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(54) **Title**: SYSTEM AND METHOD FOR PUMP VARIABLE STROKE

(57) **Abstract**: Systems and methods for providing a variable pumping stroke from a pump comprising a pumping chamber, a pump inlet, a pump outlet, a valving mechanism, and a drive piston.

DESCRIPTION

SYSTEM AND METHOD FOR PUMP VARIABLE STROKE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of priority to U.S. Patent Application Serial No. 12/425,076, filed April 16, 2009, the entire contents of which are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

Embodiments of the present invention generally relate to pumps. More specifically, and not by way of limitation, embodiments of the present invention relate to positive displacement pumps for the circulation of fluids.

2. Description of Related Art

Many natural and manmade fluids contain molecules that can be damaged or destroyed by excessive shearing strains or stagnation that can occur in devices that attempt to pump these fluids. Fluids containing molecules with high molecular weights such as proteins, long stranded synthetic polymers, DNA, RNA, or fluids such as blood, which contain concentrations of delicate cells, are especially susceptible to being compromised by many conventional pumping techniques.

Typical axial flow and centrifugal pumps operate by rotating an impeller at very high speeds, often exceeding 12,000 RPM. The shearing stresses that can arise at these velocities can strain larger fluid molecules until they break, leading to destruction or undesirable alteration of the pumping medium. For instance, it is well documented that the pumping of blood using centrifugal and axial flow pumps shears the phospholipid bilayer of erythrocytes and platelets to the point of lysing the cells and releasing their cytosolic proteins and organelles into the blood stream. This phenomenon, known as hemolysis, is an issue in the field of artificial blood circulation because the releasing of hemoglobin into the blood stream can cause kidney failure in patients who receive this blood. Thus, there is useful need for pump designs that can provide fluid circulation without damaging a delicate pumping medium such as blood.

Further objects and advantages of this system and method will become apparent from a consideration of the drawings and ensuing description.

SUMMARY OF THE INVENTION

Embodiments of the present disclosure provide systems and methods for pumping fluids. While certain embodiments may be particularly suited for pumping delicate fluids with low shearing strains, it is understood that embodiments of the present disclosure are not limited to pumping such fluids. Other embodiments may be used to pump fluids that are not delicate or do not have low shearing strains.

Certain embodiments comprise: a pumping chamber forming a loop; a pump inlet in fluid communication with the pumping chamber; a pump outlet in fluid communication with the pumping chamber; a first piston disposed within the pumping chamber; a second piston disposed within the pumping chamber; an electric motor; and an electromagnet, wherein the system is configured such that during operation: the electromagnet is initially coupled to the first piston; the electric motor is initially coupled to the second piston; the electromagnet is subsequently coupled to the second piston; and the electric motor is subsequently coupled to the first piston. In certain embodiments, the electromagnet is coupled to either the first or second piston when the electromagnet is energized and the electromagnet is not coupled to either the first or second piston when the electromagnet is de-energized. Certain embodiments further comprise a magnetic ring, and are configured such that during operation: the electric motor exerts a first magnetic force on the first piston; the magnetic ring exerts a second magnetic force on the first piston; and the first magnetic force opposes the second magnetic force. In certain embodiments, the magnetic ring and/or the pistons comprise a permanent magnet or Halbach array. In certain embodiments, the system is configured such that during operation: the motor comprises a rotor with a magnetic link (which may comprise a permanent magnet or Halbach array) and the magnetic link is initially coupled to the second piston and subsequently coupled to the first piston.

Certain embodiments are configured such that during operation a portion of the magnetic link extends beyond a leading face of the piston. In certain embodiments, the system is configured such that during operation the pump inlet is inserted into a ventricle and the pump outlet is in fluid communication with the ascending aorta, the descending aorta, or a pulmonary artery. In certain embodiments, the system is configured such that: the motor comprises a rotor coupled to a linking arm; the linking arm is coupled to a first magnet,

wherein the first magnet is located on a first side of the piston during operation; the linking arm is coupled to a second magnet, wherein the second magnet is located on a second side of the piston during operation; and the first side is opposed to the second side. In certain embodiments, the first piston or the second piston comprise a hydrodynamic bearing surface.

Other embodiments comprise a method of pumping a fluid, the method comprising: providing a pumping chamber, wherein the pumping chamber contains the fluid; providing a pump inlet in fluid communication with the pumping chamber; providing a pump outlet in fluid communication with the pumping chamber; providing a first piston disposed within the pumping chamber; providing a second piston disposed within the pumping chamber; providing an electric motor comprising a rotor; providing an electromagnet; coupling the electromagnet to the first piston; coupling the rotor to the second piston; holding the first piston in a first location with the electromagnet; rotating the rotor and moving the second piston closer to the first piston so that a portion of the fluid is forced out of the pump outlet; de-energizing the electromagnet and uncoupling the electromagnet from the first piston; energizing the electromagnet so that it couples to the second piston; and coupling the rotor to the first piston. Certain embodiments further comprise rotating the rotor and moving the first piston closer to the second piston so that a portion of the fluid is forced out of the pump outlet. In certain embodiments, the first location is between the pump inlet and the pump outlet.

Still other embodiments comprise: a pumping chamber comprising an inner surface forming a loop; a pump inlet in fluid communication with the pumping chamber; a pump outlet in fluid communication with the pumping chamber; a piston disposed within the pumping chamber; and a first electric motor magnetically coupled to the piston, wherein: the piston comprises a hydrodynamic bearing surface configured to repel the piston away from the inner surface as the piston moves within the pumping chamber. In certain embodiments, the loop is centered about a central axis; the piston comprises an upper surface, a lower surface, an inner surface, an outer surface, a leading face, and a trailing face; and the inner surface comprises an upper wall, a lower wall, an inner wall and an outer wall.

In certain embodiments, during operation: a first lower gap exists between the lower surface and the lower wall proximal to the leading face; a second lower gap exists between the lower surface and the lower wall proximal to the trailing face; the first lower gap is larger than the second lower gap; a first upper gap exists between the upper surface and the upper wall proximal to the leading face; a second upper gap exists between the upper surface and

the upper wall proximal to the trailing face; and the first upper gap is larger than the second upper gap. In certain embodiments, a portion of the lower surface is not perpendicular to the central axis and a portion of the upper surface is not perpendicular to the central axis.

In certain embodiments, a first outer gap exists between the outer surface and the outer wall proximal to the leading face; a second outer gap exists between the outer surface and the outer wall proximal to the trailing face; and the first outer gap is larger than the second outer gap. Certain embodiments comprise a pinch valve between the pump inlet and the pump outlet. Certain embodiments also comprise a second piston disposed within the pumping chamber, and a second electric motor coupled to the second piston, wherein the second piston comprises a hydrodynamic bearing surface configured to repel the second piston away from the inner surface as the second piston moves within the pumping chamber.

Certain embodiments comprise: a power supply; a driver circuit electrically coupled to the electric motor and the power supply; a microprocessor electrically coupled to the driver circuit; and a sensor for sensing a position of the piston within the pumping chamber, wherein: the driver circuit is configured to selectively couple the power supply to the electric motor upon receiving a control signal; the sensor is electrically connected to the microprocessor; the microprocessor is configured to interpret the position from the sensor; the microprocessor is configured to output the control signal to the driver circuit. In certain embodiments, a position and a velocity of the piston are controlled to produce a predetermined waveform in an outlet flow from the pump outlet. Certain embodiments comprise a fluid within the pumping chamber and a sensor configured to measure a property of the fluid. In certain embodiments, the piston or inner surface comprise one or more of the following: a nanoparticulate surface, a microporous coating, or a fibrous flocking. In certain embodiments the nanoparticulate surface, microporous coating, or fibrous flocking are configured to facilitate endothelial or pseudoneointimal protein or cell aggregation.

Certain embodiments comprise a pacemaker and a microprocessor, wherein: the pacemaker comprises one or more electrodes electrically coupled to a heart; the pacemaker is electrically coupled to the microprocessor; the pacemaker provides a depolarization output to the one or more electrodes; and the heart is controlled to contract at a predetermined time relative to an actuation stroke of the pump. Certain embodiments comprise a sensor, wherein the sensor is configured to sense a physiological parameter and the system is configured to increase or decrease a volumetric flow rate from the pumping chamber based on the physiological parameter. In certain embodiments the sensor comprises one or more electrodes

for measuring thoracic impedance, p-wave activity, renal sympathetic nerve activity, or aortic nerve activity. In other embodiments, the sensor comprises an accelerometer for sensing heart contraction, diaphragm motion, bodily inclination, or walking pace.

Certain embodiments comprise a pump for circulating fluid comprising: a pumping chamber; a pump inlet in fluid communication with the pumping chamber; a pump outlet in fluid communication with the pumping chamber; a drive piston disposed within the pumping chamber; and a hollow valve sleeve configured to recess into the pump outlet.

Other embodiments comprise: a pumping chamber forming a loop; a pump inlet in fluid communication with the pumping chamber; a pump outlet in fluid communication with the pumping chamber; a piston disposed within the pumping chamber; an electric motor comprising a rotor coupled to a shaft; a magnet coupled to an end of the shaft; a sensor proximal to the magnet; and a control system, wherein: the electric motor is magnetically coupled to the piston; the magnet produces a magnetic vector that rotates with the rotor; the sensor is configured sense the magnetic vector; and the control system is configured to determine the angular position of the rotor. In certain embodiments, the sensor is a 2-axis Hall effect sensor and the electric motor is an axial flux motor. In certain embodiments, the control system is configured to access a lookup table.

Certain embodiments comprise a pumping chamber comprising an inner surface forming a loop; a pump inlet in fluid communication with the pumping chamber; a pump outlet in fluid communication with the pumping chamber; a first piston disposed within the pumping chamber; and a series of electromagnets disposed around the pumping chamber, wherein: the series of electromagnets are configured to move the first piston around the pumping chamber; and the first piston comprises a hydrodynamic bearing surface configured to repel the first piston away from the inner surface as the first piston moves within the pumping chamber. Certain embodiments further comprise a second piston disposed within the pumping chamber, wherein: the series of electromagnets are configured to move the second piston around the pumping chamber; and the second piston comprises a hydrodynamic bearing surface configured to repel the second piston away from the inner surface as the second piston moves within the pumping chamber. Certain embodiments further comprise a pinch valve between the pump inlet and pump outlet.

Certain embodiments comprise a pumping chamber forming a loop; an inlet and outlet in communication with the pumping chamber so as to form a first and second path around the loop; a drive piston disposed within the pumping chamber, a valve piston disposed within the

pumping chamber, a motor for actuating the drive piston, and a means for selectively deploying or recessing the valve piston, wherein the system is configured such that during operation, the motor is coupled to the drive piston, the drive piston starts in a first position, the valve piston is coupled to a deploying or recessing means, and the valve piston starts in a deployed position between the inlet and outlet so as to substantially occlude the second path, the drive piston is actuated so as to draw fluid from the inlet and force fluid through the outlet by means of moving through the first path, the valve piston is actuated to recess between the inlet and outlet port whereby the second path becomes opened, the drive is actuated to traverse the second path between the inlet and outlet, the valve piston is redeployed by the valve actuation means to substantially occlude the second path.

Certain embodiments further comprise one or more magnets disposed within the valve piston and one or more electromagnets, and are configured such that during operation the electromagnets exert a force or torque on the valve magnets so as to control its position. Certain embodiments further comprise a valve piston with a cylindrical face or a valve piston that has an extruded C-shape. Further embodiments comprise a valve piston that rotates on a shaft or contact point that is in communication with a bearing.

Certain embodiments further comprise a first set of one or more magnets disposed within the valve piston, a second set of on or more magnets attached to a motor, wherein the system is configured such that during operation the rotation of the motor induces rotation in the valve piston through the engagement of the first set of magnets with the second set of magnets. Certain embodiments further comprise the arrangement of the first and second set of magnets so as to create an angular dependent magnetic gear ratio between the first and second set of magnets, wherein during operation of the system the rotational velocity of the first set of magnets creates a rotational velocity in the second set of magnets that varies with the rotational position of the first set of magnets. Certain embodiments further comprise a first set of one or more magnets disposed within the valve piston, a second set of one or more magnets attached to a motor, and a third set of one or more magnets disposed within a rotating disk residing between the motor and the valve piston, wherein the system is configured such that during operation the motor rotates the disk by means of the second set of magnets engaging the third set of magnets, and the disk rotates the valve piston by means of the third set of magnets engaging the first set of magnets. Further embodiments comprise the first, second, and third magnet sets engaging in an angular dependent gear ratio.

Certain embodiments further comprise a first set of magnets disposed within the valve piston, and one or more permanent magnets, electromagnets, or pieces of permeable material disposed within the walls of the pumping chamber, wherein the system is configured such that during operation the valve piston can be held in a predetermined position by the permanent magnets, electromagnets, or permeable material. Certain embodiments further comprise permeable material or permanent magnets embedded in the pumping chamber walls that produce an angular dependent permeability or magnetic field respectively, whereby the valve piston is induced to rotate by the permeable or magnetic material.

Other embodiments comprise a method of pumping a fluid, the method comprising: providing a pumping chamber, wherein the pumping chamber contains the fluid; providing a pump inlet in fluid communication with the pumping chamber; providing a pump outlet in fluid communication with the pumping chamber; providing a first fluid path between the inlet and outlet; providing a second fluid path between the inlet and outlet; providing a drive piston disposed within pumping chamber; providing a valve piston disposed substantially within the first path between the inlet and outlet; providing a means for actuating drive piston; providing a means for selectively recessing and deploying valve piston; deploying the valve piston to substantially occlude fluid from flowing between the first path between the inlet and outlet; moving the drive piston around the second path of the pumping chamber so that a portion of the fluid is drawn into the pump inlet and a portion of the fluid is forced out of the pump outlet; recessing the valve piston between the inlet and outlet allowing the drive piston to move through the first path; deploying the valve piston to occlude the first path after the drive piston has passed.

Embodiments of the present invention relate generally to the method of control of positive displacement pumps. More specifically, and not by way of limitation, embodiments of the present invention relate to the method of control of positive displacement ventricular assist devices (VADs).

VADs are used in parallel of the failing heart. They remove blood from either the ventricle or atria and deliver it to the arterial tree, bypassing the aortic (or pulmonary valve), and possibly the mitral (or tricuspid) valve in the case of atrial inflow, thus the term parallel has been used.

VADs provide support for patients with heart failure. At first, they were used for potential transplant patients as a bridge to transplant (BTT), but recent studies have shown that VADs provide sufficient ventricular unloading for the potential of ventricular recovery,

or bridge to recovery (BTR). As VAD technology advances and has the potential to last upwards of ten years, or more, the use as a bridge to destination (BTD) is also being explored. Many of these patients require different levels and types of support. For example, many of the BTT or BTD patients require full support, while the BTR patients may require partial support with a weaning protocol in place to allow for ventricular recovery.

Current positive displacement pumps do not aspirate and eject fluid simultaneously. These functions must be performed in separate steps facilitated by prosthetic valves. They are typically run in a fill-to-empty or fixed rate mode, but they are occasionally run in a counter-pulsing mode where they fill during ventricular systole and eject during ventricular diastole, though this mode is uncommon in clinical settings. The benefits of synchronous assist were first realized with the intra aortic balloon pump (IABP), which augments arterial pressure during diastole and reduces aortic pressure just prior to LV ejection. These actions effectively unload the LV and improve its pumping ability which increases cardiac output somewhat.. But IABPs cannot be used for long term support, and they cannot significantly increase cardiac output. VADs, on the other hand, can provide sufficient long term support but have rarely utilized synchronicity, despite claims of the benefits it would provide in terms of ventricular unloading, coronary perfusion, and cardiac output.

Pulsatile VADs that do provide synchronous counterpulsation can actually provide too much support for a recovering ventricle. As a result, atrophy of the myocardium has been observed, which significantly reduces the chances of ventricular recovery and weaning potential.

Existing continuous flow VADs are generally not configured to produce pulsatile flow or produce periods of zero flow. The body's natural pump, the heart, functioning in its healthy state is sensitive to the body's natural feedback mechanisms, namely heart rate, ventricular pre-load, and ventricular afterload.

The response to preload and afterload is typically referred to as the Frank-Starling law of the heart which says that preload (atrial pressure) increases lead to stroke volume increases; preload decreases lead to stroke volume decreases; afterload (arterial pressure) increases lead to stroke volume decreases, and afterload decreases lead to stroke volume increases. Through these mechanisms, the body finds a balance between the arterial and pulmonary systems.

Current VAD technology does not allow for the proper response of these natural circulatory feedback mechanisms. Pulsatile VADs, which typically use a pusher-plate or

compressed air to drive the blood flow, are insensitive to outlet pressure, which could lead to over pumping in a fixed rate or fill-to-empty mode. Over pumping can lead to high blood pressure and stroke.

Current continuous flow VADs are hypersensitive to the differential pressure across the pump compared to the normal functioning myocardium. Also, continuous flow blood pumps are mostly insensitive to variation in heart rate compared to the normal functioning myocardium. Furthermore, continuous devices are mostly insensitive to ventricular preload. This insensitivity has led to many cases of ventricular suction which can cause arrhythmias, hemolysis, thrombus release, myocardial tissue damage, and right heart failure. These difficulties have led to difficulty managing patients who receive these devices in the post-operative setting. Patients require frequent observation and pump speed adjustments to maintain beneficial physiological effects.

There is a need for a blood pump which is appropriately sensitive to these natural feedback mechanisms provided by the body.

In addition, certain prior art devices (for example, pumps similar to that disclosed in U. S. Patent No. 6,576,010 are limited in that the stroke volume cannot be varied while maintaining complete cycles of the pistons. In order to reduce the volume ejected in a single stroke from the pump, the drive piston must be partially cycled so that it displaces a fraction of the total stroke volume. Upon the beginning of the next stroke, the partially actuated piston must be again moved the remainder of the fraction of rotation that it executed in the previous stroke. While this complicated means exists for reducing the stroke volume, there is no apparent way to increase the stroke volume from that defined by the physical geometry of the pumping chamber.

Furthermore, for purely positive displacement pumps, all of the stroke volume is directly controlled by the displacement of the piston in the chamber, minus any leakage flow that moves around the pistons. This has a disadvantage in the setting of pumping blood in a ventricular assist or total artificial heart application in that the ejected volume of the pump is invariant with changes in the inlet pressure (preload) and outlet pressure (afterload). Positive displacement pumps with this insensitivity to preload or afterload used in ventricular assist applications are capable of creating dangerously high blood pressures in some patients due to the inability for the pump to sense that the afterload resistance is too high and to cut back on the ejected stroke volume. Results of this hyperperfusion can be stroke, intracranial hemorrhage, and aneurism rupture.

In comparison, the flow rates of centrifugal or axial flow pumps are inherently very sensitive to the inlet and outlet pressure differential and will curb or increase flow accordingly. In the application of pumping blood in a ventricular assist setting, these pumps exhibit hypersensitivity to the pressure changes at the inlet and outlet, resulting in an excessive diminution of flow when the outlet pressure increases. Results of this hypoperfusion in the setting of patient exercise, when blood pressures increase and higher flow is needed, can result in fainting and inadequate organ perfusion.

Pumps similar to those disclosed in U. S. Patent No. 6,576,010 are also limited in that the needed stroke volume directly controls the size of the pumping chamber and thus the size of the device. Since the stroke volume is contained within the toroidal chamber prior to actuation, there is no apparent way to increase the stroke volume without increasing the pumping chamber size. This may be problematic in the application of implantable devices where size is a critical limitation. In general, pulsatile assist devices are larger than continuous flow devices because the entire stroke volumes of these pumps must be contained within the device.

Pumps similar to those disclosed in U. S. Patent No. 6,576,010 are limited in that they aspirate and eject fluid at the same time. This feature has the disadvantage in that the inertia (inertance) of the fluid in both the inflow and outflow lines is coupled to the drive piston and must be accelerated each time a stroke is performed. This dynamic effect can generate significant pressures on the pistons, which requires additional power for actuation and can lead to pump malfunction or diminished performance if the pressures exceed actuation and coupling limits.

Furthermore, pumps similar to those disclosed in U. S. Patent No. 6,576,010 are limited by the fact that when a piston crosses a port opening, it completely occludes the port area, which has the effect of rapidly increasing the resistance to flow through this area. If the fluid in the inflow or outflow lines have energy when the rapid increase in resistance occurs, a significant back pressure (fluid hammer) can arise which can generate pressures that make the pistons very hard to control. In order to prevent this fluid hammer, the energy of the fluid in the inflow and outflow lines should be significantly reduced before the port is occluded, which requires power and time. Reducing the energy of the fluid in the inflow and outflow lines also reduces pumping capability. In an application where the inflow or outflow inertances are large (*e.g.*, long lines, dense fluid, small cross sectional flow area), this type of

pump can suffer a significant reduction in pumping efficiency and generate high dynamic pressures across the inlet and outlet ports.

Embodiments of the present disclosure improve upon previous pulsatile assist devices by allowing a controllable portion of the volume in the inflow cannula to be a part of the stroke volume by shaping the port area and controlling the drive piston actuation to allow fluid energy to carry extra volume through the pump each stroke. This configuration provides several benefits. For example, it allows for a variable stroke volume through variation of the fluid energy with drive piston speed. This configuration can also allow for a reduction of the pumping chamber size without reducing the ejected stroke volume. Such a configuration can reduce or eliminate fluid hammer effects by letting the energy of the fluid to do work against the outlet pressure instead of as a pressure on the piston faces. This configuration allows for a portion of the total stroke volume to be sensitive to preload and afterload, restoring the hearts native sensitivity to such parameters.

Furthermore, because the portion of the stroke volume that comes from the energy depends on the inlet and outlet pressure, embodiments of the present disclosure can be tuned to produce a precise sensitivity to preload and afterload that can be controlled by controlling the energy of the fluid using the drive piston velocity. This offers the advantage of restoring the native Frank Starling response observed of a healthy heart with a VAD.

Certain embodiments of the present disclosure comprise a pumping chamber forming a loop; and inlet and outlet port in fluid communication with the loop; a first volume of fluid in the loop; a second volume of fluid in the inlet or outlet port; a drive piston residing within the loop; a valve piston residing between the inlet and outlet port; a means for actuating the drive piston; a means for recessing and deploying the valve piston, wherein actuation of the drive piston provides energy to the first and second volumes of fluid and ejects the first volume of fluid by means of positive displacement, and wherein recession of the valve piston in relation to a predetermined drive piston position creates a shunt that allows the energy of the fluid to carry the second volume of fluid through the outlet port. Certain embodiments of the present invention further comprise a pumping chamber forming a loop; and inlet and outlet port in fluid communication with the loop; a first volume of fluid in the loop; a second volume of fluid in the inlet or outlet port; a first piston residing in the first path within the loop; a second piston residing in the second path of the loop; a means for actuating the first and second pistons, wherein actuation of the first piston provides energy to the first and second volumes of fluid and ejects the first volume of fluid by means of positive

displacement, and wherein further actuation of the first piston into a position creates a shunt that allows the energy of the fluid to carry the second volume of fluid through the outlet port.

Other embodiments comprise a method of pumping a fluid, the method comprising: providing a pumping chamber forming a loop; providing a first fluid volume disposed within loop; providing a pump inlet and outlet in fluid communication with the pumping chamber; providing a second fluid volume disposed within pump inlet providing a first fluid path between the inlet and outlet; providing a second fluid path between the inlet and outlet; providing a first piston disposed within the first path of the pumping chamber; providing a second piston disposed within the second path of the pumping chamber; providing a means for actuating the first and second pistons; actuating the second piston into a position to substantially occlude fluid from flowing through the second path between the inlet and outlet; actuating the first piston around the first path of the pumping chamber so that a portion of the fluid is drawn into the pump inlet and a portion of the fluid is forced out of the pump outlet, wherein energy is generated in the fluid from the actuation of the first piston; actuating the first piston into the second path between the inlet and outlet, creating a shunt between the outlet and inlet through the first path; allowing the energy of the fluid to expel the second volume of fluid into the outlet through the shunt created in the first path; actuating the second piston into a position in the first path wherein the shunt between the inlet and outlet through the first path is occluded.

Certain embodiments comprise a pump system comprising: a pumping chamber forming a loop; a pump inlet in fluid communication with the pumping chamber; a pump outlet in fluid communication with the pumping chamber; a drive piston disposed within the pumping chamber; a drive mechanism coupled to the drive piston; a valve mechanism disposed between the pump inlet and pump outlet; a sensor configured to sense an external variable and to provide an output signal; and a microprocessor configured to receive the output signal from the sensor and to change an operating parameter of the pump in response to the output signal. In certain embodiments, the operating parameter is a movement of the drive piston and/or a movement of the valve mechanism.

In specific embodiments, the valve mechanism comprises a valve piston and/or a pinch valve. In certain embodiments, the sensor is configured to sense an external variable selected from the group consisting of: ventricular pressure, ventricular depolarization, heart contraction, diaphragm motion, bodily inclination, and bodily movement. In particular

embodiments, the sensor comprises one or more electrodes. The sensor may comprise an accelerometer in certain embodiments.

In certain embodiments, the pump system is configured such that the drive piston completes one revolution around the pumping chamber during a pump cycle, the sensor is configured to detect a cardiac cycle of the patient, and the pump cycle is synchronized with the cardiac cycle of a patient during use. In specific embodiments, during use, the pump cycle comprises a portion of increased flow rate and the portion of increased flow rate is delayed for a period of time after a heart beat of a patient. In certain embodiments, the pump system is configured such that during use two or more pump cycles occur during one cardiac cycle of a patient.

In certain embodiments, the pump system is configured such that during use two or more cardiac cycles occur during one pump cycle of a patient. In particular embodiments, the pump system is configured such that during use the pump system can detect if the cardiac cycle becomes irregular, and where the pump system operates in an asynchronous mode if the cardiac cycle becomes irregular. In certain embodiments, the pump system is configured to operate in a counterpulsation mode during use.

Particular embodiments comprise method for controlling the operation of a positive displacement pump, where the method comprises providing a system including: a pump having a pumping chamber forming a loop; a pump inlet in fluid communication with the pumping chamber; a pump outlet in fluid communication with the pumping chamber; a drive piston disposed within the pumping chamber; a drive mechanism coupled to the drive piston; a valve mechanism disposed between the pump inlet and pump outlet; a sensor; and a microprocessor. In particular embodiments, the method also comprises: sensing an external variable with the sensor; sending a first output signal from the sensor to the microprocessor; sending a second output signal from the microprocessor to the pump; and changing an operating parameter of the pump in response to the second output signal from the microprocessor.

In certain embodiments, the method comprises moving the drive piston in response to the second output signal. In particular embodiments, the method comprises opening or closing the valve mechanism in response to the second output signal. In certain embodiments, the external variable corresponds to a cardiac cycle of a patient. In particular embodiments, the external variable corresponds to a heart beat of a patient, changing the operating parameter of the pump provides an increase in flow from the pump, and there is a delay between the

heart beat of the patient and the increase in flow from the pump. In certain embodiments, changing an operating parameter of the pump comprises varying the velocity of the drive piston. In particular embodiments, changing an operating parameter of the pump comprises varying the acceleration of the drive piston. In certain embodiments, the sensor comprises one or more electrodes configured measuring ventricular depolarization. In particular embodiments, the sensor comprises an accelerometer for sensing a heart contraction, a diaphragm motion, a bodily inclination, or bodily movement.

Certain embodiments include a system comprising: a pumping chamber forming a loop; a pump inlet in fluid communication with the pumping chamber; a pump outlet in fluid communication with the pumping chamber; a drive piston disposed within the pumping chamber; a drive mechanism coupled to the drive piston; and a valve piston disposed between the pump inlet and pump outlet, wherein the valve piston is configured to rotate between a first position within the pumping chamber and a second position outside of the pumping chamber.

Certain embodiments comprise a magnetic gear configured to rotate the valve piston from the first position to the second position. In specific embodiments, the magnetic gear comprises a first set of one or more magnets coupled to the valve piston and a second set of one or more magnets coupled to the drive mechanism. In certain embodiments, the drive mechanism is an electric motor. In particular embodiments, the valve piston has a cylindrical face. In certain embodiments, the valve piston comprises a C-shape. The valve piston may pivot on a bearing in particular embodiments, and there may be one or more magnets disposed within the valve piston in certain embodiments.

In certain embodiments, one or more electromagnets are configured to deploy the valve piston to the first position and to recess the valve piston to the second position. Embodiments may also comprise one or more permanent magnets, electromagnets, or pieces of permeable material disposed within a wall of the pumping chamber, where the system is configured such that during operation, the valve piston can be held in a predetermined position by the one or more permanent magnets, electromagnets, or pieces of permeable material.

Certain embodiments include a system comprising: a pumping chamber forming a loop; a drive piston disposed within the pumping chamber; a pump inlet in fluid communication with the pumping chamber; a pump outlet in fluid communication with the pumping chamber; a drive mechanism coupled to the drive piston; a valve piston; and a

magnetic gear configured to rotate the valve piston from a first position to a second position. In particular embodiments, the valve piston is disposed within the pumping chamber when the valve piston is in the first position and wherein the valve piston is disposed outside of the pumping chamber when the valve piston is in the second position. In certain embodiments, the valve piston is configured to substantially occlude a fluid flow past the valve piston when the valve piston is in the first position. In particular embodiments, the valve piston is disposed between the pump inlet and the pump outlet.

In certain embodiments, the magnetic gear comprises a first set of one or more magnets coupled to the valve piston and a second set of one or more magnets coupled to the drive mechanism. In particular embodiments, the drive mechanism is an electric motor. The valve piston may have a cylindrical face and/or comprise a C-shape in certain embodiments. In certain embodiments, the valve piston pivots on a bearing. One or more magnets disposed within the valve piston in particular embodiments.

Certain embodiments include a method of pumping a fluid, where the method comprises: providing a pumping chamber containing a fluid; providing a pump inlet in fluid communication with the pumping chamber; providing a pump outlet in fluid communication with the pumping chamber; providing a first fluid path between the pump inlet and the pump outlet; providing a second fluid path between the pump inlet and the pump outlet; providing a drive piston disposed within pumping chamber; providing a valve piston disposed substantially within the first path between the inlet and outlet; providing a means for actuating drive piston; providing a means for selectively recessing and deploying valve piston; deploying the valve piston to substantially occlude fluid from flowing between the first fluid path between the inlet and outlet; moving the drive piston around the second path of the pumping chamber so that a portion of the fluid is drawn into the pump inlet and a portion of the fluid is forced out of the pump outlet; recessing the valve piston between the pump inlet and the pump outlet; moving the drive piston through the first fluid path; and deploying the valve piston to occlude the first fluid path after the drive piston has passed.

In certain embodiments, the valve piston rotates in a first direction to recess and the opposite direction of the first direction to deploy. In particular embodiments, the valve piston rotates in a first direction to recess and rotates in the same direction as the first direction to deploy. In certain embodiments, the means for selectively recessing and deploying the valve piston comprises a magnetic gear. In particular embodiments, the magnetic gear comprises an angular dependent gear ratio.

Embodiments may also include a method of pumping a fluid, where the method comprises providing a pump comprising a pumping chamber, an pump inlet, and a pump outlet, where the pumping chamber forms a loop; the pump inlet and the pump outlet are in fluid communication with the pumping chamber; and the pumping chamber comprises a first fluid path between the pump inlet and the pump outlet and the pumping chamber comprises a second fluid path between the pump inlet and the pump outlet. The method may also comprise providing fluid in the pumping chamber and in the pump inlet; providing a drive piston disposed within the first fluid path of the pumping chamber; providing a valve mechanism configurable in a first position to substantially occlude flow in the second fluid path and a second position to permit flow in the second fluid path; placing the valve mechanism in the first position; moving the drive piston within the first fluid path, where fluid is drawn from the fluid inlet into the pumping chamber; fluid drawn from the fluid inlet into the pumping chamber is trailing the drive piston; and fluid leading the drive piston is forced from pumping chamber into the pump outlet. The method may also comprise positioning the drive piston so that a shunt is created in the first fluid path between the pump inlet and the pump outlet; and allowing fluid trailing the drive piston to flow from the pumping chamber to the pump outlet.

In certain embodiments, the valve mechanism comprises a valve piston, and the valve piston may rotate from the first position to the second position. In particular embodiments, a magnetic gear rotates the valve piston from the first position to the second position. In certain embodiments, the magnetic gear comprises an angular dependent gear ratio. In certain embodiments, the valve piston rotates in one direction when moving from the first position to the second position and rotates in the opposite direction when moving from the second position to the first position. In certain embodiments of the method, the valve piston rotates in the same direction when moving from the first position to the second position and when moving from the second position to the first position.

Embodiments may also comprise a method of pumping a fluid, where the method comprises: providing a pumping chamber containing a fluid; providing a pump inlet in fluid communication with the pumping chamber; providing a pump outlet in fluid communication with the pumping chamber, where the pumping chamber comprises a first fluid path between the pump inlet and the pump outlet and the pumping chamber comprises a second fluid path between the pump inlet and the pump outlet; providing a drive piston disposed within the first fluid path of the pumping chamber; providing a valve piston disposed within the second path

of the pumping chamber; and providing a drive mechanism for actuating the drive piston. Embodiments of the method may also comprise providing a mechanism for moving the valve piston into and out of the second fluid path of the pumping chamber; actuating the drive piston around the first path of the pumping chamber so that energy is transferred from the drive piston to the fluid and so that a portion of the fluid is drawn into the pump inlet and a portion of the fluid is forced out of the pump outlet; moving the valve piston out of the second fluid path; actuating the drive piston so that a shunt is formed by the first fluid path between pump inlet and the pump outlet; allowing energy of the fluid in the pumping chamber to continue to draw fluid from the fluid inlet and expel fluid out of the fluid outlet; actuating the drive piston into a position in the first path, wherein the shunt formed by the first fluid path between pump inlet and the pump outlet is occluded; and moving the valve piston into the second fluid path. In certain embodiments of the method, the pumping chamber forms a loop. Particular embodiments comprise providing a controller configured to control the velocity of the drive piston; and varying the velocity of the drive piston as the drive piston is actuated around the first path of the pumping chamber to control the amount of fluid trailing the drive piston that is expelled from the pumping chamber to the pump outlet.

In particular embodiments, the mechanism for moving the valve piston into and out of the second fluid path of the pumping chamber comprises a magnetic gear with an angular dependent gear ratio. In specific embodiments, a portion of the fluid trailing the drive piston is expelled from the pumping chamber to the pump outlet when a shunt is formed by the first fluid path between pump inlet and the pump outlet.

Embodiments also include a pump system comprising: a pumping chamber forming a loop; a pump inlet in fluid communication with the pumping chamber; a pump outlet in fluid communication with the pumping chamber; a drive piston disposed within the pumping chamber; and a valve mechanism disposed between the pump inlet and pump outlet. In particular embodiments, the pump inlet is in fluid communication with the pumping chamber regardless of the location of the drive piston within the pumping chamber; and the pump outlet is in fluid communication with the pumping chamber regardless of the location of the drive piston within the pumping chamber.

In certain embodiments, the pump inlet intersects the pumping chamber in a first transition zone with a first cross-sectional area; the drive piston comprises an outer surface with an outer surface area; and the first cross-sectional area is greater than the outer surface area. In particular embodiments, the length of the first transition zone is greater than the

length of the outer surface of the drive piston. In certain embodiments, the width of the first transition zone is greater than the width of the outer surface of the drive piston.

In particular embodiments, the pump outlet intersects the pumping chamber in a second transition zone with a second cross-sectional area; the drive piston comprises an outer surface with an outer surface area; and the second cross-sectional area is greater than the outer surface area. In particular embodiments, the length of the second transition zone is greater than the length of the outer surface of the drive piston. In certain embodiments, the width of the second transition zone is greater than the width of the outer surface of the drive piston. In particular embodiments, during use the pump inlet is in fluid communication with a ventricle and the fluid outlet is in fluid communication with an aorta.

Embodiments also include pump system comprising: a pumping chamber comprising a wall forming a loop; a pump inlet in fluid communication with the pumping chamber; a pump outlet in fluid communication with the pumping chamber; and a drive piston disposed within the pumping chamber. In certain embodiments, the drive piston comprises a leading face and a trailing face; the drive piston comprises a deformable surface extending between the leading face and the trailing face; and the deformable surface is proximal to the wall of the pumping chamber.

In particular embodiments, the deformable surface comprises polyurethane. In certain embodiments, the deformable surface is configured to provide elastohydrodynamic lubrication between the drive piston and the wall of the pumping chamber during operation. In particular embodiments, the deformable surface is configured deform at least 0.001 inches, 0.0001 inches, or 0.00001 inches during operation. In certain embodiments, the drive piston comprises a non-deformable central portion. In particular embodiments, the non-deformable central portion is magnetic. Certain embodiments comprise a valve piston configured to rotate into and out of the pumping chamber and a magnetic gear.

Particular embodiments comprise a gap between the deformable surface and the non-deformable central portion. Certain embodiments further comprise a compressible fluid contained within the gap. In particular embodiments, the deformable surface comprises an extension proximal to the trailing face of the drive piston.

Embodiments may also comprise method of pumping fluid, where the method comprises: providing a pump comprising a pumping chamber, a pump inlet, and a pump outlet, wherein the pumping chamber forms a loop and the pump inlet and the pump outlet are

in fluid communication with the pumping chamber; providing fluid in the pumping chamber; providing a drive piston disposed within the pumping chamber, wherein the drive piston comprises a deformable surface proximal to a wall of the pumping chamber; and moving the drive piston within the pumping chamber, wherein the deformable surface is deformed away from the wall of the pumping chamber as the drive piston moves within the pumping chamber.

In certain embodiments, moving the drive piston within the pumping chamber provides elastohydrodynamic lubrication between the drive piston and the wall of the pumping chamber. In particular embodiments, the drive piston comprises a leading face and a trailing face, and the deformable surface extends between the leading face and the trailing face. In certain embodiments, the pressure of the fluid in a region between the leading face and the trailing face is increased sufficiently to deform the deformable surface when the drive piston is moving in the pumping chamber. In particular embodiments, the pressure of the fluid in a region between the leading face and the trailing face is increased at least 50, 100, 200, 300, 400, 500, 600, 700, 800, 900 or 1,000 mmHg.

Particular embodiments include a method comprising providing a non-deformable central portion of the drive piston. In certain embodiments, the non-deformable central portion is magnetic. In specific embodiments, the method comprises providing a valve piston configured to rotate into and out of the pumping chamber, and providing a magnetic gear configured to control the position of the drive piston and the valve piston. Embodiments may also comprise providing a gap between the non-deformable central portion and the deformable surface of the drive piston. In particular embodiments, the gap comprises a compressible fluid.

As used herein, the terms "a" and "an" are defined as one or more unless this disclosure explicitly requires otherwise.

The term "substantially" and its variations are defined as being largely but not necessarily wholly what is specified as understood by one of ordinary skill in the art, and in one non-limiting embodiment the term "substantially" refers to ranges within 10%, preferably within 5%, more preferably within 1%, and most preferably within 0.5% of what is specified.

The terms "comprise" (and any form of comprise, such as "comprises" and "comprising"), "have" (and any form of have, such as "has" and "having"), "include" (and any form of include, such as "includes" and "including") and "contain" (and any form of

contain, such as "contains" and "containing") are open-ended linking verbs. As a result, a method or device that "comprises," "has," "includes" or "contains" one or more steps or elements possesses those one or more steps or elements, but is not limited to possessing only those one or more elements. Likewise, a step of a method or an element of a device that "comprises," "has," "includes" or "contains" one or more features possesses those one or more features, but is not limited to possessing only those one or more features. Furthermore, a device or structure that is configured in a certain way is configured in at least that way, but may also be configured in ways that are not listed.

The term "coupled," as used herein, is defined as connected, although not necessarily directly, and not necessarily mechanically.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of one embodiment of the present disclosure.

Figure 2 is a section view of the embodiment of Figure 1.

Figure 3 is a side view of one embodiment of the present disclosure.

Figure 4 is a side view of one embodiment of the present disclosure.

Figure 5 is a schematic of a control system used in certain embodiments of the present disclosure.

Figure 6 is a schematic of a driver circuit diagram used in certain embodiments of the present disclosure.

Figures 7-13 are section views of one embodiment of the present disclosure during operation.

Figure 13A is a perspective view of magnetic shielding clips used in certain embodiments of the present disclosure.

Figure 13B is a perspective view of a magnetic shielding clip of the embodiment shown in Figure 13A.

Figure 14 is a side view of one embodiment of the present disclosure.

Figure 15 is a section view of the embodiment of Figure 14.

Figure 16 is a perspective view of one embodiment of the present disclosure.

Figure 17 is an exploded view of the embodiment of Figure 16.

Figure 18 is an exploded view of one embodiment of the present disclosure.

Figure 19 is a section view of one embodiment of the present disclosure.

Figure 20 is a section view of the embodiment of Figure 19.

Figure 21 is a section view of one embodiment of the present disclosure.

Figure 22 is a section view of the embodiment of Figure 21.

Figure 23 is a side view of the embodiment of Figure 21.

Figure 24 is a section view of one embodiment of the present disclosure.

Figure 25 is a section view of the embodiment of Figure 25.

Figure 26 is a view of one embodiment of the present disclosure in operation..

Figure 27 is a section view of one embodiment of the present disclosure.

Figure 28 is a section view of the embodiment of Figure 28.

Figure 29 is a section view of one embodiment of the present disclosure.

Figure 30 is a section view of the embodiment of Figure 29.

Figure 31 is perspective view of a piston in one embodiment of the present disclosure.

Figure 32 is a section view of a component of one embodiment of the present disclosure.

Figure 33 is a section view of multiple embodiments of the present disclosure.

Figures 34A-34D are section views of an embodiment of the present disclosure in different stages of operation.

Figure 35 is a schematic of an embodiment of the present disclosure.

Figure 36 is a partial side section view of an embodiment of the present disclosure.

Figure 37 is a partial end section view of the embodiment of Figure 36.

Figure 38 is a partial top section view of the embodiment of Figure 36.

Figure 39 is a partial end view of an embodiment of the present disclosure.

Figure 40 is a partial end view of an embodiment of the present disclosure.

Figure 41 is a partial end view of an embodiment of the present disclosure.

Figure 42A is a partial end view of an embodiment of the present disclosure.

Figure 42B is a partial side view of different embodiments of the present disclosure.

Figure 42C is a partial top view of an embodiment of the present disclosure.

Figure 43 is an exploded view of an embodiment of the present disclosure.

Figure 44 is an assembled view of a portion of an embodiment of the present disclosure.

Figure 45 is a side view of a portion of an embodiment of the present disclosure.

Figure 46 is a perspective view of a portion of an embodiment of the present disclosure.

Figure 47 is a side view of a portion of an embodiment of the present disclosure.

Figure 48 is a flowchart of a control system used for an embodiment of the present disclosure.

Figure 49 is an exploded view of an embodiment of the present disclosure.

Figure 50 is a section view of the embodiment of Figure 49.

Figure 51 is a perspective view of a portion of an embodiment of the present disclosure.

Figures 52-56 are section views of a portion of an embodiment of the present disclosure.

Figures 57-62 are section views of a portion of an embodiment of the present disclosure.

Figure 63 is a perspective view of a portion of an embodiment of the present disclosure.

Figure 64 is a perspective view of an embodiment of the present disclosure.

Figures 65-66 are views of an embodiment of the present disclosure inserted in a patient.

Figure 67 is an exploded view of an embodiment of the present disclosure.

Figure 68 is a side view of a portion of the embodiment of Figure 67.

Figure 69 is a top view of the embodiment of Figure 67.

Figures 70-78 are section views of one embodiment of the present disclosure shown in a first mode of operation.

Figures 79-84 are section views of one embodiment of the present disclosure shown in a second mode of operation.

Figure 85 is a perspective view of a component of one embodiment of the present disclosure.

Figures 86-87 are perspective views of the component of Figure 85 during operation.

Figure 88 is a perspective view of a component of one embodiment of the present disclosure.

Figures 89-90 are perspective and orthogonal views of a component of one embodiment of the present disclosure.

Figure 91 is a perspective view of a component of one embodiment of the present disclosure.

Figure 92-93 are perspective views of a component of one embodiment of the present disclosure.

Figure 94 is a perspective view of a component of one embodiment of the present disclosure.

Figures 95-96 are perspective view of components of one embodiment of the present disclosure shown in different positions.

Figures 97-98 are perspective views of components of one embodiment of the present disclosure.

Figure 99 is a section view of one embodiment of the present disclosure.

Figure 100A is an exploded view of one embodiment of the present disclosure.

Figure 100B is a section view of the embodiment of Figure 100A.

Figure 101 is an exploded view of one embodiment of the present disclosure.

Figures 102-109 are section views of the embodiment of Figure 101 shown in different positions during operation.

Figure 110 is a block diagram of a control scheme for one embodiment of the present disclosure.

Figures 111-118 are graphs of various calculated pump parameters resulting from control schemes according to embodiments of the present disclosure.

Figure 119 is a graph of a calculated pump flow rates at different heart rates for one embodiment of the present disclosure.

Figure 120 is a graph of a calculated pump flow rates at different mean arterial pressures for one embodiment of the present disclosure.

Figure 121 is a potential operational map according to one embodiment of the present disclosure.

Figure 122 is a graph of left ventricular pressure-volume loops according to one embodiment of the present disclosure.

Figure 123 is graph of calculated pump and native flow rates according to one embodiment of the present disclosure.

Figures 124-129 are cross-sectional views of one embodiment of the present disclosure in various positions during operation.

Figures 130-131 are perspective sectional views of a pumping chamber and a pump inlet and outlet of one embodiment of the present disclosure.

Figure 132 is a perspective view of a drive piston of one embodiment of the present disclosure.

Figure 133 is a side view of a piston and a wall of a pumping chamber of one embodiment of the present disclosure.

Figure 134 is a side view of a piston and a wall of a pumping chamber of one embodiment of the present disclosure.

Figure 135 is a side view of a piston and a wall of a pumping chamber of one embodiment of the present disclosure.

Figure 136 is a side view of a piston and a wall of a pumping chamber of one embodiment of the present disclosure.

DETAILED DESCRIPTION OF THE INVENTION

Figures 1 and 2 show a perspective and sectioned view, respectively, of a pump 100 with an inlet 110 and an outlet 120. It should be appreciated that pump 100 shown in Figures 1 and 2 is one exemplary embodiment, and the present invention should not be limited to the embodiment shown. The same is true for all other Figures, which are provided as examples only.

The embodiments illustrated in Figures 1-13 show a pumping chamber 130 forming a loop or ring comprised of an inner wall 140 and an outer wall 150 defining a lumen generated by the revolution of a two-dimensional enclosed contour, in this case a circle, about a coplanar axis lying outside the contour. It should be appreciated that many two dimensional enclosed contours can be used to define the lumen including a square, ellipse, polygon, conic, etc. It should also be appreciated that the revolution path should not be restricted to a circle. For instance, the enclosed contour may be swept around an oval, ellipse, etc. Pumping chamber 130 is comprised of a rigid plastic material such as poly ether ether ketone (PEEK) blow molded or injection molded into shape. However, pumping chamber 130 can consist of a variety of materials including plastic, titanium, stainless steel, aluminum, or a photo-reactive polymeric resin used in stereolithography. Pumping chamber 130 contains a first orifice 115 and second orifice 125 located along its outer perimeter sized so that a pair of pistons 160 and 170 residing within pumping chamber 130 cannot enter the orifices or catch along the interface where the orifice 115 meets inlet 110 or orifice 125 meets outlet 120. Inlet 110 is in fluid communication with first orifice 115 of pumping chamber 130 such that inlet 110 joins pumping chamber 130 at an angle 180. Outlet 120 is in fluid communication with second orifice 125 of pumping chamber 130 such that outlet 120 joins pumping chamber 130 at an angle 190. It should be appreciated that the position of first orifice 115 and second orifice 125 are not required to reside along the radial perimeter of pumping chamber 130, but could exist in various positions elsewhere on pumping chamber 130. It should also be appreciated that inlet 120 and outlet 130 could intercept the pumping chamber at a variety of angles. It should further be appreciated that the outer wall of the pumping chamber need not be an identically shaped offset of the inner wall of the pumping chamber. Where inner wall 140 has a direct relationship to the volume created by the revolution of the two-dimensional enclosed contour, outer wall 150 of pumping chamber 130 can adopt many different shapes to accommodate the need for mounting sensors, electromagnets, wires, etc. In the embodiment shown, pumping chamber 130 is composed of two halves 132 and 134, which separate and

attach along a plane 200. Between and nearest the inflow and outflow conduits 110 and 120, a flange 135 exists on each half 132, 134 of pumping chamber 130. Flange 135 comprises counter-bored clearance holes 137 in which fasteners 138 are inserted and tightened down to create a hermetic seal. No flange exists along the second attachment surface 139 to allow for a plurality of solenoids 145 to be slid onto each half 132, 134 of pumping chamber 130. The attachment of each half 132, 134 at second attachment surface 139 is sealed by ultrasonic welding of the contact seam. It should be appreciated that many materials and methods may be used to attach the chamber halves 132, 134 together including adhesives, snap fits, press fits, fasteners, ultrasonic welding, laser welding, etc. In certain embodiments, inner wall 140 of pumping chamber 130 is coated with a hydrophilic lining (not shown) that partially absorbs fluid to enhance lubricity. The inner lining of pumping chamber 130 and/or the pistons 160, 170 may be coated in the following material types for the facilitation of protein or cellular aggregation for increasing lubricity, sealing, durability, and lowering hemolysis and thrombosis: a nano-particulate surface (carbon, silicate, or titanium based), a micro-porous ceramic, or a fibrous flocking material. It should be appreciated that many other surface coatings, such as diamond-like carbon and titanium nitride, may be used to provide increases in biocompatibility, lubricity, sealing, and durability, and decreases in thrombosis and hemolysis, and that these materials serve only as an example of several embodiments.

The present embodiment further shows two pistons 160, 170 residing within the lumen of pumping chamber 130. Each piston 160, 170 contains a rare earth magnetic sphere 161, 171 encapsulated by two halves 162, 172 of a rigid housing that joins and seals along an edge with epoxy 9 (not shown). The magnetic spheres 161, 171 are fixed at the center of pistons 160, 170 with epoxy so that the spheres 161, 171 cannot rotate within pistons 160, 170. The housing of each piston 160, 170 conforms to a great extent with the inner shape of the lumen or pumping chamber 130, the pistons 160, 170 having a toroidal curvature terminating on both ends with a planar face. In the embodiment shown, the two planar end faces of pistons 160, 170 are configured so that the end faces are parallel. However, it should be appreciated that many different piston shapes could be used including pistons whose end faces are angled and pistons with sculpted extensions to facilitate the smooth transition of fluid into and out of the pump. In certain embodiments, all edges along the piston are filleted to minimize frictional wear and a hydrophilic coating (not shown) that partially absorbs fluid surrounds each piston 160, 170, enhancing its lubricity. While residing in pumping chamber 130, small clearance gaps 163 and 167 exist between piston 160 and pumping chamber 130 allowing

piston 160 to move within pumping chamber 130 without significant contact friction. Similarly, small clearance gaps 173 and 177 exist between the piston 170 and pumping chamber 130. The orientation of spherical magnet 161, 171 within each piston 160, 170 are set such that the net magnetic vector points substantially parallel to the instantaneous velocity vector of the piston as it moves in the pumping chamber 130. Pistons 160, 170 are placed within pumping chamber 130 at orientations such that pistons 160, 170 magnetically oppose one another as they reside within pumping chamber 130. Pistons 160, 170 are also sized to prevent their insertion or collision with orifices 115, 125 of pumping chamber 130.

Figures 1-13 further show one embodiment of a means for actuating pistons 160, 170 within pumping chamber 130. In the embodiments shown, a plurality of solenoids 145 are discretely placed along outer wall 150 of pumping chamber, each solenoid 145 consisting of a wound conductor supported by a resin to retain a self standing ring shape that extends around pumping chamber 130. Each solenoid 145 is slid onto pumping chamber 130 and mounted into place using an adhesive (not shown). It should be appreciated that the conducting wire of each solenoid 145 can be chosen from a wide variety of metals such as copper, aluminum, gold, silver, Litz wire, etc and the gauge of the wire can be varied. Each solenoid 145 conforms along its inner surface with the curvature of the outer wall 150 of pumping chamber 130. Each solenoid 145 is also tapered so that the thickness (shown as dimension "T" in Figure 2) of the solenoid decreases as one moves radially inward from the outer edge of pump 100 towards the center, facilitating a maximal packing factor of coils onto pumping chamber 130. In the embodiments shown, solenoids 145 take the aspect ratio approximating a Brook's coil so as to maximize the force transduced between each piston 160, 170 and each solenoid 145. It should be appreciated that in other embodiments, more or less solenoids could be used and that the solenoids can be of a wide range of shapes and each need not be of identical shape.

Figure 3 shows one embodiment of a means for sensing the angular positions of the magnetic pistons 160, 170 using a 2-axis Hall effect sensor 155 located in the void at the center of the pump. Sensor 155 can be mounted on a variety of support structures (not shown) extending from outer wall 150 of pumping chamber 130 into void 156 at the center of pump 100. For purposes of clarity, solenoids 145 or other means for actuating pistons 160, 170 are not shown in Figure 3.

Figure 4 shows another embodiment of a means for sensing the angular positions of the magnetic pistons 160, 170 using a plurality of single axis Hall effect sensors 157

positioned around the perimeter of outer wall 150 of pumping chamber 130 and mounted with an adhesive (not shown) or other suitable means. For purposes of clarity, solenoids 145 or other means for actuating pistons 160, 170 are not shown in Figure 4.

As shown in Figure 5, one embodiment of a control system 111 for operating pump 100 comprises a power supply 101, a microprocessor 102, a driver circuit 103, a plurality of solenoids or electromagnets 104, and a plurality of sensors 105. It should be appreciated that microprocessor 102 could take the form of a real time operating system, microcontroller, CPU, etc. Microprocessor 102 is electrically connected to a driver circuit 103 and sensors 105 located on pump 100. Driver circuit 103 is electrically connected to power supply 101 and electrically connected to solenoids or electromagnets 104 (or other means for actuating pistons 160, 170 within pumping chamber 130). It should be appreciated that power supply 101 can comprise a bench top alternating or direct voltage source, a battery, a fuel cell, a bank of capacitors, etc.

As shown in Figure 6 one embodiment of driver circuit 101 comprises a full bridge MOSFET driver 133 with pullup capacitors 116 and 117 and flyback diodes 114.

In the embodiment shown, pump 100 circulates fluid (not shown) in two phases, a drive phase and a transition phase, which are cyclically alternated in the operation of pump 100. Figure 7 shows piston 160 in a first position with piston 170 located substantially between inlet 110 and outlet 120 and the piston 160 residing close to piston 170 near inlet 110. This position marks the end of the transition phase and the beginning of the drive phase. In the embodiment shown, one cycle of the drive phase occurs by actuating piston 160 in a clockwise motion around the lumen of pumping chamber 130 while maintaining piston 170 in the position between inlet 110 and outlet 120. Piston 160 is actuated clockwise in the embodiment shown by delivering a current to solenoid 145b in a direction which produces an attractive force on the piston 160. It should be appreciated that the solenoids 145c and 145d may also be energized to produce additional attractive forces on the piston 160 as well, as is the case when needing a higher force to pump fluid against a higher pressure at outlet 120. It should also be appreciated that the solenoid 145a may be energized to produce a repelling force to further accelerate piston 160 in a clockwise direction. However, in the embodiment shown, first solenoid 145a remains off in this initial sequence to prevent producing an attractive force on the piston 170. Piston 170 is located close to solenoid 145a and therefore could move if solenoid 145a were energized to repel piston 160. The forces placed on piston 160 by the solenoid 145b cause it to move clockwise. As piston 160 begins to move, it

pushes on the fluid that resides in the volume between its leading face and outlet 120. Due to the close clearance between the inner wall 140 and piston 160, which is enhanced by the hydrophilic coating that further facilitates a sealing effect, the fluid does not substantially leak around piston 160, but is rather forced to move with piston 160. Simultaneously, the solenoid 145m is delivered current by control system 111 (schematically shown in Figure 5) to produce a holding force which isolates piston 170 in the position between inlet 110 and outlet 120. Piston 170, due to its geometry and hydrophilic coating, also produces a substantial occlusion to the fluid flow. It is in this fashion that the piston 160 pressurizes fluid between its leading face and piston 170, causing the fluid to exit pumping chamber 130 through outlet 120. Simultaneously, the expanding volume change induced by the motion piston 160 creates a lower pressure between its lagging face and piston 170. This low pressure forces fluid to enter into pumping chamber 130 through inlet 110. As piston 160 moves clockwise, the solenoids it approaches are delivered currents by control system 111 to further attract piston 160 and the solenoids that piston 160 has recently passed through are delivered reversed currents by control system 111 to further repel piston 160. As piston 160 crosses the midplane of each solenoid, control system 111 reverses the direction of the current supplied to that particular solenoid in order to produce a repelling force which expels piston 160 through the solenoid along the same clockwise direction. The use of solenoids to produce both an attracting force and a repelling force provides greater efficacy in the transportation of piston 160, and surpasses the performance of the prior art designs which only utilize attractive forces to propel the piston around the pumping chamber.

Figures 8-13 show the progression of piston 160 around pumping chamber 130 during operation of pump 100. Figures 8-10 show the completion of the drive phase of the pump operation, in which piston 160 forces fluid to exit through outlet 120 and enter through inlet 110. Figures 11 and 12 show the transition phase of pump operation, in which piston 160 and piston 170 effectively switch functions. During this phase, piston 160 is transitioning from the "drive" piston to the "stationary" piston. Similarly, piston 170 is no longer stationary and is now being positioned for use as the drive piston. In Figure 13, pump 100 has completed one cycle of operation and is ready to begin a second cycle, using piston 170 as the drive piston and piston 160 as the stationary piston. Pump 100 repeats the cycle described above during continued operation.

Referring back now to Figures 3-5, control system 111 uses knowledge of the instantaneous position of pistons 160, 170 and the absolute position of the coils (not shown)

to make the decision of when to turn each solenoid 145 on and off and which direction to send the current while each solenoid 145 is on. The position of pistons 160, 170 is sensed by a single 2-axis Hall effect sensor 155 or a series of single axis Hall effect sensors 157 mounted around pumping chamber 130. Sensors 155, 157 sense the magnitude and direction of the magnetic field and relay this information as a voltage level to microprocessor 102 which translates this data through a conversion algorithm into the angular positions of pistons 160, 170. Following a programmed algorithm, microprocessor 102 then outputs an array of digital signals to a plurality of driver circuits 103. In a preferred embodiment, each driver circuit 103 is comprised of a full-bridge configuration of MOSFETs connected to a single solenoid and a power supply. This full-bridge MOSFET configuration can be found prefabricated on an integrated circuit chip such as the L298 produced by ST electronics. Upon receiving the appropriate digital signal from microprocessor 102, driver circuit 103 places the voltage of power supply 101 in a forward or reverse bias direction across the terminals of a solenoid 145. Driver circuit 103 can also remove the voltage from the terminals of the solenoid 145 when microprocessor 102 directs the solenoid 145 to be turned off. Microprocessor 102 can send either TTL or pulse width modulated signals to driver circuit 103 to control the direction and magnitude of the current delivered to the solenoid 145. It should be appreciated that the level of current that is delivered to the solenoid 145 can be used to control the drive piston at variable speeds. Flyback diodes are used to prevent current spikes from damaging the MOSFET chip due to the high inductance of the solenoid 145.

Referring additionally to Figures 7-12, while piston 160 is being driven around pumping chamber 130, piston 170 is held in place by attractive and repulsive forces created by solenoids 145a and 145m. The direction and magnitude of the currents delivered to solenoids 145a and 145m is controlled by control system 111 such that the forces the piston 170 experiences from pressure differences across its two faces are canceled by the solenoid forces, resulting in a zero net force on the 170 piston, which makes it remain stationary. A simple feedback loop is used in the microprocessor 102 to deliver the correct currents to keep it held in place. For instance, this can be accomplished in some cases by repelling the piston 170 with both solenoids 145a and 145m, effectively trapping piston 170 in position.

Solenoids 145b through 145L drive the piston 160 in a clockwise rotation around pumping chamber 130 while the piston 170 is held in place. In this fashion, the bolus of fluid that originally existed between the leading face of the piston 160 and the trailing face of the piston 170 is effectively ejected from the pump through outlet 120. Likewise, a fresh bolus of

fluid enters the lumen through inlet 110 by means of a vacuum force that arises by the expanding volume generated between the lagging face of the piston 160 and the leading face of piston 170. In this fashion, piston 170 is isolated and acts as an isolation member or a virtual "valve" in the sense that it prevents fluid from flowing from the high pressure side to the low pressure side of pumping chamber 130. It should be appreciated that the angle of the piston faces and the angle and shape of inlet 110 and outlet 120 are designed to provide a smooth transition of the fluid into and out of pump 100 without causing turbulence, eddies, stagnation points, or shearing stresses sufficient to damage delicate fluid particles.

As the piston 160 nears the end of the drive stroke it comes into close contact with the piston 170. At this point the drive phase has ended and the transition phase begins. During the transition phase piston 160 and piston 170 move together in a clockwise direction until the piston 160 resides in the isolation position where the piston 170 previously resided, located substantially between inlet 110 and outlet 120 and the piston 170 resides in the position to begin the drive phase. Control system 111 can achieve this synchronized jog of both pistons 160, 170 in one embodiment by controlling solenoid 145a to attract the second piston and directing solenoid 145m to repel the first piston. Once pistons 160, 170 have completed this transition phase piston 170 is now in position to execute the drive stroke of the drive stage and piston 160 is positioned to be isolated between inlet 110 and outlet 120 to provide proper occlusion. It is in this way that each piston alternates being the driven piston and the isolated or stationary piston. The speed at which each of these cycles is performed, controlled by the magnitude of currents delivered to solenoids 145a-145m, dictates the flow rate of pumping. It is important to note that this is a positive displacement pump in the sense that the displacement of the drive piston is proportional to the displacement of fluid that enters and leaves the pumping chamber. In this way the pump is largely capable of delivering pulsatile outputs by ejecting discrete boluses of fluid.

In the embodiment shown, the movement of fluid was from inlet 110 to outlet 120 through the clockwise actuations of drive piston 160. However, it should be appreciated that the pumping direction is easily reversed by actuating the pistons in a counterclockwise fashion and performing a similar set of steps.

Referring now to Figure 13A, a plurality of magnetically permeable shrouding clips 144 are shown arranged in a circle. In certain embodiments, shrouding clips 144 are positioned around solenoids 145 (shown in Figures 1 and 2) for increasing and ducting magnetic flux towards pistons 160 and 170, resulting in improved force transduction and

higher efficiencies. As shown in Figure 13A, discrete spacing of shrouding clips 144 provides air gaps for the prevention of eddy current generation. Figure 13B illustrates a detailed view of a shrouding clip 144.

Figures 14-15 show an additional embodiment comprising an alternative means for actuating and holding the pistons within the pumping chamber. In this embodiment, a pump 200 comprises an inlet 210, an outlet 220, a pair of pistons 260, 270 and a pumping chamber 230 with an inner wall 240 and an outer wall 250. Pump 200 further comprises a pair of DC pancake torque motors 245, 246 located in the void at the center of pumping chamber 230. It should be appreciated that a variety of motor types could be used including alternating current motors, direct current motors, stepper motors, induction motors etc. Each motor 245, 246 has a cylindrical shape. Electric motor 245 is positioned above the electric motor 246 such that the two motors share a common plane. Each electric motor 245, 246 has a rotor (not shown) and an arm extending from the rotor towards outer wall 250 of pumping chamber 230. A first arm 247 is connected to the first rotor through a press fit on the shaft of the rotor and a hole on arm 247. The distal end of arm 247 takes the shape of crescent so that arm 247 wraps around a portion of outer wall 250 of pumping chamber 230 leaving space so as not to interfere with inlet 210 and outlet 220 of pumping chamber 230. The distal end of arm 247 is comprised either wholly or partially of a magnetic material so that a magnetic force is transferred between the distal portion of arm 247 and magnetic piston 260 residing within the lumen of pumping chamber 230. Second arm 248 is similarly connected to the second rotor (not shown) of second motor 246 and coupled magnetically to second piston 270. However motor 246 is oriented such that arm 248 is located on the opposite side of pump 200 from first arm 247 so that each arm 247, 248 does not interfere with the other.

In the embodiment shown in Figures 14-15, arms 247, 248 magnetically couple to pistons 260, 270, respectively, within the lumen of pumping chamber 230 with sufficient magnetic force such that an angular displacement of each arm 247, 248 moves its coupled piston by the same angular amount. In this way, each motor 245, 246 is able to control the precise location and motion of the internal pistons 260, 270 through the rotation of each arm 247, 248. Pumping of fluid is achieved with the similar piston motion as described in the solenoid actuated piston embodiment. In order to achieve this piston motion, each motor is controlled by a control circuit (not shown) similar to that previously described to either rotate its coupled piston or to hold it stationary. The microcontroller thus controls arms 247, 248 to

perform the motion described previously to achieve the expulsion of fluid from the lumen through outlet 220 and the refilling of the lumen through inlet 110.

Referring now to Figures 16-17 another embodiment comprises a pump 300 with a pair of electric motors 345, 385 having a different configuration than motor 245, 246 of Figures 14-15. In this embodiment, electric motors 345, 385 are not located within the void at the center of the pumping chamber 330, but instead are adjacent to pumping chamber 330. Electric motor 345 comprises a coil core plate 346, coils 347, magnets, 348, and a magnet core plate 349. Similarly, electric motor 385 comprises a coil core plate 386, coils 387, magnets 388, and a magnet core plate 389. Linkage 350 couples either electric motor 345 or 385 with magnetic piston 360. For purposes of clarity, Figures 16-17 show only one piston 360; however, an additional piston can be incorporated in this embodiment so that one piston acts as a driving piston and the other piston acts as a stationary piston. The operation of this embodiment is similar to that of previously-described embodiments.

Figure 18 shows yet another embodiment comprising a pump 400 with a pumping chamber 430, a motor 445 and a pair of pistons (not shown). In this embodiment, motor 445 comprises a first magnet core plate 446 with a first linking arm 447, a first plurality of magnets 448, a first coil 449, a first coil core plate 450, a second coil plate 451, a second coil 452, a second plurality of magnets 453, and a second magnet core plate 454 with a second linking arm 455. Motor 445 further comprises a shaft 456, a first bearing 457 and a second bearing 458. Although motor 445 is configured differently than the motors described in the discussion of previous embodiments, the embodiment of Figure 18 operates in a manner similar to the previously-described embodiments.

Figure 19-20 shows a section view of another embodiment. In this embodiment, a pump 500 comprises a piston 560 and a pumping chamber 530 with an inlet 510 and outlet 520. Pumping chamber 530 further comprises an elastic segment 531 that extends between inlet 510 and outlet 520. A pinch valve 535 acts as an isolation member and is positioned about elastic segment 531. In this embodiment the pinch valve comprises a pair of rollers 536 positioned opposite each other with elastic segment 531 positioned in between rollers 536. Rollers 536 reside on a pair of rods 537. Rods 537 are mounted inside pinch valve housing 538, which contains an actuator for actuating and holding rods 537 at precise positions. This actuator can be electromagnetic, hydraulic, mechanical, etc.

The operation of pump 500 involves the use of pinch valve 535 to substantially occlude the fluid flow between inlet 510 and outlet 520. Pinch valve 535 eliminates the need

for the stationary piston utilized in previously described embodiments. Use of pinch valve 535 further eliminates the need for the extra solenoids or an extra motor which are necessary to drive the second piston in other embodiments. In the embodiment of Figures 19-20, pinch valve 535 actuates elastic segment 531 of pumping chamber 530 such that the elastic segment 531 can be open or closed. When elastic segment 531 is open, drive piston 560 freely passes through elastic segment 531. When elastic segment 531 is closed, neither fluid nor piston 560 can pass through elastic segment 531. During operation, drive piston 560 is actuated in a clockwise fashion by either type of actuation means previously described (solenoids or motor) or a similar actuation means. As drive piston 560 is actuated, pinch valve 535 remains closed, clamping down on elastic segment 531 to prevent the flow of fluid through elastic segment 531. In essence, pinch valve 535 acts similar to a secondary piston suspended in the isolation position described previously. As drive piston 560 is actuated, fluid enters the pump in the expanding volume created behind its lagging face and fluid exits through outlet 520 by means of the pressure created between the leading face of drive piston 560 and pinch valve 535. The only time elastic segment 531 is actuated to open is at the completion of the drive phase when drive piston 560 passes through elastic segment 531. At all other times elastic segment 531 is pinched shut, so as to act as a valve prohibiting the flow of fluid through the segment. During the transitional phase pinch valve 531 is directed by the control system (not shown) to open. A sensor array similar to previously described embodiments is used to detect the position of the drive piston and signal when it is appropriate to open pinch valve 535. A driver circuit (not shown) then delivers current to a set of solenoids (also not shown) within pinch valve housing 538 which exert a force on rods 537 of pinch valve 535 such that they are pulled away from each other, thus opening elastic segment 531. In this embodiment, rods 537 are electromagnetically actuated, but it should be appreciated that they could also be mechanically or hydraulically actuated to cause the elastic segment 531 to expand and collapse (*i.e.,* open and close). It should be further appreciated that elastic segment 531 is easily deformed by external forces and can be quickly pinched shut so that fluid is substantially occluded through arc segment 531. The elastic material is also sufficiently elastic to expand back into its original shape if external forces are removed. It should also be appreciated that an elastic polymer is used as the arc segment that will not deteriorate or fatigue from prolonged deformation cycles. After drive piston 260 passes through elastic segment, 531 the microprocessor (not shown) directs the drive system to actuate pinch valve 535 to close. After pinch valve 535 closes, the system is ready to perform another pumping

stroke. In this fashion, pumping strokes are repetitively performed to achieve the pumping of fluid.

Referring now to Figures 21-23, an embodiment comprises a pump 600 with a pumping chamber 630 having an inlet 610 and an outlet 620. Pump 600 further comprises a drive piston 660 and an isolation member or isolation sleeve 670 that is hollow and curved in shape. Figures 21 and 22 show pump 600 from a top view, while Figure 23 displays pump 600 from a side view. As shown in Figures 21 and 22, fluid enters pump 600 orthogonally to the plane of rotation of isolation sleeve 670, through inlet 110 pointing into the page. When drive piston 660 is detected, the isolation sleeve 670 is electromagnetically actuated to recess into the outlet 620 to allow piston 660 to pass, as shown in Figure 22. Actuation is achieved by electromagnets, which are positioned external to the torus or pumping chamber 630 and generate a force on magnetic material imbedded within isolation sleeve 670. Once piston 660 passes, isolation sleeve 670 returns to the configuration shown in Figure 21. Pump 600 is configured so that the structure of pumping chamber 630 and isolation sleeve 670 bear the load created by the fluid pressure differential across valve sleeve 670. By utilizing the pump's structure to bear the static load, pump 600 does not require electromagnetic energy to maintain isolation sleeve 670 is a fixed position.

Another embodiment is shown in Figures 24-25 comprising a pump 700 with a pumping chamber 730, a recess 735, an inlet 710, and an outlet 720. Pump 700 further comprises a piston 760 and an isolation piston 770. Pump 700 operates in a manner similar to the embodiment of Figures 21-23 by moving isolation piston 770 into recess 735. However, unlike isolation sleeve 670 of the embodiment in Figures 21-23, isolation piston 770 is solid rather than hollow. isolation piston 770 can then rotate completely around recess 735 to flush out any fluid that stagnates during the pumping cycle.

Another embodiment of an isolation mechanism is shown in Figure 26. In this embodiment, a portion of a pumping chamber 830 is shown in fluid communication with a pump outlet 820. A drive piston 860 is propelled within pumping chamber 830 in a manner provided for in previous embodiments, such as solenoids or electric motors. In addition, a hollow isolation piston 870 is located in outlet 820. As drive piston 860 approaches outlet 820, hollow isolation piston 870 is retracted further into outlet 820 and away from pumping chamber 830. This allows drive piston to continue through pumping chamber 830 and begin a new pumping cycle. When hollow isolation piston 870 is in the position shown at the far left of Figure 26, it allows fluid to exit outlet 820, but prevents fluid from bypassing outlet 820

and back flowing through an inlet (not shown, but connected to pumping chamber 830 downstream of outlet 820 so that drive piston 860 first passes by outlet 820 and then the inlet). In this manner, hollow isolation piston 870 functions similar to the occlusion devices described in the discussion of previous embodiments. In the embodiment shown, hollow isolation piston 870 is retracted into outlet 820 by the use of electromagnetic force. In other embodiments, the leading face of drive piston 860 can be tapered so that it engages the tapered end of hollow isolation piston 870 and forces hollow isolation piston 870 to recess into outlet 820.

Another embodiment is shown in Figures 27-28. In this embodiment, a pump 900 comprises a pumping chamber 930, an inlet 910, an outlet 920, a drive piston 960, and an occlusion or isolation piston 970. The general principles of operation for pump 900 are similar to those of the previously described embodiments. However, in this embodiment, occlusion piston 970 comprises a slot 971 that engages a projection 972. The engagement of projection 972 and slot 971 provides for a structural load bearing mechanism to hold occlusion piston in place during the drive cycle of pump 900. As drive piston 960 approaches occlusion piston 970, occlusion piston 970 is withdrawn via electromagnetic or other suitable force, to allow drive piston 960 to pass.

Another embodiment is shown in Figures 29-30. In this embodiment, a pump 1000 comprises an inlet 1010, an outlet 1020, a pumping chamber 1030, a drive piston 1060, and an isolation piston 1070. Pump 1000 operates in the same general manner as previously described embodiments, but incorporates isolation piston 1070 that has an upper hollow portion 1071 and a solid lower foot 1072. With this configuration, isolation piston allows fluid to enter pumping chamber 1030 when it is in the position shown in Figure 29. In addition, solid lower portion 1072 seals off inlet 1110 when isolation piston 1070 is in the position shown in Figure 30, thereby reducing backflow.

One advantage of recessing valve embodiments, such as those shown in Figures 21-29 is that each piston can be specifically designed for a single function instead of each piston having to take turns being either the drive piston or the isolation piston, thus sharing functions. By allowing for each piston to have a separate and individual function, each piston can be optimized to perform its function without making design concessions needed for the piston to serve both the drive and isolation functions. Specifically, the isolation piston can be designed to bear hydrostatic and dynamic fluid loads structurally to minimize the power consumed to occlude fluid flow. The isolation piston can also be shaped to provide smooth

inflow and outflow fluid transition. The drive piston, relieved of its duty to act as an isolation piston every other cycle, can be optimized for a more continuous actuation cycle, low drag, and stability. The actuation and valving power can also be significantly reduced as compared to designs that require the control system to hold the isolation piston in place.

Another embodiment of the present invention utilizes raised or grooved sections of the torus and/or pistons to control the position and the points where the piston contacts the inner torus wall. Referring now to Figure 31, a piston 1100 comprise four raised ridges 1101. Ridges 1101 provide contact points with the torus wall (not shown in Figure 31) that can be employed to minimize the contact area, decrease shearing stresses, decrease stagnation points, provide a controllable piston position, control the wear of the contact surface, and provide a lubricious sliding surface. Raised ridges 1101 may be comprised of a different material than the rest of piston 1100 and can be made of a ceramic or ultrahigh density polymer for favorable long term wear and lubricity characteristics.

Referring now to Figure 32, another embodiment comprises ridges 1151 employed along an inner wall 1152 of a torus 1150. Ridges 1151 are similar to ridges 1101 in the previously described embodiment.

Additional embodiments shown in Figure 33 show four configurations for piston wall contact ridges in cross section. In addition to the embodiments previously described in Figures 31 and 32, an embodiment comprises a torus 1160 that utilizes raised portions 1161 to create circumferential grooves 1163. In this embodiment, piston 1165 has ridges 1164 that engage grooves 1163.

Yet another embodiment comprises a piston 1170 with grooves 1171 and a torus 1175 with grooves 1176. This embodiment also includes ball bearings 1177 engaged with grooves 1171 and 1176, which provides a low friction surface contact.

Referring now to Figures 34A – 34D, another embodiment of the present invention comprises a pump 1200 for the circulation of two independent circuits of fluid. In the embodiment shown, a toroidal pumping chamber 1250 contains three pistons 1210, 1211 and 1212 and has two inlet ports 1240, 1260 and two outlet ports 1270, 1280. The three pistons 1210-1212 are comprised of a magnetic material and can be actuated by a variety of means, including those previously described, such as a motor or electromagnets. The pumping of both chambers of fluid is performed in four steps. In the first step Piston 1212 is in a position 1 where it occludes fluid flowing through outlet port 1240. Piston 1210 is in position 2 and

occludes fluid from flowing through inlet port 1240. Piston 1211 is positioned by electromagnets or other means (not shown) to reside in position 4 where it occludes fluid from flowing through inlet port 1240. The first bolus is pumped, as seen in the Figure 34A by the actuation of piston 1210 from position 2 to position 3. During this actuation, fluid enters the chamber through inlet port 1240 and exits the chamber through port 1270, effectively pumping the chamber volume through port 1270 and refilling the chamber volume through port 1240. As seen in figure 34B, the next step, a transitional step, is performed by actuating piston 1212 to move from position 1 to position 2. In this position it now occludes inlet port 1240 and has opened outlet port 1280 for fluid transport. As seen now in Figure 34C the third step in the pumping cycle is performed. In this step, the second chamber is pumped by the actuation of piston 31211 from position 4 to position 1. During this actuation the second chamber of fluid exits port 1280 and fluid refills the chamber behind piston 1212 by entering through port 4. Piston 1211 ends its actuation stroke at position 1 where it occludes port 1280. A second transitional step in Figure 34D is then performed by actuating piston 1210 from position 3 into position 4 so that it occludes inlet port 1240. At the end of this transitional step, the pump has returned to its original state and is ready to perform the previous four steps again. In this way, two independent chambers of fluid may be pumped.

The embodiment shown in Figure 35 pertains to the use of a pacemaker 1310 connected to a pumping system 1399 in the application of ventricular assistance or biventricular cardiac pumping support. Many patients who suffer from congestive heart failure require ventricular assistance in the presence of a pacemaker. The embodiment of Figure 35 illustrates a system that employs both a pump 1300 and the pacemaker 1310 that can control both the timing of the pump ejection and the timing of cardiac contraction. In this way the pump ejection can be timed to coincide with any particular part of the cardiac cycle. This is advantageous because synchronicity of pump ejection can greatly decrease the cardiac workload and can lead to healing of the damaged myocardium. A pacemaker is connected to a single or plurality of depolarizing electrodes 1320 that are inserted or attached to the native heart 1330. The pacemaker generates a depolarizing electric field at the electrode tip (not shown) that creates a depolarization of the myocardium resulting in contraction. The pacemaker generates these depolarizing stimuli at a periodicity that can be fixed or controlled either by pacemaker 1310 itself or by a microprocessor 1340 of pump system 1399. Pacemaker 1310 is electrically connected to microprocessor 1340 and information can flow freely between them. Microprocessor 1340 can direct pacemaker 1310 to change its

periodicity of heart stimulation by means of a control signal. Likewise, the pacemaker can direct the microprocessor to cause the pump to eject by means of a control signal. Microprocessor 1310 is electrically connected to a control circuit or driver circuit 1350 which is connected to pump 1300. Pump 1300 is outfitted with one or more sensors 1360 which feedback position information to control circuit 1350 and which allows for proper actuation of the internal pistons (not shown) of pump 1300. Physiological sensing electrodes 1370 are connected to the patient's body 1380 and can be employed to measure changes in needed circulatory demand as the patient's activity level is changed. These physiological sensing electrodes 1370 can be made to measure a variety of metrics that indicate the need to increase or decrease heart rate such as the thoracic impedance, renal sympathetic nerve activity, aortic nerve activity, p-wave of the heart, acceleration of the body, or lactic acid levels. Upon receiving an input from physiological sensing electrodes 1370, pacemaker 1310 may increase or decrease its frequency of depolarization. This information may be relayed to microprocessor 1340 which could increase the rate at which the pump executes its pumping stroke in order to stay in sync with native heart 1330. Pacemaker 1310 can possess its own internal power supply such as a small battery (not shown) or can be powered by means of the same supply that drives the operation of pump 1300. Microprocessor 1340 is connected to a power supply 1390 which powers its internal circuits as well as directs power to pump 1300 when in operation.

Referring now to Figure 36, a side section view illustrates one embodiment of a piston 1400 disposed within a pumping chamber 1430. In certain embodiments pumping chamber 1430 is configured as a torus (or any other continuous ring or loop). However, piston 1400 may be incorporated into any of the exemplary embodiments of pumps disclosed herein. In the embodiment shown, pumping chamber 1475 comprises an inner perimeter 1459 having an upper chamber wall 1445, a lower chamber wall 1455, an inner chamber wall 1460 and an outer chamber wall 1465. In the view shown in Figure 36, piston 1400 is moving to the left within pumping chamber 1475, while in Figure 37 piston 1400 is moving toward the viewer. Pumping chamber 1430 is centered on a central axis 1471, as shown in Figure 37. Figure 38 represents a top view of piston 1400, which is traveling up in this view. Piston 1400 comprises an inner surface 1420, an outer surface 1425, an upper surface 1431, a lower surface 1435, a leading face 1426 and a trailing face 1421. It is understood that the terms "upper", "lower", "inner" and "outer" are used herein as labels for convenience as shown in figures and not necessarily indicative of position during actual use. In general, inner surface

1420 is closer to central axis 1471 than is outer surface 1475. The terms "leading" and "trailing" are used to indicate the surfaces facing toward and away from the direction of piston travel, respectively. Upper surface 1431 and lower surface 1435 are adjacent to both leading and trailing faces 1426 and 1421 as well as inner and outer surfaces 1420 and 1425. In the embodiment shown, upper surface 1431 is proximal to upper chamber wall 1445, lower surface 1435 is proximal to lower chamber wall 1455, inner surface 1420 is proximal to inner chamber wall 1460, and outer surface 1425 is proximal to outer chamber wall 1465. Piston 1400 is magnetically coupled to upper magnetic linkage 1440 through upper torus wall 1445 and to lower magnetic linkage 1450 through lower chamber wall 1455.

In exemplary embodiments, one or more of inner surface 1420, outer surface 1425, upper surface 1431, and lower surface 1435 comprise a hydrodynamic bearing surface. In addition, a piston surface may comprise a hydrodynamic bearing surface which resists displacement in more than one axis. For example, as shown in the embodiment of Figures 36-38, upper surface 1431 and lower surface 1435 act as hydrodynamic bearings. In the primary direction of travel for piston 1400 (*i.e.*, around pumping chamber 1475), hydrodynamic forces arise from the top and bottom surfaces which act to resist displacement of the piston towards the outer chamber wall as well as towards the upper and lower chamber walls.

Hydrodynamic bearing surfaces are incorporated on piston 1400 in order to offset forces (such as gravity, magnetic, and centrifugal forces) that would tend to bring piston 1400 into contact with pumping chamber 1475. By reducing the likelihood of contact between the piston and the chamber walls, shearing stresses can be greatly reduced and mechanical wear to the pistons and chamber walls can be prevented. Hydrodynamic bearing surfaces create "lift" (*i.e.* a force directing piston 1400 away from a stationary surface in a direction normal to the bearing surface) as piston 1400 moves within pumping chamber 1475. The hydrodynamic surfaces create lift by allowing a portion of fluid within pumping chamber 1475 to backflow across a surface of piston 1400 as it travels through the fluid and within pumping chamber 1475.

As shown in Figure 36, upper and lower surfaces 1430 and 1435 are slightly angled so that the distance between upper surface 1435 and upper chamber wall 1445 decreases between leading face 1426 and trailing face 1421. It is understood that the Figures are not to scale, and that the angles of certain surfaces may be exaggerated to provide clarity. The distance between lower surface 1435 and lower chamber wall 1455 also decreases between leading face 1426 and trailing face 1421. As a result, the thickness of a fluid film between piston

1400 and lower chamber wall 1455 changes from a maximum lower film thickness 1481 to a minimum lower film thickness 1482. Under conservation of mass principles, with relative motion between lower surface 1435 and lower chamber wall 1455, the fluid between piston 1400 and lower chamber wall 1455 can create a hydrodynamic force (represented by arrow 1485) that acts on piston 1400 and directs it away from lower chamber wall 1455. As a result, friction or drag forces between piston 1400 and lower chamber wall 1455 and shearing stresses in the respective film layer are reduced. In certain embodiments, upper surface 1431 may also comprise a hydrodynamic bearing surface to produce a force directing piston 1400 away from upper chamber wall 1445. In this manner, upper and lower surfaces 1430, 1435 may be "tuned" so that piston 1400 should not contact either upper or lower chamber wall 1445, 1455 during normal operation. In still other embodiments, it may be possible to eliminate the hydrodynamic bearing surface on upper surface 1435 and allow gravity or magnetic link forces to repel upper surface 1435 from upper chamber wall 1445. However, because the ultimate orientation of a pump incorporating piston 1400 may not be known, it may be necessary to provide hydrodynamic bearing surfaces on both upper and lower surfaces 1430 and 1435.

Referring now to Figure 38, a top view illustrates that leading face 1426 may be smaller than trailing face 1421. As a result, the distance between outer surface 1425 and outer chamber wall 1465 decreases from a maximum film thickness 1483 at leading face 1426 to a minimum film thickness 1484 at trailing face 1421. Under the same principles discussed in the description of Figure 36, a hydrodynamic force (represented by arrow 1486) can be created to act on piston 1400 and direct it away from outer chamber wall 1465. Hydrodynamic force 1486 may be used to counteract the centrifugal force or magnetic link forces created during normal operation that tends to direct piston 1400 towards outer chamber wall 1465.

In addition, the gap between inner surface 1421 and inner chamber wall 1460 also may decrease between leading face 1426 and trailing face 1421 to create a hydrodynamic force to direct piston 1400 away from inner chamber wall 1460. However, because centrifugal force or magnetic link forces will direct piston 1400 away from inner chamber wall 1460 during operation (regardless of the orientation of the pump), it may not be necessary to include a hydrodynamic bearing surface on inner surface 1420.

Referring now to Figure 37, an end section view of piston 1400 within pumping chamber 1475 is shown. As shown in this embodiment, upper surface 1431, lower surface

1435, upper chamber wall 1445 and lower chamber wall 1455 are not perpendicular to a plane that extends through central axis 1471 perpendicular to the page. Upper surface 1431, lower surface 1435, upper chamber wall 1445 and lower chamber wall 1455 are also angled relative to a plane extending through lateral axis 1472 perpendicular to the page. Therefore, as piston 1400 moves towards outer chamber wall 1465 (*e.g.*, due to centrifugal force), an upper gap 1487 between upper surface 1431 and upper chamber wall 1445 (and a lower gap 1488 between lower surface 1435 and lower chamber wall 1455) will decrease. As the upper and lower gaps 1487, 1488 decrease, the pressure on a fluid between piston 1400 and upper and lower chamber walls 1445, 1455 will increase. As a result, a pair of forces (represented by arrows 1491 and 1492) acting on piston 1400 will be generated. Forces 1491 and 1491 each have a component that resists displacement of the piston 1400 towards outer wall 1465 and a component that resists displacement of piston 1400 towards the upper 1445 or lower 1455 chamber walls during operation.

While piston 1400 is illustrated in this embodiment with hydrodynamic bearing surfaces on upper surface 1431, lower surface 1435, inner surface 1420, and outer surface 1425, it is understood that other embodiments may comprise a piston with hydrodynamic bearing surfaces on fewer surfaces. For example, the hydrodynamic bearing surfaces may be eliminated on inner surface 1420 and outer surface 1425. In such embodiments, upper surface 1431 and lower surface 1435 may be configured as shown in Figures 36 and 37 to provide stabilization forces both laterally and vertically. As discussed in the description of Figure 37, upper and lower surfaces 1430 and 1435 can be configured to generate forces 1491 and 1492 to balance the centrifugal and magnetic forces and therefore provide lateral stabilization. As a result it may not be necessary to provide hydrodynamic bearing surfaces on inner surface and outer surfaces 1420 and 1425. However, it may be desirable to provide hydrodynamic bearing surface on inner and outer surfaces 1420 and 1425 to provide additional forces directing piston 1400 away from inner wall 1421 and outer wall 1425. It should be understood that passive levitation of piston 1400 while it is moving can be achieved through use of hydrodynamic surfaces in this manner. Displacement of piston 1400 from its levitating position will increase hydrodynamic forces which act to resist the displacement and restore piston 1400 back to its levitating equilibrium position.

While exact dimensions will depend on numerous factors (such as the overall piston size and configuration, the fluid properties, etc.) in certain embodiments the minimum film thickness is approximately 0.00025 – 0.001 inches and the maximum film thickness is

approximately 0.003 – 0.004 inches. Other factors, such as surface finish, may also affect the ability to generate hydrodynamic forces. In certain embodiments, the surface finish of piston 1400 and the interior walls of pumping chamber 1475 is between 1 and 16 microinches (as defined by the centerline average surface finish R_a).

It is also understood that in certain embodiments a piston may comprise a cross-section different than piston 1400 shown in Figure 37. Examples of various end views of exemplary pistons are provided in Figures 39-42A. As shown in Figure 39, piston 1401 comprises an upper surface portion 1407 that is not perpendicular to axis 1471 and is angled down towards a lower surface portion 1408 (which is also not perpendicular to axis 1471 and is angled up towards upper portion 1407). Similarly, piston 1402 shown in Figure 40 comprises an upper surface portion 1417 that is not perpendicular to axis 1471 and is angled down towards lower surface portion 1418 (which is not perpendicular to axis 1471 and is angled up towards upper surface portion 1417). As shown in Figure 41, piston 1403 comprises an upper surface portion 1427 that is not perpendicular to axis 1471 and is angled down towards a lower surface portion 1428 (which is also not perpendicular to axis 1471 and is angled up towards upper portion 1427). In other embodiments, a piston may have a cross-section in which the entire upper or lower surfaces are perpendicular to the central axis of the pumping chamber. One example is shown in Figure 42A, in which piston 1404 comprises a rectangular cross-section. Similar to the description of Figures 36-38, displacement of a piston 1401, 1402, 1403 or 1404 in any direction which results in a decrease in the distance between a piston surface and a chamber wall gives rise to hydrodynamic forces which resist this displacement and acts to restore the piston back to the equilibrium position. By reducing the likelihood of contact between the piston and the chamber walls, shearing stresses in the fluid are minimized.

Referring now to Figure 42B, detailed views of exemplary embodiments of hydrodynamic bearing surfaces are shown to comprise various different shapes. In the embodiments shown, a plurality of pistons 1801-1808 comprise a hydrodynamic bearing surface 1811-1818 proximal to a stationary surface 1850 (such as an inner surface of a pumping chamber). A first embodiment shows piston 1801 with hydrodynamic bearing surface 1811 comprising a tapered surface 1821 across piston 1801. In a second embodiment, piston 1802 comprises a hydrodynamic bearing surface 1812 that forms a convex curved surface 1822 across piston 1802. As shown, a third embodiment comprises piston 1803 with hydrodynamic bearing surface 1813 forming a concave curve surface 1823 across piston

1803. Referring now to piston 1804, hydrodynamic bearing surface 1814 comprises a single step 1824 proximal to stationary surface 1850. As shown on piston 1805, hydrodynamic bearing surface 1815 comprises an angled surface 1825 that extends partially across piston 1805. Piston 1806 comprises a hydrodynamic bearing surface 1816 that includes an angled surface 1826 and a step 1836. As shown on piston 1807, hydrodynamic bearing surface 1817 includes two separate angled surfaces 1827, 1837 with angled surface 1827 extending part of the way across piston 1807 and angled surface 1837 extending part of the way across piston 1807. Referring now to piston 1808, hydrodynamic bearing surface 1818 comprises a first step 1828 and a second step 1838. It is understood that each of the shapes shown in hydrodynamic bearing surfaces 1801-1808 are merely examples of a multitude of different configurations that can be used to create hydrodynamic bearing surfaces. A hydrodynamic bearing may comprise any surface configured to create "lift" by allowing fluid backflow between stationary and moving surfaces that are proximal to each other. Backflow occurs when a portion of the fluid moves against the predominant direction of fluid flow (*e.g.*, in a direction from the trailing face towards the leading face.)

Furthermore, exemplary embodiments may comprise hydrodynamic bearing surfaces on stationary components. Referring now to Figure 42C, one exemplary embodiment comprises a piston 1900 disposed within a pumping chamber 1930 comprising an inner wall 1960 and an outer wall 1965. In the embodiment shown, piston 1900 comprises a leading face 1926 and a trailing face 1921, as piston 1900 moves toward the right. Inner wall 1960 comprises a plurality of tapered surfaces 1961 that act as hydrodynamic bearing surfaces when piston 1900 moves relative to tapered surfaces 1961. Similarly, outer wall 1965 comprises a plurality of tapered surfaces 1966 that act as hydrodynamic bearing surfaces when piston 1900 moves relative to tapered surfaces 1966. In this embodiment, the same principles of operation used to create "lift" apply as those described in embodiments with hydrodynamic bearing surfaces placed on moving components. It is understood that while inner wall 1960 and outer wall 1965 are shown to comprise angled surfaces, other embodiments may comprise different configurations (for example, similar to those described in Figure 42B).

Referring now to Figures 43-48, another embodiment of a pumping system comprises a pair of motors 1545 and 1546 driving a pump 1500. Motors 1545 and 1546 are generally equivalent in design, and therefore only motor 1545 (shown in exploded view) will be discussed in detail. It is understood that motor 1546 comprises features equivalent to those

discussed regarding motor 1545. Pump 1500 comprises a pumping chamber 1530 and a pair of pistons 1560, 1570. Pumping chamber 1530 comprises a removable cap 1531 to allow for pistons 1560, 1570 to be loaded into the pumping chamber. In this embodiment, motor 1545 comprises a rotor 1544 with a linking arm 1547 having extensions 1571 and arm magnets 1572 that are disposed on either side of piston 1560 (which comprises a casing 1561 and piston magnets 1562). Pump 1500 also comprises a plurality of rotor magnets 1548, a set of coils 1549, and a stator plate 1551. Motor 1545 further comprises a shaft 1556 and a bearing 1557. While Figure 43 represents an exploded view of motor 1545, Figure 44 represents an assembled view of motor 1546.

In this embodiment, motor 1545 is an axial flux gap motor which provides for more precise control as compared to other motor configurations. As shown in Figure 45, there is an axial gap between coils 1549 and rotor magnets 1548. As shown in the detail views in Figures 46 and 47, a magnet 1566 can be coupled to the end of shaft 1556 to provide a signal that allows for the rotational position of rotor 1544 to be determined. Specifically, magnet 1566 creates a magnetization vector 1569 that will rotate with the position of the rotor 1544. In the embodiment shown in Figure 47, a sensor 1567 (such as a 2-axis Hall effect sensor) is coupled to a printed circuit board 1568, which is coupled to a microprocessor (not shown).

Figure 48 provides a flowchart illustrating the basic steps in one embodiment of a control system 1590 that can be used to control motor 1545. Other embodiments may use different control systems. In summary, the microprocessor takes information from sensor 1567, conditions it, interprets it to an angular position, compares it with a desired angular position to get an error signal, multiplies this error signal by a gain, translates the control signal to a pulse width modulated signal, and then applies this to the correct phases of motor 1545 via a commutation sequence.

In step 1591, the microprocessor receives two lines of information from each motor 1545, 1546, which are output from sensor 1567 (and the sensor for motor 1546). For purposes of clarity, only the control system for motor 1545 will be discussed in detail. It is understood that the control of motor 1546 operates under the same general principles. This information contains the Cartesian components of the net magnetization vector 1569 that exists over sensor 1567, which is directly produced by magnet 1566. When rotor 1544 and shaft 1556 rotate, so does magnet 1566. As a result, the magnetization vector 1569 rotates proximal to sensor 1567. As magnet 1566 rotates, the magnitude and direction of the x and y components change according to tan(theta)=y/x, where theta is the angular position of the

magnetization vector 1569 in the plane parallel to the sensing plane of sensor 1567. Thus, contained in the x and y signal lines lies the information to deduce the angular position of rotor 1544.

The x and y signals enter the microprocessor via data acquisition hardware (not shown) that samples at a frequency (*e.g.* 250 kHz) sufficient to detect rapid changes in the position of rotor 1544. In certain embodiments, the samples are conditioned in step 1592 via a 4^{th} order Butterworth filter to remove high frequency noise. This conditioned x and y data are then passed to the next operation in step 1593.

The Look up Angular Position loop in step 1593 (operating at 1 microsecond per loop iteration in certain embodiments) takes the conditioned x and y data and, using comparison operations, selects one of four lookup tables to determine the theta position of rotor 1544 based on the x and y data. The loop first determines which variable (x or y) is most sensitive at that given point in time by comparing the values of x and y to a predetermine table. After it has been determined which variable is more sensitive, one of four lookup tables, which have been pre-calibrated with the x and y variable data for each ¼ degree angular position of the rotor to determine the rotor's position within ¼ of a degree for that point in time. The angular position is output in bits, each of which correspond to .25 degrees in certain embodiments.

Once the theta position of rotor 1544 has been determined, this information passes to two separate operation loops. The Tracking Control loop in step 1594 (executing at a speed controlled by the user, typically .1-10 msec per loop iteration) looks at the current angular position of rotor 1544. It then compares this to a desired position for rotor 1544 for that particular point in time and calculates the error by taking the difference. In certain embodiments, the Tracking Control loop in step 1594 has its own clock that starts at zero and steps through consecutive values at the loop rate specified by the user. A look-up table containing the desired position of rotor 1544 as a function of time takes the present clock value and returns the desired rotor position for that time. The desired position is then compared to the actual position of rotor 1544 and an error is computed. As the Tracking Control loop in step 1594 cycles, the clock increments and returns the next desired theta value from the lookup table. In this way, a desired position versus time profile for rotor 1544 to follow can be implemented. The internal clock of this loop is reset by a trigger that is activated when the position of second piston 1570 crosses a certain threshold. The output from this loop is the difference between the rotor position and the desired rotor position. This error signal is then sent to the PID Controller.

The PID Controller in step 1595 takes the error signal and computes a gain by multiplying the error, the integral of the error, and the derivative of the error by a proportional gain variable, integral gain variable, and derivative gain variable respectively. The values of these three variables are specified and tuned by the user. The PID controller in step 1595 then sums these errors and outputs an overall Gain which will be used to tell the rotor of the motor which direction to move and how strongly to move in this direction. This particular PID controller 1595 also uses anti-windup capability which allows for the integral gain to be reset to zero on certain events. This is used to prevent large overshoots of the desired position when rotor 1544 is told to stop at a certain position.

The gain from the PID Controller in step 1595 and the angular position information from the Look-up Angular Position loop in step 1593 are then processed by the Commutator/PWM Output loop in step 1596. In certain embodiments, this loop executes in 25 nanoseconds. This loop performs two operations and outputs the information to control the driver circuit 1597 which ultimately controls the magnitude and direction of the current that is applied to each phase of motor 1545. The Commutator portion of loop 1596 uses the current angular position of rotor 1544 to determine which phases to activate in order to actuate rotor 1544. In certain embodiments, motor 1545 is a brushless DC motor with six pole pairs and nine coils. This yields six symmetric configurations of the rotor and coils. For each of these six repeating sequences there are six commutation steps. This design follows a basic six-step commutation scheme for brushless DC motors. In certain embodiments, this scheme is as follows:1 0 -1 : phase 1 FWD, phase 2 OFF, phase 3 REV.

1 -1 0 : phase 1 FWD, phase 2 REV, phase 3 OFF
0 -1 1 : phase 1 OFF, phase 2 REV, phase 3 FWD
-1 0 1 : phase 1 REV, phase 2 OFF, phase 3 FWD
-1 1 0 : phase 1 REV, phase 2 FWD, phase 3 OFF

Where FWD refers to applying a forward bias drive voltage to the phase, REV refers to applying a reverse bias drive voltage to the phase, and OFF refers to applying no voltage to the phase.

By stepping through each of these configurations in a certain order, rotor 1544 can be made to rotate by the magnetic fields produced by the phases. Thus in order to achieve a single 360 degree rotation of motor 1545, this six step commutation sequence must be stepped through six times for a total of 36 steps per rotation. Stepping through each of the 36 phase configurations is performed by the Commutator loop in step 1596 by comparing the current

angular position of rotor 1544 to an array which tells which of the six steps to use for a particular range in angular position values. For instance, when rotor 1544 is between zero and ten degrees it would use one of the six commutation steps, upon crossing into the 10 to 20 degree range, it would use the next phase activation configuration and so on.

The second part of the Commutation/PWM loop in step 1596 is the translation of the gain signal into a pulse width modulated signal for the driver circuitry. In certain embodiments, each phase is driven by an h-bridge MOSFET that takes a single pulse width modulated input to control both the magnitude and direction of the voltage applied to coils 1549. In certain embodiments, when the input line to the MOSFET is at a 50% duty cycle, the bias voltage across the phase coils is zero. For a PWM duty cycle of 100% (i.e. 5V DC), the coil is forward biased with the full driving voltage (e.g. 12 V). For a PWM duty cycle of 0% (0 V DC), the phase receives the full drive voltage in the reverse bias direction. For a duty cycle of 75%, the phase receives 50% of the drive voltage in the forward biases direction, and so on.

In certain embodiments, the algorithm in the Commutation/PWM loop in step 196 generates this signal in the following way. There is a counter in the loop that increments every tick of the 40 MHz FPGA clock (25 nsec). This counter is programmed to reset every 2000 ticks (50 usec). For each phase, the loop determines how many ticks out of the 2000 tick period that the lines should be turned on. On the rising edge of each 50 usec pulse period the angular position of the motor is used to determine the commutation step to use (1, -1, or 0). The magnitude of the gain from the PID controller is then multiplied by this commutation step to generate the on-time for that particular 50 usec pulse period. The value of 1000 is added to the gain signal in order to account for the fact that an on-time of 1000 ticks is needed to produce zero voltage across a phase (1000/2000 = 50% duty cycle = 0 Volts across phase). Finally, the sign of the gain signal is used to determine which direction to apply the voltage (forward or reverse bias). If the gain is negative, the PWM signal is inverted, thus a 75% on, 25% off PWM signal to the driver circuit which would generate a 50% forward voltage across the phase, would be switched to a 25% on, 75% off PWM signal which would create a 50% reverse voltage to be applied to the phase. This is one advantage of having the zero voltage of the driver existing at a duty cycle of 50%; inversion of the duty cycle reverses the direction but leaves the magnitude the same. For instance, a gain of 500 with a commutation step of 1,-1, 0 would tell phase 1 to turn on for 1500 (500+1000) ticks of the 2000 tick pulse period, resulting in a duty cycle of 75% to the driver circuit which would apply 50% of the drive

voltage in the forward position to phase 1, 50% reverse bias for phase 2, and zero volts for phase 3. As the gain varies depending on how close the angular position is to the tracking target angle, the PWM duty cycle varies to apply more or less of voltage to the phases and to move the rotor in a clockwise or counterclockwise direction to minimize said angular error. In this fashion rotor 1544 can be controlled to follow many entered position-time profiles as well as stopping and holding on any particular angle.

By having a tracking controller in which rotor 1546 follows a particular path as it cycles, the position of the piston 1560 can be actuated to generate a variety of hydraulic output profiles. Such profiles may be used in applications requiring pulsatility. The position and velocity of the piston may also be controlled to produce a predetermined waveform in the outlet flow of fluid from the pump.

Referring now to Figures 49-51, another embodiment of a pump 1600 comprises a lower casing 1610, an upper casing 1620, a pumping chamber 1630, an inlet conduit 1640, and inlet port 1641 and an outlet 1650. Pump 1600 further comprises a pair of pistons 1660, 1670 driven by a motor 1645, which comprises a rotor 1625, a bearing 1657, a set of coils 1649, and magnets 1648. Pump 1600 also comprises a magnetic ring 1655 and an electromagnet 1615. It is understood that magnetic ring 1655 may not form a complete circle; for example, magnetic ring 1655 may comprise a gap 1653 in which electromagnet 1615 is positioned. Similar to previously-described embodiments, shaft 1656 may contain a magnet 1666 that is detected by a sensor 1667 to determine the rotational position of rotor 1625.

Unlike previous embodiments which require a separate motor to move each piston around the pumping chamber, pump 1600 moves both pistons 1660, 1670 with a single motor 1645. In certain embodiments, a magnetic link 1647 is coupled to a rotor 1644. Magnetic link 1647 is first coupled to piston 1660, while piston 1670 is held in place by an electromagnet 1615. Figures 52-56 illustrate one embodiment of how magnetic link 1647 transitions from being initially coupled to piston 1660 and being subsequently coupled to piston 1670 (while both piston 1660 and piston 1670 are located in pumping chamber 1630). The labels "N" and "S" refer to the north and south poles of the magnets, respectively. It is also understood that while pistons 1660 and 1670 are shown with tapered surfaces that can act as hydrodynamic bearing surfaces, other embodiments may not include hydrodynamic bearing surfaces. Referring initially to Figures 52 and 53, magnetic link 1647 is linked to piston 1660 and piston 1670 is held stationary by electromagnet 1615. As rotor 1625 rotates, piston 1660 is directed around pumping chamber 1630. With piston 1670 held in place, the movement of

piston 1660 forces fluid from pumping chamber 1630 to exit through outlet 1650 (shown in Figures 49 and 50). As shown in Figure 54, when piston 1660 approaches piston 1670, electromagnet 1615 is momentarily turned off so that piston 1670 is no longer held in place by electromagnet 1615. Piston 1670 is then displaced by piston 1660 (or fluid pressure between pistons 1660 and 1670). In certain embodiments, the current applied to electromagnet 1615 can be reversed to apply a repulsive force to piston 1670. As shown in Figure 55, magnetic link 1647 then moves piston 1660 into the location previously occupied by piston 1670. At this point, electromagnet 1615 is re-energized so that it holds piston 1660 in place. Referring now to Figure 56, magnetic link 1647 then directs piston 1670 around pumping chamber 1630 while piston 1660 is held stationary. While piston 1670 travels around pumping chamber 1630, it forces fluid to exit through outlet 1650. As piston 1670 approaches piston 1660, electromagnetic 1615 is again de-energized so that piston 1660 is no longer held in place. Piston 1670 (or fluid pressure between fluid 1660 and 1670) displaces piston 1660 from its location. Rotor 1625 and magnetic link 1647 then move piston 1670 into the location previously occupied by piston 1670. Electromagnet 1615 is re-energized so that it holds piston 1670 in place. Rotor 1625 and magnetic link 1647 then direct piston 1660 around pumping chamber 1630 and the cycle is repeated. In this manner, the movement of both pistons 1660 and 1670 is controlled by a single motor 1645.

Referring now to Figures 57-62, various embodiments of magnetic link 1647, piston 1660, and magnetic ring 1655 are shown. In Figure 57, magnetic link 1647 and piston 1660 are permanent magnets that are generally the same width. In Figure 58, magnetic link 1647 is comprised of two permanent magnets, with a stronger permanent magnet located under piston 1660 and a smaller magnet extending beyond the leading face 1623 of piston 1660. As shown in Figure 59, magnetic link 1647 comprises a permanent magnet with a constant thickness that extends beyond the leading face 1623 of piston 1660. Referring now to Figure 60, magnetic link 1647 comprises a permanent magnet that extends beyond the leading face 1623 of piston 1660 and tapers to a thinner cross-section. In the embodiment of Figure 61, piston 1660 and magnetic link 1647 also each comprise a Halbach array. In the embodiment shown in Figure 62, piston 1660 and magnetic link 1647 each comprise a Halbach array. In addition, magnetic link 1647 further comprises an extension of magnetically permeable material 1646. The inclusion of an extension of magnetic link 1647 past the leading face 1623 of piston 1660 may provide for a smoother transition from piston 1660 to piston 1670.

Because magnetic link 1647 acts on only one side of pistons 1660, 1670 the forces on piston 1600 may not be balanced. Pistons 1660 and 1670 can therefore experience increased drag or friction forces against the portion of pumping chamber 1630 that is proximal to magnetic link 1647. To counteract this force, certain embodiments of pump 1600 comprise magnetic ring 1655 positioned so that pistons 1660, 1670 are located between magnetic link 1647 and magnetic ring 1655. As shown in the detail view of Figure 51, magnetic ring 1655 can be positioned so that it is generally parallel with rotor 1625. Therefore, magnetic ring 1655 can offset the magnetic forces exerted on pistons 1660, 1670 by magnetic link 1647 and reduce the drag or friction forces created when pistons 1660, 1670 move within pumping chamber 1630. In other embodiments, other features may be used to offset the magnetic forces acting on pistons 1660, 1670, and a magnetic ring may not be used. For example, pistons 1660, 1670 may incorporate a hydrodynamic bearing surface that creates a force opposing the magnetic force provided by magnetic link 1647. Additionally, magnetic ring 1655 can be used in combination with hydrodynamic bearing surfaces to enable passive levitation of the piston as it moves within the chamber.

Referring now to Figure 63, a detailed view of one embodiment of magnetic ring 1655, piston 1660, magnetic link 1647 and rotor 1625 illustrates how Halbach arrays may be incorporated to reduce the required magnet size and / or increase the magnetic forces created. As understood by those skilled in the art, a Halbach array is an arrangement of magnets which increase the magnetic field on one side of the array, and reduces the magnetic field on the opposing side. Additionally, the Halbach array can be used to prohibit excessive drifting of piston 1660 relative magnetic link 1647 when forces arise to displace piston 1660 from magnetic link 1647. In the embodiment shown in Figure 63, magnetic ring 1655 comprises a Halbach array configured to increase the magnetic field on the side closest to piston 1660. In addition, piston 1660 comprises two Halbach arrays (which may be joined with epoxy or any other suitable means) configured to increase the magnetic field on the side closest to magnetic ring 1655. In addition, magnetic link 1647 comprises a Halbach array configured to increase the magnetic field on the side closest to piston 1660. It is understood that Figure 63 is just one exemplary embodiment, and that other embodiments may not comprise Halbach arrays in magnetic ring 1655, piston 1660, or magnetic link 1647.

Referring back now to Figure 50, inlet conduit 1640 is shown to extend from the central portion of pumping chamber 1630 rather than the perimeter. As shown in the perspective view of Figure 64, inlet conduit 1640 also extends generally perpendicular to

pumping chamber 1630 and outlet 1650. Referring now to Figures 65 and 66, such a configuration allows pump 1600 to be placed in the human body so that inlet conduit 1640 extends into a patient's left ventricle 1683. Outlet 1650 may be coupled to ascending aorta 1684 via conduit 1685 as shown in Figure 65. Outlet 1650 may also be coupled to descending aorta 1686 via conduit 1687, as shown in Figure 66. In certain embodiments, outlet 1650 is anastomosed to ascending aorta 1684 or descending aorta 1686.

Referring now to Figures 67-69, another embodiment of a pump 1700 utilizes a single motor 1745 to drive a pair of pistons 1760, 1770. However, the basic configuration of this pump more closely resembles that of pump 1500 shown in Figure 43, rather than pump 1600 shown in Figure 49. More specifically, inlet 1740 and outlet 1750 do not extend perpendicular to each other and lie in the same plane as pumping chamber 1730. Components in Figure 67 that are equivalent to components in Figure 43 are labeled with like numbers, with the exception that Figure 67 components begin with "17xx" and components in Figure 43 begin with "15xx". In the interest of brevity, a full description of the components will not be repeated here.

Pump 1700 differs from pump 1500 in that pump 1700 comprises a single motor 1745 to control both pistons 1760 and 1770. In addition, pump 1700 comprises an electromagnet 1575 comprising a permeable core 1573 and a coil 1574. Pump 1700 operates with the same general principles as those described in the discussion of pump 1600. However, pump 1700 may not require a magnetic ring similar to magnetic ring 1655 because arm magnets 1772 are disposed above and below pistons 1760 and 1770. Therefore, the magnetic forces acting on pistons 1760 and 1770 can be balanced without the use of a separate magnetic ring.

It should be appreciated that the exemplary embodiments previously described can be operated in a forward direction where fluid is drawn into the pump through the inlet conduit and ejected through the outlet conduit or in a reverse direction where the fluid enters the outlet and exits through the inlet conduit. Reverse operation in achieved by simply actuating the pistons in the reverse direction.

Still other embodiments comprise a valve piston that is configured to rotate from into and out of the pumping chamber. Referring initially to FIGS. 70-78, a pump 2100 comprises an inlet 2130, an outlet 2140, and a pumping chamber 2150 forming a loop. Pump 2100 further comprises a valve piston 2110 located between the inlet 2130 and outlet 2140, as well as a drive piston 2120 disposed within the pumping chamber. The loop of pumping chamber 2150 includes a first fluid path that extends clockwise (as shown in FIGS. 70-78) from outlet

2140 to inlet 2130. The loop of pumping chamber 2150 also includes a second fluid path that extends clockwise (as shown in FIGS. 70-78) from inlet 2130 to outlet 2140. During operation, valve piston 2110 is configured to rotate from a first position within the pumping chamber (shown in FIGS. 70-72) to a second position outside of the pumping chamber (shown in FIG. 74). As shown in FIGS. 70-78, when valve piston 2110 is in the first position it will occlude flow in the first fluid path. In addition, when valve piston 2110 is in the second position, it will not occlude flow in the first fluid path.

As explained more fully below, in this embodiment valve piston 2110 is configured to rotate a full 360 degrees during a pumping cycle. As shown in FIG. 70, drive piston 2120 is proximal to pump inlet 2130 during the initial stage of a pumping cycle. A drive mechanism (not shown in FIGS. 70-78) is coupled to drive piston 2120 and configured to move drive piston 2120 around pumping chamber 2150 during operation.

The hydraulic effects of moving drive piston 2120 around pumping chamber 2140 are similar to the effects described in previously-described embodiments. Consequently, such effects will not be described in great detail here. In summary, as drive piston 2120 moves around pumping chamber 2150 and toward outlet 2140, it forces fluid contained within pumping chamber 2150 out of pumping chamber 2150 and out of outlet 2140. As shown in FIGS. 70-73, valve piston 2110 occludes fluid from flowing through pumping chamber 2150 past valve piston 2110, causing fluid to be directed through outlet 2140. As driver piston 2120 moves away from pump inlet 2130, drive piston 2120 also draws fluid through inlet 2130 into pumping chamber 2150.

As shown in FIGS. 73-75, as drive piston 2120 moves clockwise around pumping chamber 2150 and approaches valve piston 2110, valve piston 2110 begins to rotate in a counter-clockwise fashion. The rotation of valve piston 2110 allows drive piston 2120 to move past valve piston 2110 and return to the position shown in FIG. 70. This allows pump 2100 to begin a new pumping cycle and continue the pumping process.

Referring now to FIGS. 79-84, pump 2100 is shown in a slightly different mode of operation. In this mode, valve piston 2110 does not make a complete revolution during a pumping cycle. Instead, valve piston 2110 rotates approximately 90 degrees (or slightly more) as it rotates from the first position within pumping chamber 2150 to the second position outside of pumping chamber 2150. In other respects, the operation of pump 2100 in this mode is equivalent to the mode disclosed in FIGS. 70-68.

Valve piston 2110 is shown in the first position in FIGS. 79-81. As drive piston 2120 approaches valve piston 2110, valve piston 2110 rotates counterclockwise to the second position shown in FIG. 82. After drive piston 2120 has passed valve piston 2110, valve piston 2110 rotates clockwise back to the first position, as shown in FIG. 84 (which is equivalent to the position of valve piston 2110 shown in FIGS. 79-81).

Referring now to FIG. 85, a detailed view of a specific embodiment of valve piston 2110 illustrates that valve piston 2110 comprises a shape that is generally a half-cylinder. In this embodiment, valve piston 2110 comprises a flat surface 2112 and a semi-circular surface 2113. In addition, valve piston 2110 comprises a shaft 2111 extending through valve piston 2110 at the midpoint of flat surface 2112. During operation, valve piston 2110 can be configured to rotate around shaft 2111.

A detailed view of this embodiment of valve piston 2110 during operation is shown in FIGS. 86 and 87. As shown in FIG. 86, valve piston 2110 may be initially located in a first position within pumping chamber 2150. During operation valve piston 2110 may then be rotated to a second position outside of pumping chamber 2150, as shown in FIG. 87. In this embodiment, shaft 2111 may be secured by providing recesses or divots (not shown) in the housing of pump 2100 that engage the ends of shaft 2111, or in other manners known to those skilled in the art. Referring now to FIG. 88, shaft 2111 may be configured so that it can be coupled to pump 2100 without valve piston 2110. Valve piston 2110 may then be coupled to shaft 2111 by inserting shaft 2111 through an aperture extending through valve piston 2110.

Referring now to FIGS. 89-90, another embodiment of valve piston 2110 comprises upper bearing 2114 and lower bearing 2115 contacting the ends of shaft 2111. Upper and lower bearings 2114 and 2115 may be inserted into recesses formed in the housing of pump 2100. Upper and lower bearings 2114 and 2115, as well as shaft 2111, may be formed of materials with excellent wear characteristics to provide for a long operating life for pump 2100. In specific embodiments, upper and lower bearings 2114 and 2115 may be jewel bearings. As shown in FIG. 90, the end portions of shaft 2111 contact upper bearing 2114 and lower bearing 2115 when the pump is fully assembled.

Referring now to FIG. 91, another embodiment comprises a valve piston 2210 with an extended portion 2211 that engages a channel 2212 extending into the region outside of pumping chamber 2250. In this embodiment, valve piston 2210 does not pivot around a shaft extending through the center of the valve piston. Instead, the rotation or pivoting movement of valve piston 2210 is controlled by the engagement of extended portion 2211 and channel

2212. In other aspects, the operation of the embodiment shown in FIG. 91 is equivalent to previously-described embodiments incorporating a rotating valve configuration.

Referring now to FIGS. 92-93, another embodiment incorporates a valve piston with a slightly different configuration than that shown in FIG. 91. In this embodiment, valve piston 2310 comprises a generally "C-shaped" configuration when viewed from above or below (in the orientation shown in FIGS. 92-93). During operation, valve piston 2310 rotates into and out of a channel 2312 that is located outside of pumping chamber 2350. As shown in FIG. 92, channel 2312 (and valve piston 2310) extend around a region 2315 between inlet 2330 and outlet 2340. In certain embodiments an actuating mechanism for valve piston 2310 can be placed in region 2315.

In exemplary embodiments, actuation of the valve piston can be accomplished in any manner suitable to impart a rotational force to the valve piston. In certain embodiments, actuation of the piston valve can be accomplished by a "magnetic gear". As used herein, the term "magnetic gear" includes a first set of magnets and a second set of magnets configured such that rotation of the first set of magnets about a first axis results in rotation of the second set of magnets about a second axis. It is understood that in certain embodiments, a magnetic gear may comprise additional sets of magnets, *e.g.* a third set of magnets disposed proximal to the first set and the second set of magnets.

In specific embodiments, a first set of magnets may be coupled to a piston valve, while one or more magnets (or magnetic material) are located proximal to the piston valve. In certain embodiments, the magnets coupled to the piston valve may be embedded in the piston valve. The magnets coupled to the piston valve may comprise radial magnets (*e.g.*, magnets with attractive or repulsive forces directed towards or away from the center of rotation of the piston valve) and/or axial magnets (*e.g.* magnets with attractive or repulsive forces directed along an axis parallel to the axis of rotation for the piston valve). Referring now to FIG. 94, a piston valve 2410 is shown with a portion of the external cover removed so that the internal components are visible. As shown in FIG. 94, piston valve 2410 comprises radial magnets 2401 and axial magnets 2402. Referring now to FIG. 95, a set of magnets 2415 and magnetic material 2416 (*e.g.*, steel or another alloy comprising iron) are shown disposed in an arc around the curved portion of the outer surface of piston valve 2410.

Magnets 2401 and 2402 (visible in FIG. 94) and magnets 2415 can be configured so that the valve piston 2410 has two equilibrium positions (*e.g.*, a position in which the magnetic forces are in equilibrium and the valve piston is stationary). In one exemplary

embodiment, a first equilibrium position is shown in FIG. 95, while a second equilibrium position is shown in FIG. 96. The position shown in FIG. 95 will be referred to as the "open" position, while the position shown in FIG. 96 will be referred to as the "closed" position. As shown in FIG. 99, when valve piston 2410 is in the closed position, it will substantially occlude fluid from flowing past valve piston 2410 in pumping chamber 2450 of pump 2400. If valve piston 2410 were in the open position (*e.g.*, rotated 180 degrees from the open position), valve piston 2410 would not substantially occlude fluid from flowing past valve piston 2410 in pumping chamber 2450. In certain embodiments, when valve piston 2410 is in the closed position, it will occlude flow from flowing past valve piston 2410 such that 90 percent or more of the total fluid flow is directed through the pump outlet.

It is understood that the configurations shown in the figures are only exemplary embodiments of possible magnetic configurations. In other embodiments, for example, the magnets proximal to valve piston 2410 may be staggered in length or spacing in relation to valve piston 2410. Referring to FIG. 97, magnets 2417 comprise a series of magnets of varying size, so that the attractive forces will be greater at one end of the magnets than the other end. Referring now to FIG. 98, a series of magnets 2418 are arranged so that one end of the magnets is closer to valve piston 2410 than the other end of the magnets. This configuration will also allow the magnetic force to be greater at one end of the magnets than at the other end of the magnets. Other magnetic configurations are also possible that provide for two equilibrium positions of valve piston 2410.

As described more fully below, magnets coupled to a valve piston may interact with additional magnets (or magnetic material) coupled to a drive mechanism that is configured to move a drive piston around a pumping chamber. The interaction between the valve piston magnets and the drive mechanism magnets can cause the valve piston to rotate from a closed equilibrium position to an open equilibrium position and then back to a closed equilibrium position.

Referring now to the exploded view shown in FIG. 100A, pump 2400 comprises a valve piston 2410, a drive piston 2420, a housing 2460 (with a pumping chamber 2450), and a drive mechanism 2470. Drive mechanism 2470 further comprises a motor 2471 and a pair of discs 2472 with drive magnets 2473 that magnetically couple drive piston 2420 to discs 2472. Discs 2472 further comprise drive gear magnets 2474. Although not visible in FIG. 100, lower disc 2472 also comprises drive magnets 2473 and gear magnets 2472 that are equivalent to those visible in upper disc 2472.

When assembled, drive piston 2420 is disposed within pumping chamber 2450 and discs 2472 are located above and below pumping chamber 2450. In addition, valve piston 2410 is coupled to radial magnets 2401 and axial magnets 2402, and valve piston 2410 pivots around shaft 2411. Magnet 2419 is proximal to valve piston 2410 and is configured to create a variable magnetic field around the circumference of valve piston 2410 so that valve piston 2410 may be position in one of two equilibrium positions. As previously described, valve piston 2410 may be positioned in an "open" equilibrium position in which valve piston 2410 is located outside of pumping chamber 2450, or a "closed" equilibrium position in which valve piston 2410 is located within pumping chamber 2450. It is understood that in "closed" position, a portion of valve piston 2410 may still be located outside of pumping chamber 2450, so long as a portion of valve piston 2410 is within pumping chamber 2450. As previously described, in the closed position, valve piston 2410 will substantially occlude fluid from flowing past valve piston 2410 in pumping chamber 2450.

During operation, motor 2471 causes discs 2472 to rotate so that drive magnets 2473 direct drive piston 2420 around pumping chamber 2450. As drive gear magnets 2474 approach valve piston 2410, the interaction between drive gear magnets 2474 and radial magnets 2401 and axial magnets 2402 causes valve piston 2410 to rotate from the closed equilibrium position towards the open equilibrium position. The interaction between magnet 2419 and radial magnets 2401 and axial magnets 2402 causes valve piston 2410 to be placed in the open equilibrium position in the manner previously described. This movement allows drive piston 2420 move past valve piston 2410 while valve piston 2410 is in the open equilibrium position.

As drive piston 2420 moves away from valve piston 2410, the interaction between drive gear magnets 2474 and radial magnets 2401 and axial magnets 2402 causes valve piston 2410 to rotate from the open equilibrium position towards the closed equilibrium position in the manner previously described. As drive gear magnets 2474 are rotated further away from valve piston 2410, the interaction between magnets 2419 and radial magnets 2401 and axial magnets 2402 causes valve piston to be placed in the closed equilibrium position. During operation, drive mechanism 2470 will continue to direct drive piston 2420 around pumping chamber 2450. The magnetic gear formed between drive gear magnets 2474, radial magnets 2401, axial magnets 2402 and magnet 2419 causes valve piston 2410 to move between the open and closed equilibrium positions as drive piston 2420 is moved around pumping chamber 2450 by drive mechanism 2470.

The magnetic gear (*e.g.*, drive gear magnets 2474, radial magnets 2401, axial magnets 2402 and magnet 2419) provides for an efficient, automatic control system for controlling the position of valve piston 2410 in relation to the position of drive piston 2420. Variables in the design criteria of the magnetic gear (*e.g.*, the magnet size, shape, location, and relative proximity to each other) allow for a "non-linear" gear ratio between the rotation of drive piston 2420 and valve piston 2410. For example, the magnets can be configured so that there is not a one-to-one correlation between the rotation of valve piston 2410 and that of drive piston 2420. In certain embodiments, the gear ratio is dependent upon the angular position of the magnetic gear. Referring now to FIG. 100B, a specific configuration of drive gear magnets 2474 is shown for one exemplary embodiment. As shown, driver gear magnets 2474 have a particular shape that imparts a desired magnetic force on valve piston 2410 as driver gear magnets 2474 are rotated around pump 2400.

For example, depending on the desired fluid dynamics, it may be desirable to have valve piston 2410 remain in the closed equilibrium position until drive piston 2420 is relatively close, and then have valve piston move from the closed position to the open position at a greater angular velocity than that of drive piston 2420. Drive piston 2420 can therefore be rotated at a constant angular velocity (such as provided by electric motor 2471) while valve piston 2410 can be quickly accelerated between the closed and open equilibrium positions. The magnetic gear also provides a control system that does not require external control mechanisms to coordinate the positions of drive piston 2420 and valve piston 2410.

Referring now to FIGS. 101-102, another exemplary embodiment of a pump 2500 is shown with a different magnetic gear configuration from that shown in FIGS. 100A and 100B. In this embodiment, pump 2500 comprises a valve piston 2510, a drive piston 2520, a housing 2560 (with a pumping chamber 2550), and a drive mechanism 2570. Drive mechanism 2570 further comprises a motor 2571 and a pair of discs 2572 with linking arms 2575 and drive magnets 2573 that magnetically couple drive piston 2520 to discs 2572. Drive mechanism further comprises a set of gear magnets 2474 coupled to each disc 2472.

Unlike the embodiment of FIG. 100, pump 2500 does not comprise a magnet similar to magnet 2419 that extends partially around the circumference of valve piston 2510. Pump 2500 does comprise a pair of discs 2521 with magnets 2522 and 2519 that are placed on each side of valve 2510 (*e.g.* above and below valve piston 2510 in the position shown in FIG. 101). Magnets 2519 are magnetically coupled to magnet 2501, which is coupled to valve piston 2510. As discs 2521 rotate, magnets 2519 will also cause valve piston 2510 to rotate.

In general, pump 2500 operates in a manner similar to that described of pump 2400. During operation, motor 2571 causes discs 2572 to rotate so that drive magnets 2573 direct drive piston 2520 around pumping chamber 2550. As shown in FIG. 102, when pump 2500 is assembled, discs 2572 and 2521 are positioned so that the outer circumferences of each disc are in close proximity to each other. As drive gear magnets 2574 rotate and approach valve piston 2510, the interaction between drive gear magnets 2574 and magnets 2522 causes discs 2521 to rotate. In certain embodiments, drive gear magnets 2574 comprise a first portion and a second portion that are radially spaced apart. As described below, the first portion of drive gear magnets 2574 may be used to rotate valve piston 2510 from a closed position to an open position, while the second portion of drive gear magnets 2574 may be used to rotate valve piston 2510 from the open position to the closed position.

Referring now to FIG. 103, valve piston 2510 (visible in this partial section view) is shown in an initial open position (*e.g.*, outside of pumping chamber 2550). Discs 2574 are positioned so that the first and second portions of driver gear magnets 2574 are positioned on each side of valve piston 2510. As shown in FIGS. 104-106, as discs 2574 rotate clockwise, the second portion of drive gear magnets 2574 are placed proximal to magnets 2522. The interaction between driver gear magnets 2574 and magnets 2522 causes discs 2521 to rotate counterclockwise. In certain embodiments driver gear magnets 2574 and magnets 2522 are formed by individual magnets with alternating orientations so that alternating magnets have attractive forces directed towards or away from the center of the respective discs 2574 and 2521.

Referring now to FIG. 107, valve piston 2510 is shown in the closed equilibrium position. Valve piston 2510 will remain in this position as discs 2574 rotate because the magnetic forces on discs 2521 and valve piston 2510 remain constant until discs 2574 rotate to the position shown in FIG. 108. At the position shown in FIG. 108, the first portion of drive gear magnets 2574 begin exerting a magnetic force sufficient to cause rotation of discs 2521 and valve piston 2510. As shown in FIG. 109, further rotation of discs 2574 causes additional rotation of valve piston towards the open equilibrium position. The progression of driver piston 2520 is also visible in the partial section views of FIGS. 104-109.

In this embodiment, the rotation of discs 2521 causes valve piston 2510 to rotate from the open equilibrium position towards the closed equilibrium position (via the magnetic coupling with magnets 2519 and 2501). When the first portion of drive gear magnets 2574 rotate past discs 2521, magnets 2522 hold discs 2521 (and valve piston 2510) in the open

equilibrium position. Discs 2521 and valve piston 2510 can be held in the open equilibrium position via a steady-state magnetic attraction to a component that does not create a varying magnetic attraction to magnets 2522 when driver gear magnets 2574 are not close enough to cause a rotation of discs 2521. In certain embodiments, the outer portions of discs 2572 (not occupied by drive gear magnets 2574) may be a magnetic material that creates a steady-state magnetic attraction to magnets 2522 and/or 2519 and causes discs 2521 to remain stationary. In such embodiments, when drive gear magnets 2574 are not proximal to magnets 2522, discs 2521 (and valve piston 2510) will remain stationary because the magnetic force will remain relatively constant as discs 2572 rotate. Characteristics of the magnets (*e.g.*, size, orientation, spacing, strength, etc.) in the magnetic gear, particularly driver magnets 2574, can be selected to produce a desired rotation of valve piston 2510. For example, it may be desired to have valve piston 2510 rotate at different angular velocities and/or accelerations depending on the position of drive piston 2520.

SYSTEMS AND METHODS OF CONTROLLING OPERATION

Certain embodiments of the present invention consist of systems and methods for controlling the speed, pulse profile, and timing of a positive displacement pump to synchronize with external loads utilizing a sensor to measure external variables. As illustrated in the schematic of an exemplary embodiment in FIG. 110, a pump and control system 2600 may comprise a graphical user interface (GUI) 2610 and a sensor 2620 configured to provide output signals 2611 and 2621, respectively, to a microprocessor 2630. Sensor 2620 may be configured to measure one or external variables, including for example, a pressure or flow in a particular region (*e.g.* ventricular pressure), ventricular depolarization, a heart contraction, a diaphragm motion, and/or a bodily inclination or movement. GUI 2610 can be configured to allow a user to select a specific operating mode (described more fully below). Based on the operating mode selected and the input from sensor 2620, microprocessor 2630 can provide an output signal 2631 to a pump 2650. In specific embodiments, microprocessor 2630 can control an operational parameter, *e.g.* the rotational position, velocity, and acceleration of a drive piston (not visible in the schematic of FIG. 110) with the output signal sent to pump 2650. In certain embodiments, microprocessor 2630 can control an operational parameter related to a valve mechanism disposed between the inlet and outlet of the pump. For example, microprocessor 2630 can control the position of a valve piston or the opening and closing of a pinch valve disposed between the inlet and outlet of the pump.

As demonstrated in FIG. 111, the flow rate for pump 2650 can be varied based on the output signal from microprocessor 2630. The flow curves shown in FIG. 111 are examples of just a few of the many curves that may be generated according to embodiments of the present disclosure. Through control of the position of the piston within the pumping chamber, the shape of the pump flow rate curve can be precisely controlled in exemplary embodiments. Similarly, the duration of the pump stroke can be controlled so as to deliver volume more quickly, which may have beneficial consequences on hemodynamic pulsatility.

In certain embodiments, pump 2650 can be run at a variably controlled, fixed rate, utilizing a specific curve shape, and can produce output flows from zero to ten liters (or more) per minute. With input from sensor 2620 which can sense, *e.g.*, left ventricular pressure, electrical activity, myocardial contraction, or any other external variable, pump 2650 can be configured such that a pump cycle (*e.g.* one revolution of the drive piston around the pumping chamber of the previously-described pump embodiments) is synchronized with the cardiac cycle of a patient.

A pump used in exemplary embodiments of the present disclosure can include a positive displacement device, similar to current pulsatile pump technology. However, a pump in exemplary embodiments of this disclosure can be configured to aspirate and eject blood simultaneously, similar to the current continuous pump technology. This unique combination of features and capabilities allows for the possibility of various pumping modes not available with existing systems. These operational modes have the potential to restore the natural sensitivity to preload, afterload, and heart rate and also have the potential for new and beneficial weaning protocols.

In certain embodiments, the pump can be controlled in an asychronous manner (as illustrated in FIG. 112), *e.g.* wherein the pumping cycle or stroke is not timed with or triggered by the patient's heart beat. In still other embodiments, the pump can be controlled in a synchronous manner so that the timing of the pumping stroke is related to the patient's heart beat. As illustrated in FIG. 113, the pump stroke can occur during ventricular diastole. The pump cycle is triggered by the patient's heart beat, but a delay is provided between the heart beat and the increase in flow rate from the pump. In the embodiment illustrated in FIG. 114, the pump stroke occurs during the ventricular systole. Again, the pump cycle is triggered by the patient's heart beat, but a delay is provided between the heart beat (*e.g.* the contraction of the patient's heart muscle) and the increase in flow rate from the pump.

In exemplary embodiments of the present disclosure, the pump can be used as a ventricular assist device and is specifically meant to synchronize with the natural rhythm of the heart. When synchronized with the heart, the pump can perform in any of various operations modes. One such operation mode is a single pump stroke per heart beat. The timing of the pump stroke within the cardiac cycle can be timed with variable delay using the external sensor as the trigger mechanism. Other operation modes could include two or more pump strokes per heart beat (as illustrated in FIG. 115), one stroke every other heart beat (1:2) (as illustrated in FIG. 116), one stroke every three heart beats (1:3), two strokes every three heart beats (2:3) (as illustrated in FIG. 117), or any other combination of pump strokes to heart beats. In certain embodiments, the control system can be configured to provide one stroke for two consecutive heart beats and then two strokes for the third heart beat (as illustrated in FIG. 118). In exemplary embodiments, the pump can detect when the cardiac cycle or heart beat is regular (*e.g.*, occurring at a consistent frequency and within normal variations due to fluctuations in load) and maintain a synchronous pump cycle. However, in certain exemplary embodiments, the pump can also detect when the patient's heart beat becomes irregular (*e.g.* not occurring at a consistent frequency and within normal variations due to fluctuations in load) or absent. In such instances, the pump can revert to an asynchronous mode if the native cardiac rhythm becomes irregular, allowing full support of the left-sided circulation.

In certain embodiments, the pump operational mode can be modified in response to a change in heart rate of the patient. For example, as shown in FIG. 119, the operational mode can be changed at approximately 90, 110, and 130 beats per minute to increase the flow rate of the pump. Such changes in operational mode allow the pump to more closely approximate the response of a normal or healthy heart. Similarly, as shown in FIG. 120, the pump operation can be controlled to more closely approximate a normal response to a decrease in mean arterial pressure.

Referring now to FIG. 121, an "operational map" may be used to take into account the level of heart failure and the heart rate when determining the operational mode of the pump.

FIG. 122 provides simulated and predicted pressure loops (corresponding to mycordial oxygen consumption) for heart failure, counter-pulse VAD support, and co-pulse VAD support. Both counter-pulse and co-pulse modes reduce left ventricular end diastolic volume (LEDV), and co-pulse significantly reduces mycardial oxygen consumption (MVO_2).

FIG. 123 provides computational predictions of the percent of support required to produce cardiac output of 5 L/min in severe heart failure with pump support under various types of control schemes. A counterpulsation control scheme allows for more pump flow through the aortic valve. Because this flow is a significant portion of the cardiac output, it is appropriately sensitive to preload and afterload variation. Counterpulsation flow also has the potential to restore the cardiac output response to the body's natural feedback control mechanisms.

In certain exemplary embodiments, a pump can be operated in a counterpulsation mode (*e.g.*, simultaneously aspirating and ejecting during ventricular diastole). In such embodiments, there are much different effects than existing pulsatile pumps which aspirate during systole and eject during diastole in synchronous mode. For example, during systole, the heart has the opportunity to eject through the aortic valve into the arterial tree. This 'native-flow' is appropriately sensitive to the body's natural feedback mechanisms, especially preload and afterload. This sensitivity allows the cardiac output to adjust itself using the natural means. This has the potential to allow normal responses to basic activities such as exercise which require increased heart rate or sleeping which tends to decrease heart rate.

In counterpulsation, a significant portion of cardiac output is still assumed by the ventricle through the aortic valve. This effectively reduces the amount of flow required for a simultaneously aspirating and ejecting pulsatile pump as compared to existing pulsatile and continuous VAD technologies.

In certain exemplary embodiments, a pump can be operated in a co-pulsation mode (simultaneously aspirating and ejecting during ventricular systole). Such embodiments provide significant unloading of the ventricle, which has the potential to lower myocardial oxygen consumption and encourage myocardial recovery. This mode may be especially beneficial in bridge to recovery patients who have a greater chance of recovery. Because the pump in such embodiments would take over the majority or all of the flow in this situation, it would be possible, and even beneficial, to allow the ventricle to eject through the aortic valve every fourth or fifth beat (for example). This could prevent aortic root stagnation which can lead to thrombotic complications.

In certain exemplary embodiments, a pump can be operated in a partial support mode (*e.g.* with a ratio of pump strokes to heart beats of 1:2, 2:3, 1:3, *etc.*), which allows for synchronicity to be maintained while reducing support. These modes could be utilized for

weaning, which would allow the ventricle to begin assuming more and more of the cardiac output and work and avoid atrophy.

Referring now to FIGS. 124-132, an exemplary embodiment includes a pump 2700 that comprises an inlet 2730, an outlet 2740, and a pumping chamber 2750 forming a loop. Pump 2700 further comprises a valve piston 2710 located between the inlet 2730 and outlet 2740, as well as a drive piston 2720 disposed within the pumping chamber. Other embodiments may comprise a valving mechanism other than a valve piston. For example, other embodiments may comprise a pinch valve or other suitable valving mechanism as described in previous embodiments. In the exemplary embodiment shown in FIG. 124, valve piston 2710 and drive piston 2720 are configured to serve interchangeable functions similar to the embodiment illustrated in FIGS. 1-13 (*e.g.*, wherein valve piston 2710 becomes drive piston 2720 and vice versa during operation of pump 2700). It is understood that in other embodiments, the valve piston may be configured similar to other previously described embodiments.

In this embodiment, the cross-sectional area of pump inlet 2730 and pump outlet 2740 (at the region where pump inlet 2730 and pump outlet 2740 intersect pumping chamber 2750) are greater than the outer surface area of drive piston 2720. Referring now to FIGS. 130 and 132, area A1 represents the cross-sectional area of the transition zone between pump outlet 2740 in the region where it intersects pumping chamber 2750. Area A1 has a length L1 (measured along the path that drive piston 2720 travels in pumping chamber 2750) and a width W1 (measured perpendicular to length L1).

As shown in FIG. 132, drive piston 2720 has an outer surface 2721 with a surface area A2. Area A2 has a length L2 (measured along the path that drive piston 2720 travels in pumping chamber 2750) and a width W2 (measured perpendicular to length L2). In exemplary embodiments, outer surface 2721 is configured so that it does not block area A1 when the drive piston 2720 is in the region where pump inlet 2730 or pump outlet 2740 intersects pumping chamber 2750. For example, outer surface 2721 can be configured so that fluid is allowed to pass from pumping chamber 2750 to pump outlet 2740 regardless of the position of drive piston 2720. Drive piston 2720 and area A1 are configured so that drive piston 2720 does not seal or isolate pump outlet 2740 from pumping chamber 2750. Therefore, pump outlet 2740 is in fluid communication with pumping chamber 2750 regardless of the location of drive piston 2720 within pumping chamber 2750. In certain embodiments, length L1 of area A1 is greater than length L2 of area A2. In certain

embodiments, width W1 of area A1 is greater than width A2 of area A2. In particular embodiments, A1 comprises a greater area than A2.

Referring now to FIG. 131, pump inlet 2730 intersects pumping chamber 2750 in a transition zone with an area A3 (representing the cross-sectional area of the transition zone between pump inlet 2730 and pumping chamber 2750). Area A3 has a length L3 (measured along the path that drive piston 2720 travels in pumping chamber 2750) and a width W3 (measured perpendicular to length L3). Area A3 is also configured so that drive piston 2720 does not seal or isolate pump inlet 2730 from pumping chamber 2750, regardless of the position of drive piston 2720. In certain embodiments, length L3 of area A3 is greater than length L2 of area A2. In certain embodiments, width W3 of area A3 is greater than width A2 of area A2. In particular embodiments, A1 comprises a greater area than A2.

During operation, this configuration allows fluid to flow from pumping chamber 2750 to pump outlet 2740 regardless of the position of drive piston 2720 within pumping chamber 2750 (including when drive piston 2720 is in the region where pump outlet 2740 intersects pumping chamber 2750). Similarly, this configuration allows fluid to flow from pump inlet 2730 to and into pumping chamber 2750 regardless of the position of drive piston 2720 within pumping chamber 2750 (including when drive piston is in the region where pump inlet 2730 intersects pumping chamber 2750). The flow of fluid between pump inlet 2730, pumping chamber 2750, and pump outlet 2750 will depend on other factors (*e.g.*, pressure differential) but will not be prevented

Referring now to FIG. 124, pump 2700 is shown during operation when drive piston 2720 is located in a position proximal to pump inlet 2730. In this position, a first volume of fluid 2731 is located within pumping chamber 2750 between drive piston 2720 and pump outlet 2740 (*e.g.*, leading drive piston 2720). As shown in FIG. 124, when drive piston 2720 is in this position, area A2 of surface 2721 (visible in FIG. 132) does not block off area A3 (shown in FIG. 131) where pump inlet 2730 intersects pumping chamber 2750. A second volume of fluid 2732 trailing drive piston 2720 can therefore begin flowing from pump inlet 2730 into pumping chamber 2750. When drive piston 2720 has progressed to the position shown in FIG. 125, second volume of fluid 2732 has completely entered pumping chamber 2750. Second volume of fluid 2732 continues to trail drive piston 2720 as it progresses around pumping chamber 2750.

When drive piston 2720 reaches approximately the position shown in FIG. 126, a portion of second volume of fluid 2732 begins to exit pumping chamber 2750 and flow into

pump outlet 2740. As shown in this position, both pump inlet 2730 and pump outlet 2740 are in fluid communication with pumping chamber 2750. In the position shown, neither drive piston 2720 nor valve piston 2710 are occluding fluid flow between pump inlet 2730, pumping chamber 2750 and pump outlet 2740. When pistons 2710 and 2720 are in the position shown, pumping chamber 2750 acts as a shunt and creates a first fluid path between pump inlet 2730 and pump outlet 2740. The first fluid path extends clockwise (as shown in FIG. 126) from pump inlet 2730 around pumping chamber 2750 to pump outlet 2740. A second fluid path extending clockwise from pump outlet 2740 to pump inlet 2730 is blocked by valve piston 2710, as shown in FIG. 126. In certain embodiments, the fluid pressure in the region in pumping chamber 2750 trailing drive piston 2720 is greater than the fluid pressure in pump outlet 2740 when the drive piston 2720 is in the position shown in FIG. 126. This difference in pressure can provide a motive force for second volume of fluid 2732 to flow from pumping chamber 2750 to pump outlet 2740.

During operation of pump 2700, the first volume of fluid 2731 is forced from pumping chamber 2750 in a manner consistent with a positive displacement pump. For example, the movement of drive piston 2720 around pumping chamber 2750 forces first volume of fluid 2731 out of pumping chamber, provided drive piston 2720 continues to travel around pumping chamber 2750. So long as the drive mechanism (not shown) coupled to drive piston 2720 provides sufficient motive force to move drive piston 2720 around pumping chamber 2750, the volume of fluid contained in first volume of fluid 2731 (*e.g.*, the volume of fluid forced out of pumping chamber 2750 ahead of drive piston 2720) will remain constant.

However, the volume of fluid contained in second volume of fluid 2732 will depend on other operational factors. For example, the volume of fluid contained in second volume of fluid 2732 can depend on the pressure differential between pump inlet 2730 and pump outlet 2740 when drive piston 2720 is at particular locations within pumping chamber 2750. This allows a portion of the total volume of fluid pumped by pump 2700 to be sensitive to the loading (or pressures) upstream and downstream of the pump, and restores the heart's native sensitivity to such parameters. These characteristics can also provide for smoother transitions in the flow rate from pump 2700 as compared to pumps that provide flow only through positive displacement pumping methods.

Referring now to FIG. 127, valve piston 2710 begins to move away from the location between pump inlet 2730 and pump outlet 2740 and drive piston 2720 begins to move into the region between pump inlet 2730 and pump outlet 2740. Referring now to FIGS. 128 and 129,

the two pistons have now reversed roles (as compared to the functions described in FIGS. 124-127) so that the previous drive piston is functioning as the valve piston and vice versa.

In certain embodiments, exemplary embodiments of the present disclosure may include components with surfaces that comprise polycarbonate urethane (PCU) or other materials that allow for soft elastohydrodynamic lubrication (SEHL) between the components as they move relative to one another. Other embodiments may include components comprising other materials. For example, other embodiments may comprise a polyurethane material. Specific embodiments may include components comprising polycarbonate urethane, polyether urethane, silicon polycarbonate urethane, or silicon polyether urethane. Specific embodiments may comprise polyurethanes with surface modifying endgroups (SMEs), including for example, silicone, sulfonate, fluorocarbon, polyethylene oxide, or hydrodcarbon. Specific examples of materials that may be used in certain embodiments are disclosed in U.S. Patent Publication 20070219640, entitled "Ceramic-on-Ceramic Prosthetic Device Coupled to a Flexible Bone Interface" and incorporated by reference herein.

SEHL is a form of hydrodynamic lubrication where the surfaces are highly deformable and adaptive to pressure buildup in the gap, similar phenomenon can be seen in rotary lip seals, windshield wipers, flexible thrust pad bearings, soft-lined journal bearings, and hydroplaning tires. While PCU is utilized in one exemplary embodiment, any biocompatible material with suitable wear characteristics and sufficient deformability to allow for SEHL may also be utilized. In certain embodiments, a drive piston is coated in PCU to provide for SEHL between the drive piston and the pumping chamber when the drive piston moves relative to the pumping chamber during operation.

PCU's are currently used as compliant lubrication layers in artificial hips and knees as surrogates for the body's natural contact layer, cartilage. PCU's have proven themselves as biocompatible and long-lasting surfaces in *in vivo* artificial hip trials lasting 5 to 10 years.

In the presence of SEHL, the minimum film thickness between the surfaces can be an order of magnitude less than that of a traditional hydrodynamic bearing with hard surfaces, less than the diameter of a red blood cell.

To encourage lubrication between the piston and the pumping chamber, a highly deformable material could be used on either surface. The interaction between a highly deformable surface and its rigid counterpart has the potential to produce soft elastohydrodynamic lubrication during piston actuation with very small running clearances.

Reducing the operating clearances can provide low coefficients of friction ($\mu \sim 0.01$). In certain embodiments, the operating clearances can be reduced to an acellular level. The reduction in operating clearances to an acellular level can potentially reduce hemolysis generated in the high shear region between the surfaces, and low wear and long-lasting surfaces.

Referring now to FIG. 133, a side view of a drive piston 2820 in proximity to a wall 2851 of a pumping chamber 2850 during operation. In certain embodiments, pumping chamber 2850 forms a loop and wall 2851 can be an outer or inner wall, or an upper or lower wall of pumping chamber 2850. Drive piston comprises a leading face 2823, a trailing face 2824, and a deformable surface 2828 extending between the leading face 2823 and the trailing face 2824. As used herein the term "deformable" (and variations thereof) includes materials or surfaces that are deformed at least 0.000001 inches during operation. The deformed profile 2821 of drive piston 2820 is represented by the solid profile line in FIG. 133, while an undeformed profile 2822 of drive piston 2820 is represented by the dashed line in FIG. 133. It is understood that the figures illustrating SEHL properties are not drawn to scale and that certain features may be exaggerated for purposes of clarity. For example, the distance of the gap (illustrated as dimension F) formed between the leading face 2823 and pumping chamber wall 2851 could be approximately 0.010 inches in certain embodiments. In other embodiments the gap between the leading face of a moving component and a stationary component may be 0.005 - 0.010 inches, 0.010 – 0.015 inches, 0.015 – 0.020, 0.020 – 0.025 inches or more.

A graph of the pressure profile of the fluid between drive piston 2820 and pumping chamber wall 2851 is shown below the side view of drive piston 2820 and pumping chamber 2850. As shown in FIG. 133, drive piston 2820 is moving in the direction of arrow 2829 (*e.g.* towards the left in FIG. 133) and pumping chamber wall 2851 is stationary. In this exemplary embodiment, drive piston measures 0.5 inches across (from leading face 2823 to trailing face 2824). When drive piston begins moving toward the left as shown in FIG. 133, fluid that is present in pumping chamber 2850 is directed into the gap between leading face 2823 and pumping chamber wall 2851. As drive piston 2820 continues to move toward the left, the fluid in the area between drive piston 2820 and pumping chamber wall 2851 is compressed as a result of the tapered profile of drive piston 2820. In exemplary embodiments, the fluid present in pumping chamber 2850 is less compressible than the profile of drive piston 2820.

The interaction between the fluid and drive piston 2820 causes the profile of drive piston 2820 to deform from the undeformed profile 2822 to the deformed profile 2821.

As illustrated in the pressure profile graph, the pressure of the fluid between drive piston 2820 and pumping chamber wall 2851 is at its maximum in the area between the middle portion of drive piston 2820 and pumping chamber wall 2851 (*e.g.*, approximately 0.25 inches from leading face 2823 and trailing face 2824). In this particular embodiment, the fluid pressure increases to approximately 1,000 mmHg at the maximum value. It is understood that in other embodiments, the pressure increase may be more or less than the value shown in FIG. 133. As shown in FIG. 133, the region that exhibits the highest fluid pressure corresponds to the greatest amount of deformation of drive piston 2820. As shown in FIG. 133, the profile of drive piston may also include a taper between the center region and the trailing face 2824. This allows for the fluid pressure to return to the levels existing before the interaction with drive piston 2820.

In this embodiment drive piston 2820 comprises a flexible or deformable material (for example PCU or other suitable material) in the area that is in proximity to pumping chamber wall 2851. As drive piston 2820 moves relative to pumping chamber wall 2851, the increase in fluid pressure between drive piston 2820 and pumping chamber wall 2851 causes drive piston 2820 to take the shape of deformed profile 2821. During operation, the profile of drive piston 2820 deforms until an equilibrium of forces acting on drive piston 2820 is established.

Referring now to FIG. 134, a cross-section view of an exemplary embodiment comprises a drive piston 2920 having a central portion 2925 with an outer covering 2926 comprising flexible material (*e.g.* PCU). This embodiment is similar to the embodiment described in FIG. 133, but includes a gap 2927 between outer covering 2926 and central portion 2925. In particular embodiments, central portion 2925 may comprise a material that is magnetic (*e.g.*, a permanent magnet, an electromagnet or a ferromagnetic material) to allow drive piston 2920 interact with other magnetic components in the pump. In specific embodiments, a magnetic gear can be used to control the interaction between drive piston 2920 and a valve piston (not shown in FIG. 133).

In certain embodiments gap 2927 may comprise air or another compressible fluid. In this embodiment, outer covering 2926 comprises a deformable region 2928 between gap 2927 and a wall 2951 of pumping chamber 2950.

During operation, this configuration allows deformable region 2928 to deform and compress the fluid in gap 2927. In exemplary embodiments, the fluid in gap 2927 is more easily compressed than the material comprising deformable region 2928 (*e.g.* the material comprising deformable region 2928 has a higher modulus of elasticity in compression than the fluid contained in gap 2927). In addition, the bending stiffness of deformable region 2928 is less than the compression stiffness of the material of outer covering 2926. Therefore, during operation the fluid pressures and forces required to deform or deflect deformable region 2928 away from wall 2951 will be reduced as compared to a configuration that did not include gap 2927.

Such a configuration may also allow for reduced tolerance constraints during manufacturing of components. In addition, the configuration shown in FIG. 134 may provide easier assembly (*e.g.*, by allowing drive piston 2920 to be fitted into the pumping chamber by deforming outer covering 2926 and compressing the fluid in gap 2927).

Referring now to FIG. 135, a cross-section view of an exemplary embodiment comprises a drive piston 3020 having a central portion 3025 with an outer covering 3026 comprising flexible material (*e.g.* PCU). In this embodiment, outer covering 3026 comprises a shape that is generally parallel to a wall 3051 of pumping chamber 3050. However, outer covering 3026 includes a lip or extension 3027 proximal to trailing face 3024 that extends closer to wall 3051 of pumping chamber 3050. During operation, drive piston 3020 will move in the direction of leading face 3023 (to the left as depicted in FIG. 135). A tapered section 3029 will direct fluid between outer covering 3026 and wall 3051. The fluid will form an EHL layer between extension 3027 and wall 3051, causing extension 3027 to deflect away from wall 3051. Extension 3027 can maintain close proximity to wall 3051 during operation, thereby minimizing fluid losses.

Referring now to FIG. 136, a cross-section view of an exemplary embodiment comprises a drive piston 4020 having a central portion 4025 with an outer covering 4026 comprising flexible material (*e.g.* PCU). In this embodiment, outer covering 4026 comprises a shape that is generally parallel to a wall 4051 of pumping chamber 3050. However, outer covering 4026 includes tapered sections 4027 and 4029 at each end of the surface that is parallel to wall 4051. Tapered sections 4029 will direct fluid between outer covering 4026 and wall 4051 depending on the direction of travel of drive piston 4020 (which can be either to the left or the right as shown in FIG. 136).

Although FIGS. 133-136 depict embodiments that provide for elastohydrodynamic lubrication between a drive piston and the wall of a pumping chamber, it is understood that other embodiments may provide for EHL between any components that move relative to each other. For example, certain embodiments may provide for EHL between a valve piston and a pumping chamber wall. Other embodiments may also provide elastohydrodynamic lubrication between a drive piston and the wall of a pumping chamber by providing a pumping chamber wall with a deformable surface and a drive piston that does not deform under operating conditions.

While the above description contains many specifics, these should not be construed as limitations on the scope of the invention, but as exemplifications of the presently preferred embodiments thereof. Many other modifications and variations are possible within the teachings of the invention such as using the pump to oscillate fluid through a flow circuit or using the pump for the precise delivery of discrete and metered fluid quantities to a system. Other embodiments may comprise additional features, such as one or more sensors configured to measure properties of the pumped fluid (*e.g.*, temperature, pH, pressure, etc.)

Thus the scope of the invention should be determined by the appended claims and their legal equivalents, and not by the examples given.

REFERENCES

The following references, to the extent that they provide exemplary procedural or other details supplementary to those set forth herein, are specifically incorporated herein by reference.

U.S. Patent No. 6,576,010

U.S. Patent No. 5,089,016

U.S. Patent Publication 20070219640

CLAIMS

1. A method of pumping a fluid, the method comprising:

providing a pump comprising a pumping chamber, an pump inlet, and a pump outlet, wherein:

the pumping chamber forms a loop;

the pump inlet and the pump outlet are in fluid communication with the pumping chamber; and

the pumping chamber comprises a first fluid path between the pump inlet and the pump outlet and the pumping chamber comprises a second fluid path between the pump inlet and the pump outlet;

providing fluid in the pumping chamber and in the pump inlet;

providing a drive piston disposed within the first fluid path of the pumping chamber;

providing a valve mechanism configurable in a first position to substantially occlude flow in the second fluid path and a second position to permit flow in the second fluid path;

placing the valve mechanism in the first position;

moving the drive piston within the first fluid path, wherein:

fluid is drawn from the fluid inlet into the pumping chamber;

fluid drawn from the fluid inlet into the pumping chamber is trailing the drive piston; and

fluid leading the drive piston is forced from pumping chamber into the pump outlet;

positioning the drive piston so that a shunt is created in the first fluid path between the pump inlet and the pump outlet; and

allowing fluid trailing the drive piston to flow from the pumping chamber to the pump outlet.

2. The method of claim 1 wherein the valve mechanism comprises a valve piston.

3. The method of claim 2 wherein the valve piston rotates from the first position to the second position.

4. The method of claim 3 wherein a magnetic gear rotates the valve piston from the first position to the second position.

5. The method of claim 4 wherein the magnetic gear comprises an angular dependent gear ratio.

6. The method of claim 3 wherein the valve piston rotates in one direction when moving from the first position to the second position and rotates in the opposite direction when moving from the second position to the first position.

7. The method of claim 3 wherein the valve piston rotates in the same direction when moving from the first position to the second position and when moving from the second position to the first position.

8. A method of pumping a fluid, the method comprising:

providing a pumping chamber containing a fluid;

providing a pump inlet in fluid communication with the pumping chamber;

providing a pump outlet in fluid communication with the pumping chamber, wherein the pumping chamber comprises a first fluid path between the pump inlet and the pump outlet and the pumping chamber comprises a second fluid path between the pump inlet and the pump outlet;

providing a drive piston disposed within the first fluid path of the pumping chamber;

providing a valve piston disposed within the second path of the pumping chamber;

providing a drive mechanism for actuating the drive piston;

providing a mechanism for moving the valve piston into and out of the second fluid path of the pumping chamber;

actuating the drive piston around the first path of the pumping chamber so that energy is transferred from the drive piston to the fluid and so that a portion of the fluid is drawn into the pump inlet and a portion of the fluid is forced out of the pump outlet;

moving the valve piston out of the second fluid path;

actuating the drive piston so that a shunt is formed by the first fluid path between pump inlet and the pump outlet;

allowing energy of the fluid in the pumping chamber to continue to draw fluid from the fluid inlet and expel fluid out of the fluid outlet;

actuating the drive piston into a position in the first path, wherein the shunt formed by the first fluid path between pump inlet and the pump outlet is occluded; and

moving the valve piston into the second fluid path.

9. The method of claim 8 wherein the pumping chamber forms a loop.

10. The method of claim 8, further comprising:

providing a controller configured to control the velocity of the drive piston; and

varying the velocity of the drive piston as the drive piston is actuated around the first path of the pumping chamber to control the amount of fluid trailing the drive piston that is expelled from the pumping chamber to the pump outlet.

11. The method of claim 8 further wherein the mechanism for moving the valve piston into and out of the second fluid path of the pumping chamber comprises a magnetic gear with an angular dependent gear ratio.

12. The method of claim 8 wherein a portion of the fluid trailing the drive piston is expelled from the pumping chamber to the pump outlet when a shunt is formed by the first fluid path between pump inlet and the pump outlet.

13. A pump system comprising:

a pumping chamber forming a loop;

a pump inlet in fluid communication with the pumping chamber;

a pump outlet in fluid communication with the pumping chamber;

a drive piston disposed within the pumping chamber; and

a valve mechanism disposed between the pump inlet and pump outlet, wherein:

the pump inlet is in fluid communication with the pumping chamber regardless of the location of the drive piston within the pumping chamber; and

the pump outlet is in fluid communication with the pumping chamber regardless of the location of the drive piston within the pumping chamber.

14. The pump system of claim 13 wherein:

the pump inlet intersects the pumping chamber in a first transition zone with a first cross-sectional area;

the drive piston comprises an outer surface with an outer surface area; and

the first cross-sectional area is greater than the outer surface area.

15. The pump system of claim 14 wherein the length of the first transition zone is greater than the length of the outer surface of the drive piston.

16. The pump system of claim 14 wherein the width of the first transition zone is greater than the width of the outer surface of the drive piston.

17. The pump system of claim 13 wherein:

the pump outlet intersects the pumping chamber in a second transition zone with a second cross-sectional area;

the drive piston comprises an outer surface with an outer surface area; and

the second cross-sectional area is greater than the outer surface area.

18. The pump system of claim 17 wherein the length of the second transition zone is greater than the length of the outer surface of the drive piston.

19. The pump system of claim 17 wherein the width of the second transition zone is greater than the width of the outer surface of the drive piston.

20. The pump system of claim 13 wherein during use the pump inlet is in fluid communication with a ventricle and the fluid outlet is in fluid communication with an aorta.

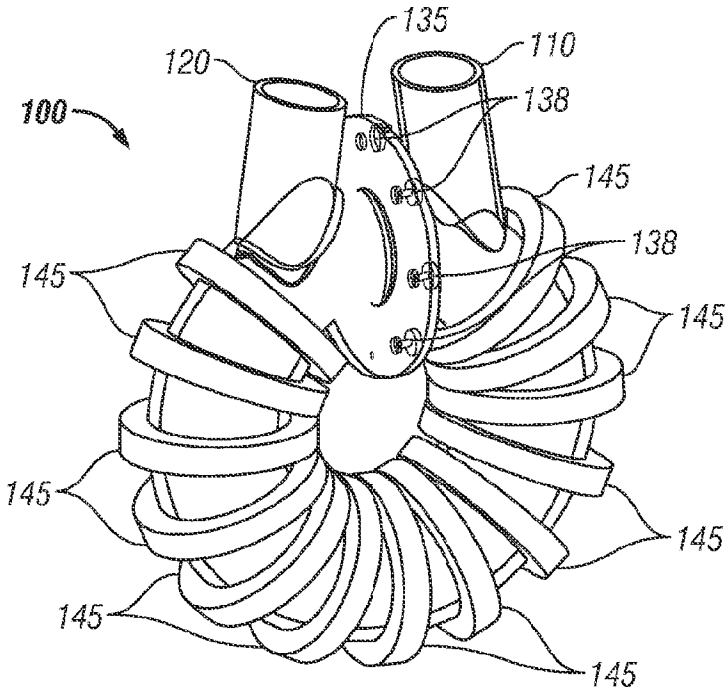

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FIG. 1

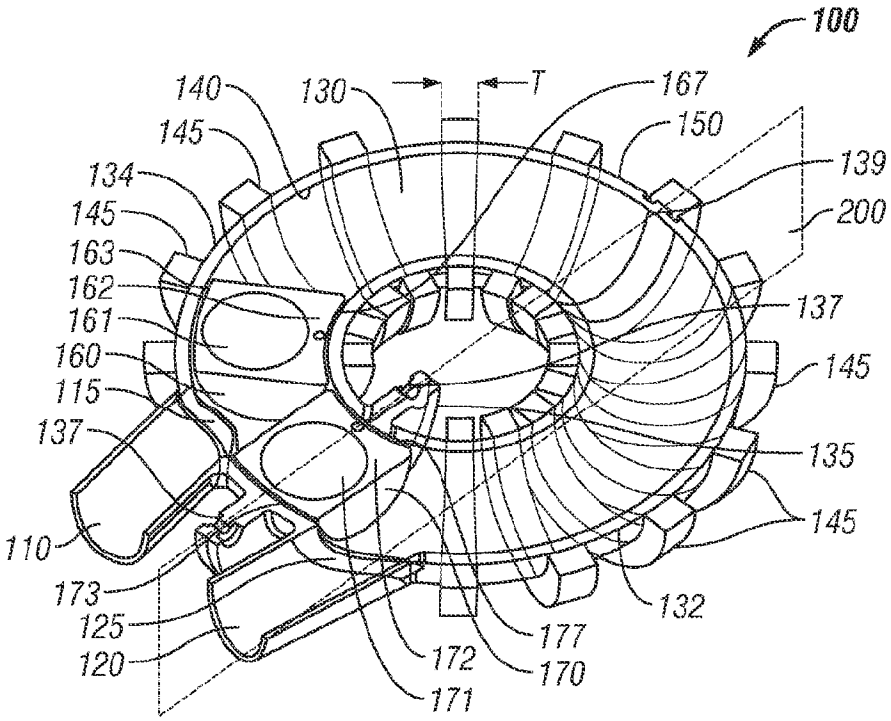

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FIG. 2

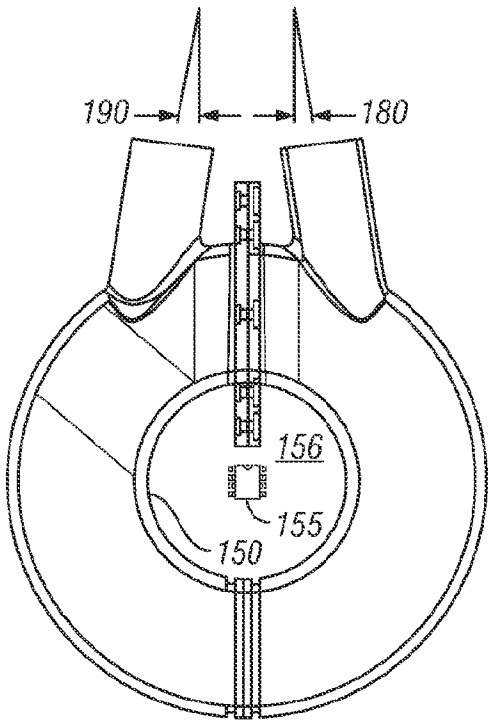


FIG. 3

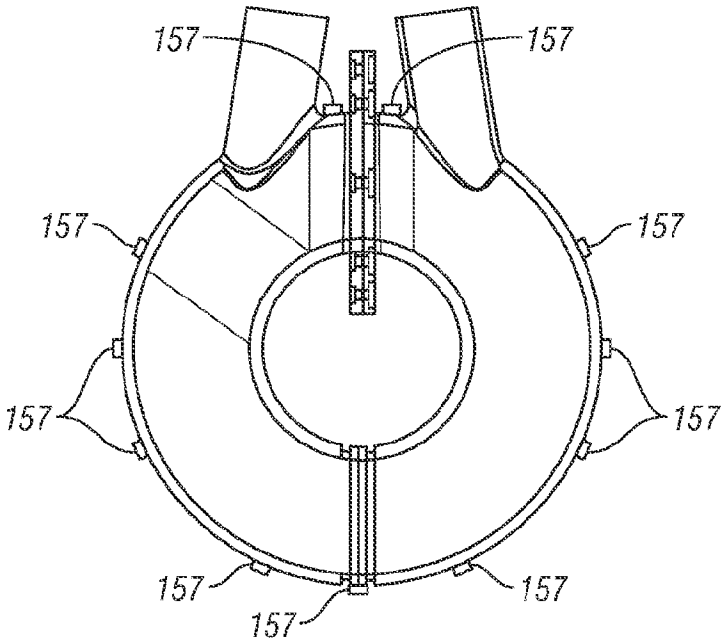


FIG. 4

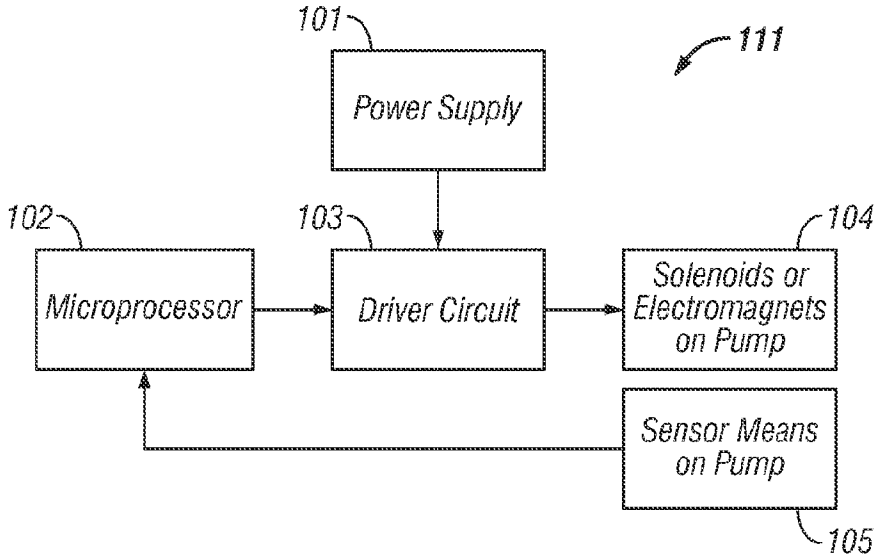

101
111
Power Supply
102
103
104
Microprocessor
Driver Circuit
Solenoids or Electromagnets on Pump
Sensor Means on Pump
105

FIG. 5

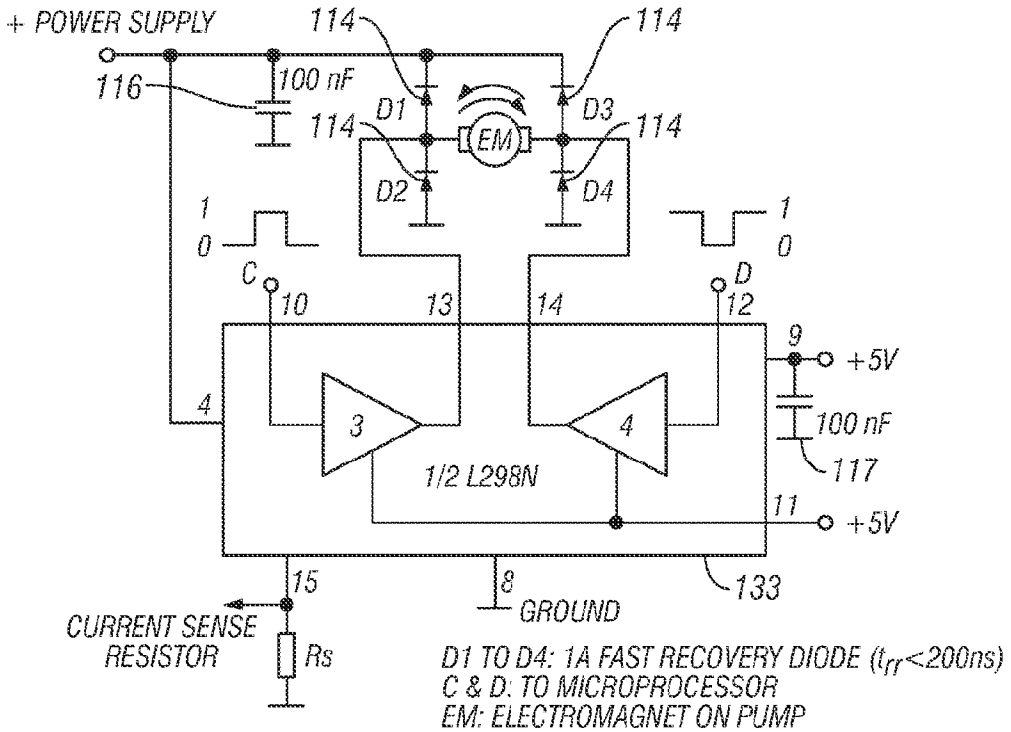

+ POWER SUPPLY
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116
100 nF
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114
114
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D2
D4
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1
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D
10
13
14
12
9
+5V
4
3
4
100 nF
117
1/2 L298N
11
+5V
15
8
133
CURRENT SENSE RESISTOR
Rs
GROUND
D1 TO D4: 1A FAST RECOVERY DIODE (t_{rr}<200ns)
C & D: TO MICROPROCESSOR
EM: ELECTROMAGNET ON PUMP

FIG. 6

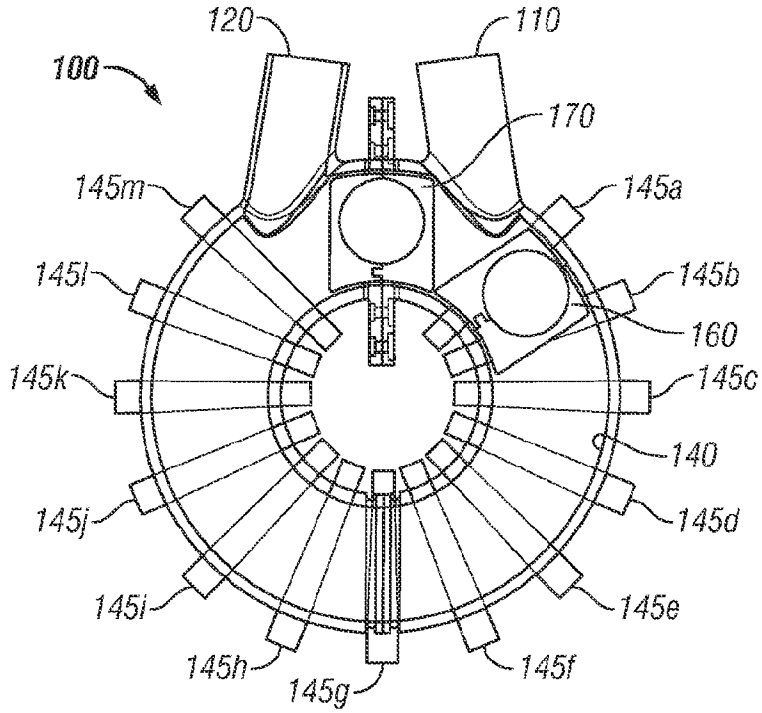

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FIG. 7

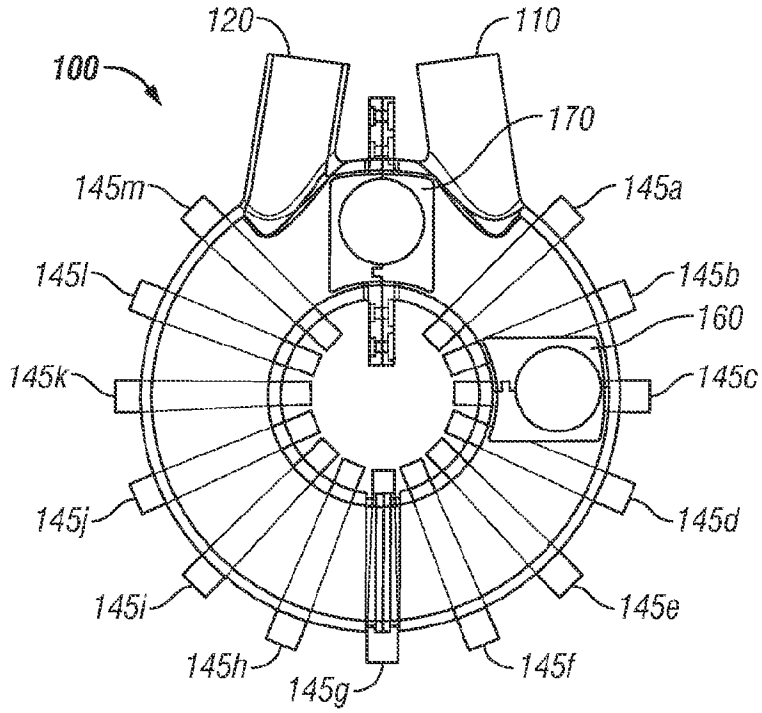

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FIG. 8

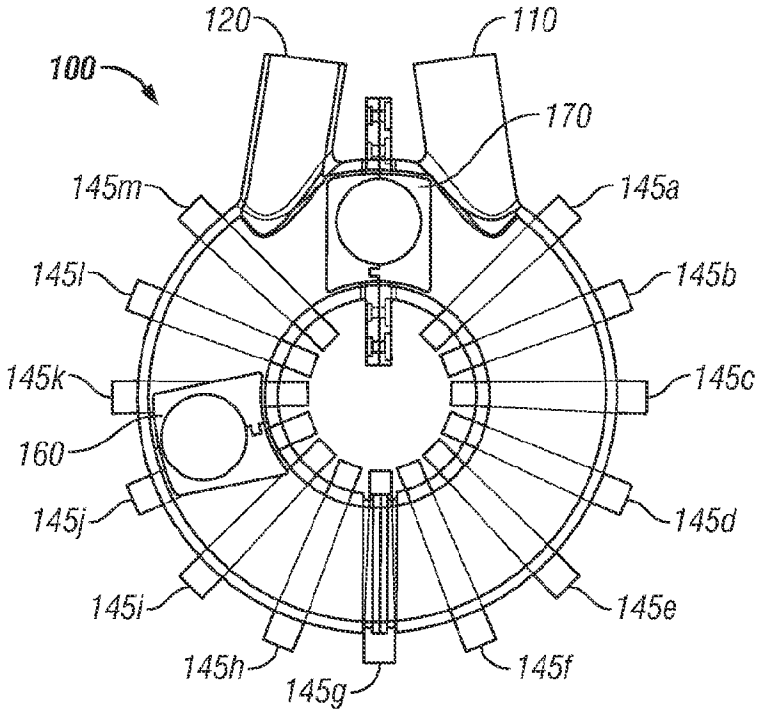

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FIG. 9

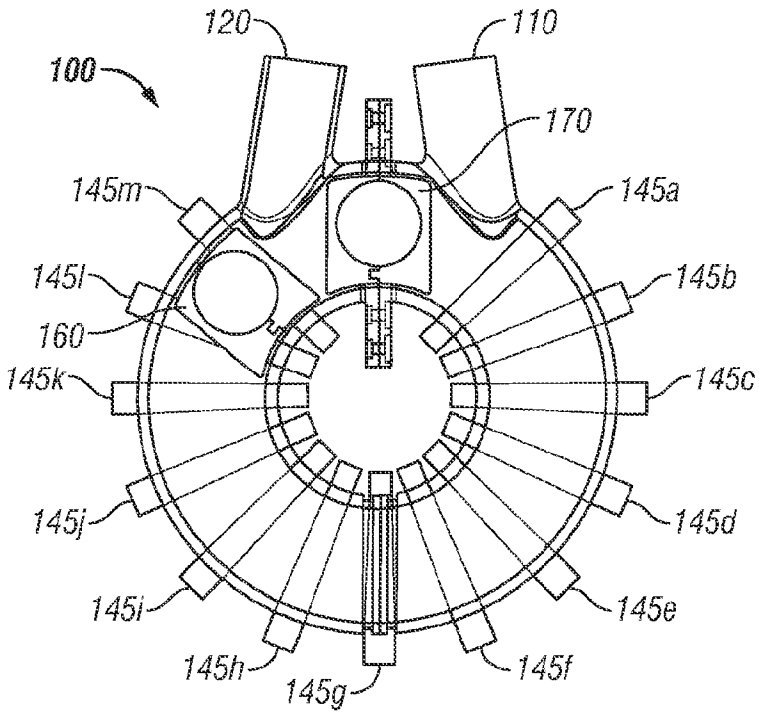

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FIG. 10

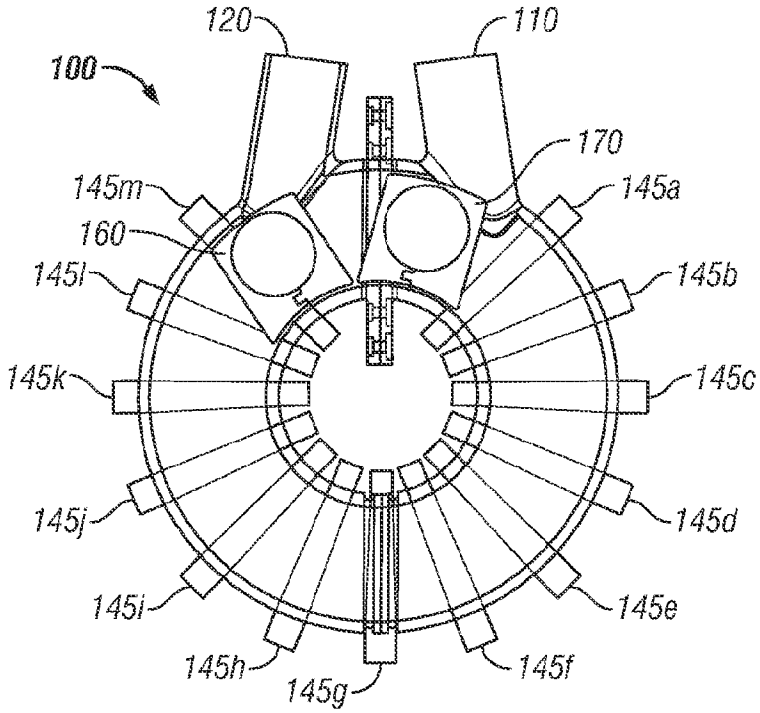

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FIG. 11

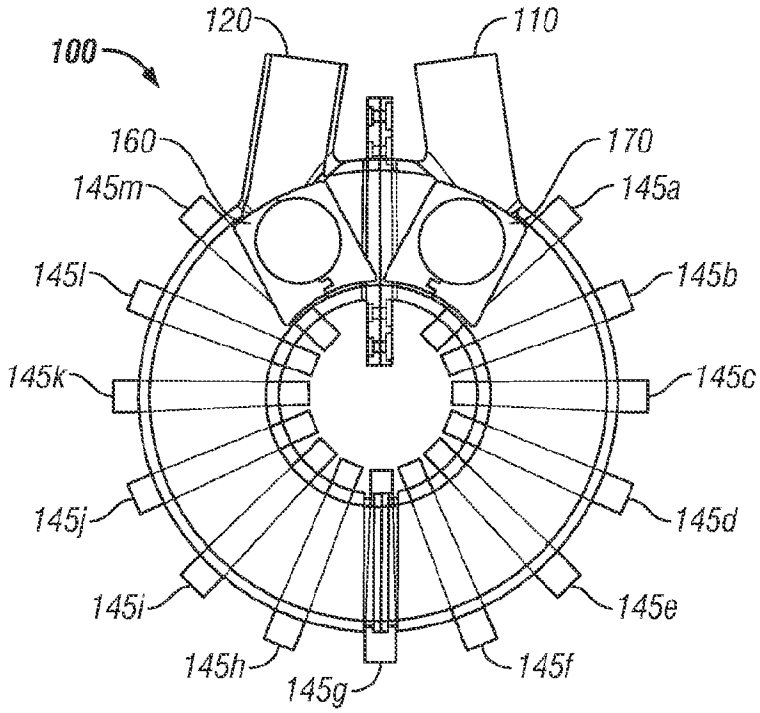

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FIG. 12

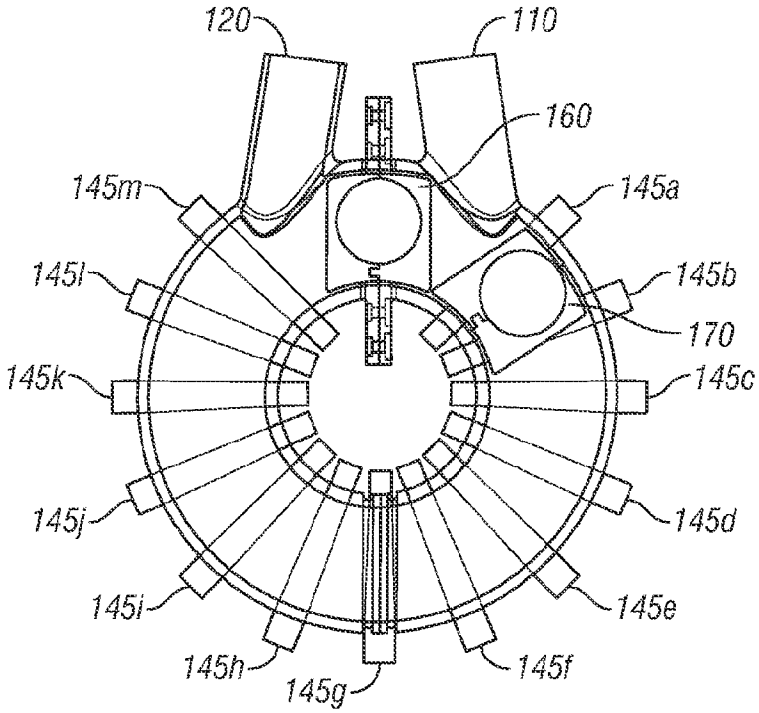


FIG. 13

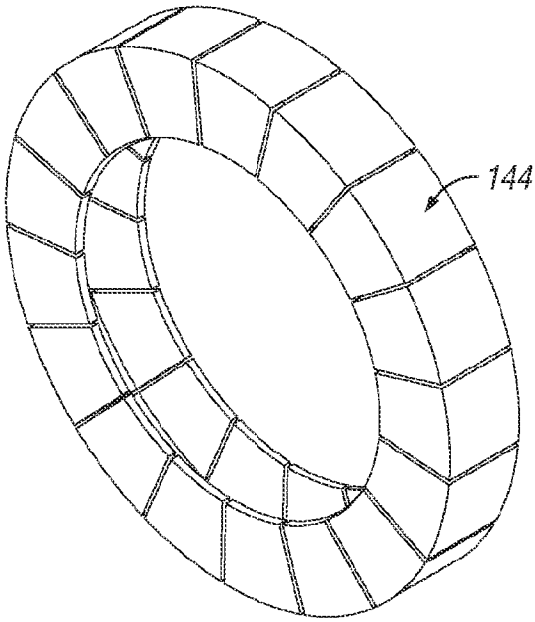


FIG. 13A

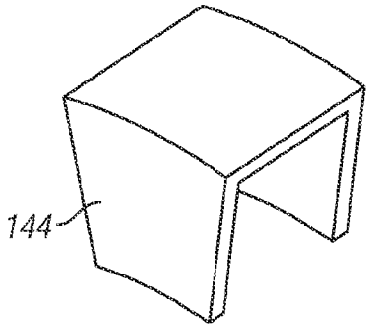


FIG. 13B

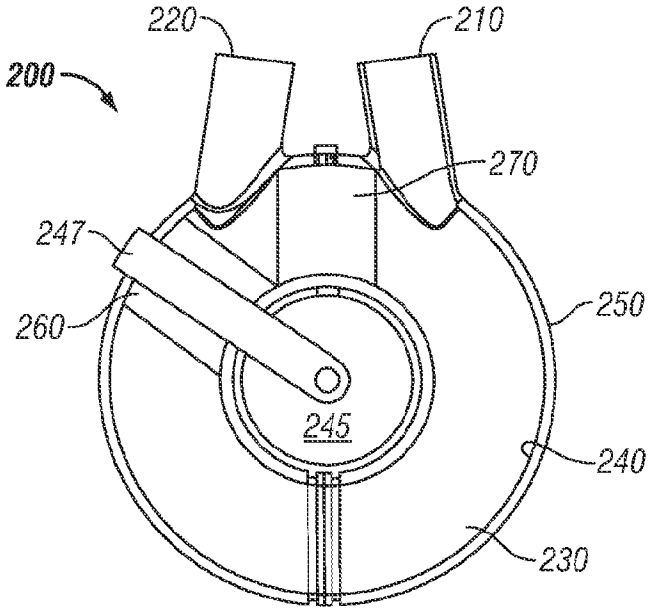


FIG. 14

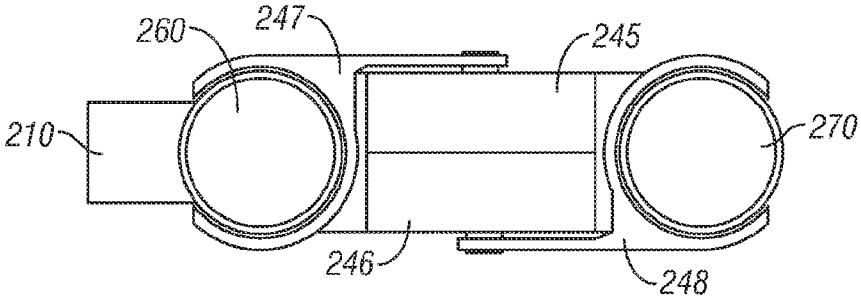


FIG. 15

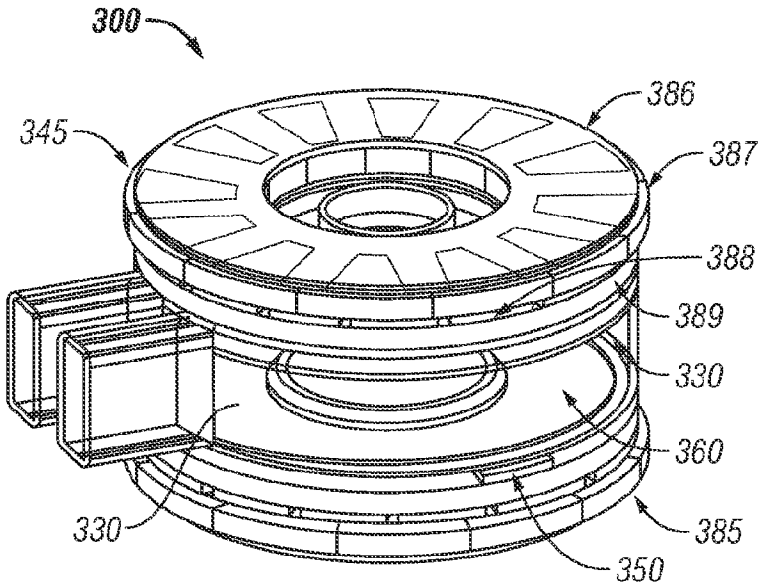

300
345
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FIG. 16

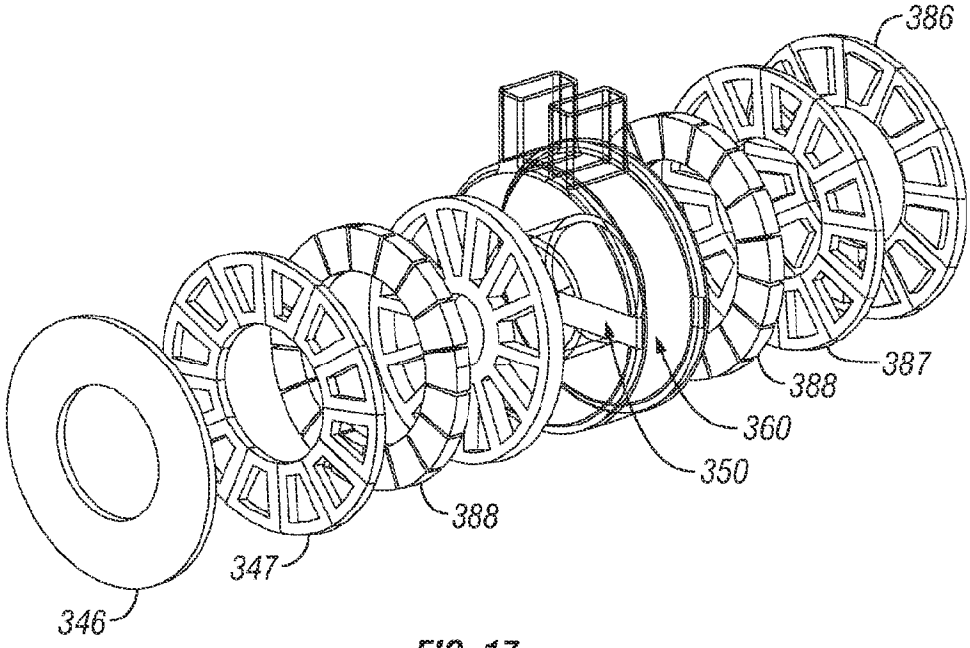

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FIG. 17

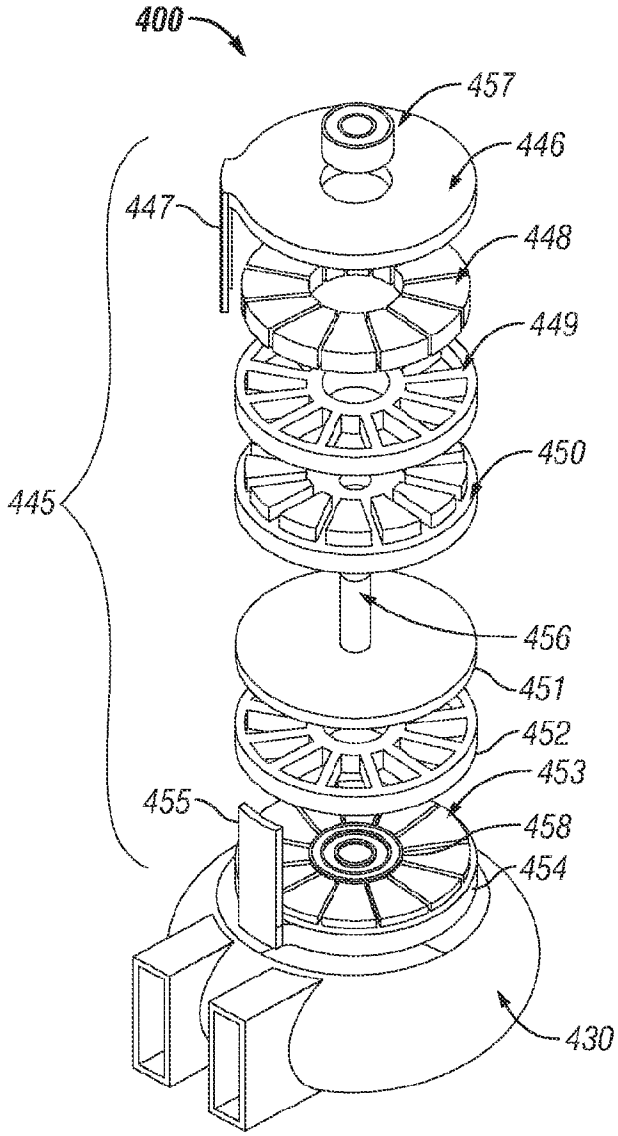


FIG. 18

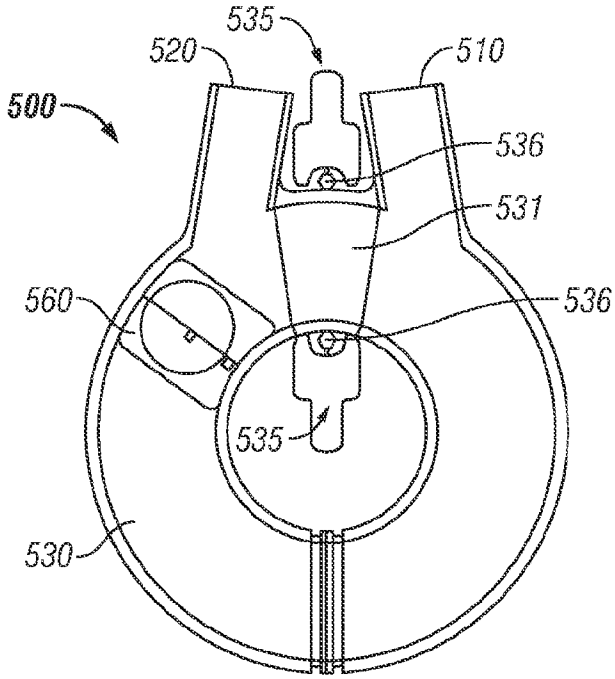

535
520
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531
560
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530

FIG. 19

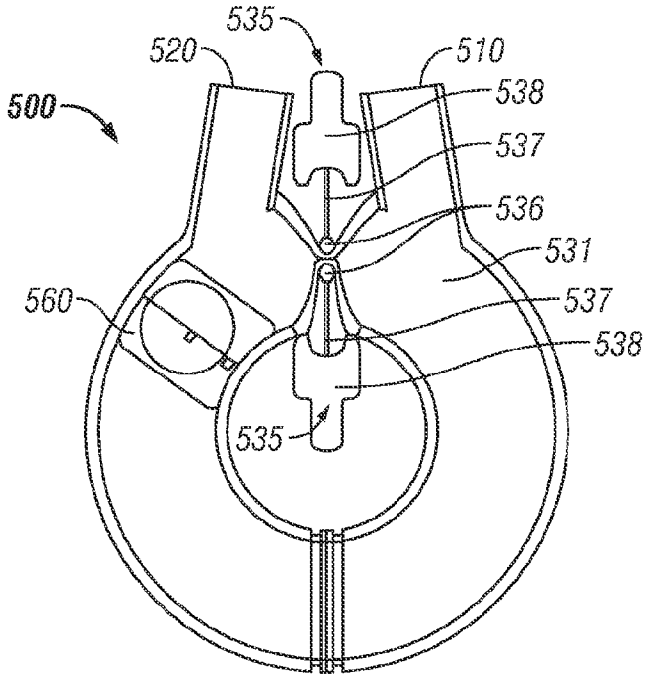

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FIG. 20

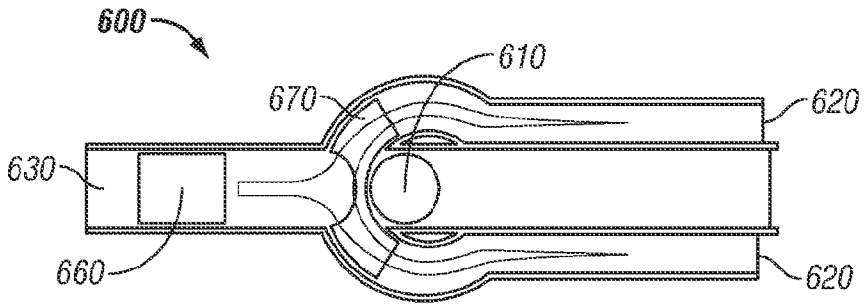


FIG. 21

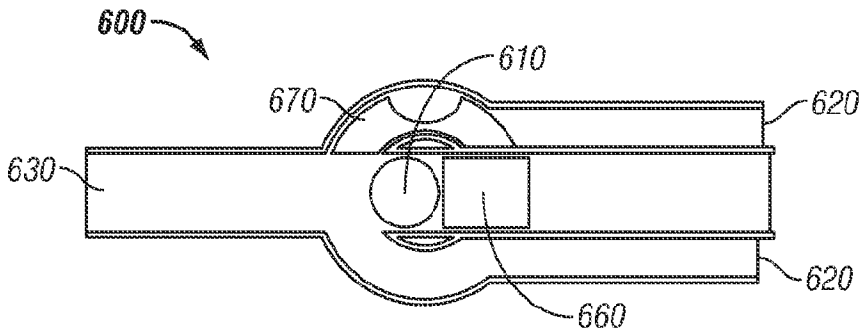


FIG. 22

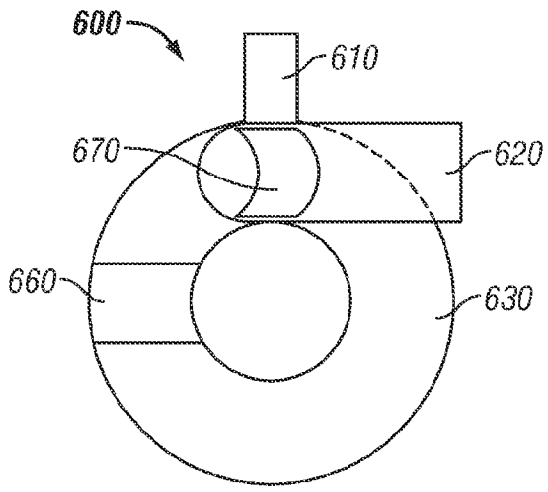


FIG. 23

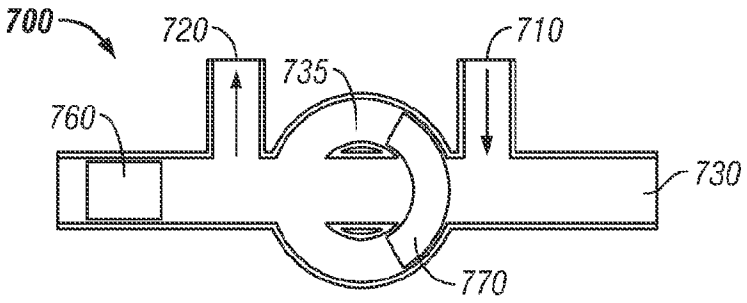


FIG. 24

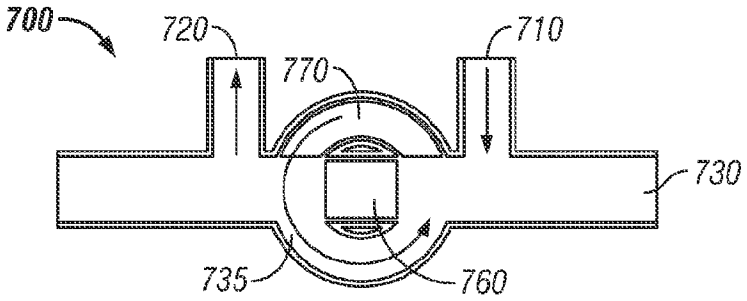


FIG. 25

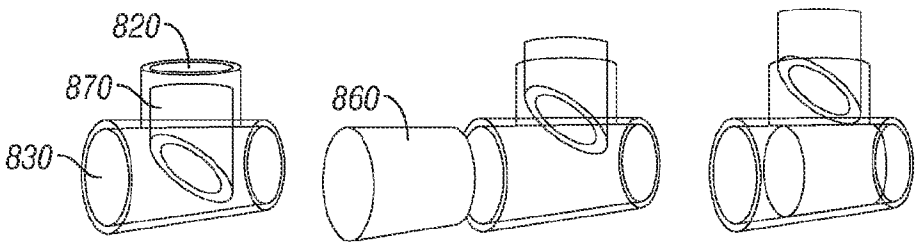


FIG. 26

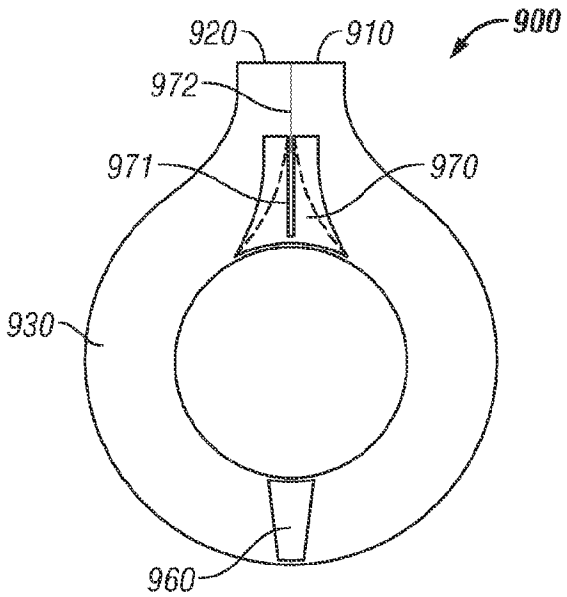


FIG. 27

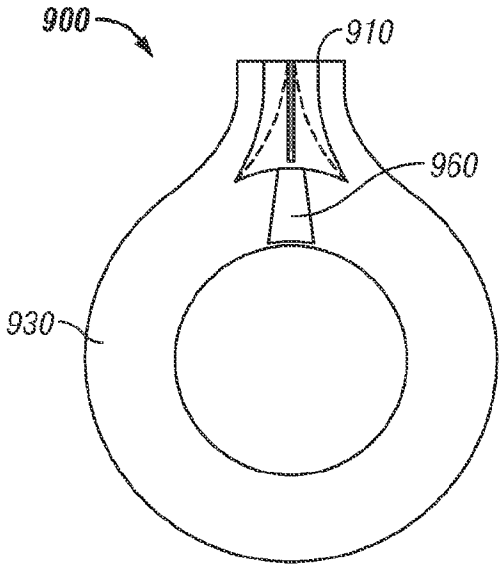


FIG. 28

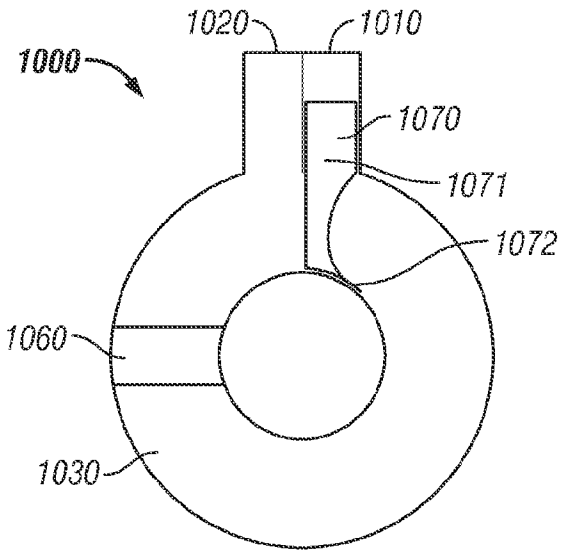

1020
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FIG. 29

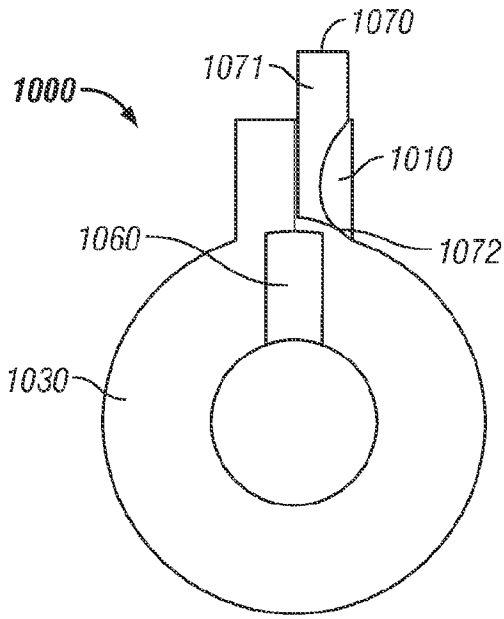

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1072
1030

FIG. 30

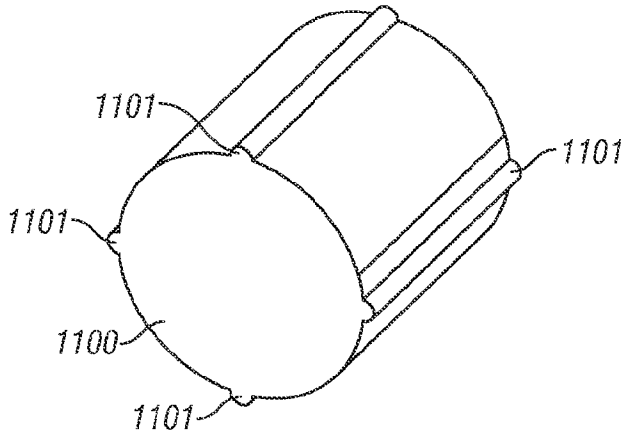


FIG. 31

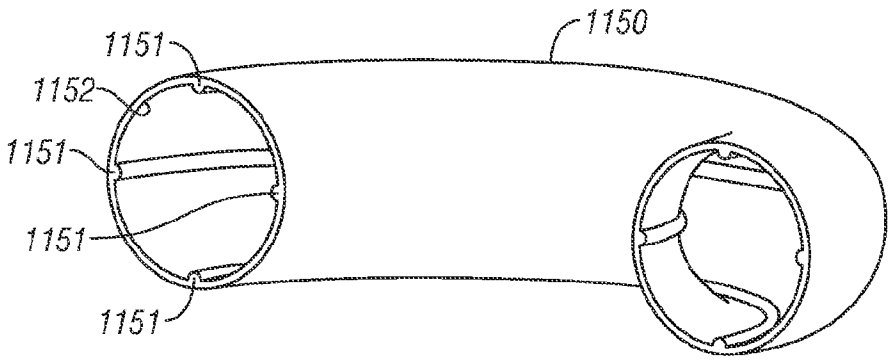


FIG. 32

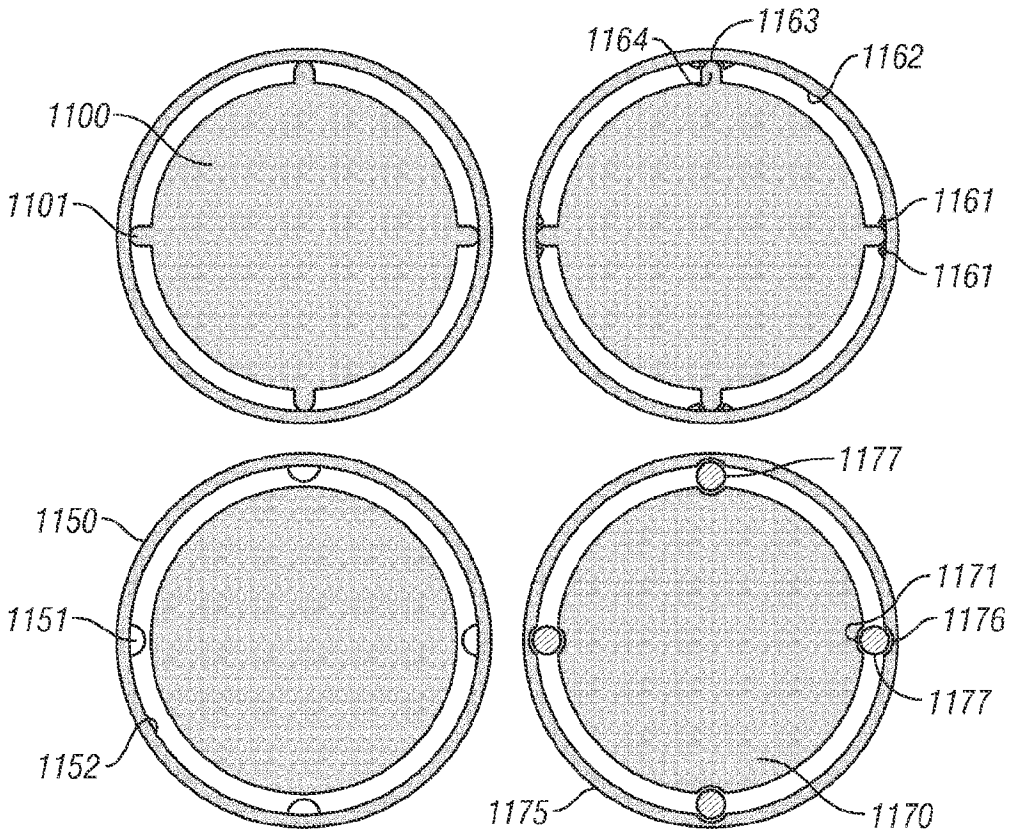

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1170

FIG. 33

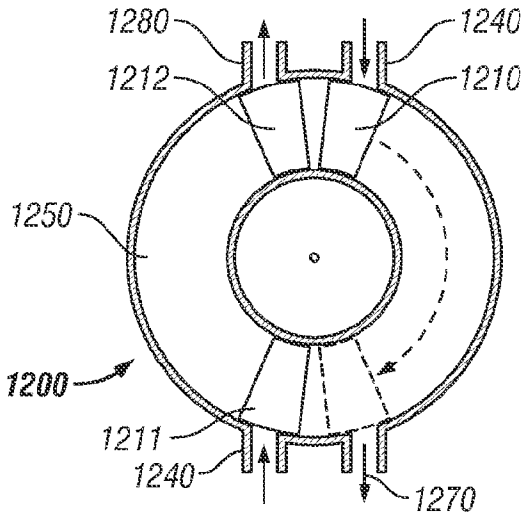


FIG. 34A

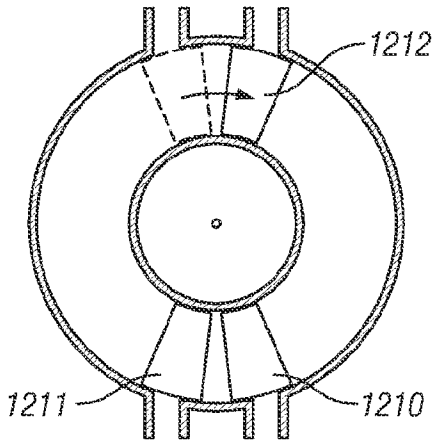


FIG. 34B

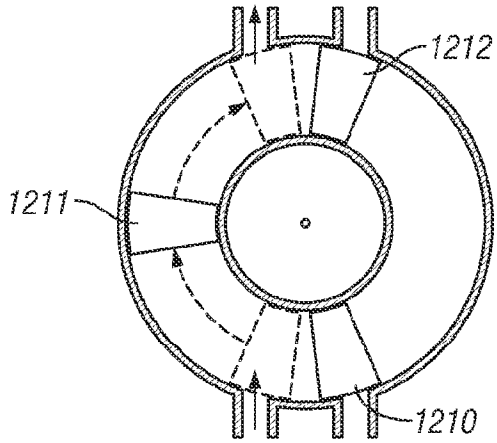


FIG. 34C

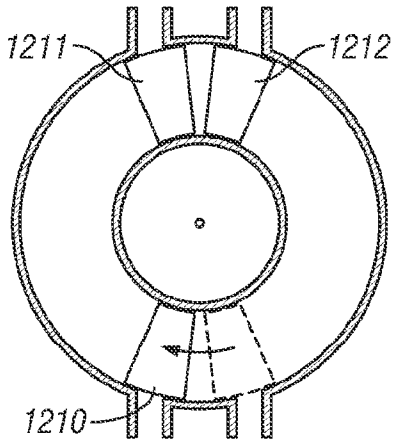


FIG. 34D

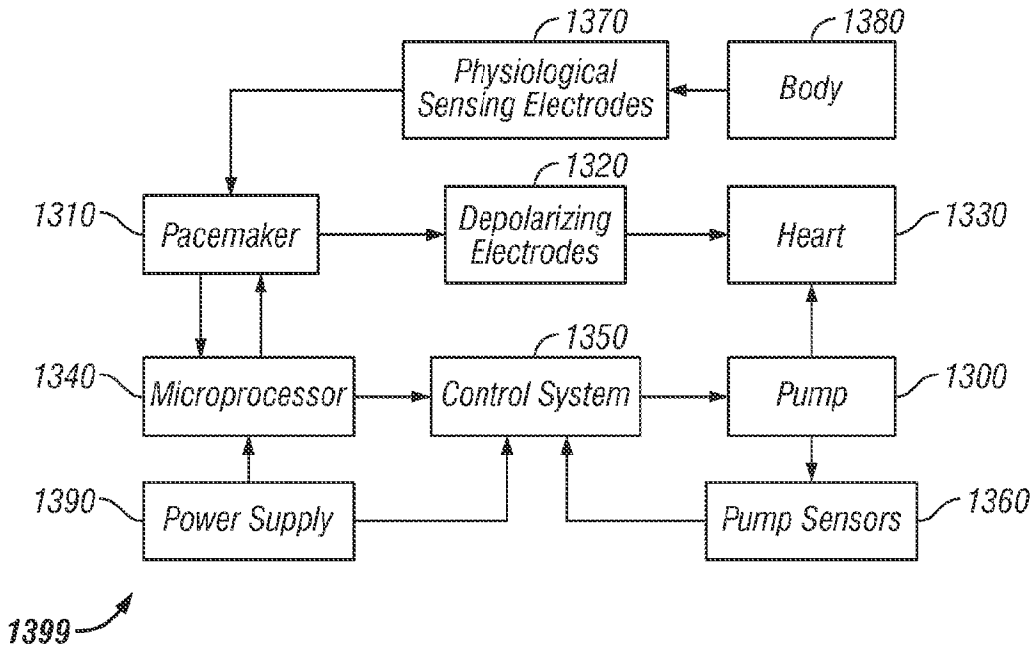

1370
Physiological Sensing Electrodes
1380
Body
1320
1310
Pacemaker
Depolarizing Electrodes
Heart
1330
1350
1340
Microprocessor
Control System
Pump
1300
1390
Power Supply
Pump Sensors
1360
1399

FIG. 35

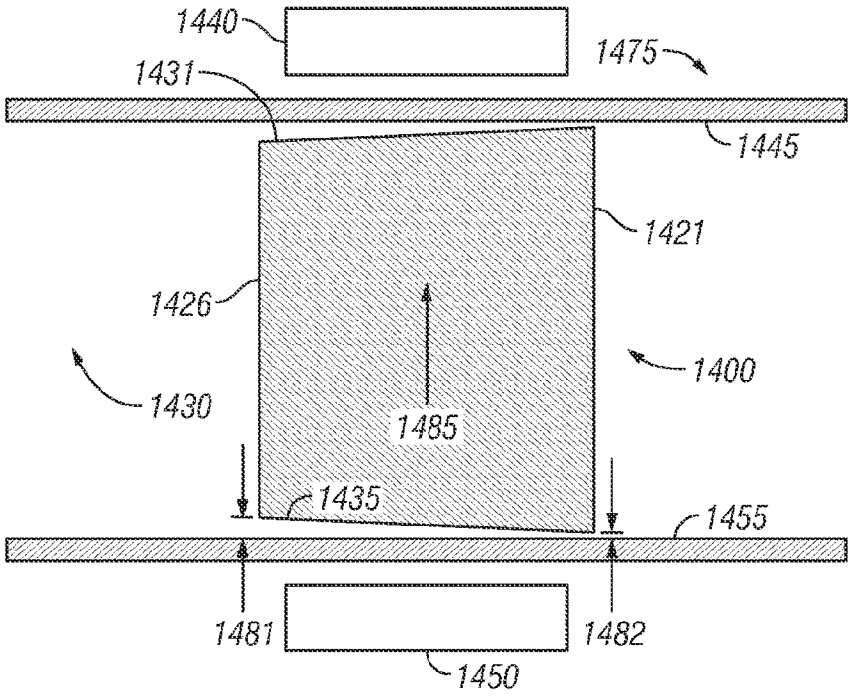

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1400
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1485
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1481
1482
1450

FIG. 36

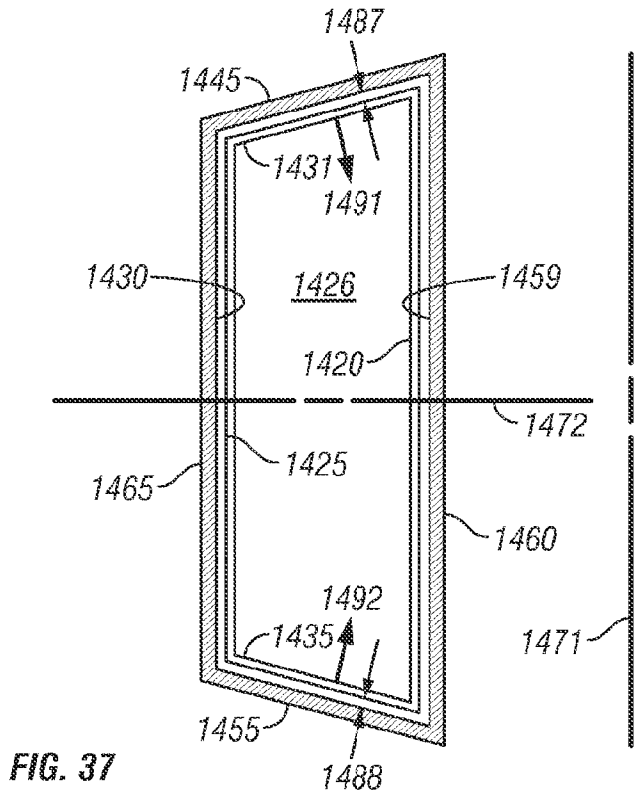

1487
1445
1431
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1459
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1472
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1465
1460
1492
1435
1471
1455
1488

FIG. 37

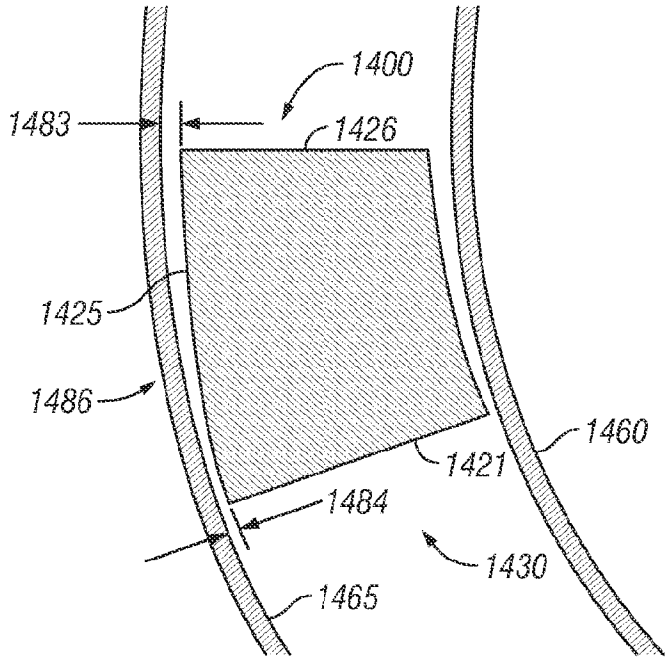

1400
1483
1426
1425
1486
1460
1421
1484
1430
1465

FIG. 38

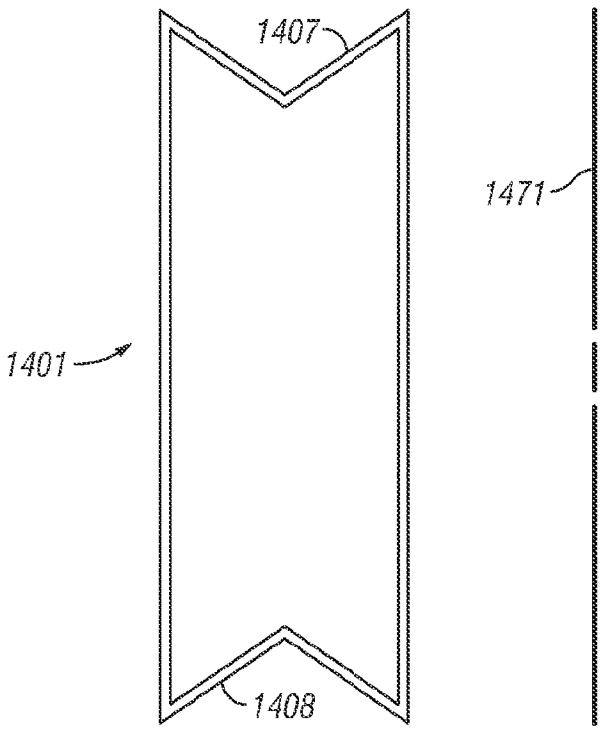

1407
1471
1401
1408

FIG. 39

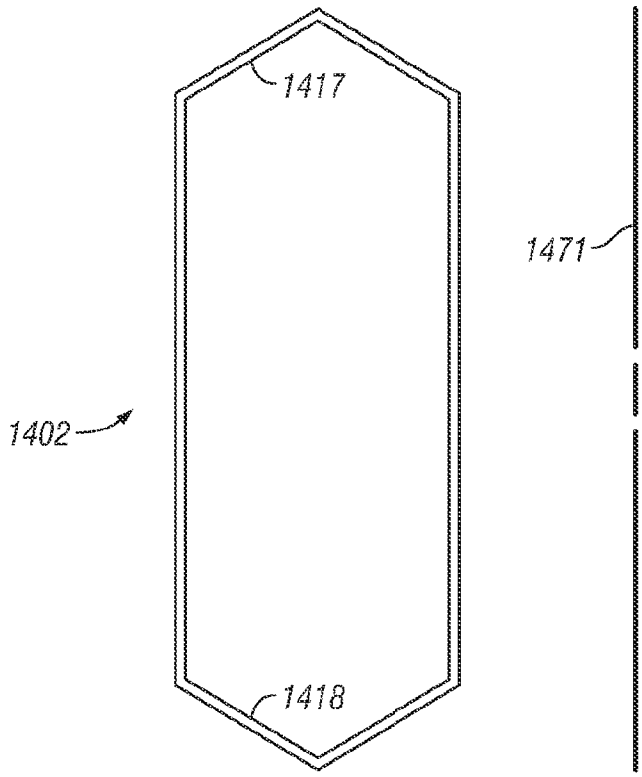


FIG. 40

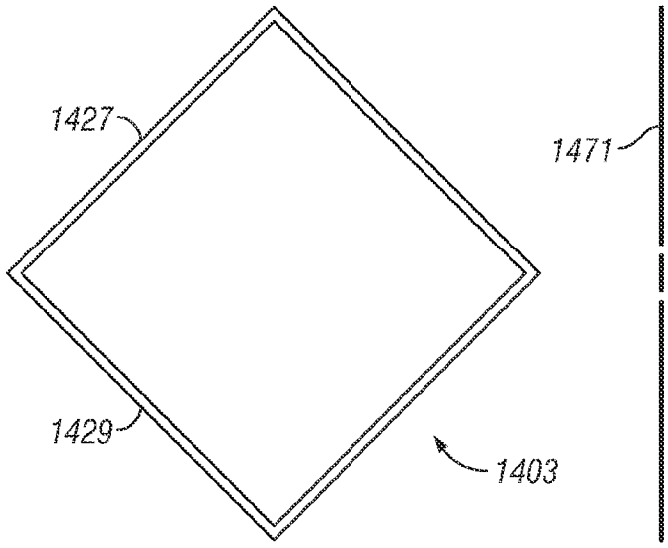


FIG. 41

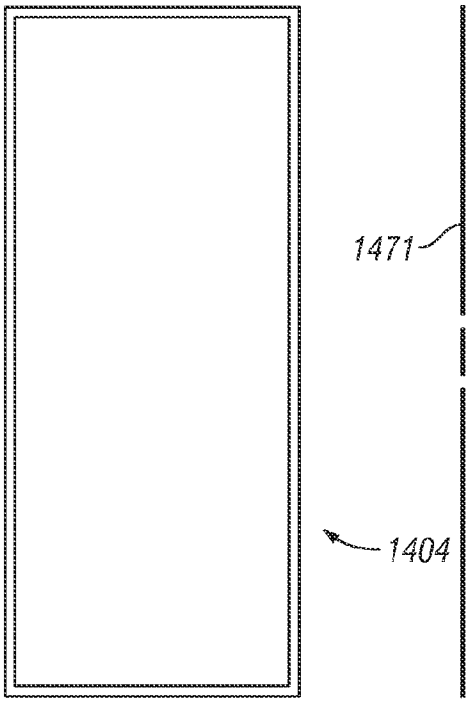


FIG. 42A

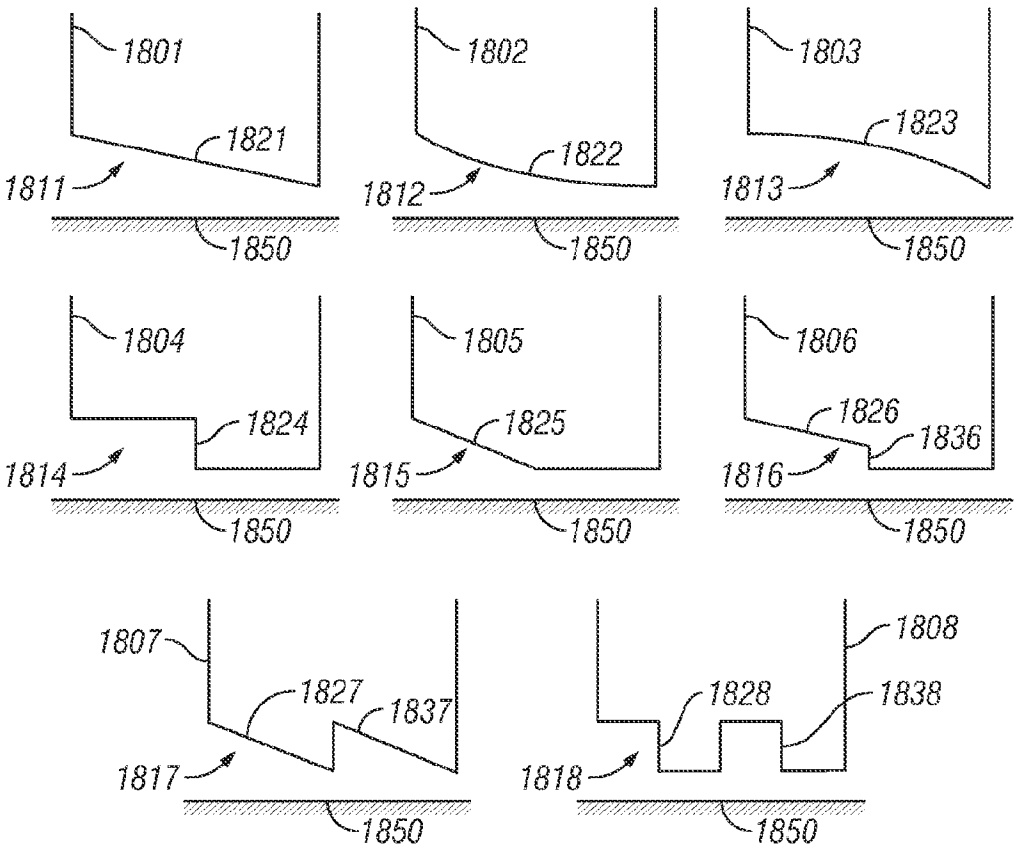


FIG. 42B

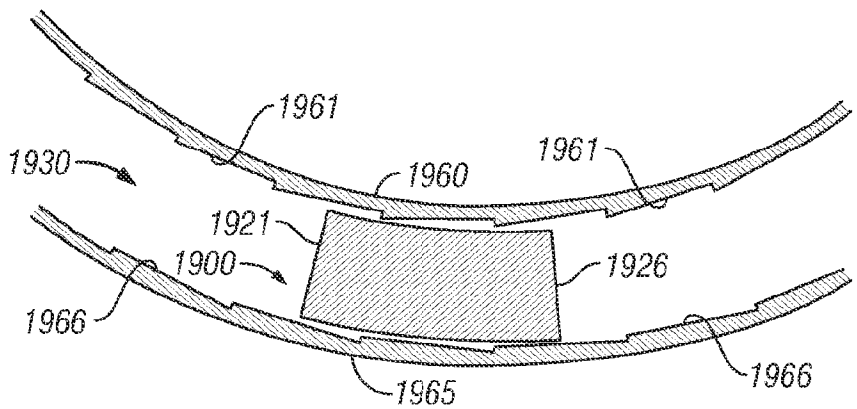


FIG. 42C

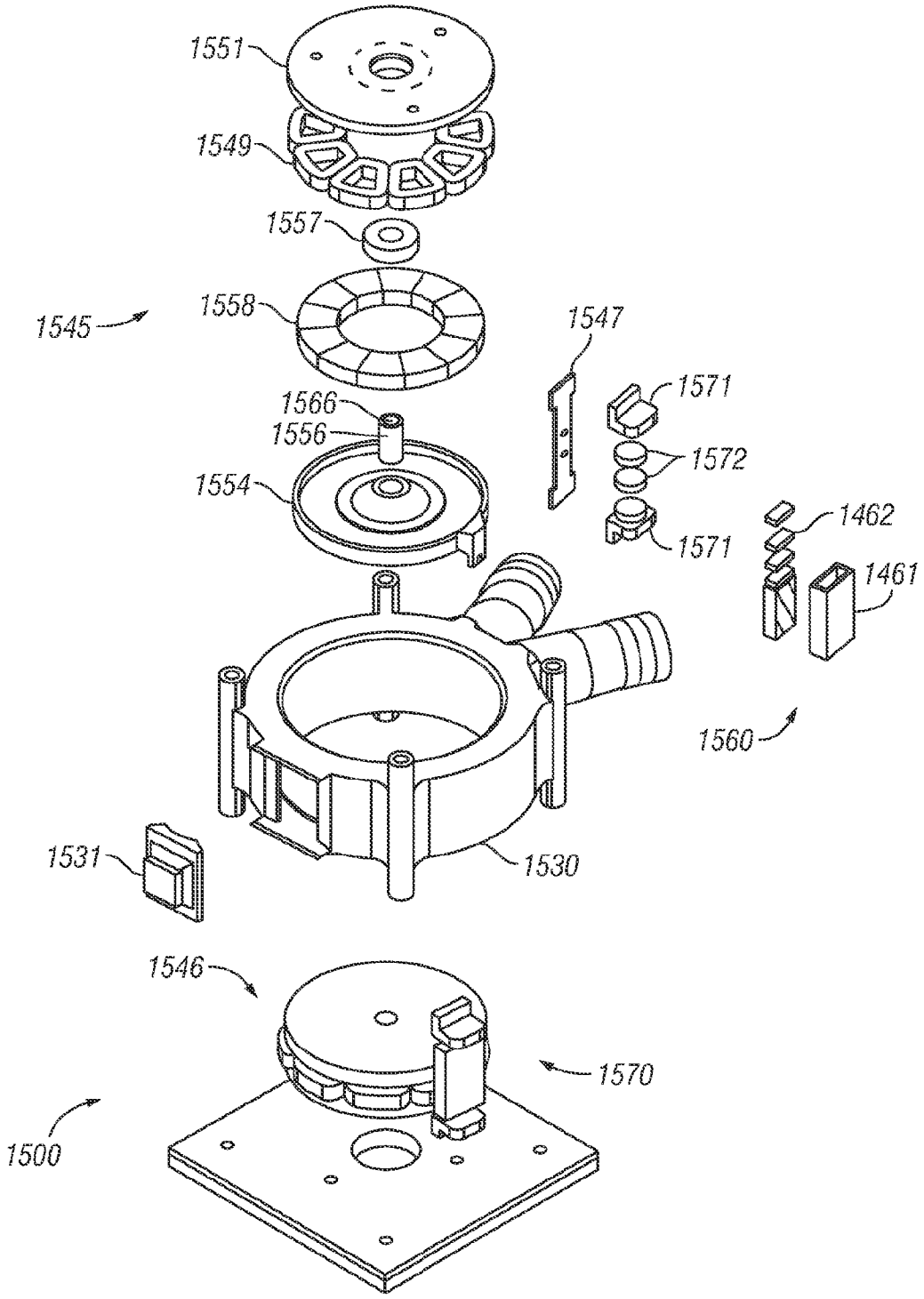

1551
1549
1557
1558
1545
1547
1571
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1556
1572
1554
1571
1462
1461
1560
1531
1530
1546
1570
1500

FIG. 43

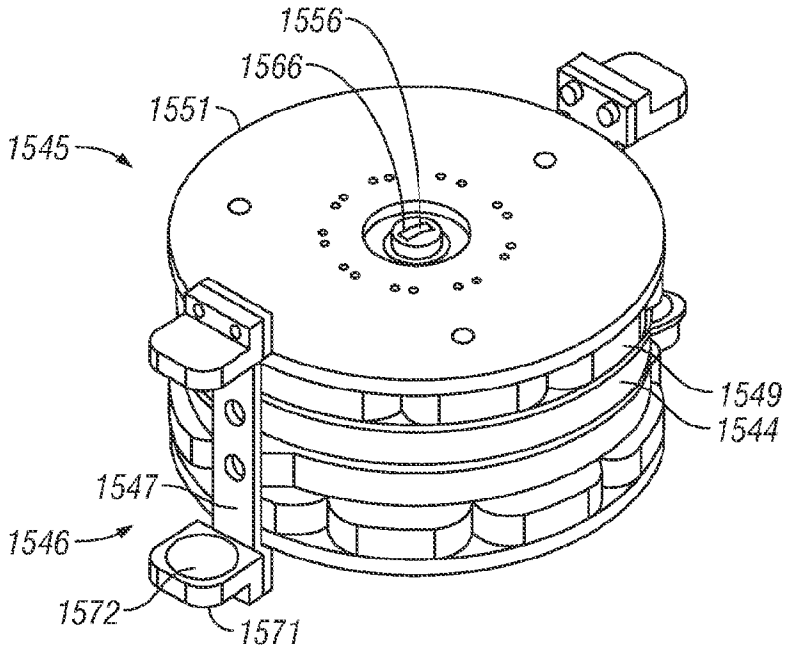

1556
1566
1551
1545
1549
1544
1547
1546
1572
1571

FIG. 44

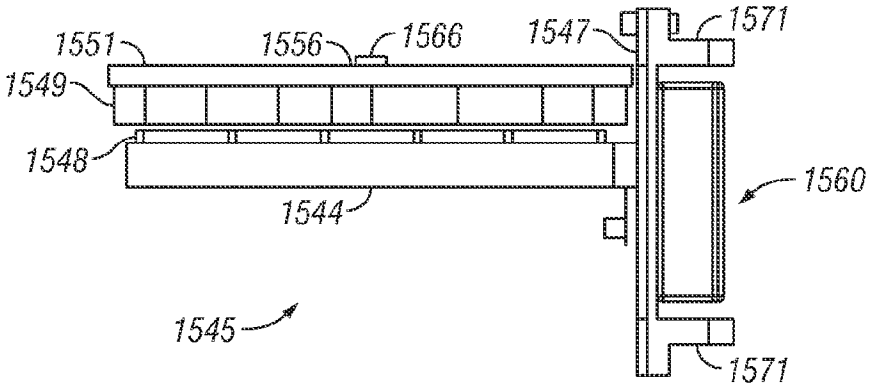

1551
1556
1566
1547
1571
1549
1548
1560
1544
1545
1571

FIG. 45

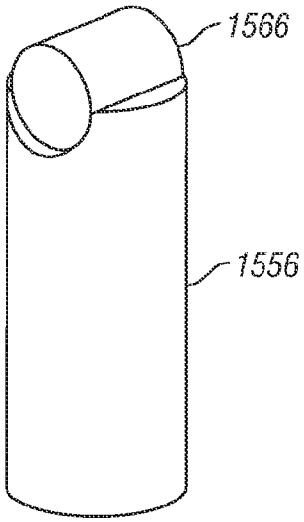


FIG. 46

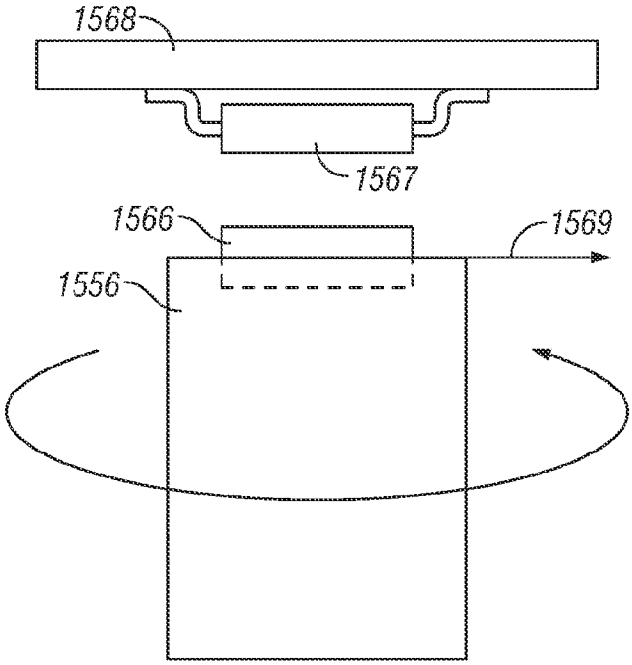


FIG. 47

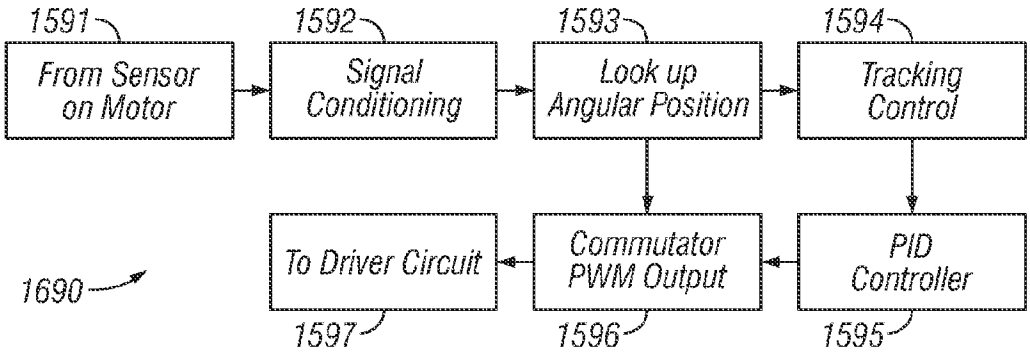

1591
From Sensor on Motor
1592
Signal Conditioning
1593
Look up Angular Position
1594
Tracking Control
1690
To Driver Circuit
1597
Commutator PWM Output
1596
PID Controller
1595

FIG. 48

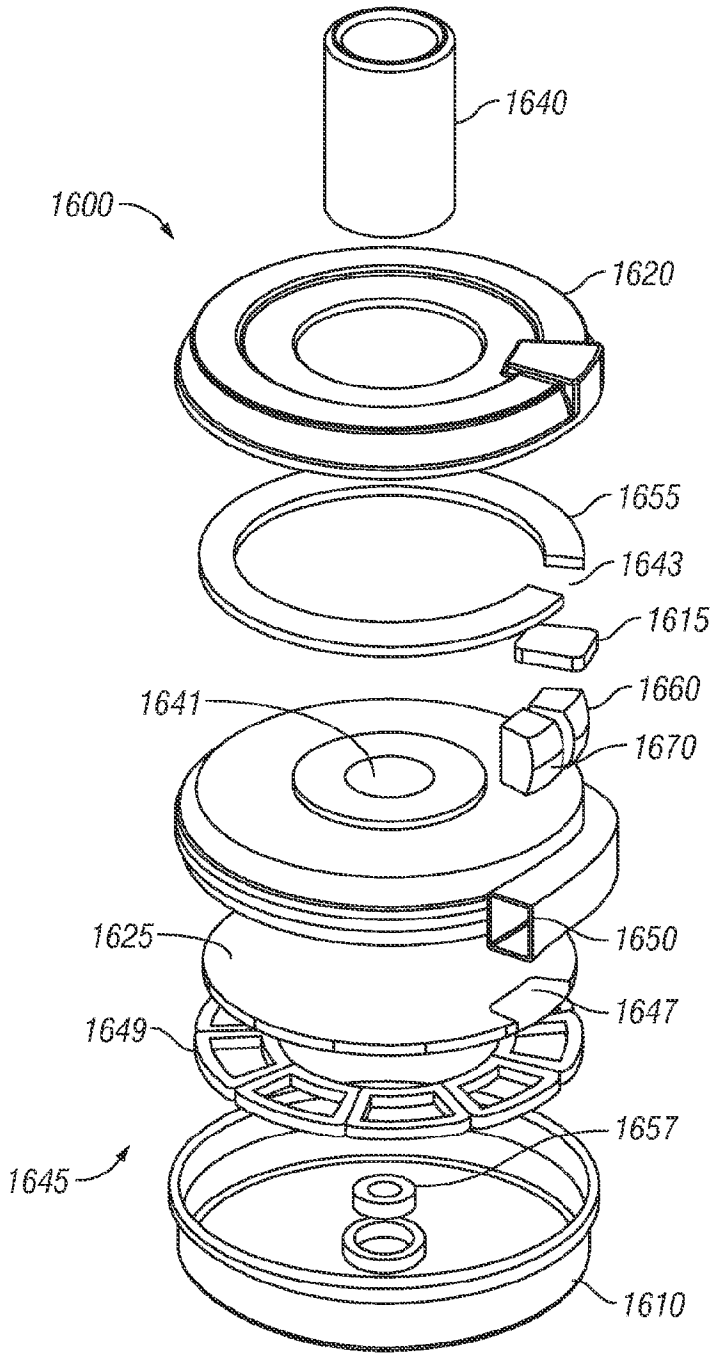

1640
1600
1620
1655
1643
1615
1660
1641
1670
1625
1650
1647
1649
1657
1645
1610

FIG. 49

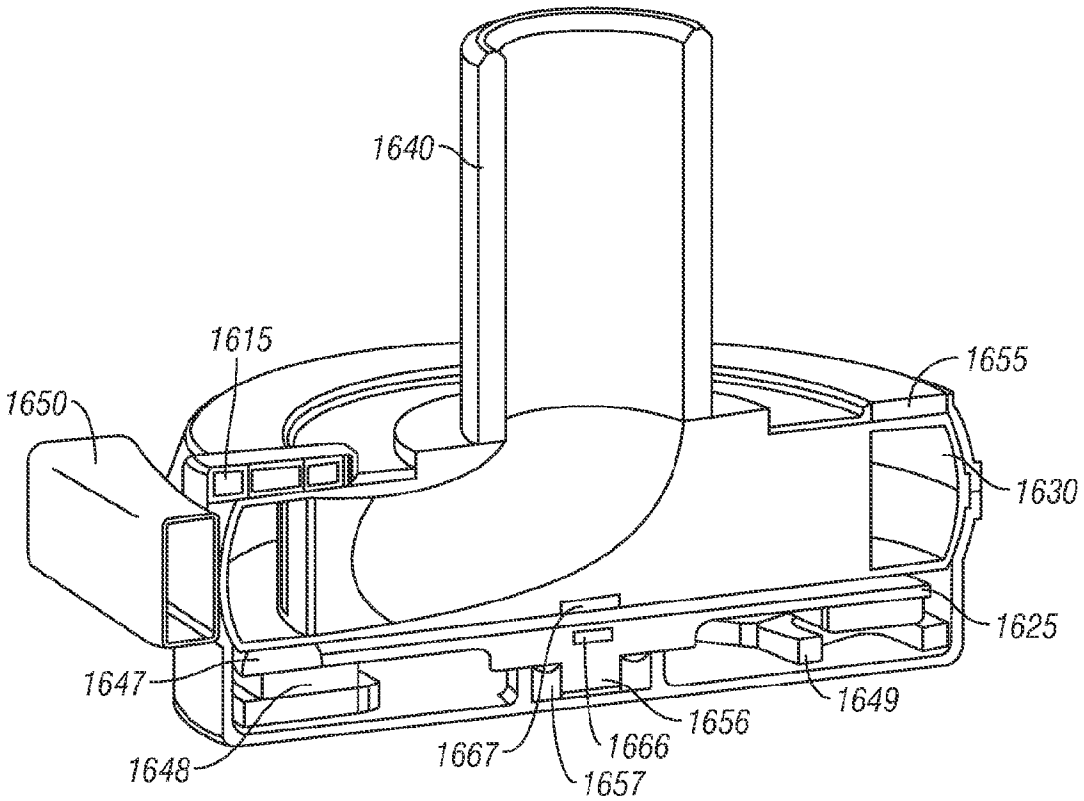

1640
1615
1650
1655
1630
1625
1647
1649
1656
1667
1666
1657
1648

FIG. 50

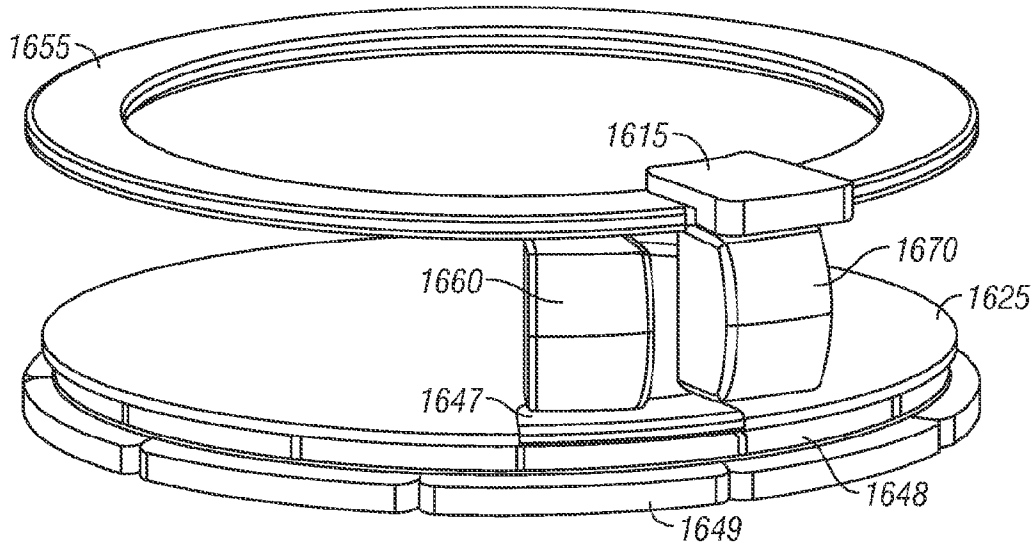


FIG. 51

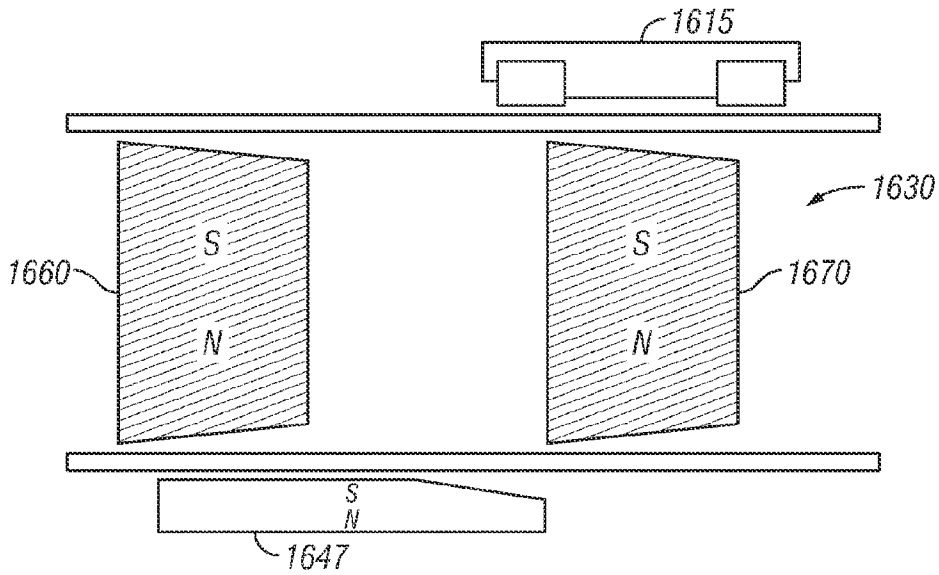

1615
1630
1660
1670
S
N
S
N
S
N
1647

FIG. 52

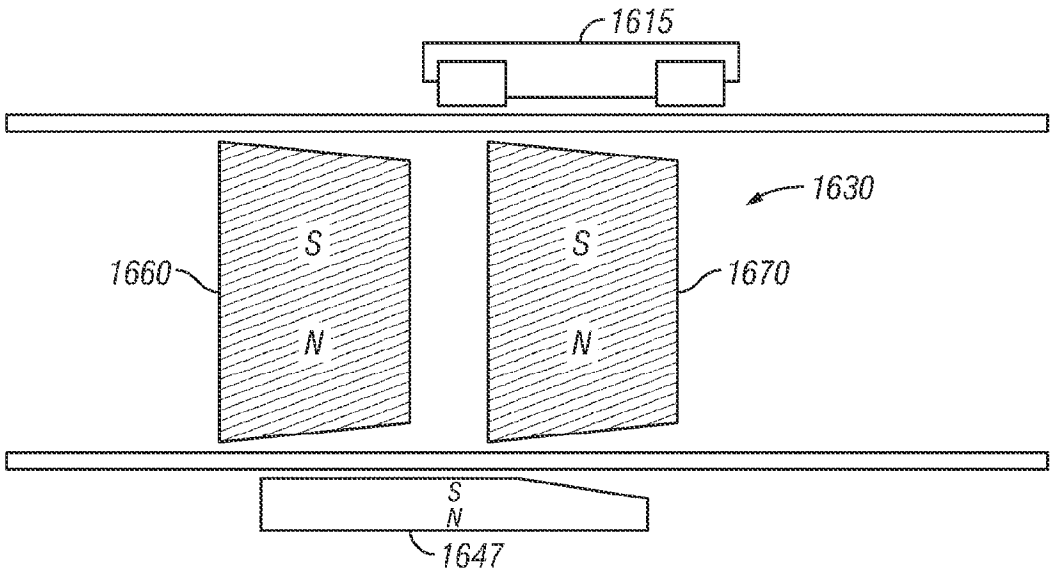

1615
1630
1660
1670
S
N
S
N
S
N
1647

FIG. 53

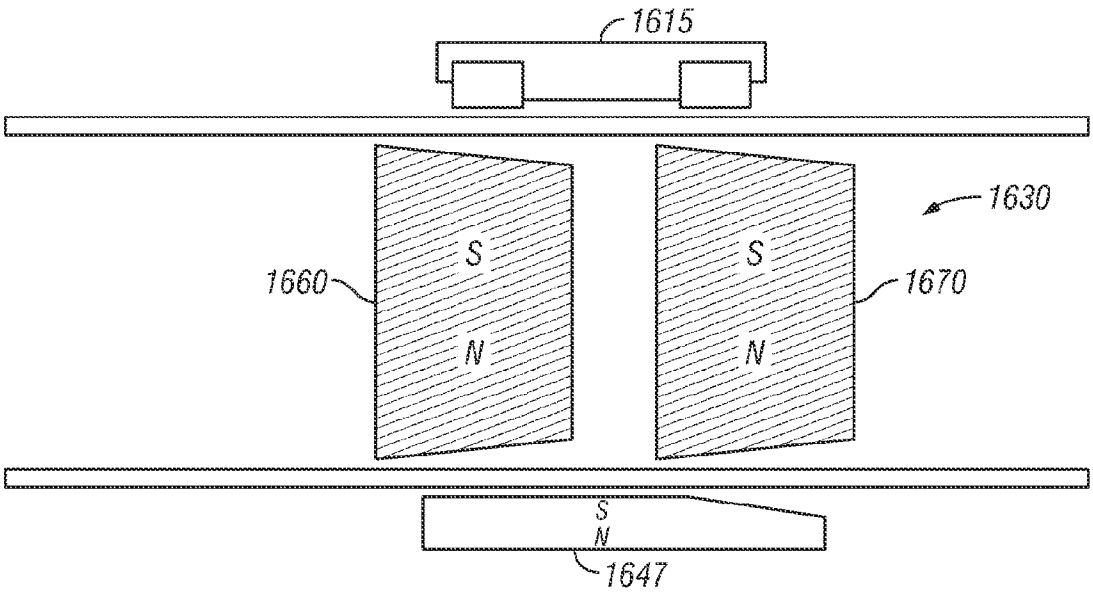

1615
1630
1660
1670
S
N
S
N
S
N
1647

FIG. 54

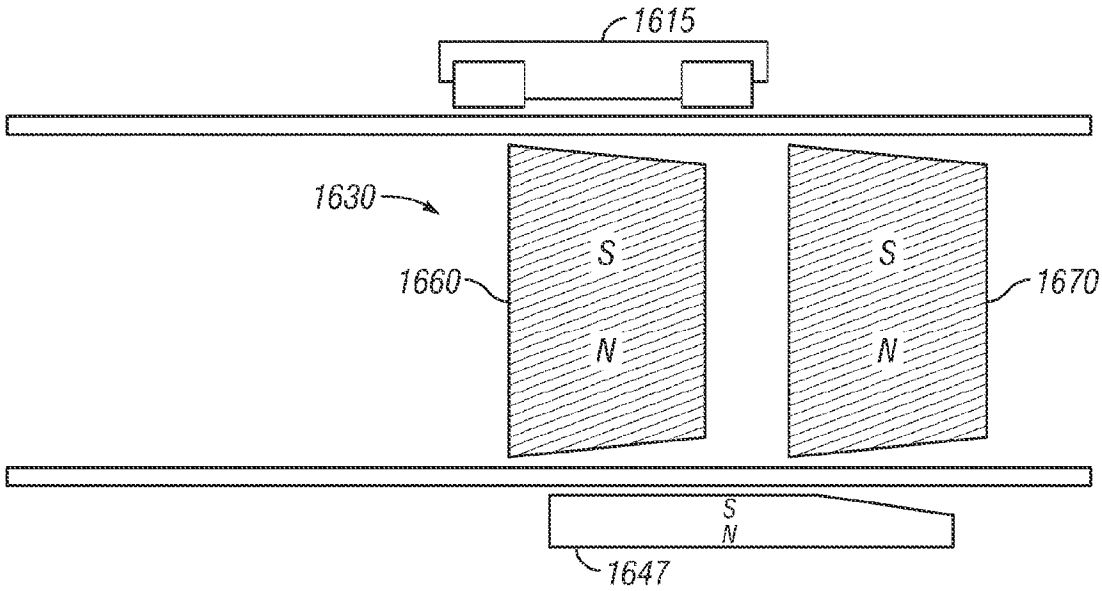

1615
1630
1660
1670
S
N
S
N
S
N
1647

FIG. 55

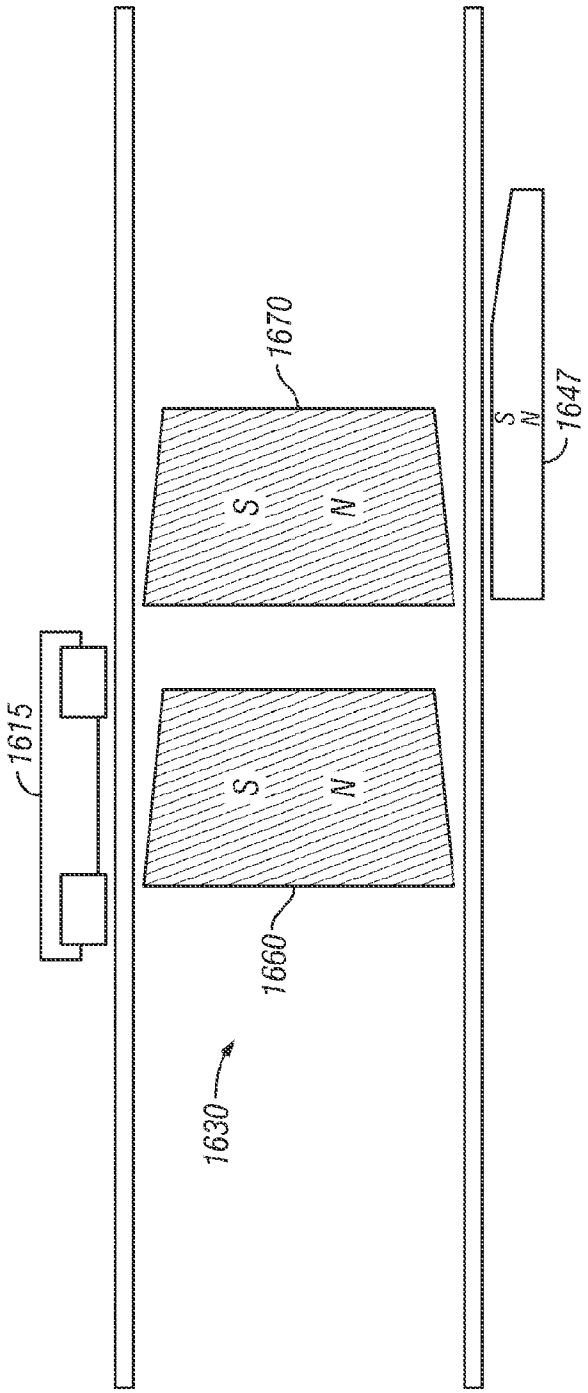


FIG. 56

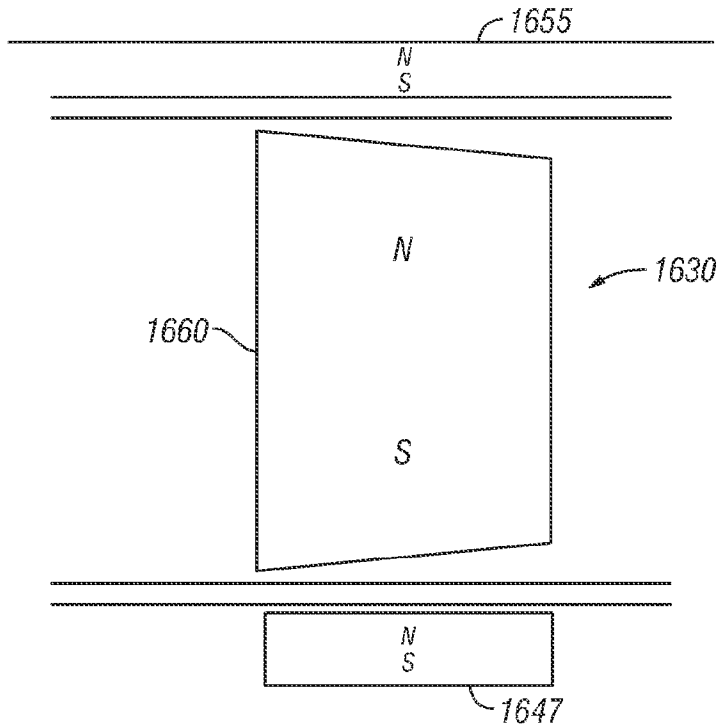

1655
N
S
N
S
1630
1660
N
S
N
S
1647

FIG. 57

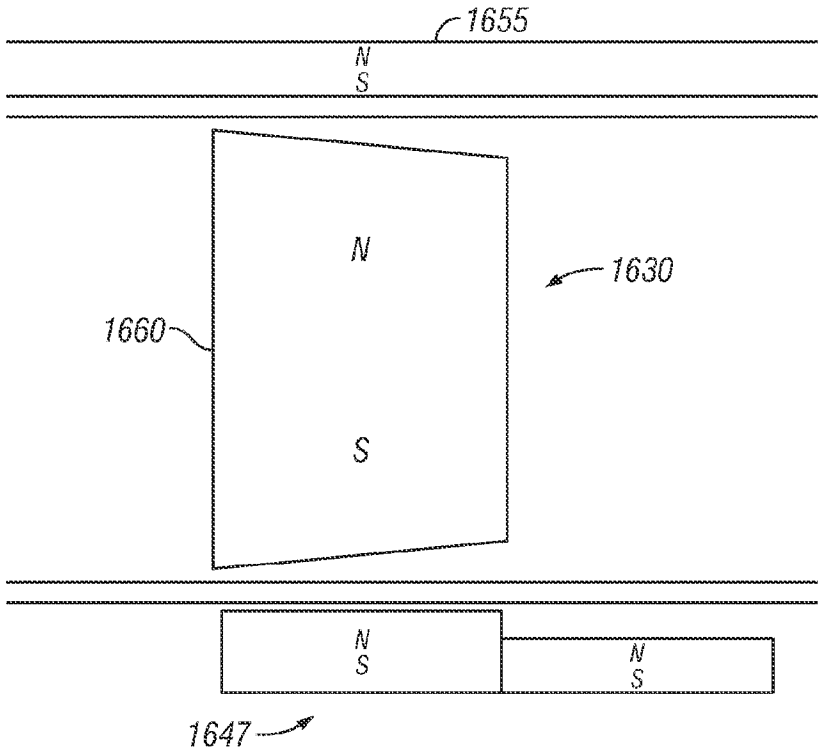

1655
N
S
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S
1630
1660
N
S
N
S
N
S
1647

FIG. 58

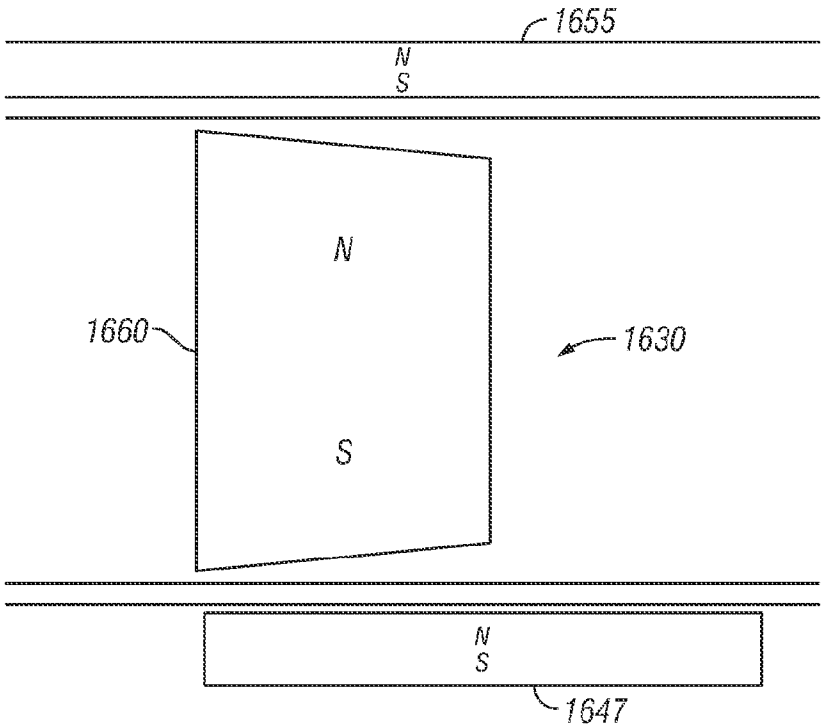


FIG. 59

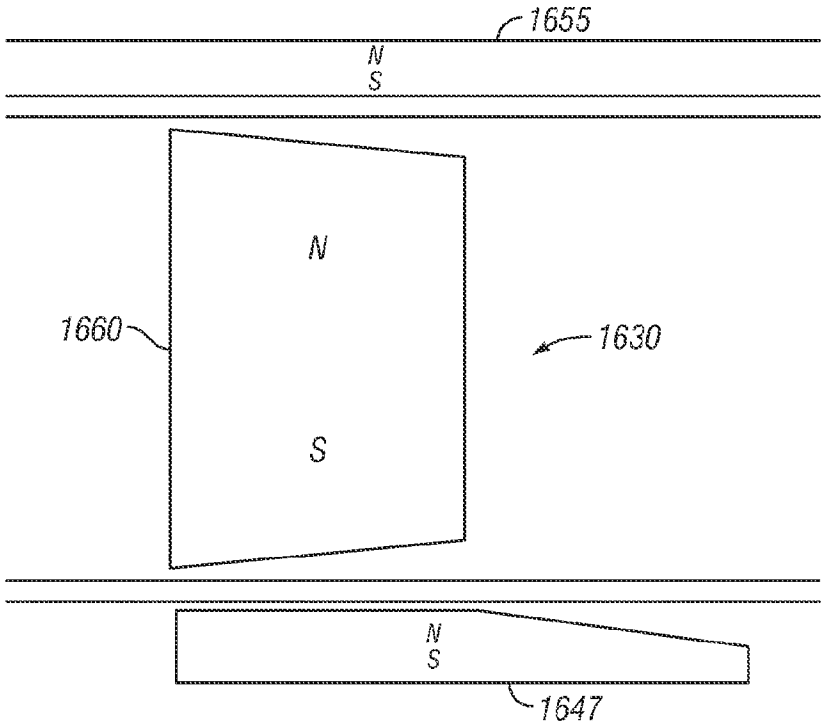


FIG. 60

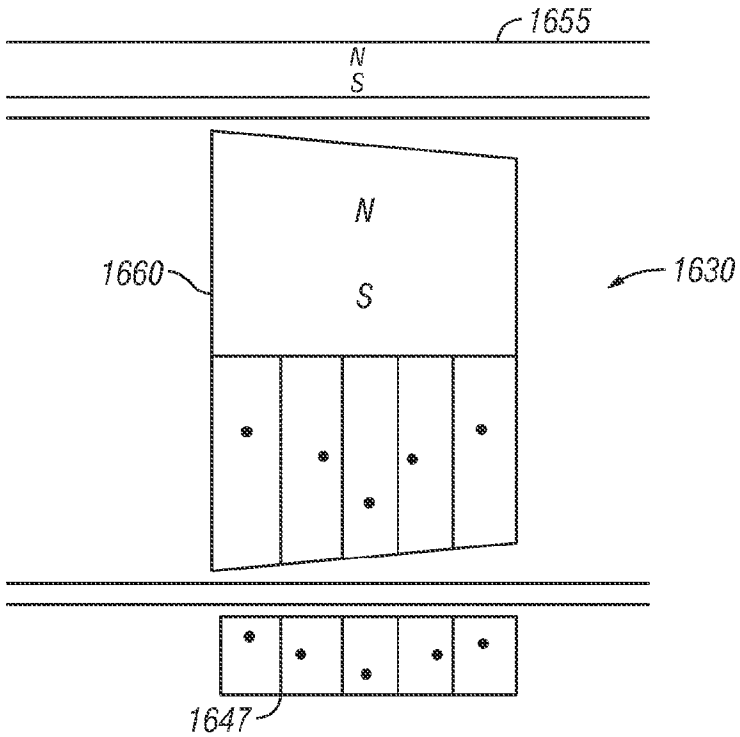


FIG. 61

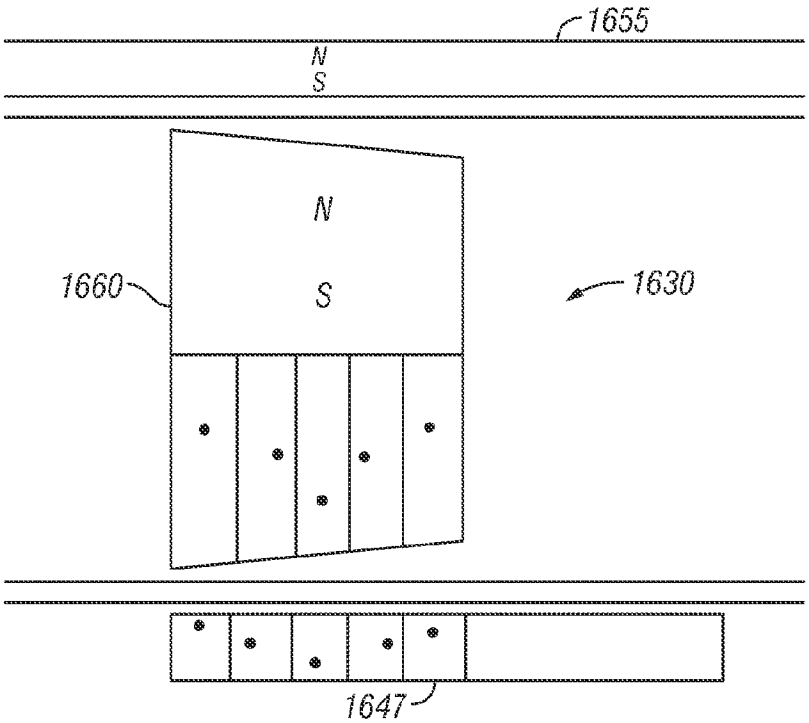


FIG. 62

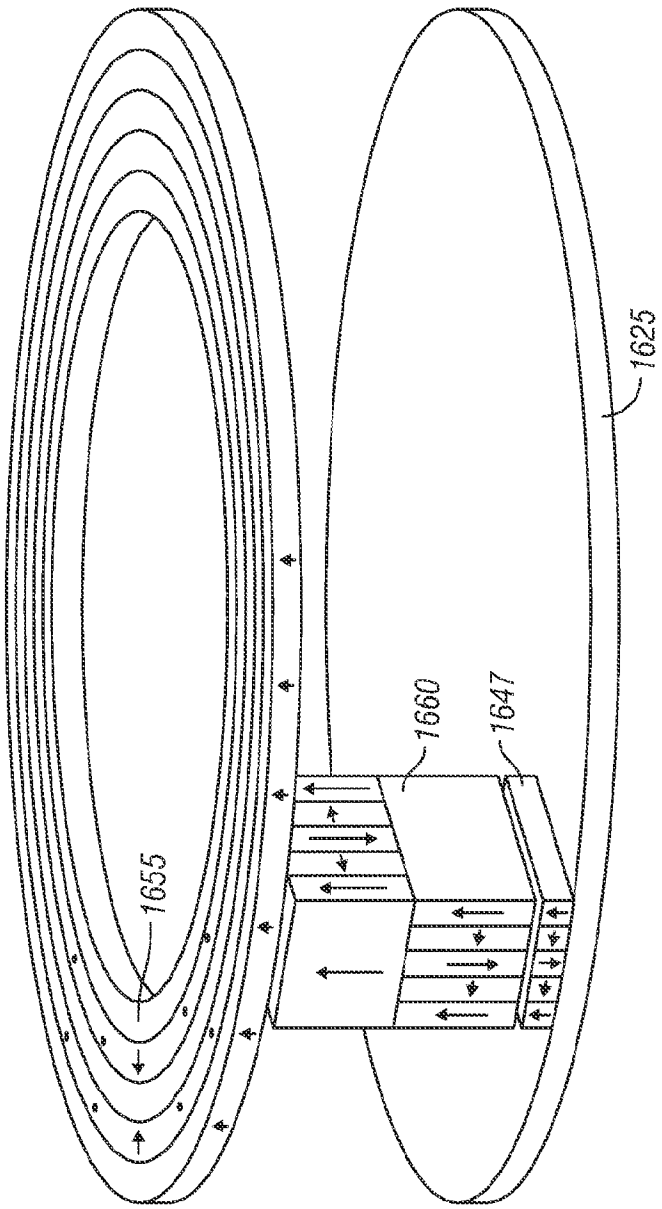


FIG. 63

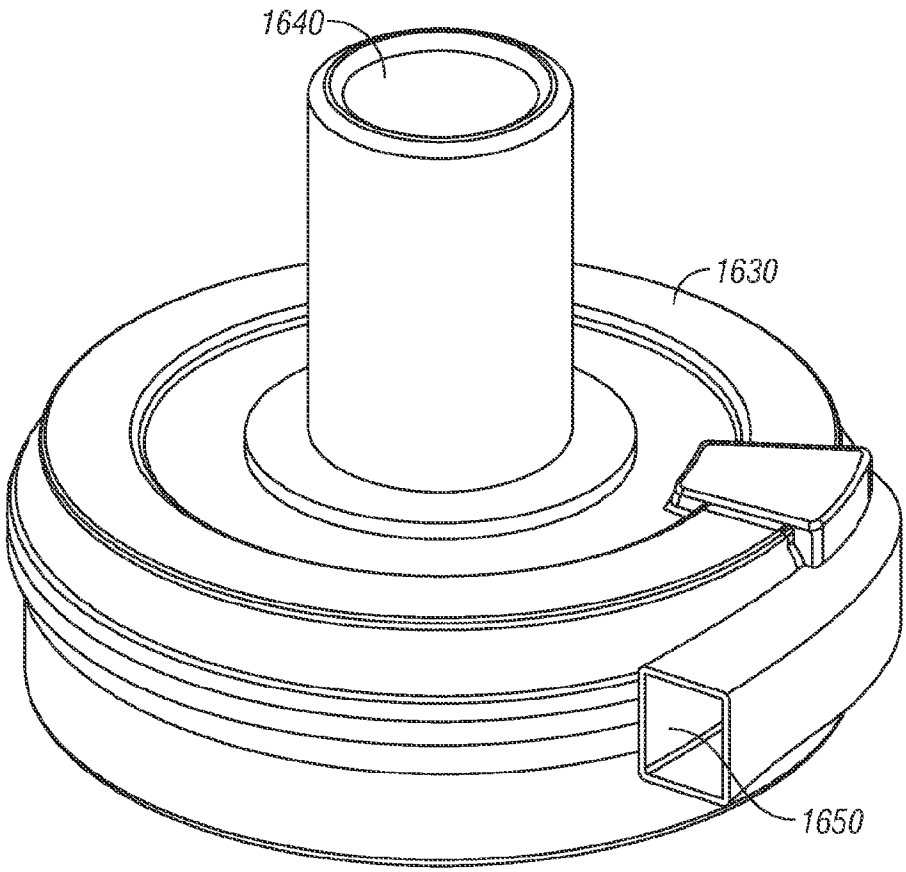


FIG. 64

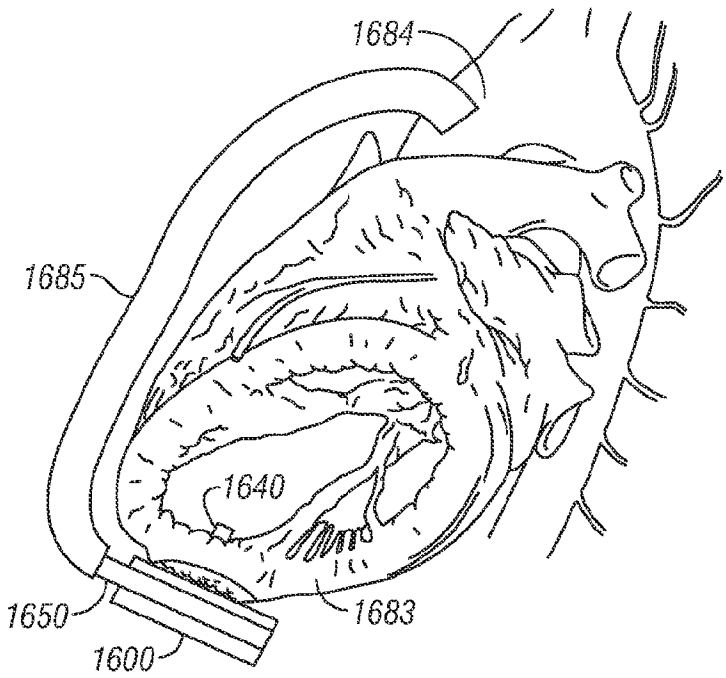


FIG. 65

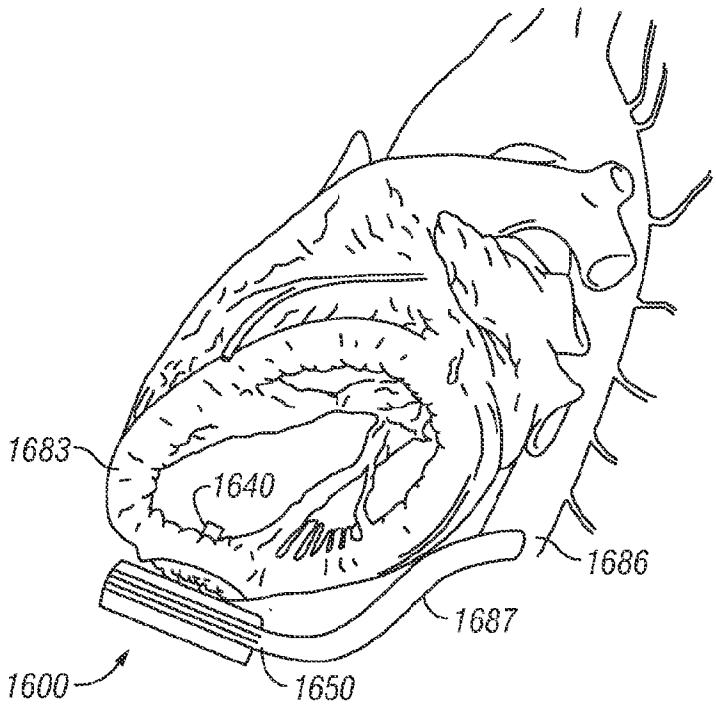


FIG. 66

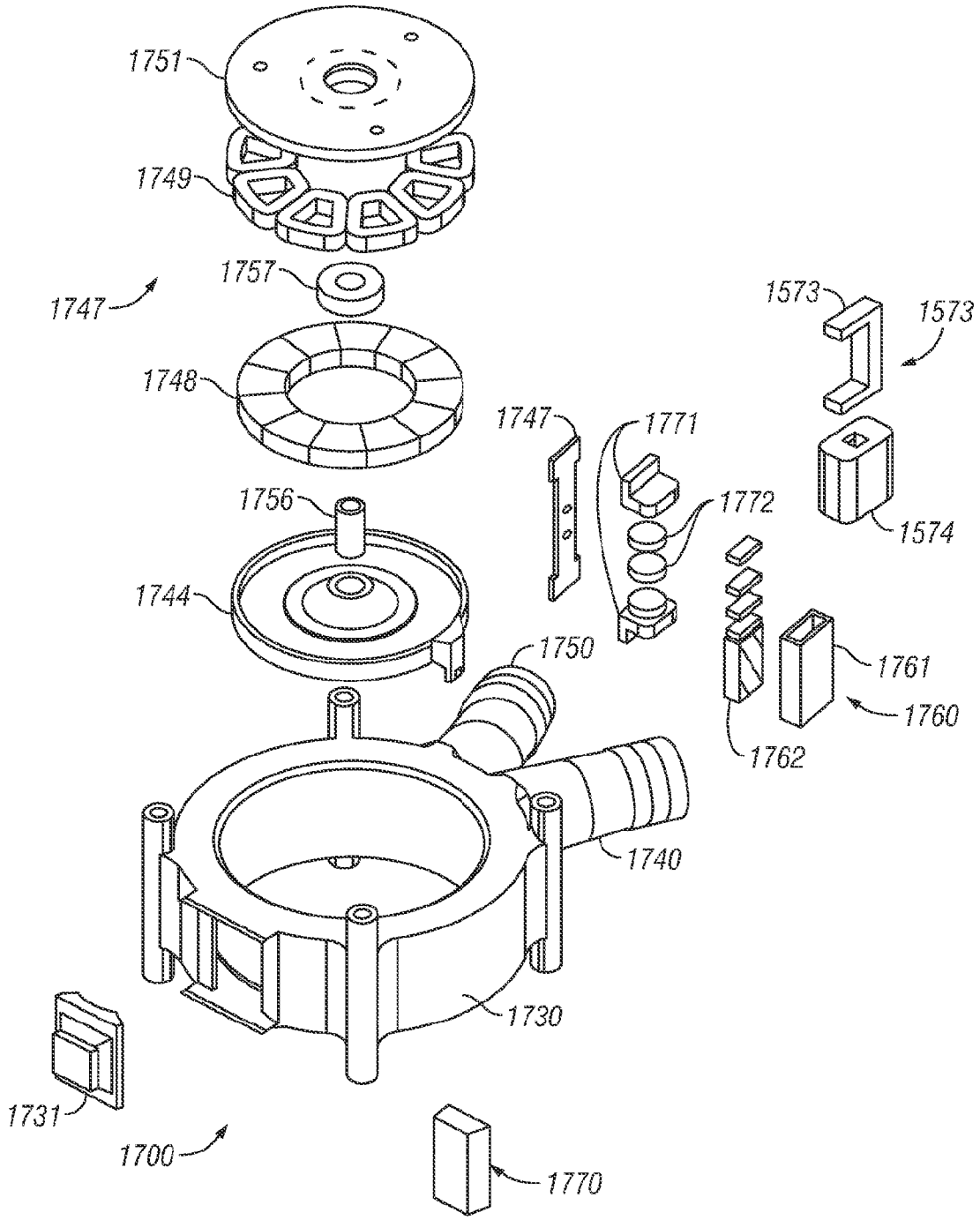

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FIG. 67

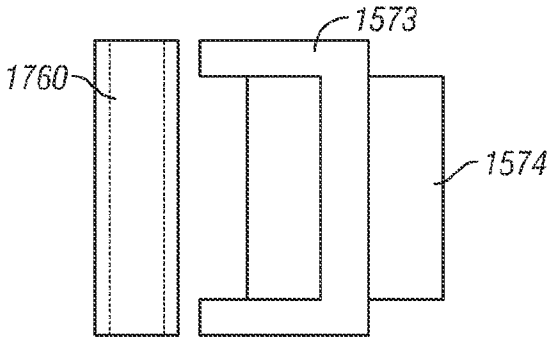


FIG. 68

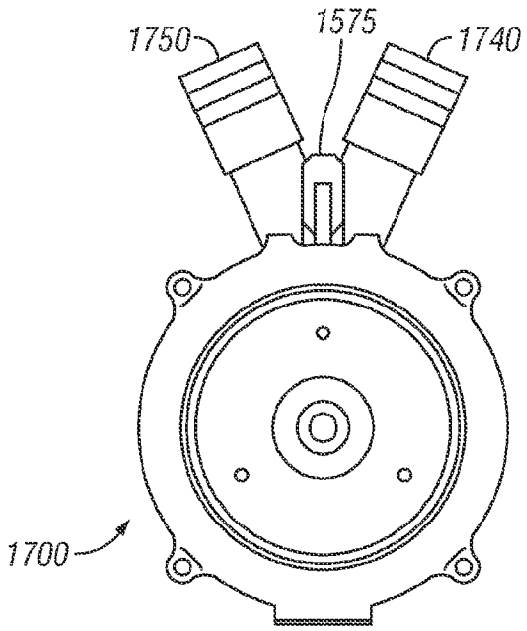


FIG. 69

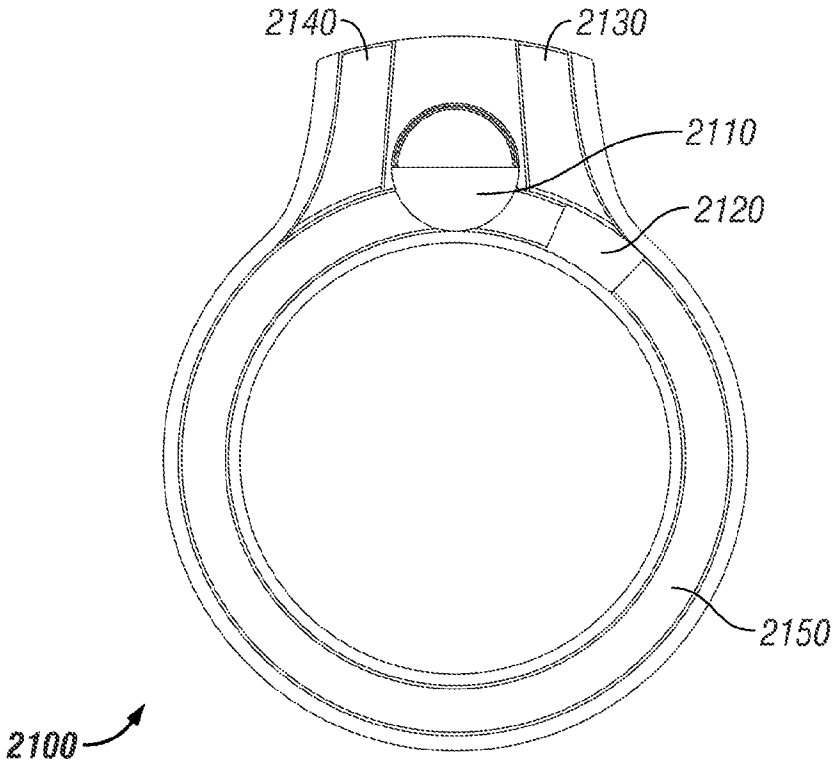


FIG. 70

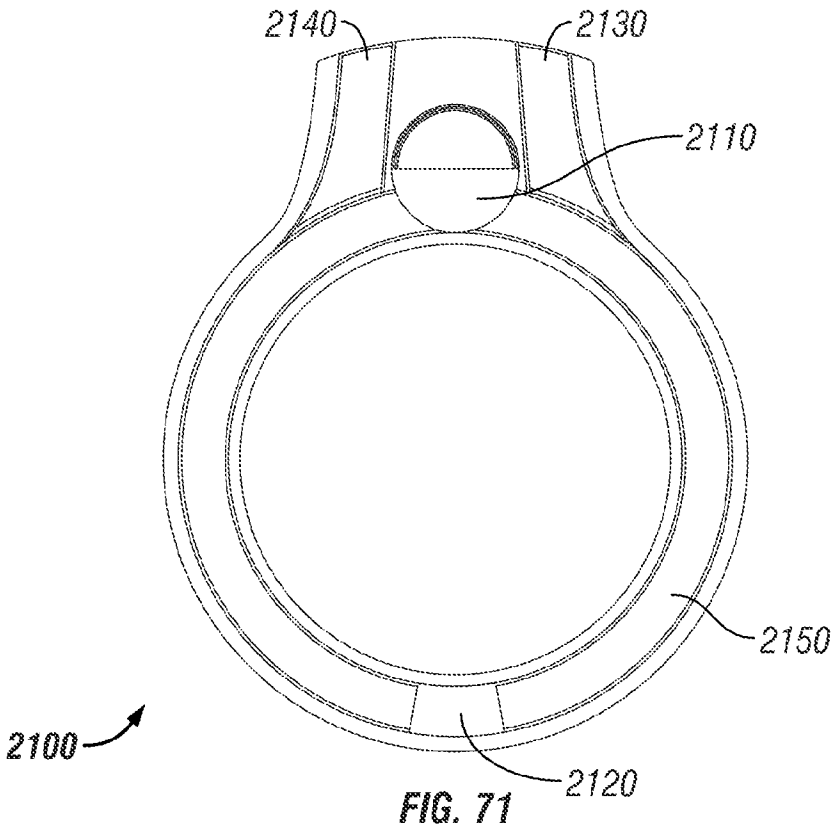


FIG. 71

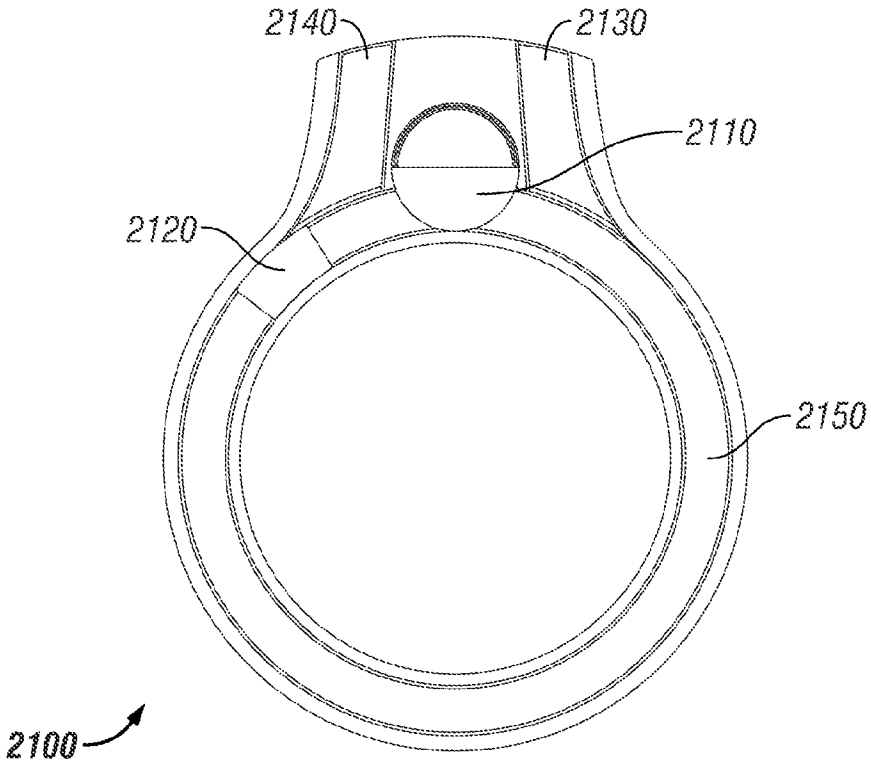


FIG. 72

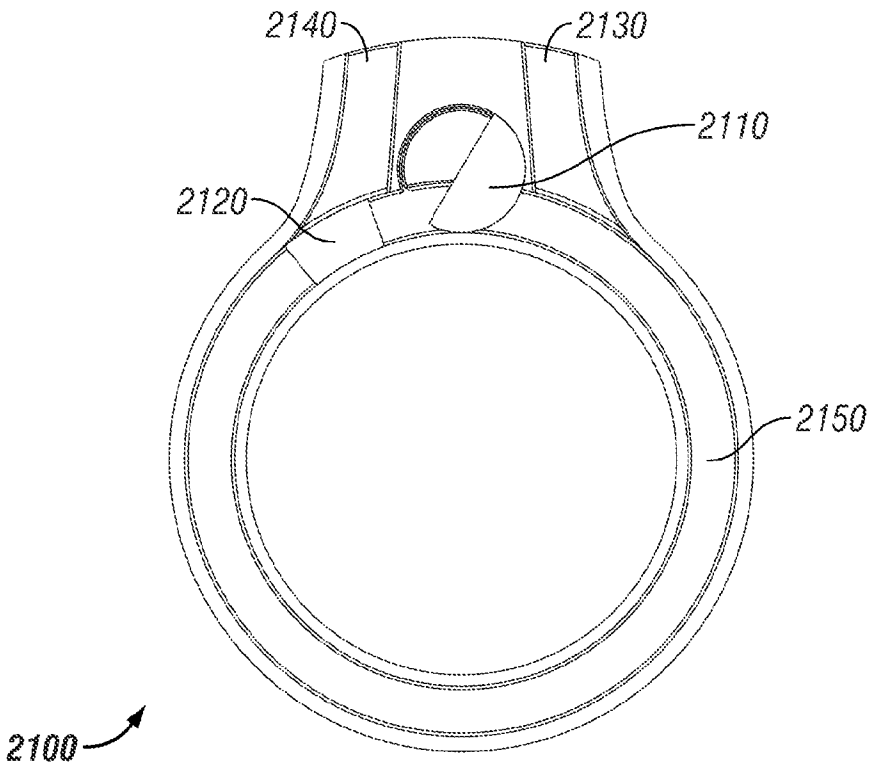


FIG. 73

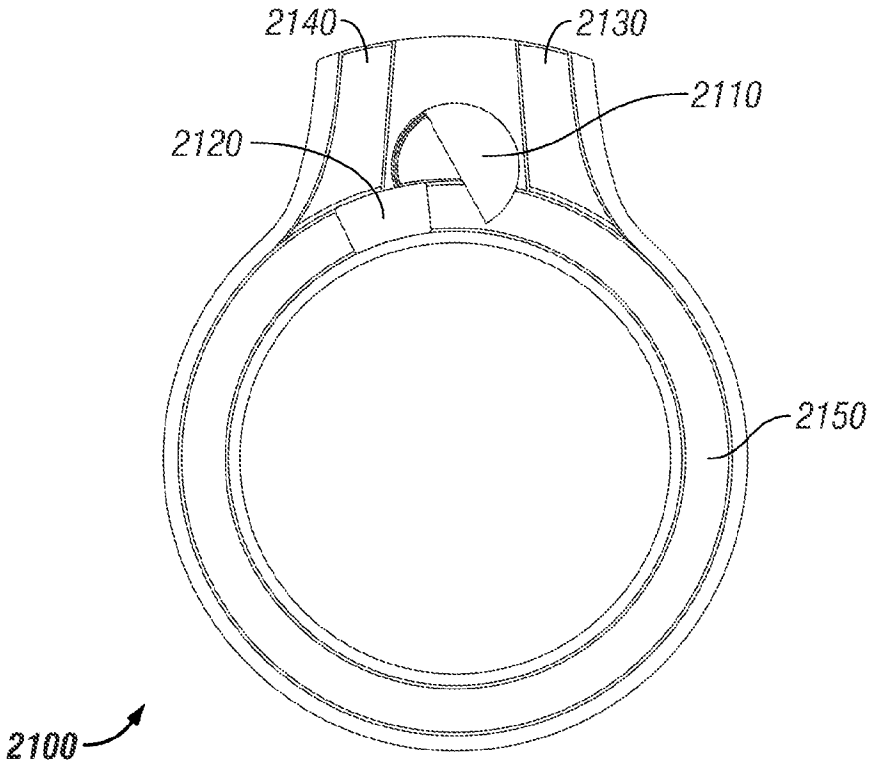


FIG. 74

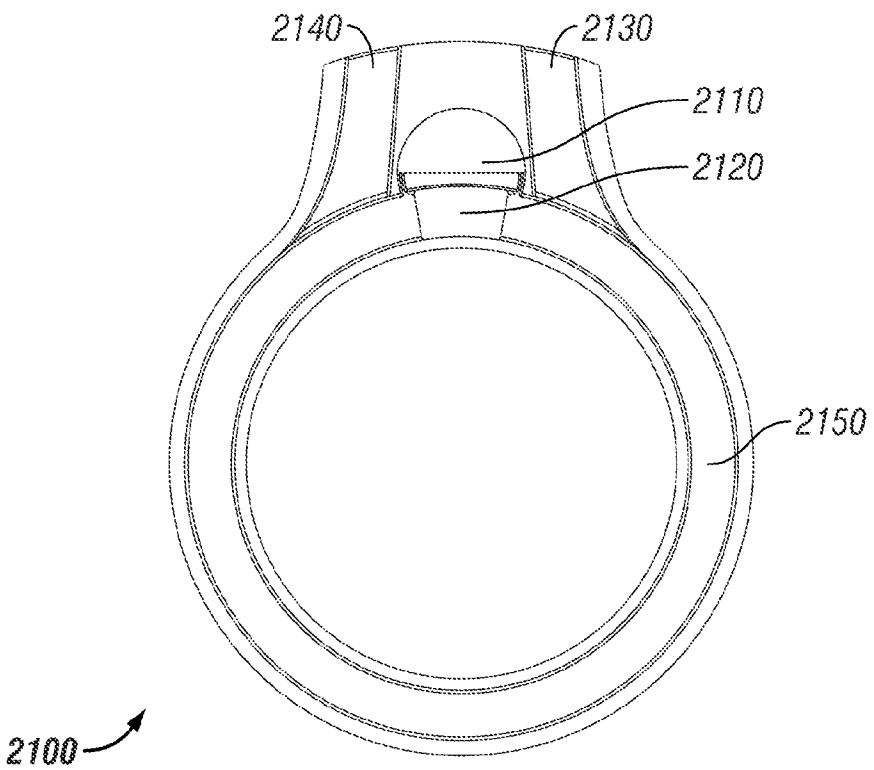


FIG. 75

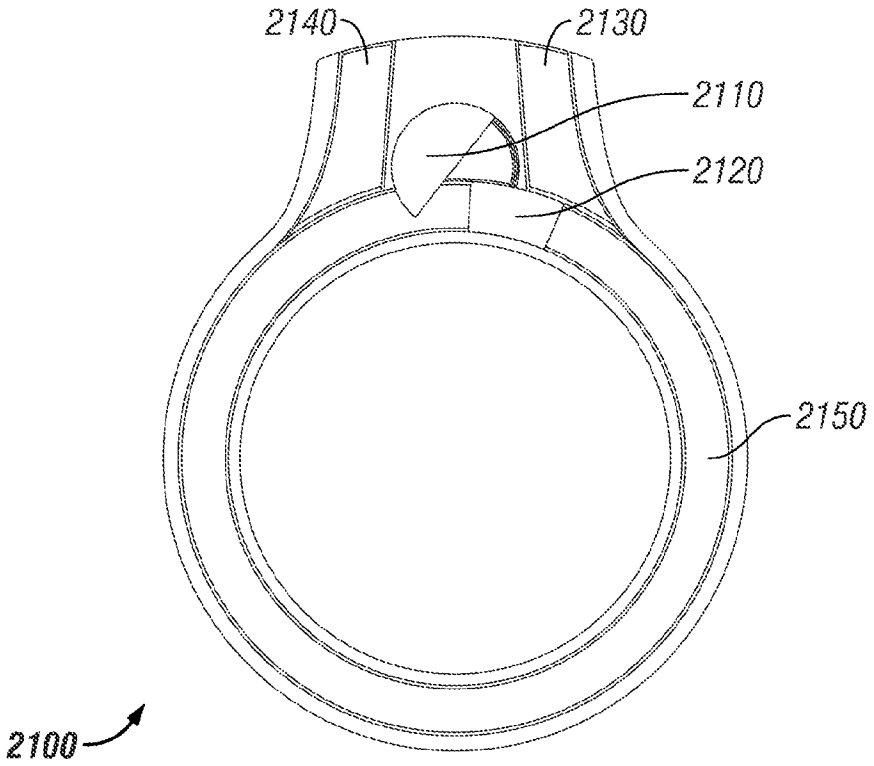


FIG. 76

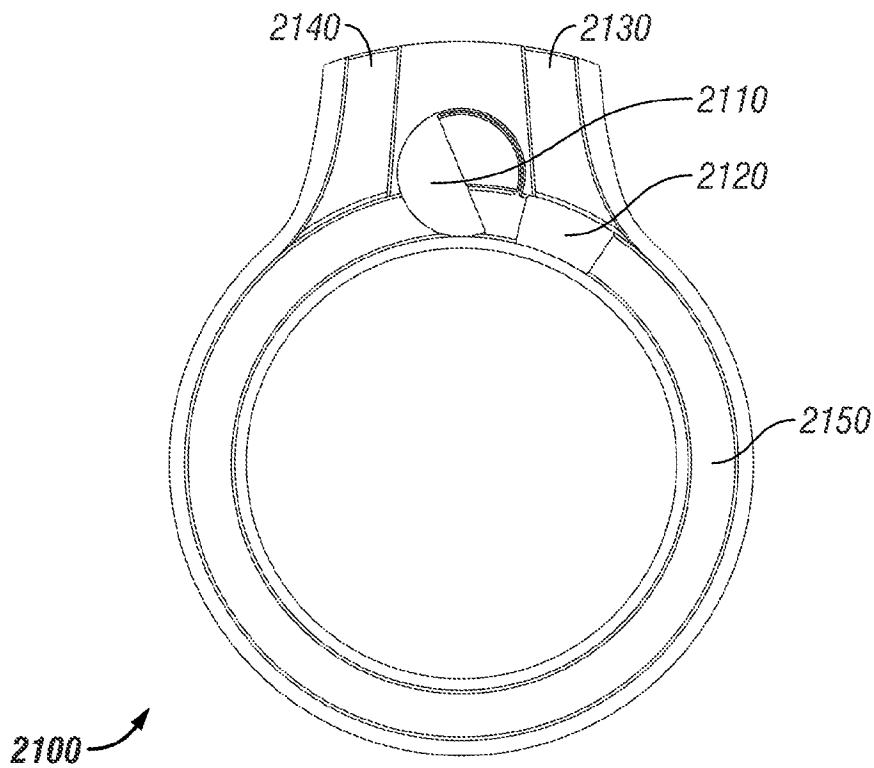


FIG. 77

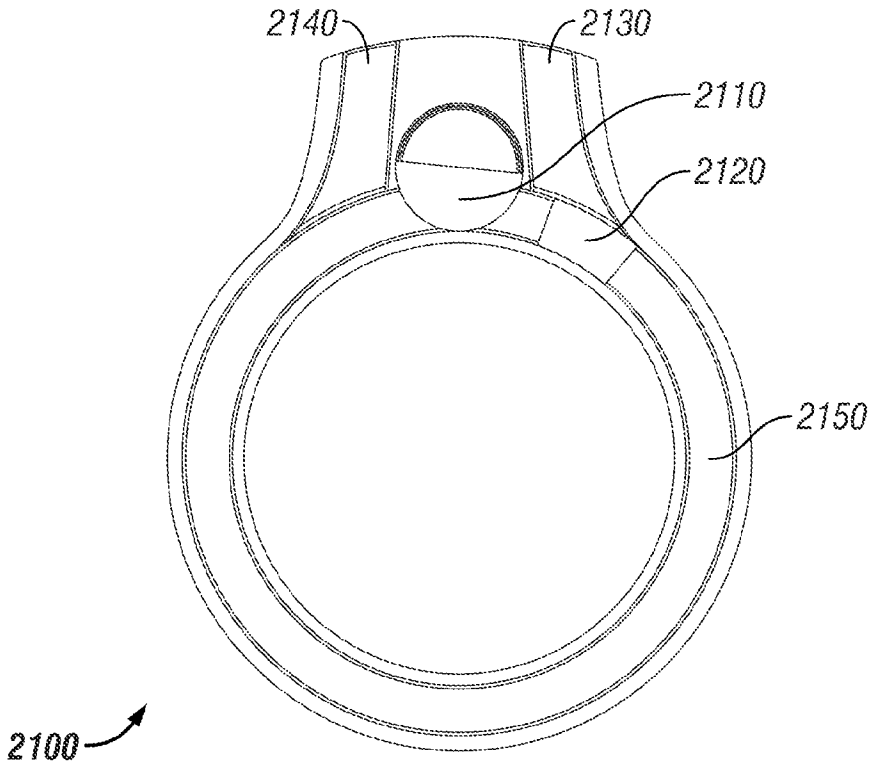


FIG. 78

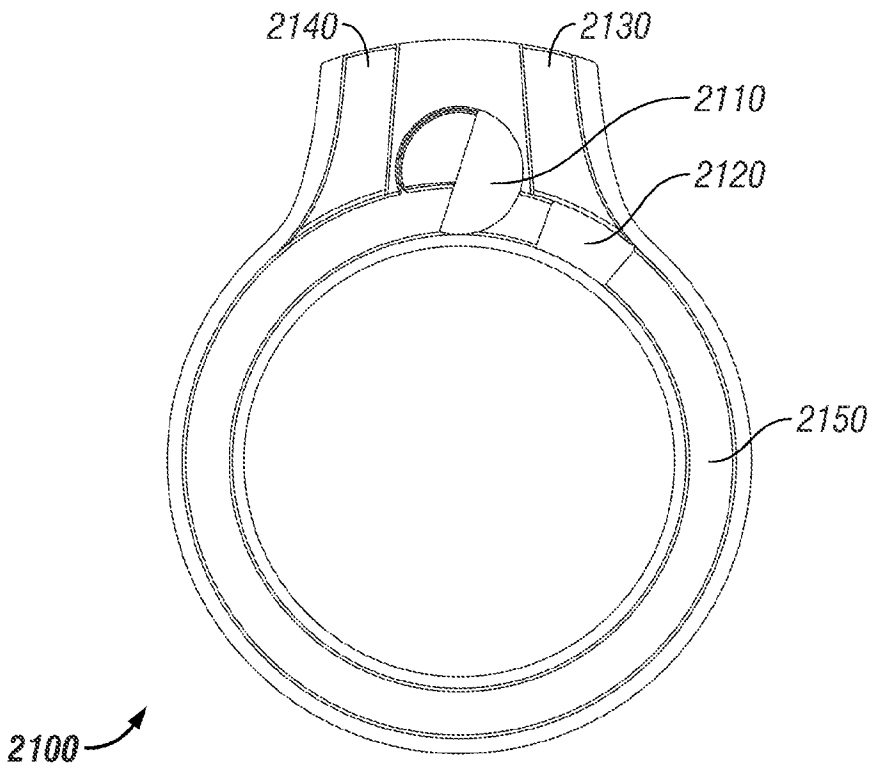


FIG. 79

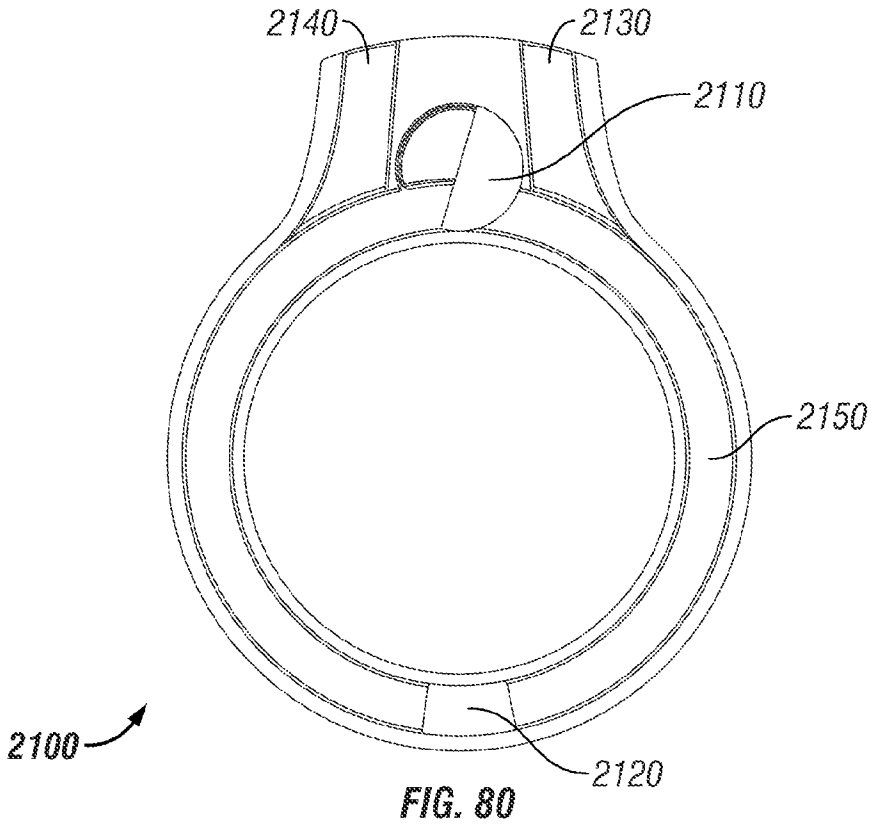


FIG. 80

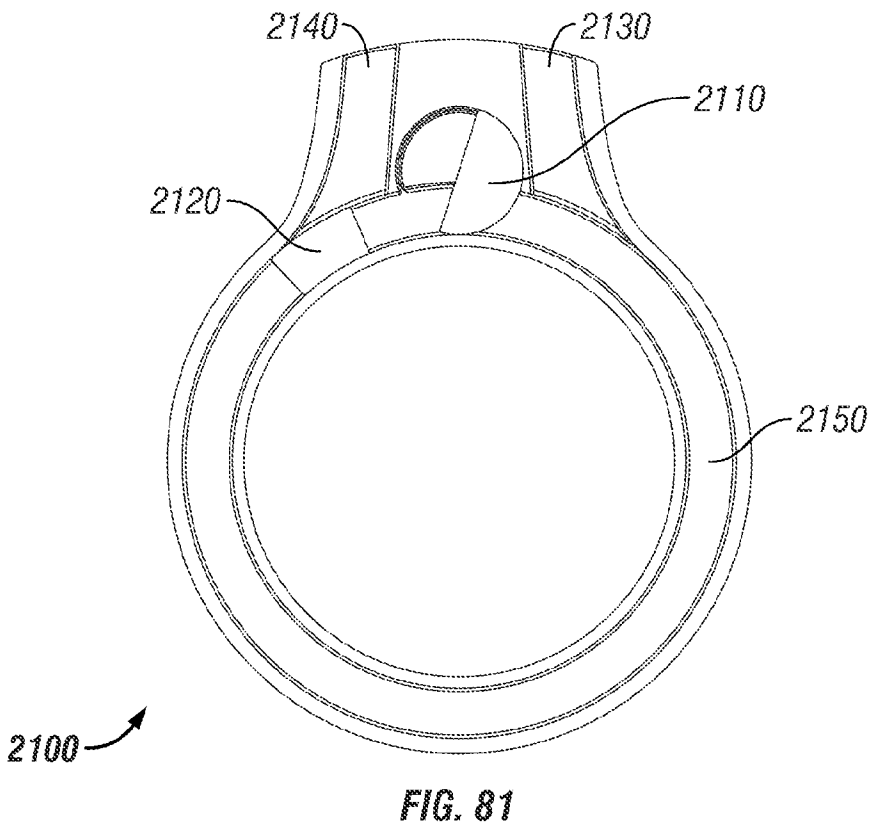


FIG. 81

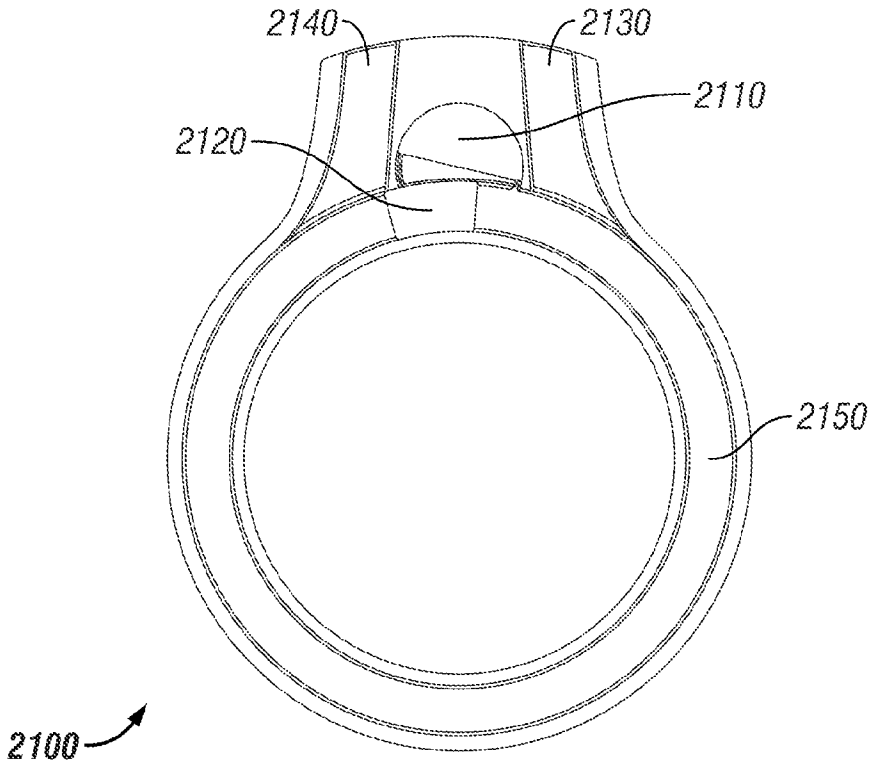


FIG. 82

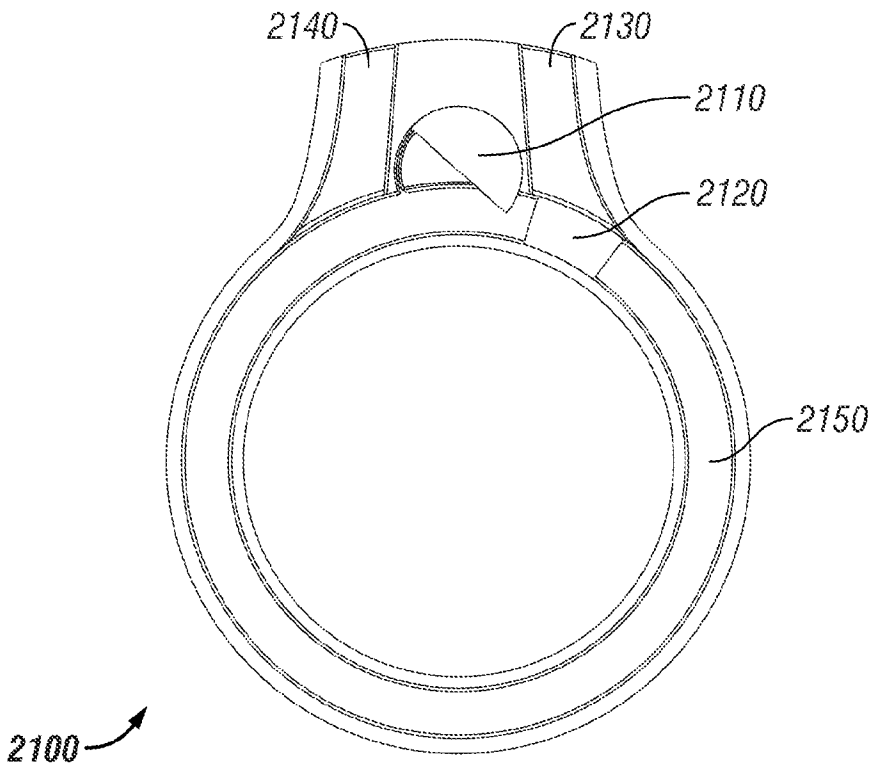


FIG. 83

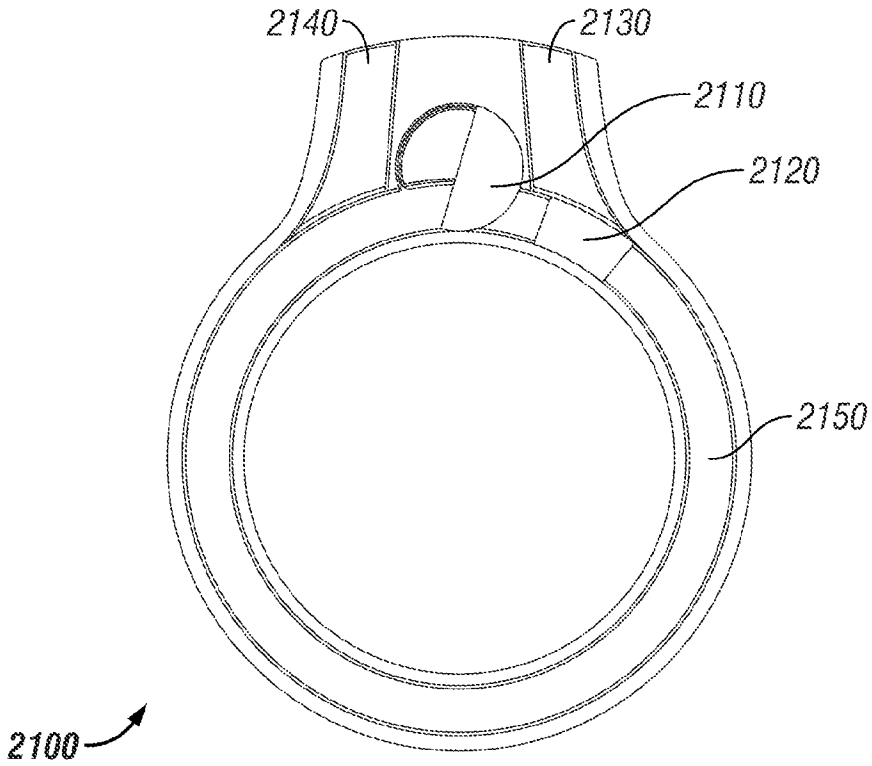


FIG. 84

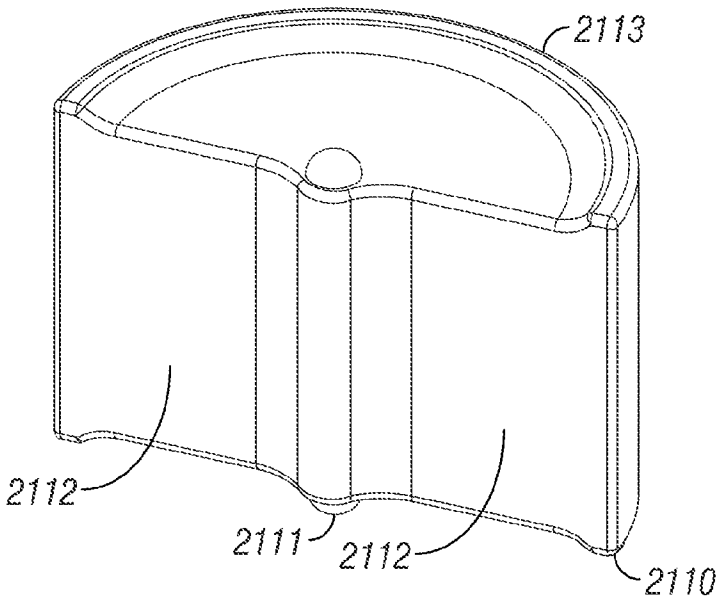


FIG. 85

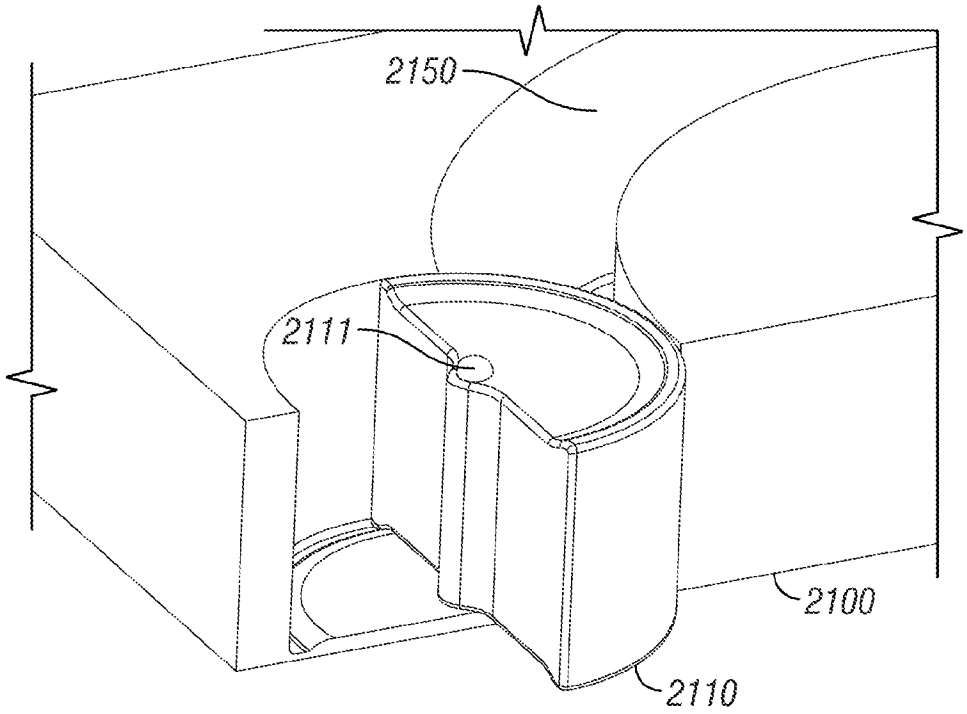


FIG. 86

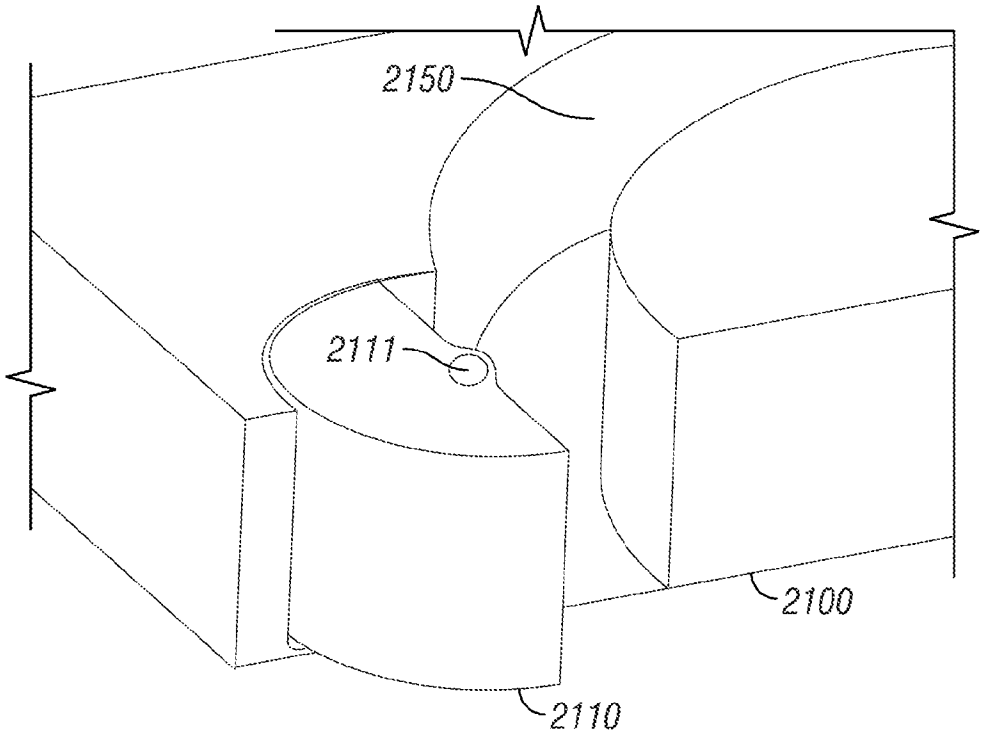


FIG. 87

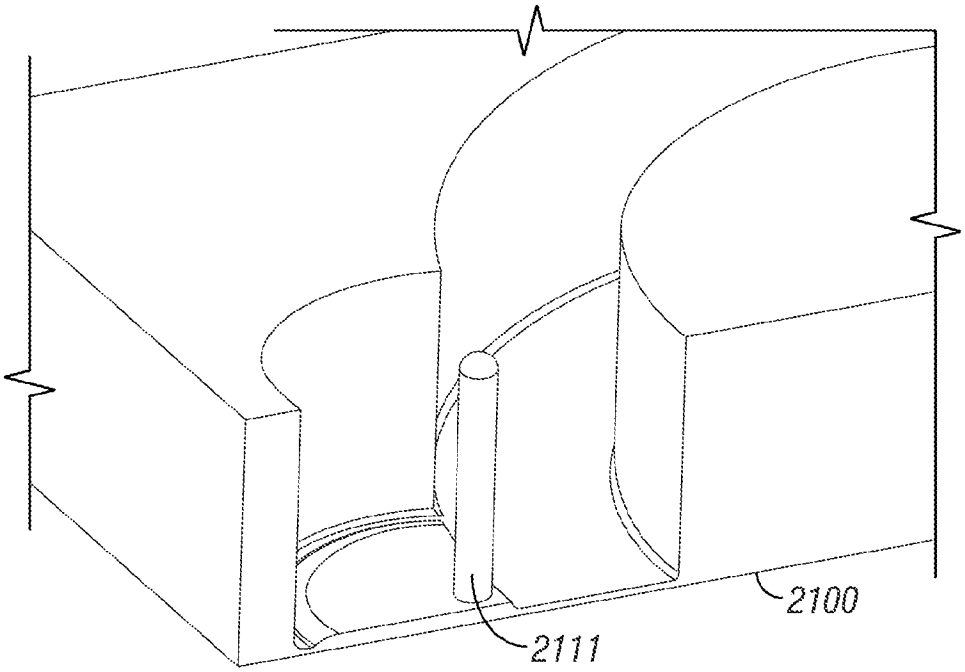


FIG. 88

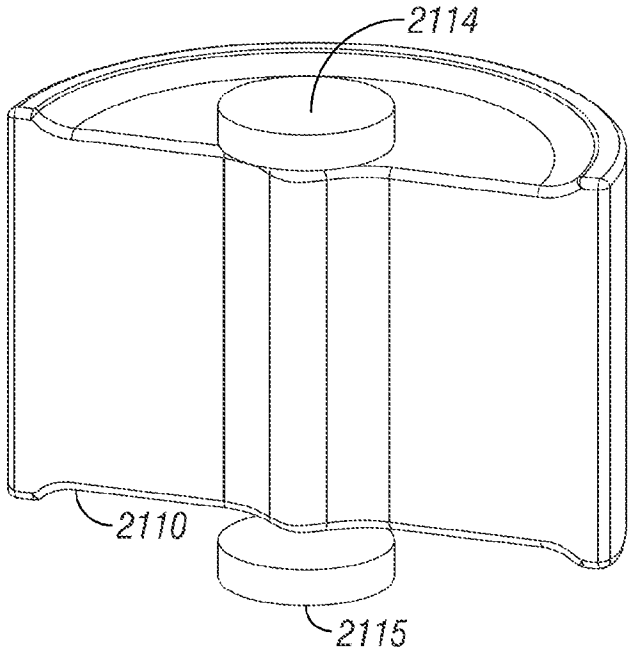


FIG. 89

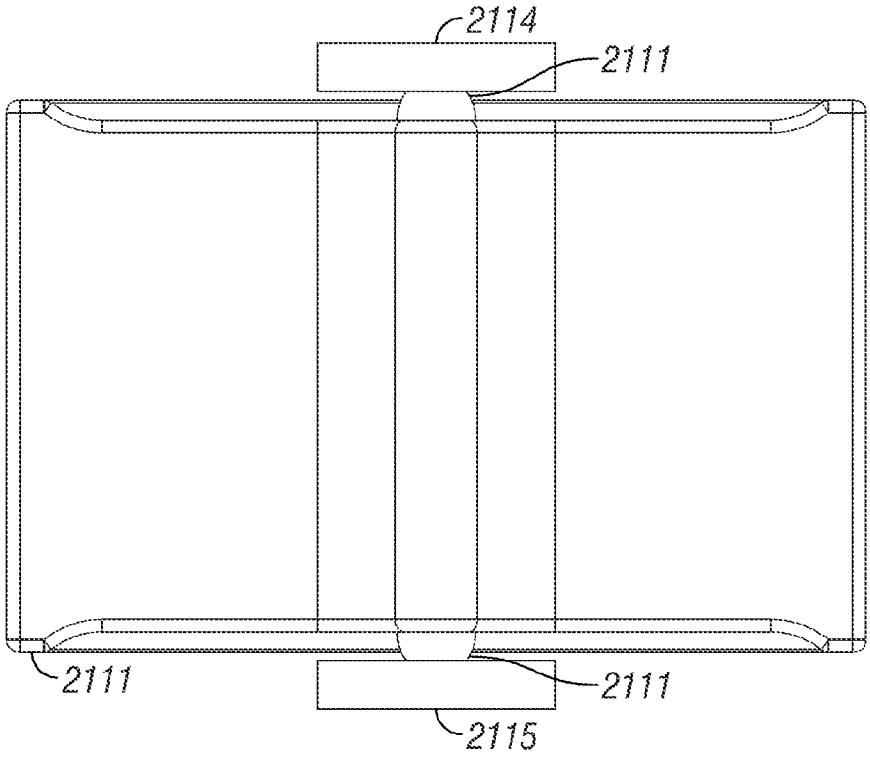


FIG. 90

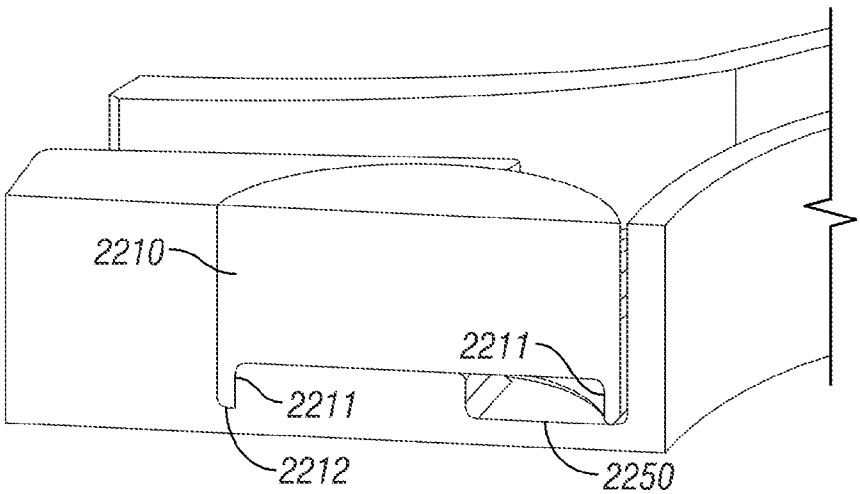


FIG. 91

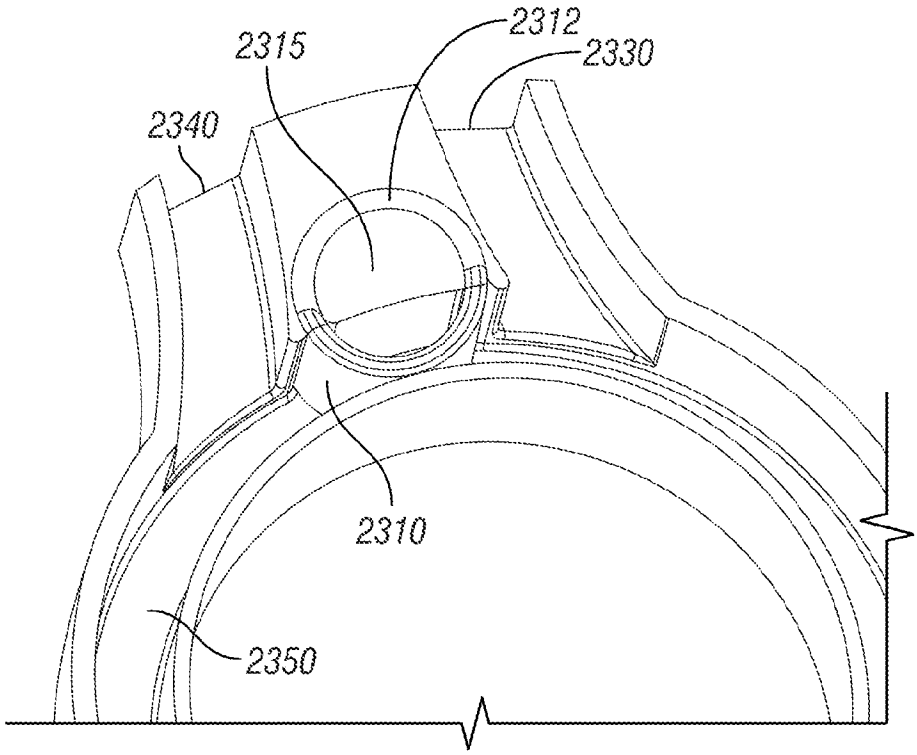


FIG. 92

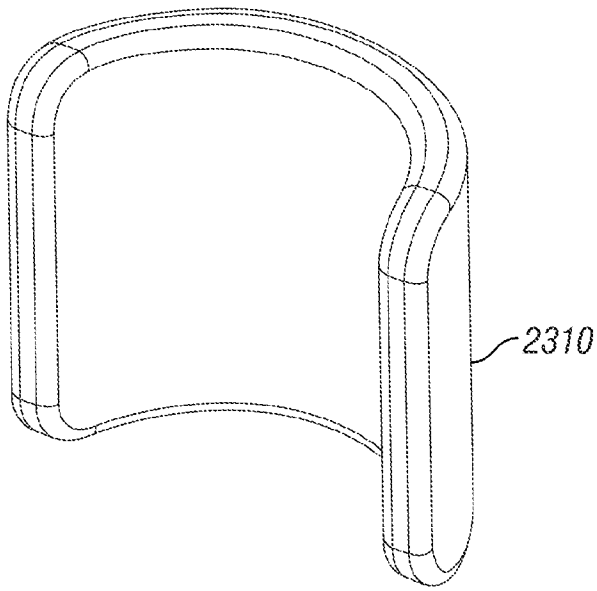


FIG. 93

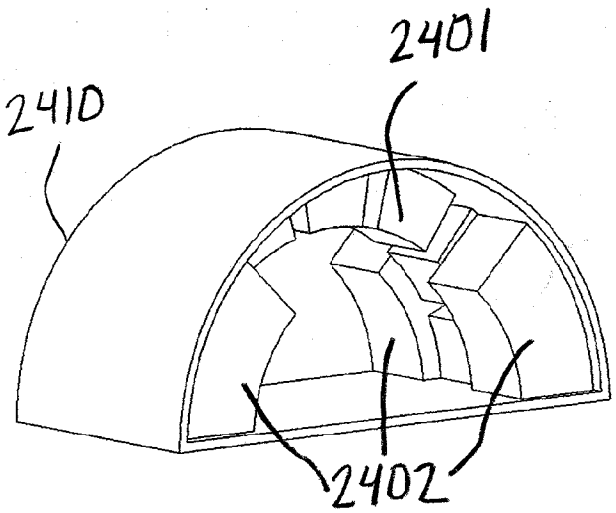


FIG. 94

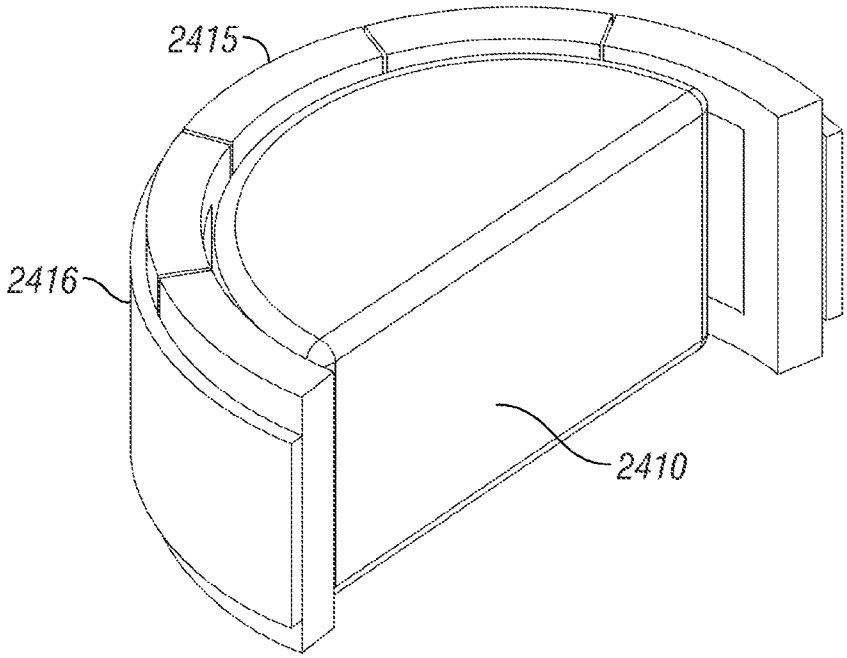


FIG. 95

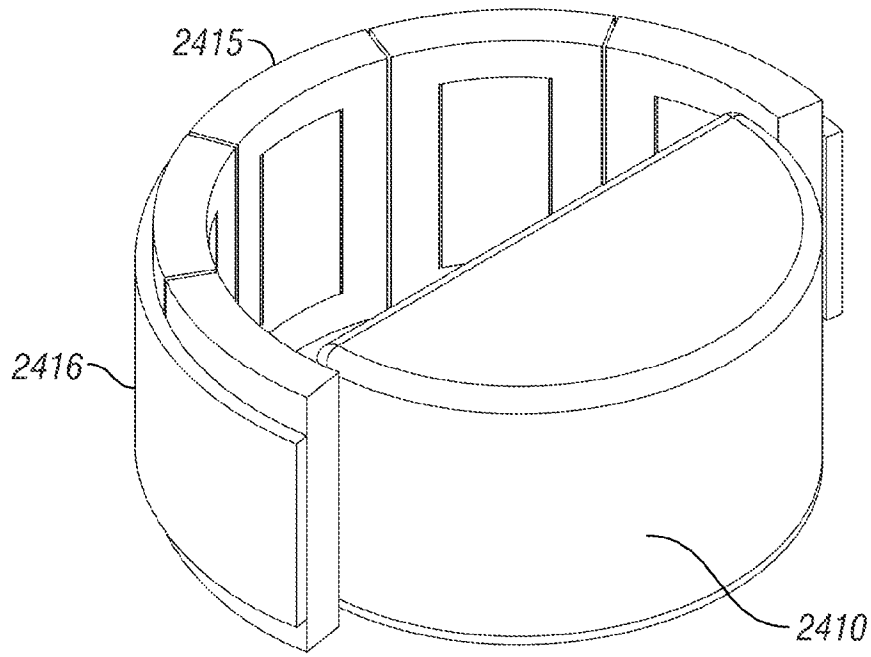


FIG. 96

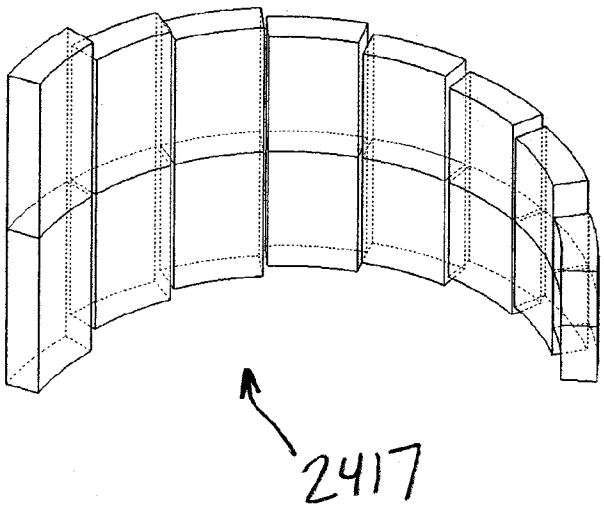


FIG. 97

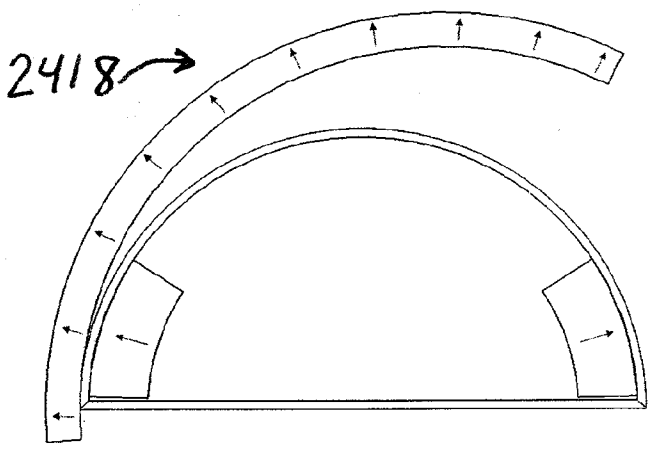


FIG. 98

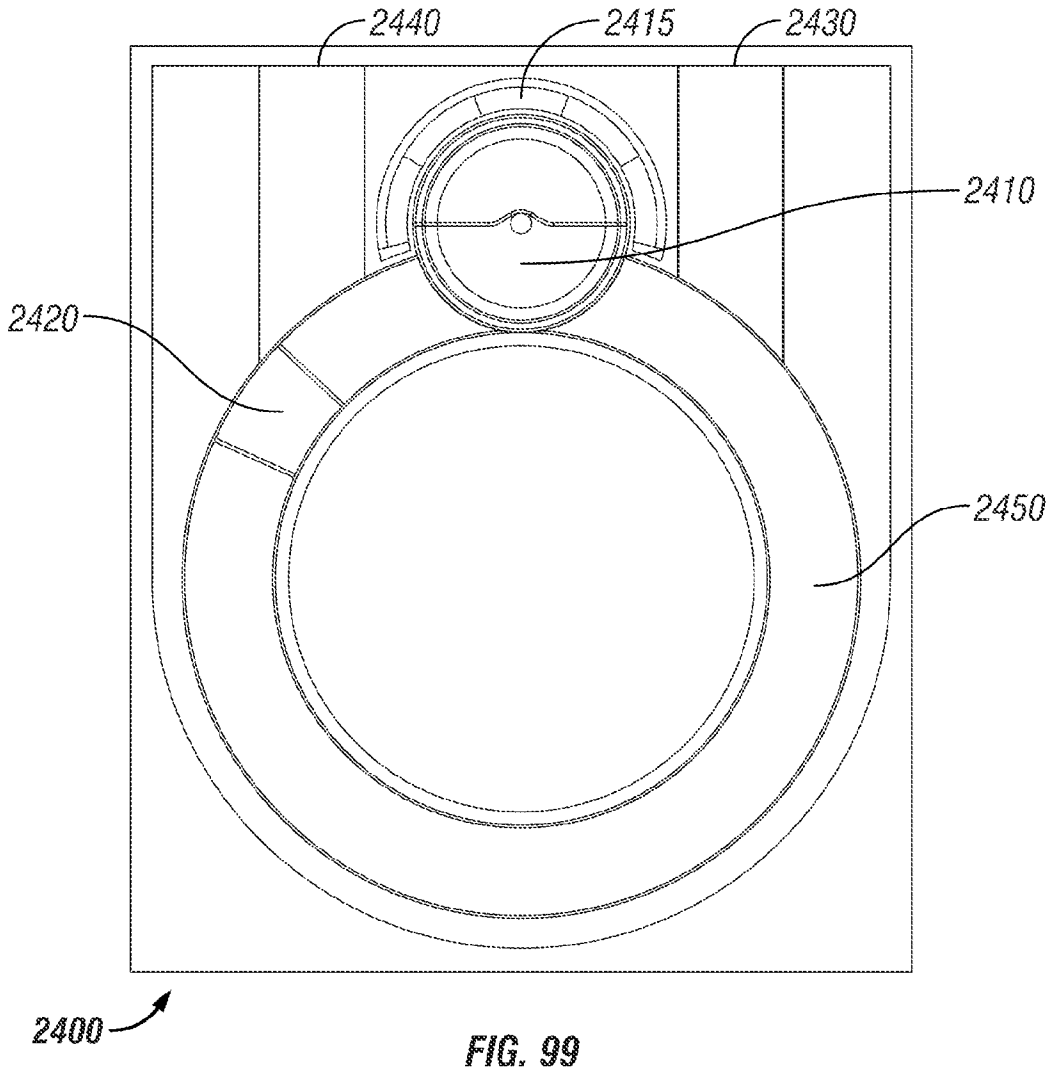


FIG. 99

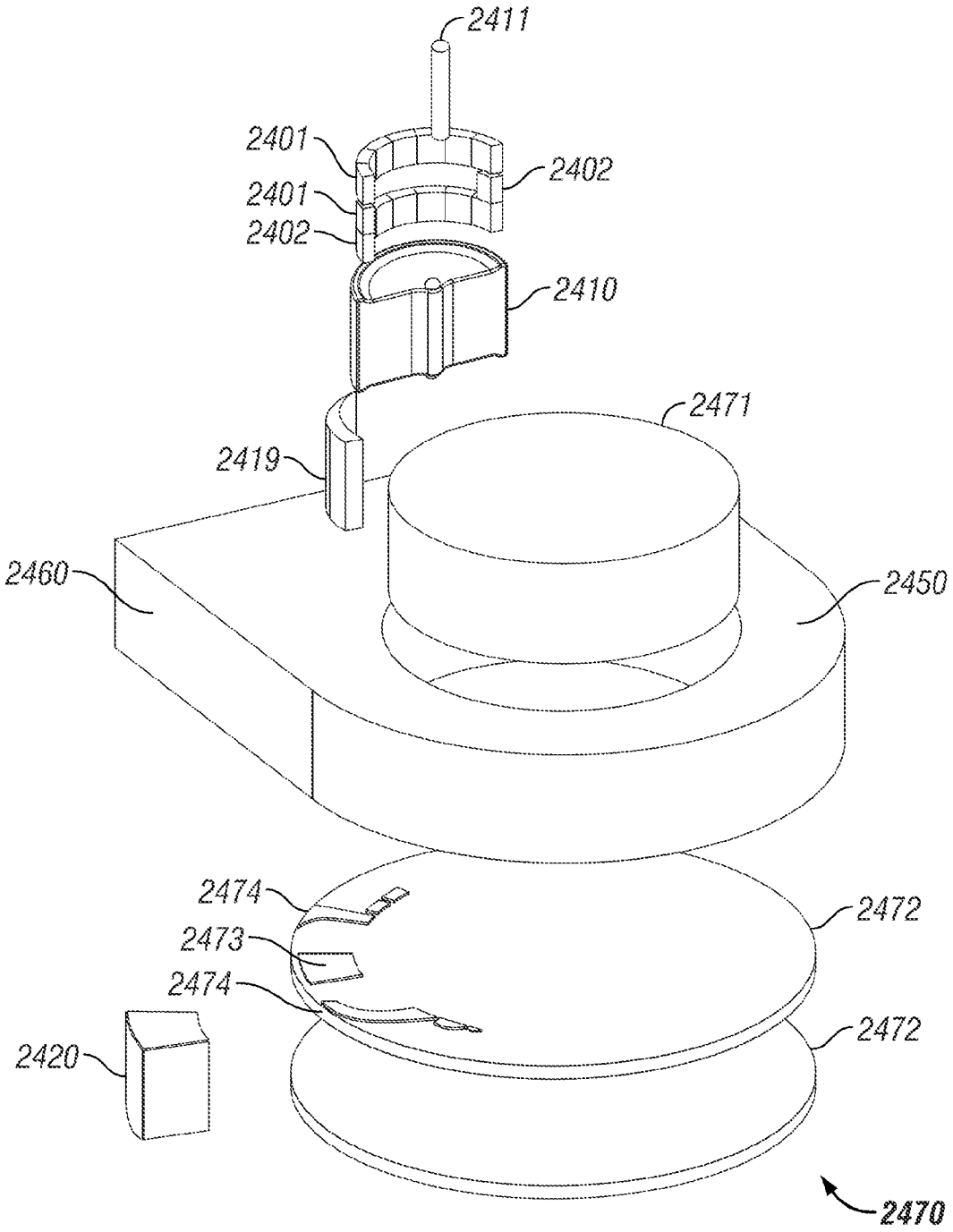

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FIG. 100A

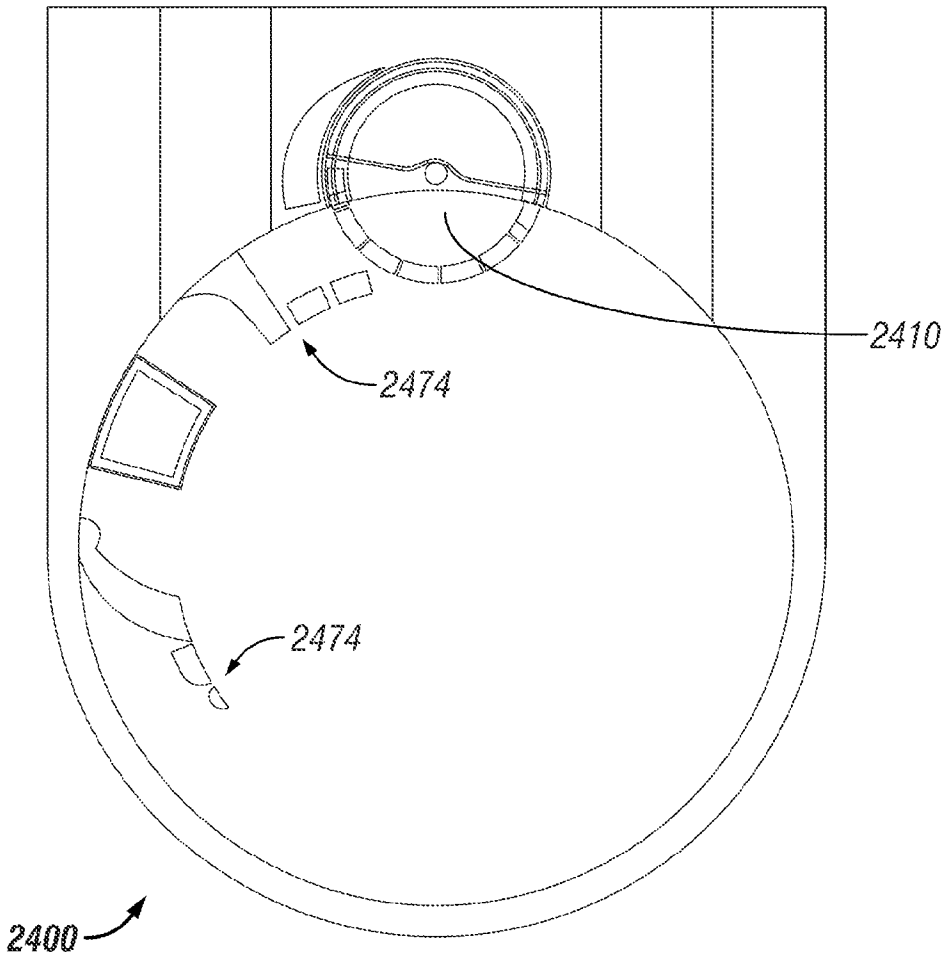


FIG. 100B

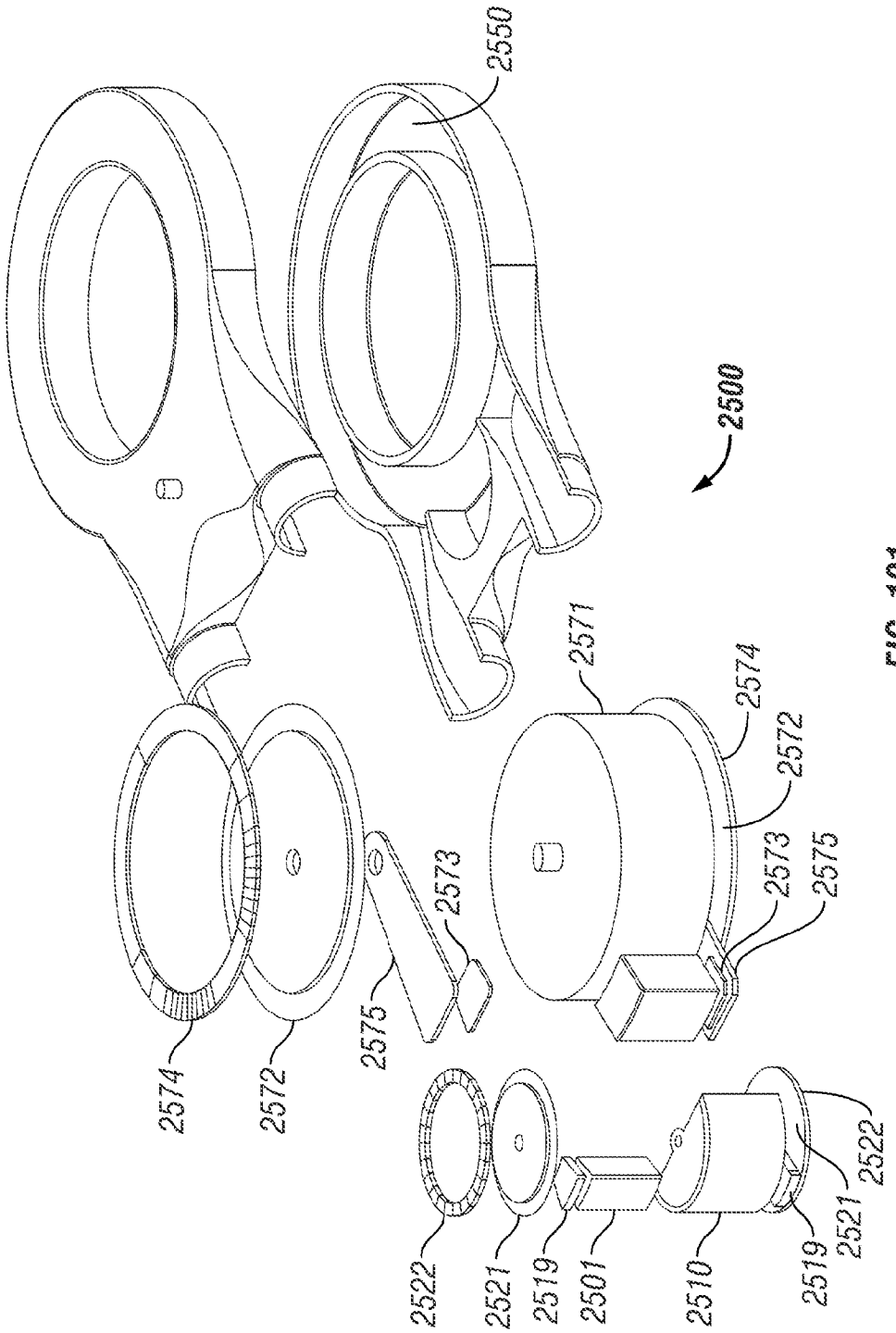

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FIG. 101

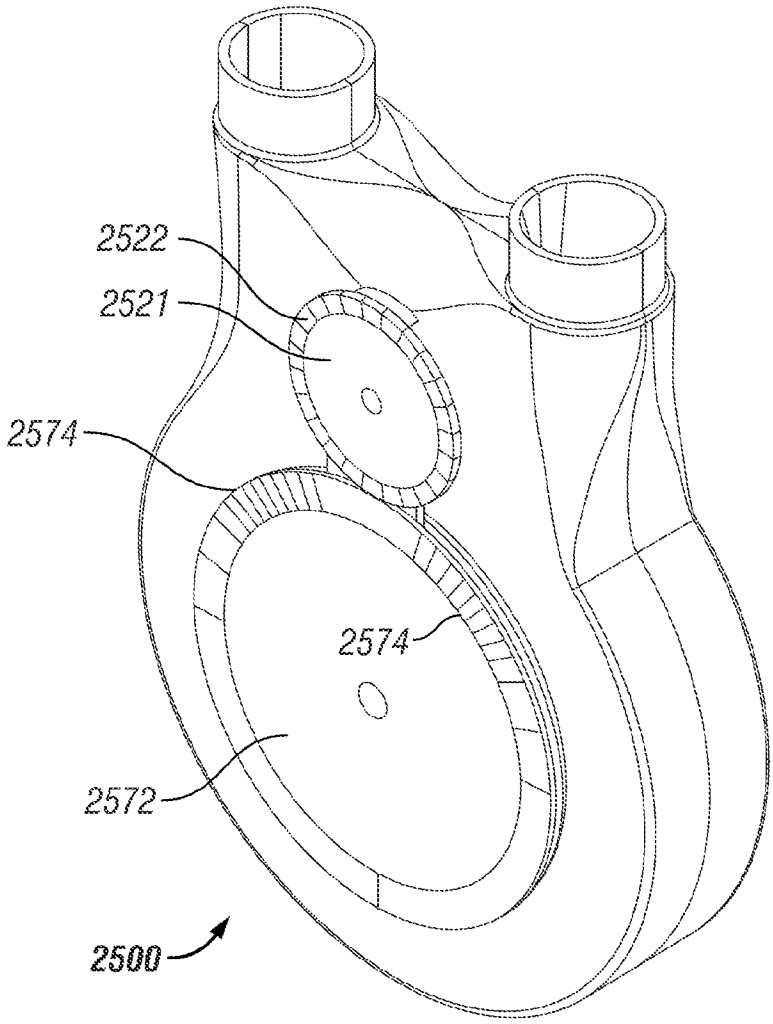


FIG. 102

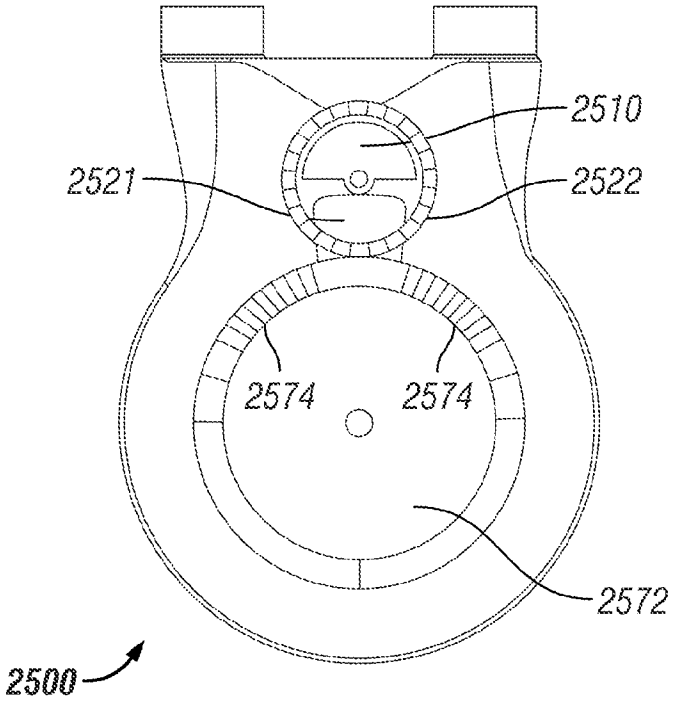


FIG. 103

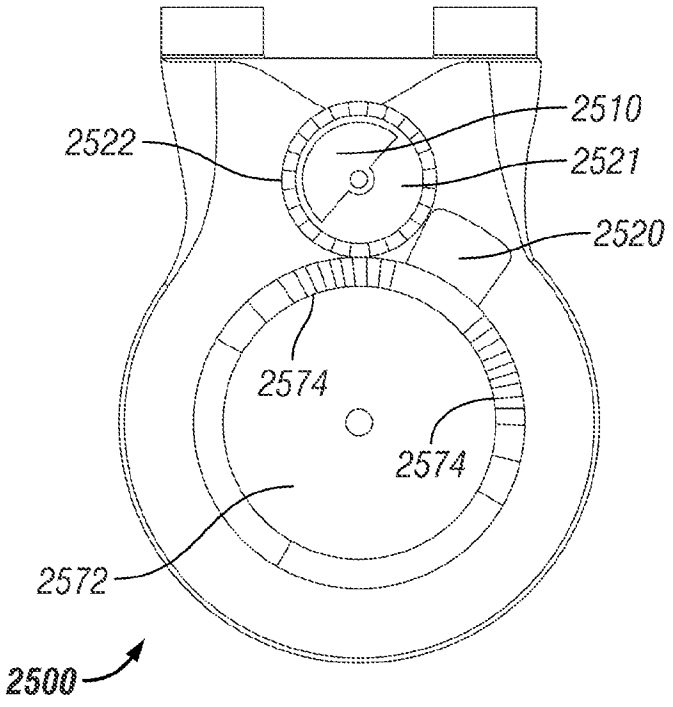


FIG. 104

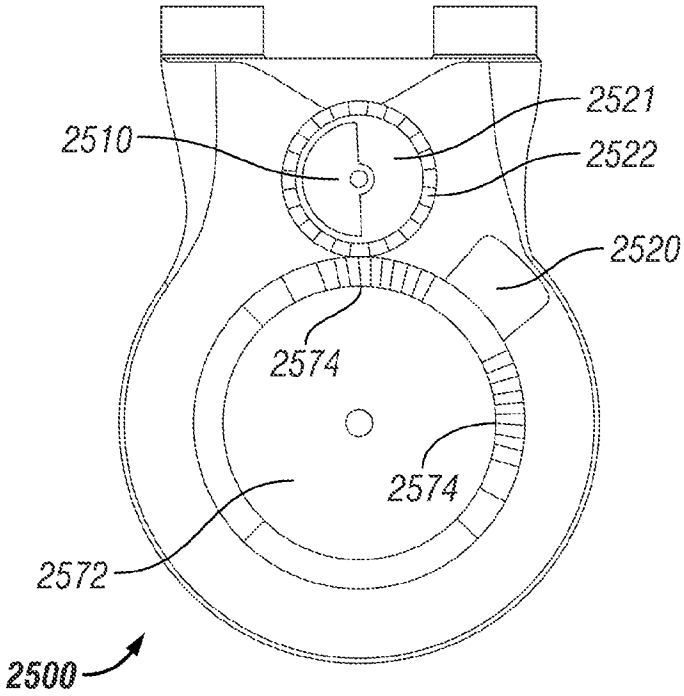


FIG. 105

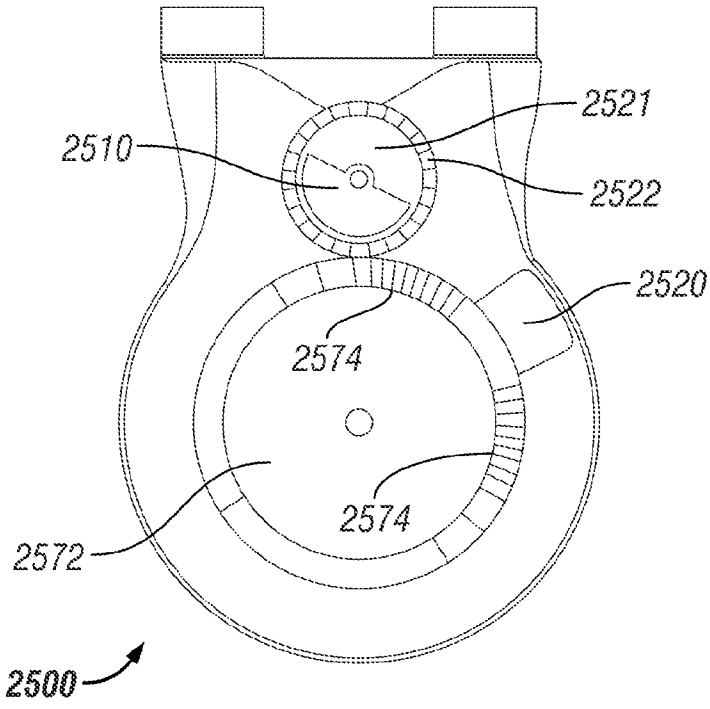


FIG. 106

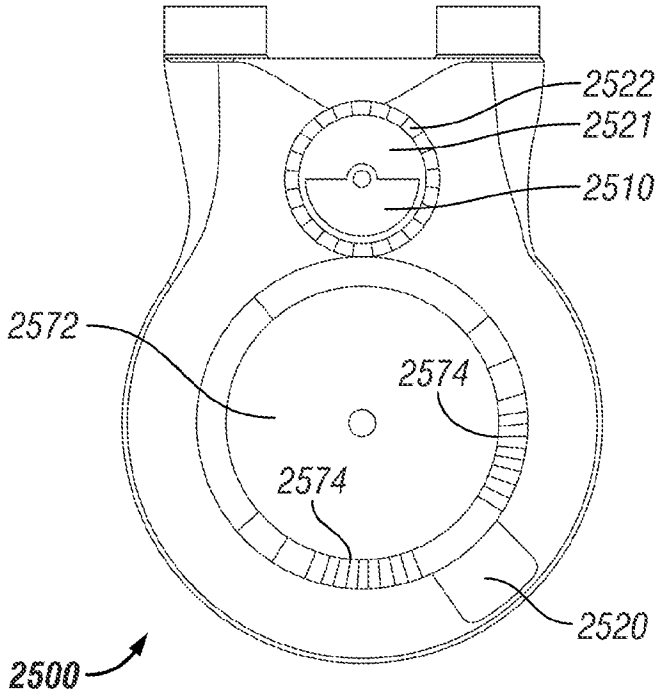


FIG. 107

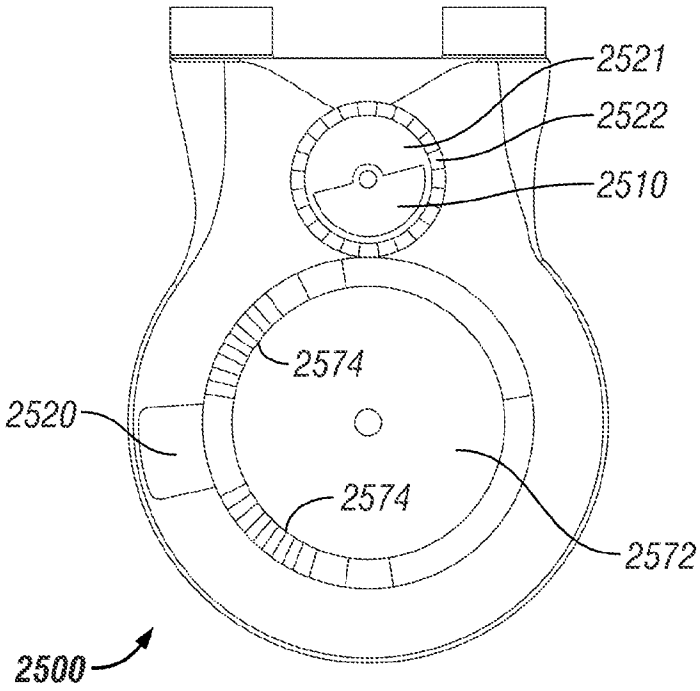


FIG. 108

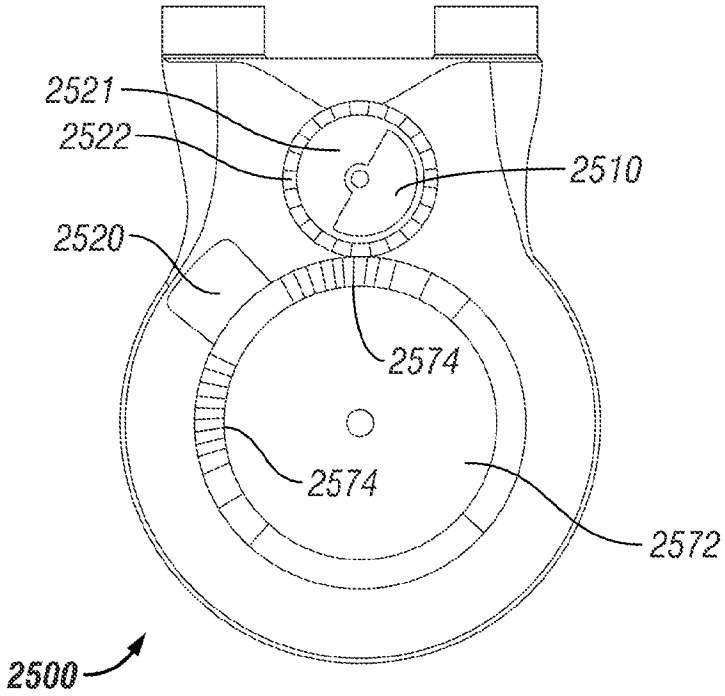
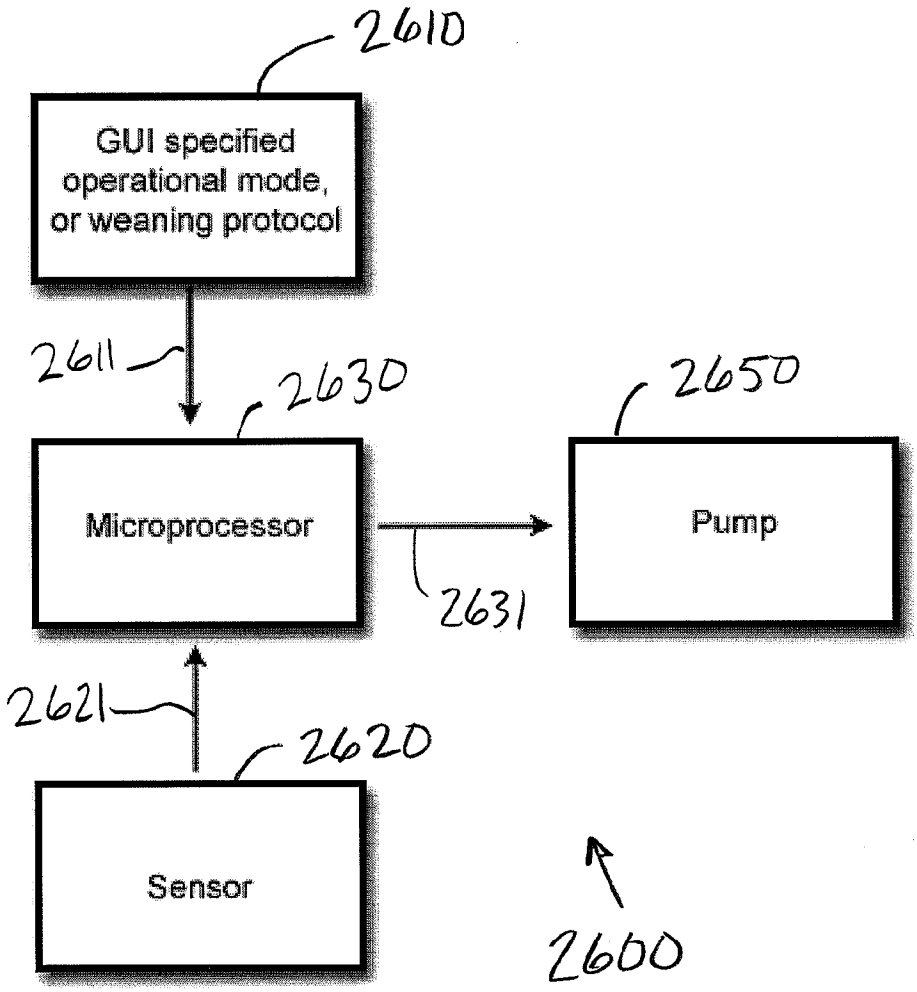
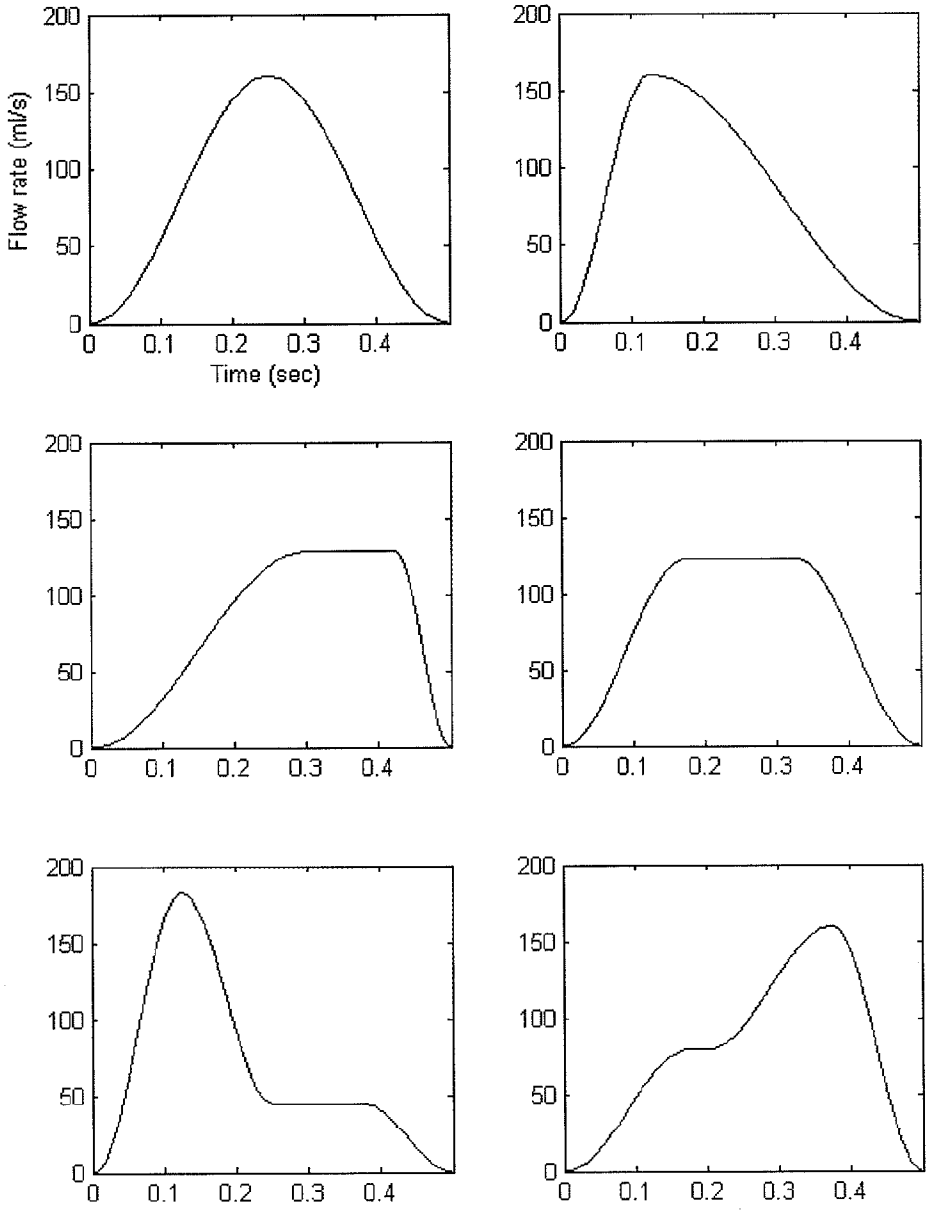


FIG. 109



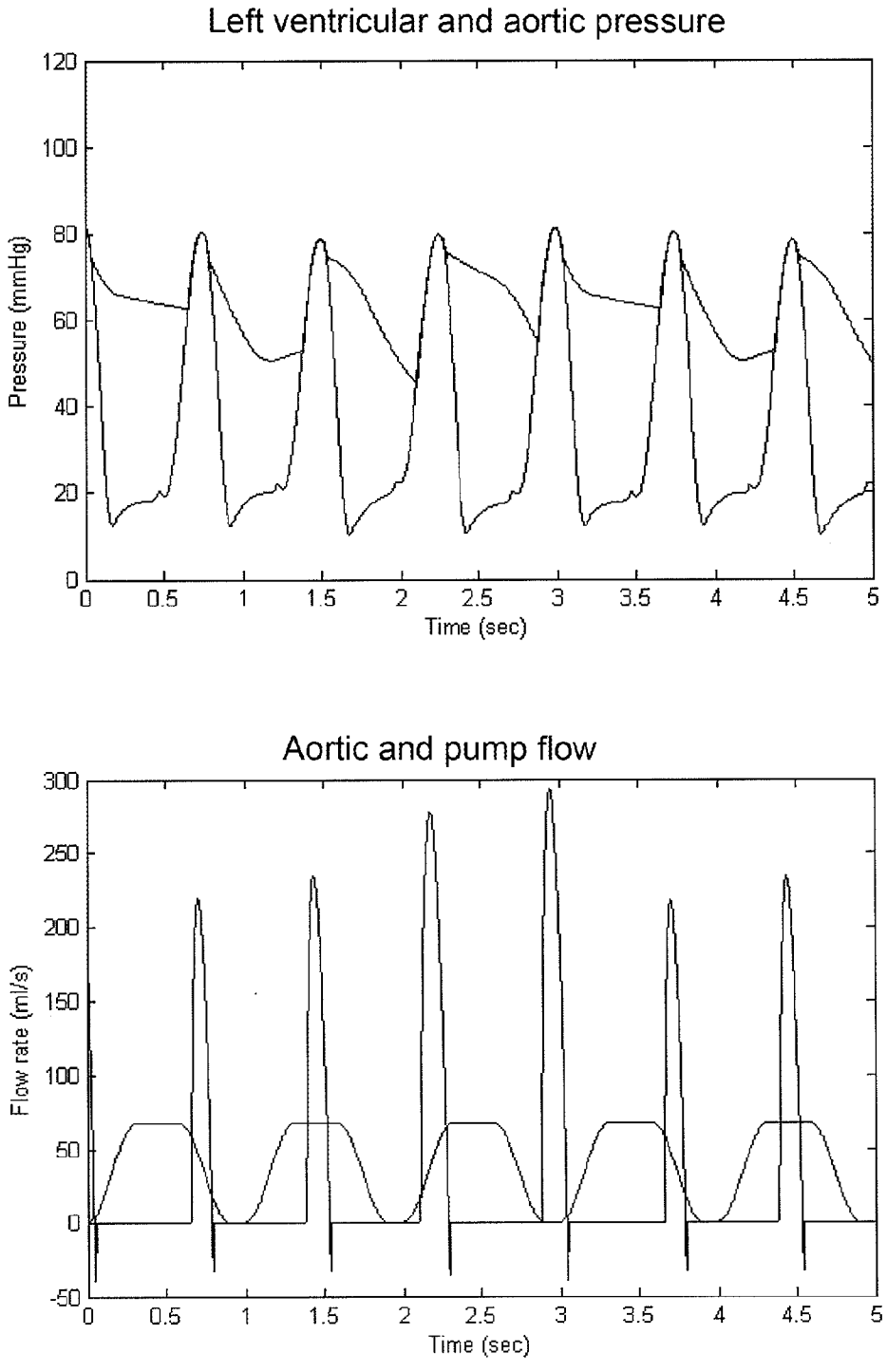
Block diagram of the control scheme

FIG. 110



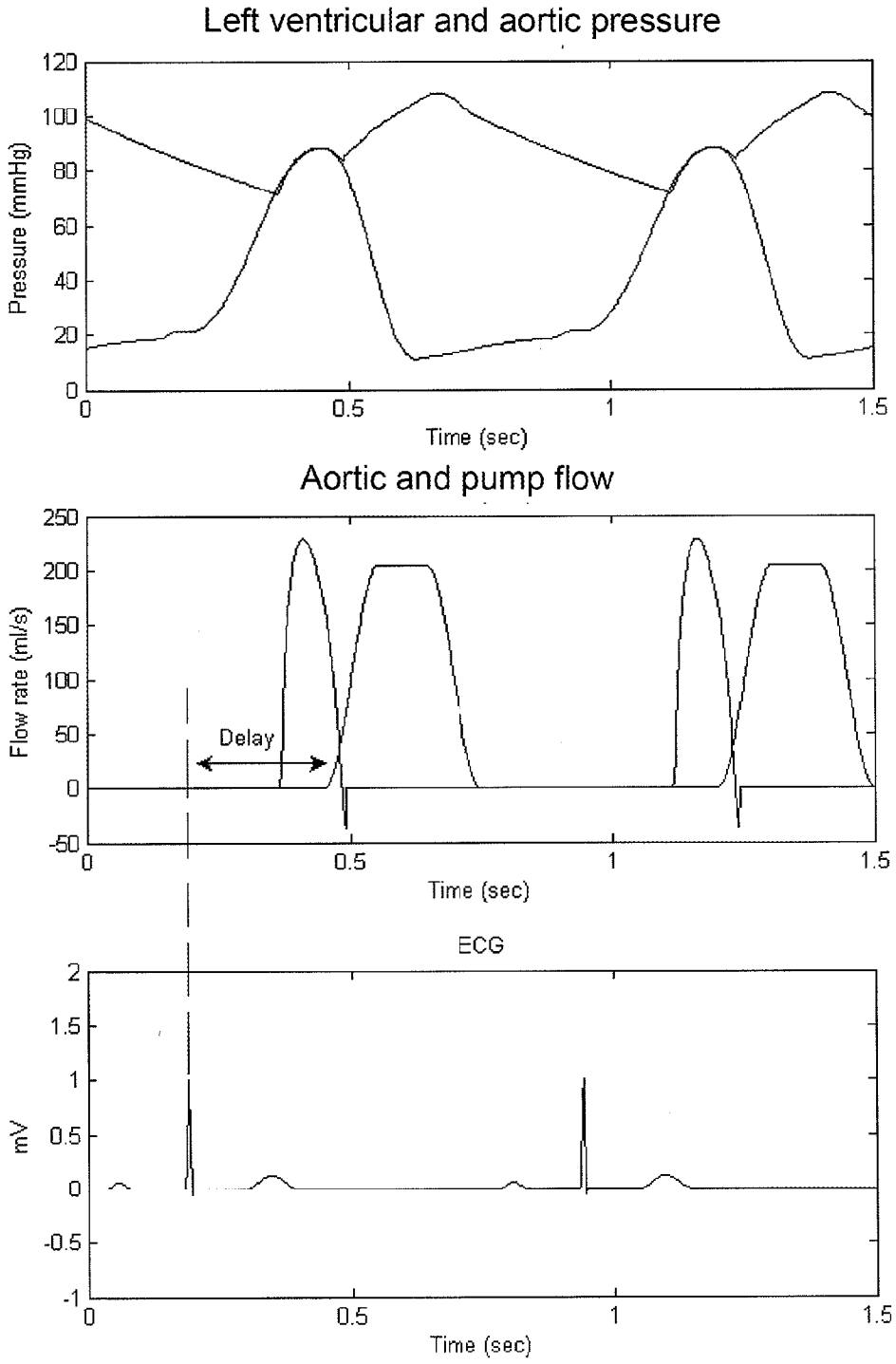
Demonstrates the variability in pump shape which is possible through position control piston through sample curves.

FIG. 111



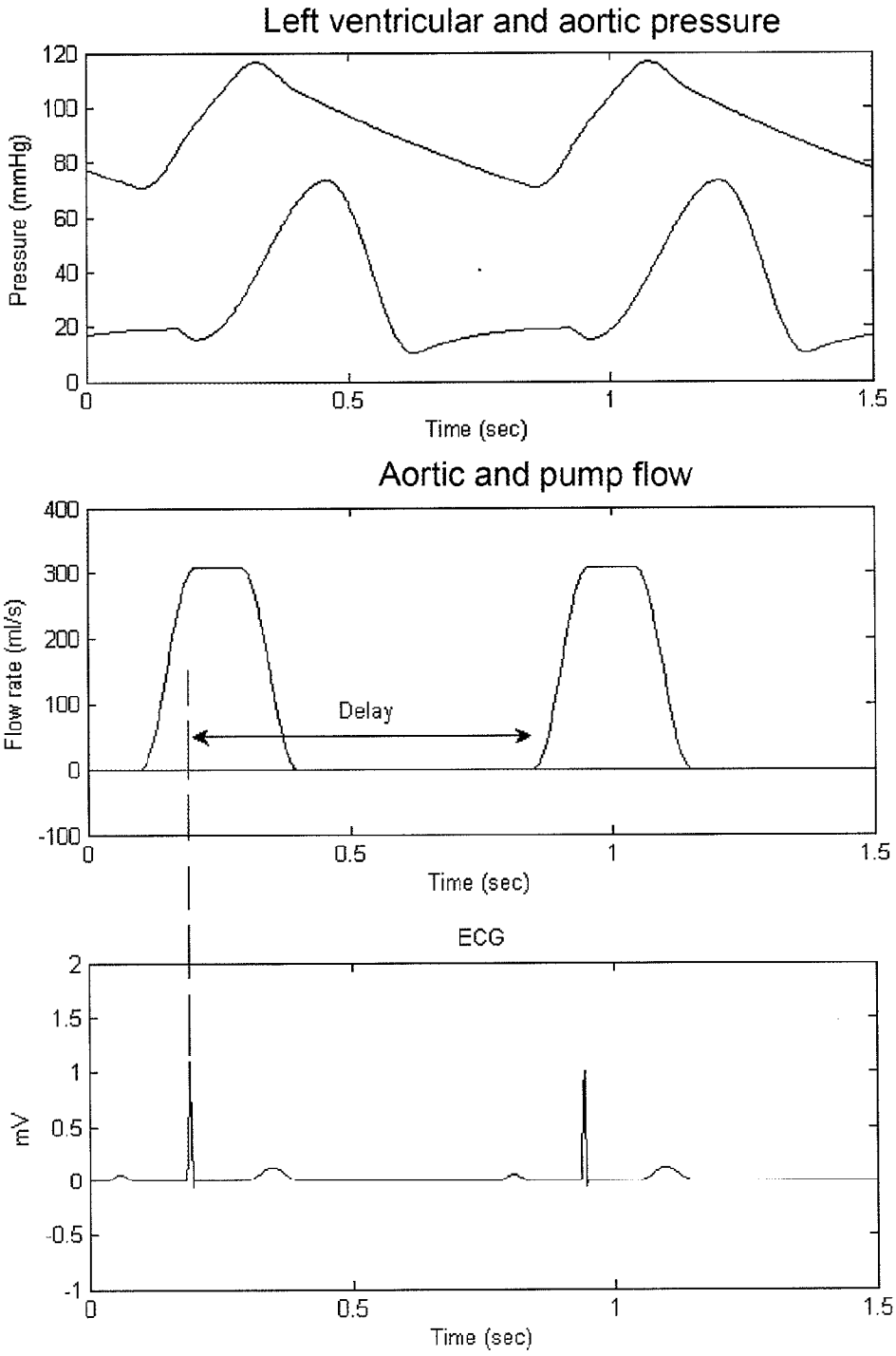
A computational example of asynchronous control of the pump

FIG. 112



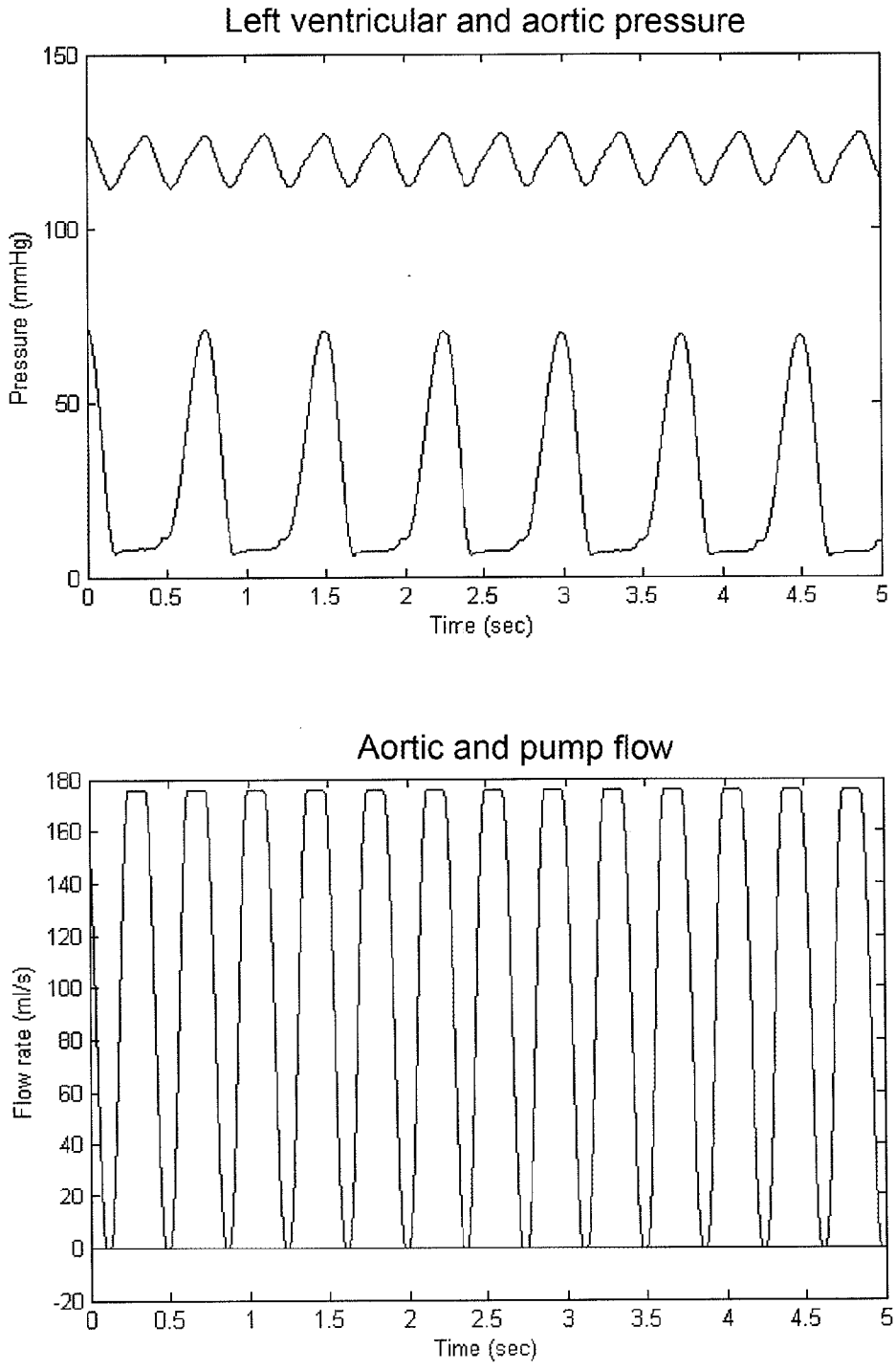
A computational example of synchronous control of the pump, where the pump stroke occurs during ventricular diastole.

FIG. 113



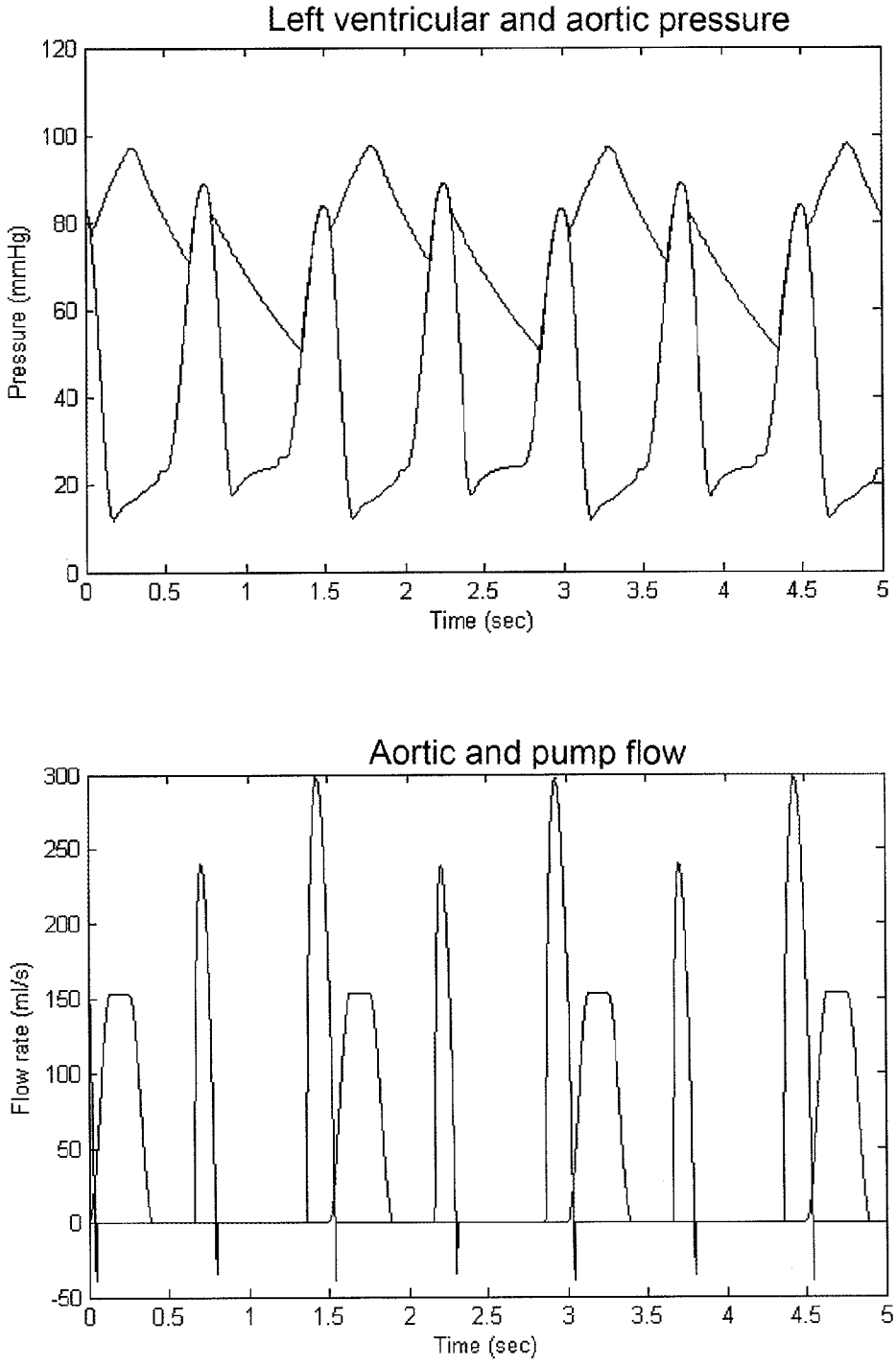
A computational example of synchronous control of the pump, where the pump stroke occurs during ventricular systole.

FIG. 114



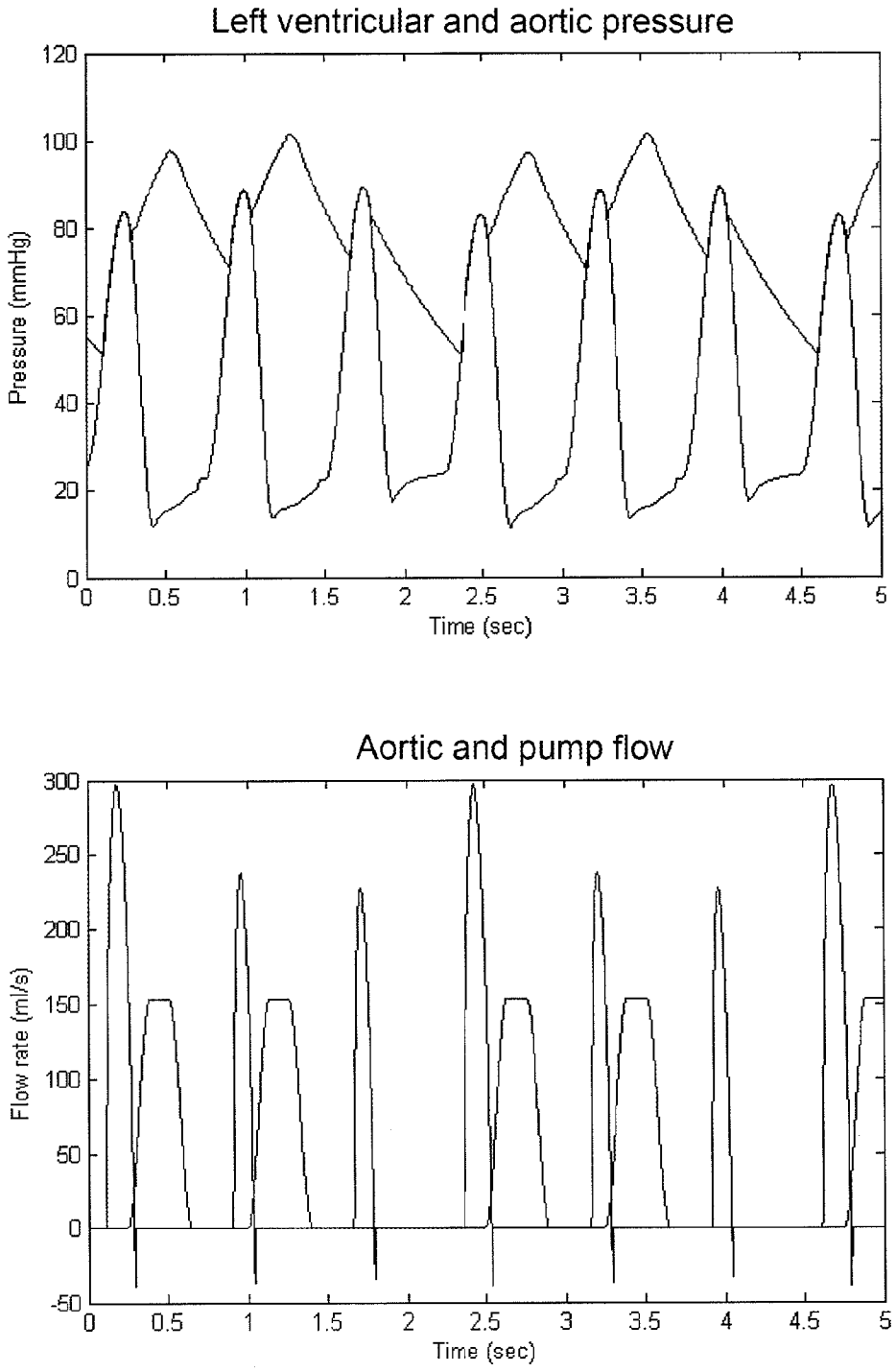
A computational example of synchronous control of the pump, where the pump stroke occurs twice during a single cardiac cycle.

FIG. 115



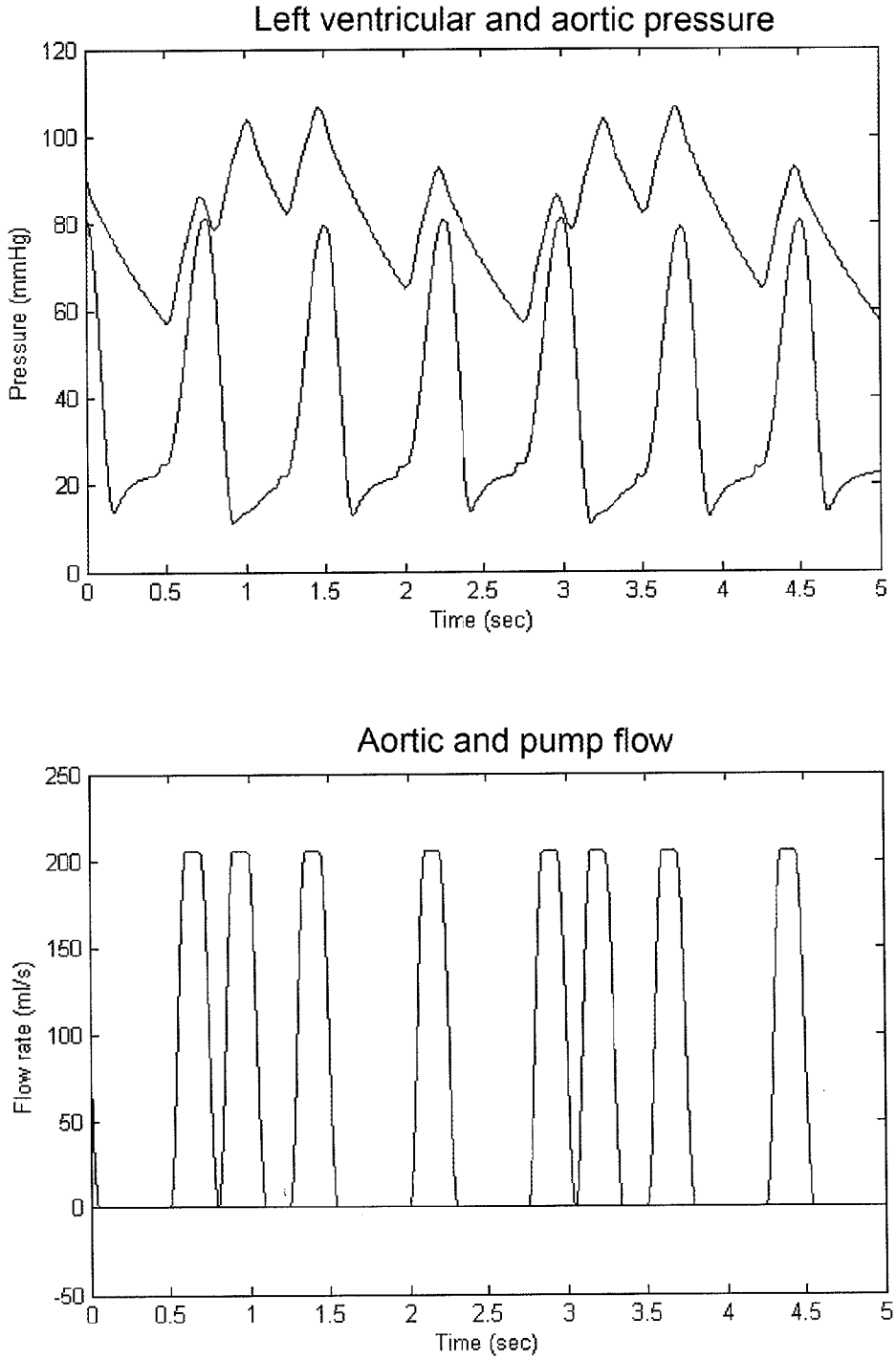
A computational example of synchronous control of the pump, where the pump stroke occurs once during ventricular disastole every other heart beat (1:2).

FIG. 116



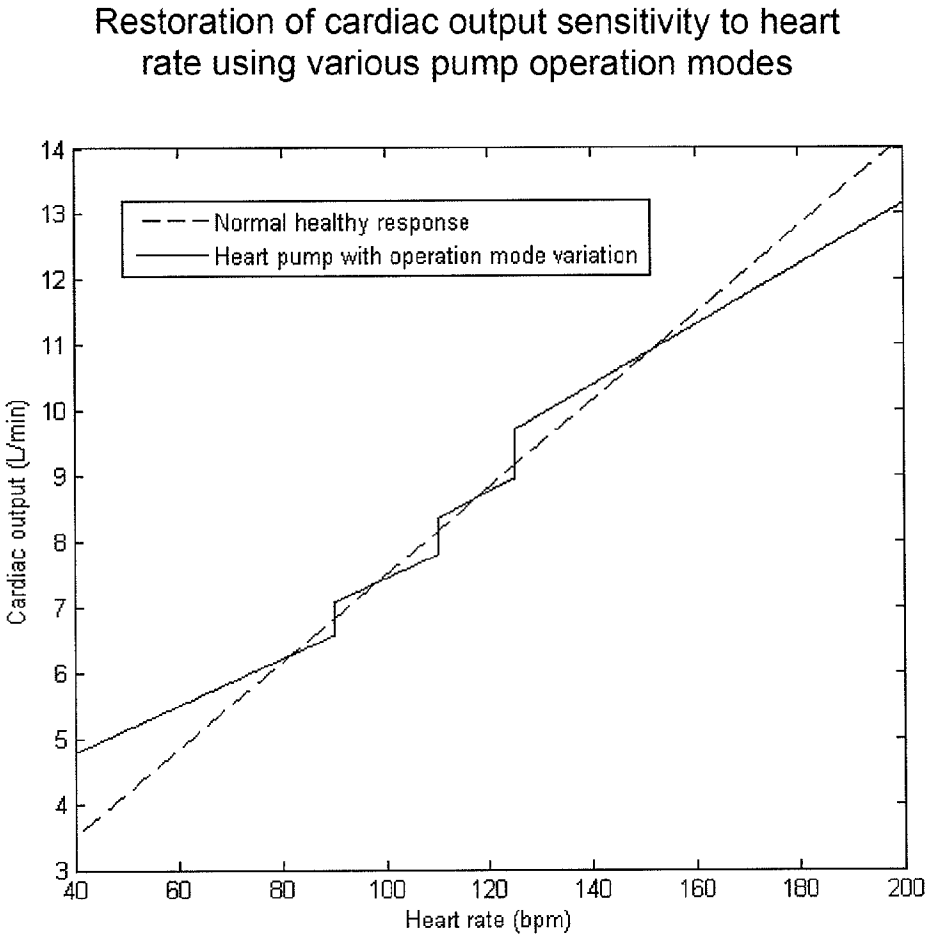
A computational example of synchronous control of the pump, where the pump stroke occurs once during ventricular diastole every other heart beat (2:3).

FIG. 117



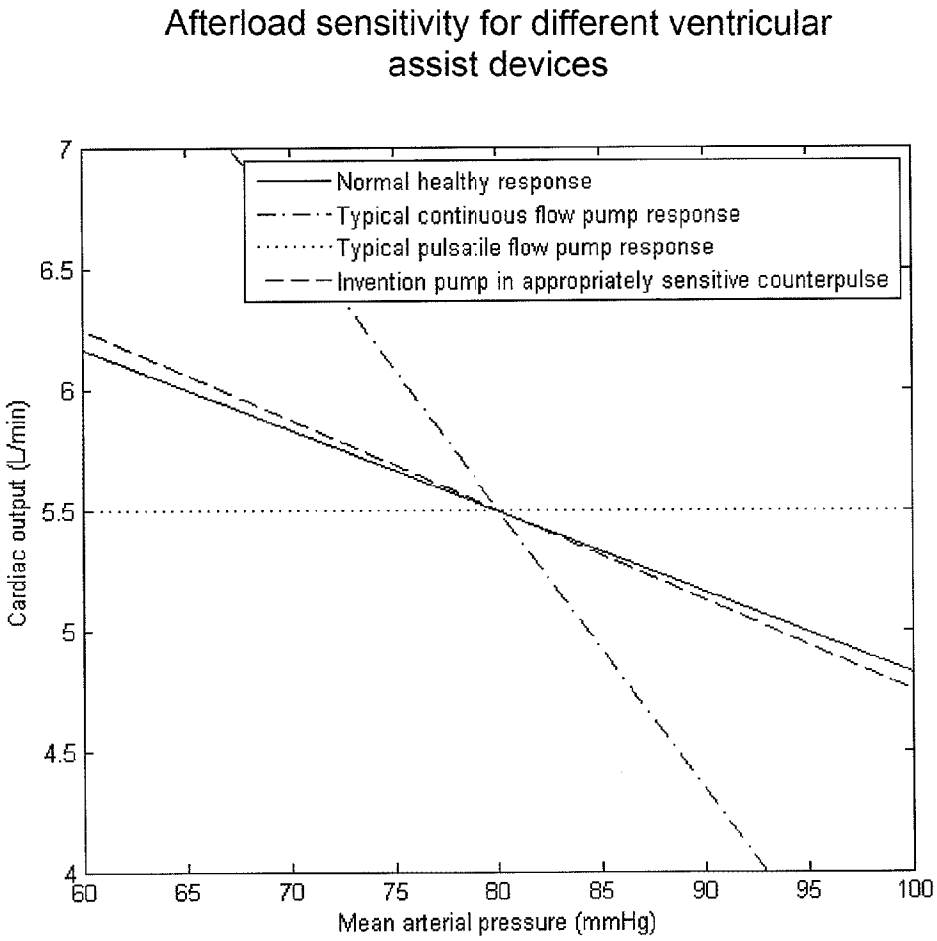
A computational example of synchronous control of the pump, where the pump stroke occurs once every two out of three heart beats and twice every one out of three beats.

FIG. 118



A computational example of the present embodiment's variational sensitivity to heart rate changes where different modes of operation are used at various heart rate intervals.

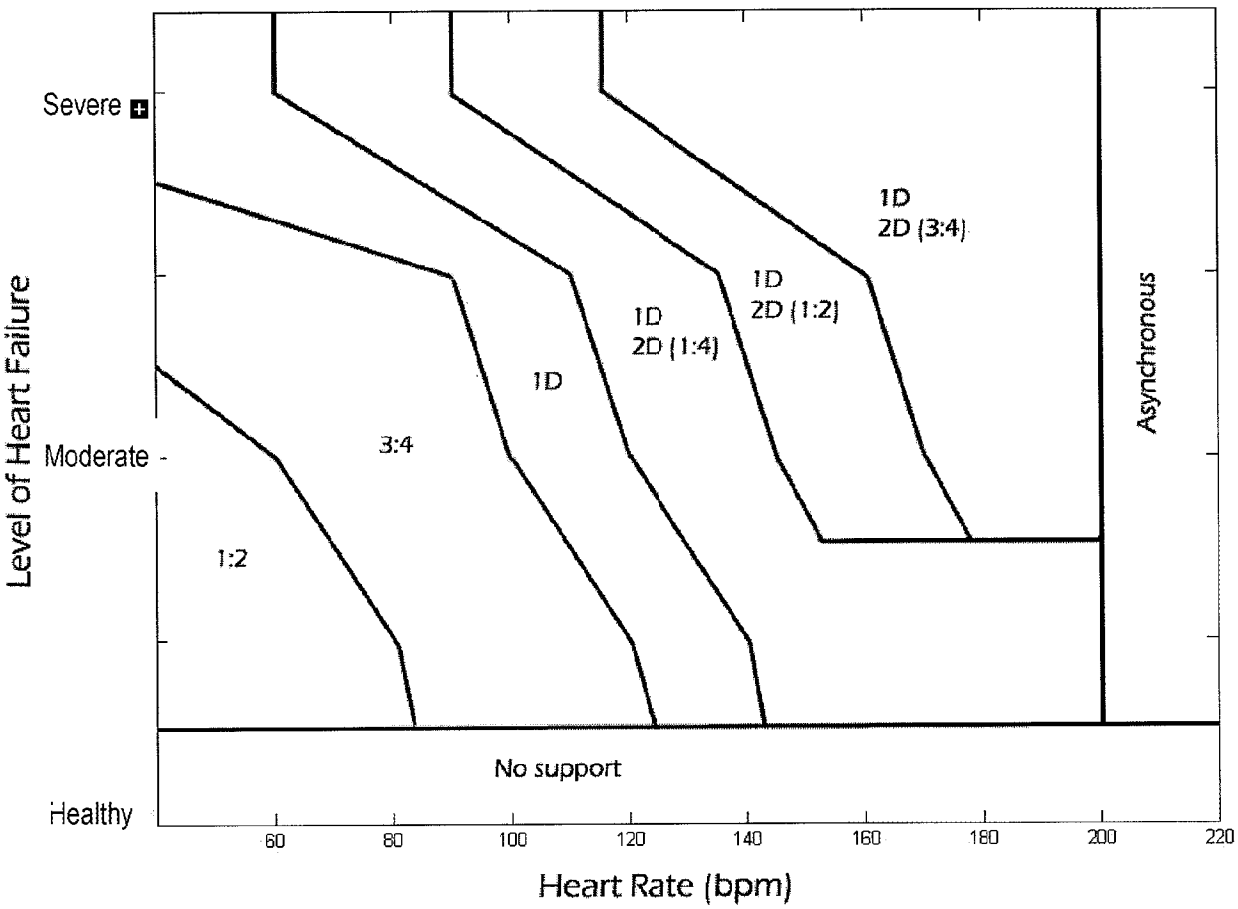
FIG. 119



A computational example of the present embodiment's variational sensitivity to ventricular afterload, or mean arterial pressure, as compared to typical continuous and pulsatile pumps.

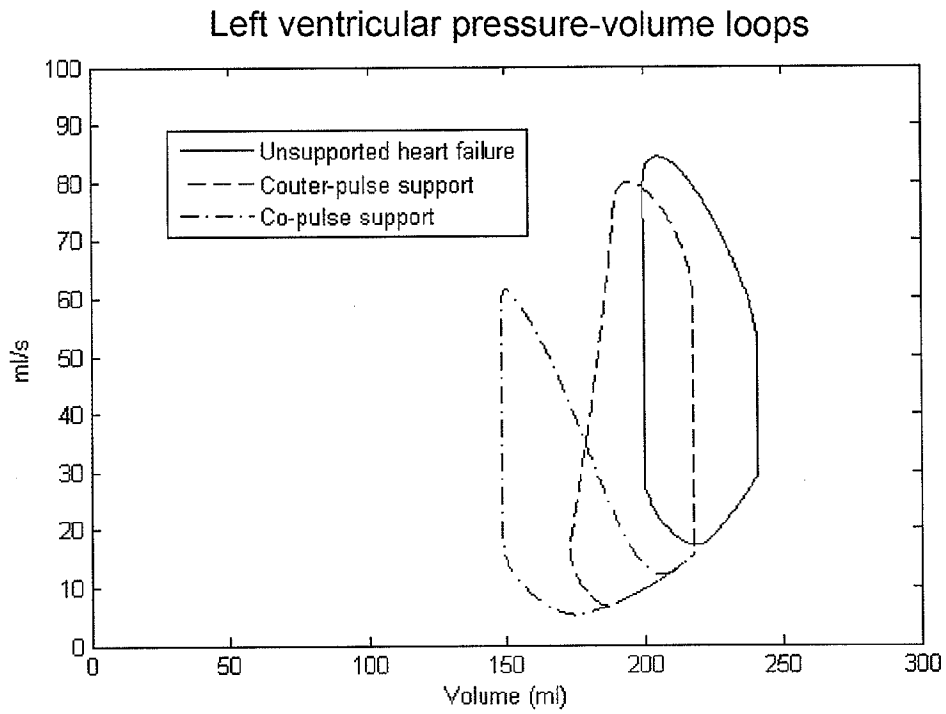
FIG. 120

Operation map for achieving normal cardiac output response to HR
Stroke volume - 40 ml
1 D is a diastolic pulse
3:4 is 3 VAD strokes (in diastole) for every 4 heart beats
1D, 2D (1:4) is two strokes during a single diastole every 4 heart beats, and 1D otherwise



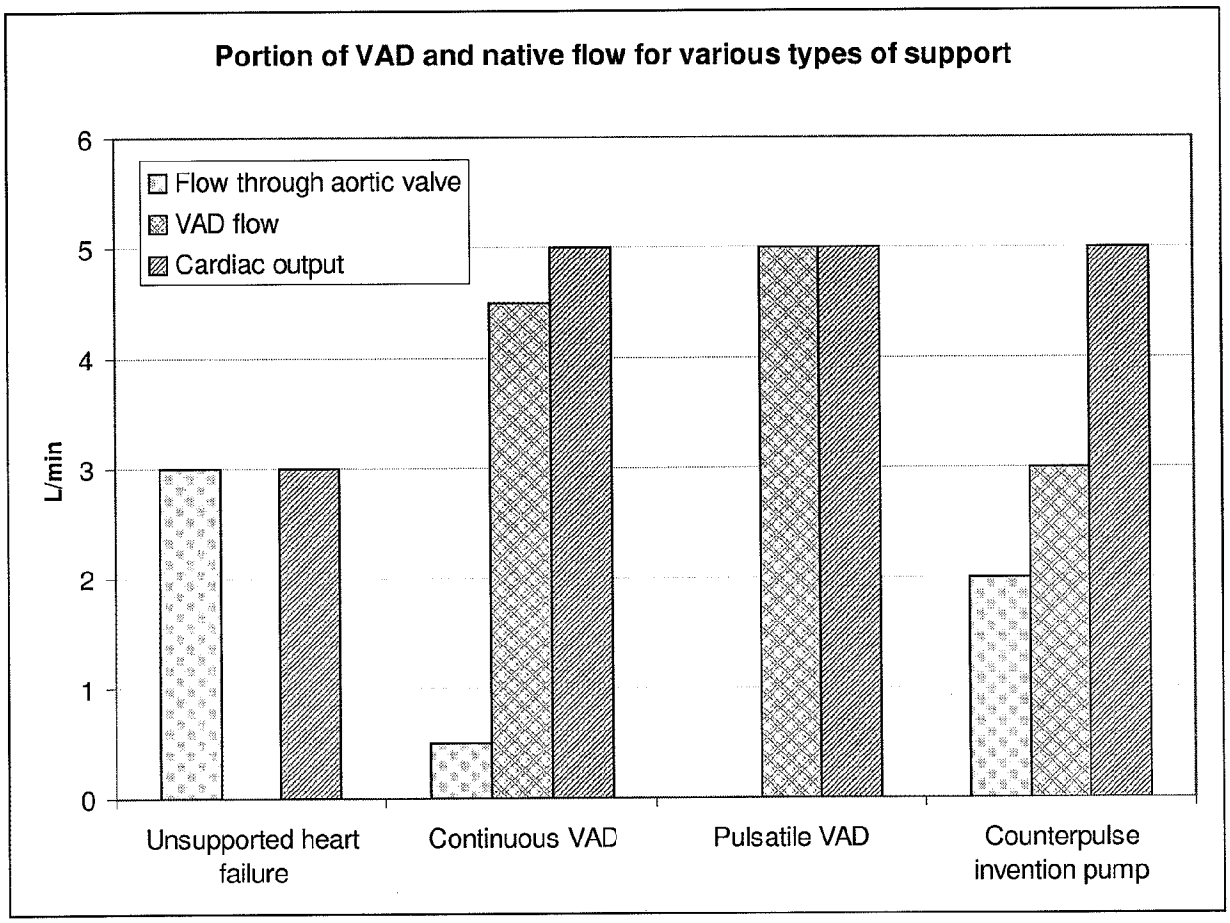
Example of a potential operational map which takes heart failure severity and heart rate as inputs and changes the operational mode accordingly in order to maintain sufficient cardiac output.

FIG. 121



Simulated and predicted pressure volume loops (which correspond to myocardial oxygen consumption) for heart failure, counter-pulse VAD support, and co-pulse VAD support. Both modes reduce left ventricular end diastolic volume (LVEDV). Co-pulse greatly reduces myocardial oxygen consumption (MVO_2)

FIG. 122



Computational predictions of the percent of support required to produce healthy cardiac output of 5L/min in severe heart failure with various types of support. Counterpulsation of the invention pump allows for more flow through the aortic valve. Because this flow is a significant portion of the cardiac output, it is appropriately sensitive to preload and afterload variation, and has the potential to restore the cardiac output response to the body's natural feedback control mechanisms.

FIG. 123

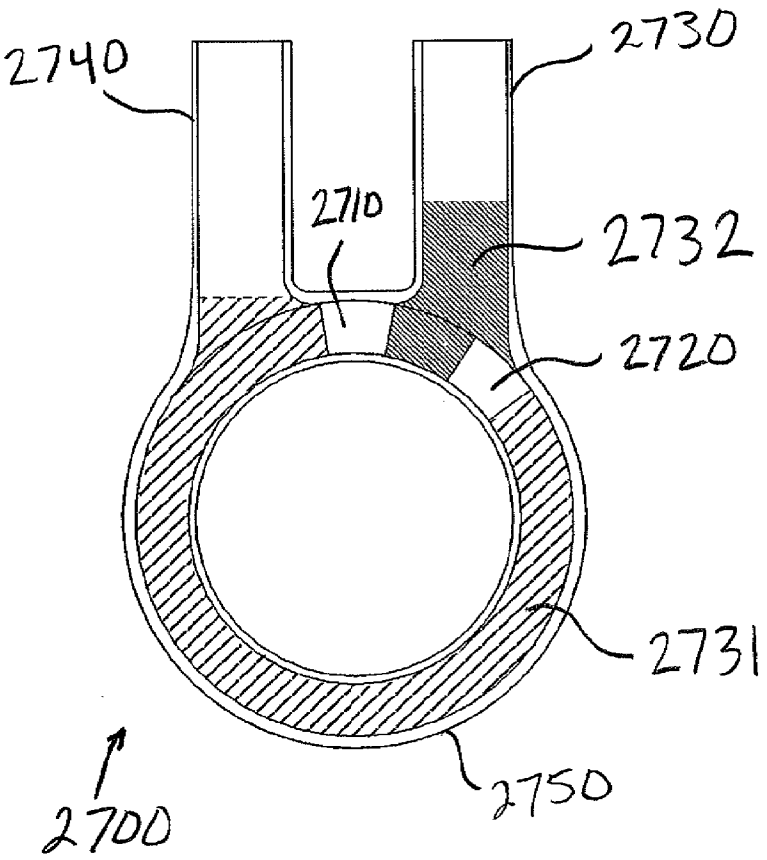


FIG. 124

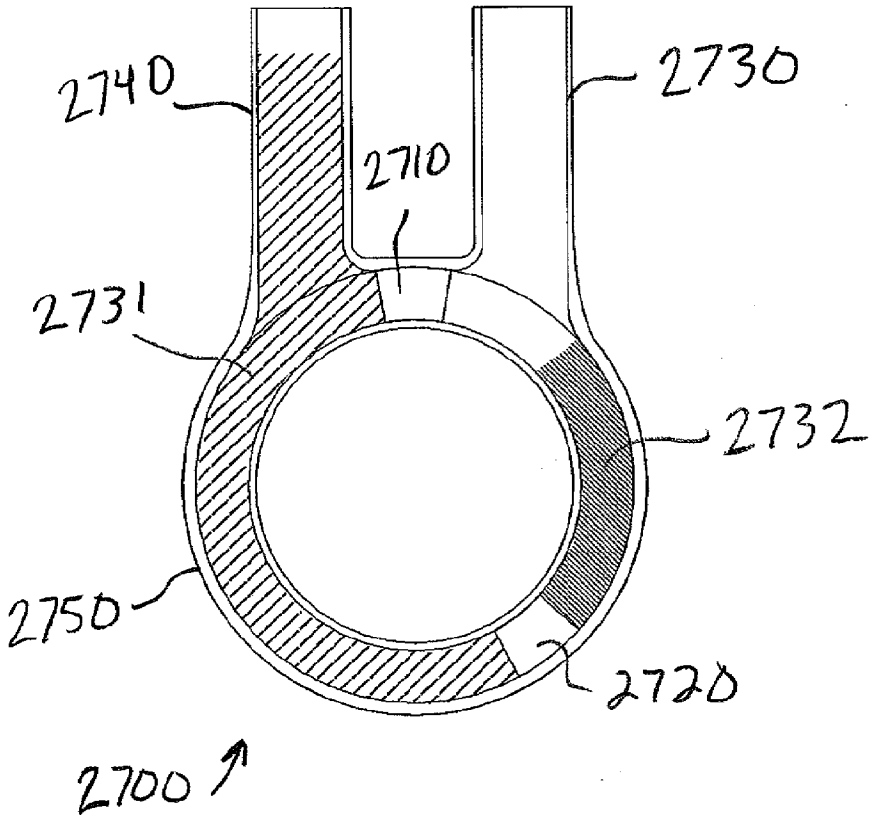


FIG.125

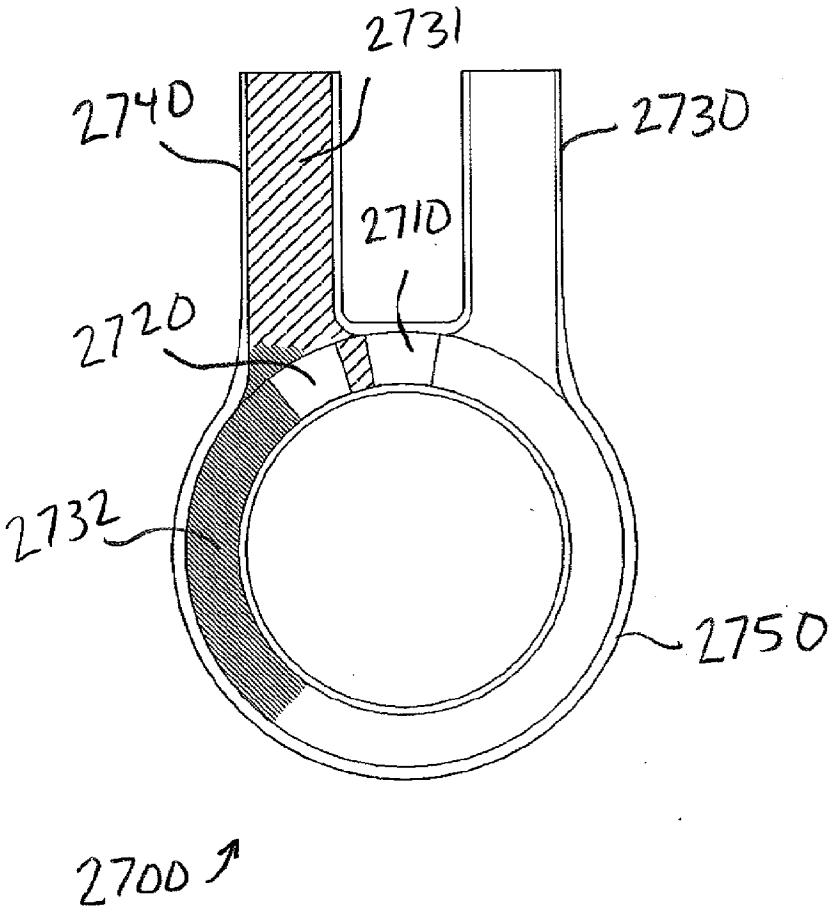


FIG. 126

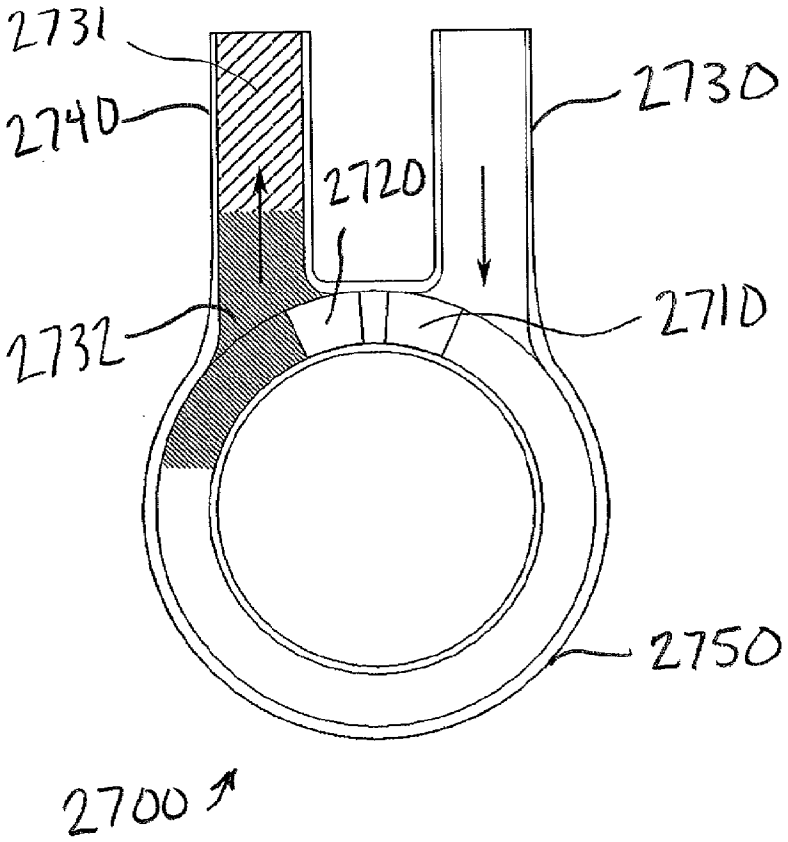


FIG. 127

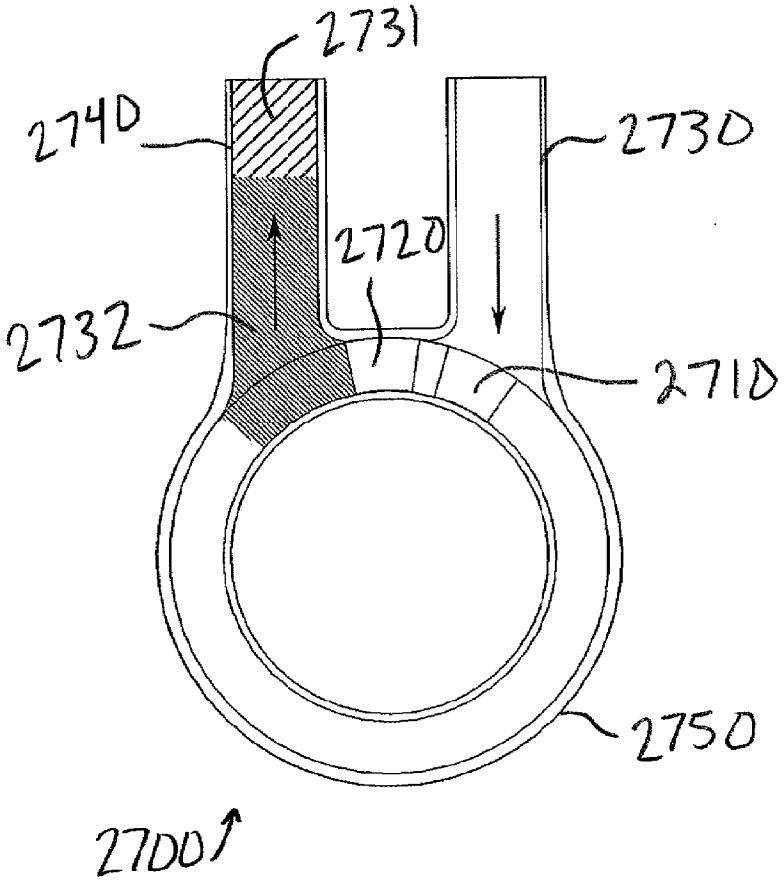


FIG. 128

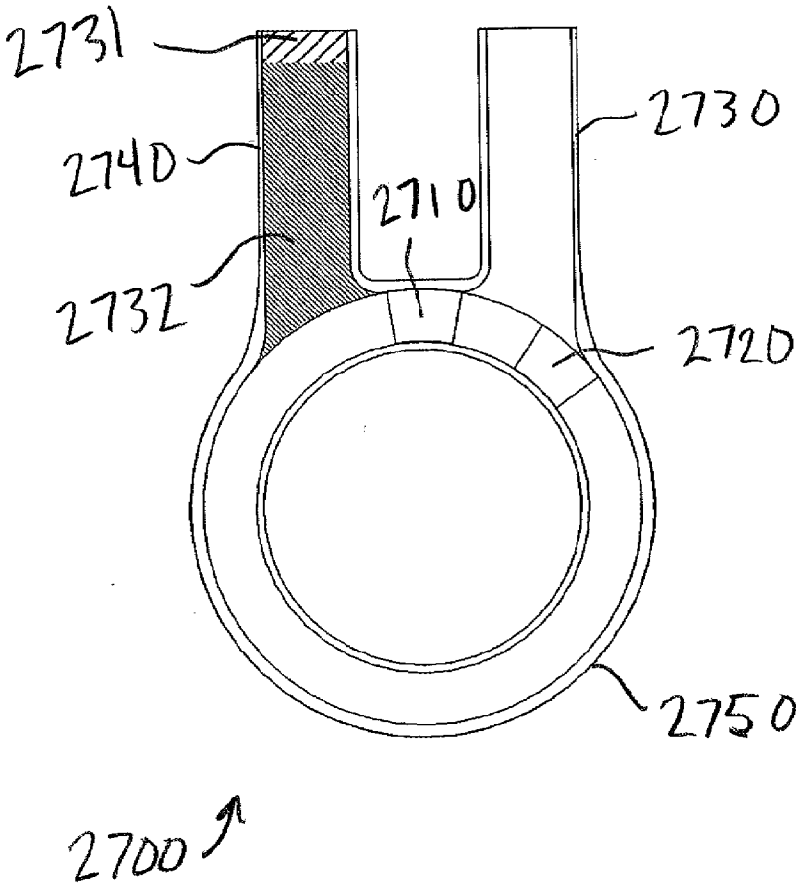


FIG. 129

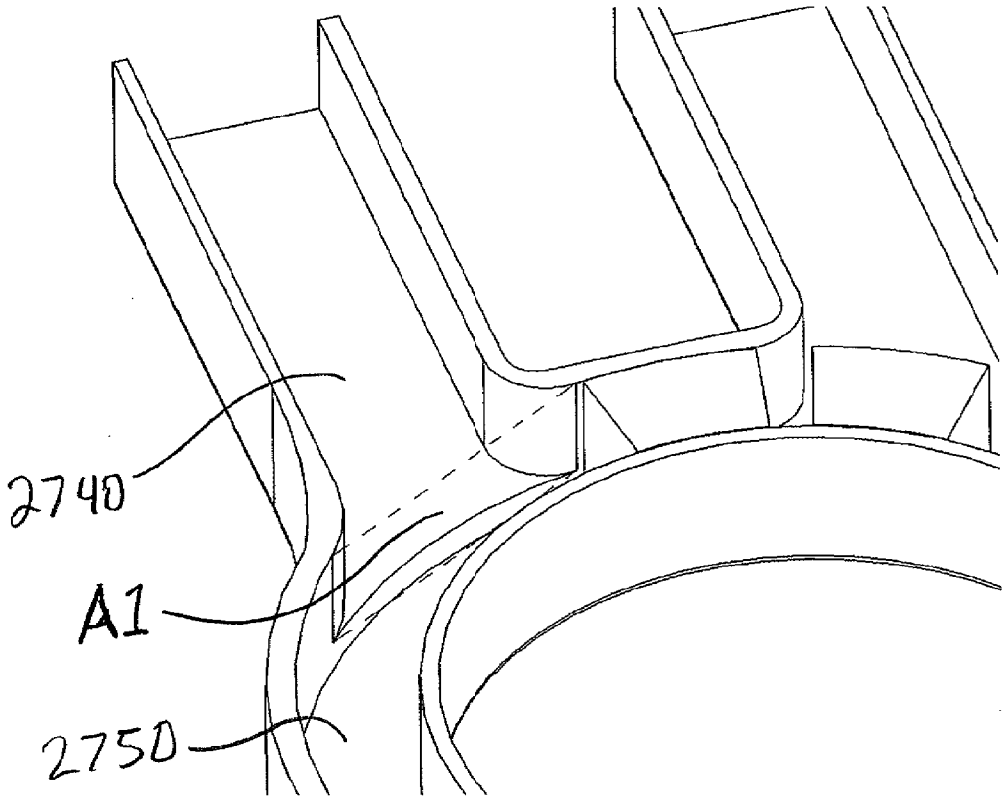


FIG. 130

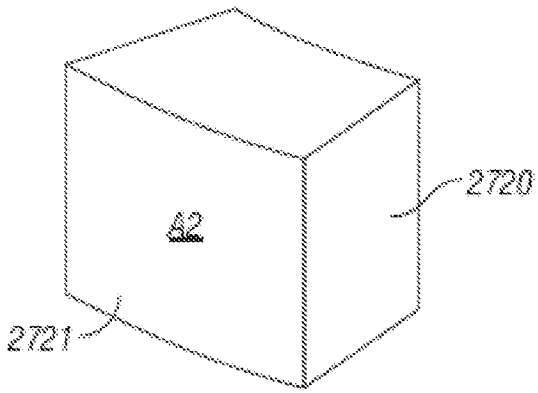


FIG. 131

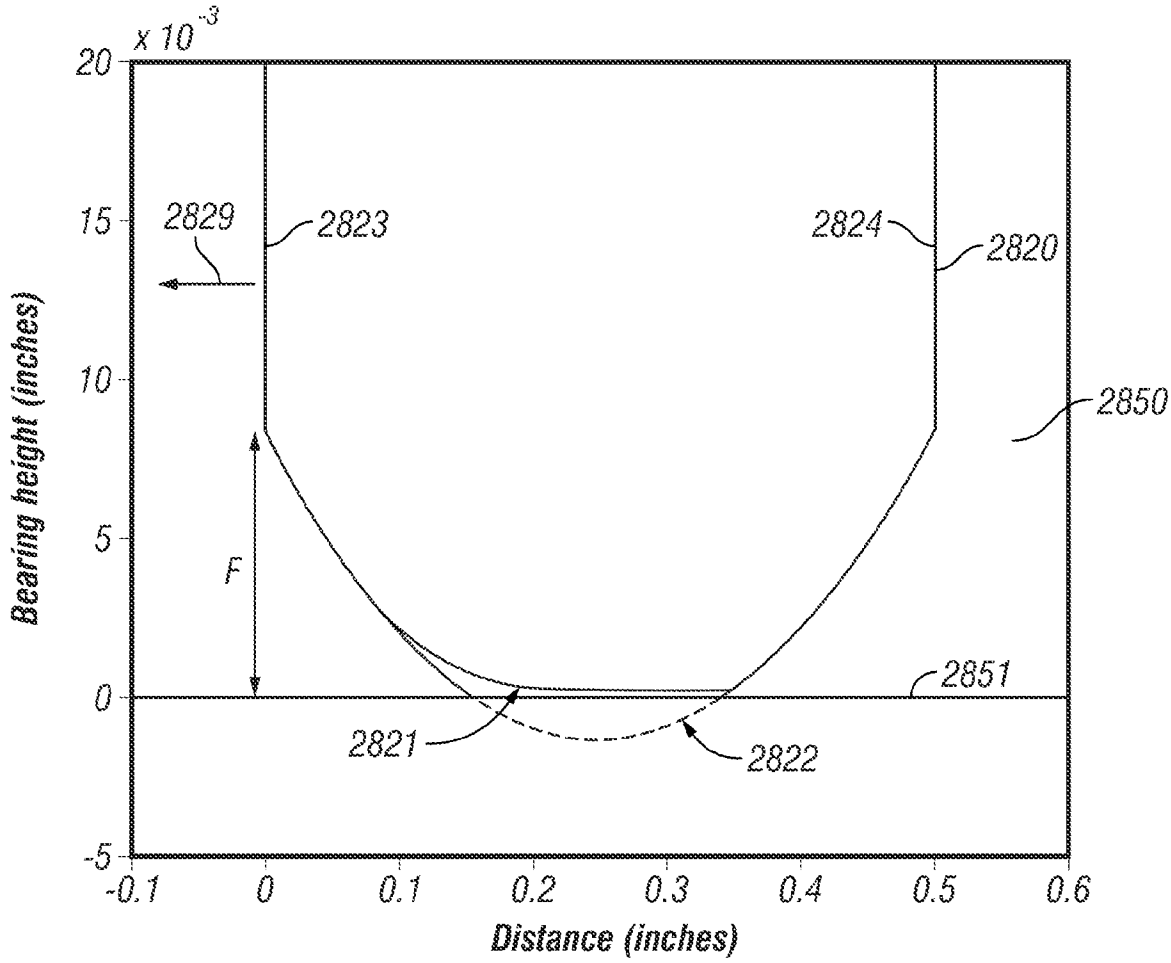


FIG. 132

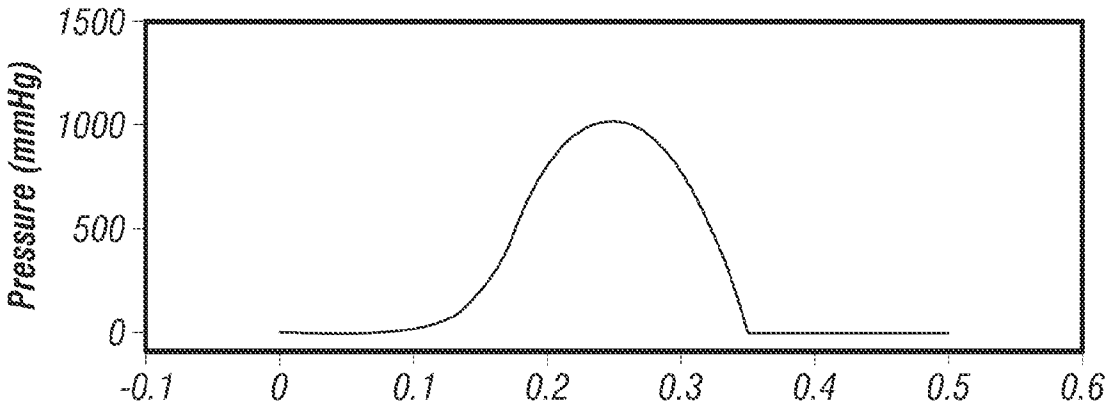


FIG. 133

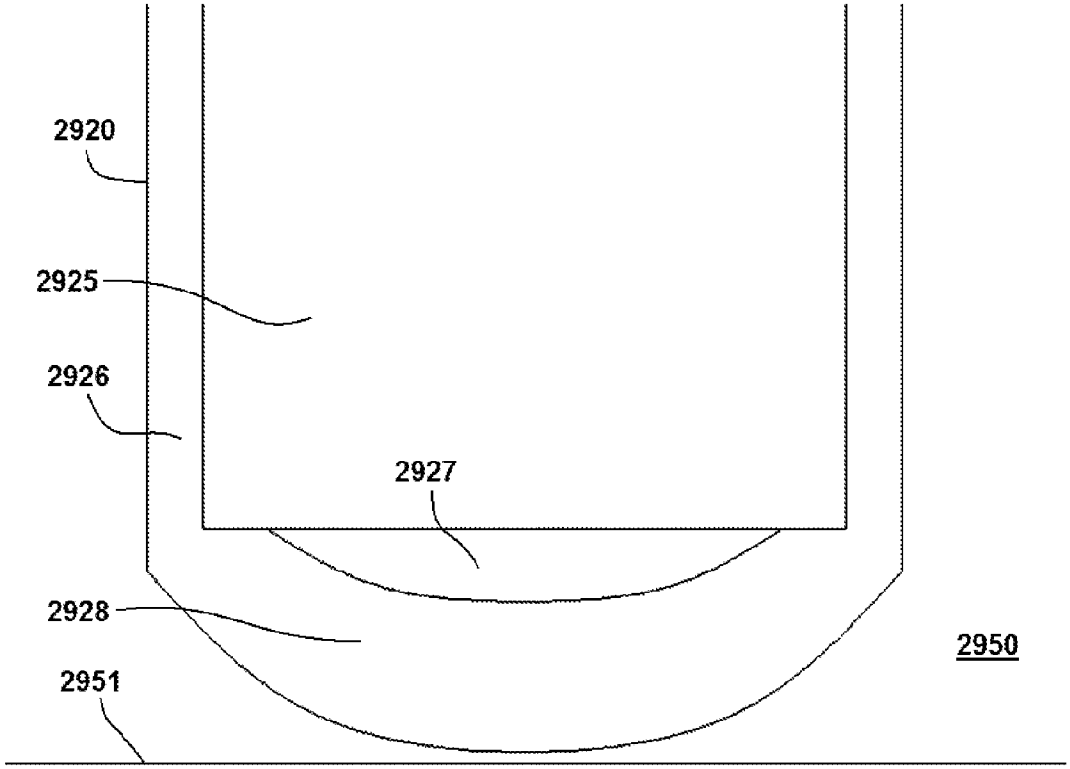


FIG. 134

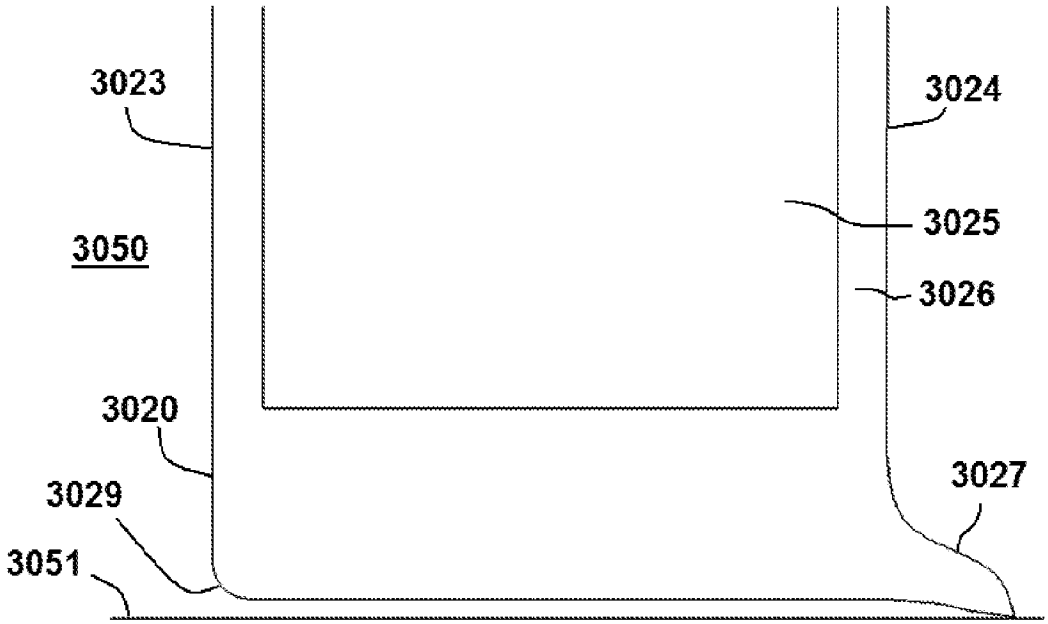


FIG. 135

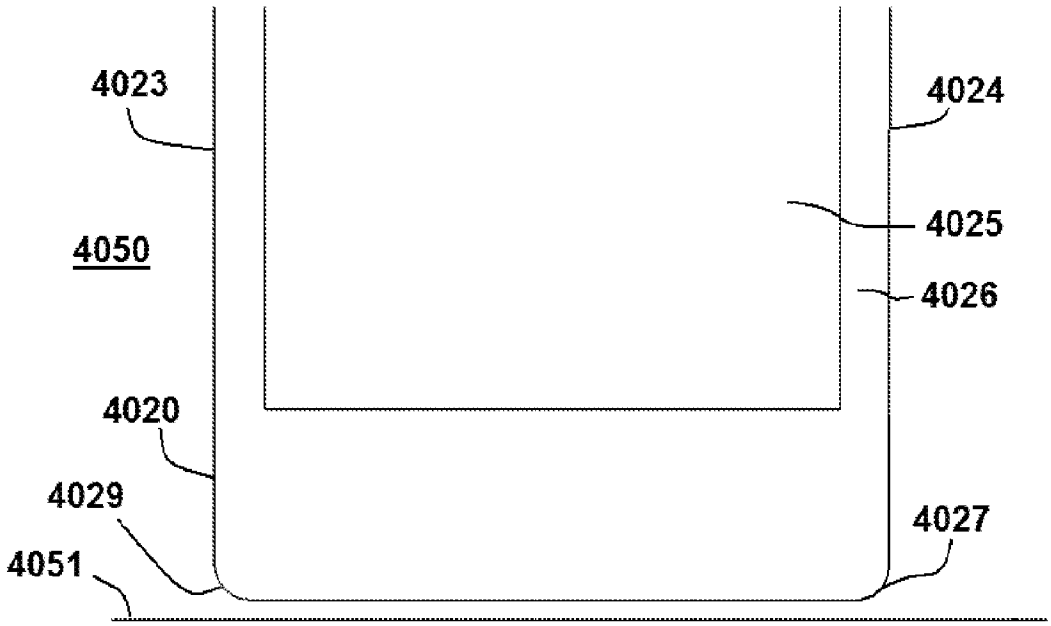


FIG. 136