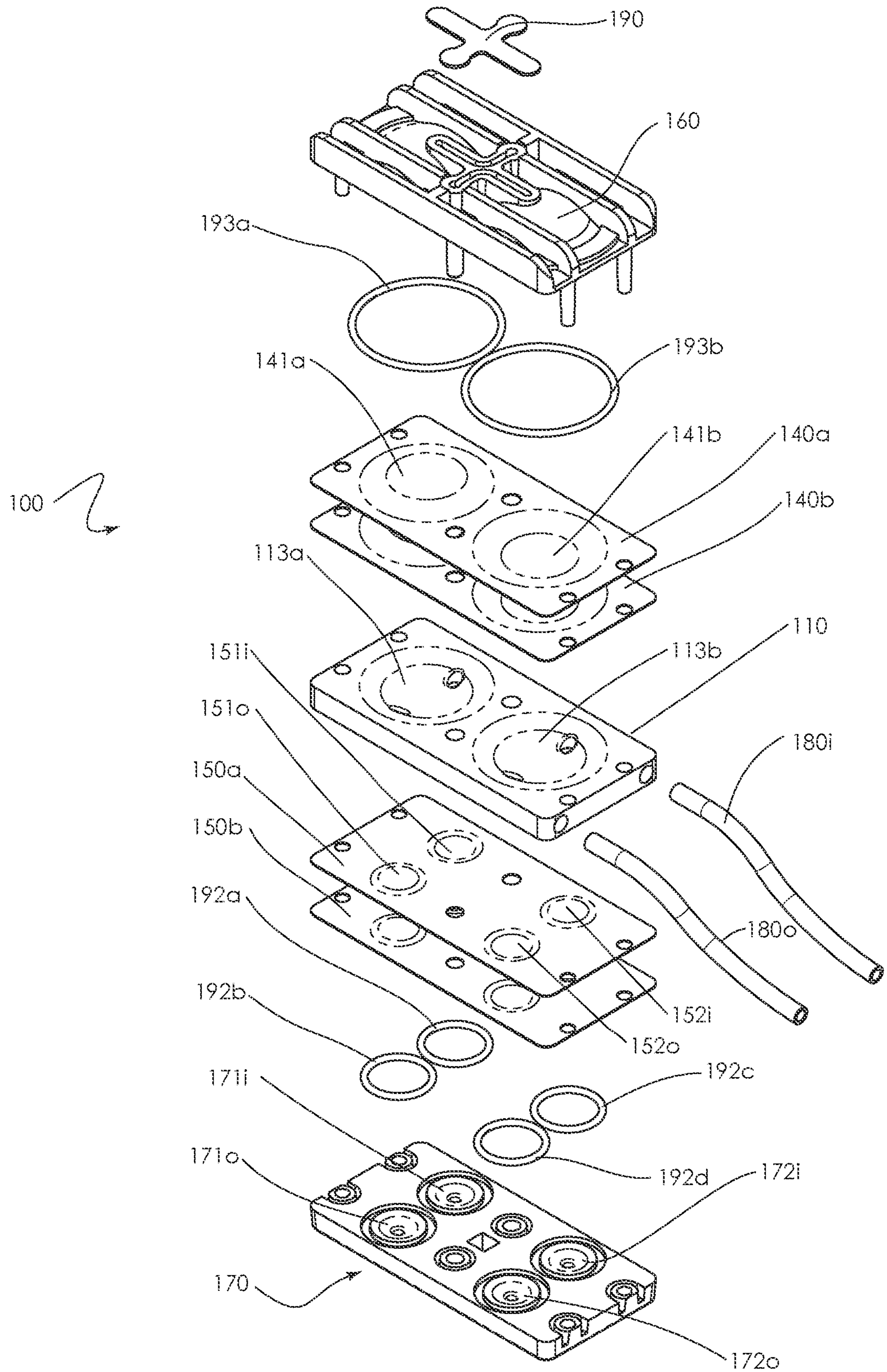
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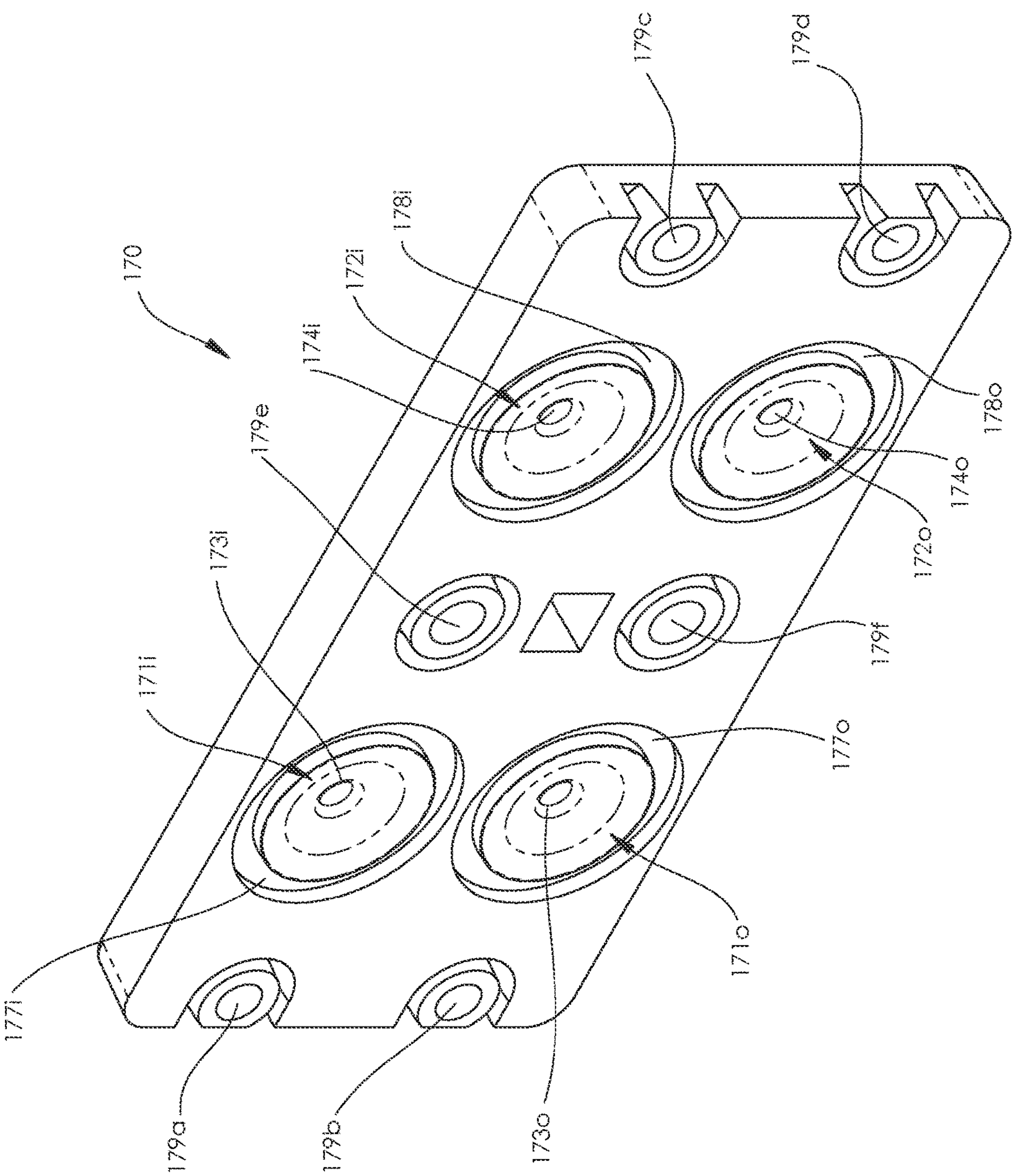
152i
152o
192c
171i
192d
171o
172i
170
172o

Fig. 2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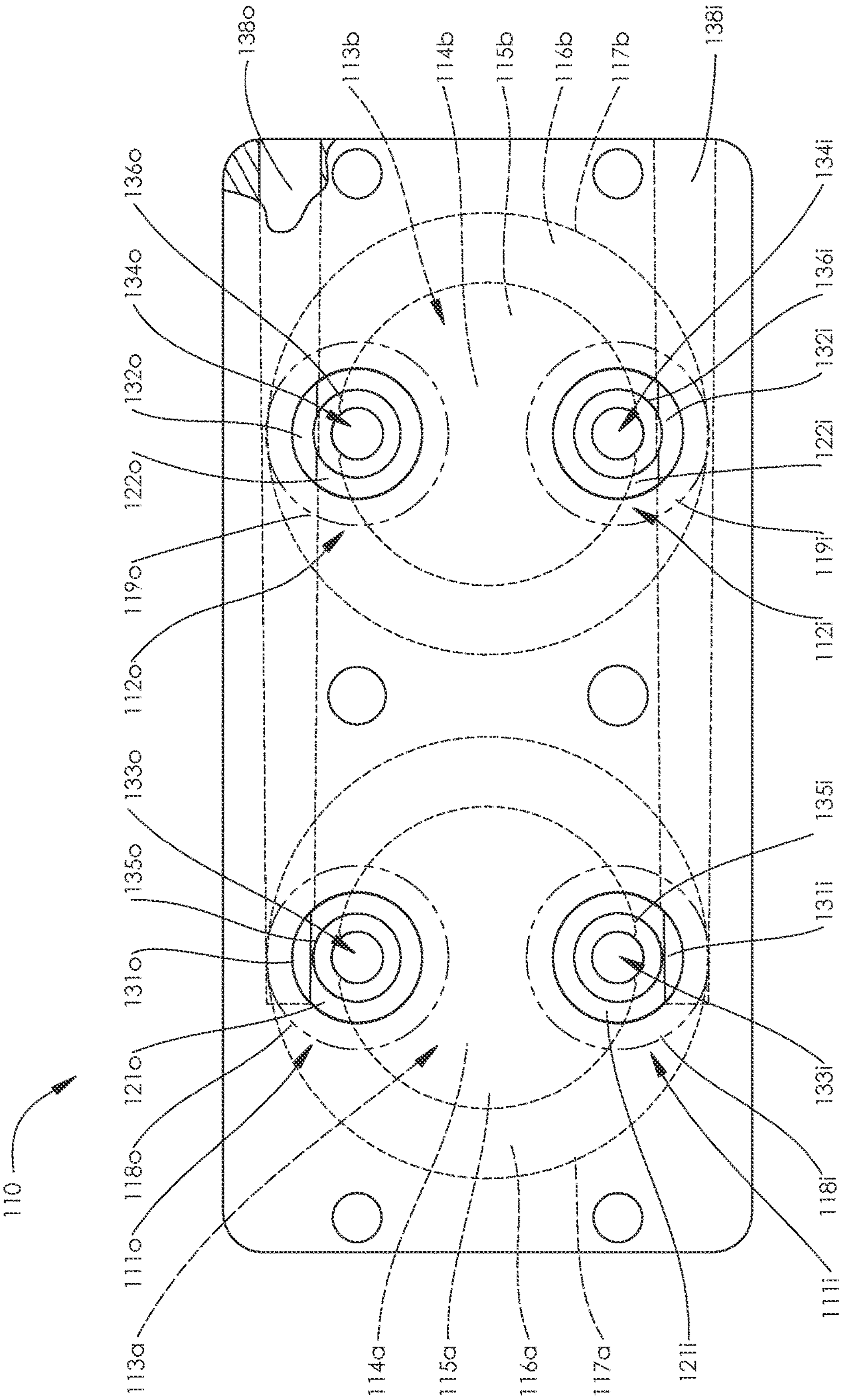
179b
173o

Fig. 3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113b
114b
115b
116b
117b
138i
134i
136i
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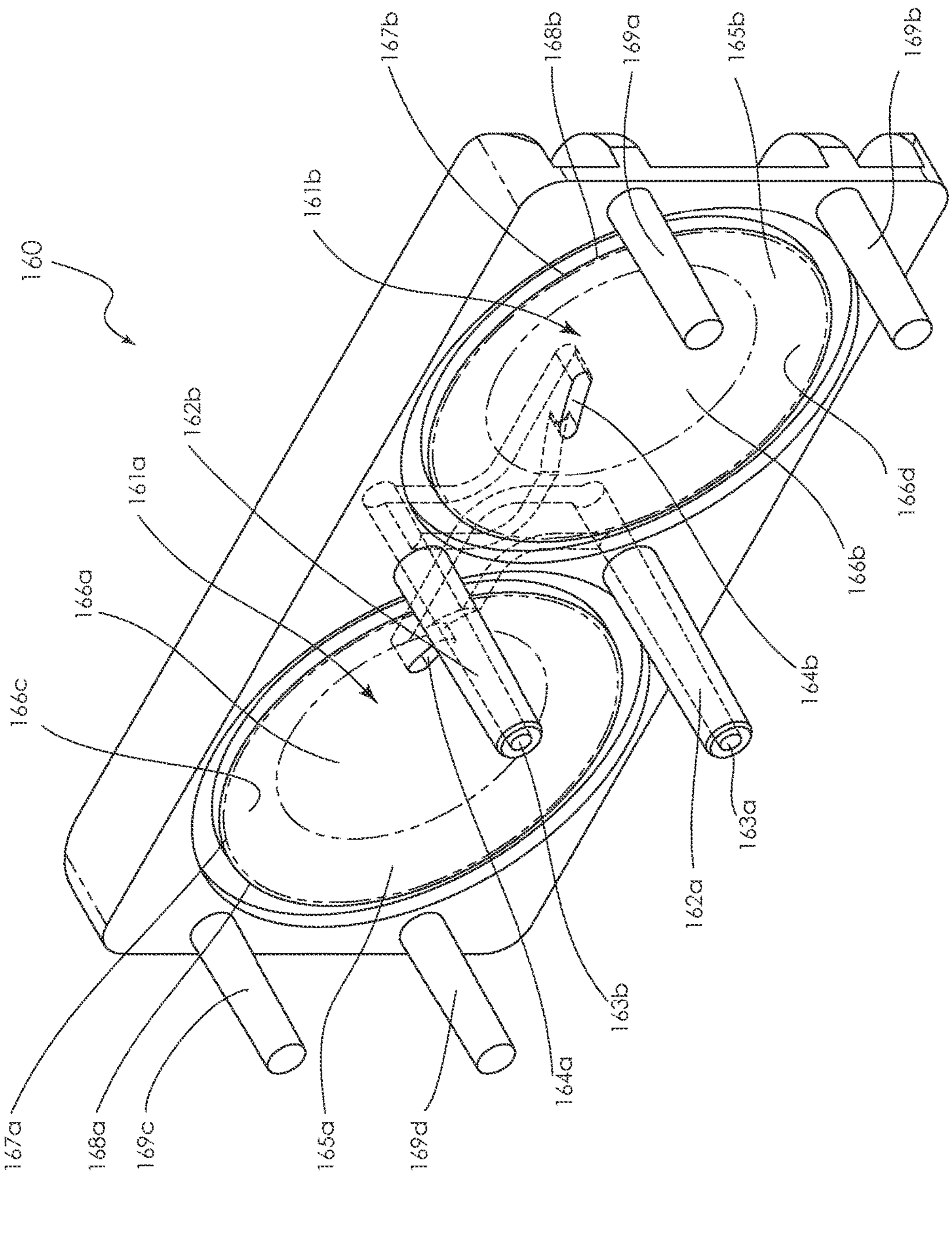
133i
118i
111i
121i
117a
116a
115a
114a

Fig. 4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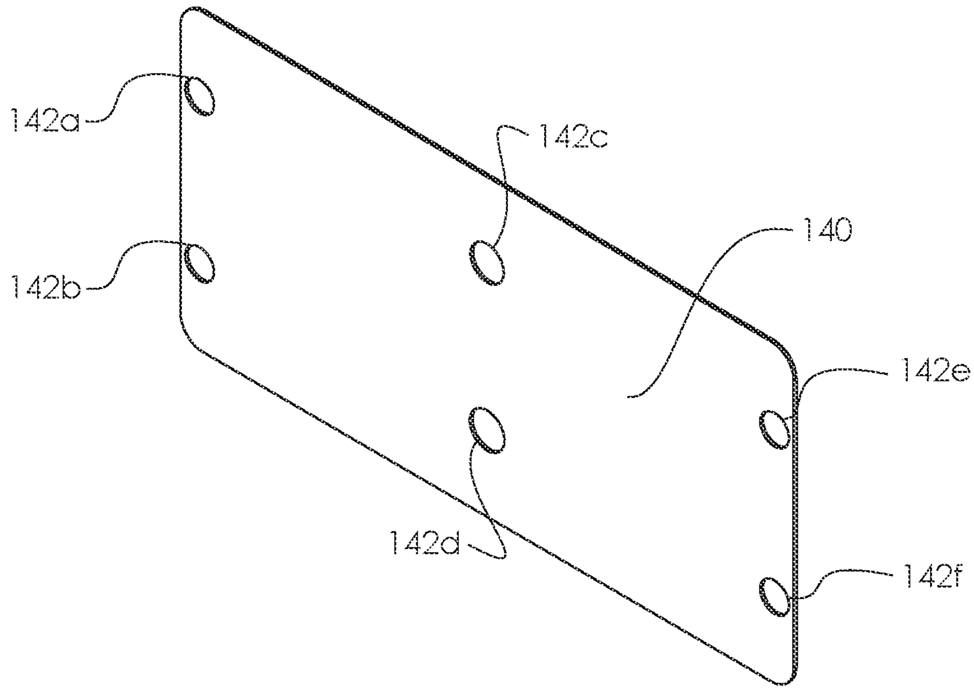
168b
169a
169b
169c
169d

Fig. 5



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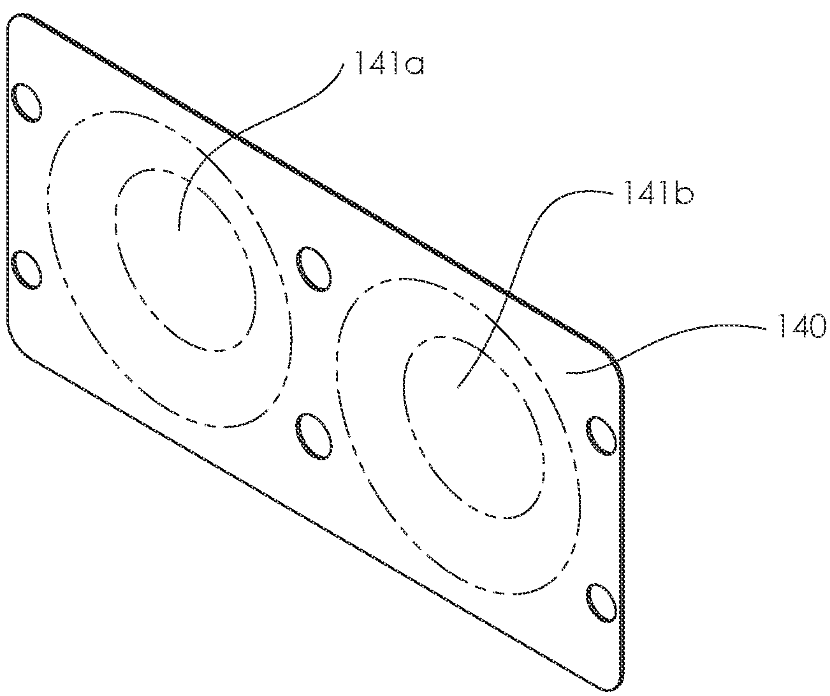
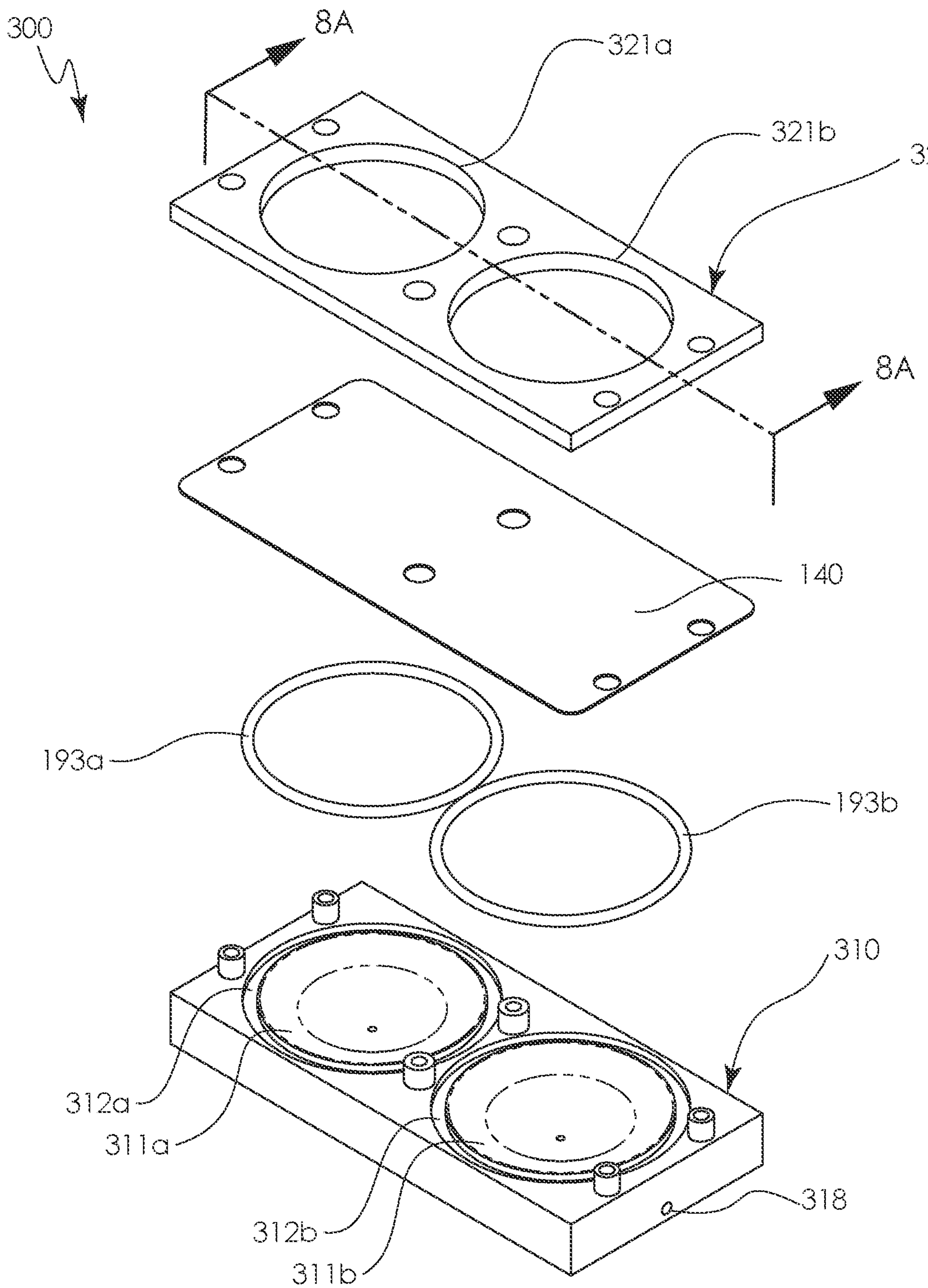


Fig. 6B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8A
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312a
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312b
311b
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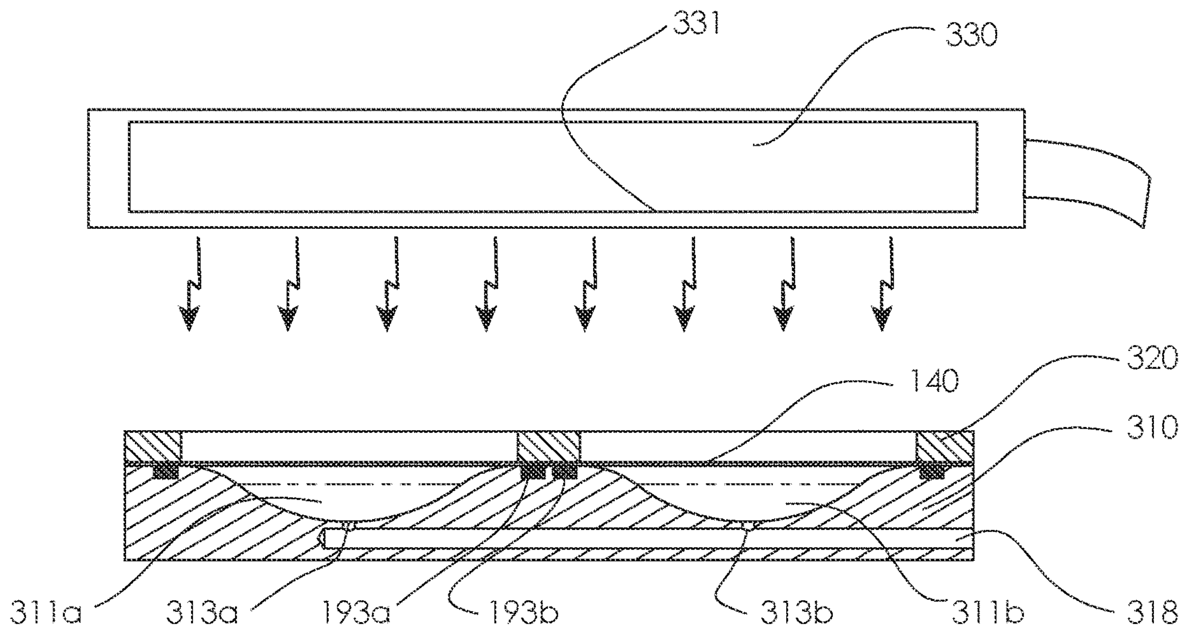
Fig. 7



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311b
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Fig. 8A

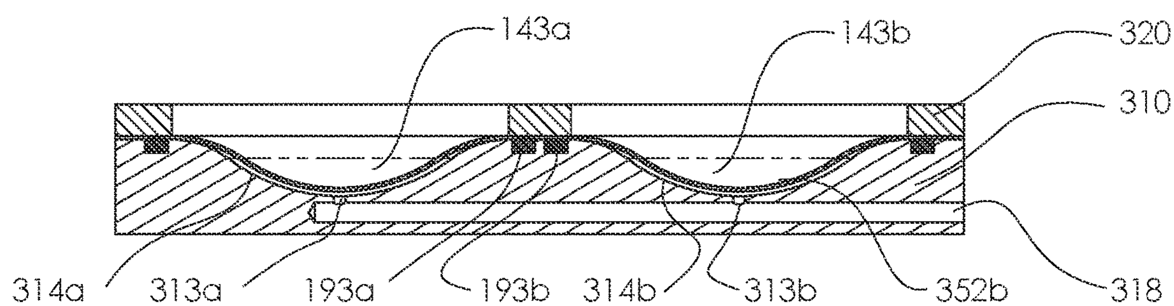

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Fig. 8B

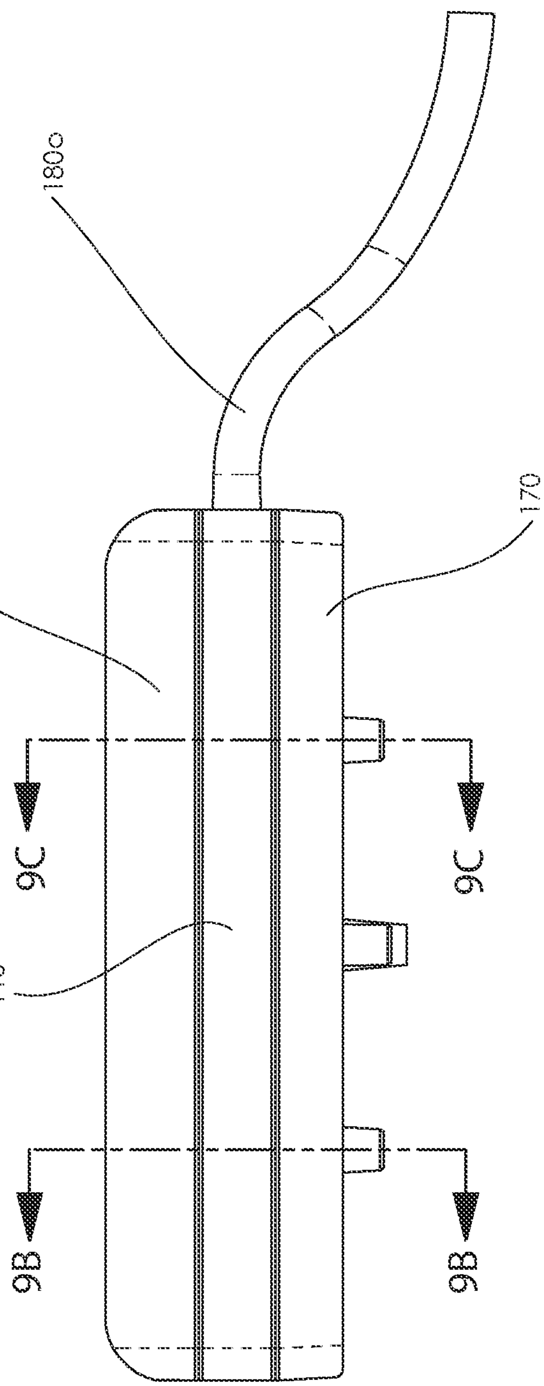
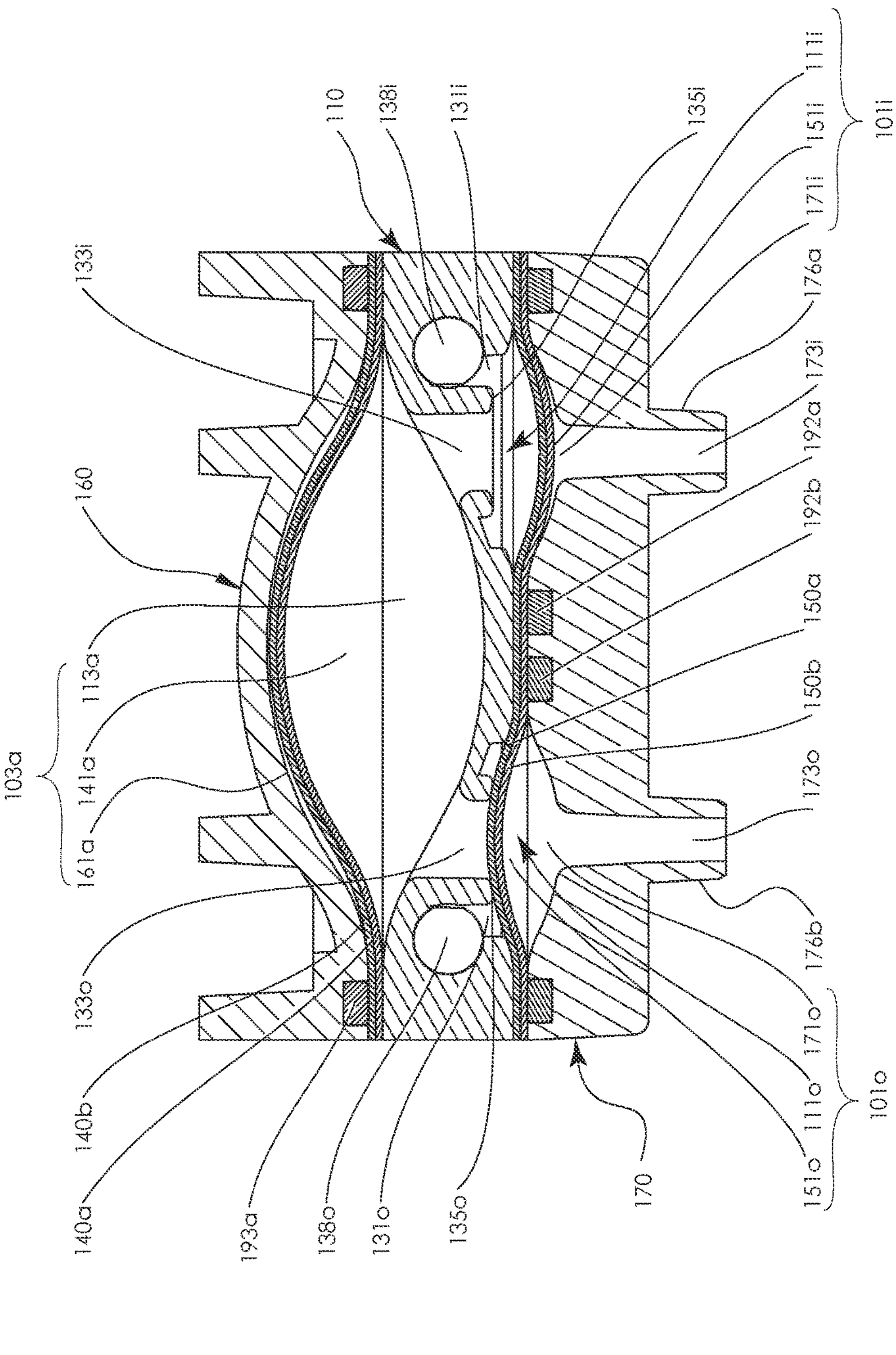


Fig. 9A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113a
141a
161a
173o
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151o
101o
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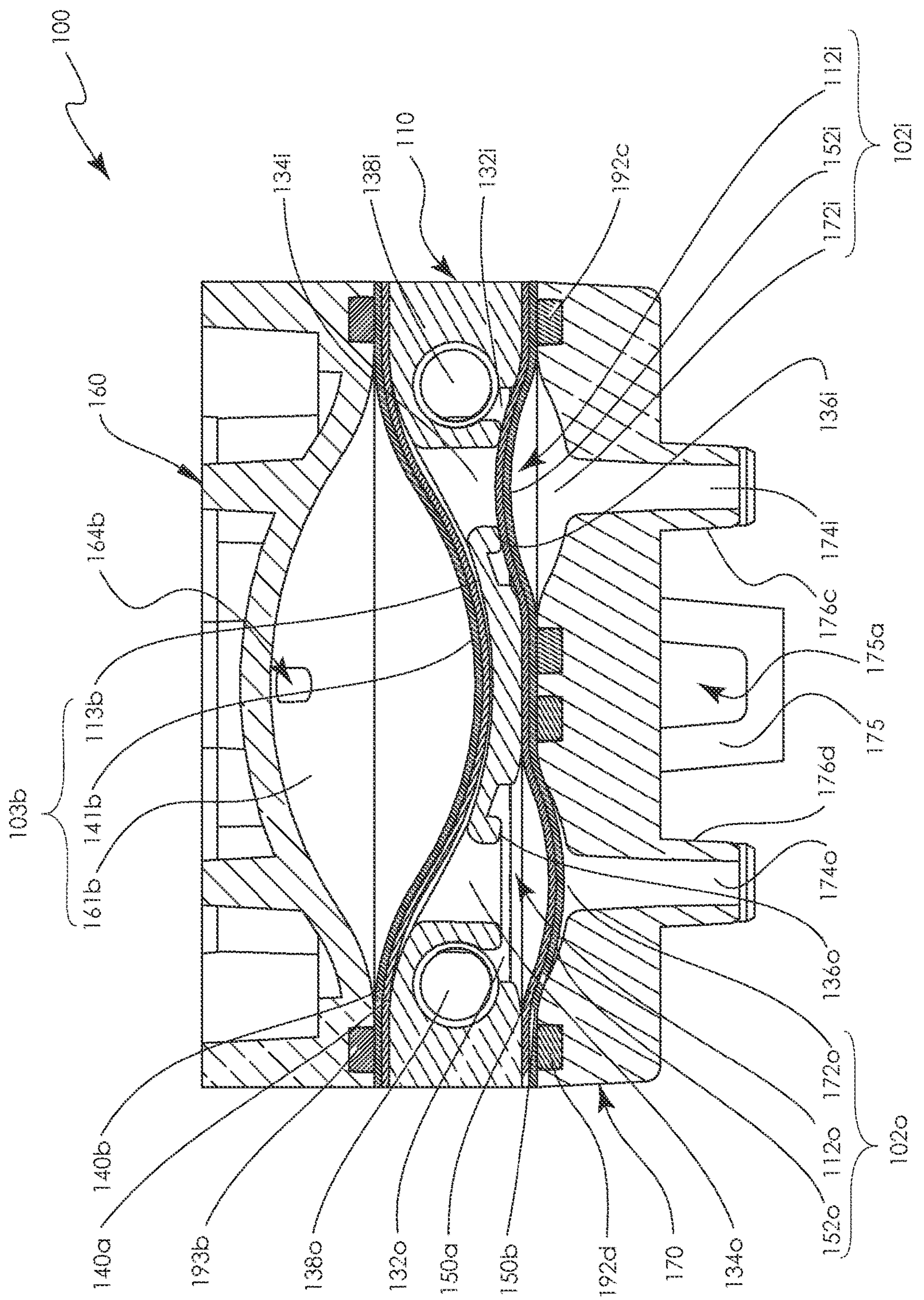
140b
140a
193a
138o
131o
135o
170

Fig. 9B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132i
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152i
172i
102i
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176c
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175
176d
174o
136o
172o
102o
112o
152o
134o
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113b
103b

Fig. 9C

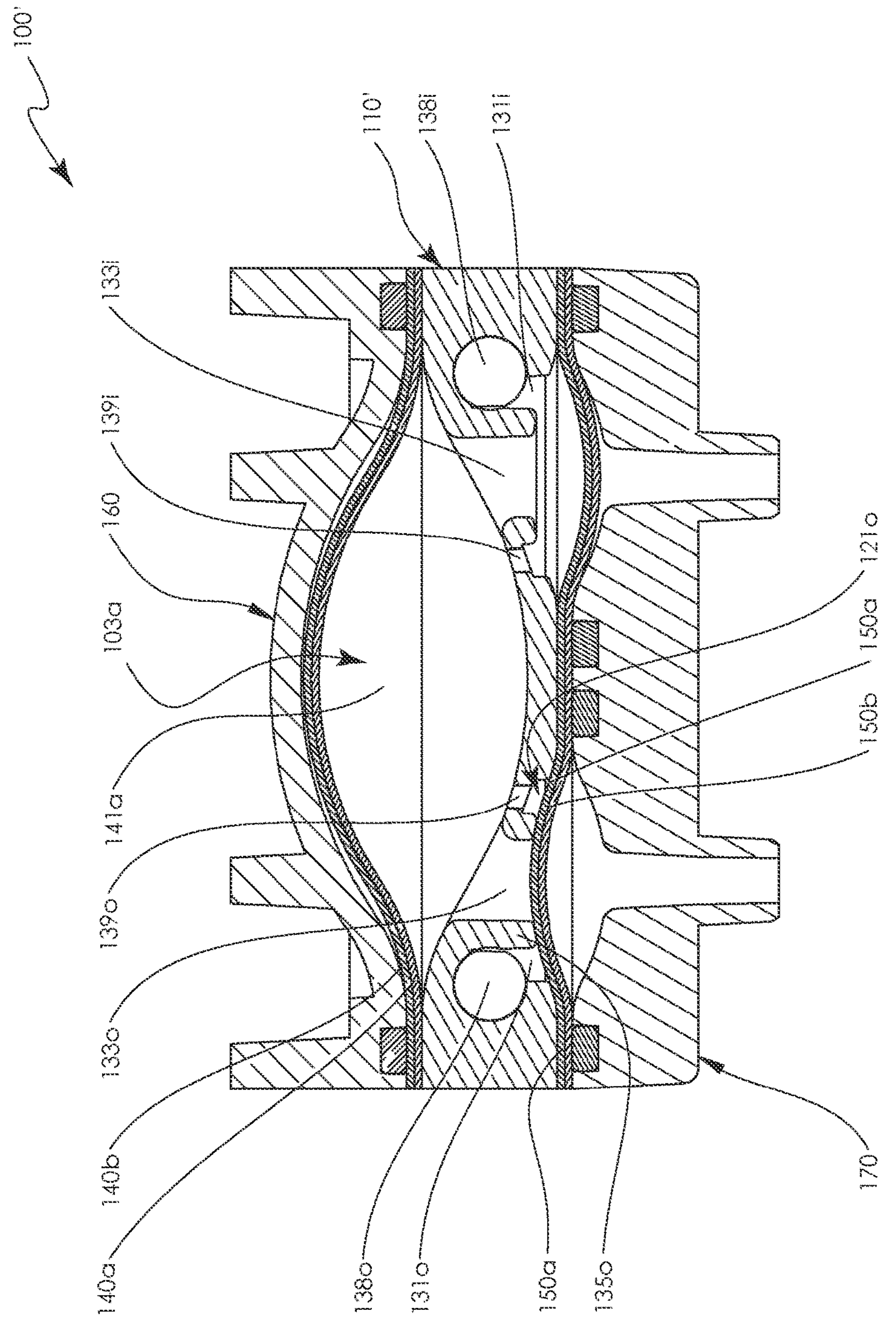
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Fig. 10

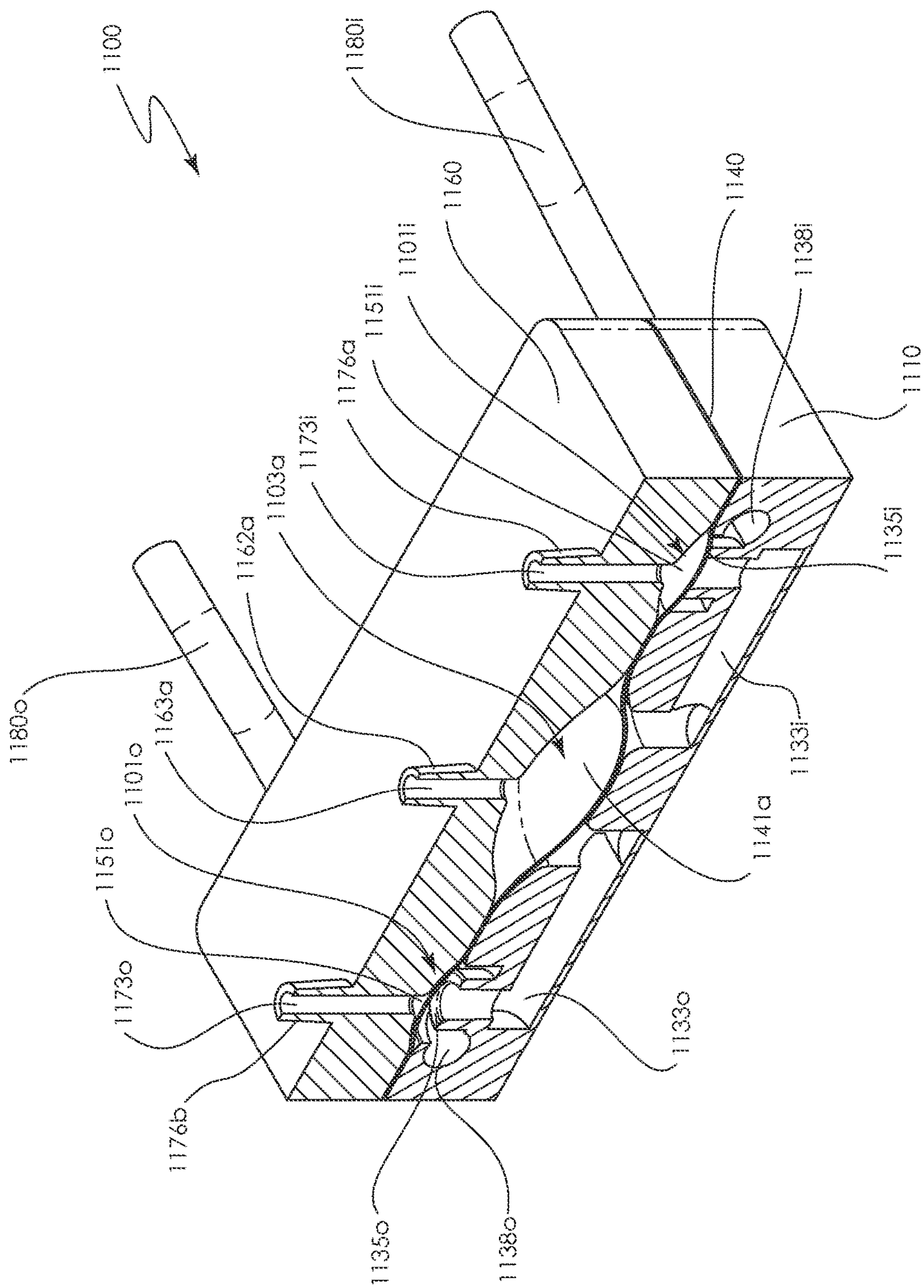
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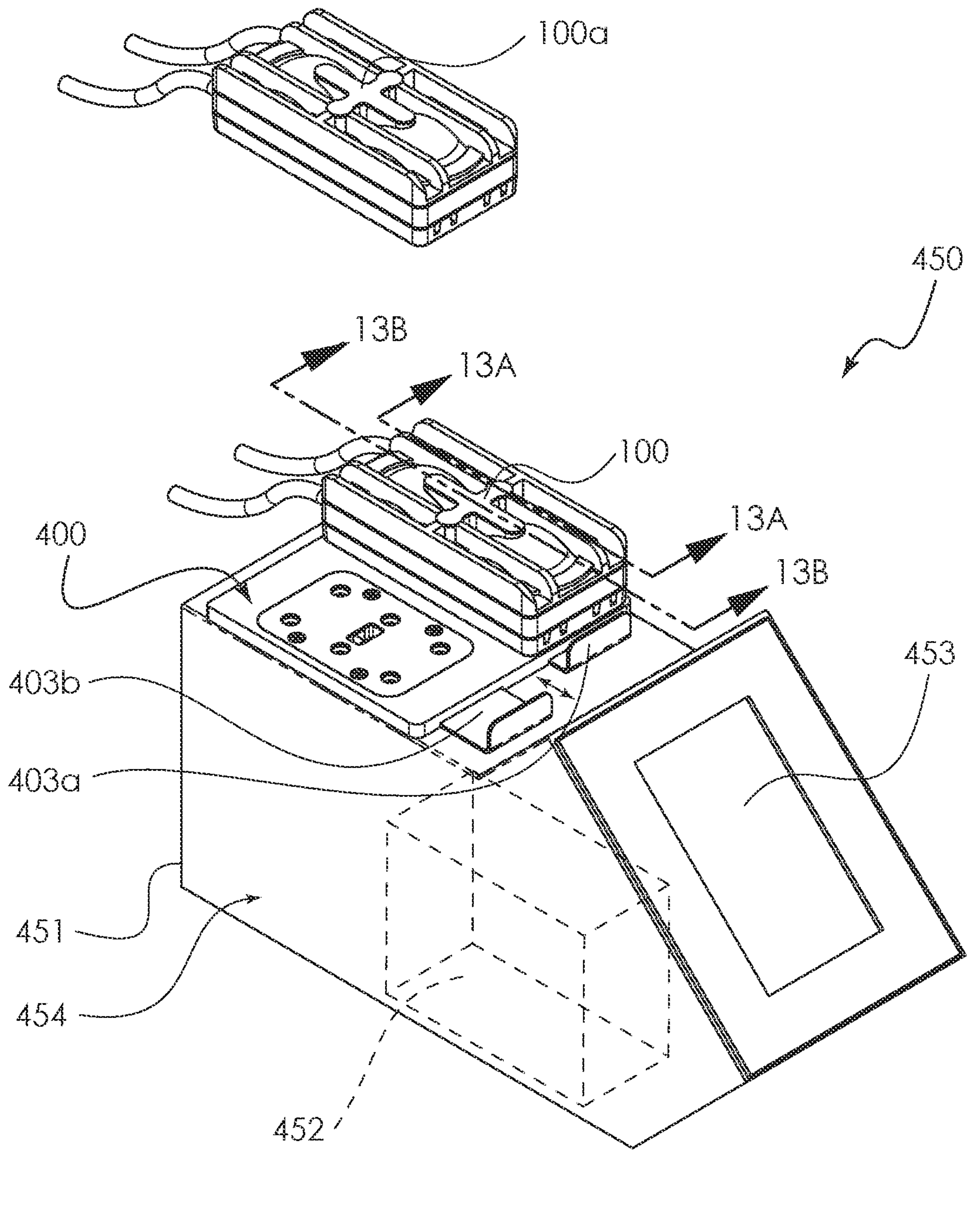
Fig. 11



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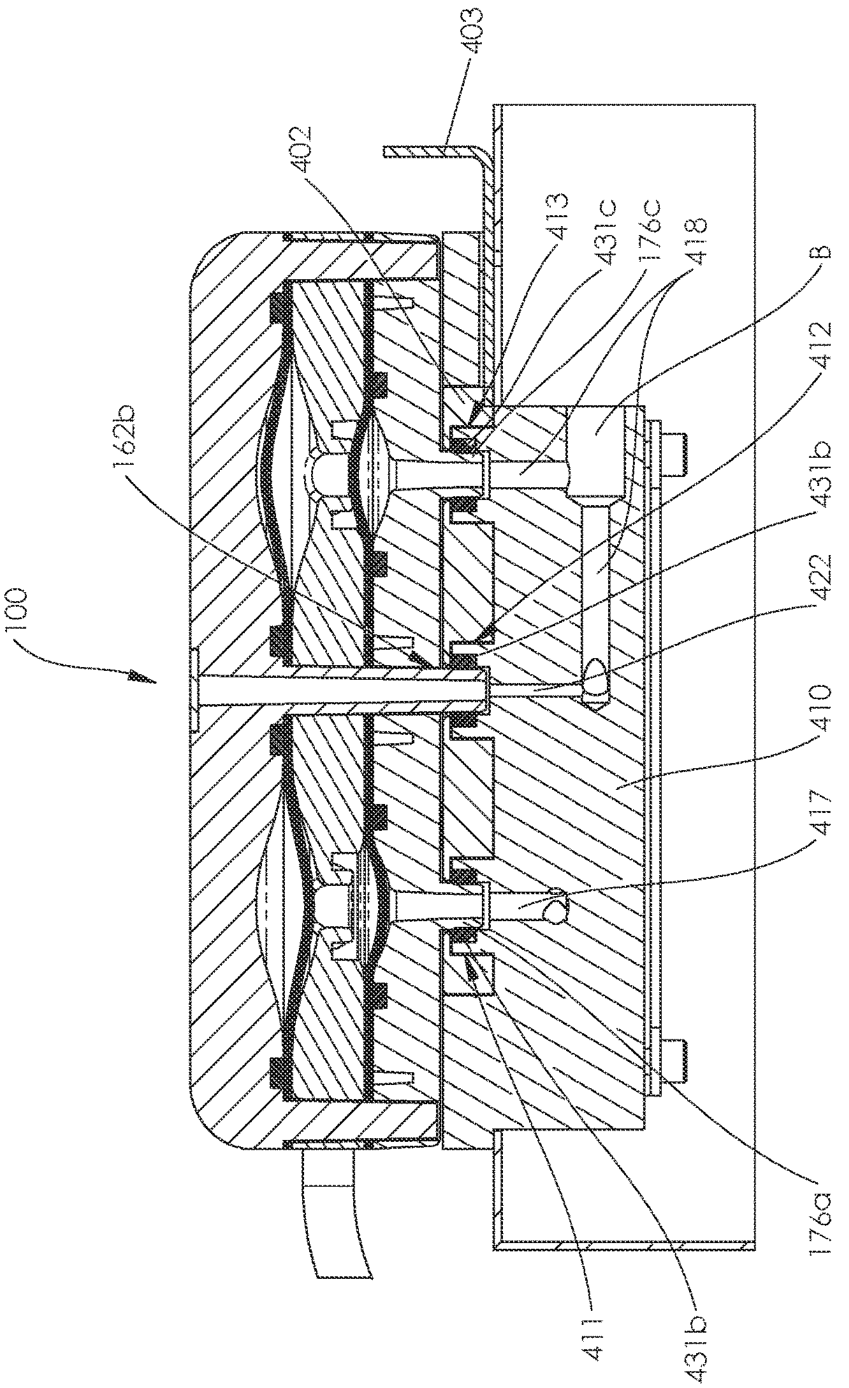
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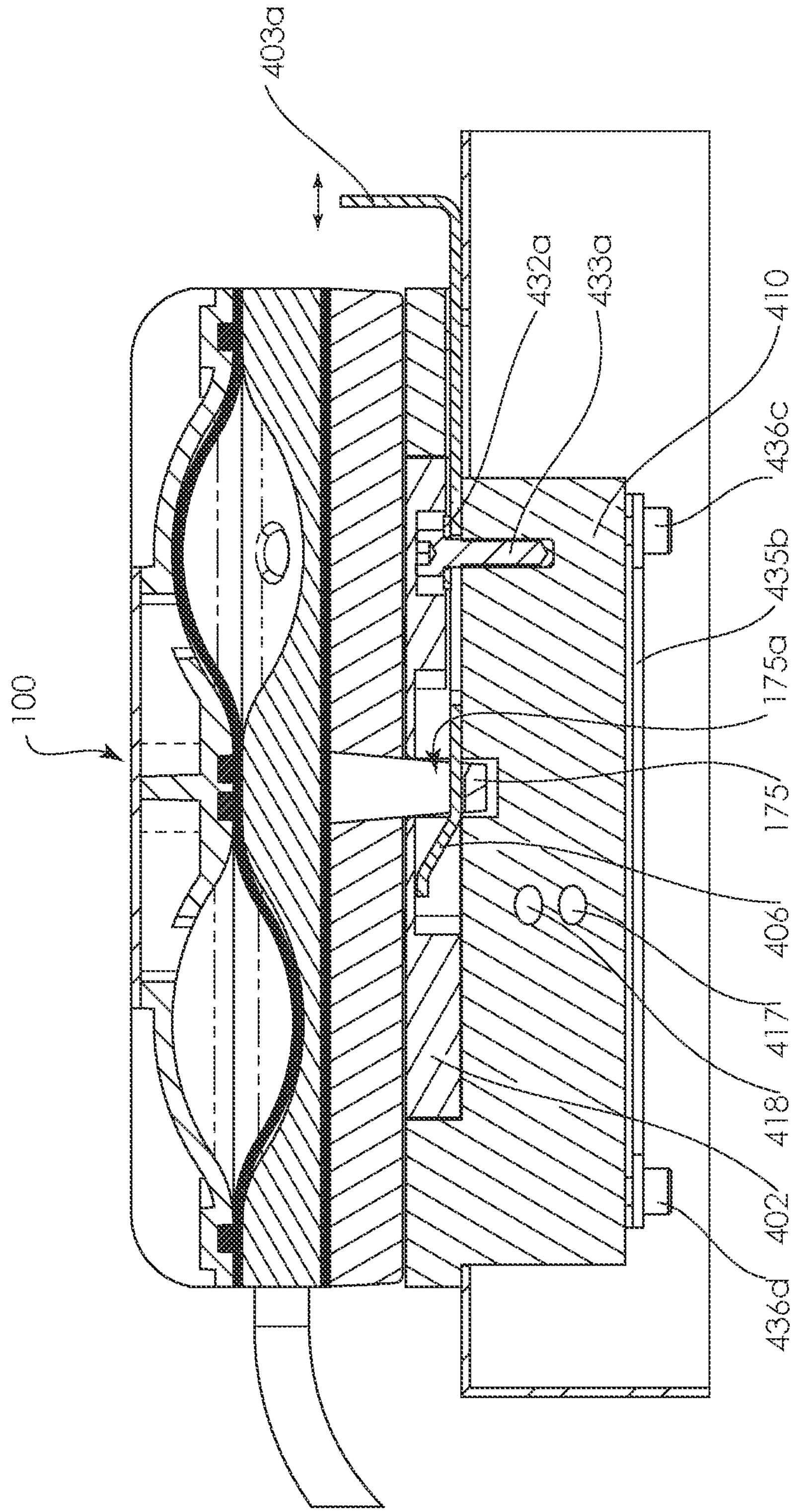
Fig. 13A



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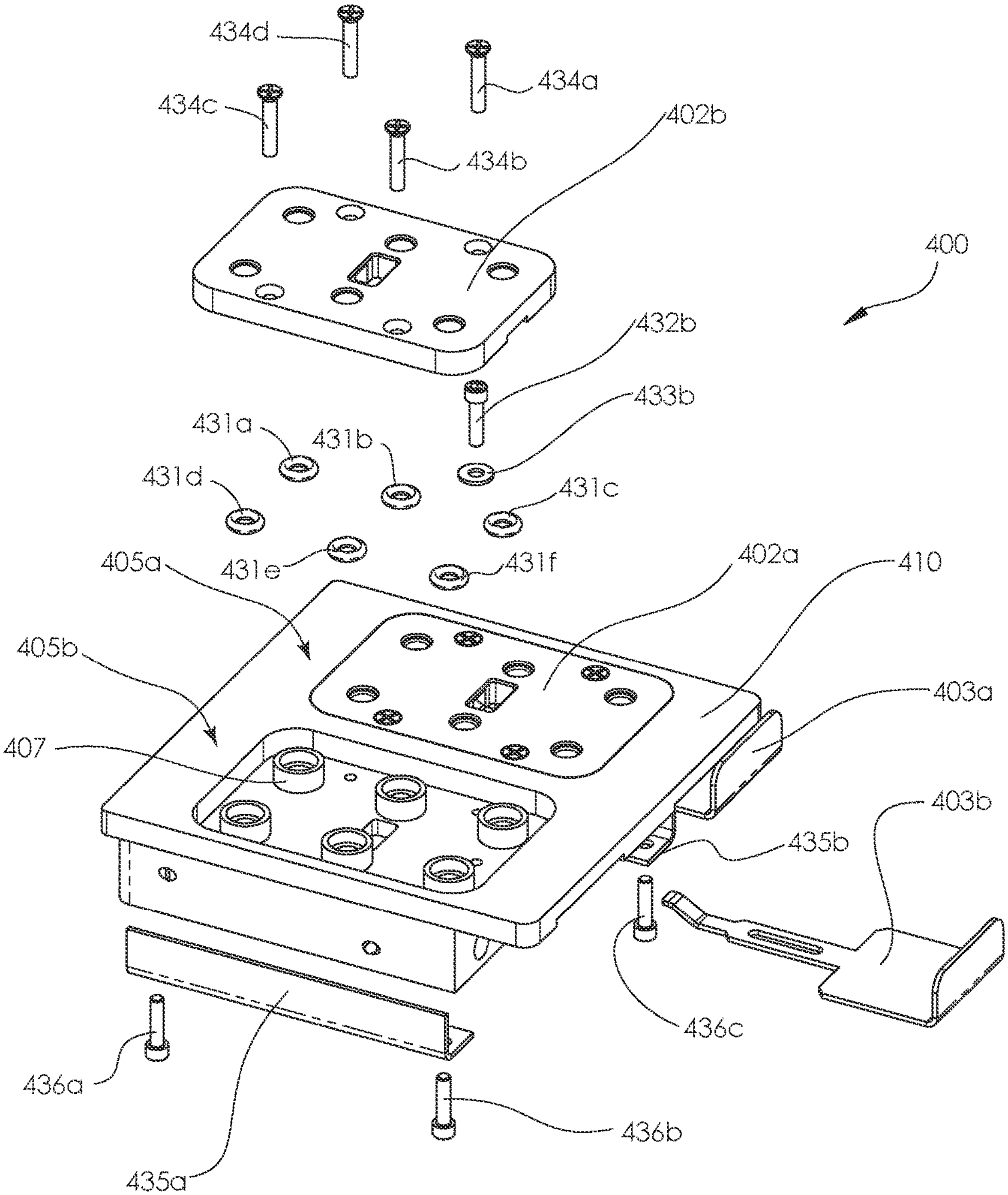
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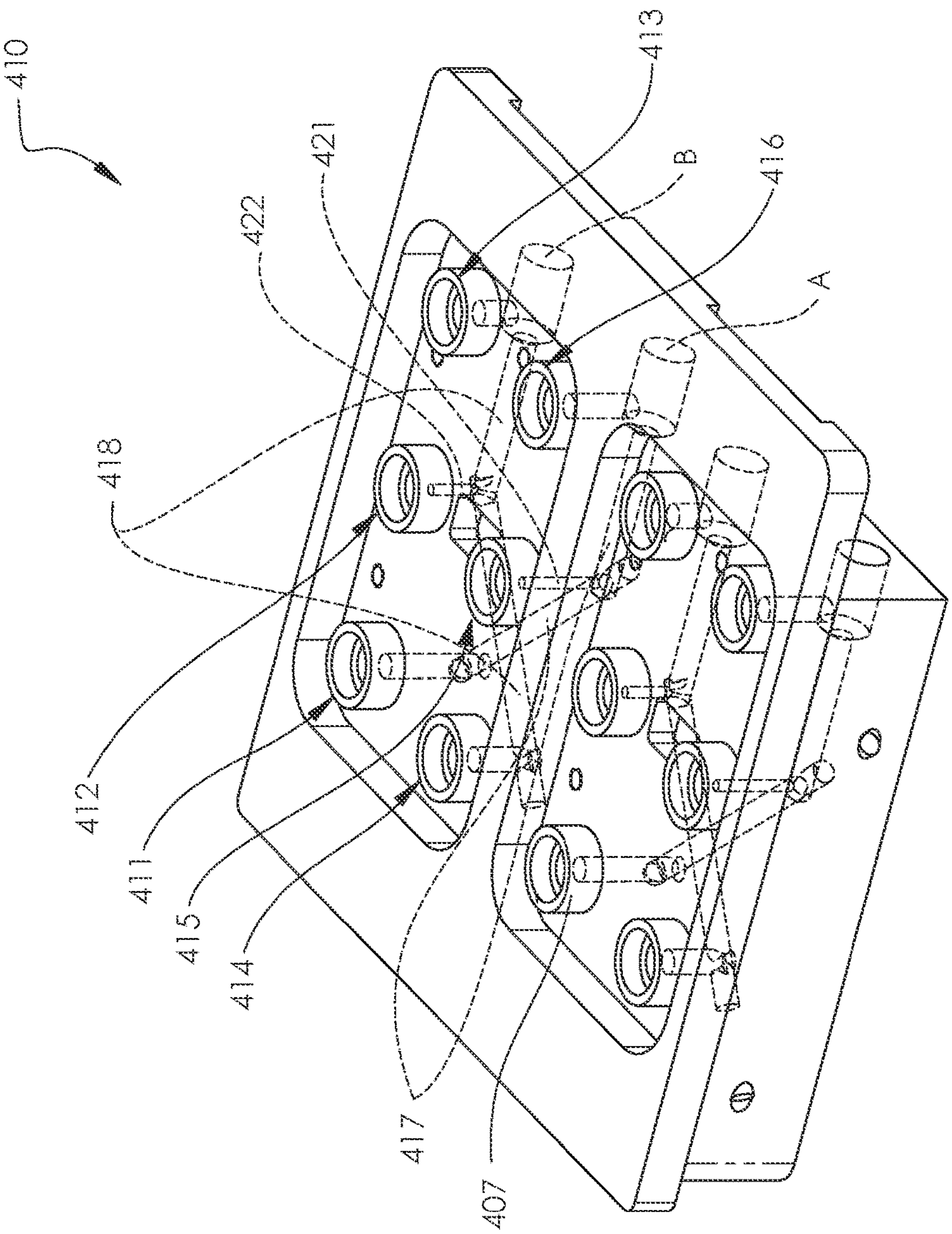
Fig. 14



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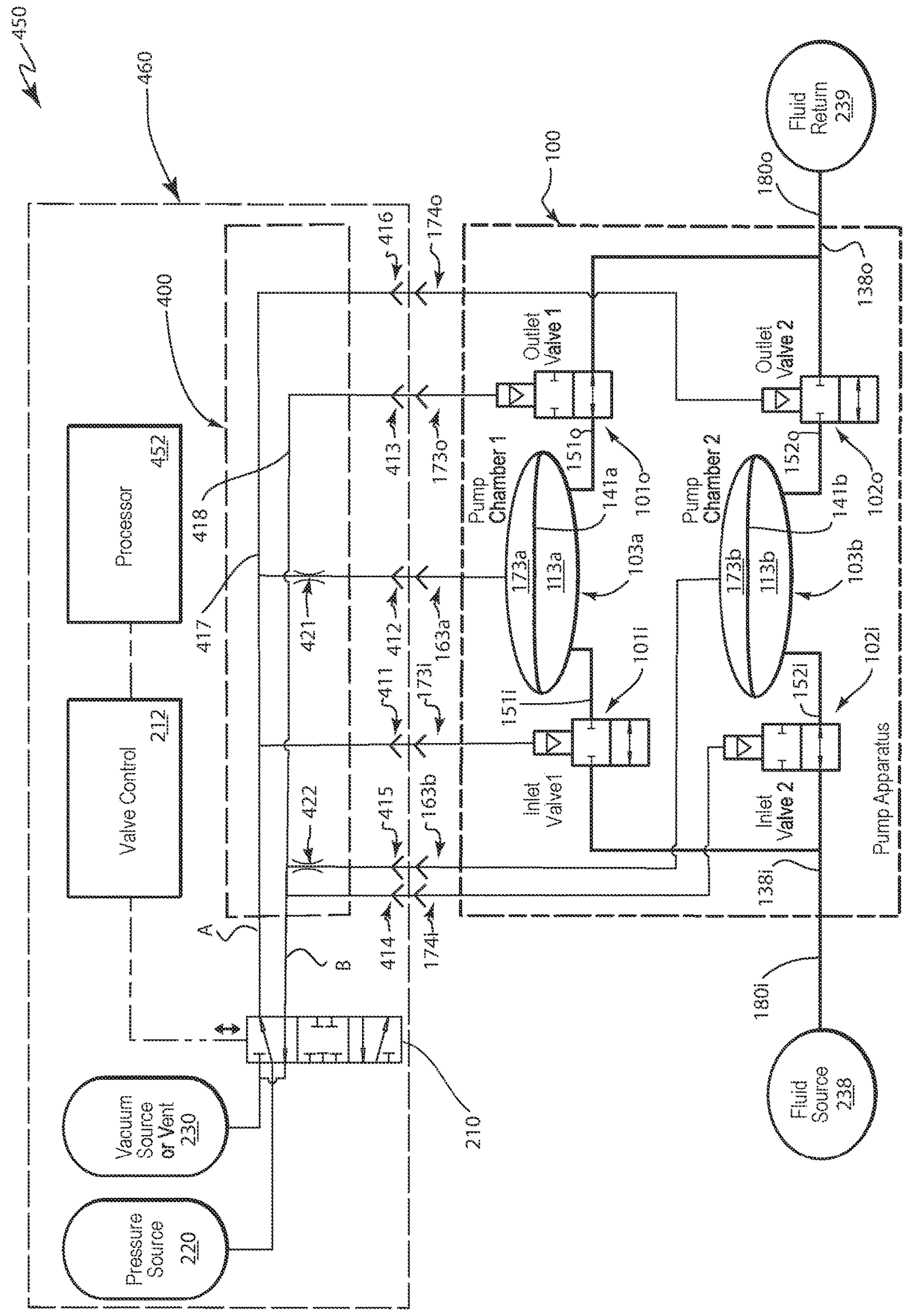
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141a
103a
151i
151o
101i
101o
Inlet Valve1
Outlet Valve 1
Pump Chamber 2
173b
113b
141b
103b
152i
152o
102i
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Fluid Source
238
Fluid Return
239

Fig. 16

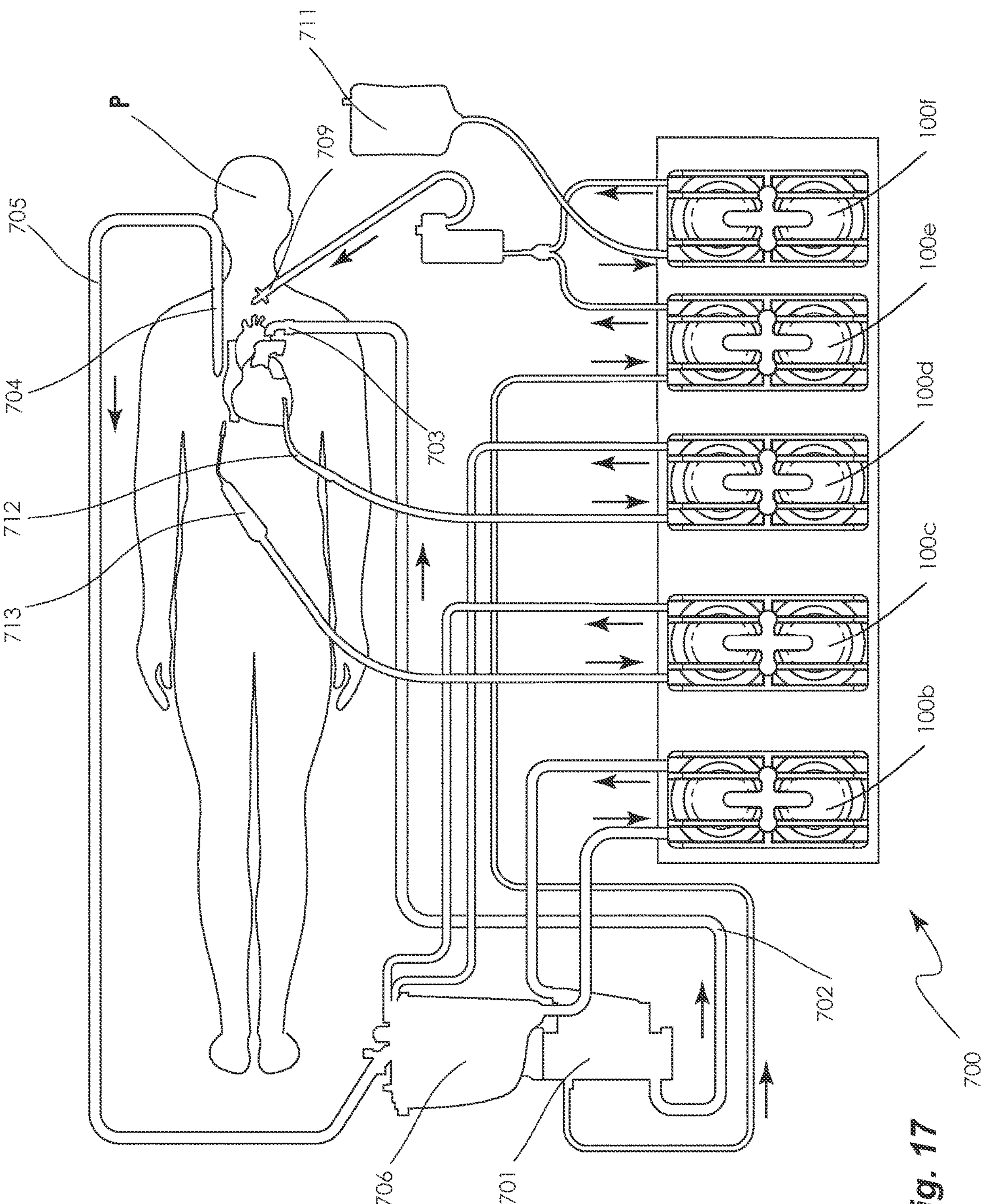
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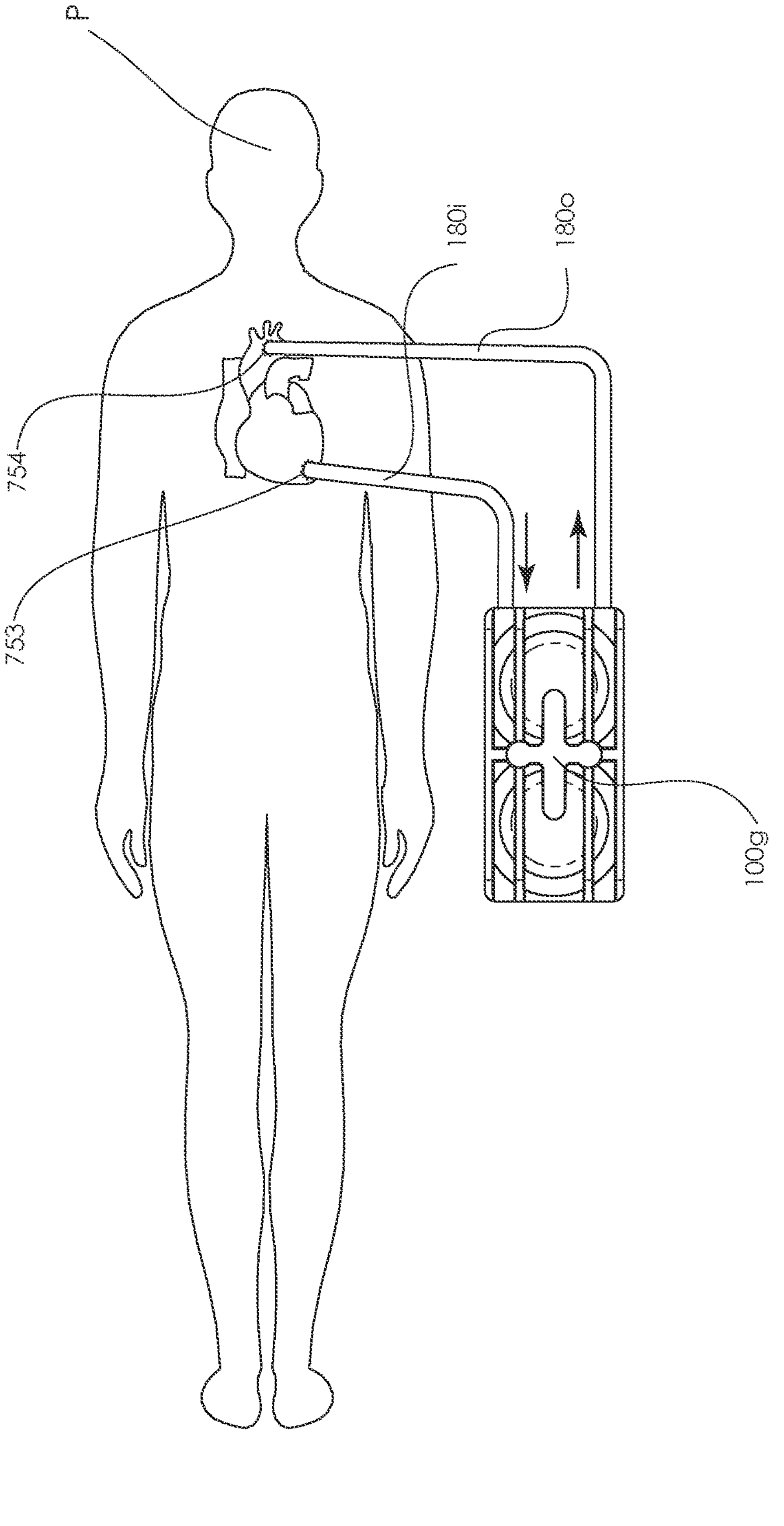
Fig. 17



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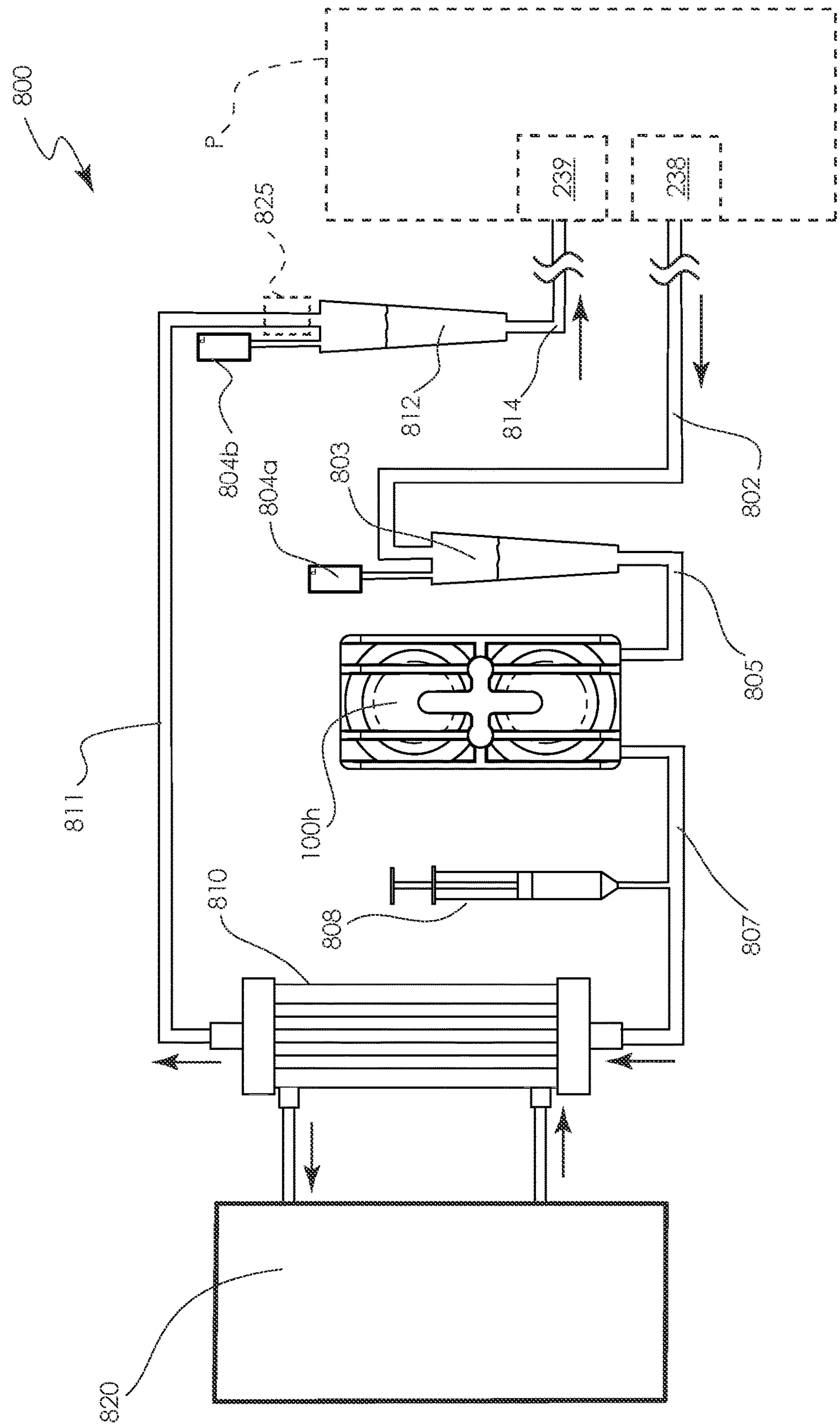
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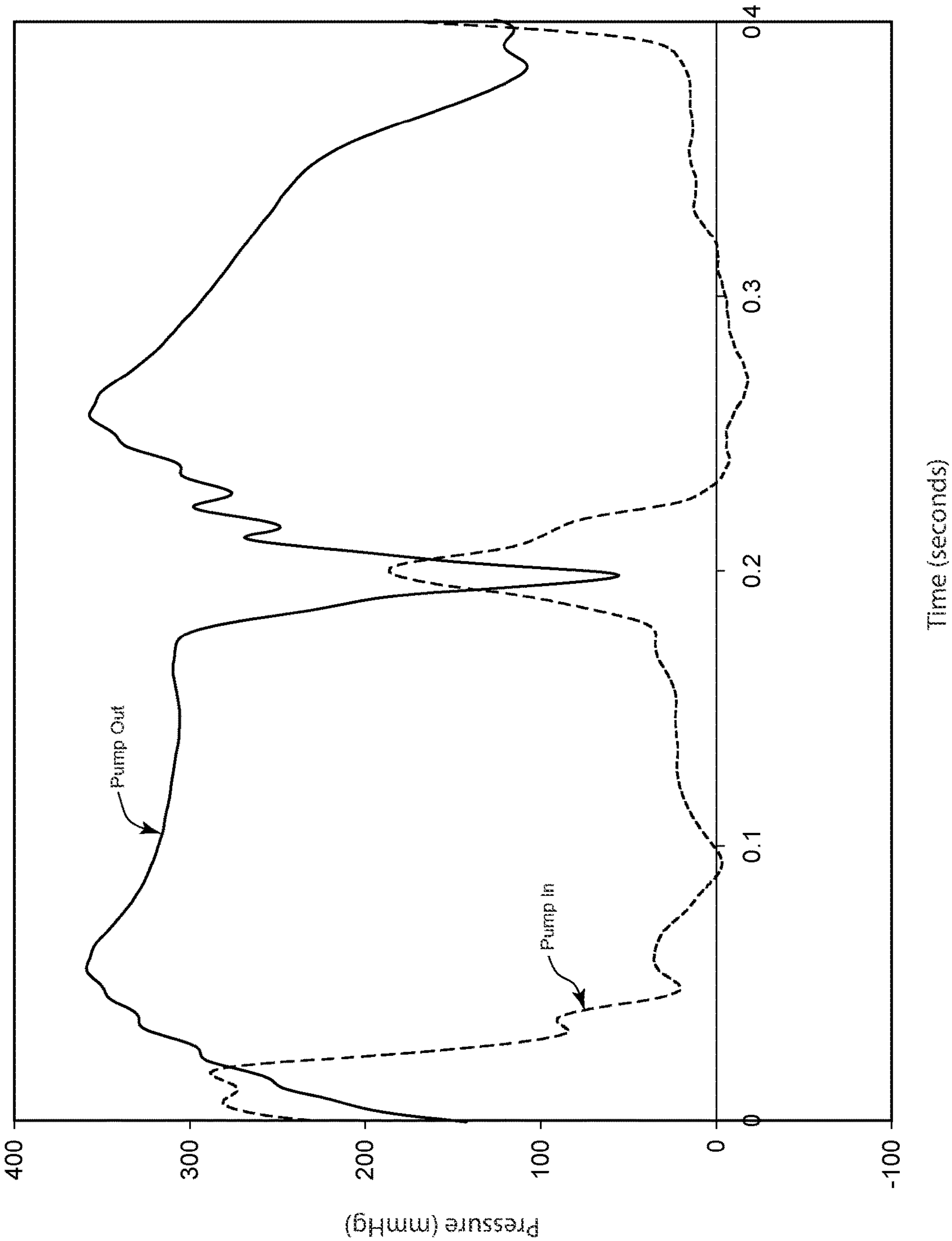
Fig. 19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-100
Time (seconds)
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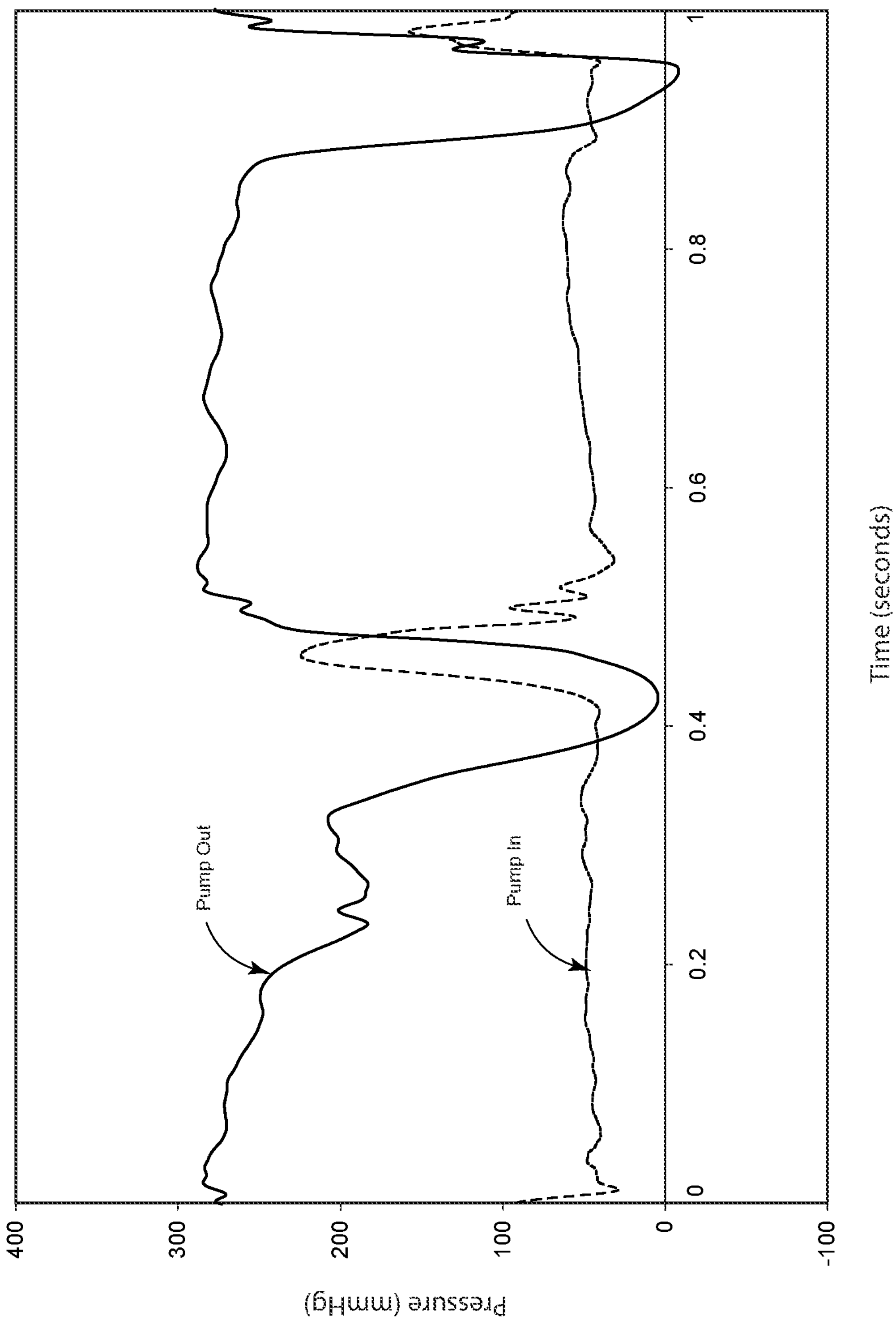
0.2
0.3
0.4
Pump Out
Pump In

Fig. 20


Pump Out
Pump In
Pressure (mmHg)
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200
100
0
-100
Time (seconds)
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0.2
0.4
0.6
0.8
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Fig. 21

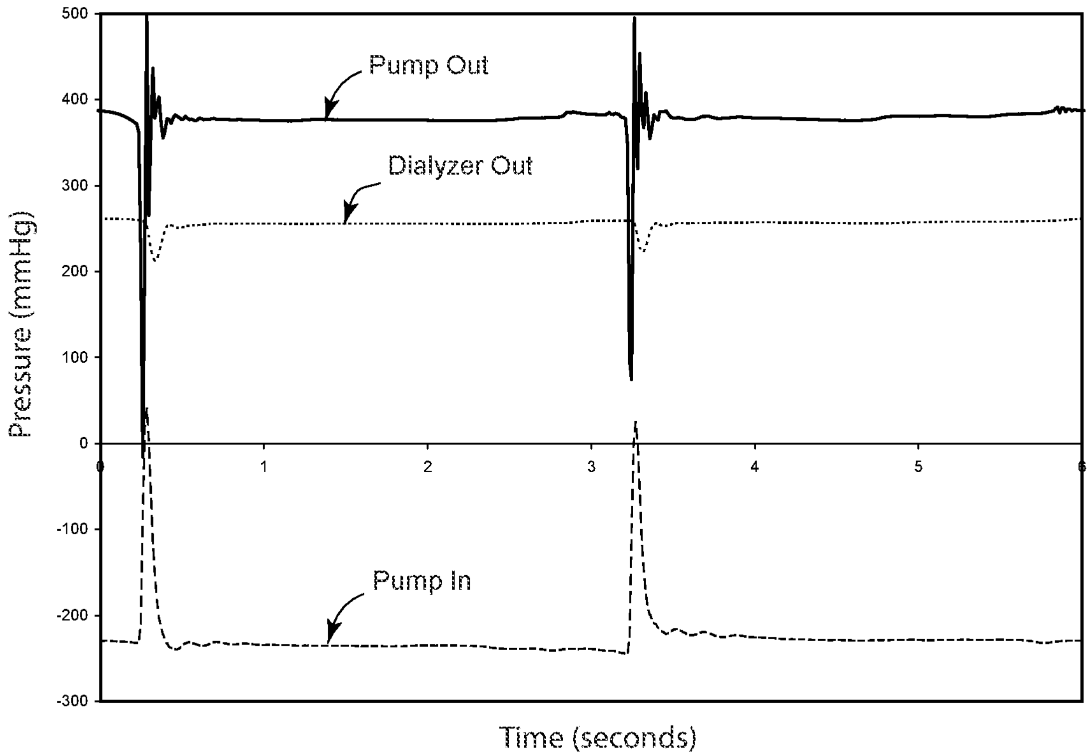

Fig. 22A

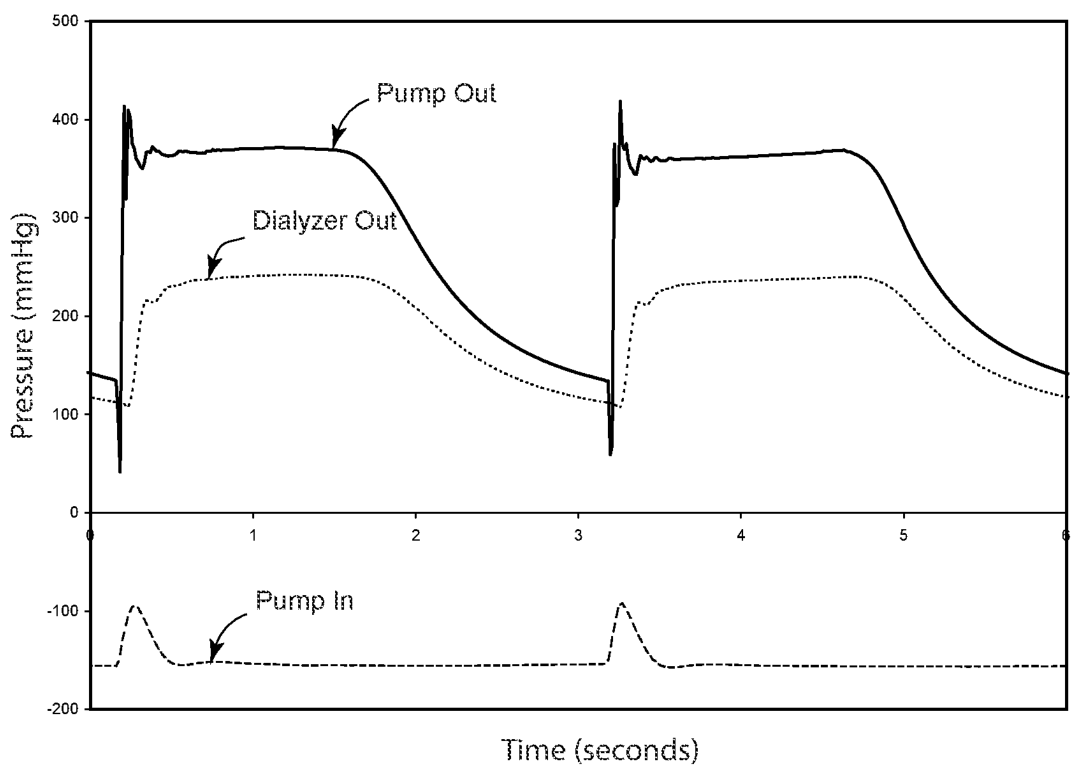

Fig. 22B

MEDICAL FLUID PUMPING SYSTEM HAVING BACKFLOW PREVENTION

PRIORITY CLAIM

This application claims priority to and the benefit as a continuation of U.S. patent application Ser. No. 16/355,170, filed Mar. 15, 2019, entitled BLOOD TREATMENT SYSTEM HAVING PULSATILE BLOOD INTAKE, now U.S. Pat. No. 11,384,748 issued Jul. 12, 2022, which is a continuation of U.S. patent application Ser. No. 14/558,021, filed Dec. 2, 2014, entitled DIAPHRAGM PUMPS AND PUMPING SYSTEMS, now U.S. Pat. No. 10,670,005 issued Jun. 2, 2020, which is a continuation of U.S. patent application Ser. No. 13/472,099, filed May 15, 2012, entitled DIAPHRAGM PUMP AND PUMPING SYSTEMS, now U.S. Pat. No. 8,932,032 issued Jan. 13, 2015, which is a continuation of U.S. patent application Ser. No. 11/945,177, filed Nov. 26, 2007, entitled DIAPHRAGM PUMP AND RELATED METHODS, now U.S. Pat. No. 8,197,231 issued Jun. 12, 2012, which is a continuation-in-part of U.S. patent application Ser. No. 11/484,061, filed Jul. 11, 2006, entitled DOUBLE DIAPHRAGM PUMP AND RELATED METHODS, now U.S. Pat. No. 7,717,682 issued on May 18, 2010, which claims priority to U.S. Provisional Application No. 60/699,262, filed Jul. 13, 2005, entitled DOUBLE DIAPHRAGM PUMP AND RELATED METHODS, the entire contents of each of which are incorporated herein by reference and relied upon.

TECHNICAL FIELD

Certain embodiments described herein relate generally to the field of fluid transfer. More particularly, some embodiments described herein relate to fluid transfer having a relatively small amount or no amount of impurities introduced to the fluid being transferred and/or relatively little or no damage to the fluid being transferred.

BRIEF DESCRIPTION OF THE DRAWINGS

Understanding that drawings depict only typical embodiments of the invention and are not therefore to be considered to be limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings. The drawings are listed below.

FIG. **1** is a perspective view of an embodiment of a double diaphragm blood pump.

FIG. **2** is an exploded perspective view of the double diaphragm blood pump of FIG. **1**.

FIG. **3** is a perspective view of an inner side of an embodiment of a valve plate.

FIG. **4** is a plan view of one side of an embodiment of a pump body with a portion of the interior of the pump body shown in phantom and a portion of an opposite side of the pump body shown in phantom.

FIG. **5** is a perspective view of the inner side of an embodiment of a chamber plate with interior features thereof shown in phantom.

FIG. **6**A is a perspective view of an embodiment of diaphragm media before regions have been formed.

FIG. **6**B is a perspective view of the diaphragm media of FIG. **6**A after the regions have been formed.

FIG. **7** is an exploded perspective view of an embodiment of a forming fixture used to form the regions in the diaphragm.

FIG. **8**A is a cross-sectional view of a forming fixture after a diaphragm media has been loaded to form the regions in the chamber diaphragm.

FIG. **8**B is a cross-sectional view such as the view in FIG. **8**A showing the forming fixture after the regions in the diaphragm media have been formed.

FIG. **9**A is a side view of the double diaphragm pump of FIG. **1** which shows cutting lines **9**B-**9**B and **9**C-**9**C.

FIG. **9**B is a cross-sectional view of the double diaphragm pump of FIG. **1** taken along cutting line **9**B-**9**B in FIG. **9**A.

FIG. **9**C is a cross-sectional view of the double diaphragm pump of FIG. **1** taken along cutting line **9**C-**9**C in FIG. **9**A.

FIG. **10** is a cross-sectional view of another embodiment of the double diaphragm pump of FIG. **1** taken along cutting line **9**B-**9**B in FIG. **9**A showing valve bypass passages.

FIG. **11** is a cross-sectional perspective view of another embodiment of a diaphragm pump.

FIG. **12** is a partially exploded perspective view of two double diaphragm blood pumps configured for operative association with a reusable pump control system.

FIG. **13**A is a partial cross-sectional view of a double diaphragm pump and manifold taken along cutting line **13**A-**13**A in FIG. **12**.

FIG. **13**B is a partial cross-sectional view of a double diaphragm pump and manifold taken along cutting line **13**B-**13**B in FIG. **12**.

FIG. **14** is a partially exploded perspective view of an embodiment of a manifold mounting assembly.

FIG. **15** is a perspective view of an embodiment of a manifold base with a portion of the interior features of the manifold base shown in phantom.

FIG. **16** is a schematic view of an embodiment of a double diaphragm pump as used in a method and system for transferring fluid.

FIG. **17** is a schematic view of an embodiment of a cardiopulmonary by-pass system that includes multiple double diaphragm pumps.

FIG. **18** is a schematic view of an embodiment of a heart-assist system using an embodiment of the double diaphragm pump.

FIG. **19** is a schematic view of an embodiment of a hemodialysis system using an embodiment of the double diaphragm pump to effect flow through the system.

FIG. **20** is a chart showing an example of the pressure over time of blood entering and also of blood exiting an embodiment of a double diaphragm pump of the system depicted in FIG. **17** when configured for relatively constant flow operation.

FIG. **21** is a chart showing an example of the pressure over time of blood entering and also of blood exiting an embodiment of a double diaphragm pump of the system depicted in FIG. **18** when the pump is configured for pulsatile outflow operation and relatively constant inflow operation.

FIG. **22**A is a chart showing an example of the pressure over time of blood entering and also of blood exiting an embodiment of a double diaphragm pump of the system depicted in FIG. **19**, as well as the pressure over time of blood exiting the dialyzer, when the pump is configured for use in a hemodialysis procedure and controlled for relatively constant inflow operation and relatively constant outflow operation.

FIG. **22**B is a chart showing an example of the pressure over time of blood entering and also of blood exiting the double diaphragm pump in the system depicted in FIG. **19**, as well as the pressure over time of blood exiting the dialyzer, when the pump is configured for use in a hemodialysis procedure and controlled for relatively constant inflow operation and pulsatile outflow operation.

INDEX OF ELEMENTS IDENTIFIED IN THE DRAWINGS

Elements numbered in the drawings include:

100 double diaphragm pump
100a-h double diaphragm pumps
101i first inlet valve chamber
101o first outlet valve chamber
102i second inlet valve chamber
102o second outlet valve chamber
103a first pump chamber
103b second pump chamber
110 pump body
110' pump body with valve bypass channels
111i first inlet valve seat
111o first outlet valve seat
112i second inlet valve seat
112o second outlet valve seat
113a first chamber cavity
113b second chamber cavity
114a surface of first chamber cavity 113a
114b surface of second chamber cavity 113b
115a inclined region of first pump chamber 113a
115b inclined region of second pump chamber cavity 113b
116a rim of first pump chamber 113a
116b rim of second pump chamber cavity 113b
117a perimeter of first pump chamber cavity 113a
117b perimeter of second pump chamber cavity 113b
118i perimeter of first inlet valve seat 111i
118o perimeter of first outlet valve seat 111o
119i perimeter of second inlet valve seat 112i
1190 perimeter of second outlet valve seat 112o
121i groove of first inlet valve seat 111i
1210 groove of first outlet valve seat 111o
122i groove of second inlet valve seat 112i
122o groove of second outlet valve seat 112o
131i first inlet valve portal for fluid communication between inlet channel 138i and first inlet valve seat 111i
131o first outlet valve portal for fluid communication between first outlet valve seat 111o and outlet channel 138o
132i second inlet valve portal for fluid communication between inlet channel 138i and second inlet valve seat 112i
132o second outlet valve portal for fluid communication between second outlet valve seat 112o and outlet channel 138o
133i chamber channel for fluid communication between first chamber cavity 113a and first inlet valve seat 111i
133o chamber channel for fluid communication between first chamber cavity 113a and first outlet valve seat 111o
134i chamber channel for fluid communication between second chamber cavity 113b and second inlet valve seat 112i
134o chamber channel for fluid communication between second chamber cavity 113b and second outlet valve seat 112o
135i seat rim of first inlet valve seat 111i
135o seat rim of first outlet valve seat 111o
136i seat rim of second inlet valve seat 112i
136o seat rim of second outlet valve seat 112o
138i inlet channel
138o outlet channel
139i bypass channel between inlet channel 138i and first pump chamber 103a
139o bypass channel between first pump chamber 103a and outlet channel 138o
140a&b chamber diaphragms
141a first pump chamber diaphragm region of chamber diaphragms 140a, b
141b second pump chamber diaphragm region of chamber diaphragms 140a, b
142a-f holes in chamber diaphragm for assembly
150a&b valve diaphragms
151i first inlet valve region of valve diaphragms 150a&b
151o first outlet valve region of valve diaphragms 150a&b
152i second inlet valve region of valve diaphragms 150a&b
152o second outlet valve region of valve diaphragms 150a&b
160 chamber plate
161a first chamber actuation cavity
161b second chamber actuation cavity
162a&b air transfer bosses
163a passage between opening 164a and boss 162a
163b passage between opening 164b and boss 162b
164a opening between first chamber cavity 161a and passage 163a
164b opening between second chamber cavity 161b and passage 163b
165a&b cavity surface 166a&b
166a&b recess
166c&d inclined regions
167a&b rims
168a&b perimeters
169a-d assembly posts
170 valve plate
171i actuation cavity of first inlet valve 101i
171o actuation cavity of first outlet valve 101o
172i actuation cavity of second inlet valve 102i
172o actuation cavity of second outlet valve 102o
173i passage between actuation cavity 171i of first inlet valve 101i and boss 176a
173o passage between actuation cavity 171o of first outlet valve 101o and boss 176b
174i passage between actuation cavity 172i of second inlet valve 102i and boss 176c
174o passage between actuation cavity 172o of second outlet valve 102o and boss 176d
175 mounting hook
175a opening defined by mounting hook
176a-d air transfer bosses
177i groove for o-ring 192a
177o groove for o-ring 192b
178i groove for o-ring 192c
178o groove for o-ring 192d
179a-f assembly holes
180i inlet line
180o outlet line
190 manifold cover plate
192a-d valve o-rings
193a & b chamber o-rings
210 motive fluid valve
212 valve controller
220 pressure source
230 vacuum source
238 fluid source or blood uptake
239 fluid return, receiver, or destination

300 forming fixture
310 first plate
311*a&b* chamber region recess
312*a&b* o-ring groove
313*a&b* openings between forming recess **311***a, b* and vacuum port **318**
314*a&b* surface of recess
318 vacuum port or passage
320 second plate
321*a&b* heating windows or portals
330 heater
331 heater surface
400 manifold mounting assembly
402*a&b* manifold covers
403*a&b* mounting latches
406 catch
407 motive fluid transfer boss
410 manifold base
411 motive fluid transfer boss
412 motive fluid transfer boss
413 motive fluid transfer boss
414 motive fluid transfer boss
415 motive fluid transfer boss
416 motive fluid transfer boss
417 transfer passage of manifold between air transfer bosses **412**, **413**, **414** and portal B
418 transfer passage of manifold between air transfer bosses **411**, **415**, **416** and portal A
421 flow restriction between air transfer boss **412** and transfer passage **418**
422 flow restriction between air transfer boss **415** and transfer passage **417**
431*a-f* o-rings
432*a&b* screws
433*a&b* washers
434*a-d* screws
435*a&b* brackets
436*a-d* fasteners
450 pump assembly
451 pump control system
452 processor
453 user control interface
454 enclosure
700 cardiopulmonary by-pass system
701 oxygenator
702 arterial tubing segment
703 arterial cannula
704 venous return catheter
705 venous tubing segment
706 reservoir
709 cardioplegia cannula
711 medical fluid bag
712 vent catheter
713 suction device
750 heart-assist system
753 cannula or attachment to vascular system on venous side
754 cannula or attachment to vascular system on arterial side
800 extracorporeal circuit
802 tubing segment on blood uptake from patient vascular system
803 drip chamber
804*a&b* pressure transducers
805 tubing segment
807 tubing segment
808 heparin pump
810 dialyzer
811 tubing segment
812 drip chamber
814 tubing segment on blood return to patient vascular system
820 dialyzing liquid system
825 air detector
1100 pump
1101*i* first inlet valve
1101*o* first outlet valve
1103*a* first pump chamber
111*o* pump body
1133*i* chamber channel between first inlet valve and first pump chamber
1133*o* chamber channel between first pump chamber and first outlet valve
1135*i* rim of first inlet valve
1135*o* rim of first outlet valve
1138*i* inlet channel
1138*o* outlet channel
1140 one or more diaphragms
1141*a* diaphragm actuation region of first pump chamber
1151*i* diaphragm actuation region of first inlet valve
1151*o* diaphragm actuation region of first outlet valve
1160 chamber plate
1162*a* motive fluid transfer boss
1163*a* motive fluid passage
1173*i* motive fluid passage
1173*o* motive fluid passage
1176*a* motive fluid transfer boss
1176*b* motive fluid transfer boss
1180*i* inlet line
1180*o* outlet line
A first supply port connection between air valve **210** and manifold plate **400**
B second supply port connection between air valve **210** and manifold plate **400**
P patient

DETAILED DESCRIPTION

This disclosure relates to a pump apparatus and related methods and systems. Various views of an illustrative embodiment of a pump are provided in FIGS. **1-6**B and **9**A-**11**. FIGS. **7-8**B relate to an embodiment of a forming fixture used to shape regions of a chamber diaphragm which can be used in a pump. An embodiment of pumping system utilizing a double diaphragm pump is shown in FIGS. **12-15**. FIG. **16** provides a schematic view of an embodiment of a system utilizing a double diaphragm pump. The schematic views provided in FIGS. **17-19** illustrate various applications of embodiments of double diaphragm pumps in medical applications in which blood is pumped.

It is noted that similar or duplicate features are referred to with a unique alphanumeric designation. Certain features common to various embodiments may be designated with a primed numeral in some figures. In either case, duplicate elements will not be described in further detail to the extent their performance is similar to the embodiments previously described. For example, the chamber diaphragms illustrated in FIG. **2** will be referred to as **140***a* and **140***b*, and various diaphragm blood pumps are referred to in FIG. **17** as **100***b*, **100***c*, **100***d*, etc. A pump body in one embodiment is referred to in FIG. **9**C as **110** and a pump body in another embodiment is referred to in FIG. **10** as **110'**.

Certain diaphragm pumps can have application as a single use disposable medical blood pump. For example, a pump can be used to move blood through an extracorporeal circuit. An advantage of pumping blood with certain pumps as described herein is that, in various embodiments, a relatively small amount, a minimal amount, a negligible amount, or even no amount of synthetic pump material particles is released into the flow of blood that is caused by rubbing, sliding, or straining of materials typically used in other types of pump mechanisms to energize fluid flow. Synthetic particulates generated by certain pumps that move fluids to and from a patient have the potential to create adverse health effects including embolisms or microembolisms in the vascular system. Further, the toxicity of materials introduced or generated by such pumps can be delivered to the patient and can be left residing in the vascular system of the patient.

Certain embodiments of a pneumatically actuated diaphragm pump can be advantageous because of the inherent control that may be achieved for delivering fluids within physiologically acceptable pressure ranges. For example, if a blockage occurs in the process fluid lines connected to an embodiment of a pump, some embodiments of the pump may only generate pressure in the process fluid at a level that is at or near those of the motive fluid pressures that are driving the pump. In the case of pumping blood, such a pump can reduce or eliminate excessive pressures or high vacuums in the fluid lines that can potentially damage blood or cause air embolisms by out-gassing the blood under high suction levels.

Some embodiments of pumping systems that may be used in single-use disposable medical applications can advantageously be comprised of a removable and/or separable disposable pumping component and a reusable pump control system. The disposable pumping component can be packaged and pre-sterilized for use in a medical application related to an individual patient. In some embodiments, the disposable pumping component can be coupled in operative association with the reusable pump control system for a single patient during a medical application, and then removed and disposed.

In some embodiments, the reusable pump control system can be isolated from the flow of biological fluids and may selectively control and operate a plurality of disposable pumping components-one or more for each of a multiple number of patients or applications, in some instances-without being sterilized between uses. The removable/disposable pumping component may include pump chambers, inlet and outlet valves, inlet and outlet lines, and other components which are in contact with the blood or biological fluid. In some embodiments, the removable/disposable pumping component comprises a double diaphragm pump. As discussed below, in some embodiments, the double diaphragm pump can be configured and designed with a plurality of pump chambers, flow paths, valves, etc. that are specifically designed for a particular application. For example, some embodiments of double diaphragm pumps can be configured for use in such medical applications as cardiopulmonary bypass, surgical perfusion support, heart assist, and hemodialysis, as further described below.

Various embodiments of double diaphragm pumps also enable fluids to be transferred in a wide variety of other fields. For example, such pumps can be used in the transfer of high purity process fluids. Some embodiments of double diaphragm pumps can be advantageous in transferring high purity process fluids, as the pump avoids, minimizes, or otherwise reduces the introduction or generation of contaminants or particulate matter that can be transferred downstream by reducing or eliminating rubbing and sliding components within the pump. Downstream transfer of contaminants or particulate matter may effect the desired outcome of using the high purity process fluid. Also for shear sensitive fluids, some pumps can be operated to gently move fluid from a source to a destination.

FIG. **1** provides a perspective view of an embodiment of a double diaphragm pump at **100**. The pump **100** can comprise a plurality of housing members or housing components, which in some embodiments may be substantially rigid, as discussed below. In some embodiments, the housing members comprise a pump body **110**, a chamber plate **160** and a valve plate **170**. In some embodiments, the pump **100** further comprises a plurality of diaphragms. For example, in some embodiments, the pump **100** comprises one or more chamber diaphragms **140***a*, **140***b*, which can be located between chamber plate **160** and pump body **110**, and further comprises one or more valve diaphragms **150***a*, **150***b*, which can be located between valve plate **170** and pump body **110**. The chamber diaphragms **140***a, b* and valve diaphragms **150***a, b* are not identified in FIG. **1** but are shown in FIGS. **2**, **9**B, and **9**C. While these diaphragms may not necessarily extend to the perimeter of pump body **110**, chamber plate **160**, or valve plate **170**, in some embodiments, the media can extend to the perimeter or beyond so that the media protrudes beyond an outer edge of the pump body **110**. As further discussed below, in some embodiments, manifold cover plate **190** seals or closes motive fluid passages defined by chamber plate **160**.

FIG. **1** and FIG. **4** show features related to the inlet and outlet lines for the passage of process fluid through the pump body **110**. In particular, inlet line **180***i* is connected with inlet channel **138***i* and outlet line **180***o* is connected with outlet channel **138***o*, as shown. Inlet channel **138***i* and outlet channel **138***o* are shown in more detail in FIG. **4**, FIGS. **9**B-**10** and FIG. **16**. In the embodiment illustrated in FIGS. **1** and **4**, representative connections between inlet line **180***i* and inlet channel **138***i* and between outlet line **180***o* and outlet channel **138***o* are shown. Similar connections can be made to other external fluid lines or devices. The connection between these components can include solvent bonding, adhesives, mechanical fittings (including barbed nipple tube fittings), or other methods well known in the art.

Some of the components which comprise the valves and the pump chambers are shown in FIG. **2**, however, the valves and the pump chambers are not identified in FIG. **2**, as this figure represents an exploded perspective view of a double diaphragm pump **100**. As illustrated in FIGS. **9**B-**9**C and FIG. **10**, certain embodiments of the double diaphragm pump **100** can comprise a first inlet valve **101***i*, first outlet valve **101***o*, second inlet valve **102***i*, second outlet valve **102***o*, first pump chamber **103***a*, and second pump chamber **103***b*. FIG. **2** also shows a plurality of valve seals or o-rings **192***a-d* and chamber seals or o-rings **193***a, b*, which can be used in some embodiments to assist in sealing valves and pump chambers. For example, in some embodiments, the valve plate **170** comprises grooves **177***i*, **177***o*, **178***i*, and **178***o* (see FIG. **3**) for receiving o-rings **192***a-d*. Similarly, chamber plate **160** can comprise grooves for receiving o-rings **193***a, b*.

Other means of sealing the valves and chambers can also be used, including adhesives, heat bonding, and welding. In certain embodiments, the diaphragms **140***a, b* and **150***a, b* and pump body **110** can be fabricated with similar materials that will bond together when heated. In some embodiments, fluorinated ethylene propylene (FEP) materials can be used for both of the diaphragms **140***a, b*, **150***a, b* and the pump body **110**, and heat can be used to bond the diaphragms to the body. Other heat sealable materials that can be used for both of the diaphragms **140**_a, b_, **150**_a, b_ and the pump body **110** include polyvinylchloride (PVC), polyurethane (PU), and polypropylene (PP). In some embodiments, an adhesive, such as Scotch Weld Acrylic DP-8005 adhesive manufactured by **3**M—Industrial Business, Industrial Adhesives and Tapes Division, St. Paul, Minn., is used to attach the chamber plate **160** assembly posts **169**_a-d_ and air bosses **162**_a, b_ (see, e.g., FIG. **5**) to the valve plate **170** assembly holes **179**_a-f_ (see, e.g., FIG. **3**). Components of a double diaphragm pump **100**, such as the components shown in FIG. **2** can be assembled together in any other suitable manner, such as via mechanical fasteners (for example nuts and bolts, clamps, screws, etc.); adhesives; welding; bonding; or other mechanisms. These mechanisms are all examples of means for maintaining the plates and body together and sealing chambers created between the plates and body.

FIG. **2** provides the best view of the chamber diaphragms **140**_a, b_ and valve diaphragms **150**_a, b_. In the illustrated embodiment, each diaphragm **140**_a, b_ and **150**_a, b_ has a specific region corresponding with a particular chamber. In some embodiments, the regions are preformed or pre-shaped prior to assembly of the pump **100**. In some embodiments, a single diaphragm is used between pump body **110** and chamber plate **160** and/or a single diaphragm is used between pump body **110** and valve plate **170**. In other embodiments, two or more diaphragms are utilized between one or more sets of neighboring components, which can provide a pump **100** with one or more redundant layers for safety purposes. For example, in the unlikely event that one of the diaphragms were to fail due to a rare manufacturing defect, interaction with a sharp object in the air or fluid flow, cyclic fatigue cracking, or other cause of failure, the pump could safely operate using a redundant diaphragm. In some embodiments, each chamber or valve uses a separate diaphragm or diaphragms that are not integrated into a multi-chamber diaphragm. Additionally, the separate diaphragms can also include preformed or pre-shaped actuation regions. In some embodiments, the actuation regions are configured to move between a natural shape and an inversion of the natural shape without significant stretching, as further discussed below. The actuation regions can be configured to flex, in some embodiments. Methods for forming diaphragms with pre-shaped regions are discussed below with reference to FIGS. **6**A, **6**B, **7**, **8**A, and **8**B.

In certain embodiments, the preformed actuation regions of chamber diaphragm **140**_a_ include first pump chamber region **141**_a_ and second pump chamber region **141**_b_. The preformed actuation regions of valve diaphragm **150**_a_ include first inlet valve region **151**_i_, first outlet valve region **151**_o_, second inlet valve region **152**_i_, and second outlet valve region **152**_o_. Each media **140**_a, b_ and **150**_a, b_ can also have holes **142**_a-f_ (see FIG. **6**A) for manufacturing and assembly, as further discussed below.

With reference to FIGS. **2**, **9**B, and **9**C, first pump chamber **103**_a_ is divided by first pump chamber region **141**_a_ into first pump chamber cavity **113**_a_ and first actuation cavity **161**_a_. Similarly, second pump chamber **103**_b_ is divided by second pump chamber region **141**_b_ into second pump chamber cavity **113**_b_ and second actuation cavity **161**_b_. Each of the valves **101**_i_, **101**_o_, **102**_i_, and **102**_o_ is also divided by its respective diaphragm regions. In particular, each of valves **101**_i_, **101**_o_, **102**_i_ and **102**_o_ comprises an actuation cavity and a valve seat. The valve seats include first inlet valve seat **111**_i_, first outlet valve seat **111**_o_, second inlet valve seat **112**_i_, and second outlet valve seat **112**_o_. The actuation cavities include actuation cavity **171**_i_ of first inlet valve **101**_i_, actuation cavity **171**_o_ of first outlet valve **101**_o_, actuation cavity **172**_i_ of second inlet valve **102**_i_ and actuation cavity **172**_o_ of second outlet valve **102**_o_. Together, a given valve seat/actuation cavity pair can define a valve chamber through which a diaphragm region can move. For example, with reference to FIG. **9**B, the first outlet valve region **151**_o_ can move within a valve chamber that is comprised of the first outlet valve seat **111**_o_ and the actuation cavity **171**_o_.

The flow paths of the process fluid in some embodiments of the double diaphragm pump **100** are described below with reference to FIG. **4** and FIG. **16**. The flow path is also described with reference to FIGS. **9**A-**10**. Before providing a comprehensive overview of the flow path, the components of double diaphragm pump **100** are described below with occasional reference to the flow path. However, it should be understood that a process fluid is pumped into and out of first pump chamber **103**_a_ and second pump chamber **103**_b_ so that the process fluid enters and exits pump body **110**. It should also be understood that the different regions of the diaphragm media are moved by alternating applications of pressure and vacuum to the pump chambers and valves to pump the process fluid into and out of pump chambers **103**_a_ and **103**_b_ and allow or prevent flow through valves **101**_i_, **101**_o_, **102**_i_, and **102**_o_. The pressure and vacuum can be provided by one or more fluids (also referred to as motive fluids) at differing pressure levels. In many embodiments, the motive fluids used with a pump **100** comprise air. Accordingly, reference throughout this disclosure may be made to "air" when describing the movement of motive fluid or when describing components associated with and/or that contact motive fluid during operation of a pump **100**. Such references are not intended to be limiting, but rather, are made only to facilitate the discussion herein. For any such reference, other suitable fluids are also possible, such as, for example one or more liquids and/or gases.

In certain embodiments, different regions of the chamber diaphragms **140**_a_ and **140**_b_ and valve diaphragms **150**_a_ and **150**_b_ can be moved by applying pressure of the motive fluid which is greater than the pressure of the process fluid at the process fluid destination, receiver, or return **239** (see FIG. **16**) and alternating with application of pressure of the motive fluid which is less than the pressure of the process fluid at the process fluid source **238** (see FIG. **16**).

The amount of pressure or vacuum applied can vary significantly depending on the intended use of the pump **100**. For example, in some embodiments, the double diaphragm pump **100** delivers a fluid at a pressure in a range of between about 0 mmHg (millimeters of mercury) and about 1500 mmHg, between about 50 mmHg and about 500 mmHg, between about 50 mmHg and about 700 mmHg, or between about 80 mmHg and about 500 mmHg. Similarly, in some embodiments, the double diaphragm pump **100** may receive fluid from a source or generate suction in a range of between about −500 mmHg and about 0 mmHg, between about −250 mmHg and about 0 mmHg, between about −120 mmHg and about 0 mmHg, or at an amount that is less than the fluid pressure at the process fluid source **238**.

In some embodiments of the double diaphragm pump **100** that are configured to be used as a blood pump, blood is received into the pump and delivered from the pump in a range between about −250 mmHg and about 500 mmHg. While blood pressure in a patient vasculature system is typically in a range of 0 mmHg to 200 mmHg, depending on the location of blood in the system and condition of the patient, the blood pump **100** may operate at higher pressures and with vacuum assisted suction to overcome pressure losses in the extracorporeal circuit. These pressure losses can occur as blood flows through cannulae, connection lines, blood treatment devices, filters, reservoirs, and connectors. The blood pump may be operated to cause the blood to be drawn from and return to the patient vascular system at safe levels. These safe levels of blood pressure at the fluid source **238** may be above 0 mmHg and the blood pressure at the fluid return **239** may be below 150 mmHg. The blood may also be drawn into the pump without a vacuum source supplied to the pump (e.g., by application of about OmmHg relative pressure via a vacuum source or vent **230**). Gravity feed into the pump may also be used to assist in filling the pump chambers. For example, in some embodiments, the process fluid source **238** is at an elevated pressure and at an elevated location from the pump and the resultant blood pressure at the pump causes the pump valves and chambers to vent the motive fluid and actuate the diaphragms when the pressure source **220** is removed (e.g., about 20 mmHg relative to atmosphere and located 24 inches higher in elevation). A motive fluid at a pressure higher than the elevated pressure of the blood entering the pump and also higher than the pressure at the fluid return **239** can be used to operate the pump and expel the process fluid from the pump **100** to deliver blood through an external circuit to the process fluid return **239** at acceptable physiological pressures (e.g., in some cases at about an average pressure of 80 mmHg).

FIG. **3** and FIGS. **9**B-**9**C show actuation cavity **171***i* of first inlet valve **102***i*, actuation cavity **171***o* of first outlet valve **102***o*, actuation cavity **172***i* of second inlet valve **102***i*, and actuation cavity **172***o* of second outlet valve **102***o*. Passages **173***i*, **173***o*, **174***i*, and **174***o* provide fluid communication to the actuation cavities through the air transfer bosses **176***a-d*. The air transfer bosses **176***a-d* may also be referred to as connections, connectors, posts, protrusions, interfaces, passageways. These terms can also be used to describe other bosses described herein.

FIG. **5** shows the chamber plate **160**, which can include first chamber actuation cavity **161***a* and second chamber actuation cavity **161***b*. The chamber plate **160** can include passages **163***a* and **163***b*. As shown, for example, in FIG. **1**, the manifold plate **190** can be sealed over passages **163***a* and **163***b*. With reference again to FIG. **5**, passage **163***a* provides fluid communication to actuation cavity **161***a* via opening **164***a*, and passage **163***b* provides fluid communication to actuation cavity **161***b* via opening **164***b*.

In certain embodiments, actuation cavities **161***a, b* are defined by cavity surfaces **165***a, b* that extend to outer perimeters **168***a, b*, respectively. The cavity surfaces **165***a, b* can include recesses **166***a, b*, respectively. An edge of each recess **166***a, b* is shown with dashed lines in the embodiment illustrated in FIG. **5**. In some embodiments, one or more of the recesses **166***a, b* are substantially rounded, and may be concavely rounded. The cavity surfaces **165***a, b* can include inclined regions **166***c, d* that extend from the recesses **166***a, b* and outer rims **167***a, b* of the actuation cavities **161***a, b*, respectively. In some embodiments, the inclined regions **166***c, d* are also rounded, and may be convexly rounded. In some embodiments, rounded recesses **166***a, b* and rounded inclined regions **166***c, d* can limit the mechanical strain and increase cyclic life induced by limiting the minimum radius of bending curvature of the integrated diaphragm media **140***a, b* in the diaphragm actuation region **141***a, b* between the constrained edge of the diaphragm actuation region and a slope inflection point of the diaphragm actuation region as the diaphragm actuation region **141***a, b* transitions between end-of-stoke positions.

FIG. **4** shows a plan view of a first face or a first side of pump body **110**, and illustrates first inlet valve seat **111***i*, first outlet valve seat **111***o*, second inlet valve seat **112***i* and second outlet valve seat **112***o*. First pump chamber cavity **113***a* and second pump chamber cavity **113***b*, which are located on the opposite face or side of pump body **110**, are shown in phantom. Each valve seat has a groove **121***i*, **121***o*, **122***i*, **122***o* around a corresponding rim **135***i*, **135***o*, **136***i*, **136***o*. A valve portal **131***i*, **131***o*, **132***i*, **132***o* provides fluid communication between each valve seat and its corresponding line. For example, inlet channel **138***i*, which is shown in phantom, is in fluid communication with first inlet valve portal **131***i* and second inlet valve portal **132***i*. Similarly, outlet channel **138***o*, which is also partially shown in phantom and partially shown in the broken section view, is in fluid communication with first outlet valve portal **131***o* and second outlet valve portal **132***o*.

Chamber passages or channels **133***i* and **133***o* provide fluid communication respectively between first inlet valve seat **111***i* and first pump chamber cavity **113***a* and between first outlet valve seat **111***o* and first pump chamber cavity **113***a*. Similarly fluid communication between second inlet valve seat **112***i* and second pump chamber cavity **113***b* and between second outlet valve seat **112***o* and second pump chamber cavity **113***b* is achieved, respectively, via chamber channels **134***i* and **134***o*. This configuration permits first inlet valve seat **111***i* and second inlet valve seat **112***i* to be in fluid communication with inlet channel **138***i* and to alternatively receive process fluid. Similarly, first outlet valve seat **111***o* and second outlet valve seat **112***o* are in fluid communication with outlet channel **138***o* and alternatively deliver process fluid.

FIG. **4** also shows other features of the pump chamber cavities **113***a* and **113***b*. Surfaces of each pump chamber cavity, which can be recessed surfaces, are identified respectively at **114***a* and **114***b* with an inclined region for each identified at **115***a* and **115***b*, respectively. A rim **116***a, b* and a perimeter **117***a, b* are also identified for each of the pump chamber cavities **113***a, b*, respectively. The perimeters of the valve seats are also shown in FIG. **4**. The perimeter of first inlet valve seat **111***i* and the first outlet valve seat **111***o* are respectively shown in phantom and identified as **118***i* and **118***o*. The perimeter of second inlet valve seat **112***i* and the second outlet valve seat **112***o* are respectively identified at **119***i* and **119***o*.

With continued reference to FIG. **4** and, additionally, with reference to FIGS. **9**B and **9**C, in certain embodiments, the pump chamber cavities **113***a, b* can define a smooth transition from a face of the pump body **110** to the recessed surfaces **114***a, b*. For example, in some embodiments, the perimeters **117***a, b* of the pump chamber cavities **113***a, b* are located at a substantially planar face of the pump body **110**. The rims **116***a, b* can be substantially rounded, and can provide a smooth transition from the planar face at the perimeters **117***a, b* to the inclined regions **115***a, b*.

Similarly, the valve seats **111***i*, **111***o*, **112***i*, **112***o* can define a smooth transition from a face of the pump body **110** to a more recessed portion of the pump body **110**. For example, the valve seat **111***i* can smoothly slope inward from the perimeter **118***i*, which can be at a substantially planar first face of the pump body **110**, toward a more recessed portion of the valve seat **111***i* that is closer to an opposite face of the pump body **110**.

In certain embodiments, smooth, tangent, or rounded transitions such as just described can limit the mechanical strain by limiting the minimum radius of bending curvature of the diaphragm actuation region between the constrained perimeter of the diaphragm and a slope inflection point in the diaphragm as the diaphragm actuation region transitions between end-of-stoke positions. Reduced mechanical strain can result in a longer lifespan of the chamber diaphragms **140***a, b* and valve diaphragms **150***a, b*, in certain embodiments. In some embodiments, the diaphragms are constrained to flex at the smooth or rounded transitions (e.g., to flex over the rounded lips **116***a, b*). In some embodiments, the amount of strain induced in a flexing diaphragm is inversely related to the radius of curvature in these regions; as a result, longer mechanical life of the diaphragms can be achieved with relatively gradually sloping transition regions. In other embodiments, relatively sharp transitions in these regions can cause the diaphragm to flex across a plastic-like hinge. A diaphragm actuation region could incur high cyclic strain in certain of such embodiments, and might rapidly fail due to cyclic fatigue.

The valve diaphragms **150***a*, **150***b* can have additional support as the diaphragms rest on seat rims **135***i*, **135***o*, **136***i*, and **136***o* in a closed valve position, which can be at a position near a preformed dome height of the valve diaphragm valve regions **151***i*, **151***o*, **152***i*, **152***o*. If the diaphragm material is too stretchable or if the diaphragm valve regions **151***i*, **151***o*, **152***i*, **152***o* are formed with excessive dome heights, high strain plastic-like hinges can form on the edges of the seat rims, and may cause high cyclic strain and short cyclic fatigue life. In some embodiments, the diaphragm valves desirably actuate from an open to a closed position at a differential pressure less than that provided by the pressure source **220** and at a differential pressure level less (e.g., less negative) than that provided by the vacuum source **230** (see FIG. **16**). This can allow the valves to quickly open and close prior to the pump chamber causing a substantial amount of process fluid to flow back through the closing valves.

In some embodiments, chamber diaphragms **140***a, b* and valve diaphragms **150***a, b* have actuation regions, which are pre-shaped or formed prior to assembly of the pump **100**, as further discussed below. The actuation regions can protrude from a plane defined by a relatively flat portion of a diaphragm **140***a, b*, in some embodiments. In further embodiments, the actuation regions naturally protrude and/or are naturally rounded in a convex manner when in a first state or resting state, and can be transitioned to a concave orientation when in a second state or displaced state. The second state can be stable or metastable, in some embodiments, and the actuation regions can define a variety of other shapes in the first and/or the second states. In some embodiments, the actuation regions can be readily transitioned between the first and second states, and the regions can deform, flex, or otherwise change shape by application of a relatively small amount of pressure, as compared with a substantially flat diaphragm without actuation regions which is stretched to conform to the same shape of the first or second state of an actuation region.

FIG. **6**B depicts chamber diaphragm **140***a* after the formation of first pump chamber region **141***a* and second pump chamber region **141***b*. Preforming the chamber regions **141***a, b* of the chamber diaphragms **150***a, b* and the valve regions **151***i*, **151***o*, **152***i*, **152***o* of the valve diaphragms **140***a, b* can enable the valve regions to be seated and the chamber regions to move fluid into and out of the chambers based only on sufficient pressure (positive or negative) for movement of the regions, in some arrangements. Stated otherwise, after these regions of the diaphragm film material have been formed by, for example, heat forming or stretching, the regions can move in response to fluid pressure with low strain as each valve or chamber cycles like a fluid isolating membrane.

In some embodiments, the diaphragm regions are preformed in such a manner that the cord length of the valve regions and the chamber regions remains substantially constant while cycling. In other embodiments, the diaphragm regions stretch by a relatively small amount. One method to quantify diaphragm stretch is the change in cord length as the diaphragm flexes from end-of-stroke positions, where the cord length is the length of a cord if positioned on the surface of the diaphragm such that the cord extends from one point on the perimeter of the formed region and continues through the center point of the region to a second point on the perimeter of the formed region, with the first and second points being opposite from each other relative to the center point. For example, in various embodiments, the cord length can change by less than about 10%, less than about 5%, or less than about 3% during each pump cycle. The cord length can be sufficient to enable the diaphragm regions **150***a, b* and **151***i*, **151***o*, **152***i*, **152***o* to flex and pump the fluid in the pump chamber and to flex and controllably seal the fluid flow through the pump valves at the same or substantially the same pressures. By preforming the regions of the diaphragm media in some embodiments, the valve regions can be seated without application of additional pressure, as compared with the pressure used to move the region of the diaphragm within the pump chamber. By controlling the cord length of a diaphragm in certain embodiments, the mechanical cycle life of the diaphragm can be increased by minimizing material strain when flexing from one end-of-stroke condition to the other end-of-stroke condition, and the diaphragm can be capable of reaching the end-of-stroke condition without (or substantially without) the material of the diaphragm stretching. In certain embodiments, since pressure is applied for movement or is applied for movement and at most a nominal amount for stretching the preformed actuation regions, the amount of pressure needed to actuate the diaphragm region is low and the lifespan of the diaphragm media is extended due to the gentler cycling. In some embodiments, since material strain is reduced using thin film materials in the construction of the flexing chamber diaphragms **140***a, b* and valve diaphragms **150***a, b*, the material strain caused by in-plane stretching can be controlled by the support of the pump chamber and valve cavities at end-of-stroke conditions, and long mechanical life of the diaphragms can be achieved.

In certain embodiments, higher ratios of the maximum distance between opposing sides of a perimeter or perimeter width (e.g., the diameter of a circumference) of a diaphragm region **141***a, b*, **151***i*, **151***o*, **152***i*, **152***o* to a dome height of the region can promote long mechanical cyclic life of the diaphragms **140***a, b*, **150***a, b* without material fatigue failure. In some embodiments, the dome height of a region is defined as the maximum distance from a plane defined by a maximum perimeter of the region (e.g., a maximum circumference of the region) to any portion of the diaphragm material that comprises the region along a line normal to the plane. The term "dome height" is a broad term and is not limited to situations in which an actuation region **141***a, b*, **151***i*, **151***o*, **152***i*, **152***o* shaped substantially as a rounded dome. For example, a region having a substantially pyramidal configuration could also define a dome height.

In some embodiments, the diaphragm media is reshaped when traveling between end-of-stroke positions and the reshaping can cause the material to strain. With relatively low ratios between the perimeter width and the dome height of a region, the diaphragm material in some embodiments creates relatively sharp folds in order for the dome to move from one end-of-stroke condition to another which can cause relatively high material strain and a relatively short mechanical life for the diaphragm. With relatively high ratios between the perimeter width and the dome height of a region, the size of some embodiments of the double diaphragm pump **100** can be relatively large, which can increase material costs and other costs for manufacturing the pump **100**.

In various embodiments, the ratio of the perimeter width to the dome height of the actuation regions **141** *a, b* of the chamber diaphragms **140***a, b* is between 4:1 and about 30:1, between about 5:1 and about 20:1, or between about 6:1 and about 10:1. In some embodiments, the ratio is about 8:1. In certain of such embodiments, the actuation regions **141***a, b* have diameters of about 2.7 inches and dome heights of about 0.36 inches. For such embodiments, the actuation regions **141***a, b* can have a stroke volume of about 25 cubic centimeters (cc) when the dome moves from one end-of-stroke position to the other.

In various embodiments, the ratio of the diameter to the preformed dome height of the actuation cavities **171***i*, **171***o*, **172***i*, **172***o* of the valve diaphragms **150***a*, **150***b* is between about 4:1 and about 30:1, between about 5:1 and about 20:1, or between about 6:1 and about 10:1. In some embodiments, the ratio is about 8:1. In certain of such embodiments, the actuation cavities **171***i*, **171***o*, **172***i*, **172***o* have diameters of about 1.12 inches and dome heights of around 0.14 inches. For such embodiments, the actuation cavities **171***i*, **171***o*, **172***i*, **172***o* can have a valve actuation stroke volume of about 1.5 cubic centimeters (cc) when the dome moves from one end-of-stroke position to the other.

In certain embodiments, to actuate the chamber diaphragms **140***a, b* and valve diaphragms **150***a, b* from one end-of-stroke position to another, a certain pressure differential level between the fluid on one side of a diaphragm and the actuation chamber pressure on the other side of the diaphragm is provided to overcome the structural stiffness of the diaphragms. If the structural stiffness of the diaphragms is too high, the pressure used to actuate the regions **141***a, b*, **151***i*, **151***o*, **152***i*, **152***o* may exceed the desired operating pressure of the pump. However, some embodiments also benefit from the structural stiffness of the diaphragms not being too low. For example, in some embodiments, the diaphragms desirably have enough structural rigidity to not plastically deform under the operating pressures and also to bridge over regions of the diaphragms that are not supported at their end-of-stoke positions.

In various embodiments, the differential pressure used to actuate the chamber diaphragms **140***a*, **140***b* and valve diaphragms **150***a*, **150***b* is in a range of between about 5 mmHg and about 200 mmHg, between about 20 mmHg and about 100 mmHg, or between about 30 mmHg and about 60 mmHg. In some embodiments, a relatively small initial pressure differential is sufficient to actuate preformed regions **141***a, b*, from a first end-of-stroke position to a second end-of-stroke position. In some embodiments, a relatively small initial pressure differential is sufficient to actuate preformed regions **151***i*, **151***o*, **152***i*, **152***o* from an open valve position to a closed valve position.

Once a valve is in the closed position, the valve can remain in the closed position so long as the fluid pressure that acts on one side of the associated region to maintain the valve in the closed position exceeds the fluid pressure on the opposite side of the region by an amount greater than the amount of pressure required to actuate the valve. For example, in some embodiments, the region **151***o* can be actuated from the closed valve position illustrated in FIG. **98** to an open valve position when the pressure in the first chamber cavity **113***a* exceeds the pressure in the actuation cavity **171***o* by an amount greater than the pressure required to move the region **151***o* out of the closed orientation. In various embodiments, a valve can be maintained in the closed position when a differential pressure on opposite sides of a diaphragm actuation region is less than about 300 mmHg, less than about 200 mmHg, less than about 100 mmHg, less than about 50 mmHg, less than about 25 mmHg, less than about 10 mmHg, less than about 10 mmHg, or is about 0 mmHg. Similarly, in various embodiments, a valve can be maintained in the open position when a differential pressure on opposite sides of a diaphragm actuation region is less than about 300 mmHg, less than about 200 mmHg, less than about 100 mmHg, less than about 50 mmHg, less than about 25 mmHg, less than about 10 mmHg, less than about 10 mmHg, or is about 0 mmHg.

Some embodiments can include diaphragms **140***a, b*, **150***a, b* that comprise elastomeric material in a flat sheet configuration. Certain of such embodiments, however, can exhibit performance characteristics that are not present or are much less pronounced in some embodiments that include diaphragms **140***a, b*, **150***a, b* having actuation regions **141***a, b*, **151***i*, **151***o*, **152***i*, **152***o*. For example, in some embodiments having a flat sheet configuration, operation of the pump can cause repeated in-plane stretching of diaphragm material as displacement volumes are created, which can cause a diaphragm to fail as a result of low cycle, high strain material fatigue. In some embodiments, the pressure and suction levels needed to stretch the material by an amount sufficient to actuate the valves can exceed the available pressure level in the pressure source **220** and/or the available vacuum level in the vacuum source **230** (see FIG. **16**). Therefore, such embodiments might employ higher levels of pressure and vacuum to actuate the valves **101***i*, **101***o*, **102***i*, **102***o* to prevent the fluid pressures created in the pumping chambers **103***a, b* from overcoming the valve actuation pressures.

Further, variation in fluid pressures can be created in the pumping chambers **103***a, b* during a pumping stroke. In certain embodiments that include a sheet-like diaphragm without preformed actuation regions **141***a, b*, **151***i*, **151***o*, **152***i*, **152***o*, the diaphragm stretches to fill and discharge fluid and uses a dynamically changing portion of the pressure supplied to the pump chamber **103***a, b* in the stretching process. The pressure within the pump chamber as the chamber fills with fluid is related to the difference between the pressure supplied by a pressure source and the changing amount of pressure used to actuate and stretch the flat sheet diaphragm in its travel through a stroke. When the pump chamber discharges from a filled state, energy stored in the stretched diaphragm releases and increases the pressure supplied to the pump actuation chamber, which may result in pressure spikes in the outlet line **180***o*. In some embodiments, such pressure spikes can be undesirable. Similarly, when the pump chamber is filled from a discharged state, the energy stored in the stretched diaphragm releases and increases the suction supplied to the pump chamber **103***a, b*, which may result in suction spikes in the inlet line **180***i*. In some embodiments, such suction spikes can be undesirable. Some embodiments that include actuation regions **141***a, b* **151***i*, **151***o*, **152***i*, **152***o* thus can provide inlet line **180***i* and/or outlet line **180***o* pressures that have fewer spikes or fluctuations as a result of the actuation regions **141***a, b*, **151***i*, **151***o*, **152***i*, **152***o* transitioning between first and second states.

In certain embodiments, each of the diaphragms **140***a*, **140***b*, **150***a*, **150***b* is formed from a film having a substantially uniform thickness. The thickness of a diaphragm may be selected based on a variety of factors, such as the material or materials of which the diaphragm is composed, the size of the valve or chamber in which the diaphragm moves, etc. A diaphragm can be configured to separate a motive fluid from the process fluid during all stages of a stroke cycle and can be supported intermittently by surface features of the pump cavities (such as, for example, the seat rims **135***i*, **135***o*, **136***i*, **136***o* of the inlet and outlet valves **101***i*, **101***o*, **102***i*, **102***o* and/or the recesses **114***a, b*, **166***a, b* of the pump chambers **103***a, b*) when at an end of a stroke cycle. Accordingly, in some embodiments, the diaphragm media thickness is sufficiently thick to provide a substantially impermeable barrier between the process fluid and the motive fluid and to provide sufficient stiffness to resist substantial deformation when pressed against the surface features of the pump cavities. In some embodiments, the diaphragm thickness is also sufficiently flexible or pliable to transition between open and closed valve positions or between filled and discharged chamber positions with application of relatively small pressure differentials. In some embodiments, a thin diaphragm can have a lower level of mechanical strain when cycled between open and closed valve positions or between filled and discharged chamber positions than can a thicker diaphragm of otherwise like construction. The lower cyclic strain of a thin diaphragm can increase the lifespan of the diaphragm before mechanical failure of the material. In various embodiments, the diaphragm media has a thickness in a range between about 0.001 inches and about 0.060 inches, between about 0.002 inches and about 0.040 inches, between about 0.005 inches and about 0.020 inches, or between about 0.005 and about 0.010 inches.

In certain embodiments, higher ratios of minimum radius of bending curvature of the profile of the flexing portion of a preformed diaphragm to the diaphragm thickness may increase diaphragm cyclic life as the diaphragm transitions from one end-of-stroke position to another. In various embodiments, this ratio is in a range between about 5:1 and about 100:1, between about 10:1 and about 50:1, or between about 20:1 and about 30:1. In one embodiment, the diaphragm has a minimum radius of bending curvature of 0.25 inches and a diaphragm thickness of about 0.010 inches with a resulting ratio of 25:1.

FIG. **6**A depicts an embodiment of a chamber diaphragm **140** before the regions **141***a*, **141***b* have been preformed or pre-stretched. In the illustrated embodiment, the diaphragm has been cut from a sheet of film. The diaphragm initially has a substantially uniform thickness and is then shaped to yield preformed or pre-stretched regions. FIG. **6**B depicts chamber diaphragm **140** as it appears after being formed in forming fixture **300** as shown in FIGS. **7**-**8**B. Other methods of forming actuation regions **141***a*, **141***b* in the diaphragm **140** are also possible, and the example described with respect to FIGS. **7**-**8**B is merely provided by way of illustration.

FIGS. **7**-**8**B depict the use of heat and vacuum to shape the regions **141***a, b* of a diaphragm **140**. Many combinations of pressure, vacuum, and heat could also be used separately or together to form the regions in the diaphragms. For example, if only pressure is used, the residual stresses in the diaphragm shapes can cause the diaphragm form to change as the diaphragms are repeatedly cycled. In other embodiments, pressure is used to form the diaphragm regions and then the diaphragms are annealed by heating. For example, in some embodiments, the chamber diaphragms **140***a, b* are made of FEP film material that has a thickness of about 0.007 inches and a formed region perimeter of about 2.7 inches is overformed to a dome height of about 0.72 inches under pressure, then heated to approximately 60° C. for about 2 hours for a resulting dome height of about 0.36 inches. In a second example of pressure forming, in some embodiments, the chamber diaphragms **140***a, b* are made of PTFE film material that has a thickness of about 0.010 inches and a formed region diameter of 2.7 inches is overformed to a dome height of about 0.58 inches under pressure, then heated to approximately 60° C. for about 2 hours for a resulting dome height of about 0.36 inches. In various embodiments, the preformed diaphragm regions have a thickness in a range from about 0.001 inches to about 0.060 inches, from about 0.002 inches to about 0.040 inches, from about 0.005 inches to about 0.020 inches, or from about 0.005 to about 0.010 inches.

FIG. **7** depicts first plate **310** and second plate **320** of forming fixture **300** in an exploded view. Because forming fixture **300** is shown being used to produce a chamber diaphragm **140** (such as either of the diaphragms **140***a* or **140***b*), the o-rings depicted include o-rings **193***a*, **193***b*. First plate **310** can include chamber region recesses **311***a, b* that are circumscribed by o-ring grooves **312***a, b*. Plate **320** has portals **321***a, b* to allow heat to reach areas of the diaphragm that are being formed.

FIG. **8**A shows a cross-sectional view of fixture **300** with a diaphragm media **140** between first plate **310** and second plate **320**. The fixture **300** can be clamped together with mechanical fasteners or other assembly mechanisms to hold the diaphragm in position and seal the chambers created between the diaphragm and the chamber region recesses **311***a, b*. A vacuum is placed in fluid communication with these chambers via passage **318**, which can include openings **313***a, b* into the chamber region recesses **311***a, b*, respectively.

A heater **330** (such as, for example, an infrared heater) is positioned to heat the regions of the diaphragm that are to be pre-shaped. In some embodiments, the diaphragm is substantially planar upon initial positioning between the first plate **310** and the second plate **310**. The diaphragm film material can sag to a substantially non-planar configuration as it is heated and is exposed to a pressure differential, and the diaphragm material can conform to the surfaces **314***a, b* (see FIG. **8**B) of the chamber region recesses **311***a, b* to form first pump chamber region **141***a* and second pump chamber region **141***b*. In some embodiments, the first plate **310** acts as a heat sink when regions of the diaphragm sag and come in contact therewith, and can prevent the diaphragm material from reaching a material transition temperature. Thus, in some embodiments, regions are fully formed after contact is made between the sagging portion of the diaphragm media and the first plate **310**. FIG. **8**B shows the fully formed chamber diaphragm **140** with the infrared heater removed.

In some embodiments, the chamber diaphragms **140***a, b* are made of FEP film material with a thickness of about 0.007 inches and assembled in a forming fixture **300** that is at a temperature of about 20° C. to about 40° C. In certain of such embodiments, a vacuum of about −10 psi is applied to passage **318** and an infrared heater **330** with a heater surface **331** operating at a temperature of 315° C. is positioned substantially parallel to and about 1.5 inches away from the surface of the flat diaphragm for about 1 minute.

The heater is then removed. In certain embodiments, without being limited by theory, a diaphragm **140** formed via thermoforming techniques retains its shape as it is repeatedly cycled in the pump because internal stresses in the diaphragm material are relieved during the heat forming process.

While FIGS. **7**-**8**B depict the forming of chamber diaphragm **140***a* and **140***b*, a forming fixture configured uniquely to form the valve diaphragm regions and similar to forming fixture **300** can be used to form valve regions **151***i*, **151***o*, **152***i*, and **152***o* in valve diaphragms **150***a* and **150***b*.

FIGS. **98** and **9**C are transverse cross-sectional views taken along the cutting lines shown in FIG. **9**A to show the operation of an embodiment of first inlet valve chamber **101***i*, first outlet valve chamber **101***o*, second inlet valve chamber **102***i*, second outlet valve chamber **102***o*, first pump chamber **103***a*, and second pump chamber **103***b*. FIGS. **9**B and **9**C also show the operation of first chamber diaphragm region **141***a* and second chamber diaphragm region **141***b* of chamber diaphragms **140***a, b*.

FIG. **9**B shows first inlet valve chamber **101***i*, first outlet valve chamber **101***o*, and first pump chamber **103***a* at the end of a fluid draw stroke. In FIG. **9**B, the first chamber diaphragm region **141** *a* of chamber diaphragms **140***a, b* is shown at an end-of-stroke position, where pressure has been applied through passage **173***o* to first outlet valve chamber **101***o* and vacuum is supplied through passage **173***i* to first inlet valve chamber **101***i* and also through passage **163***a*, as identified in FIG. **5**, to first pump chamber **103***a*. Pressure in first outlet valve chamber **101***o* causes outlet valve region **151***o* of valve diaphragms **150***a* **150***b* to move (e.g., flex) and rest on or in close proximity to first outlet valve seat rim **135***o*, which in some instances can result in a substantially fluid-tight seal. The seal thus formed can substantially prevent fluid communication between first pump chamber **103***a* and outlet channel **138***o* via chamber channel **131***o*.

In some embodiments, suction in first outlet valve chamber **101***o* causes first inlet valve region **151***i* of valve diaphragms **150***a*, **150***b* to move (e.g., flex) away from first inlet valve seat rim **135***i*, thereby permitting fluid communication between inlet channel **138***i* and first pump chamber **103***a* via chamber channel **131***i*. Suction provided via passage **163***a* (see FIG. **5**) can simultaneously move first pump chamber region **141***a* of chamber diaphragms **140***a, b* away from the pump body **110**. In some embodiments, the suction can continue to move chamber region **141***a* after fluid communication between inlet channel **138***i* and first pump chamber **103***a* has been established, and can draw process fluid into the first pump chamber **103***a*. Process fluid can proceed through inlet line **180***i* (see, e.g., FIG. **1**), through inlet channel **138***i*, through valve portal **131***i*, into first inlet valve chamber **101***i*, through chamber channel **133***i*, and into first pump chamber **103***a*.

FIG. **9**C shows the second inlet valve chamber **102***i*, second outlet valve chamber **102***o* and second pump chamber **103***b* at the end of a fluid expel stroke. The second chamber diaphragm region **141***b* of chamber diaphragms **140***a*, **140***b* is shown at an end-of-stroke position where pressure has been applied through passage **174***i* to second inlet valve chamber **101***i* and through passage **164***b* (see also FIG. **5**) to second pump chamber **103***b*, and a vacuum has been supplied through passage **174***o* to second outlet valve chamber **102***o*. In such an arrangement, pressure in second inlet valve chamber **102***i* prevents fluid communication between inlet channel **138***i* and second pump chamber **103***b* via chamber channel **134***i* and valve portal **132***i* by flexing second inlet valve region **152***i* of chamber diaphragms **150***a*, **150***b* to rest on or in close proximity to second inlet valve seat rim **136***i*. Simultaneously, suction applied to second outlet valve chamber **102***o* flexes first outlet valve region **152***o* of chamber diaphragms **150***a*, **150***b* away from second outlet valve seat rim **136***o* and allows fluid communication between second pump chamber **103***b* and outlet channel **138***o* via chamber channel **134***o* and valve portal **132***o*. Simultaneously, pressure provided to chamber **103***b* continues to push against second pump chamber region **141***b* of chamber diaphragms **140***a*, **140***b* and expels process fluid through chamber channel **134***o* into second outlet valve chamber **102***o* and then through valve portal **132***o* into outlet channel **138***o*, which is in fluid communication with outlet line **180***o*.

In some embodiments, the inlet valves **101***i*, **102***i* actively control ingress of process fluid into the first and second pump chambers **103***a, b*, and the outlet valves **101***o*, **102***i* actively control egress of process fluid from the first and second pump chambers **103***a, b*, respectively. As used herein, the term "actively control" means that the valves **101***i*, **101***o*, **102***i*, **102***o* can be actuated without dependency on the direction of the flow of process fluid through the pump **100**. For example, the actuation medium that controls the transitioning and positioning of the valves **101***i*, **101***o*, **102***i*, **102***o* can do so independent of the reversal of flow of process fluid through the valve.

In some embodiments a preformed diaphragm region (e.g., **141***b*, **152***i*, **152***o*) defines its natural preformed shape when in an end-of-stroke position. For example, the preformed region **152***o* shown in FIG. **9**C can be in its natural state in the illustrated end-of-stroke position. When in another end-of-stroke position, the preformed region can define an inversion of the natural preformed shape. For example, in some embodiments, the preformed region **152***o* is in its natural preformed shape when in the end-of stroke position shown in FIG. **9**C, and can move to inversion of its natural preformed shape when moved to another end-of-stroke position at or near the seat rim **136***o* (such as the position of preformed region **151***o* shown in FIG. **9**B). Alternatively, the preformed region **152***o* can be in its natural preformed shape when in an end-of-stroke position at or near the seat rim **136***o* and can transition to an inversion of the preformed shape at an opposite end-of-stroke position.

In some embodiments, it can be desirable for a preformed diaphragm region to be in its natural preformed shape when at an end-of-stroke position, as this can reduce strain on the diaphragm region in certain arrangements. In other embodiments, the diaphragm region can pass through its preformed shape before reaching an end-of-stroke position, which may, in some instances, cause the region to stretch in order to reach the end-of-stroke position. In still other embodiments, the diaphragm region may be prevented from achieving its natural preformed shape when operating within a pump chamber or valve chamber.

In some embodiments, it can be advantageous to switch from an expel stroke to a draw stroke before a diaphragm reaches an end-of-stroke condition, such as the position shown in FIG. **9**C. Similarly, in some embodiments, it can be advantageous to switch from a draw stroke to an expel stroke before a diaphragm travels to an end-of-stroke condition such as that shown in FIG. **9**B. In some embodiments, when the pump chambers are alternately and repeatedly switched between a draw stroke and an expel stroke prior to the chamber diaphragms **140***a*, **140***b* reaching an end-of-stroke position during the draw stroke, fluid flow through the inlet line **180***i* can be substantially constant. In other embodiments in which expel strokes allow the chamber diaphragms **140***a*, **140***b* to reach an end-of-stroke position, the pause in displacement of fluid during the duration of time at the end-of-stroke can cause a pulsatile output flow in the outlet line **180***o*. In some applications it can be advantageous to balance the pump **100** to control the pump chambers to switch from a draw stroke to an expel stroke prior to the chamber diaphragms reaching either end-of-stroke position.

FIG. **10** shows another embodiment of a double diaphragm pump **100'** shown in cross-section with a view such as that shown in FIG. **9**B. In certain embodiments, the pump **100'** is configured to stall if air is drawn into the pump **100'** along with the process fluid. In some embodiments, it can be advantageous in blood pumping applications to cause the pump to stall if a significant air volume is drawn into the inlet channel **138***i*. Such air intake could be due, in some rare instances, to negative suction in the inlet line that entrains air through a leak in a fitting or, in other rare instances, at the connection to a patient or by inadvertent error by the practitioners. The pump body **110'** can include bypass channels **139***i*, **139***o* that allow continuous or uninterrupted fluid communication between the inlet channel **138***i* and the first pumping chamber **103***a* and between the first pumping chamber **103***a* and the outlet channel **138***o*, respectively. For example, in the illustrated embodiment, although the diaphragm **150***a* forms a seal with seat rim **135***o*, fluid communication is still possible between the first pumping chamber **103***a* and the outlet channel **138***o* because the bypass channel **139***o* provides a fluid path from the pumping chamber **103***a* to the groove **121***o*, which is in fluid communication with the outlet channel **138***o* (compare FIG. **4**). The pump body **110'** can include similar bypass channels that provide continuous or uninterrupted fluid communication between the inlet channel **138***i* and the second pumping chamber **103***b* and between the second pumping chamber **103***b* and the outlet channel **1380**.

The bypass channels **139***i*, **139***o* can have flow areas that are much smaller than those defined by the valve portals **131***i*, **131***o* and chamber channels **133***i*, **133***o*. A volume of air can flow through an opening at a faster rate than a like volume of liquid. Accordingly, in the event of a significant volume of air being introduced into inlet channel **138***i* along with process fluid, the double diaphragm pump **100** will cause liquid to flow less efficiently through the pump, and air will fill the pump chambers **103***a*, **103***b* through the bypass channels **139***i*, **139***o* and then return back through the bypass channels and may prevent continually expelling air into the outlet channel **138***o* and then into the outlet line **180***o*.

For example, in some embodiments, a mixture of process fluid and air may enter the first chamber **103***a* from the inlet channel **138***i* during a fluid draw stroke. As the diaphragms **140***a, b* move toward the pump body **110'** to decrease the volume of the chamber **103***a* during an expel stroke, air within the chamber **103***a* may preferentially exit the chamber **103***a* via the bypass channel **139***i* and return to inlet channel **138***i*. This air, and possibly additional air received via the inlet channel **138***i*, may gather or collect in the chamber **103***a* and may cycle back and forth through the bypass channels **139***i*, **139***o* over the course of repeated intake and expel strokes. Eventually, sufficient air may gather in the chamber **103***a* to cause the pump **100'** to operate less efficiently or to stall. For example, as an increasing volume of air passes through the bypass channel **139***o* to gather in a chamber **103***a*, the amount of blood that can be drawn into the chamber **103***a* and subsequently expelled from the chamber **103***a* can decrease due to the presence of the air.

With reference again to FIG. **9**C, in certain embodiments, the pump **100** comprises a mounting hook **175**. In some embodiments, the mounting hook **175** extends from the valve plate **170** in a direction substantially orthogonal to a plane defined by a base surface of the valve plate **170**. The mounting hook **175** can define an opening **175***a*. In some embodiments, the hook **175** extends in substantially the same direction as the bosses **176***a-d*. The hook **175** and bosses **176***a-d* are further discussed below.

In some embodiments, the double diaphragm pump **100** is constructed with the inlet and outlet valve chambers **101***i*, **101***o*, **102***i*, **102***o* and the pump chambers **103***a, b* located on the same side of the pump body **110**. The pump chambers **103***a, b* can also be located on opposite sides of the pump body **110** while the inlet and outlet valves **101***i*, **102***i*, **101***o*, **102***o* can be located on the opposite side of the pump body **110** from their associated pump chamber **103***a, b*. The pump body **110** can be constructed with more than two pump cavities **103***a, b*, more than two inlet valves **101***i*, **102***i*, and more than two outlet valves **112***i*, **112***o* to cooperatively work in pumping a single fluid. Also, multiple double diaphragm pumps **100** can be constructed on a single pump body **110**. The diaphragms **140***a, b*, **150***a, b* can also have more valve regions **151***i*, **151***o*, **152***i*, **152***o* and pump chamber regions **141***a*, **141***b* than those shown in the depicted embodiments.

Components of the double diaphragm pump **100**, or portions thereof, that are exposed to a process fluid (such as, for example, blood) can be constructed of any suitable material that is compatible with the process fluid. For example, in some embodiments, the pump **100** comprises any suitable blood-compatible material, whether currently known in the art or yet to be devised. Examples of such candidate materials can include plastic materials, such as polycarbonate (PC), polyvinyl chloride (PVC), polypropylene (PP), polyethylene (PE), polytetrafluoroethylene (PTFE), polyperfluoroalkoxyethylene (PFA), fluorinated ethylene propylene (FEP), and polyurethane (PU). In some embodiments, metal materials can be used, such as stainless steel 316L and/or titanium. In some embodiments, the body **110** is constructed of PC. The body **110** can be substantially rigid and relatively inflexible, in some arrangements.

In certain embodiments, the chamber diaphragms **140***a*, **140***b* and valve diaphragms **150***a*, **150***b* may be formed from a polymer or an elastomer. In some embodiments, polymers that have high endurance to cyclic flexing may be used, such as, for example, a fluorpolymer, such as polytetrafluoroethylene (PTFE), polyperfluoroalkoxyethylene (PFA), or fluorinated ethylene propylene (FEP). Other nonelastomer film materials may be used, such as PE, PVC, PP. In some embodiments, an elastomeric material such as silicone or polyurethane can be used for the diaphragms **140***a, b*, **150***a, b*. In certain of such embodiments, it is preferable that supporting structures be configured so as to prevent plastic hinges (e.g., relatively sharp bends in material where the diaphragm is forced by pressure into contact with features in the actuation cavities) that may cause cyclic failure.

In some embodiments, components of the pump **100** that do not contact a process fluid can be constructed of any of a variety of materials without consideration of possible incompatibilities among the materials and the process fluid. For example, in some embodiments, materials used for the chamber plate **160** and valve plate **170** can be any suitable plastic or metal material. In many embodiments, the chamber plate **160** and the valve plate **170** are substantially rigid and can be relatively inflexible.

The inlet line **180**i and outlet line **180**o can be made from any suitable material, and can be compatible with the process fluid. In some embodiments, the lines **180**i, **180**o comprise a blood compatible PVC material containing softening plasticizers, such as Tygon® S-95-E tubing available from Saint Gobain Performance Plastics, Akron, Ohio.

FIG. **11** illustrates an embodiment of a pump **1100**. The pump **1100** can include features such as those described above with respect to the illustrated embodiments of the pumps **100** and **100'**. Accordingly, features of the pump **1100** are identified with reference numerals incremented by 1000 relative to reference numerals used to identify like features of the pumps **100**, **100'**.

In certain embodiments, the pump **1100** can be in fluid communication with an inlet line **1180**i and an outlet line **1180**o. The pump **1100** can comprise a pump body **111**o, which can define an inlet channel **1138**i in fluid communication with the inlet line **1180**i and an outlet channel **1138**o in fluid communication with the outlet line **1180**o. The pump **1100** can further comprise a chamber plate **1160**, which can cooperate with the pump body **111**o to at least partially define a first pump chamber **1103**a, a first inlet valve **1101**i, and a first outlet valve **1101**o. In some embodiments, one or more diaphragms **1140** are included between the pump body **111**o and the chamber plate **1160**. The one or more diaphragms **1140** can include one or more diaphragm actuations regions **1141**a, **1151**i, **1151**o configured to move within the first pump chamber **1103**a, the first inlet valve **1101**i, and the first outlet valve **1101** o, respectively.

In some embodiments, the pump body **111**o, the chamber plate **1160**, and the one or more diaphragms **1140** further define a second pump chamber, a second inlet valve, and a second outlet valve (not shown) such as the illustrated first pump chamber **1103**a, first inlet valve **1101**i, and first outlet valve **1101**o, respectively. The inlet channel **1138**i can extend between the first inlet valve **1101**i and the second inlet valve, and the outlet channel **1138**o can extend between the first outlet valve **1101**o and the second outlet valve.

In some embodiments, the first inlet valve **1101**i includes a seat rim **1135**i and the second inlet valve **1101** o includes a seat rim **1135**o. The pump body **111**o can define a chamber channel **1133**i that provides fluid communication between the seat rim **1135**i of the first inlet valve **1101**i and the first pump chamber **1103**a and can define another chamber channel **1133**o that provides fluid communication between the pump chamber **1103**a and the seat rim **1135**o of the first outlet valve **1101**o. In some embodiments, the diaphragm actuation region **1151**i is configured to selectively permit fluid communication between the inlet channel **1138**i and the chamber channel **1133**i. Similarly, the diaphragm actuation region **1151**o can be configured to selectively permit fluid communication between the chamber channel **1133**o and the outlet channel **11380**.

In some embodiments, the chamber plate **1160** defines a motive fluid passage **1173**i in fluid communication with the first inlet valve **1101**i, a motive fluid passage **1173**o in fluid communication with the first outlet valve **1101**o, and a motive fluid passage **1163**a a in fluid communication with the first pump chamber **1103**a. The motive fluid passages **1173**i, **1173**o, and **1163**a can be at least partially defined by motive fluid transfer bosses **1176**a, **1176**b, and **1162**a, respectively. In some embodiments, the bosses **1176**a, **1176**b, and **1162**a are configured to be connected with a motive fluid control device. In some embodiments, motive fluid is provided to the valves **1101**i, **1101**o and the pump chamber **1103**a to actuate the diaphragm actuation regions **1151**i, **1151**o, and **1141**a, respectively. In some embodiments, such as that illustrated in FIG. **11**, motive fluid at a first pressure can be provided to both the first inlet valve **1101**i and the first pump chamber **1103**a, and motive fluid at a second pressure can be provided to the first outlet valve **1101**o.

With reference to FIGS. **12-13**B, in certain embodiments, a pump assembly **450** can include a reusable control base or pump control system **451** and one or more double diaphragm pumps **100**, **100**a. The control system **451** and one or more diaphragm pumps **100**, **100**a can be configured to selectively couple and decouple. In some embodiments, the one or more diaphragm pumps **100**, **100**a can be used with the control system **451** in a single procedure or a limited number of procedures, removed from the control system **451**, and then discarded. Additional diaphragm pumps **100**, **100**a can replace the discarded diaphragm pumps **100**, **100**a in one or more additional procedures. Accordingly, in some embodiments, the control system **451** can be used in multiple procedures (whether of the same or different variety) with a plurality of disposable diaphragm pumps **100**, **100**a.

As further discussed below, in some embodiments, the control system **451** can control the manner in which the pumps **100**, **100**a operate. The control system **451** can operate a set of pumps **100**, **100**a in a variety of different modes, depending on the type of procedure involved. In some embodiments, the control system **451** is reconfigurable, such that the manner in which the control system **451** controls the pumps **100**, **100**a can be altered. The control system **451** can comprise a fluid logic system configured to direct motive fluids from different sources (e.g., motive fluids at different pressure levels) to different portions of each pump **100**, **100**a, and in further embodiments, can alternate which motive fluids sources are directed to the portions of the pumps **100**, **100**a.

In certain embodiments, the control system **451** comprises a processor **452**, which can comprise any suitable logic processor or controller, and may comprise, for example, an on-board computer. In some embodiments, the processor **452** is configured to run executable computer code, and can include volatile and/or non-volatile memory. In further embodiments, the processor **452** can be configured to communicate with other devices, and may be part of a network.

In some embodiments, the control system **451** includes a user control interface **453**. The interface **453** can be of any suitable variety, and can be configured to communicate information to and/or from the processor **452**. For example, the interface **453** can include one or more display screens, touch screens, keyboards, mouse controllers, switches, indicators, and/or speakers. In some embodiments, instructions can be provided to the processor **452** via the interface **453**. For example, in some embodiments, the processor **452** is capable of operating in a variety of different modes and the interface **453** can be used to select among the available modes. The interface **453** may also be used to program the processor **452** to operate in a new or different mode.

As further discussed below, in some embodiments, the control system **451** comprises one or more pneumatic regulators and/or vacuum generators, which can control the pressure level of a pressure source **220** and/or a vacuum source **230** (see FIG. **16**); one or more motive fluid valves **210** (see FIG. **16**), which can comprise one or more air valves, and/or other pneumatic control and conditioning devices; and/or other suitable control hardware. In some embodiments, the pressure source and vacuum source can be supplied to the control system by connections to external systems that are configured to supply pressurized gases or suction of gases. In some embodiments, such components and devices can be in communication with and/or controlled by the processor **452** (e.g. the setting of the pneumatic regulators that control the pressure level in a motive fluid source may be controlled by the processor).

With continued reference to FIG. **12**, in certain embodiments, the control system **451** comprises an enclosure **454** and a manifold mounting assembly **400**. In some embodiments, the enclosure **454** and the manifold mounting assembly **400** cooperate to form a cavity in which one or more components of the control system **451** (e.g., the processor **452**, pressure source **220**, and/or vacuum source **230**) are contained. The manifold mounting assembly **400** can be configured to interface with one or more pumps **100**, **100***a* and to selectively couple the pumps **100**, **100***a* with the system **451**. FIG. **12** shows an embodiment of a pump **100** in locked engagement with the manifold mounting assembly **400** and a second pump **100***a* disengaged from the manifold mounting assembly **400**. The illustrated embodiment is particularly suited for use with one or two pumps **100**, **100***a*. In some embodiments, the mounting assembly **400** can be used with more pumps than pumps **100**, **100***a*.

FIG. **14** illustrates a partially exploded perspective view of an embodiment of the manifold mounting assembly **400**. The illustrated embodiment includes two pump mounting areas **405***a, b*, each of which includes similar components and features. Accordingly, for convenience and not by way of limitation, the following discussion may refer to a feature of one of the pump mounting areas **405***a, b* without referring to a like feature of the other mounting area, or may refer to like features interchangeably. Other embodiments can include more than two pump mounting areas **405***a, b* and/or can include pump mounting areas that include dissimilar features.

In certain embodiments, each pump mounting area **405***a, b* of the manifold mounting assembly **400** comprises a manifold cover **402***a, b*. The manifold cover **402***b* can extend over and substantially shield a series of air transfer bosses **407** (see also FIG. **15**). The cover **402***b* can define an opening associated with each air transfer boss **407** of the manifold mounting assembly **400** for receiving an air transfer boss **162***a,b* or **176***a-d* of a pump **100***a*. As further discussed below, the air transfer bosses **162***a,b*, **176***a-d* of the pump **100***a* can extend through the openings and into the air transfer bosses **407**. The manifold cover **402***b* can further define an opening through which a mounting hook **175** can extend (see FIGS. **9**C and **13**B).

In certain embodiments, each air transfer boss **407** can receive a sealing element, such as an o-ring **431***a-e*, to facilitate or enable creation of a fluid-tight seal between the air transfer bosses **407** and the air bosses **162***a, b*, **176***a-d* of the pump **100***a*. Once the o-rings **431***a-e* are in place, the manifold cover **402***b* can be placed over the air transfer bosses **407** and secured to the manifold mounting assembly **400** via any suitable fastener, such as one or more screws **434***a-d*. In some embodiments, each o-ring **431***a-e* is retained between and is in fluid-tight contact with a ridge of an air transfer boss **407** and an underside of the manifold cover **402***b*.

In some embodiments, the manifold mounting assembly **400** comprises latches **403***a, b* that interact with the mounting hook **175** (see FIGS. **9**C and **13**B) of a pump **100** to selectively secure the pump **100** to the manifold mounting assembly **400**. As depicted by double-headed arrows in FIGS. **12** and **13**B, the latch **403***a* can move outward or inward relative to a pump **100**. In some embodiments, the latch **403** is moved inward relative to the pump **100** and advanced through the mounting hook **175** to secure the pump **100** to the manifold mounting assembly **400**, and is moved outward relative to the pump **100** and removed from the opening **175***a* defined by the hook **175** to permit removal of the pump **100** (see FIG. **13**B).

In some embodiments, the latch **403***a* comprises a catch **406** (see FIG. **13**B). The catch can provide leveraged force against the mounting hook **175** as it is slid forward to assist in energizing the radial o-ring seals **431***a-f* for creating sealed fluid interfaces between pump **100** and manifold mounting assembly **400**.

In certain embodiments, a screw **432***b* and a washer **433***b* are used in conjunction with a manifold plate **410** to constrain the motion and positioning of latch **403***b*. For example, in the embodiment illustrated in FIG. **13**B, the screw **432***a* extends through the washer **433***a*, through an opening in the latch **403***b*, and into the manifold plate **410**. In other embodiments, one or more other mechanisms may be used to selectively attach a pump **100** to the manifold mounting assembly **400**. For example, clips, bolts, screws, clamps, or other fasteners could be used.

With reference to FIGS. **13**B and **14**, in some embodiments, the manifold mounting assembly **400** includes one or more brackets **435***a, b* and fasteners **436***a-d*, which can be used to secure the manifold mounting assembly **400** to enclosure **454**.

With reference to FIG. **15**, in certain embodiments, the manifold mounting assembly **400** includes air passages **417**, **418** (see also FIGS. **13**A and **13**B). In some embodiments, air passage **417** provides fluid communication between a first supply port A and air transfer bosses **411**, **415**, and **416** and air passage **418** provides fluid communication between a second supply port B and air transfer bosses **412**, **413**, and **414**. As further discussed below, in some embodiments, the supply ports A, B are in fluid communication with a motive fluid control valve **210** (see FIG. **16**), which can be configured to selectively permit one or more motive fluids to flow to or from the supply ports A, B.

In some embodiments, when the pump **100** is connected to the control system **451**, the air transfer bosses **162***a, b*, **176***a-d* of the pump **100** are in fluid communication with the air transfer bosses **411**-**416** of the manifold mounting assembly **400**. For example, in some embodiments, the air transfer bosses **412**, **413**, and **414** are connected with air transfer bosses **176***c*, **162***b*, and **176***b* of the double diaphragm pump **100** to provide for actuation of the second inlet valve **102***i*, second pump chamber **103***b*, and first outlet valve **101***o*. Similarly, the air transfer bosses **411**, **415**, and **416**, are connected with air transfer bosses **176***d*, **162***a*, **176***a* of the air diaphragm pump **100** to provide for actuation of the first inlet valve **101***i*, first pump chamber **103***a*, and second outlet valve **102***o*.

In some embodiments, the air passages **417**, **418** include restrictions **421**, **422**, respectively. For example, the air passages **417**, **418** can include transfer passages to redirect the flow of motive fluid toward the air transfer bosses **411**-**416** (see FIGS. **13**A and **15**). In some embodiments the transfer passages associated with air transfer bosses **412** and **415** are smaller than those associated with air transfer bosses **411**, **413**, **414**, and **416**. Accordingly, in some embodiments, the restrictions **421**, **422** comprise the smaller transfer passages, and can reduce the rate of change in motive fluid pressure in pump chambers **103***a, b* by restricting air flow through air transfer bosses **412** and **415** as compared with the rate of change in motive fluid pressure in valve chambers by not significantly restricting air flow to or from the bosses **411**, **413**, **414**, and **416**. This permits the inlet and outlet valves to open and close rapidly relative to the filling and discharging of the pump chambers. Further, in some embodiments, the volume of the valves **101***i*, **101***o*, **102***i*, **102***o* is also smaller than the volume of the pump chambers **103***a, b*, which can permit the valves to remain open or closed during a substantial portion of a given stroke cycle. In some embodiments, pressure sensors can be placed in fluid communication with the air transfer passages on the pump side of the restrictions **421**, **422**. The process fluid inlet pressure to the pump and outlet pressure from the pump can be monitored due to the motive fluid pressure at these locations and the process fluid pressure are closely related when the diaphragm regions **141***a, b* are not in an end-of-stroke position during the pump cycle.

In some embodiments, such as the embodiment illustrated in FIGS. **12-15**, the control system **451** is capable of actuating the flow control valves **101***i*, **101***o*, **102***i*, **102***o* and the pump chambers **103***a, b* using a single level of pressure in one of the passages **417**, **418** and a single level of suction in the other passage **417**, **418** during a given stroke or portion of a stroke. Such a configuration can reduce the number of air valves, air regulators, and air control devices (such as those described below) used by the pump control system **451**, which can, in some cases, reduce the manufacturing costs, reduce the complexity, decrease the potential probability of mechanical failure, and/or increase the ease of use and/or the reliability of the pump assembly **450**.

FIG. **16** depicts a schematic illustration of another embodiment of the pump assembly **450**, and includes like reference numerals to identify like features disclosed in other figures of the present disclosure. The pump assembly **450** can comprise a motive fluid logic system **460** configured to control a double diaphragm pump **100**. In some embodiments, the motive fluid logic system **460** comprises the control system **451** (see FIG. **12**). The logic system **460** can comprise a processor **452** such as described above. In some embodiments, the processor **452** is in communication (e.g., electrical, wireless, or other communication) with a valve controller **212** and can control the operation thereof. As discussed above, in some embodiments, the processor **452** is pre-programmed with one or more operational modes by which it controls the controller **212**, and in further embodiments, the processor **452** can be reconfigurable.

In some embodiments, the valve controller **212** is configured to effect transition of a motive fluid valve **210** among a variety of operational states. In some embodiments, the valve controller **212** comprises an electrical actuator (or controller) or a pneumatic actuator (or controller), which can transition the valve **210** among the operational states.

In some embodiments, the valve **210** is configured to operate in two or more positions and may include a resting state, a first state, and a second state. In the illustrated embodiment, the resting, disconnected, closed, or shutoff state of the valve **210** corresponds with the middle rectangular section, the first operational state corresponds with the top rectangular section, and the second operational state corresponds with the bottom rectangular section. In some embodiments, the resting state of the valve **210** substantially prevents fluid communication between the pump **100** and the pressure source **220** and vacuum source **230**. The valve **210** can be positioned in this state, for example, during installation and removal of the pump **100** or during a pump "off" condition or pump "shut down" condition.

In some embodiments, the valve **210** provides fluid communication between a pressure source **220** and the supply port A and between a vacuum source **230** and the supply port B when in the first state, and provides fluid communication between the pressure source **220** and the supply port B and between the vacuum source **230** and the supply port A when in the second state. As indicated by the double-headed arrow, in some embodiments, the valve **210** passes through the resting state when transitioning between the first and the second operational states. Other arrangements of the valve **210** are also possible. For example, the first and second operational states of the valve **210** can be positioned adjacent to each other such that the valve **210** does not pass through the resting state in transitioning between the first and second operational states. In other embodiments, multiple motive fluid valves **210** can be used.

The pressure source **220** can comprise any suitable source of motive fluid such as, for example, an air compressor, a pressurized canister, connection to a pressurized air line, etc. Similarly, the vacuum source **230** can comprise any suitable source of motive fluid (or, in some instances, a relative lack thereof), such as, for example, a connection to a rarefied air line or a vacuum generator or an air compressor configured to evacuate or partially evacuate a chamber. In some embodiments, the vacuum source **230** comprises a vent to atmosphere, and the pressure source **220** is pressurized to a level that exceeds that of atmospheric pressure. In some embodiments, the pressure source **220** and/or the vacuum source **230** can comprise one or more pneumatic regulators to help achieve a relatively constant pressure level. As an example, in some embodiments, the pressure source **220** can comprise a first motive fluid, such as compressed air at a first pressure level (e.g., about 300 mmHg (millimeters of mercury)), and the vacuum source **230** can comprise a second motive fluid, such as rarefied air at a second pressure level (e.g., about −200 mmHg vacuum pressure).

In certain embodiments, the pump **100** is in fluid communication with a process fluid source **238**, which can comprise any fluid for which pumping is desired. For example, in some medical applications, the process fluid source **238** comprises blood circulating in the vasculature of a patient. Other fluids at a variety of pressures and/or at a variety of viscosity levels are also possible. The pump **100** can further be in fluid communication with the process fluid source **238** via the inlet line **180***i*. The pump **100** can further be in fluid communication with a process fluid destination, discharge, receiver, or return **239** via the outlet line **180***o*. In some embodiments, the process fluid source **238** and the process fluid return **239** are at about the same pressure. In other embodiments, the process fluid source **238** is at a lower pressure than the process fluid return **239**. Other arrangements and configurations are also possible.

FIG. **16** illustrates that the motive fluid of pressure source **220** and the vacuum source **230**, respectively, are in selective fluid communication with pump **100** via the manifold mounting assembly **400**. In certain embodiments, the vacuum source **220** (which may be a vent) can be at a pressure that is less than the process fluid source **238** pressure to allow intake of the process fluid into the pumping chambers, and the pressure source **230** can be at a pressure level that is greater than that of the process fluid return **239**. The pressure levels or suction levels can be selectively controlled by pressure regulators (not shown in FIG. **16**) or other devices to the desired levels for pumping the process fluid. In various embodiments, the pressure level of motive fluid provided by the pressure source **220** can be between about 0 mmHg and about 1000 mmHg, between about 50 mmHg and about 500 mmHg, or between about 100 mmHg and about 200 mmHg. In various embodiments, the pressure level of motive fluid provided by the vacuum source **230** can be between about −500 mmHg and about 0 mmHg, between about −250 mmHg, or between about −100 mmHg and about-50 mmHg.

In some embodiments, the control valve **210** is alternated between operational states to cyclically apply pressure and vacuum to supply ports A and B prior to the chamber diaphragms **140***a, b* reaching the end-of-stroke or pump chamber surfaces **114***a*, **114***b* and/or the chamber cavity surfaces **165***a, b*. In certain of such embodiments, the pressure and flow of the process liquid at the process fluid receiver **230** can be maintained at a substantially constant level.

In certain embodiments, as the pump **100** causes fluid to flow from the process fluid source **238** to the process fluid return **239**, the flow can be restricted by the capacities of fluid carrying components that may be located between the process fluid source **238** and the inlet line **180***i* and/or between the outlet line **180***o* and the process fluid receiver **239**. In some embodiments, the pressure levels of the pressure source **220** and/or the vacuum source **230** and/or the operational speed or cycling rate of the valve **210** can be adjusted to achieve a desired flow rate of the process fluid.

In certain embodiments, the pressure levels of the sources **220**, **230** and/or the cycling rate (or rates) of the valve **210** can be selectively changed to cause the double diaphragm pump **100** to operate in one or more different desired operating modes. For example, in a first illustrative mode, the valve **210** can switch the first supply port A from being in fluid communication with the pressure source **220** to being in fluid communication with the vacuum source **230** and can substantially simultaneously switch the second supply port B from being in fluid communication with the vacuum source **230** to being in fluid communication with the pressure source **220**. The change in supply sources **220**, **230** can cause the chamber diaphragms **140***a, b* to switch stroke direction prior to one of the pump chambers **103***a, b* being completely filled and prior to the other pump chamber **103***a, b* being completely emptied. With the pump chambers **103***a, b* operating opposite from each other (e.g., one chamber **103***a* draws process fluid from the fluid source **238** while the other chamber **103***b* expels process fluid to the fluid return **239**), the pump **100** can draw process fluid and expel process fluid at a substantially constant rate.

In another mode, the pump **100** can be controlled to provide a substantially constant draw pattern or fill rate and a pulsatile discharge pattern by adjusting the cyclic speed of the control valve **210**, the vacuum level of the vacuum source **230**, and/or the pressure level of the pressure source **220**. For example, in some embodiments, one of the chamber diaphragm regions **141***a, b* can switch stroke direction prior to completely filling one of the chambers **103***a, b* with process fluid when the valve **210** transitions from an open state to a closed state, and can completely discharge the contents of the chamber **103***a, b* and contact one of the chamber cavity surfaces **114***a, b* for a period of time before the valve **210** transitions from the closed state back to the open state. Likewise, the other chamber diaphragm region **141***a, b* can reach the end-of-stroke condition when it completely discharges the contents of the other chamber **103***a, b* and can be in contact with the other chamber cavity surface **114***a, b* for a period of time prior to the valve **210** transitioning from a closed state to an open state, and can fail to reach the fill end-of-stroke condition of the chamber **103***a, b* with process fluid prior to the valve **210** transitioning from the open state back to the closed state.

Similarly, in yet another mode, the pump can operate in a pulsatile fill pattern and substantially constant discharge pattern. In certain of such embodiments, one of the chamber diaphragm regions **141***a, b* can permit one of the chambers **103***a, b* to completely fill with process fluid and can contact one of the cavity surfaces **165***a, b* for a period of time before the valve **210** transitions from a substantially full state to a partially emptied state, and can fail to completely discharge the contents of the chamber **103***a, b* before the valve **210** transitions from the partially emptied state back to the substantially full state. Likewise, the other chamber diaphragm region **141***a, b* can fail to completely discharge the contents of the other chamber **103***a, b* before the valve **210** transitions from a partially emptied state to a substantially full state, and can permit the other chamber **103***a, b* to completely fill with process fluid and can contact the other cavity surface **165***a, b* for a period of time before the valve **210** transitions from the substantially full state back to the partially emptied state.

Other embodiments of supplying motive fluid to the double diaphragm pump **100** are also possible. For example, in some embodiments, multiple air control valves **210** may be employed. In further embodiments, a common motive fluid supply to one or more of the valves **101***i*, **101***o*, **102***i*, **102***o* and/or a common motive fluid supply provided to the pump chambers **103***a*, **103***b* can instead be replaced with a separate supply of motive fluid to each valve **101**, **102** and chamber **103**. For example, certain embodiments of the two air transfer passages **417**, **418** could be replaced with six separate passages (one for each air transfer boss **411-416**).

In some embodiments, the valves **101***i*, **101***o*, **102***i*, **102***o* and chambers **103***a, b* can be sequenced electronically to provide operating modes such as those described above. In further embodiments, operating a pump in a flow forward mode and then in a flow reverse mode by changing the sequencing of actuating the valves **101***i*, **101***o*, **102***i*, **102***o* and chambers **103***a, b* can also be achieved. In some embodiments, individual control of the pump valves **101***i*, **101***o*, **102***i*, **102***o* and pump chambers **103***a, b* can also allow other pump operating modes that can create constant (or substantially constant) and pulsatile flow from the process fluid source **238** to the process fluid receiver **239** (or vice versa). In some embodiments, time delays between allowing fluid communication between motive fluid sources (e.g., sources **220**, **230**) and one or more of the chambers **103***a, b* and valves **101***i*, **101***o*, **102***i*, **102***o* using individual controls can be advantageous. For example, in some embodiments, it can be desirable to actuate one or more of the valves **101***i*, **101***o*, **102***i*, **102***o* prior to actuating the chambers **103***a, b*

FIG. **17** is a schematic illustration of an embodiment of a cardiopulmonary bypass system **700** that includes multiple double diaphragm blood pumps **100***b-f*. The system **700** can further include one or more reservoirs **706**, blood oxygenators **701**, fluid conduits, such as tubing segments **702**, **705**, catheters **704**, **712**, cannulae **703**, **709**, medical fluid sources **711**, heat exchangers, and/or filtration units. Certain embodiments of the system **700** include components and subsystems that are not shown in FIG. **17** for purposes of clarity. However, it will be understood that such components and sub-systems are conventional and readily available from numerous well-known sources. In some embodiments, the system **700** uses cannulae that are either inserted directly into the right atrium of the heart (as illustrated in FIG. **17**), to the vena cava, or at another desired location of the patient P. Interconnections between devices or components of the system **700** can include, in some embodiments, segments of surgical tubing. For example, in some embodiments, conventional ⅜ or ¼ inch inner diameter surgical polyvinylchloride tubing is used.

In certain embodiments, one or more of the diaphragm blood pumps **100***b-f* may have separately selectable and controllable pressure levels. For example, in some embodiments, each blood pump **100***b-f* is connected to a separate pressure source **220** and/or a separate vacuum source **230**. In further embodiments, one or more of the pumps **100***b-f* can include a valve **210** that cycles at a different rate. In some embodiments, one or more of the pumps **100***b-f* share a common pressure source **220** and/or vacuum source **230**. In certain of such embodiments, pneumatic regulators can be placed in line from the main pressure source **220** and vacuum source **230** to create unique pressure and/or suction levels for each pump **100***b-f*.

In some embodiments, one or more of the diaphragm blood pumps **100***b-f* may have separate motive fluid control valves **210**, and one or more controllers **212** associated with each control valve **210** may operate the pumps **100***b-f* at different rates, which may be dependent upon the function the pump serves within the cardiopulmonary by-pass system **700**. In some embodiments, a single processor **452** controls the one or more valve controllers **212** and the cycle rates or cycle patterns of the one or more valves **210**. In other embodiments, multiple processors may provide the pumps **100***b-f* with different pumping rates and/or modes.

In certain embodiments, the reservoir **706** is supplied with blood flow from the patient P from the venous return catheter **704** via the venous tubing segment **705** and from the interconnections with the diaphragm blood pumps **100***c* **100***d*, and may be interconnected with other components of the system **700**. Blood can be pumped from the reservoir **706** using a double diaphragm blood pump **100***b*, through the blood oxygenator **701**, and back to the patient P via arterial tubing segment **702** and arterial cannula **703**.

In some embodiments, the double diaphragm pump **100***b* may be operated in a manner that provides pulsatile blood flow to the patient P through the arterial cannula **703**. A time delay between the cyclically controlled discharge of the pump chambers **103***a, b*, such as described above, can cause the pump **100***b* to create a more physiological "heart-like" flow through the circuit. Many of the components in the system **700** can act to dampen the effect of pulsation created by the pump **100***b* before the blood is returned to the patient P. In some embodiments, the pump **100***b* can be controlled to offset these effects. For example, in some embodiments, a processor **452** includes programmed instructions and/or implements one or more algorithms to counteract pulsation dampening provided by the system **700**. In some embodiments, the processor **452** can utilize information regarding the amount of dampening provided by the system to dynamically alter operation of the pump **100***b* and thereby provide a desired pulsatile pumping pattern. For example, in some embodiments, the system **700** includes one or more flow meters or pressure sensors (not shown) that provide information to the processor **452** regarding the pressure and/or the flow rate of blood within the tubing segment **702**.

In certain embodiments, the pump **100***b* operates in a mode that creates a substantially constant flow into the venous return catheter **704** from the patient P and a pulsatile outlet flow out of the arterial cannula **703** and to the patient P. Dampening of the pump-created pulsations in the various reservoirs, tubing segments, and other devices in the circuit may occur. The dampening effects can be offset by controlling the vacuum source **220**, pressure source **230**, and pump cycle rate to cause the pump **100***b* to expel fluid at a faster rate than blood is drawn, which can create an end-of-stroke discharge condition during each pump stroke. In other embodiments, the pump **100***b* can exhibit substantially equivalent discharge and fill times, which can create a substantially constant flow into the venous return catheter **704** from the patient and a substantially constant flow out of the arterial cannula **703** and into the patient P. Pump-created process fluid pressure pulsations can be dampened by the various reservoirs, tubing segments, and other devices in the circuit causing a substantially uniform flow into and out of the extracorporeal circuit.

In certain embodiments, when the diaphragm blood pump **100***b* is used to effect blood flow both away from patient P, such as via the venous return catheter **704** and into the patient, such as via arterial cannula **703**, flow rates through the pump can be in a range of, for example, between about 1.0 and about 7.0 liters per minute, between about 1.0 and about 5.0 liters per minute, between about 1.0 and about 3.0 liters per minute, no more than about 7.0 liters per minute, no more than about 6.0 liters per minute, no more than about 5.0 liters per minute, no more than about 4.0 liters per minute, no more than about 3.0 liters per minute, no less than about 1.0 liters per minute, no less than about 2.0 liters per minute, or no less than about 3.0 liters per minute, depending on the medical procedure involved.

With continued reference to FIG. **17**, blood may be removed and recovered from a surgical field via one or more suction devices **713** that can be positioned or manipulated in the surgical field and interconnected to a diaphragm blood pump **100***c*. Examples of such a suction device that can be suitable for operation with the pump **100***c* are available, for example, from Medtronic DLP, Inc. of Grand Rapids, Mich.

Blood can also be recovered through the vent catheter **712**, which may be placed inside a cavity of the heart or other cavity of a patient to withdraw blood and control the pressure or suction level inside the cavity. In such applications, it can be desirable to operate the pump **100***d* with near uniform suction by cyclically switching the filling and discharge of the pump chambers **103***a, b* before the diaphragms reach an end-of-stroke fill position. The recovered blood may be sequestered in a separate reservoir (not shown) and may be selectively returned to the reservoir **706**. The recovered blood may also be processed through a system (not shown) configured to clean the blood before it is returned to the reservoir **706**. In some embodiments, flow rates through the diaphragm blood pumps **100***c*, **100***d* used to effect blood flow from patient P via the suction device **713** and the vent catheter **712** to the reservoir **706** can be in the range of between about 0 and about 1.0 liters/minute, depending on the medical procedure being performed.

As shown in FIG. **17**, in some embodiments, a medical fluid source **711** is coupled with a pump **100***f*. In some embodiments, the medical fluid source **711** comprises cardioplegia fluid, which can be mixed with blood and supplied to the patient P by operation of the diaphragm blood pumps **100***e, f*. In some embodiments, controlling the cardioplegia fluid mixture and delivery rate (e.g., before returning the mixture to the patient P) can be accomplished by controlling the discharge pressure of one or more of the pumps **100***e, f*. For example, in some embodiments the pressure level of one or more pressure sources **220** and/or vacuum sources **230** associated with one or more of the pumps **100***e, f* can be adjusted. In some embodiments, the process fluid discharged from one or more of the pumps **100***e, f* can be passed through one or more flow restrictors (not shown). In certain embodiments, the rate of flow can be nearly constant at a given pressure difference across the restrictors, even with small changes in fluid conditions, such as temperature and/or viscosity fluctuations.

In some embodiments, one or more flowmeters (not shown) can be included in the outlet fluid lines of one or more of the pumps **100***e, f* and can sense the flow rate of fluid discharged from the pumps **100***e, f* The one or more flowmeters can provide feedback information regarding the flow rate to one or more processors **452** that control the pumps **100***e, f*. In some embodiments, the pressure level in the pressure source **220** and/or the vacuum source **230** can be adjusted in response to the feedback information to cause the flow rate from the pumps **100***e, f* to increase or decrease to obtain a desired level of mixing and a desired delivery rate of mixed fluid to the patient P. In some embodiments, the cycle rate at which diaphragm actuation regions of a given pump **100***e, f* are actuated can be adjusted to provide increased or decreased fluid flow from that pump **100***e, f* In certain embodiments, appropriately mixed and/or heated or cooled cardioplegia fluid can be delivered via a tubing segment and cardioplegia cannula **709** to the patient P.

In certain embodiments, the pumps **100***b-f* can provide desirable pressure levels for the system **700**. In some embodiments, the pumps **100***b-f* may be safer than pumps conventionally used in some of the applications described above, such as roller pumps. For example, if a vascular access connection to the patient P is somehow degraded or a blockage occurs in the system **700** (e.g., via a kink in a portion of tubing), certain embodiments of the pumps **100***b-f* have limited capability to generate high pressure and/or high suction levels that may damage the blood in the system **700** and/or that might otherwise be hazardous to the patient P. For example, in some embodiments, the pressure sources **220**, **230** can be at pressure levels that limit the amount of pressure and/or suction provided to extracorporeal blood within the system **700**. In various embodiments, the pressure of extracorporeal blood within the system is within a of between about −250 mmHg and about 500 mmHg, between about −200 mmHg and about 400 mmHg, or between about −100 mmHg and about 300 mmHg. In some embodiments the pressure of extracorporeal blood within the system **700** is no less than about −250 mmHg, no less than about −200 mmHg, no less than about −150 mmHg, no less than about −100 mmHg, no greater than about 500 mmHg, no greater than about 400 mmHg, no greater than about 300 mmHg, or no greater than about 200 mmHg.

Further, some embodiments of the pumps **100***b-f* do not significantly raise the temperature of blood within the system **700** if a vascular access connection to the patient P is somehow degraded or a blockage occurs in the system **700**. In various embodiments, the pumps **100***b-f* change (e.g., raise) the temperature of extracorporeal blood within the system **700** by no more than about 3° C., no more than about 4° C., no more than about 5° C., or no more than about 6° C.

FIG. **18** is a schematic illustration showing an embodiment of a heart-assist system **750** that comprises a double diaphragm pump **100***g*. The pump **100***g* can be attached to an inlet line **180***i* and an outlet line **180***o*. In the illustrated embodiment, the inlet line **180***i* provides fluid communication between the vasculature of the patient P and the pump **100***g*. In some embodiments, the inlet line **180***i* is attached to a lower pressure blood vessel, such as a vein or ventricle, via a cannula or an anastomosis attachment **753**. Similarly, the outlet line **180***o* can be attached to a higher pressure blood vessel, such as an artery or aorta, via a cannula or anastomosis attachment **754**. In some embodiments, each of the inlet lines **180***i* and outlet lines **180***o* comprises a tubing segment. The tubing sections may be percutaneous and can allow the pump **100***g* to run externally to the patient P.

In some embodiments, the heart-assist system **750** comprises additional components and devices that are known in the art (not shown). For example, in various embodiments, the heart-assist system **750** comprises one or more reservoirs, air bubble traps, filters, and/or other devices.

In various embodiments, the system **750** can provide flow rates to or from the patient P in the range of about 1.0 liters/minute to about 8.0 liters/minute, depending on the amount of heart support needed. In certain embodiments, the pump **100***g* comprises pump chambers **103***a*, **103***b* that each have a volume of between about 15 cubic centimeters and about 50 cubic centimeters, between about 20 cubic centimeters and about 30 cubic centimeters, no more than about 25 cubic centimeters, or about 25 cubic centimeters. In some embodiments, the pump **100***g* is operated at a rate between about 10 and about 200 cycles per minute, between about 90 and about 130 cycles per minute, between about 100 and about 120 cycles per minute, no more than about 200 cycles per minute, no more than about 150 cycles per minute, no more than about 120 cycles per minute, no less than about 10 cycles per minute, no less than about 50 cycles per minute, no less than about 100 cycles per minute, or about 120 cycles per minute. In various embodiments, the pump **100***g* can deliver blood to the patient P at a rate between about 2 liters per minute and about 8 liters per minute, between about 3 liters per minute and about 7 liters per minute, or between about 4 liters per minute and about 6 liters per minute. In certain embodiments, the volume of the pump chambers **103***a*, **103***b* of a pump **100***g* and the number of cycles per minute at which the pump **100***g* operates can be adjusted to provide a desired flow rate. In further embodiments, relatively lower cycles per minute can lengthen the life expectancy of the pump **100***g* and/or can aid in providing pulsatile blood flow to a patient that mimics a heartbeat.

FIG. **19** schematically illustrates a hemodialysis system that includes an extracorporeal circuit **800**. In certain embodiments, the circuit **800** includes a diaphragm pump **100***h*, a dialyzer **810**, and a dialyzing liquid system **820**. The circuit **800** can be in fluid communication with a patient P. Blood can be withdrawn from the patient P at a blood source **238** and can be returned to the patient P at a blood receiver **239**. Blood can flow through the circuit **800** in the direction of the arrows. In the illustrated embodiment, blood flows from the patient P to a drip chamber **803** via tubing **802**, from the drip chamber **803** to the pump **100***h* via tubing **805**, and from the pump **100***h* to the dialyzer **810** via tubing **807**. Blood flows from the dialyzer **810** to a drip chamber **812** via tubing **811**, and from the drip chamber **811** to the patient P via tubing **814**.

In some embodiments, uptake from the process fluid source **238** and discharge to the process fluid receiver **239** occurs via needles punctured into an artery to vein fistula or graft shunt, or alternatively, from a catheter positioned in a large central vein. In certain embodiments, for the portion of the circuit **800** between the patient P and the pump **100***h*, blood pressure can be measured and monitored by means of a pressure sensor, such as a piezo-resistive pressure transducer **804***a* that can be connected to the drip chamber **803**, whereby a hydrophobic membrane filter (not shown) serves to prevent contamination of the blood. Similarly, venous reflux pressure in the portion of the circuit **800** between dialyzer **810** and the patient P can be measured by means of a pressure transducer **804***b*. Pressure sensors can be used at other portions of the circuit **800**. For example, in some embodiments, pressure sensors can be used to monitor the pressure levels of blood entering and exiting the pump **100***h*.

Pressure sensors can also be used to determine the pressure levels of motive fluid provided to the pump **100***h*.

In certain embodiments, the blood pump **100***h* effects the flow of blood in the extracorporeal circuit **800**. In some embodiments, a heparin pump **808** provides for continuous feed of a desired heparin dose to prevent blood coagulation. The dialyzing liquid system **820** causes dialyzing liquid to flow through the dialyzer **810** and acts as a receiver of excess fluid and toxins removed from the blood that flows through the dialyzer. In some embodiments, the components of the extracorporeal blood circuit **800** are connected with each other via suitable safety devices known in the art or yet to be devised.

In some embodiments, an air detector **825** is included between the dialyzer **810** and the patient P. The air detector **825** can be configured to prevent infusion of blood foam or air, which may have entered the extracorporeal circuit **800**, into the patient P. In some embodiments, the air detector **825** recognizes whether air bubbles or microfoam are present in the drip chamber **812** or elsewhere in the circuit **800**. The air detector **825** can be in communication with a processor **452** (see, e.g., FIG. **16**), which may switch off the blood pump **100***f* in response to information received from the detector **825**.

In other embodiments, the pump **100***h* may similarly be deactivated in response to other information regarding the circuit **800**. For example, the sensors **804***a, b* may detect an undesirable increase or decrease of the arterial or venous pressure above or below a threshold level. The information can be used to deactivate the pump **100***h*. Similarly, the pump **100***h* may be deactivated as a result of a blood leak. In some embodiments, the pump **100***h* may be operatively associated with a control system **451**, which may include an interface **453**. In some embodiments, the interface **453** can display or otherwise signal information received from sensors within the circuit **800**.

In some embodiments, information regarding the pressure of blood in the circuit **800**, such as information provided by one or more of the pressure transducers **804***a, b*, is used to adjust the pressure level of motive fluid delivered to the pump **100***h*. For example, in some embodiments, the pressure transducers **804***a, b*, are configured to communicate with a processor **452** (see, e.g., FIG. **12**), such as by one or more electrical or wireless connections. The processor **452** can utilize the information thus received to selectively control the pressure levels of motive fluid delivered from motive fluid sources, such as the sources **220**, **230**, in a manner such as described above (e.g., via one or more pressure regulators) and/or to control cycle rates and stroke durations of the pump **100***h*. For example, in some embodiments, the pressure levels of the motive fluid from the pressure sources **220**, **230** and the cycle rates at which fluid communication is alternately established between distinct sets of valves and pump chambers is adjusted such that substantially constant fluid flow is established from the patient P to the extracorporeal circuit **800** and/or from the extracorporeal circuit **800** to the patient P. In some embodiments, the pump **100***h* provides pulsatile flow to the dialyzer **810** and essentially constant flow from the patient P to the extracorporeal circuit **800**.

In certain embodiments, the pump **100***h* can provide desirable pressure levels for the extra corporeal circuit **800**. In some embodiments, the pump **100***h* may be safer than conventional dialysis pumps, such as roller pumps. For example, if the vascular access connection to the patient is somehow degraded or a blockage occurs in the extracorporeal circuit **800** (e.g., via a kink in a portion of tubing), certain embodiments of the pump **100***h* have limited capability to generate high pressure and/or high suction levels that may damage the blood in the circuit **800** and/or that might otherwise be hazardous to the patient P. Further, some embodiments of the pump **100***h* does not significantly raise the temperature of blood within the circuit under such conditions of connection degradation or blockage.

In some embodiments, the diaphragm blood pump **100***f* generates two overlapping substantially square wave inflow pressure profiles and outflow pressure profiles during the pumping cycle which can result in a substantially constant blood inflow pressure and/or a substantially constant blood outflow pressure. The inflow and outflow pressures can be set near or within safety limits to provide maximum process fluid flow without triggering pressure limit alarms. The pressure profile generated by conventional roller pumps used in hemodialysis procedures is somewhat sinusoidal and may only operate at the maximum pressure level for a short duration of the pumping cycle. Accordingly, in some embodiments, as compared with such conventional pumps, the pump **100***h* can achieve higher blood flows at the same peak pressure limits. Higher flow rates can reduce the duration of a given hemodialysis procedure. In some embodiments, the inflow rate and/or the outflow rate of the pump **100***h* can be controlled or balanced (e.g., via the processor **452**) to be substantially continuous with little pulsation of pressures or flow, as compared to some roller pumps that cannot simultaneously control the inflow pressure, outflow pressure, and flowrate. In other embodiments, the pump **100***h* can be configured to operate in a manner similar to conventional roller pumps, if desired.

Non-limiting examples will now be discussed with reference to FIGS. **20**, **21**, **22**A, and **22**B. These examples provide illustrations of performance capabilities of some embodiments, and are not intended to limit the foregoing disclosure in any respect.

Example 1

FIG. **20** is a chart showing an example of pressure over time during a single pump cycle of an embodiment of a pump **100***b* used in a simulation of a cardiopulmonary bypass system such as the system **700** of FIG. **17**. The chart depicts the pressure over time of blood entering the pump **100***b* (illustrated by the curve "Pump In") and also depicts the pressure over time of blood exiting the pump **100***b* (illustrated by the curve "Pump Out"). In the illustrated example, the pump **100***b* was operated in a mode for approximately uniform flow entering an extracorporeal circuit and approximately uniform flow exiting the circuit.

Various operational parameters of the pump **100***b* of the present example or of other embodiments of the pump **100***b* can be altered such that the inflow pressure for the extracorporeal circuit and the outflow pressure for the extracorporeal circuit are more uniform than that shown. For example, in some embodiments, the valley of the "Pump Out" line at the time coordinate of 0.2 seconds is relatively more shallow (e.g., has a minimum value of between about 200 and about 300 mmHg) and/or may be relatively more constricted (i.e., span over a shorter time period). Similarly, in some embodiments, the peak of the "Pump In" line at the time coordinate of 0.2 seconds is smaller (e.g., has a maximum valve of between about 0 and about 100 mmHg) and/or may be relatively more constricted.

In some embodiments, the inflow to the pump **100***b* and outflow from the pump **100***b* are approximately uniform. As used herein, the term "approximately uniform" when used to describe a flow rate is a broad term and signifies that over a single pump cycle, the maximum flow rate deviates from the average flow rate by no more than about 25% of the average flow rate during the pump cycle.

As discussed above, in some embodiments, flow and pressure pulsations created by a pump **100***b* can be dampened by the various reservoirs, tubing segments, and other devices in a circuit, and can result in more uniform flow rates and pressures. In certain embodiments, the uptake flow rate at a blood source **238** (e.g., a patient) and/or a delivery flow rate at a blood delivery destination **239** (e.g., a patient) can be essentially constant during a pump cycle. As used herein, the term "essentially constant" when used to describe a flow rate is a broad term and signifies that over a single pump cycle, the maximum flow rate deviates from an average flow rate by no more than about 10% of the average flow rate during the pump cycle. The pump **100***b* used to create the chart of FIG. **20** comprised two chambers, each having a displacement volume of about 25 milliliters. The chart illustrates the pump **100***b* as having operated at 200 millisecond per stroke (i.e., 400 millisecond per cycle or 150 cycles per minute). The pressure level in the pressure source **220** was established at 390 mmHg, the level of suction in the suction source was established at −125 mmHg, and the flow rate of blood effected by pump **100***b* was about 4 to 5 liters per minute. Connections lines **180***i* and **180***o* were comprised of plasticized PVC tubing with an inner diameter of 0.375 inches.

Example 2

FIG. **21** is a chart showing an example of pressure over time during a single pump cycle of an embodiment of a pump **100***g* used in a simulation of a heart assist system such as the system **750** of FIG. **18**. The chart depicts the pressure over time during a single pump cycle of blood entering the pump **100***g* (illustrated by the curve "Pump In") and also depicts the pressure over time of blood exiting the pump **100***g* (illustrated by the curve "Pump Out"). The pump **100***g* was operated in a mode for relatively uniform flow entering an extracorporeal circuit and pulsatile outflow from the circuit.

Various operational parameters of the pump **100***g* of the present example or of other embodiments of the pump can be altered such that the inflow to the extracorporeal circuit is more uniform than that shown. For example, in some embodiments, the peak of the "Pump In" line at the time coordinate of about 0.45 seconds is smaller (e.g., has a maximum valve of between about 20 and about 80 mmHg) and/or may be relatively more constricted. Similarly, the pulsatile characteristics of the outflow from the extracorporeal circuit may be modified, as briefly discussed below.

The pump **100***g* used to create the chart of FIG. **21** comprised two chambers with each chamber having a displacement volume of about 25 milliliters. The chart illustrates the pump **100***g* as having operated at 500 millisecond per stroke (i.e., 1 second per cycle or 60 cycles per minute). The pressure level in the pressure source **220** was established at 300 mmHg and the level of suction in the suction source was established at 0 mmHg. The flowrate of blood effected by pump **100***g* was around 3 liters per minute. Shorter more pronounced pulse widths can be generated by extending the cycle time or increasing the pressure level in the pressure source **220**. The pump was located about 30 inches below the fluid source **238** creating a positive pressure head of about 50 mmHg. Connections lines **180***i* and **180***o* were comprised of plasticized PVC tubing with an inner diameter of 0.375 inches. The outlet line **180***o* inner diameter was further reduced to 0.25 inches inner diameter for simulating a percutaneous access and arterial connection **754**. The blood flowing through the connection lines caused pressure drops to and from the pump and the blood was delivered to the blood return **239** at less than 100 mmHg. The blood pump **100***g* of the illustrated example can create high pressures in the blood to overcome line losses, and as a result, a much smaller lumen can be used to access the vasculature of a patient P.

Example 3A

FIG. **22**A is a chart showing an example of pressure over time during a single pump cycle of an embodiment of a pump **100***h* used in a simulation of a hemodialysis system such as the system **800** of FIG. **19**. The chart depicts the pressure over time during a single pump cycle of blood entering the pump **100***h* (illustrated by the curve "Pump In"), the pressure over time of blood exiting the pump **100***h* (illustrated by the curve "Pump Out"), and also depicts the pressure over time of blood exiting the dialyzer **810** (illustrated by the curve "Dialyzer Out"). The pump **100***h* was operated in a mode for relatively uniform flow entering the circuit and relatively uniform flow exiting the extracorporeal circuit.

The chart illustrates the pump **100***h* as having operated at 3 seconds per stroke (i.e., 6 seconds per cycle or 10 cycles per minute). The pressure level in the pressure source **220** was established below about 390 mmHg, which caused the dialyzer out pressure to remain below about 250 mmHg, and the level of suction in the suction source was established above about 250 mmHg. The pump **100***h* used to create the chart of FIG. **22**A comprised two chambers with each chamber having a displacement volume of about 25 milliliters. The flowrate of blood effected by pump **100***h* was about 250 to about 350 milliliters per minute. Connection lines **180***i* and **180***o* were comprised of plasticized PVC tubing with an inner diameter of 0.25 inches and connected to a commonly used disposable hemodialysis circuit with 16 gauge hemodialysis needles as the connections to fluid source **238** and fluid return **239**. Most of the flow-driven pressure losses in the hemodialysis circuit **800** occurred through the needles and the dialyzer **810**.

Example 3B

FIG. **22**B is a chart showing an example of pressure over time during a single pump cycle of an embodiment of a pump **100***h* used in a simulation of a hemodialysis system such as the system **800** of FIG. **19**. The chart depicts the pressure over time during a single pump cycle of blood entering the pump **100***h* (illustrated by the curve "Pump In"), the pressure over time of blood exiting the pump **100***h* (illustrated by the curve "Pump Out"), and also depicts the pressure over time of blood exiting the dialyzer **810** (illustrated by the curve "Dialyzer Out"). The pump **100***h* was operated in a mode for relatively uniform flow entering the circuit and pulsatile flow exiting the extracorporeal circuit.

The pump **100***h* is illustrated as having operated at 3 seconds per stroke (i.e., 6 seconds per cycle or 10 cycles per minute). Shorter, more pronounced pulse widths can be generated by extending the cycle time or increasing the pressure level in the pressure source **220**. The pressure level in the pressure source **220** was established below about 360 mmHg, which caused the dialyzer out pressure to remain below about 250 mmHg, and the level of suction in the suction source was established above about −160 mmHg. The pump **100***h* used to create the chart of FIG. **22**B comprised two chambers with each chamber having a displacement volume of about 25 milliliters. The flowrate of blood effected by pump **100***g* was about 200 to about 300 milliliters per minute. Connections lines **180***i* and **180***o* were comprised of plasticized PVC tubing with an inner diameter of 0.25 inches and connected to a commonly used disposable hemodialysis circuit with 16 gauge hemodialysis needles as the connections to fluid source **238** and fluid return **239**. Most of the hemodialysis circuit blood flow pressure losses occurred through the needles and the dialyzer **810**. A more pronounced pulsation can be achieved at a given flowrate with a combination of longer cycle times, larger bore needles, and lower flow resistance of the dialyzer.

Various features and structures discussed herein, and equivalents thereof, can provide specific functionalities. By way of illustration, in some embodiments, the first and second pump chambers **103***a, b* are examples of first and second means for selectively drawing process fluid from a process fluid source (e.g., the fluid source **238**) and selectively expelling process fluid to a process fluid delivery destination (e.g., the process fluid delivery destination **239**); the first and second inlet valves **101***i*, **102***i* are examples of first and second means for selectively permitting process fluid to flow to the first and second means for selectively drawing process fluid from a process fluid source and selectively expelling process fluid to a process fluid delivery destination, respectively; and the first and second outlet valves **101***o*, **102***o* are examples of first and second means for selectively permitting process fluid to flow from the first and second means for selectively drawing process fluid from a process fluid source and selectively expelling process fluid to a process fluid delivery destination, respectively.

As used in this specification, including the claims, the term "and/or" is a conjunction that is either inclusive or exclusive. Accordingly, the term "and/or" either signifies the presence of two or more things in a group or signifies that one selection may be made from a group of alternatives.

Without further elaboration, it is believed that one skilled in the art can use the preceding description to utilize the claimed inventions to their fullest extent. The examples and embodiments disclosed herein are to be construed as merely illustrative and not a limitation of the scope of the present disclosure in any way. It will be apparent to those having skill in the art that changes may be made to the details of the above-described embodiments without departing from the underlying principles discussed. In other words, various modifications and improvements of the embodiments specifically disclosed in the description above are within the scope of the appended claims. For example, any suitable combination of features of the various embodiments described is contemplated. Note that elements recited in means-plus-function format are intended to be construed in accordance with 35 U.S.C. § 112 ¶6. The scope of the invention is therefore defined by the following claims.

The invention claimed is:

1. A medical fluid pumping system comprising:
- a medical fluid pump for pumping a process fluid, the medical fluid pump including
  - a first pump chamber,
  - a first inlet valve chamber in fluid communication with the first pump chamber, the first inlet valve chamber including a first inlet valve diaphragm,
  - a first outlet valve chamber in fluid communication with the first pump chamber,
  - a second pump chamber,
  - a second inlet valve chamber in fluid communication with the second pump chamber, the second inlet valve chamber including a second inlet valve diaphragm,
  - a second outlet valve chamber in fluid communication with the second pump chamber,
  - a first valve seal separate from the first inlet valve diaphragm and configured to compress the first inlet valve diaphragm around the first inlet valve chamber, wherein the first valve seal comprises an o-ring configured to fit into a groove surrounding the first inlet valve chamber, and
  - a second valve seal separate from the second inlet valve diaphragm and configured to compress the second inlet valve diaphragm around the second inlet valve chamber, wherein the second valve seal comprises an o-ring configured to fit into a groove surrounding the second inlet valve chamber; and
- a medical fluid chassis operable with the medical fluid pump, the medical fluid chassis including a motive fluid source providing a motive fluid at a motive fluid pressure, wherein the first and second inlet valve diaphragms are configured to actuate from an open position to a closed position at a differential pressure less than the motive fluid pressure to mitigate a process fluid backflow through the first and second inlet valve chambers.

2. The medical fluid pumping system of claim **1**, wherein the process fluid includes blood and the motive fluid includes air.

3. The medical fluid pumping system of claim **1**, wherein the first and second inlet valve diaphragms are provided via a same one or more diaphragm sheet.

4. The medical fluid pumping system of claim **1**, wherein the first and second inlet valve diaphragms are separate diaphragms.

5. The medical fluid pumping system of claim **1**, further comprising at least one of a first pump diaphragm provided with the first pump chamber, a second pump diaphragm provided with the second pump chamber, a first outlet valve diaphragm provided with the first outlet valve chamber, or a second outlet valve diaphragm provided with the second outlet valve chamber.

6. The medical fluid pumping system of claim **1**, wherein at least one of the first or second inlet valve diaphragms includes additional support where the at least one of the first or second inlet valve diaphragms is seated in a valve seat of the respective first or second inlet valve chamber.

7. The medical fluid pumping system of claim **1**, wherein at least one of the first or second inlet valve diaphragms includes a preformed dome.

8. The medical fluid pumping system of claim **1**, wherein the first and second inlet valve diaphragms are configured to actuate from the open position to the closed position when the differential pressure is between 5 mmHg and 200 mmHg.

9. The medical fluid pumping system of claim **1**, wherein the motive fluid pressure is substantially 300 mmHg.

10. The medical fluid pumping system of claim **1**, wherein the motive fluid source includes a positive motive fluid source, and also includes a negative motive fluid source for actuating the first and second inlet valve diaphragms and first and second outlet valve diaphragms from closed positions to open positions.

11. The medical fluid pumping system of claim **10**, wherein the first and second outlet valve diaphragms of the first and second outlet valve chambers, respectively, are configured to actuate from the closed position to the open position when the differential pressure is less than a negative motive fluid pressure held by the negative motive fluid source to mitigate process fluid backflow through the first and second outlet valve chambers.

12. The medical fluid pumping system of claim **10**, wherein the positive and negative motive fluid sources are separated from motive fluid portions of the first pump chamber, the first inlet valve chamber, the first outlet valve chamber, the second pump chamber, the second inlet valve chamber, and the second outlet valve chamber by a motive fluid valve.

13. The medical fluid pumping system of claim **12**, wherein in a first state the motive fluid valve allows (i) a positive motive fluid pressure to be supplied from the positive motive fluid source to the motive fluid portions of the first pump chamber, the first inlet valve chamber, and the second outlet valve chamber and (ii) a negative motive fluid pressure to be supplied from the negative motive fluid source to the motive fluid portions of the first outlet valve chamber, the second pump chamber, and the second inlet valve chamber.

14. The medical fluid pumping system of claim **13**, wherein in a second state the motive fluid valve allows (i) the positive motive fluid pressure to be supplied from the positive motive fluid source to the motive fluid portions of the second pump chamber, the second inlet valve chamber, and the first outlet valve chamber and (ii) the negative motive fluid pressure to be supplied from the negative motive fluid source to the motive fluid portions of the second outlet valve chamber, the first pump chamber, and the first inlet valve chamber.

15. A medical fluid pump for pumping a process fluid, the medical fluid pump comprising:

a first pump chamber;

a first inlet valve chamber in fluid communication with the first pump chamber, the first inlet valve chamber including a first inlet valve diaphragm;

a first outlet valve chamber in fluid communication with the first pump chamber;

a second pump chamber;

a second inlet valve chamber in fluid communication with the second pump chamber, the second inlet valve chamber including a second inlet valve diaphragm;

a second outlet valve chamber in fluid communication with the second pump chamber;

a first valve seal separate from the first inlet valve diaphragm and configured to compress the first inlet valve diaphragm around the first inlet valve chamber, wherein the first valve seal comprises an o-ring configured to fit into a groove surrounding the first inlet valve chamber; and

a second valve seal separate from the second inlet valve diaphragm and configured to compress the second inlet valve diaphragm around the second inlet valve chamber, wherein the second valve seal comprises an o-ring configured to fit into a groove surrounding the second inlet valve chamber,

wherein the first and second inlet valve diaphragms are configured to actuate from an open position to a closed position at a differential pressure less than a supplied motive fluid pressure to mitigate a process fluid backflow through the first and second inlet valve chambers.

16. The medical fluid pump of claim **15**, wherein at least one of the first or second inlet valve diaphragms includes additional support where the at least one of the first or second inlet valve diaphragms is seated in a valve seat of the respective first or second inlet valve chamber.

17. The medical fluid pump of claim **15**, wherein at least one of the first or second inlet valve diaphragms includes a preformed dome.

18. The medical fluid pump of claim **15**, wherein the first and second inlet valve diaphragms are configured to actuate from the open position to the closed position when the differential pressure is between 5 mmHg and 200 mmHg.

19. The medical fluid pump of claim **15**, wherein at least one of the first pump chamber, the first inlet valve chamber, the first outlet valve chamber, the second pump chamber, the second inlet valve chamber, and the second outlet valve chamber is formed via at least one rigid plate.

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