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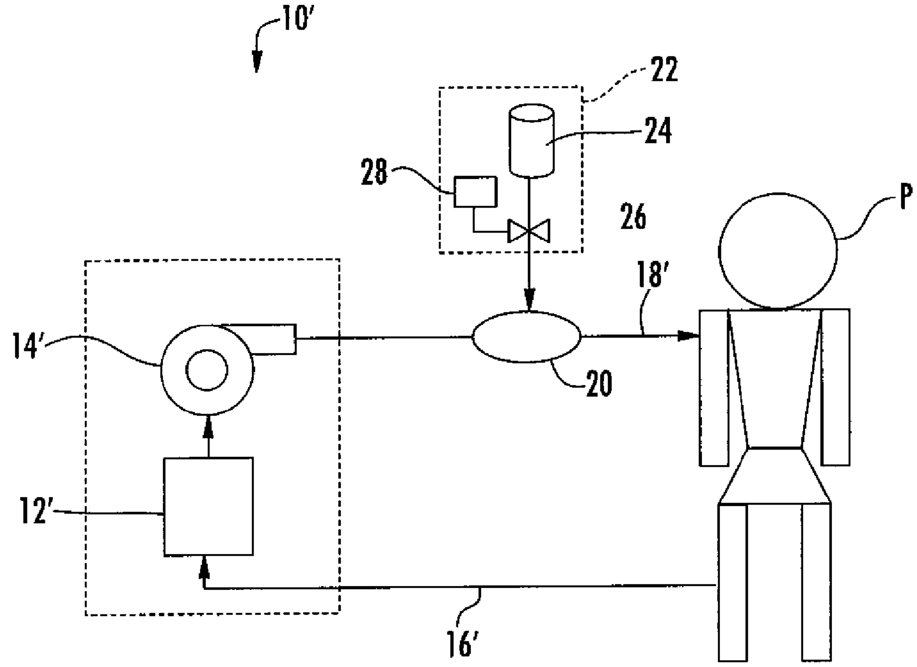
(54) Title: PULSE GENERATING DEVICE



(57) Abstract: A pulse generator has a rigid body with a resilient flow conduit passing therethrough. Pressure is periodically selectively applied to the interior of the body which compresses the flow conduit and induces a pressure pulse in the fluid contained therein. The pulse generator may be used as a stand alone pump or in concert with a continuous flow pump to provide a pulsatile output flow having customized waveform characteristics. The pulse generator may be used with medical equipment such as a heart-lung bypass machine or a dialysis machine.

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PULSE GENERATING DEVICE

BACKGROUND OF THE INVENTION

[0001] This invention relates generally to fluid circulation and pumps, and more particularly to a method for applying a pressure pulse to a fluid.

[0002] Medical procedures such as open heart surgery, heart transplants, and kidney dialysis require equipment which extracts a patient's blood, treats the blood by processes such as filtering, oxygenation, and the like, and returns the blood to the patient's body. Such equipment uses pumps with essentially constant pressure output to circulate the patient's blood through the treatment equipment. Unfortunately, this kind of flow is much different from the flow provided by a patient's heart. It has been found that this constant-pressure flow can have undesirable side effects including brain disorders and limited or reduced circulation, especially in flow restrictive areas. This places undesirable limits on the usage of this type of equipment.

BRIEF SUMMARY OF THE INVENTION

[0003] Accordingly, it is an object of the invention to provide a method and apparatus for creating a pulsating flow in a fluid.

[0004] It is another object of the invention to creating a pulsating flow in a bodily fluid while avoiding shear stress and cell damage in the fluid.

[0005] It is another object of the invention to create a preselected pressure profile in a flowing fluid.

[0006] These and other objects are met by the present invention, which according to one aspect provides a pulse generator for fluid flow, including: a substantially rigid body defining a pressure cavity; a resilient flow conduit extending through the pressure cavity and arranged to carry a first fluid therein; and a pressure inlet communicating with the pressure cavity for introducing a second fluid into the pressure cavity, such that the first fluid may be exposed to a time-varying pressure signal introduced through the pressure inlet without mixing of the first and second fluids.

[0007] According to another aspect of the invention, the flow conduit is generally S-shaped.

[0008] According to another aspect of the invention, the flow conduit has a four-sided cross-sectional shape defined by spaced-apart walls extending between radiused corners.

[0009] According to another aspect of the invention, the flow conduit has a cross–sectional shape including a pair of spaced-apart lobes connected by a pinched waist.

[0010] According to another aspect of the invention, the flow conduit has a cross–sectional shape including a pair of spaced-apart lobes connected by a pinched waist.

[0011] According to another aspect of the invention, the flow conduit has a cross–sectional shape including a plurality of spaced-apart, radially-extending lobes.

[0012] According to another aspect of the invention, the flow conduit has a cross–sectional shape including: a double-walled, generally C-shaped portion; and a plurality of spaced-apart, a flexible bridge connecting free ends of the C-shaped portion; wherein the C-shaped portion and the flexible bridge cooperate to define a central opening.

[0013] According to another aspect of the invention, the pressure cavity is shaped such that a pressure signal applied thereto will propagate symmetrically therein.

[0014] According to another aspect of the invention, a pulse generator for fluid flow includes: a substantially rigid housing which defines an open cavity, the housing including an inlet and outlet communicating with the cavity; a flexible diaphragm which closes off the cavity; and an actuator operably connected to the diaphragm and adapted to selectively move the diaphragm from a first position in which the pulse generator encloses a first fluid volume, and a second position in which the pulse generator encloses a second fluid volume less than the first fluid volume.

[0015] According to another aspect of the invention, the diaphragm forms a portion of a torus.

[0016] According to another aspect of the invention, the pulse generator further includes a programmable controller operably connected to the actuator.

[0017] According to another aspect of the invention, a fluid circulation system includes: a circulation pump for a first fluid; a first pulse generator disposed in series flow with the circulation pump, the first pulse generator including: a substantially rigid first body defining a first pressure cavity; a resilient first flow conduit extending through the first pressure cavity and arranged to carry the first fluid therein; and a first pressure inlet communicating with the first pressure cavity for receiving a second fluid into the first pressure cavity, such that the first fluid may be exposed to a pressure signal received through the first pressure inlet without mixing of the first and second fluids; and a control mechanism operably connected to the first pressure inlet and adapted to introduce a pressure signal into the first pressure cavity so as to impress a predetermined time-varying pressure profile into the first fluid through the first flow conduit.

[0018] According to another aspect of the invention, the circulation pump is a type generating a substantially constant output pressure in the first fluid.

[0019] According to another aspect of the invention, the control mechanism includes: a source of pressurized fluid; and a valve operable to selectively transfer the pressurized fluid to the first pressure inlet.

[0020] According to another aspect of the invention, the first pulse generator has a displacement capacity, and in which the control mechanism is adapted to control the circulation pump and the first pulse generator such that the first pulse generator operates in a preselected displacement range within the displacement capacity.

[0021] According to another aspect of the invention, the fluid circulation system further includes: a second pulse generator disposed in series flow with the circulation pump and the first pulse generator, the second pulse generator including: a substantially rigid second body defining a second pressure cavity; a resilient second flow conduit extending through the second pressure cavity and arranged to carry the first fluid therein; and a second pressure inlet communicating with the second pressure cavity for receiving a second fluid into the second pressure cavity, such that the first fluid may be exposed to a pressure signal received through the second pressure inlet without mixing of the first and second fluids; wherein the control mechanism is operable to selectively pressurize the second pulse generator to a degree so as to substantially close off flow through the second flow conduit.

[0022] According to another aspect of the invention the fluid circulation system further includes equipment for treatment of a bodily fluid connected in series flow therewith.

[0023] According to another aspect of the invention, a fluid circulation system includes: a first pulse generator including: a substantially rigid first body defining a first pressure cavity; a resilient first flow conduit extending through the first pressure cavity and arranged to carry the first fluid therein; and a first pressure inlet communicating with the first pressure cavity for receiving a second fluid into the first pressure cavity, such that the first fluid may be exposed to a pressure signal received through the first pressure inlet without mixing of the first and second fluids;

and a second pulse generator connected in series flow with the first pulse generator, and including: a substantially rigid second body defining a second pressure cavity; a resilient second flow conduit extending through the second pressure cavity and arranged to carry the first fluid therein; and a second pressure inlet communicating with the second pressure cavity for receiving a second fluid into the second pressure cavity, such that the first fluid may be exposed to a pressure signal received through the second pressure inlet without mixing of the first and second fluids. A control mechanism is operably connected to the first and second pressure inlets and adapted to: cyclically pressurize one of the first pulse generator so as to impress a predetermined time-varying pressure profile into the first fluid; and cyclically pressurize the second pulse generator to a degree so as to substantially close off flow through the second flow conduit in coordination with the pressurization of the first pulse generator, such that the first fluid is moved through the fluid circulation system in a single direction.

[0024] According to another aspect of the invention, the fluid circulation system further includes: a third pulse generator connected in series flow with the first and second pulse generators, and including: a substantially rigid third body defining a third pressure cavity; a resilient third flow conduit extending through the third pressure cavity and arranged to carry the first fluid therein; and a third pressure inlet communicating with the third pressure cavity for receiving a second fluid into the third pressure cavity, such that the first fluid may be exposed to a pressure signal received through the third pressure inlet without mixing of the first and second fluids; and a control mechanism operably connected to the third pressure inlet and adapted to selectively pressurize the third pulse generator to a degree so as to substantially close off flow through the third flow conduit.

[0025] According to another aspect of the invention, the fluid circulation system further includes equipment for treatment of a bodily fluid connected in series flow therewith.

[0026] According to another aspect of the invention, a method of generating a fluid pulse includes: passing a first fluid through a resilient first flow conduit arranged to carry the first fluid therein; and while the fluid is in the first flow conduit, introducing a pressurized second fluid into a first pressure cavity defined by a substantially rigid first body surrounding the first flow conduit, as to impress a predetermined time-varying pressure profile into the first fluid through the first flow conduit.

[0027] According to another aspect of the invention, the method includes passing the first fluid through a circulation pump connected in series flow relationship with the first flow conduit so as to impress a substantially constant pressure component in the first fluid.

[0028] According to another aspect of the invention, the method includes: passing the first fluid through a resilient second flow conduit arranged to carry the first fluid therein; introducing a pressurized second fluid into a second pressure cavity defined by a substantially rigid second body surrounding the second flow conduit; wherein the second flow conduit is cyclically compressed to a degree so as to substantially close off flow through the second flow conduit in coordination with the pressurization of the fluid in the first flow conduit, such that the first fluid is moved through the first and second flow conduits in a single direction.

[0029] According to another aspect of the invention, the first fluid is a bodily fluid, which is passed through equipment for treatment thereof.

[0030] According to another aspect of the invention, the first fluid is heated or cooled as it passes through the first flow conduit.

[0031] According to another aspect of the invention, the second fluid is at a lower pressure than the first fluid during at least a portion of the pressure profile.

BRIEF DESCRIPTION OF THE DRAWINGS

[0032] The invention may be best understood by reference to the following description taken in conjunction with the accompanying drawing figures in which:

[0033] Figure 1 is a schematic view of a prior art heart-lung bypass apparatus;

[0034] Figure 2 is a schematic view of a heart-lung bypass apparatus incorporating a pulse generator constructed in accordance with the present invention;

[0035] Figure 3 is a cross-sectional view of a first embodiment of a pulse generator;

[0036] Figure 4 is a cross-sectional view of a first variation of a flow conduit for use with the pulse generator of Figure 3;

[0037] Figure 5 is a cross-sectional view of another variation of a flow conduit;

[0038] Figure 6 is a cross-sectional view of another variation of a flow conduit;

[0039] Figure 7 is a cross-sectional view of yet another variation of a flow conduit;

[0040] Figure 8 is a schematic graph of a flow characteristic of the pulse generator in operation;

[0041] Figure 9 is a perspective, cut-away view of an alternative pulse generator;

[0042] Figure 10A is a graph illustrating the behavior of a pulse generator in a first condition;

[0043] Figure 10B is a graph illustrating the behavior of a pulse generator in a second condition;

[0044] Figure 10C is a graph illustrating the behavior of a pulse generator in a third condition;

[0045] Figure 11 is a schematic view of a heart-lung bypass apparatus illustrating an alternate control apparatus and method:

[0046] Figure 12 illustrates a portion of a flow circulation system incorporating multiple pulse generators;

[0047] Figure 13 illustrates a portion of an alternate flow circulation system incorporating multiple pulse generators; and

[0048] Figure 14 is a cross-sectional view of yet another variation of a flow conduit.

DETAILED DESCRIPTION OF THE INVENTION

[0049] Referring to the drawings wherein identical reference numerals denote the same elements throughout the various views, Figure 1 depicts a prior art heart-lung bypass apparatus 10 comprising treatment equipment 12 and a circulation pump 14. The treatment equipment 12 typically includes facilities for removing carbon dioxide and waste products, and supplying oxygen. The circulation pump 14 is most often a positive-displacement pump of the type referred to as a "peristaltic" pump. The apparatus 10 is connected to a patient "P" by an inlet line 16 and an outlet line 18.

[0050] In operation, blood circulates in a closed loop from the patient P to the treatment equipment 12 through the circulation pump 14 and back to the patient P. While efforts are made to select the flow rate and pressure of the circulation pump 14 to meet the patient's requirements, It has been found that the constant pressure flow from the pump 14 can result in unwanted side effects such as brain disorders (e.g. cognitive dysfunction).

[0051] Figure 2 depicts a heart-lung bypass apparatus 10' constructed according to the present invention. It should be noted that the present invention is equally applicable to other types of medical equipment, or any other fluid flow application requiring a pulsating flow. The apparatus 10' is similar to the prior art apparatus 10 and includes treatment equipment 12' and a circulation pump 14', and is connected to a patient "P" by an inlet line 16' and an outlet line 18'. The apparatus 10' also includes a pulse generator 20 connected downstream of the pump 14. The pulse generator 20, which is described in detail below, receives blood flow from the pump 14 and applies a cyclic pressure pulse thereto, so that the patient receives a pulsating flow which mimics the flow characteristics of the patient's heart. The pressure pulse is provided by a control and pressurization apparatus 22, including for example, a source of pressurized air such as the illustrated air tank 24, and a solenoid valve 26 controlled by a programmable electronic controller or computer of a known type, illustrated schematically at 28.

[0052] Figure 3 illustrates a first embodiment of the pulse generator 20 in more detail. The pulse generator 20 includes a relatively rigid body 30 which defines a pressure cavity 32 therein. A pressure inlet 34 is formed in the body 30. A flow conduit 36 having an inlet 38 and an outlet 40 passes through the body 30. The pressure cavity 32 is shaped so that a pressure signal applied thereto will be uniformly directed and will propagate symmetrically (with reduced pressure waveform reverberations). It is noted that the term "pressure signal" is used generally to refer to a fluid pressure having a preselected value, be that constant or time-varying, and that the absolute value of the pressure signal may be greater or lesser than the pressure within the flow conduit. In other words, a partial vacuum, relative to the fluid in the flow conduit 36, may be used as the pressure signal.

[0053] The interior of the flow conduit 36 is isolated from the pressure cavity 32 such that blood flowing therethrough will be subject to the prevailing pressure (i.e. positive pressure or vacuum) in the pressure cavity 32, but no mixing of the blood with the fluid in the pressure cavity 32 will take place. The path of the flow conduit 36 is chosen to expose a selected surface area to the pressure cavity 32 while minimizing the overall dimensions of the pulse generator 20. In the illustrated example, the flow conduit 36 is generally "S"-shaped, but it could also be straight, curved, coiled, looped or helical depending upon the particular application.

[0054] The flow conduit 36 is constructed of bio-compatible material of a known type, such as a medical-grade elastomer. The cross-section of the flow conduit 36 may be a simple circular shape as in ordinary tubing, or it may be a more complex shape. The mechanical response of the flow conduit 36 may be customized so that it exhibits the desired qualities in terms of volume, resilience, collapsibility, expansibility, capacitance, and restitution.

[0055] Figure 4 illustrates an example of a flow conduit 136 having a box-section shape with walls 138 extending between radiused corners 140, while Figure 5 illustrates another flow conduit 236 with a wall 238 defining a pair of spaced-apart lobes 240 connected by a pinched waist 242.

[0056] Figures 6 and 7 illustrate two variations 336 and 336' of yet another flow conduit in which a closed wall is curved into a "C"-shape. The free ends of the "C" are connected by a flexible bridges 338 and 338', respectively. In the variation shown in Figure 6, the working fluid (e.g. blood) flows through the central opening 340. The C-shaped portion may be of a hollow, double-wall construction as shown, or the wall structure may be customized by including a solid (e.g. honeycomb or web), liquid, or gas filler, or by making the C-shaped portion a relatively thick solid wall.

[0057] In the variation shown in Figure 7, working fluid flow through the double-walled C-shaped portion of the flow conduit 336', and the central opening 340' serves as a chamber that can act as a resilient "gas spring" to control recovery rates. It can also be provided with a time-varying pressure signal to further customize its response.

[0058] Figure 14 illustrates yet another flow conduit 736 in which a wall defines a plurality of spaced-apart, radially-extending lobes 738. The lobes 738 have rounded outer ends 740 and are interconnected at their inner ends by concavecurved transitional sections 742. This results in a generally star-shaped central opening 744.

[0059] It should be generally noted the cross-sectional geometry of any of the described tube sections (radii, wall thicknesses, material properties) can be modified to achieve desired collapse and restoration properties. The tube sections perform as a collapsible beam and structural engineering techniques (2D and 3D) can therefore be applied to advantageously customize the design and dimensional parameters.

[0060] Referring again to Figure 2, the pulse generator 20 operates in series flow with the circulation pump 14. The pulse generator 20 receives the blood or other working fluid. A cyclic fluid pressure pulse (signal) is provided by the control and pressurization apparatus 22 through the inlet 38. As the pressure increases in the body 30, it compresses the flow conduit 36 and the fluid inside, increasing the fluid's pressure. When the pressure pulse is terminated, the flow decreases in pressure. A vacuum component or negative pressure signal may then be applied subsequent to the positive pressure pulse. This may be used to assist in restoration of the flow conduit 36 to its original state in between positive pressure pulses. It should be noted that the operating characteristics of circulation pump 14 prevent any substantial backflow in this apparatus Therefore, no check valves are required for the pulse generator 20.

[0061] Figure 8 illustrates an example of the flow characteristics that can be obtained. The dashed line 42 represents the essentially constant pressure output of the circulation pump 14, while the solid line 44 represents the total pressure after the fluid passes through the pulse generator 20. Appropriate feedback signals are provided to the controller 28, representative of the output of the apparatus 10'. In the illustrated example, the flow has a pulsating pressure with peaks 46 occurring at regular intervals. A quasi-square-wave flow characteristic is shown; however, by careful selection of the properties of the body 30, flow conduit 36, and the pressure pulses, almost any wave shape desired can be obtained. This allows the apparatus 10' to closely simulate the flow characteristics of the patient's heart or to generate specific preferred waveforms as determined by the physician or technician involved in a particular procedure. It is thought that this will eliminate or reduce undesirable affects, including brain disorders, normally associated with heart-lung bypass equipment.

[0062] Heating or cooling of bypass blood flow is sometimes done during heart bypass surgery. In the prior art, this is performed with a separate heat exchanger. It should be noted that it is entirely practical to use the pressure transmission fluid chamber, the rigid body 30 as a heat transfer chamber such that the fluid flowing through the flow conduit 36 is heated or cooled depending on the procedure requirement. With this configuration, it would be possible to consolidate the pulse generator 20 and heat exchanger into one device, thereby reducing complexity and reducing the amount of blood required outside the patient's body to fill the system while also reducing blood-wetted surface of the apparatus 10'.

[0063] The pulse generator 20 has a finite capacity for pulse generation. In other words, the pressure, volume, and total work input capacity are each limited by the pulse generator's construction and power source. The circulation pump 14' typically has a substantially constant output pressure and flow at a given input RPM. The flow demands from the patient on the bypass apparatus 10' may vary during the course of a medical procedure. Using the feedback control described above, the behavior of the pulse generator 20 (i.e. its stroke length, acceleration, and velocity) will vary over a wide range to result in the desired total output flow characteristics.

[0064] Figures 10A, 10B, and 10C are graphs depicting the total displacement range of the pulse generator 20 between upper and lower limits noted as "H" and "L", respectively, and illustrating the pulse generator's behavior under different conditions, assuming a fixed input RPM to the circulation pump 14'. For example, if the patient demand should be relatively high, the pulse generator 20 will have to operate in a range "R1" near the upper end of its displacement capacity, as shown in Figure 10A. if the patient demand should be relatively low, the pulse generator 20 will have to operate in a range "R2" near the lower end of its displacement capacity, as shown in Figure 10B. If the patient demand is near nominal, the pulse generator 20 will operate in a "nominal" range "R3" near the center its displacement capacity, as shown in Figure 10C.

[0065] The pulse generator 20 can be forced to operate in a the nominal range R3 in order to provide a good margin of stroke or pulse volume on the compression cycle and a good margin of recovery volume on the expansion cycle, and thus achieve more consistent overall performance.

[0066] This is achieved by including both the circulation pump 14' and the pulse generator 20 in a control loop. Figure 11 depicts a heart-lung bypass apparatus 110 which is substantially identical to the apparatus 10' described above except for the method of control. The apparatus 110 includes treatment equipment 112, a circulation pump 114, inlet and outlet lines 116 and 118 connected to a patient "P", a pulse generator 120 and a control and pressurization apparatus 122, including a programmable electronic controller or computer of a known type, illustrated schematically at 128. Feedback signals (e.g. pressure, volume) representative of the total flow output to the patient are provided to the controller 128 by sensors 130, and feedback signals indicative of the range of operation of the pulse generator 120 (e.g. displacement) are provided to the controller 128 by sensors 132. The controller 128 is operatively connected to both the circulation pump 114 and the pulse generator 120.

[0067] Control of the total flow output to the patient P is as described for the apparatus 10' described above. However, the controller 128 also monitors the pulse generator 120 to determine if it is operating in its desired nominal range R3 (see Figure 10C). If not, the output of the circulation pump 114 is changed to achieve the desired pulse generator behavior, by modifying the input RPM of the circulation pump 114 or other appropriate means. For example, if the pulse generator 120 is operating in a "high" range R1 to satisfy patient demand, then the flow of the circulation pump 114 would be increased so that the pulse generator 120 operation shifts back down to the desired range R3.

[0068] Figure 9 illustrates a second embodiment of a pulse generator 420, which may be substituted for the pulse generators described above, in more detail. The pulse generator 420 includes a hollow, open-ended rigid housing 422 with an inlet 424 and an outlet 426. A flexible diaphragm 428 seals off the housing 422. The housing 422 and the diaphragm 428 are constructed of bio-compatible materials such as medical-grade plastics. The diaphragm 428 may have a partial toroidal shape as illustrated or other shape effective to minimize or eliminate lost motion (e.g. later movement) as the diaphragm 428 moves through its working range. The diaphragm 428 may also include one or more radially-extending reinforcing ribs (not shown) on its inner or outer surface (or both). The ribs, if used, stiffen the diaphragm and help it to resist compressive loads, which would occur if a vacuum were applied to the diaphragm 428. A piston 430 has a first end 432 connected to the diaphragm 428 and a second end 434 connected to a known type of linear electric motor or other suitable actuator 436. Inward motion of the diaphragm 428 increases the pressure in the fluid flowing through the pulse generator 420, which outward motion decreases the pressure.

[0069] The linear motor 436 is driven by a programmable controller 438 of a known type such as a PLC or general-purpose computer. The controller 438 is able to control the displacement, velocity, and acceleration of the piston 430 so as to obtain selected flow characteristics as described above, including positive pressure and/or vacuum pulses. The control loop described above may also be applied when using the pulse generator 420. It should be noted the housing 422 chamber bottom may be shaped similar (such as the top section of a torus) to the preshaped membrane in order to better disperse fluid impulse energy and reduce system volume requirements.

[0070] The pulse generators 20 have been described as separate units for use with circulation pumps. They may also be used as stand-alone units to provide check-valve or pumping functions by scaling, connecting, and/or combining them appropriately.

[0071] For example, Figure 12 illustrates a portion of a flow circulation system comprising a circulation pump 514 of a type such as a peristaltic pump, a first pulse generator 520A, a second pulse generator 520B, and a control and pressurization unit 522. The pulse generators 520 are substantially identical in their operation to the pulse generators 20 described above. They may have individual housings as described above, or they may take the form of chambers within a single rigid housing 524. In this configuration, the first pulse generator 520A is activated so that it acts as a check valve during the output pulse cycle to prevent back flow from the second pulse generator 520B. That is, the flow channel therein (not shown) is deflected to a degree that it is closed or nearly closed to flow therethrough when the second pulse generator 520B is discharging. It does so in a way that limits the localized acceleration / deceleration of the blood flow and/or reduces the shear stress of the blood flow within the blood flow tube.

[0072] Figure 13 illustrates a portion of an alternate flow circulation system comprising a first pulse generator 620A, a second pulse generator 620B, an optional third pulse generator 620C, and a control and pressurization unit 622. The pulse generators 620 are substantially identical in their operation to the pulse generators 20 described above. They may have individual housings as described above, or they may take the form of chambers within a single rigid housing 624. In this configuration, the first pulse generator 620A is activated so that it acts as a check valve during the output pulse cycle to prevent back flow from the second pulse generator 620B. That is, the flow channel therein (not shown) is deflected to a degree that it is closed or nearly closed to flow therethrough when the second pulse generator 620B is discharging. If the third pulse generator 620C is used, it is also activated in sequence with the first and second pulse generators 620A and

620B. For example, the third pulse generator 620C would be "open" when the second pulse generator 620B is discharging. In this system, the pulse generators 620 act as a pump and do not require a separate circulation pump to achieve the desired blood flow.

[0073] The arrangements illustrated in Figures 12 and 13 have several advantages over flow systems using conventional check valves. Their operation induces low levels of stress to the blood to prevent the formation of mircobubbles during the suction cycle. A relatively small blood volume is required for suitable performance. For example, the individual chambers may having volume flow capacities from about 30ml to about 150ml. They also produce low thrombogenic response and low levels of platelet activation compared to conventional check valves. They also avoid fluttering of blood pressure (i.e. "hammering") of flow in the outlet tubing.

[0074] The pulse generators described herein have the ability to generate a blood pulse that can reside on top of a steady pump pulse during medical procedures such as heart transplant, kidney dialysis, and the like. This has the potential to relieve steady pressure induced brain disorders and to allow procedures to last longer, such as when physicians wish to keep the patient on a bypass system for several weeks to allow the patient's heart to rest and restore itself.

[0075] The foregoing has described a pulse generator and a method of creating a pulsating flow in a fluid. While specific embodiments of the present invention have been described, it will be apparent to those skilled in the art that various modifications thereto can be made without departing from the spirit and scope of the invention. Accordingly, the foregoing description of the preferred embodiment of the invention and the best mode for practicing the invention are provided for the purpose of illustration only and not for the purpose of limitation.

WHAT IS CLAIMED IS:

1. A pulse generator for fluid flow, comprising:

(a) a substantially rigid body defining a pressure cavity;

(b) a resilient flow conduit extending through the pressure cavity and arranged to carry a first fluid therein; and

(c) a pressure inlet communicating with the pressure cavity for introducing a second fluid into the pressure cavity, such that the first fluid may be exposed to a time-varying pressure signal introduced through the pressure inlet without mixing of the first and second fluids.

2. The pulse generator of claim 1 in which the flow conduit is generally S-shaped.

3. The pulse generator of claim 1 in which the flow conduit has a four-sided cross-sectional shape defined by spaced-apart walls extending between radiused corners.

4. The pulse generator of claim 1 in which the flow conduit has a cross–sectional shape including a pair of spaced-apart lobes connected by a pinched waist.

5. The pulse generator of claim 1 in which the flow conduit has a cross–sectional shape including a pair of spaced-apart lobes connected by a pinched waist.

6. The pulse generator of claim 1 in which the flow conduit has a cross–sectional shape including a plurality of spaced-apart, radially-extending lobes.

7. The pulse generator of claim 1 in which the flow conduit has a cross–sectional shape including:

(a) a double-walled, generally C-shaped portion; and a plurality of spaced-apart, a flexible bridge connecting free ends of the C-shaped portion;

(b) wherein the C-shaped portion and the flexible bridge cooperate to define a central opening.

8. The pulse generator of claim 1 wherein the pressure cavity is shaped such that a pressure signal applied thereto will propagate symmetrically therein.

9. A pulse generator for fluid flow, comprising:

(a) a substantially rigid housing which defines an open cavity, the housing including an inlet and outlet communicating with the cavity;

(b) a flexible diaphragm which closes off the cavity; and

(c) an actuator operably connected to the diaphragm and adapted to selectively move the diaphragm from a first position in which the pulse generator encloses a first fluid volume, and a second position in which the pulse generator encloses a second fluid volume less than the first fluid volume.

10. The pulse generator of claim 9 in which the diaphragm forms a portion of a torus.

11. The pulse generator of claim 9 further including a programmable controller operably connected to the actuator.

12. A fluid circulation system, comprising:

(a) a circulation pump for a first fluid;

(b) a first pulse generator disposed in series flow with the circulation pump, the first pulse generator including:

(i) a substantially rigid first body defining a first pressure cavity;

(ii) a resilient first flow conduit extending through the first pressure cavity and arranged to carry the first fluid therein; and

(iii) a first pressure inlet communicating with the first pressure cavity for receiving a second fluid into the first pressure cavity, such that the first fluid may be exposed to a pressure signal received through the first pressure inlet without mixing of the first and second fluids; and

(c) a control mechanism operably connected to the first pressure inlet and adapted to introduce a pressure signal into the first pressure cavity so as to impress a predetermined time-varying pressure profile into the first fluid through the first flow conduit.

13. The fluid circulation system of claim 12 in which the circulation pump is a type generating a substantially constant output pressure in the first fluid.

14. The fluid circulation system of claim 12 in which the control mechanism includes:

(a) a source of pressurized fluid; and

(b) a valve operable to selectively transfer the pressurized fluid to the first pressure inlet.

15. The fluid circulation system of claim 12 in which the first pulse generator has a displacement capacity, and in which the control mechanism is adapted to control the circulation pump and the first pulse generator such that the first pulse generator operates in a preselected displacement range within the displacement capacity.

16. The fluid circulation system of claim 12 further including:

(a) a second pulse generator disposed in series flow with the circulation pump and the first pulse generator, the second pulse generator including:

(i) a substantially rigid second body defining a second pressure cavity;

(iii) a resilient second flow conduit extending through the second pressure cavity and arranged to carry the first fluid therein; and

(b) a second pressure inlet communicating with the second pressure cavity for receiving a second fluid into the second pressure cavity, such that the first fluid may be exposed to a pressure signal received through the second pressure inlet without mixing of the first and second fluids;

wherein the control mechanism is operable to selectively pressurize the second pulse generator to a degree so as to substantially close off flow through the second flow conduit.

17. The fluid circulation system of claim 12 further comprising equipment for treatment of a bodily fluid connected in series flow therewith.

18. A fluid circulation system, comprising:

(a) a first pulse generator including:

(i) a substantially rigid first body defining a first pressure cavity;

(ii) a resilient first flow conduit extending through the first pressure cavity and arranged to carry the first fluid therein; and

(iii) a first pressure inlet communicating with the first pressure cavity for receiving a second fluid into the first pressure cavity, such that the first fluid may be exposed to a pressure signal received through the first pressure inlet without mixing of the first and second fluids; and

(b) a second pulse generator connected in series flow with the first pulse generator, and including:

(i) a substantially rigid second body defining a second pressure cavity;

(ii) a resilient second flow conduit extending through the second pressure cavity and arranged to carry the first fluid therein; and

(iii) a second pressure inlet communicating with the second pressure cavity for receiving a second fluid into the second pressure cavity, such that the first fluid may be exposed to a pressure signal received through the second pressure inlet without mixing of the first and second fluids; and

(c) a control mechanism operably connected to the first and second pressure inlets and adapted to:

(i) cyclically pressurize one of the first pulse generator so as to impress a predetermined time-varying pressure profile into the first fluid; and

(ii) cyclically pressurize the second pulse generator to a degree so as to substantially close off flow through the second flow conduit in coordination with the pressurization of the first pulse generator, such that the first fluid is moved through the fluid circulation system in a single direction.

19. The fluid circulation system of claim 18 further comprising:

(a) a third pulse generator connected in series flow with the first and second pulse generators, and including:

(i) a substantially rigid third body defining a third pressure cavity;

(ii) a resilient third flow conduit extending through the third pressure cavity and arranged to carry the first fluid therein; and

(iii) a third pressure inlet communicating with the third pressure cavity for receiving a second fluid into the third pressure cavity, such that the first fluid may be exposed to a pressure signal received through the third pressure inlet without mixing of the first and second fluids; and

(b) a control mechanism operably connected to the third pressure inlet and adapted to selectively pressurize the third pulse generator to a degree so as to substantially close off flow through the third flow conduit.

20. The fluid circulation system of claim 18 further comprising equipment for treatment of a bodily fluid connected in series flow therewith.

21. A method of generating a fluid pulse, comprising:

(a) passing a first fluid through a resilient first flow conduit arranged to carry the first fluid therein; and

(b) while the first fluid is in the first flow conduit, introducing a pressurized second fluid into a first pressure cavity defined by a substantially rigid first body surrounding the first flow conduit, as to impress a predetermined time-varying pressure profile into the first fluid through the first flow conduit.

22. The method of claim 21, further comprising:

passing the first fluid through a circulation pump connected in series flow relationship with the first flow conduit so as to impress a substantially constant pressure component in the first fluid.

23. The method of claim 21, further comprising:

(a) passing the first fluid through a resilient second flow conduit arranged to carry the first fluid therein;

(b) introducing a pressurized second fluid into a second pressure cavity defined by a substantially rigid second body surrounding the second flow conduit;

wherein the second flow conduit is cyclically compressed to a degree so as to substantially close off flow through the second flow conduit in coordination with the pressurization of the fluid in the first flow conduit, such that the first fluid is moved through the first and second flow conduits in a single direction.

24. The method of claim 21, wherein the first fluid is a bodily fluid, further comprising passing the first fluid through equipment for treatment thereof.

25. The method of claim 21, further comprising heating or cooling the first fluid as it passes through the first flow conduit.

26. The method of claim 21, wherein the second fluid is at a lower pressure than the first fluid during at least a portion of the pressure profile.

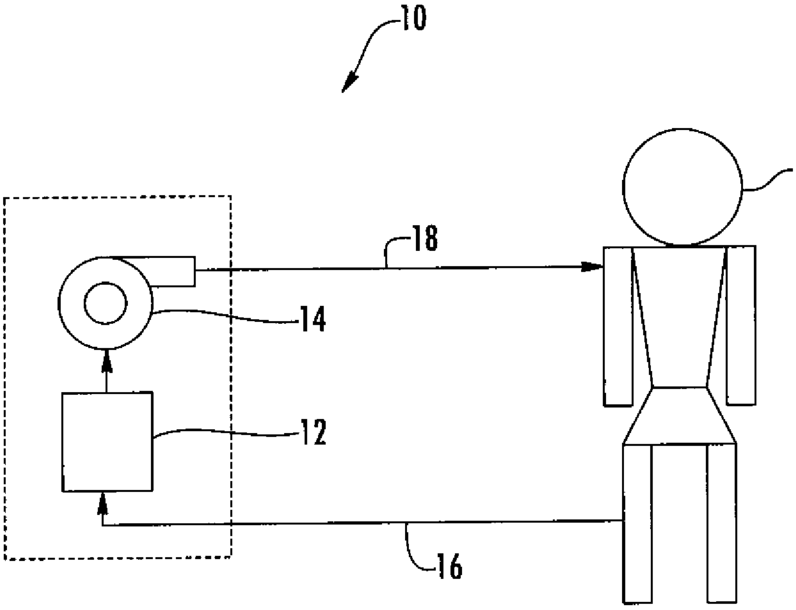

FIG. 1
(PRIOR ART)

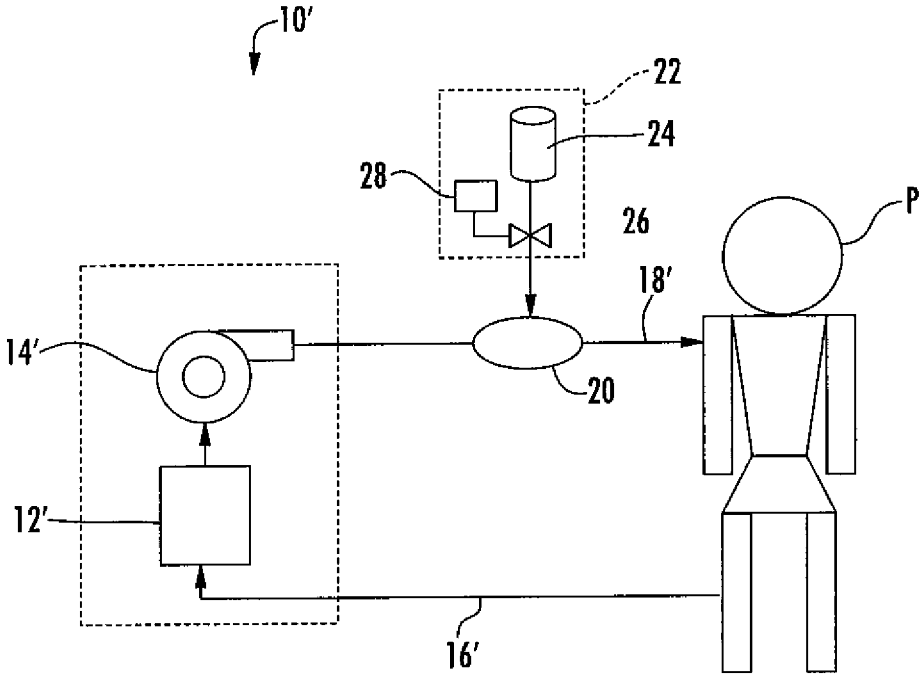

FIG. 2

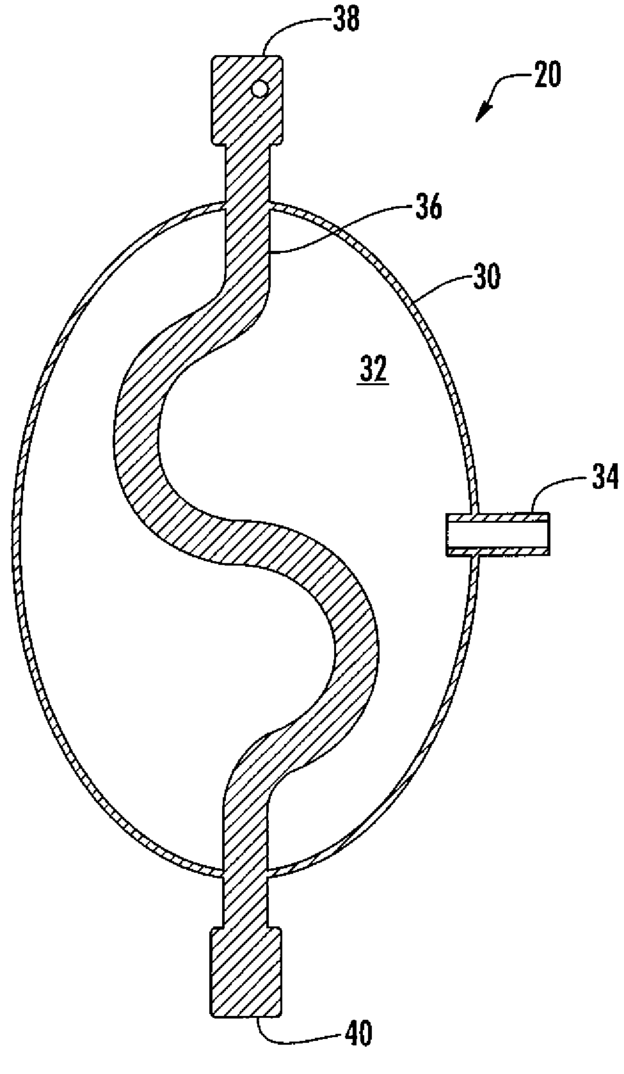

FIG. 3

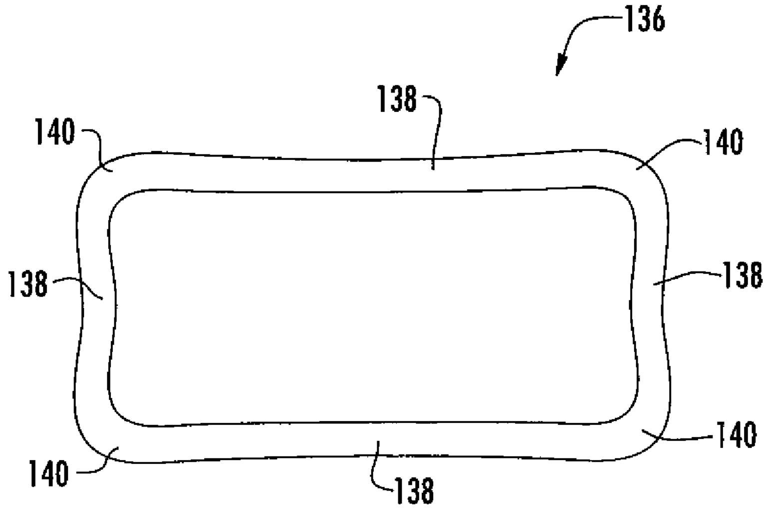

FIG. 4

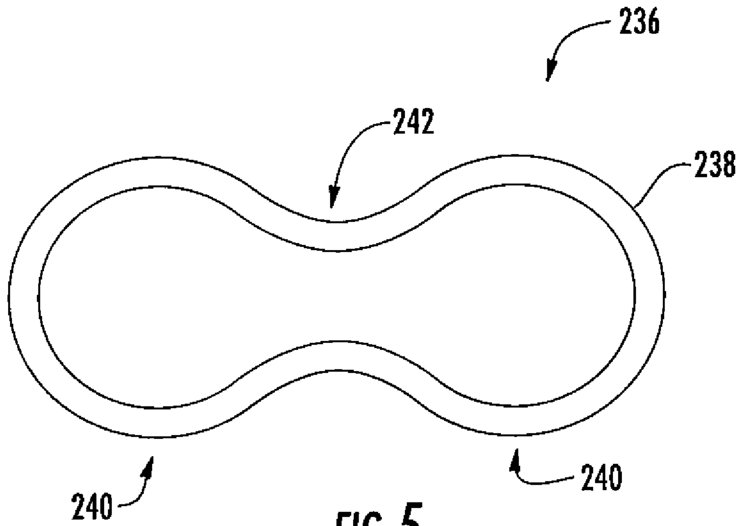

FIG. 5

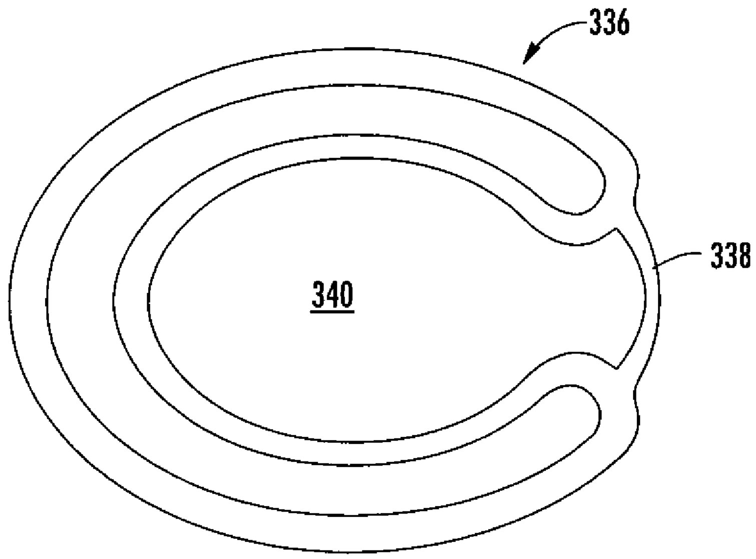

FIG. 6

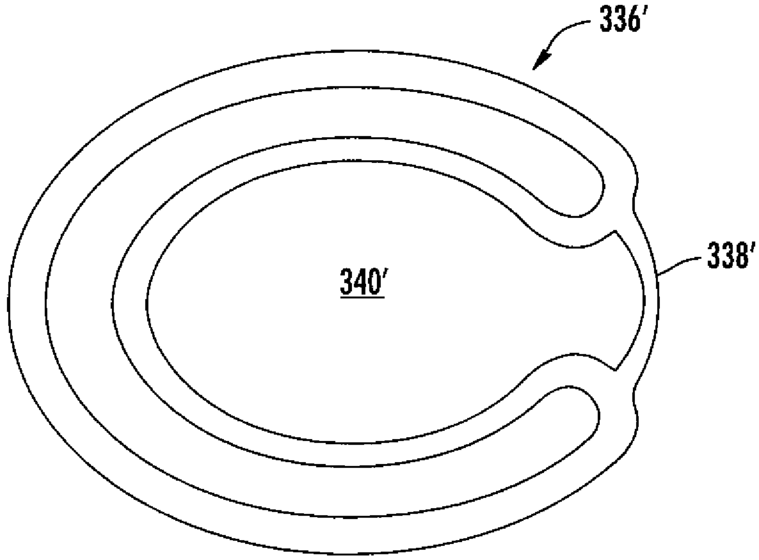

FIG. 7

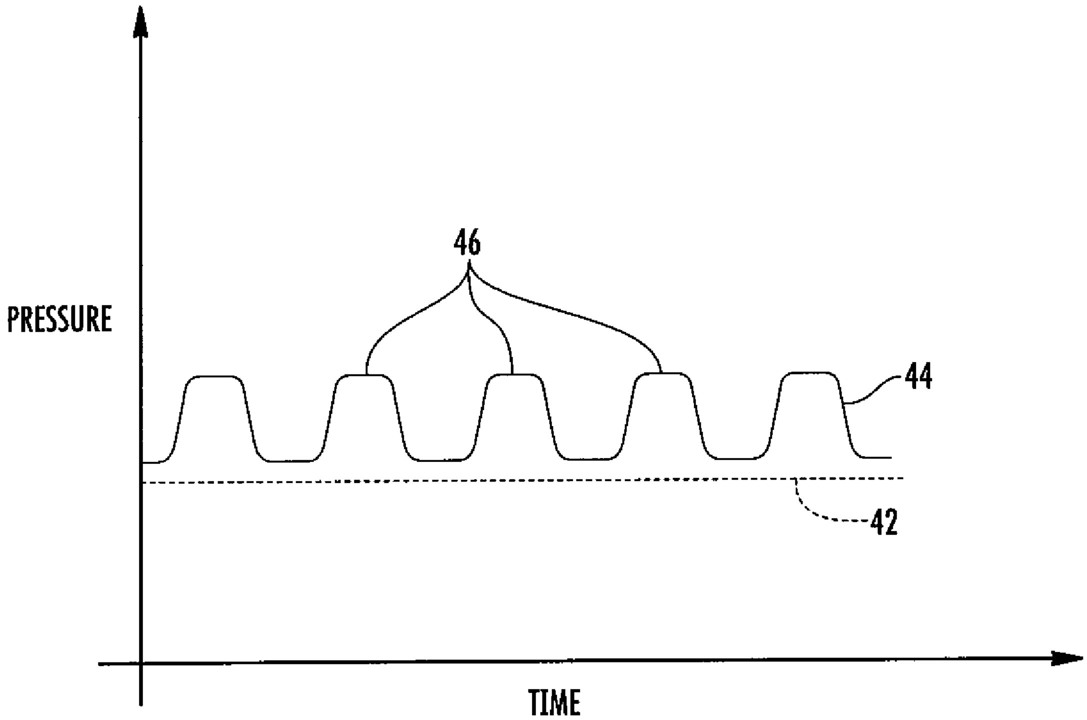

FIG. 8

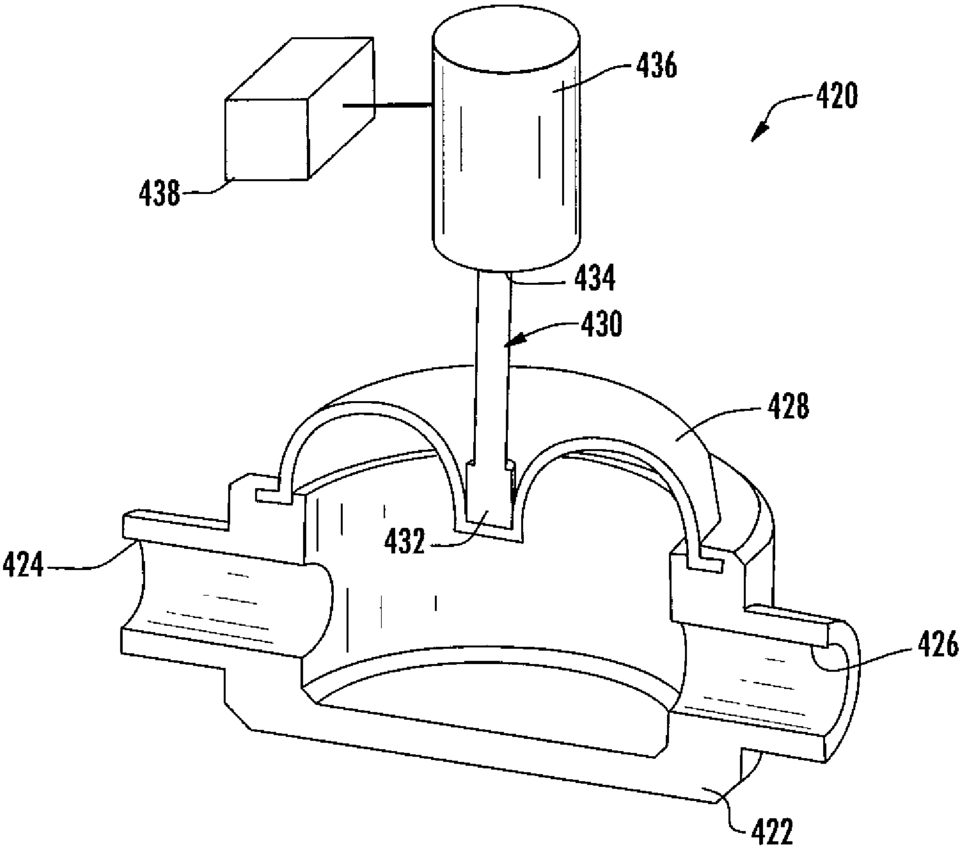

FIG. 9

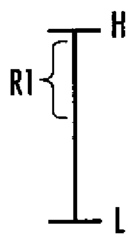

FIG. 10A

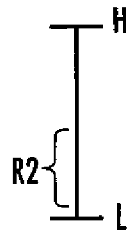

FIG. 10B

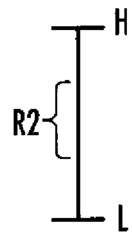

FIG. 10C

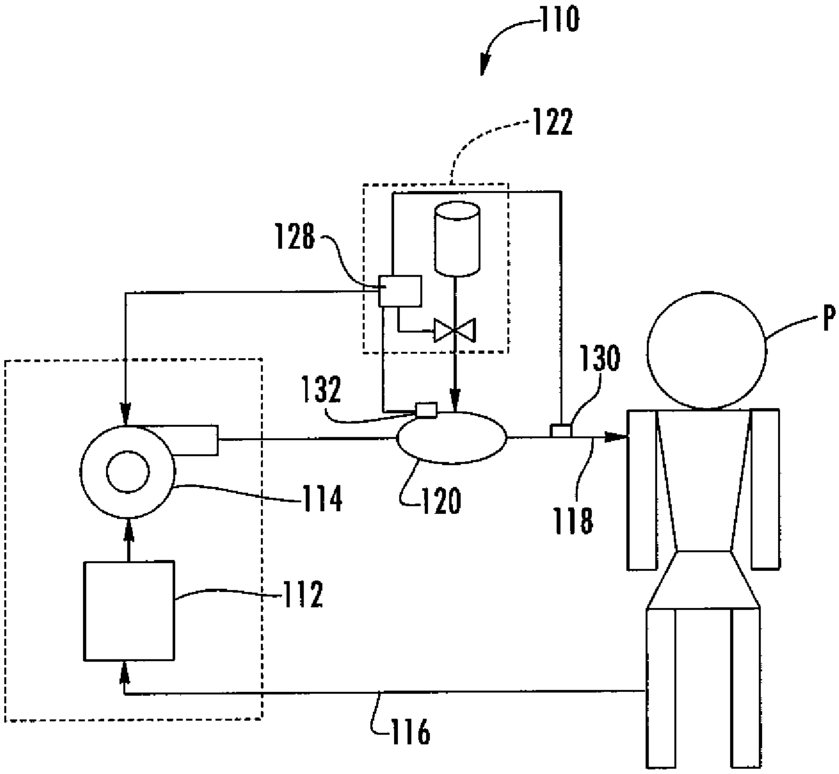

FIG. 11

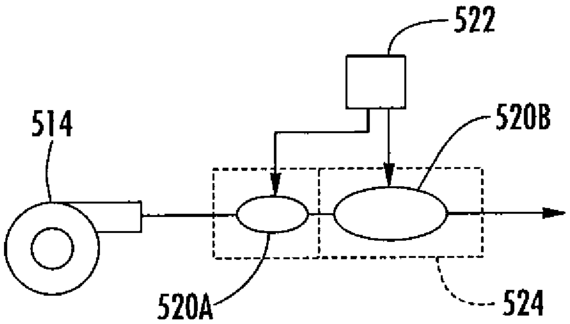

FIG. 12

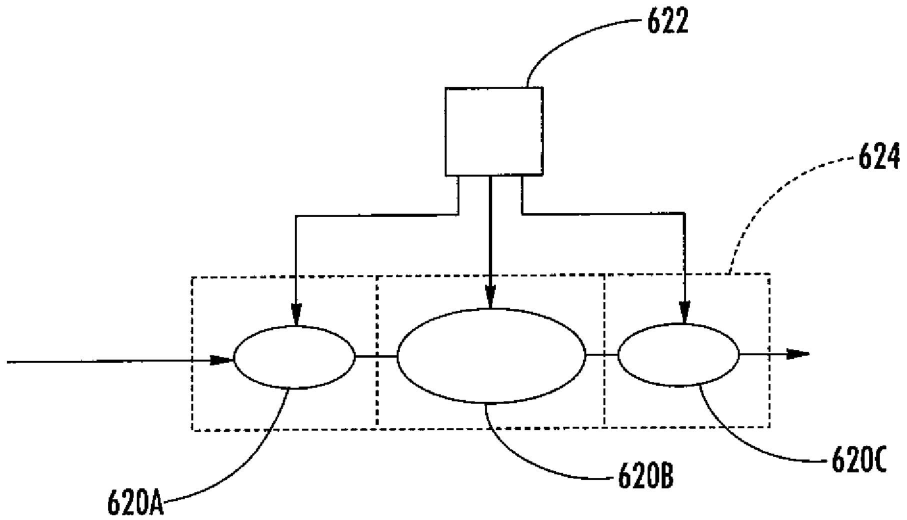

FIG. 13

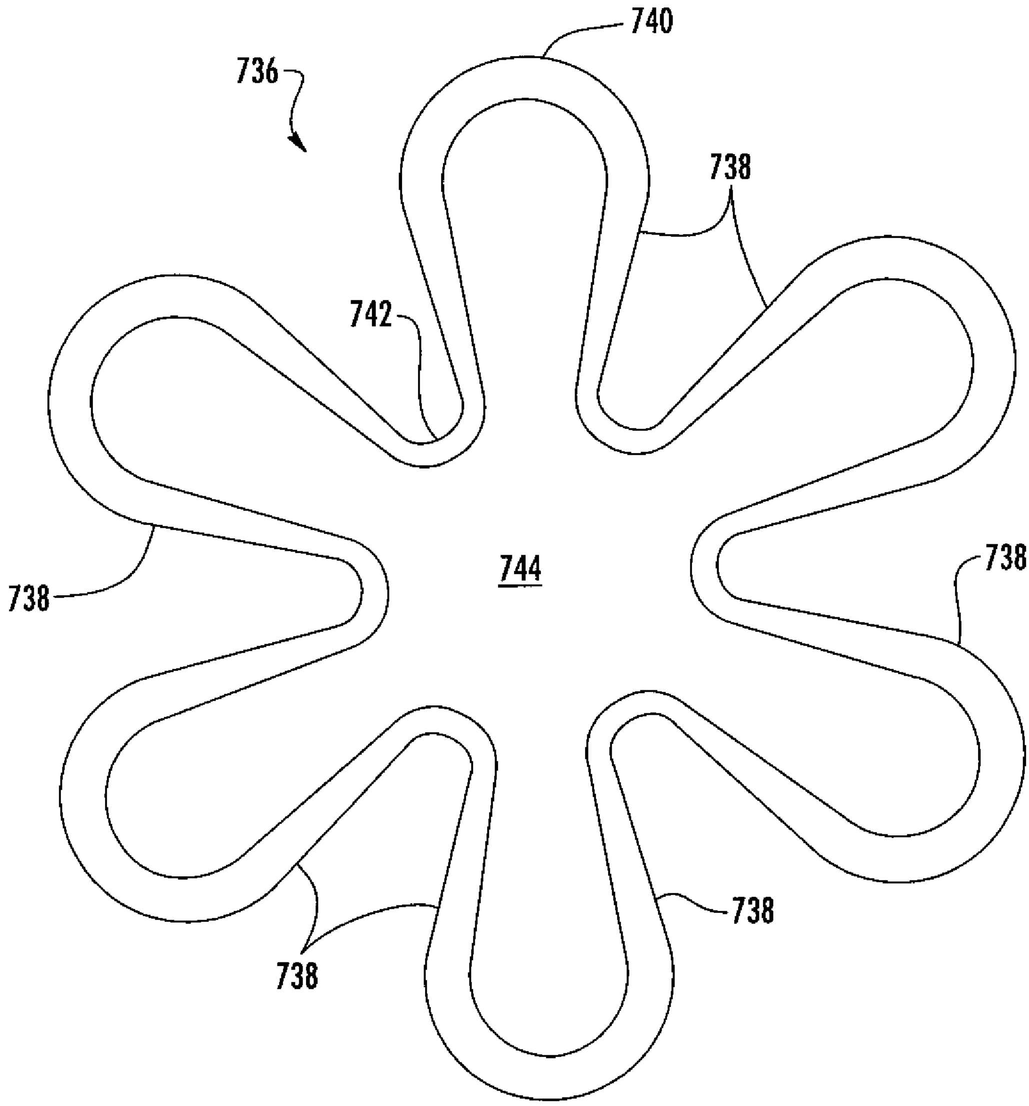

FIG. 14