

[54] **IMPLANTABLE HEART PUMP**

[75] Inventor: **Paul Knight Davis**, Alameda, Calif.

[73] Assignee: **Pacific Roller Die Co., Inc.**,
Hayward, Calif.

[22] Filed: **Nov. 19, 1974**

[21] Appl. No.: **525,131**

Related U.S. Application Data

[63] Continuation of Ser. No. 312,668, Dec. 6, 1972, abandoned.

[52] U.S. Cl. 3/1.7; 128/2.05 F; 417/389;
417/395

[51] Int. Cl.² **A61F 1/24**

[58] Field of Search 3/1.7, 1; 128/1 D, DIG. 3,
128/214 R; 417/389, 394, 395

[56] **References Cited**

UNITED STATES PATENTS

3,182,335	5/1965	Bolie	3/1.7
3,541,612	11/1970	Carney	3/1.7
3,568,214	3/1971	Goldschmied	3/1.7
3,633,217	1/1972	Lance	3/1.7
3,783,453	1/1974	Bolie	3/1.7

OTHER PUBLICATIONS

"Artificial Intracorporal Heart," by F. W. Hastings et al., Transactions A.S.A.I.O., Vol. 7, 1961, pp. 323-325.

"A Servomechanism to Drive an Artificial Heart Inside the Chest," by K. W. Hiller et al., Transactions, A.S.A.I.O., Vol. 8, 1962, pp. 125-130.

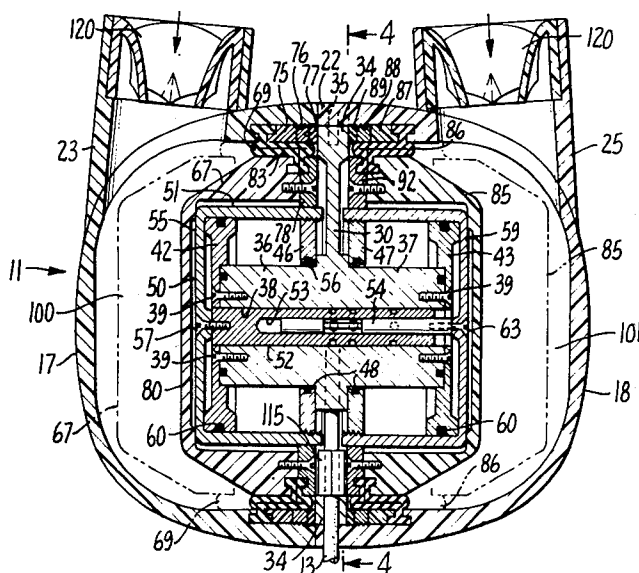
Primary Examiner—Ronald L. Frinks

[57]

ABSTRACT

An implantable Starling-type heart pump which may be adapted for use as a total artificial heart, or as a single ventricle device replacing one side of the heart. A rigid case, mounting blood input and output valves, houses a variable displacement piston pump. A separate spool-type pump control valve assembly directs motive force from a power source which may be gas or other fluid pressure, electro-mechanical or heat energy conversion for alternately initiating piston retraction and extension upon receipt of a signal pulse from the piston pump itself. Blood chamber displacement is a function of pressure and available blood volume.

18 Claims, 24 Drawing Figures



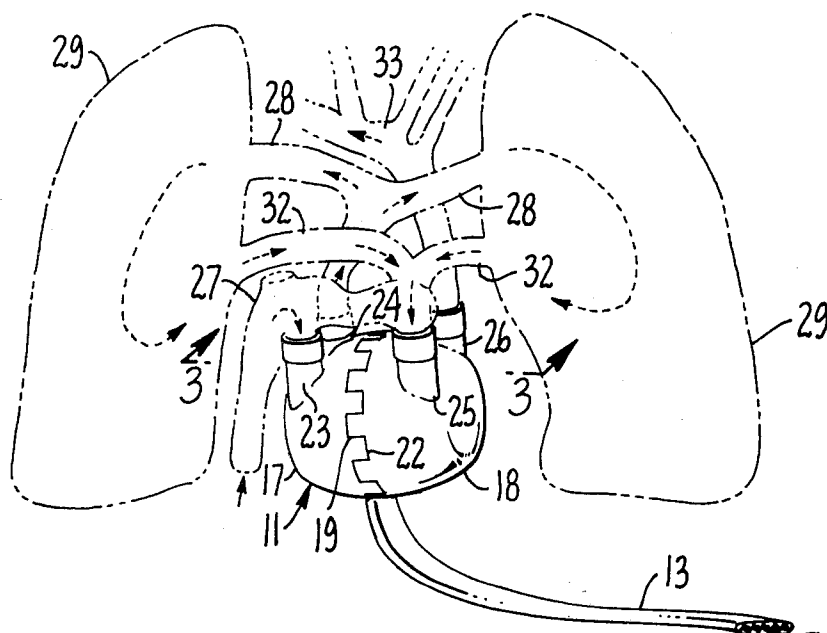


FIG. 1.

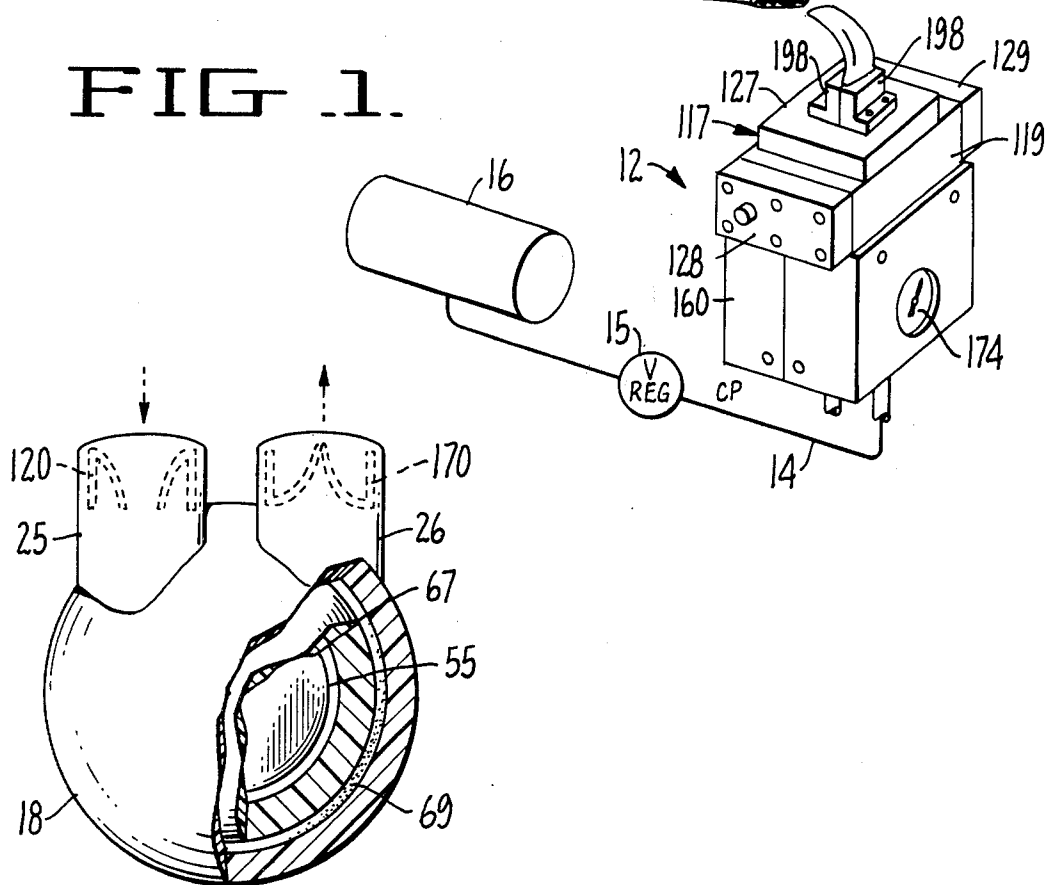
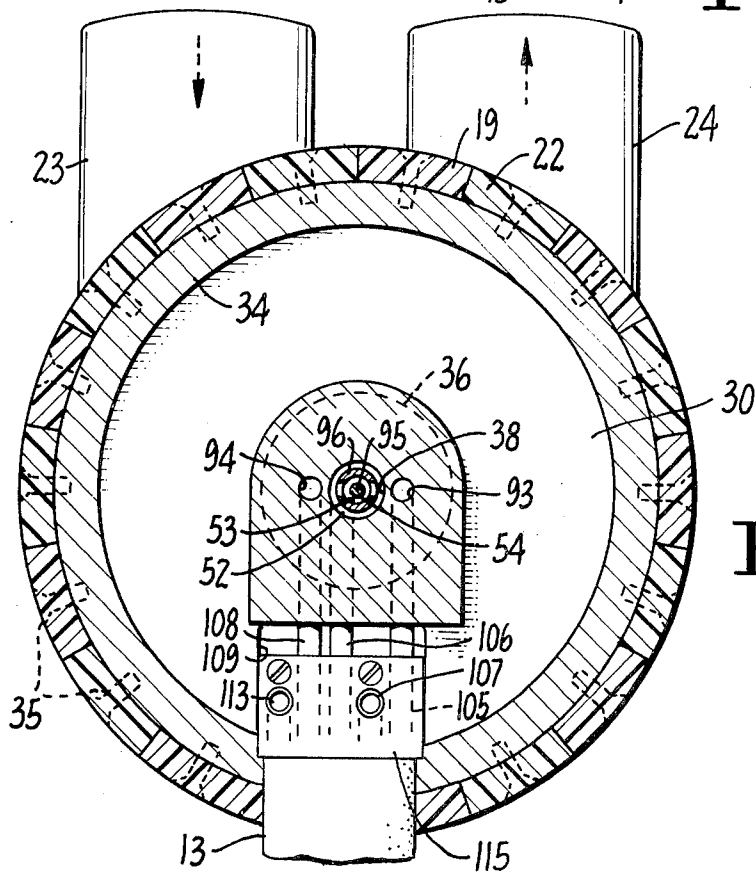
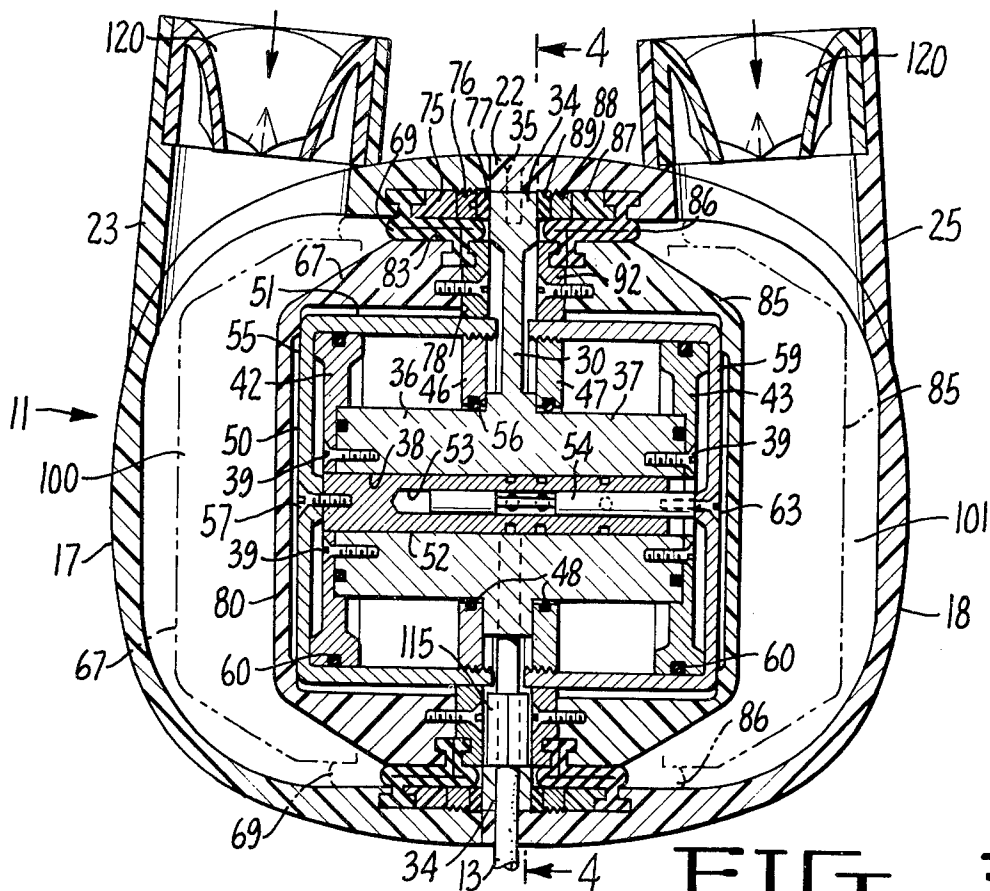


FIG. 2.



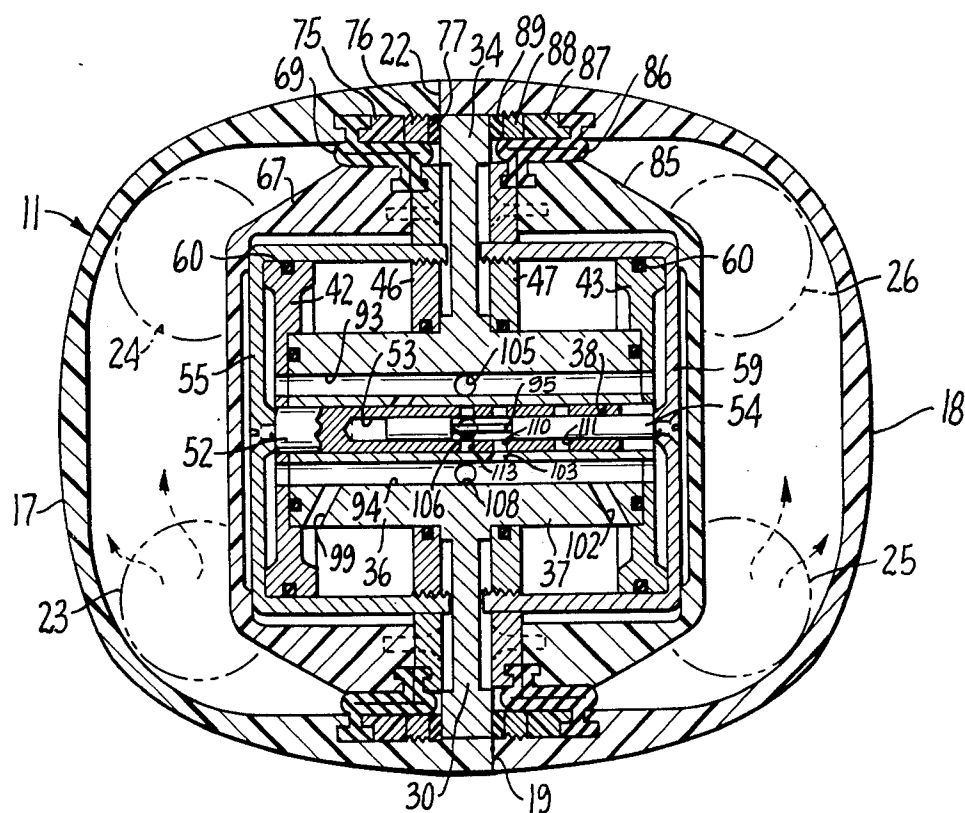


FIG. 5.

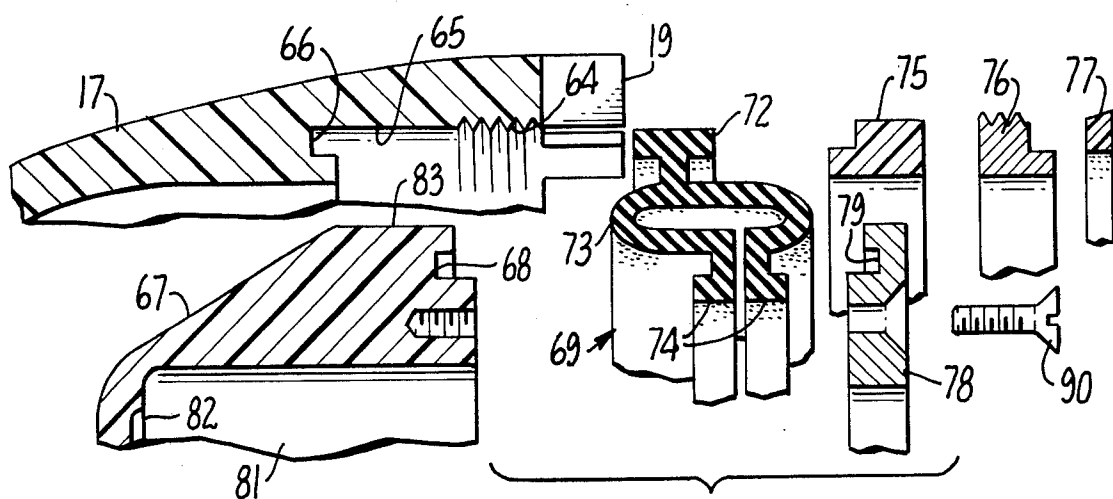


FIG. 6.

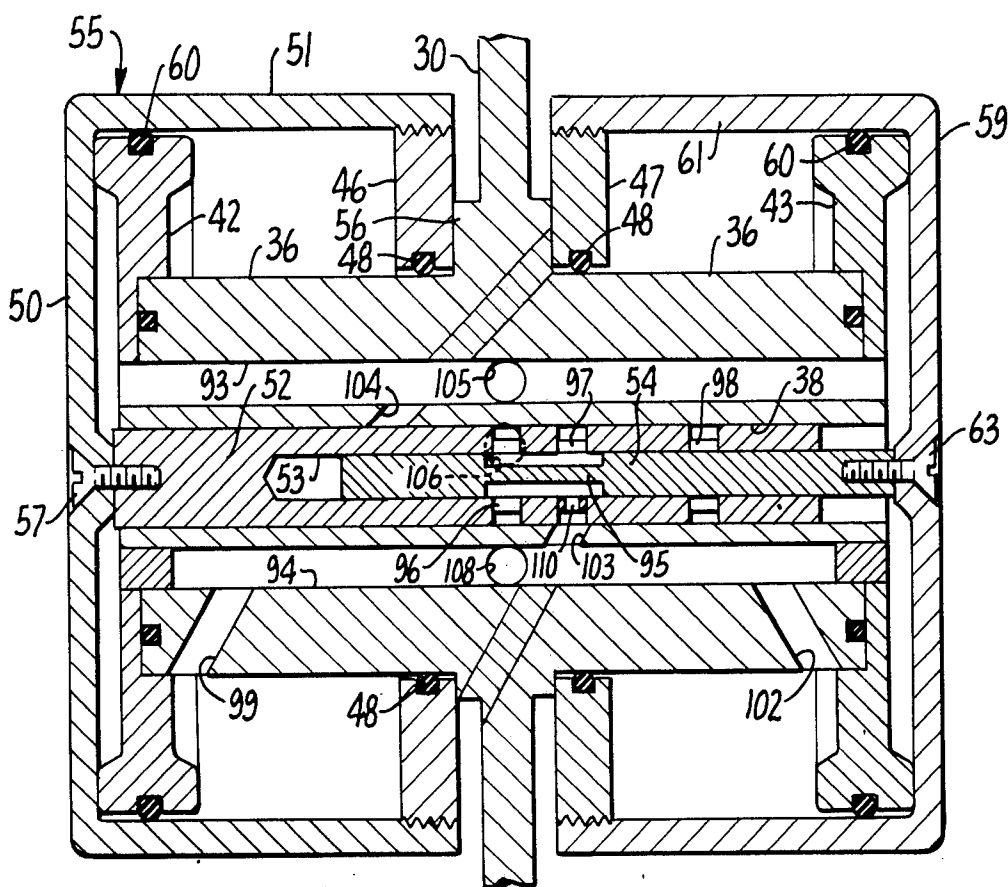


FIG. 7.

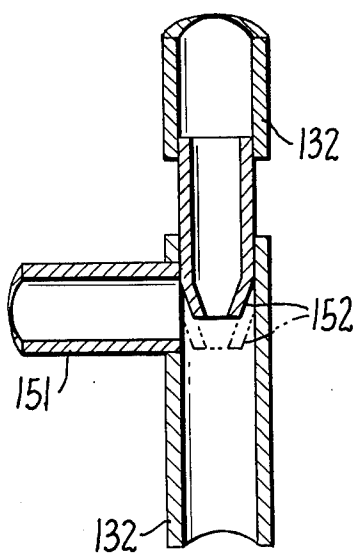
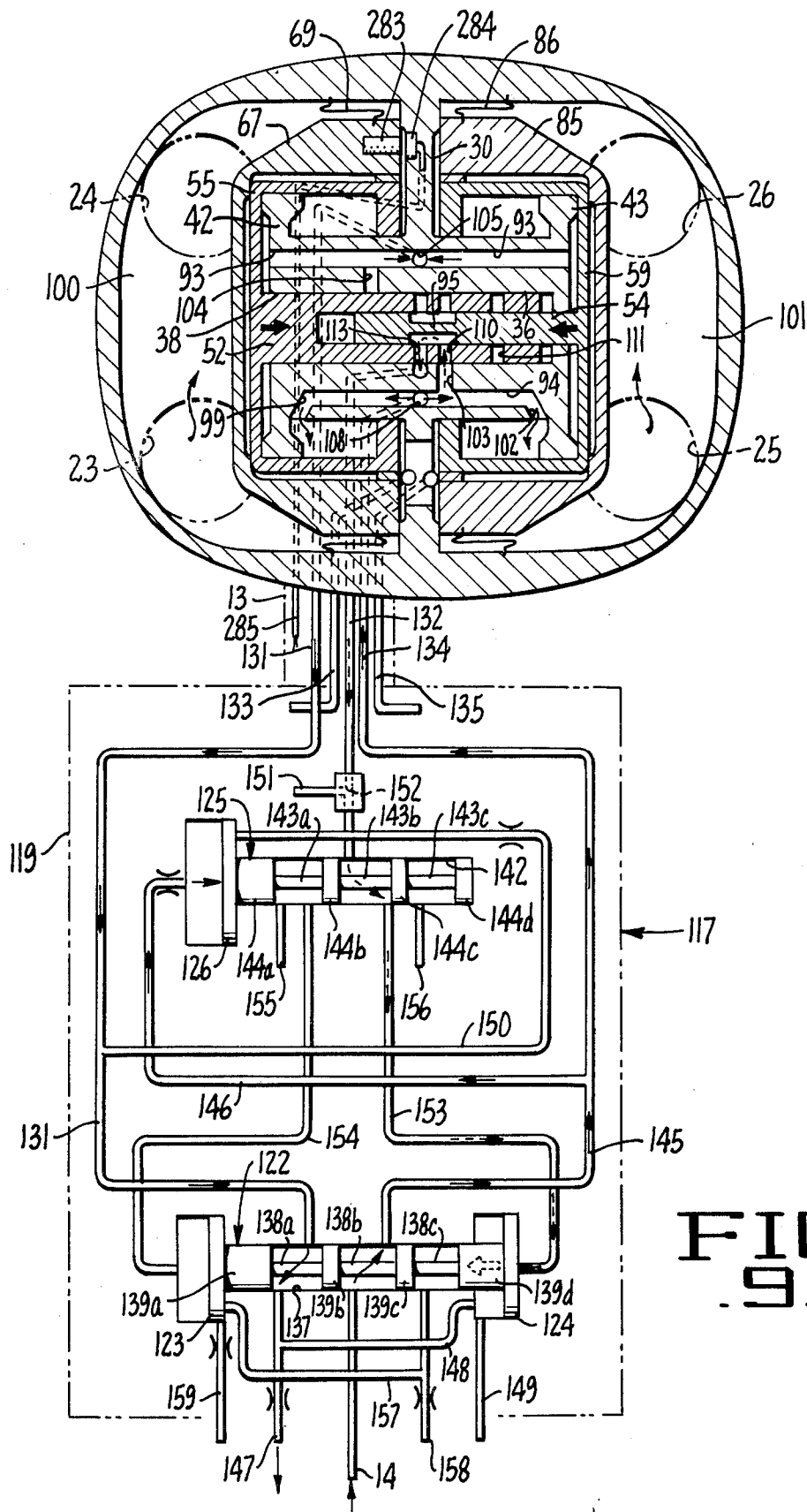


FIG. 8.



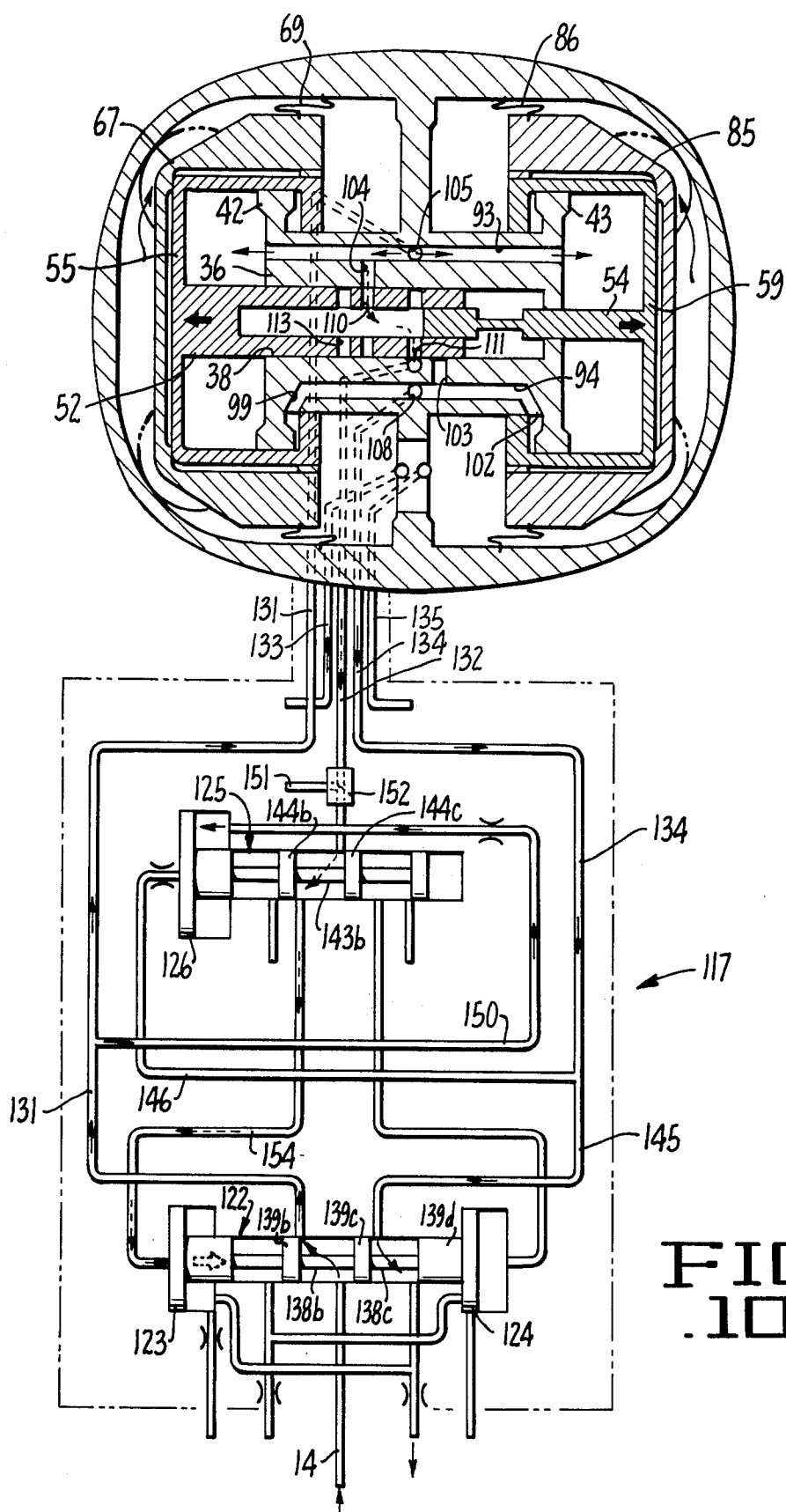
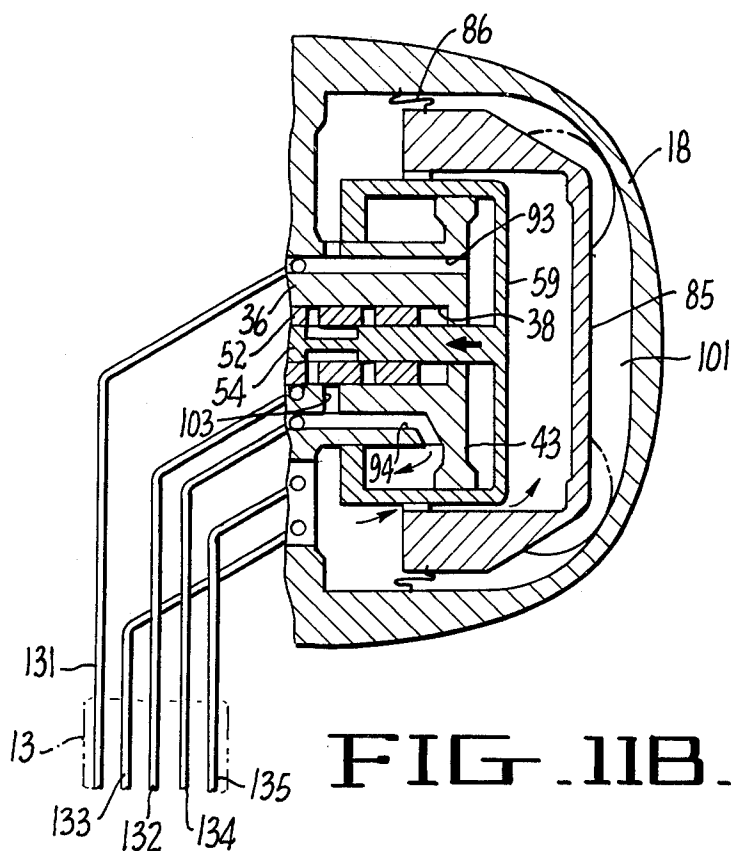
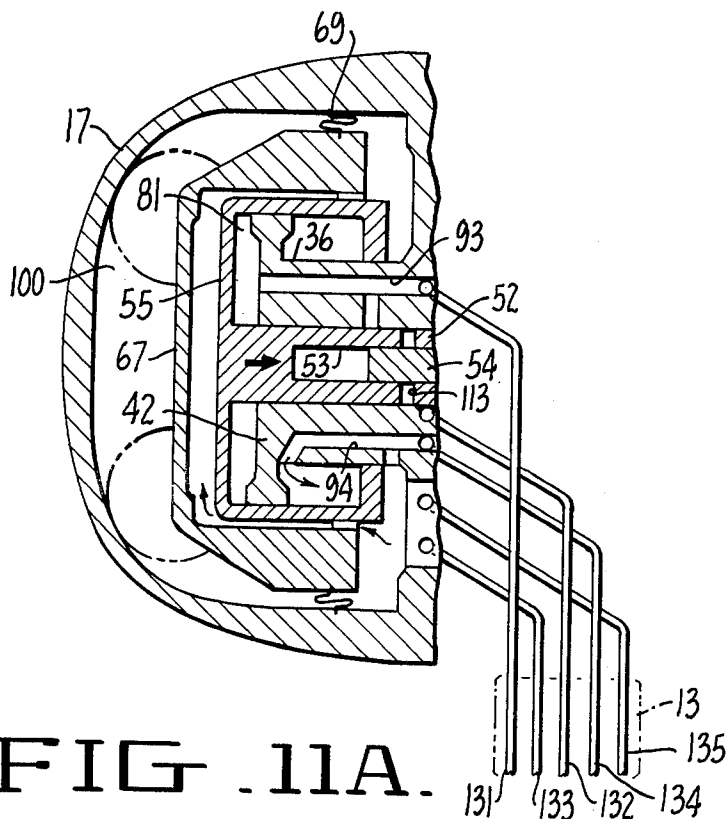
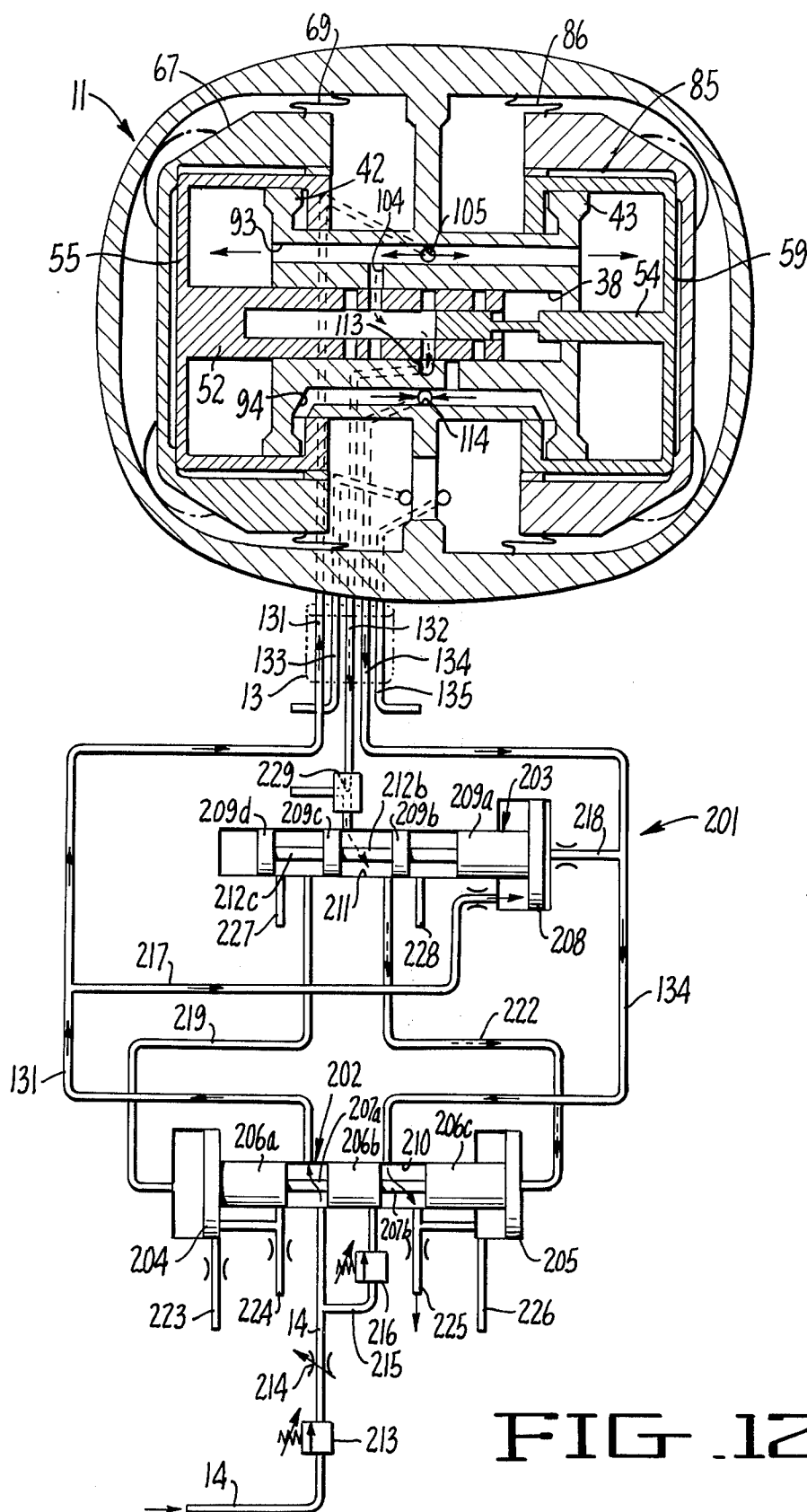


FIG.
10.





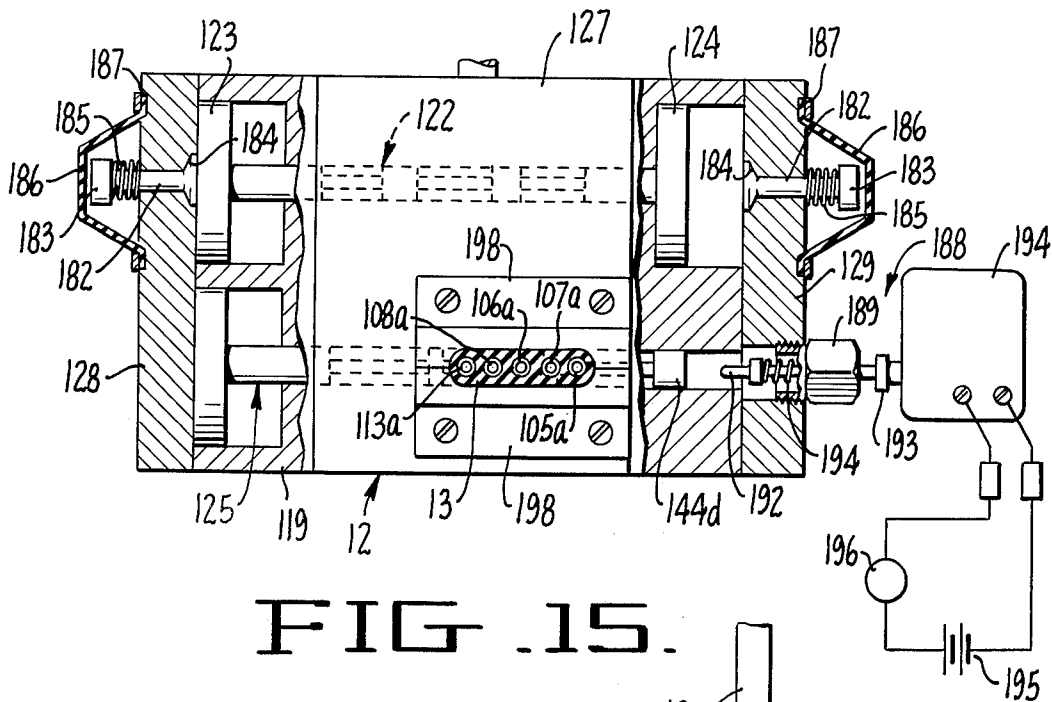


FIG. 15.

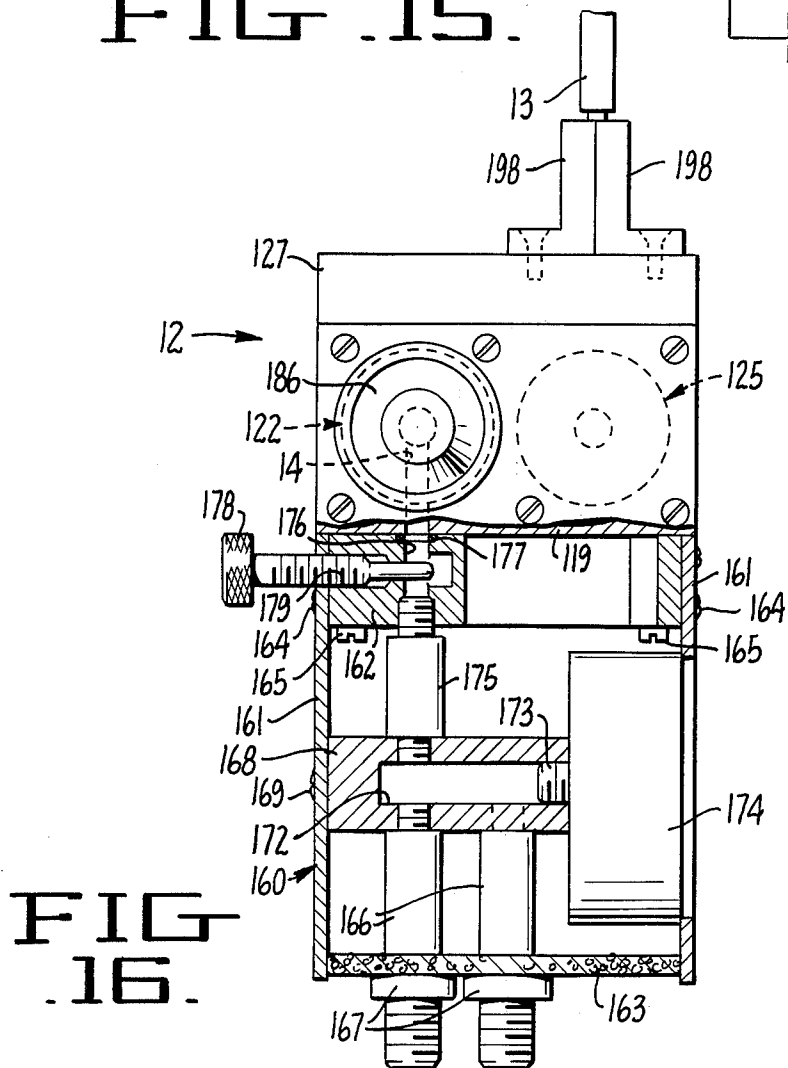
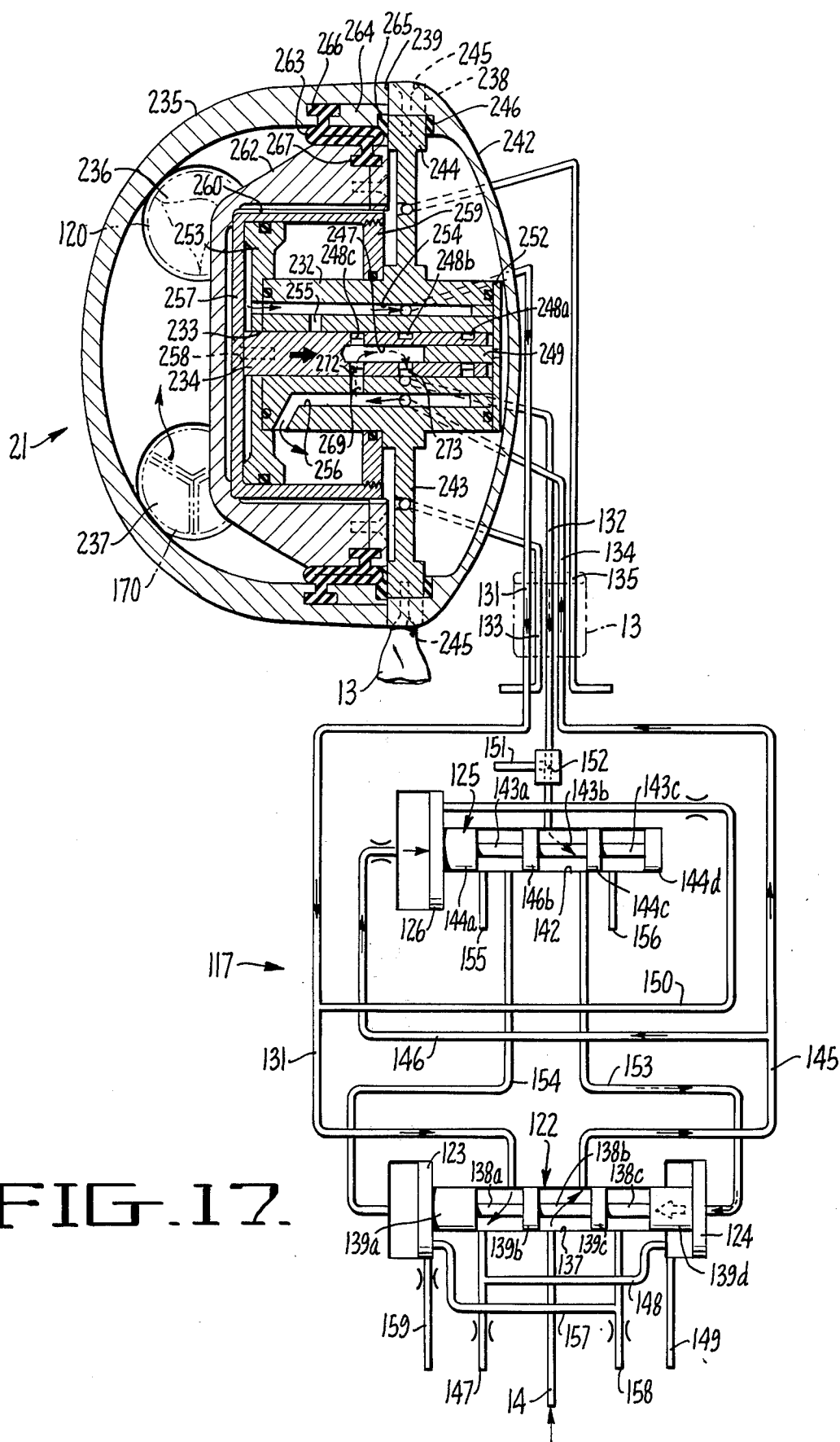
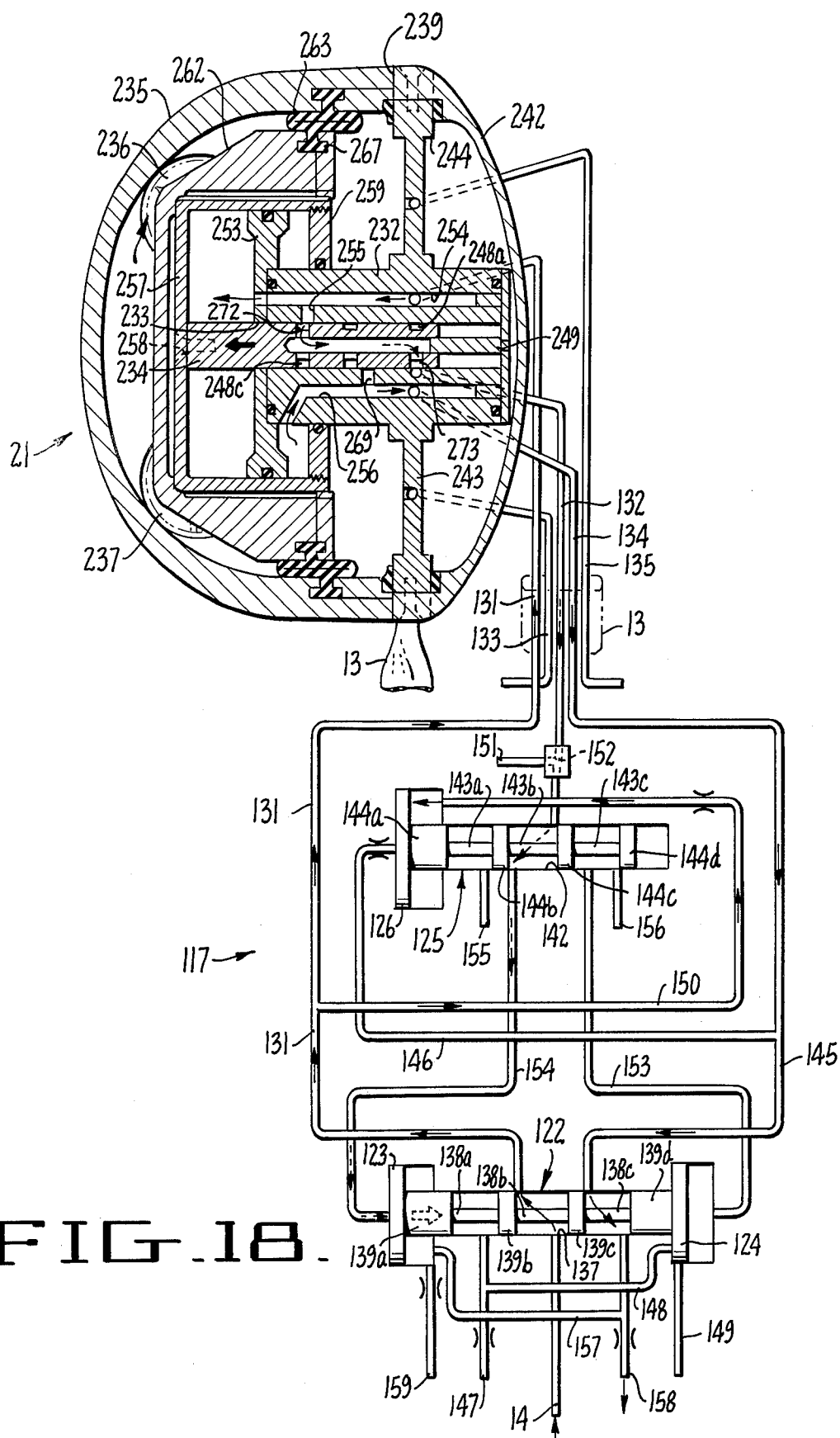


FIG. 16.





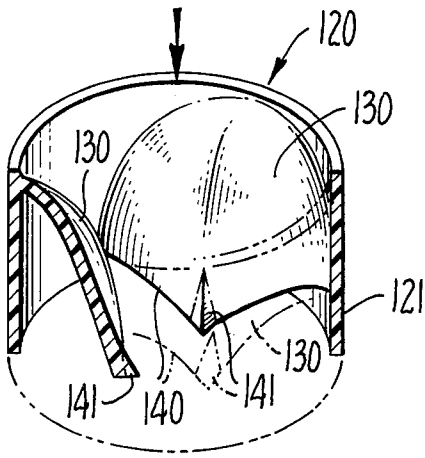


FIG. 19.

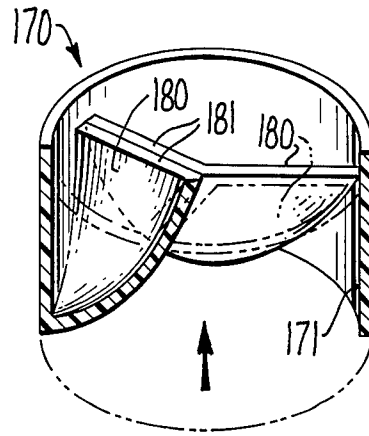


FIG. 20.

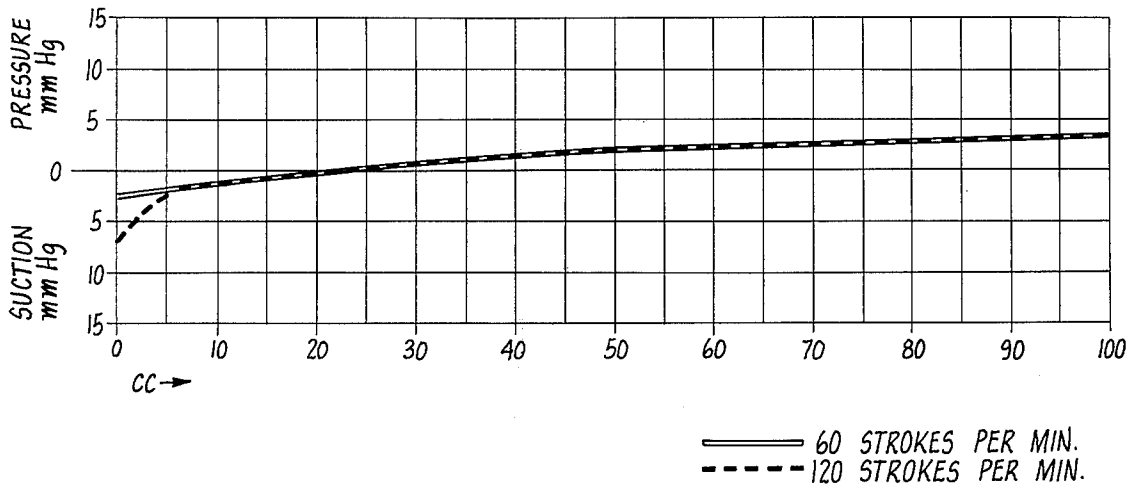


FIG. 21.

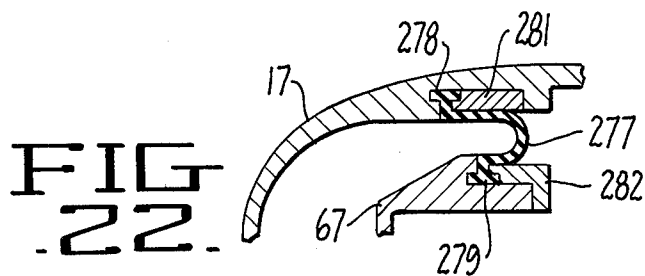


FIG. 22.

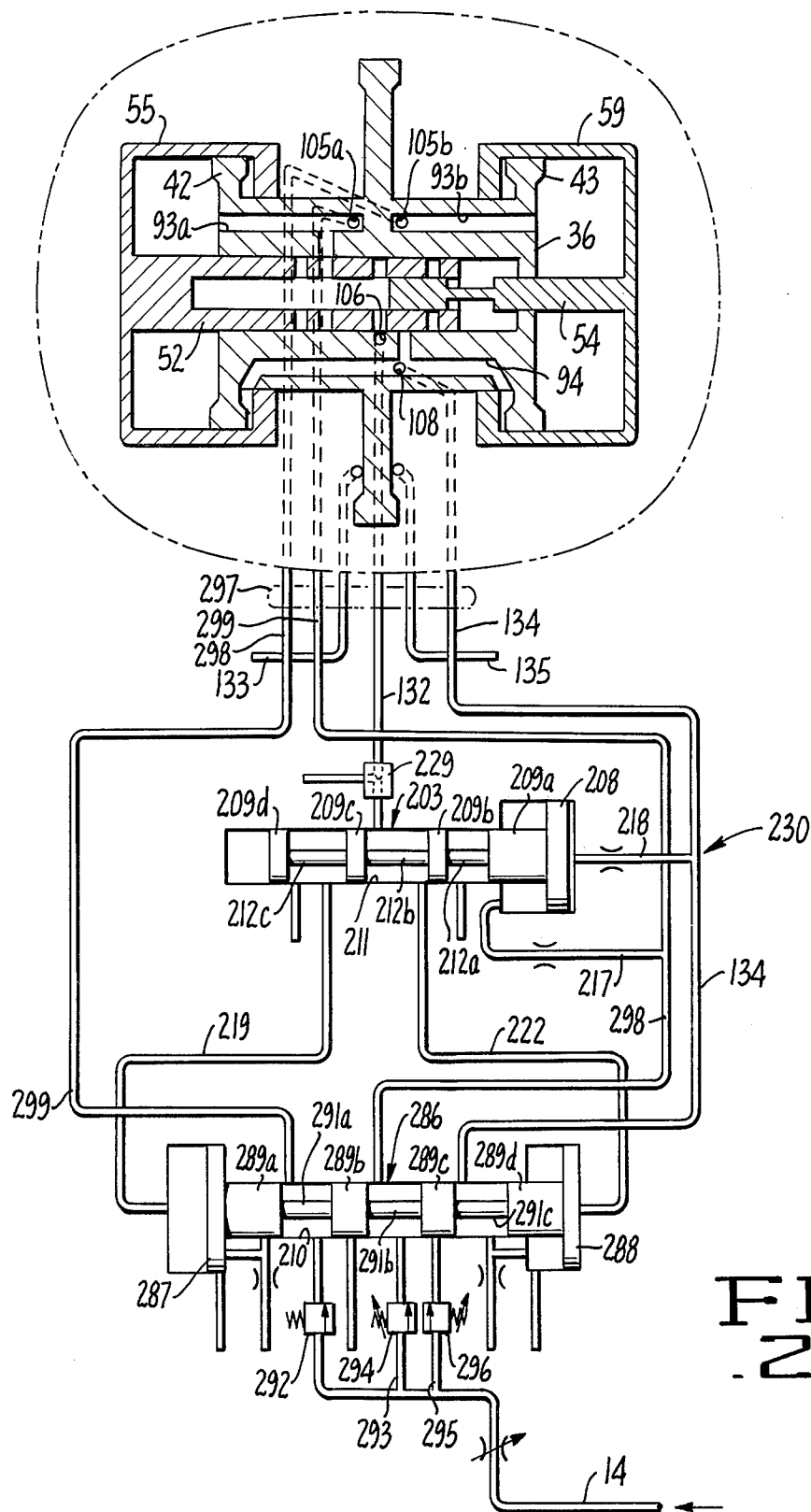


FIG.
23.

IMPLANTABLE HEART PUMP

This is a continuation of application Ser. No. 312,668, filed Dec. 6, 1972 and now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to prosthetic devices, and more particularly to a Starling-type heart pump which in alternate forms is utilizable either as a total natural heart replacement or an assist device in conjunction with the natural heart.

Hertofore, various forms of artificial blood pumps have been developed falling into either heart assist device or total artificial heart categories. Heart assist devices have been developed for supplementing the pumping action of either the left or right ventricles of the heart. However, the left ventricle is more subject to failure, since it ejects blood to the aorta, works against the resistance of the whole circulatory tree and performs several times the work or pumping action of the right ventricle emptying into the less resistant pulmonary system.

One of the known heart assist devices is designed to operate in parallel with the left ventricle through connection between the left atrium and the descending aorta, and comprises a rigid tubular housing within which is a flexible tube or bladder having valves at each end. Air pulses introduced between the rigid and flexible tubes intermittently contract and expand the flexible tube for pumping blood within the inner tube. A variation of this "in parallel" assist device utilizes a diaphragm-operated pumping chamber actuated by air pulses for pumping blood from the left ventricle to the aorta. Another existing form of air pulse driven "in parallel" assist unit is designed to be connected between the apex of the left ventricle and the descending aorta. U.S. Pat. No. 3,550,162, to Hoffman et al. discloses a form of assist device of the general type discussed.

A known form of "in-series" assist device is connected between the ascending and descending parts of the aorta, with the ascending aorta interrupted between the points of connection. In similar fashion to the parallel type devices, it is operated by air pulses and pumps blood within an intermittently expanded and contracted flexible tube. All such assist devices are capable of performing only a part of the workload of the defective side of the heart, will stall in the absence of appreciable blood volume and pressure in the left heart chamber and therefore are incapable of serving as a temporary or permanent replacement for the left or right side of the heart when it is rendered incapable of performing a filling or ejecting function. The devices all suffer common problems of objectionable blood damage, clotting and diaphragm failure.

Total artificial hearts which have been proposed have incorporated both two and four chambers, corresponding to the ventricles and atria of the heart. These total hearts have incorporated diaphragm pumps which may be actuated by air or compressed carbon dioxide pulses. One form of total heart utilizes oil as a pumping fluid to compress a sac for forcing the blood into the aorta. Problems of blood flow interference, clotting and blood damage are aggravated in total artificial hearts because of the greater number of valves, chambers, material interfaces and passages therein, resulting in greater contact with and abuse of the blood.

SUMMARY OF THE INVENTION

The two principal components of the heart pump of this invention are a variable displacement piston-type blood pumping unit, which in a preferred embodiment is air-driven, and a spool-type control assembly therefor. The pumping unit is adapted for implantation. The control assembly is external and utilizes an air supply, connections and manual emergency control means. The complete heart pump requires, in addition to the two main components, only a source of compressed air and suitable air lines, thus all equipment is readily borne by the user and is transportable.

The pumping unit has a rigid case providing either one or two major blood chambers corresponding to the ventricles of the heart, depending on whether the unit is to replace one or both sides of the natural heart, and each major blood chamber has an associated blood intake valve and a blood outlet valve. A variable displacement blood piston is mounted for reciprocation within each blood chamber for alternately causing blood to be expelled through the outlet valve (systole) and to be received through the inlet valve (diastole). In the form of pumping unit having two major blood chambers initiation of systole or diastole occurs simultaneously in both chambers as in the case of the natural heart. A significant feature of the pumping unit is the inherent sensitivity of the blood pistons to venous pressure and blood volume. As distinguished from prior artificial heart pumps, little or no venous pressure is required for blood chamber filling. Displacement of the blood piston is also affected by displacement of a pressured air driven double acting cylinder that impels the blood piston during systole.

The control assembly is a signal controlled spool-type valving assembly having only two moving parts, which are two spools respectively termed a "main spool" or "main directional spool" and a "signal directional spool" or "reversing spool." The two spools and associated ports and passages control two distinct air circuits, one of which is the working air circuit controlled by the main spool for transmitting air to drive a reciprocating air cylinder within the pumping unit and the associated blood piston. In a preferred form of control assembly, working pressures are separately regulated during the systolic and diastolic phases, which affects the working rate of the blood piston during its systolic and diastolic functions. In this way the complete pumping cycle may be made to closely approximate the pressure-time signature of the human heart. Working pressure associated with each individual blood chamber of a two chamber pumping unit may also be separately regulated. The other associated circuit is an air pulse signal circuit.

The pumping unit is so constructed that at the points of complete extension or retraction of the air cylinder(s) in the single or double chamber pumping units, an air pulse or signal circuit is opened within the pumping unit, and a pulse of air is returned from the pumping unit through the correctly positioned signal directional spool of the control assembly and directed to a portion of the main spool for displacing it to the position at which it will direct working air to the air cylinder or cylinders in the pumping unit for causing reverse displacement thereof. The rate of reciprocation of the control spools corresponds to that of the blood pistons and is the "heart beat" rate. The control assembly is therefore a passive or slave device relative to the pump-

3

ing unit in that the air pulse or signal depends only upon positioning of elements of the pumping unit itself which, in turn, are sensitive to blood pressure and volume values that control the filling and therefore the ejection volume. A multiple channel conduit is connected between the pumping unit and control assembly for providing the necessary working air, pulse signal air and case venting lines, and conductors for heart function monitoring devices when desired.

A preferred form of heart pump of this invention includes novel intake and outlet valves, both of which are of a flexible, tricuspid design characterized by extremely low pressure requirements for opening and closing, smooth operation and absence of regurgitation. Mounting of the valves in close proximity to each other is also important in order to sustain adequate flow in the blood chamber.

The air circuitry in this heart pump provides a sort or cushioned transition at reversal of blood piston displacement. The arrangement of the blood piston within a chamber is such that the circulation of blood within a blood chamber follows a generally circular path from inlet valve to outlet valve. The blood piston is maintained in a sealing relationship with the case of the pumping unit defining the blood chamber by a novel sealing ring which has a cross-sectional configuration yielding a rolling action which precludes entrapment of blood between the sealing ring and surfaces of the blood chamber and blood piston which it contacts. The overall result is reduction of blood stagnation and turbulence and blood abuse.

Important objects of the invention are provision of a highly reliable, implantable, Starling-type heart pump suitable as an assist device for one side of the heart or as a total artificial heart; and artificial heart pump which lessens damage to the pumped blood relative to that caused by prior devices; a heart pump that will continue to cycle upon loss of filling volume as a result of heart disfunction, but will cease functioning in the event of excessive arterial blockage; and a heart pump and pump system that are readily borne and transported by the user and require no auxiliary equipment.

Further objects are to provide an artificial heart pump in which relative durations of the systolic and diastolic phases and blood pressures within the pump during such phases closely approximate the corresponding characteristics of the natural heart; a heart pump having a simple beat rate control; a heart pump incorporating means for accurately monitoring blood output; and a heart pump which can readily be manually controlled in the event of automatic control function failure.

Additional objects are to provide in a heart pump combination, a pumping unit control having substantially fewer operating parts than heretofore; novel heart valves which operate in a manner less abusive of blood than prior prosthetic valves; and a novel blood sealing ring exhibiting a rolling action which precludes entrapment of blood.

Other objects and advantages of the invention will become apparent from the following description of preferred embodiments of the invention.

DESCRIPTION OF THE FIGURES

FIG. 1 is a perspective, partly schematic view of one embodiment of the heart pump of this invention incorporating a double-chamber pumping unit, showing its connection with an air source and with associated portions of the blood circulation system;

4

FIG. 2 is an end elevational view of the pumping unit of FIG. 1, with parts broken away;

FIG. 3 is an enlarged vertical cross-sectional view of the pumping unit shown in FIG. 1, taken substantially along line 3—3 thereof;

FIG. 4 is an enlarged vertical cross-sectional view of the pumping unit of FIG. 1, taken along a plane disposed 90° from the plane of FIG. 3 and along line 4—4 in FIG. 3.

FIG. 5 is an enlarged horizontal cross-sectional view of the pumping unit of FIG. 1 showing the blood pistons thereof in the fully retracted position;

FIG. 6 is an exploded fragmentary view showing a portion of the blood piston sealing ring in the pumping unit of FIG. 1, with associated parts;

FIG. 7 is a fragmentary cross-sectional view of the air cylinders and associated parts of the pumping unit of FIG. 1;

FIG. 8 is a fragmentary view of a signal jet tube assembly in the air signal circuit of the heart pump of FIG. 1;

FIG. 9 is a partially cross-sectional, partially schematic view showing the pumping unit of FIG. 1 and a form of control assembly therefor, with the parts positioned at the completion of the filling or diastolic phase of the pumping cycle;

FIG. 10 is a view similar to FIG. 9, but showing the positions of parts at completion of the blood ejection or systolic phase of the pumping cycle;

FIGS. 11a and 11b are partial cross-sectional views of the pumping unit of FIG. 1 during the diastole phase, taken along the same plane as FIG. 10, showing two stall conditions;

FIG. 12 is a partially cross-sectional, partially schematic view of the pumping unit of FIG. 1 with a modified form of dual pressure control assembly;

FIG. 13 is an exploded view of control assembly components and associated parts of the heart pump of FIG. 1;

FIG. 14 is an isometric view of the air circuitry in the control assembly of FIG. 1;

FIG. 15 is an enlarged top plan view, with parts broken away, of the control assembly of FIG. 1;

FIG. 16 is an end view, with parts broken away, of the control assembly shown in FIG. 15;

FIG. 17 is a partially cross-sectional, partially schematic view of a form of single-chamber pumping unit and control assembly therefor, showing the positions of parts at the end of the diastolic phase;

FIG. 18 is similar to FIG. 17, but shows the positions of parts at the end of the systolic phase;

FIG. 19 is a fragmentary view of a preferred form of inlet valve for the pumping unit of FIG. 1;

FIG. 20 is a fragmentary view of a preferred form of outlet valve for the pumping unit of FIG. 1;

FIG. 21 is a graph showing the relationship between venous pressure and blood filling volume exhibited by the pumping unit of this invention, when operating at 60 and 120 beats per minute;

FIG. 22 is a fragmentary view of a modified form of blood piston sealing ring; and

FIG. 23 is a schematic view of a modified form of control assembly utilizing three different operating pressures and associated parts of a double-chamber pumping unit of this invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

In detail, FIG. 1 illustrates one preferred form of the invention and the only equipment required for sustained blood pumping, being a pumping unit, generally designated 11, and a control assembly 12 therefor connected thereto by a multiple channel air conduit 13 and also connected to a source 16 of air under pressure through a supply air line 14 having a pressure regulator 15.

Double-Chamber Pumping Unit

Pumping unit 11 (FIGS. 1 and 3) comprises a rigid case formed of a pair of similar, generally hemispherical, rigid case members 17 and 18, each having square-toothed annular edge portions 19 and 22 respectively which are in interfitting relation. Each case member also has formed therein two parallel open-ended tubular protrusions 23, 24, 25 and 26 providing two ports for each case member. The case is preferably fabricated from an inert plastic material, such as polycarbonate plastic, which will be suitable for implantation and will withstand autoclave sterilization.

FIG. 1 schematically illustrates portions of the human circulatory system directly communicating with the valves of the heart, specifically, the vena cava 27, pulmonary artery 28, lungs 29, pulmonary veins 32 and aorta 33. Tubular ports 24 and 26 respectively are provided for surgical connection with the pulmonary artery 28 and the ascending portion of the aorta 33. Ports 23 and 25 respectively are adapted for surgical connection with the natural right atrium associated with the vena cava 27 and the natural left atrium associated with the pulmonary veins 32, for introduction or ejection of blood through valves to be described.

A circular plate member 30 (FIGS. 3 and 4), which may also be formed of an inert plastic material, is located within the pump case with its periphery in contact with the interior surface of edge portions 19 and 22. Member 30 has a peripheral flange portion 34 and is secured to case edge portion 19 (FIGS. 4 and 5) and 22 (FIGS. 3 and 5) by a series of screws 35. The central portion of member 30 has a cylindrical shape projecting in both directions axially of member 30 (FIGS. 3 and 7) which provides a stationary cylinder rod 36 of a double acting cylinder assembly. Respectively fixed to the ends of rod 36 in case members 17 and 18 by screws 39 are circular pistons 42 and 43, and a central bore 38 extends fully through pistons 42 and 43 and rod 36. An O-ring 60 is seated around the periphery of each piston 42 and 43.

Slidingly received within bore 38 is a rod 52 (FIGS. 3 and 7) that is slightly shorter than rod 36. Rod 52 has a central bore 53 extending from its end within case member 17 but terminating short of its opposite end. A second rod 54 is received within the bore 53, and at the outer end of rod 52 there is fixed, by a screw 57, the flat face 50 of an air cylinder 55 having its cylindrical wall 51 seated around O-ring 60 on piston 42. The open end of cylinder 55 is threaded around the periphery of a ring 46 which is slidingly fitted around rod 36 in sealing relation thereto by an O-ring 48. When cylinder face 50 is in contact with piston 42, ring 46 contacts a shoulder 56 of plate member 30. Cylinder 55 with ring 46 slides relative to rod 36 and piston 42 and carries rod 52 with it. Rod 54, received within bore 53 of rod 52 has fixed to it by a screw 63 a flat faced air cylinder 59 having a cylindrical wall 61, threaded around a ring 47. Rod 54

with cylinder 59 thereon, slides within rod 52 relative to rod 36 and piston 43. O-rings 60 and 48 are respectively seated in piston 43 and ring 47.

The inner surface of case member 17 immediately adjacent edge portion 19 (FIG. 6) is formed with a stepped section providing a threaded portion 64 and a flat portion 65 terminating in a rectangular groove 66. This section of case member 17 provides seating for elements of an assembly for mounting a hollow piston 67 (FIGS. 2, 3 and 6), which overlies air cylinder 55, and as will be described, reciprocates for pumping blood present in the chamber defined between the piston and case wall. The leading end of piston 67 is partially tapered forwardly to a flat face 80 (FIG. 3). The interior defines a cylindrical chamber 81 (FIG. 6) having an annular shoulder 82 inside its face 80. When cylinder 55 (FIG. 3) is within piston 67 with face 50 contacting shoulder 82 of the piston, there is clearance space between the opposed surfaces of the piston and air cylinder for purposes to be described.

The annular open end of piston 67 is formed with an annular groove 68 (FIG. 6) of L-shaped cross-section, and piston 67 is sealingly attached to case member 17 by a resilient sealing ring, which may be formed of silicone rubber material, and which, when in an uncompressed condition has a cross-section as shown in FIG. 6, including a T-shaped portion 72, a C-shaped portion 73 and a pair of opposed L-shaped portions 74. Ring 69 is attached to case member 17 (FIGS. 3 and 7) by the T-shaped portion 72 inserted in slot 66 and is retained therein by a retaining ring 75 received within the case portion 65 and having a notched end for mating with the portion 72. An annular retaining nut 76 is threaded into the threaded case portion 65, and resilient sealing ring 77 is compressed between nut 76 and flange portion 34 of plate member 30.

On the piston 67 itself, one of the L-shaped portions 74 of sealing ring 69 is seated within the L-shaped groove 68 and the other portion 74 is compressed thereagainst by a retaining ring 78 having an L-shaped groove 79. Retaining ring 78 is screwed to piston 67 by a series of screws 90. It is seen (FIGS. 3 and 6) that with the described assembly, portion 73 of sealing ring 69 will effect a rolling motion relative to the cylindrical surface 83 of piston 67 and the opposed surfaces of case member 17, ring 75 and nut 76, during reciprocation of piston 67, and such rolling action precludes entrapment of blood between such surfaces. A piston 85, (FIG. 3) similar to and mounted in the same fashion as piston 67 faces the opposite direction therefrom within case member 18. Mounting means for piston 85 includes sealing ring 86, retaining ring 87, retaining nut 88, sealing ring 89 and retaining ring 92.

A blood chamber 100 (FIG. 3) is defined between blood piston 67 and case member 17, and a similar blood chamber 101 is associated with piston 85. The chamber surfaces are treated with Dacron fibers to support and retain live fetal cells or natural tissue growth. Blood is drawn into chambers 100, 101 upon retraction of pistons 67 and 85, and expelled upon extension of the pistons. Port tube 23, associated with piston 67, and port tube 25, associated with piston 85, are respectively provided for surgical connection with the right atrium associated with vena cava 27 (FIG. 1) and the left atrium associated with pulmonary veins 32 and for mounting blood inlet valves. A preferred form of inlet valve 120 (FIG. 19) utilized to replace the tricuspid and mitral valves of the natural heart, is a flexible, nor-

mally open three-leafed valve, which may be molded of a silicone rubber material. Valve 120 includes a collar portion 121 for seating and vulcanizing into the outer end of a port tube 23, 25 (FIG. 3). Integral with the collar portion 121 are three similar leaves 130 (FIG. 19) each molded along a generally semicircular line of attachment with the collar portion, opening in the direction of flow into the pumping unit and spanning one-third the distance around collar portion 121. The leaf inner end 140 can best be described as resembling in shape the pointed bottom end of a shield. A dart shaped reinforcing portion 141 is molded onto the inner face of leaf 130 at the center point of inner end 140 thereof. Relative to the interior of the valve, leaf 130 is mildly convex adjacent its line of attachment to collar portion 121 and mildly concave adjacent dart shaped portion 141. In the normally open condition inner ends 140 of the three leaves together define an inwardly opening triangular mouth. The mouth is enlarged by flexing of leaves 130 during introduction of blood to the pumping unit (diastole) and is closed to flow of blood during expulsion (systole). Dart shaped portions 141 contribute to effective closure and sealing of leaves 130 during systole.

Each outlet valve 170 (FIG. 20) used is a three-leafed normally closed valve, which includes a collar portion 171 for seating in port tubes 24 and 26. Three similar leaves 180 are molded to collar portion 171 along a generally semicircular line of attachment spanning one third the distance around collar portion 171 and opening away from pumping unit 11 so that the leaves open outwardly thereof. Relative to the interior of the valve the leaves are convex, and the outer end portion 181 of each leaf (FIG. 20) includes two straight equal legs defining a 120° angle. In the closed condition, as during diastole, the end portions 181 of leaves 180 are in sealing contact to prevent reverse flow of blood. During systole or outflow the flexible leaves separate to provide a three-pointed outward opening mouth for passage of blood. Also, during outflow, the leaves exhibit an outwardly directed bulging effect which is of importance as the leaves thus impel blood which otherwise might undesirably remain at the outer surfaces of the valves.

Cylinder 55, with ring 46 and cylinder 59 with ring 47 reciprocate in opposite directions relative to rod 36 as double-acting cylinders, and their reciprocation is synchronized so that both simultaneously initiate an extension or retraction stroke. Appropriate passages and porting for synchronization include through bore 93 (FIG. 7) extending through rod 36 and pistons 42 and 43 in parallel with bore 38. Another passage 94 extends in parallel on the opposite side of bore 38, but is closed at both ends and communicates with a passage 99 leading to an area between piston 42 and ring 46, and also with a passage 102 leading to an area between piston 43 and ring 47. FIGS. 3, 5 and 7 show cylinders 55 and 59 and spools or rods 52 and 54, in the completely retracted position. Inner spool 54 includes a reduced diameter portion 95 (FIG. 7) located to span the midpoint of bore 38 when spool 54 is retracted. Outer spool 52 includes a series of three reduced diameter portions 96, 97 and 98. When spools 52 and 54 are retracted, portion 96 is at the midpoint of bore 38, portion 97 is spaced toward cylinder 59 but overlies portion 95 of inner spool 54, and portion 98 is midway between portion 97 and the free end of the spool. A passage 103 extends between passage 94 and bore 38 in

rod 36 and communicates with spool portion 97 when rod 52 is retracted. A passage 104 extends between bores 38 and 93.

Blood output from a blood chamber 100, 101 is readily and accurately measured by utilizing a small bar magnet 283 (FIG. 9) embedded within the associated blood piston 67, 85 with an end flush with the piston inner edge surface, and a sensor 284 mounted in alignment therewith on the opposed surface of central plate member 30. Sensor 284 is a Hall magnetic effect transducer which provides a varying electrical output when subjected to a varying magnetic field. The amplitude of variation in electrical output is a direct function of the variation in strength of the magnetic field. As has been described, the output of the pumping unit depends on blood piston displacement, and correspondingly, the amplitude of the change in electrical output from the transducer depends on the distance between its blood piston and stationary central plate member 30. An electrical connection 285 within an additional channel of conduit 13 is provided between transducer 284 and an external electrical recording device of conventional construction. For example, the transducer can be connected to an oscillograph which will record a plot of the electrical output variation during travel of the blood piston, i.e., a plot of blood piston displacement. Such plot readily is calibrated and translated so that blood output volume per stroke can directly be represented on the oscillograph graphs.

As seen in FIGS. 1 and 13 conduit 13 for introducing pressured air to pumping unit 11 is a flexible ribbon having multiple air channels. Conduit 13 is preferably formed of extruded silicone rubber and at the end which connects with pumping unit 11 receives multiple rigid tubes 105, 106 and 108, and T-tubes 107 and 113 (FIGS. 4 and 13) which communicate with the interior of the pumping unit. Conduit 13 extends through the case, through flange portion 34 of plate member 30 and an opening 109 therein. The rigid tubes are clamped in the end of conduit 13 by a pair of clamp plates 115 (FIGS. 4 and 3) within the opening 109. Tubes 105, 106 and 108 respectively communicate with passage 93, bore 38 and passage 94, and T-tubes 107 and 113 terminate within clamps 115 and communicate with opening 109. The opposite end of conduit 13 is adapted to be connected to a control assembly for pumping unit 11 such as control assembly 12 (FIGS. 1, 13, 15, 16), the main component of which is a spool valve assembly, e.g., 117 (FIGS. 1, 9, 10 and 14), 201 (FIG. 12) or 230 (FIG. 23).

Control Assembly

A preferred form of control assembly 12 incorporating spool valve assembly 117 (FIGS. 1, 9, 10 and 14) has an associated housing 160 (FIGS. 1 and 16) for an air pressure gage 174 (FIG. 16). Valve assembly 117 (FIGS. 13 and 15) includes a valve body 119 for seating a main spool 122 having a circular piston 123 on one end and a similar piston 124 on the opposite end, and for seating a reversing spool 125 having a single piston 126 at one end. A port plate 127 is mounted on the top surface of valve body 119, a cap 128 is at the side adjacent to piston 123 of main spool 122 and a cap 129 is at the opposite side.

The control end of conduit 13 receives rigid tubes 105a, 106a, 107a, 108a and 113a (FIG. 13) respectively in the same channels as tubes 105, 106, 107, 108 and 113. Each such tube communicates with a port in

port plate 127 (FIGS. 13 and 15) and the ribbon conduit and tubes therein are sealingly fixed to port plate 127 by a pair of L-clamps 198. The air line provided by the channel of conduit 13 and port in plate 127 associated with tubes 105, 105a (FIG. 13) is designated 131. Similarly, the air line associated with tubes 106 and 106a, is 132, and the line associated with tubes 107, 107a is 133. Air line 134 is associated with tubes 108, 108a, and air line 135 is associated with tubes 113, 113a.

The complete air circuit is shown schematically in FIG. 9, from which it is seen that air line 131 communicates with port 93 leading to the front of pistons 42 and 43 in pumping unit 11 and air line 134 communicates with the back of pistons 42, 43 through channel 94. These are driving air lines. Lines 133 and 135 communicate with the area defined between rings 46 and 47 (FIGS. 3 and 9) and are vented to atmosphere. Air line 132 (FIG. 9) communicates with porting within rods 52 and 54, and as will be explained, is appropriately termed an air pulse or air signal line. Pistons 123 and 124 of main spool 122 are on opposite ends of a rod which extends within a bore 137 within valve body 119 and which has three reduced diameter stem portions 138a, 138b and 138c, a land 139a adjacent piston 123, intervening lands 139b and 139c, and a land 139d adjacent piston 124. The rod of reversing spool 125 lies within bore 142 and has three reduced diameter portions 143a, 143b, 143c, land 144a adjacent piston 126 and lands 144b, 144c and 144d.

FIG. 9 illustrates the positions of parts when blood pistons 67 and 85 are in the completely retracted position as at the end of the blood chamber filling or diastolic phase of blood pumping. Air introduced through air supply line 14 passes stem portion 138b of spool 122 into an air passage 145 which joins with air supply line 134 and also communicates with a passage 146 leading to the front of piston 126 of reversing or signal directional spool 125. Air line 134 communicates with the back of stationary pistons 42 and 43 through passage 94, and it is seen that when supply air is present in line 134 air cylinders 55 and 59 will be retracted. With cylinders 55 and 59 fully retracted, the ports of outer spool 52 and inner spool 54 are in register such that air from passage 94 also passes through port 103 and a port 110 in rod 52, past reduced diameter portion 95 of rod 54 and through a port 113 in rod 52 to communicate with pulse air line 132. Since air is introduced into line 132 intermittently and only when appropriate portions of spools 52 and 54 register at full extension or complete retraction that line transmits only brief pulses of air from pumping unit 11 to valve assembly 117 for triggering displacement of main spool 122 and reversing spool 125.

With main spool 122 positioned as shown, the areas in front of pistons 42 and 43 are vented to atmosphere through a line that includes bore 93, air line 131, the portion of bore 137 associated with main spool stem portion 138a and an exhaust line 147. Exhaust line 147 also communicates with exhaust lines 148 and 149. An air line 150 branches from line 131 and leads to the back of piston 126 of reversing spool 125.

In order to effect extension of air cylinders 55 and 59 by introduction of supply air from line 14 through line 131, main spool 122 must be displaced. Such displacement is initiated by an air pulse transmitted in pulse line 132, which has within it a pulse jet tube 152, shown schematically in FIGS. 9 and 10 and best seen in FIG.

8. The jet tube 152 terminates in a restricted nozzle opening located at a portion of air line 132 at which there is formed a T junction, including a tube 151 vented to atmosphere. As will be more fully described, jet tube 152 governs the duration of the air pulse. After passing through the pulse jet tube, pulse air passes stem portion 143b of reversing spool 125, through passage 153 to the front of piston 124 of main spool 122 for initiating displacement of spool 122. At the same time, a passage 154 communicating with the front of piston 123 of main spool 122 is vented to atmosphere through port 155.

The several exhaust ports 147, 149, 155, 156, 158 and 159, shown in FIG. 9, pass through the bottom surface of valve body 119 (FIG. 14) to which is affixed a rectangular housing 160 (FIG. 16) having side walls 161. A spacer member 162 is adjacent the bottom surface of body 119 and confined within sidewalls 161, and a bottom wall 163 is composed of a plate of sintered bronze which is gas permeable for exhausting, muffling and filtering air therethrough from the ports in valve body 119. Spacer member 162 is fastened to valve body 119 by a plurality of screws 165 which extend therethrough and into threaded engagement with port plate 127.

A pair of air input tubes 166 are threaded through bottom wall 163 and locked thereon by nuts 167, and the upper ends thereof are threaded into a manifold block 168 which is fixed to a sidewall 161 by screws 169. Input tubes 166 communicate with a bore 172 in manifold block 168, which receives a fitting 173 of a pressure gage 174 and also communicates with an upper main air supply tube 175 which in turn communicates with a passage 176 within spacer member 162 and also a continuation of air supply line 14 formed as a passage in valve body 119. An O-ring 177 surrounds passage 176 at the upper surface of spacer member 162 to prevent air leakage from the air supply line at the interface between member 162 and valve body 119.

FIG. 15 illustrates a pair of manual spool reversing assemblies respectively mounted in end plates 128 and 129 and associated with pistons 123, 124 of main spool 122. Each assembly includes a shifter stem 182 having an enlarged outer end protruding outwardly of its associated end wall 128, 129 and an enlarged inner end 184 normally seated within a shoulder formed in the end wall and urged into seating relation by a coil spring 185 which is around shifter stem 182 and extending between the outer surface of the end wall and the opposed surface of enlarged outer end 183. The length of shifter stem 182 is such that when it is fully depressed against spring 185 inner end 184 will push the piston of main spool 122 to its innermost position. To prevent inadvertent depression of shifter stems 182 each is enclosed within a cup shaped plastic boot 186 retained in an annular groove 187 in the end wall.

Since the rate of the reciprocation of blood pistons 67, 85 corresponds to the rate of reciprocation of spools 122 and 125, an accurate beat rate sensor may be provided if adapted to sense the rate of reciprocation of, for example, reversing spool 125. For such purpose, a beat rate probe 188 (FIG. 15) extends through end plate 129 and includes an outer fitting 189 within which is slidably received a contact 192 having an enlarged outer end 193 and normally urged inwardly by a coil spring 194 so that its inner end projects into the path of movement of portion 144d of spool 125. When spool portion 144d is displaced to move contact 192,

the outer end 193 thereof engages the contact element of a microswitch 194 for closing same, and microswitch 194 is in an electric circuit which includes a power source 195 and an electric meter of a monitoring device 196 from which can be determined the rate at which the microswitch circuit is intermittently closed, i.e., the best or pulse rate.

Dual and Three Pressure Valve Assemblies

With valve assembly 117 the same pressure is applied to the pumping unit 11 during both the systolic and diastolic phases of the pumping cycle. It has been found that when equal pressure is applied during both phases the time required for the diastolic phase, i.e., blood chamber filling, is shorter than that for the systolic phase. For example, at a beat rate of 100 beats per minute the systolic phase requires approximately 60 per cent of the time required for a complete cycle and the diastolic requires the remaining 40%. In the human heart, the ratio is reversed and the diastolic phase normally takes longer than the systolic phase. In a modified form of valve assembly 201 (FIG. 12) the pressure supplied to pumping unit 11 during the diastolic phase is maintained low with respect to the pressure during the systolic phase with the result that the diastolic or filling time remains greater than that of the systolic phase, and for example, at 100 beats per minute the ratio between the diastolic and systolic phases is 70% diastolic and 30% systolic which very closely approximates the ratio occurring in the human heart.

Modified valve assembly 201 is illustrated in schematic form in FIG. 12, wherein it is seen to be similar to valve assembly 117 in that it has a main spool 202 and reversing spool 203, respectively corresponding to spools 122 and 125. Spool 202 includes pistons 204, 205, lands 206a, 206b and 206c and intervening reduced diameter stem portions 207a, 207b. Reversing spool 203 includes piston 208, lands 209a, 209b, 209c and 209d, and intervening reduced diameters stem portions 212a, 212b and 212c. Utilization of the modified valve assembly 201 does not require modification of pumping unit 11, and the multiple channel air conduit 13 connecting pumping unit 11 with valve assembly 201 includes the air line 131 communicating with the front of pistons 42, 43, the pulse air line 132, air line 134 communicating with the back of pistons 42, 43 and vent lines 133, and 135.

A pressure regulator 213 and an air volume control 214 are interposed in supply air line 14, and the regulated supply air passes to stem portion 207a of spool 202 and to air supply line 131. An air line 215 branches from line 14 at a point beyond volume control 214, and a second pressure regulator 216 is interposed therein. The stem of spool 202 is within a bore 210 which communicates with line 215, and the stem of spool 203 is within a bore 211. An air passage 217 branches from air line 131 to communicate with the back of piston 208 of reversing spool 203, and a passage 218 branches from air line 134 to communicate with the front of piston 208. Passages 219 and 222 extend from bore 211 respectively to the front of piston 204 of spool 202 and to the front of piston 205 thereof. There are exhaust ports 223, 224, 225 and 226 associated with spool 202 and exhaust ports 227 and 228 associated with spool 203. In the modified valve assembly, a pulse jet tube 229 is similar to jet tube 152 of valve assembly 117, but is positioned differently relative to its associated vent.

A further modified form of valve assembly 230 adapted particularly for a double chamber pumping unit utilizes three different operating pressures and is shown schematically in FIG. 23. As in the dual pressure assembly 201, pressure supplied to the pumping unit during diastole is maintained low relative to the pressure during systole. Further, during systole, pressure supplied to the air cylinder associated with the blood chamber functioning as the right ventricle of the heart is maintained lower than that supplied to the other air cylinder.

Since during systole the right side of the heart, or pulmonary circuit, is required to pump against less pressure than the left side, or arterial circuit, less driving pressure need be supplied to the air cylinder associated with the right side. A desirable result of lowering right side pressure is that the rates of extension of the right and left blood pistons during systole will be more nearly the same, reducing working pressure on the right side does not affect the synchronized initiation of extension and retraction of the blood pistons, which occurs only upon complete extension and retraction of rods 52, 54.

Because of a higher pressure requirement on the left side, when the same working pressure is applied to both air cylinders 55, 59, the pressure applied to cylinder 59, associated with the right side is normally greater than twice the pressure in the pulmonary arteries opposing the right side blood piston during systole. It has been found that this creates a square wave form blood pressure signature in the pulmonary arteries, while the wave form of the corresponding pressure signature occurring with the natural heart is rounded. Reducing right side working pressure to air cylinder 59 so that it is less than approximately twice the pressure in the pulmonary arteries yields a pressure signature therein more simulative of that provided by the natural heart. The three pressure valve assembly 230 enables the desired right side working pressure to be applied while working pressure during systole applied to cylinder 55, associated with the left side, can be greater as required because of higher opposing pressure in the aorta.

As seen in FIG. 23, valve assembly 230 is similar to assembly 201 of FIG. 12, except for the construction of its main spool 286 corresponding to main spool 202 and for the arrangement of air lines communicating with main spool 286. Spool 286 includes pistons 287, 288, lands 289a, 289b, 289c and 289d, and intervening reduced diameter stem portions 291a, 291b and 291c. Reversing spool 203 is constructed as shown in FIG. 12.

A pressure regulator 292 is interposed in supply air line 14 which communicates with stem portion 291a of spool 286 when spool 286 is positioned to the right as shown in FIG. 23. An air line 293 having a regulator 294 therein branches from line 14 and communicates with stem portion 291b, and a line 295 having a regulator 296 is connected between line 14 and land portion 289c.

Use of valve assembly 230 requires only slight modification to the pumping unit 11, which is the division of through bore 93 into two equal separate passages 93a and 93b. Each has an associated port provided by an end of a tube 105a and 105b instead of the single port provided by the end of tube 105. Remaining parts, including air cylinders 55, 59 (FIG. 23), stationary rod 36, piston portions 42, 43, rods 52 and 54, passage 94 and port 108 therein and port 106, are all as previously described. A six channel air conduit 297 connecting

the pumping unit to valve assembly 230 includes a pulse air line 132, air line 134 communicating with the back of pistons 42, 43, vent lines 133 and 135, an air line 298 carrying air regulated by regulator 292 to the front of piston 43 and an air line 299 carrying air regulated by regulator 294 to the front of piston 42.

Air passage 217 branches from line 298 to communicate with the back of piston 208 of reversing spool 203, and passage 218 is between line 134 and the front of piston 208. Passages 219 and 222 extend from bore 211 associated with spool 203 respectively to the front of piston 287 of spool 286 and to the front of spool 288 thereof.

Single Chamber Pumping Unit

A single chamber pumping unit 21 (FIGS. 17 and 18) comprises parts generally corresponding to those associated with case member 17 and blood piston 67 of pumping unit 11. The unit 21 includes a stationary central cylinder body 232 having a central through bore 233 within which is slidably received a rod 234.

Pumping unit 21 comprises a generally hemispherically shaped case member 235 having mounted therein an inlet valve 236 and an outlet 237 respectively corresponding to valves 120, 170, previously described with reference to pumping unit 11. Case member 235 has a square-toothed annular edge 238 which interfits with a similarly formed edge 239 of a convex cap 242 to form a rigid housing. A circular plate member 243 includes an outer annular flange 244 which is screwed to the inner surface of edge portions 238, 239 by a series of screws 245. A sealing ring 246 is seated between cap 242 and the opposed surface of flange 244. The through bore 233 in central cylinder 242 slidably receives a rod 234 constructed in similar fashion to rod 52 in pumping unit 11. A bore 247 extends from the end of rod 234 within cap 242 to a point approximately midway along rod 234, and the rod has formed therein a group of three reduced diameter portions 248a, 248b and 248c each having a port communicating with bore 247.

A rod 249 having a length approximately half that of bore 247 is slidably received therein, and the outer end of the rod 249 is fixed to a plate 252 that is sealingly fastened to the end of cylinder 232 that is within cap 242. A cylindrical piston 253 is sealingly fastened to the opposite end of cylinder 232, and a bore 254, parallel with bore 233 is formed in cylinder 232 and through piston 253. A passage 255 communicates between bore 254 and bore 233 and a passage 256 is formed on the opposite side of bore 233 and includes a portion parallel therewith and an angular portion which opens through cylinder 232 at the rear of piston 253. A cylindrical piston 257 is fixed on the end of rod 234 by a screw 258 and is in sealed, slidable contact with the periphery of piston 253. A ring 259 is threaded into the open end of piston 257 and is in sealed, sliding contact with the surface of cylinder 232, and an outer blood piston 262 surrounds piston 257.

In a manner corresponding to the construction of pumping unit 11, the inner surface of case member 235 adjacent the square-tooth edged portion 238 has a stepped portion within which is sealingly seated at T-shaped portion 266 of an annular pressure gland 263 held in place in case member 235 by a rigid seating ring 264 and sealing ring 265. The other T-shaped portion of 267 is secured to blood piston 262 by means of a ring 268 that is screwed thereto and the various lines of

multiple channel conduit 13 and the passages and parts in valve assembly 117 correspond to similarly numbered parts of the same components used with pumpin unit 11.

Operation

With reference to FIGS. 5 and 9, illustrating the double-chamber pumping unit 11 and single-pressure valve assembly 117, parts are positioned for initiation of the systolic or blood expulsion phase after the unit has been surgically implanted with the blood chambers thereof filled. Air cylinders 55 and 59 and blood pistons 67 and 85 are in the fully retracted position, and main spool 122 is so positioned within bore 137 that supply air from line 14 flows past stem portion 138b, through passage 145 (FIG. 9), through air line 134 and into passage 94 in pumping unit 11. Passage 94 communicates with the area behind pistons 42 and 43 through passages 99 and 102 (FIGS. 7 and 9). With air cylinders 55 and 59 fully retracted rods 52 and 54 respectively thereon are relatively positioned so that supply air also passes from passage 94 through port 110 in rod 52 past portion 95 or rod 54 and into tube 106 which is within the air pulse line 132 leading back to valve assembly 117. In returning to the valve assembly the air passes through pulse jet tube 152, around stem portion 144c of reversing spool 125 and through passage 153 to the front of piston 124 of main spool 122.

The pulse of air returning through line 132 must be of sufficient pressure and duration to initiate shifting main spool 122 of valve assembly. In the illustrated form of the invention initial shifting of the spool is accomplished if the pulse has a pressure within the range of approximately 1.5 to 3 psi. and lasts for a period of at least approximately 0.05 seconds.

Pulse jet tube 152 and associated vent 151 serve to regulate the duration of the air pulse applied to piston 124. As seen in FIG. 8, the nozzle end of jet tube 152 is positioned at the inner end of vent tube 151. As the air pulse or signals passes through the jet tube a portion of such air is transmitted to passage 153 and a portion is bled through vent tube 151. For correct operation of valve assembly 117 at initiation of systole the duration of a pulse transmitted to the piston of main spool 122 when spools 52 and 54 are in appropriate registry in the totally retracted position, must be restricted so that the pulse will be fully exhausted when reversing spool 125 has been displaced from the position shown in FIG. 9. Also, pulse duration must be restricted for smooth operation of the valve assembly as will be described. The same considerations apply at initiation of diastole (retraction) when rods 52 and 54 are fully extended. With jet tube 152 and vent tube 151, the pulse is regulated so that shifting of main spool 122 is initiated but excessive pulse air will not be permitted to remain in the pulse line 132 to create a false pulse prior to total extension or retraction of rods 52 and 54 and cause untimely shifting of main spool 122. The position of the nozzle end of jet tube 152 relative to vent tube 151 controls the degree of bleeding or venting 151 and thus the duration of the pulse, i.e., greater bleed occurs when the end of jet tube 152 is aligned with signal vent 151 than when the end of the jet tube is positioned slightly beyond the signal vent.

The pressure of the pulse leaving pumping unit 11 is dependent on the working pressure required to cause movement of blood pistons 67 and 85. Also, the volume of a pulse from a single-chamber pumping unit

having one half the volume of the unit of FIG. 9 would be less than that of the double-chamber unit pulse if no means were provided for adjusting the pulse. The duration of a pulse required to initiate shifting of main spool 122 is fixed. It is therefore desirable that the positioning of pulse jet tube 152 be adjustable to different positions for the single or double chamber pumps so that the appropriate pulse is provided for main spool shifting independent of the working pressure and volume required for movement of air cylinders 55 and 59 and blood pistons 67 and 85.

The course of the air for driving pumping unit 11 and also the pulse air may be followed in detail with reference to FIG. 9. Upon transmission of air pulse through passage 153, shifting of main spool 122 is initiated and communication between supply line 14 and passage 145 leading to air line 134 is obstructed by land 139c of the main spool. Upon further displacement of main spool 122, passage 145 is opened to exhaust passages 157, 158 and 159, and thereafter supply line 14 communicates with air line 131 as a result of displacement of land 139b to a position as shown in FIG. 10. When main spool 122 has shifted to the point where supply line 14 is in communication with the line 131 the directions of flow of the air utilized to drive pumping unit 11 (full line arrows in FIGS. 9 and 10) are reversed from that shown in FIG. 9. The total shifting of main spool 122 is aided by transmitting a portion of the air exhausting from passage 145, through passage 157 to the back of piston 123. Upon reversal of flow, air is transmitted from line 131 through tube 105 and bore 93 within pumping unit 11 to the area in front of pistons 42 and 43 for initiating extension of air cylinders 55 and 59 and blood pistons 67 and 85. When supply air from line 14 communicates with line 131 it also is transmitted to passage 150 leading to the back of piston 126 of reversing spool 125 for shifting same.

After exhaustion of the pulse to piston 124 a succeeding pulse cannot be generated until rods 52 and 54 are fully extended during extension of air cylinders 55 and 59 and the rods thereon. Pulse air from bore 93 (broken line arrows) is obstructed from flowing through pulse line 132 by rod 52 until rods 52 and 54 are extended so that passage 104 in cylinder rod and port 110 in rod 52 are in registration (FIG. 10) and air entering the interior of rod 52 therefrom communicates with port 111 in rod 52 and then to pulse line 132 through tube 106. When reversing spool 125 is shifted to the position shown in FIG. 10 pulse line 132 communicates with passage 154 leading to the front of piston 123 of main spool 122 so that when a pulse is transmitted therethrough at full extension of air cylinders 55 and 59 and rods 52 and 54 reversing of main spool 122 is initiated.

As main spool 122 is displaced in the opposite direction (toward the right in FIG. 10) a corresponding reverse sequence of valving occurs with air line 131 being closed by land 139b and thereafter vented through port 147, passage 148 and port 149. Further reverse shifting of main spool 122 opens supply line 14 to passage 145 communicating with 134, passages 94, 99 and 104 and the area behind pistons 42 and 43 to initiate retraction of cylinders 55 and 59. Air also is transmitted through passage 146 to the front of piston 126 of reversing spool 125 for causing reverse shifting of spool 125. The retraction phase, i.e., diastolic phase is completed when the air cylinders 55 and 59 and blood pistons 67

and 85 are completely retracted. The cycle is continuously repeated.

As has been described, upon initial displacement of spool 122 during the systolic or extension phase, line 134 receiving air from supply line 14 is closed from the supply line before the line 131 which is exhausting through passage 147 is closed from atmosphere. Also, the line 134 is vented to atmosphere prior to introduction of supply air to line 131 for reversing movement of air cylinders 55 and 59 and blood pistons 67 and 85. Thus, the supply air line is allowed to bleed prior to the point of reversal of blood piston movement and the effect is to yield a smoother transition between extension and retraction of the air cylinders and blood piston resulting in softer handling of blood within a blood chamber.

A noteworthy feature of pumping unit 11 is the means for controlling the relative position and relative motion of blood pistons 67, 85 and air cylinders 55, 59 to yield an artificial heart having more of the attributes of a natural heart, than heretofore. As seen in FIG. 3 the only point of contact between an air cylinder 55, 59 and an associated blood piston 67, 85 relating movement of the cylinder to that of the piston is provided by the contact of the front face of the air cylinder with the opposed peripheral shoulder 82 on the blood piston during the extension phase. However, when air cylinders 55, 59 and blood pistons 67, 85 are fully retracted a clearance space normally exists between the faces thereof. Clearance space of the order of 0.005 inch also exists between the opposed cylindrical surfaces of the air cylinder and blood piston and such space communicates with the space between the cylinder and piston faces and also with the area defined between a ring 46, 47 and plate member 30, which is, in turn, vented to atmosphere. The volumes of the clearance spaces are such that during initial extension of the air cylinder the force for extending the blood piston is transmitted through an air cushion, as the restricted clearance around the air cylinder does not permit instantaneous bleeding of the air from in front of the cylinder. However, the clearance is sufficient to enable total bleeding by the time the air cylinder is fully extended so that contact between the faces of the cylinder and blood piston is assured. The air cushion causes the blood piston to begin extension in a soft manner with the highly beneficial result that blood contacting the piston will be subjected to less turbulence and abuse than otherwise.

During the retraction or diastolic phase, chamber filling is a function of venous pressure and volume as in the case of the natural heart. The volume of blood drawn into the blood chamber defined between the walls of case member 17, 18 and associated blood piston 67, 85 depends on the degree of separation between blood piston and air cylinder 55, 59 at complete retraction of the air cylinder, and the degree of separation is, in turn, dependent on the differential in pressure within the blood chamber and in the area between the faces of the air cylinder and blood piston. At the beginning of the retraction phase (diastole) blood chamber pressure is the same as initial filling pressure, so that a blood piston 67, 85 is urged to retract by initial pressure and the air cylinder 55, 59 is retracted by supply air at the working pressure of approximately 5-8 psi. The greater the duration of initial filling pressure and volume the lower will be the pressure differential, and the spacing between blood piston and air cylinder will be closer so that there will be greater blood filling

volume. Correspondingly, a lower initial pressure and volume results in a greater separation between blood piston and air cylinder and therefore a lower filling volume.

By increasing clearance between a blood piston 67, 85 and its associated air cylinder 55, 59, displacement of the blood piston is rendered less dependent upon displacement of the driven air cylinder during retraction and more sensitive to and dependent on available blood volume, which is the desired result. During retraction, resilient blood piston sealing ring 59, 86 exerts retracting pressure on its associated blood piston on the order of 3–5 mm. Hg., which pressure is sufficient to fully retract the blood piston in the absence of any pressure differential between the blood chamber and the space between the blood piston and air cylinder. Since the blood piston sealing ring assists in retraction, the clearance between blood piston and air cylinder can be increased. However, excessive clearance is avoided as it is desired to have restricted venting of air around the air cylinder for obtaining the cushioning effect discussed above.

A modified form of blood piston sealing ring 277 is illustrated in FIG. 22. Ring 277 has T-shaped portions 278 and 279 corresponding to portions 72 and 74 of ring 69 shown in FIG. 6 for seating the ring in the pumping unit. Portions 278 and 279 are sealingly secured in place by retaining rings 281, 282, respectively. The modified form of ring exhibits a rolling action similar to that of ring 69 and presents a concave surface to the blood in the blood chamber. The concave surface resulting from the cross sectional configuration of modified ring 277 is believed to provide a favorable surface for support of blood tissue growth during operation of the heart pump.

FIG. 21 is a graph showing the relationship between venous pressure and blood chamber volume for pumping unit 11 having a maximum blood chamber volume at complete retraction of the blood piston, of approximately 100cc., the solid line showing the relationship at 60 beats per minute, and the broken line showing the relationship when the pumping unit is operating at 120 beats per minute. It can readily be seen that the pumping elements of this invention inherently yield a Starling effect in a highly simplified manner without the need for additional venous pressure sensing or pressure control means.

Double-acting air cylinders 55 and 59 are driven by supply air from line 14 for urging blood pistons 67 and 85 outwardly and for permitting the blood pistons to retract inwardly as a result of a pressure differential, so that little or no filling pressure is required to initiate blood chamber filling. In fact, during blood piston retraction there may be a degree of minor negative blood chamber pressure. The ability of the pumping unit to function in the absence of appreciable filling pressure distinguishes this invention from conventional heart assist or replacement devices and is an important advantage. The embodiment of double-chamber pumping unit 11 shown in FIG. 3 will not cease operation until, for example, blood chamber negative pressure reaches approximately 3 mm. Hg. at a beat rate of 70–75 strokes per minute. Inherently, the heart pump of this invention will cease functioning when there is excessive outflow restriction or inflow blockage respectively requiring an expulsion pressure or a filling suction exceeding the capability of the pumping unit. For example, FIG. 11a shows the positions of blood piston 67

and air cylinder 81 in a partial stall condition during blood filling which results when filling blood pressure drops below a critical negative pressure when the blood piston is in mid-stroke. FIG. 11b illustrates a total stall condition with blood piston 67 and air cylinder 81 at maximum separation occurring when blood volume and negative blood pressure available at the blood chamber are inadequate to initiate retraction of blood piston 67 for blood filling.

The aorta has a greater internal fluid pressure than the pulmonary system and offers two to three times more resistance to introduction of blood from pumping unit 11. Therefore, when the same working pressure is applied to cylinders 55, 59 the rate of extension of the blood pistons expelling blood to the pulmonary artery, having the lesser pressure, will be more rapid than the rate of extension of the blood piston on the aortic side. However, it is essential for generation of a constant heart beat rate that both blood pistons remain synchronous. Such result is assured by the construction of pumping unit 11 since an air pulse is transmitted through pulse line 132 from the pumping unit to the control assembly 117 for triggering initiation of travel of blood pistons 67, 85 only after both rods 52 and 54, air cylinders 55 and 59 and blood pistons 67 and 85 have completed their travel and rods 52 and 54 are either fully extended or retracted for registration of the ports thereof to pass the pulse of air. The blood piston expelling blood to the pulmonary artery completes extension before the aortic piston but initiates reverse travel at the same time as the aortic piston.

Arterial pressure most affects the rate of blood piston reciprocation, or beat rate, in that excessive arterial pressure decreases the piston extension rate. Similarly, marginal filling fluid volume and pressure results in decreased chamber filling. Since both blood pistons being withdrawal or extension at the same time any effective influence on the beat rate of one chamber will affect that of the other chamber to precisely the same degree.

The simplified, flexible thin walled construction of the three leafed inlet valves 120 and outlet valves 170 is such that virtually imperceptible pressure, approaching 0 mm. Hg. for the inlet valve and 5–8 mm. Hg. for the outlet valve, is required for flexing to open. The inlet valve requires only 3–5 mm. Hg. to close, and the outlet valve 0 mm. Hg. to close. The valves therefore, offer light resistance to blood flow. The slight flexing action required for operation of the valves results in highly reliable valve performance and soft handling of the blood passed therethrough. The valves 120, 170, represent a substantial improvement over flapper or ball and cage type valves in such respects and in the virtual elimination of blood regurgitation and fluid column shock. The flexing action also serves to clean the blood from the downstream surfaces of the valves.

The operation of single-chamber pumping unit 21 with valve assembly 117, as illustrated in FIGS. 17 and 18 is similar in virtually all respects to the operation of the double-chamber pumping unit 11 and therefore will not be described in detail. One difference in operation is the use of a stationary inner rod 249 in place of a movable rod such as rod 54 of pumping unit 11 for co-operating with the outer rod 234 to permit the transmission of an air pulse through line 132 only at full retraction or extension of air cylinder 257. As shown in FIG. 17 the air pulse required for initiating displacement of main spool 122 and triggering extension of blood piston 262 for blood expulsion is transmitted

only when the rod 234 is completely retracted. Supply air from air line 131 is transmitted through passage 256 in cylinder 232, through a passage 269 and through a port 272 in reduced diameter portion 248c of rod 234 in registry with passage 269 and opening into central bore 247 within the rod. The air then passes through a port 273 in the reduced diameter portion 248b in registry with the end of pulse line 132. As shown in FIG. 18, at complete extension of air cylinder 257 the air pulse is transmitted to pulse line 132 through a circuit comprising line 131, passage 254 in cylinder 232, bore 247 therein and port 273 communicating with the end of pulse line 132. Use of the stationary rod 249 avoids air leakage and possible false pulse since there is no perceptible pulse air around the rod.

In operating single-chamber pumping unit 21 requiring one-half the volume of working air than required for the double-chamber unit 11, the positioning of the nozzle end of signal jet 152 (broken line in FIG. 8) is at a point slightly beyond pulse vent 151, so that less pulse air is bled through the vent. This adjustment assures that the pulse transmitted to control assembly 117 has the duration required for correct operation, since the pulse requirements are independent of the working air requirements of the pumping unit.

The dual-pressure valve assembly 201, operates with either a single or double-chamber pumping unit similarly to valve assembly 117, except that the pressure applied to air cylinders 55 and 59 (or 257) during the diastolic or filling phase is maintained low relative to the pressure during the systolic or expulsion phase. For example, a practical pressure applied during the diastolic phase is approximately 5-8 psig. and the pressure during systole is approximately 20-25 psig. As has been described, the application of different pressures for each phase effects control of the time required for completing the stroke. Thus, when the working pressure of 20-25 psig. is applied during systole and 5-8 psig. during diastole at a beat rate of 100 beats per minute, systole occurs during thirty per cent of the total cardiac cycle closely approximating the relationship found to exist in the human heart. With such time relationship, a plot having coordinates representing time and blood chamber pressure closely resembles the time-pressure signature displayed by the human heart. There is thus provided an artificial heart pump highly simulative of the natural heart.

In FIG. 12 parts of dual-pressure control assembly 201 are positioned as at completion of the systolic phase during which air regulated by pressure regulator 213 is transmitted through air line 131, through passage 93 and into the areas behind the pistons 42 and 43 of air cylinders 55 and 59. Since the air cylinders are fully extended, the rods 52 and 54 respectively thereon are positioned to allow passage of the pulse through pulse line 132 past reversing spool 203 and to the front of piston 205 of main spool 202 for causing displacement of the spool. Main spool displacement effects venting of air through line 131 and passage of air through pressure regulator 216 in branch passage 215, past portion 207b of main spool 202, through line 134 and passage 94 to the area behind the pistons 42 and 43 for causing retraction of air cylinders 55 and 59. Pressure regulator 216 maintains the air pressure in such air circuit during diastole at the desired low pressure relative to systole pressure, for lengthening the time of the diastolic phase and obtaining a time-blood pressure signature closely approximating that of the human heart.

The operation of valve assembly 230 (FIG. 23) utilizing three different working pressures corresponds to that of dual pressure valve assembly 201, except that during the systolic phase as shown in FIG. 23, air regulated by pressure regulator 294 is transmitted past stem portion 291b of spool 286, through line 298, port 105a and passage 93a and to the front of piston 42 only for causing extension of the one cylinder 55. Extension of cylinder 59 occurs when air separately regulated by pressure regulator 292 is transmitted past stem portion 291a, through line 299, port 105b and passage 93b to the front of piston 43.

Cylinder 55 is associated with the blood chamber replacing the left ventricle and the air pressure applied thereto is higher than that applied to cylinder 59. Typical working pressure values which yield desired operation of pumping unit 11 and closer simulation of the natural heart function are 5-8 psig. to both cylinders during diastole, and, during systole, 17-20 psig. to cylinder 55 and 10-12 psig. to cylinder 59.

It is to be understood that the claims appended hereto are intended to cover all changes and modifications of the examples herein chosen for purposes of disclosure which do not depart from the spirit and scope of the invention. For example, the total system may be adapted for implantation and may be powered by a nuclear energy source instead of the gas pressure source shown. Moreover, additional variations encompass rotational electric drives, solenoidal electric drives and steam mechanical drives for the reciprocating cylinders.

I claim:

1. A heart pump, comprising:

- a. a housing;
- b. a blood pumping element mounted in said housing for opposed systolic and diastolic displacement relative to a portion of said housing and defining with said portion a blood chamber;
- c. inlet means and outlet means communicating with said chamber;
- d. drive means in said housing having an independent, predetermined driving period;
- e. means substantially associating said drive means with said pumping element during said period for effecting systolic displacement of said element; and
- f. said drive means being substantially disassociated from said pumping element during diastolic displacement, whereby diastolic displacement of said element is substantially directly related to blood pressure and volume presented at said inlet means.

2. The heart pump of claim 1 in which:

- g. a pair of said blood pumping elements and a pair of portions of said housing define a pair of blood chambers;
- h. a pair of said drive means, each associated with one of said elements, having the same driving period.

3. The heart pump of claim 1, including:

- g. means yieldably urging said element in the direction of diastolic displacement.

4. The heart pump of claim 1, in which:

- g. said driving period includes extension and retraction; and
- h. means temporarily associating said drive means with said element during the initial portion of retraction for initiating diastolic displacement of said element.

5. The heart pump of claim 1, including:

- g. means temporarily cushioning the association of said drive means with said element during the initial portion of said driving period.
6. An implantable heart pump, comprising:
- a. means defining at least one blood chamber;
 - b. blood inlet means for each said chamber;
 - c. blood outlet means for each said chamber;
 - d. a housing for pump components;
 - e. each said blood chamber partially defined by an associated portion of said housing;
 - f. a blood pumping element associated with each said chamber and defining a portion thereof;
 - g. each said pumping element being adapted for variable reciprocating displacement relative to said associated portion of said housing along a path of displacement;
 - h. each said pumping element including within said housing venous blood response means for directly relating said displacement to blood pressure and volume presented at said blood inlet means associated therewith whereby the volume of blood filling of said chamber inherently is responsive to the blood volume and pressure so presented;
 - i. sealing means associated with each said blood chamber between said portion of said housing and said pumping element;
 - j. said pumping element having a wall with a first surface for contacting blood in said blood chamber and an opposite second surface sealed from said first surface by said sealing means;
 - k. cylinder means adapted for reciprocating displacement along said path and having a surface in opposed relation to said second surface of said wall;
 - l. drive means for imparting said reciprocating displacement to said cylinder means;
 - m. said pumping element and said cylinder means being operably connected such that they are displaceable relative to each other and also are adapted for displacement together.
7. The implantable heart pump of claim 6, wherein:
- n. said drive means for said cylinder means is responsive to displacement of said cylinder means.
8. The implantable heart pump of claim 7, wherein:
- o. said drive means is a gas actuated means.
9. An implantable heart pump, comprising:
- a. a housing;
 - b. a blood chamber partially defined by a portion of said housing;
 - c. a blood inlet for said chamber;
 - d. a blood outlet for said chamber;
 - e. a blood pumping piston defining a portion of said chamber and being adapted for reciprocating variable displacement relative to said portion of said housing along a path of displacement;
 - f. resilient sealing means between said portion of said housing and said piston;
 - g. means in said housing for rendering the displacement of said piston relative to said portion of said housing dependent on the volume and pressure of blood presented at said blood inlet means for filling of said chamber;
 - h. said piston having a hollow portion opening away from said chamber in the direction of said path of displacement;
 - i. a double acting gas cylinder located within said hollow portion and displaceable along said path for initiating said displacement of said piston;
 - j. a source of gas under pressure;

- k. a gas conduit between said source and portions of said gas cylinder;
 - l. a gas control assembly interposed between said gas cylinder and said gas source for directing said gas to different portions of said gas cylinder for alternately initiating forward and reverse displacement of said gas cylinder;
 - m. said cylinder and said control assembly being operatively connected such that the initiation of displacement of said gas cylinder is responsive to positioning of said gas cylinder along said path.
10. The implantable heart pump of claim 9, including:
- n. a stationary rod extending axially within said cylinder and having gas passages therein;
 - o. a central bore in said stationary rod;
 - p. a central rod within said bore and fixed to said cylinder for displacement therewith and having gas passages therein;
 - q. said passages in said stationary rod and in said central rod being alignable according to said positioning of said cylinder for passage of gas from said source for initiation of said displacement of said cylinder.
11. The implantable heart pump of claim 9, wherein:
- n. said piston and said cylinder have opposed surfaces with clearance space therebetween; and
 - o. said clearance space is in communication with atmospheric air.
12. The implantable heart pump of claim 9, wherein:
- n. said gas control assembly includes:
 - 1. a valve body having gas passages therein;
 - 2. a main spool means seated within said valve body for displacement under urging of said gas for controlling passage of said gas through said passages to said main spool means for initiating displacement thereof;
 - 4. said cylinder and said control assembly being operably connected such that passage of said gas from said reversing spool to said main spool is responsive to displacement of said cylinder.
13. The implantable heart pump of claim 9, wherein:
- 1. said resilient sealing means has a fixed connection with said portion of said housing and with said piston.
14. An implantable heart pump, comprising:
- a. a rigid pump case;
 - b. a variable displacement blood piston in said case;
 - c. means for displacing said blood piston;
 - d. a blood inlet valve and a blood outlet valve mounted in said case respectively for passage of blood thereinto upon retraction of said piston and therefrom upon extension of said piston;
 - e. a control assembly for alternately initiating extension and retraction of said piston;
 - f. means for generating a signal within said case;
 - g. said control assembly initiating said displacement of said piston responsive to transmission of said signal from within said case;
 - h. the distance of displacement of said piston being dependent upon the volume and pressure of blood presented at said blood inlet valve; and
 - i. movable means at the proximal side of said piston for displacement in the direction of displacement of said piston and relative thereto, said transmission of said signal to said control assembly being dependent upon the position of said movable means.

23

15. In an implantable heart pump including at least one variable displacement blood pumping piston and a gas driven means for alternately initiating systolic and diastolic displacement of said piston, gas control means, comprising:

- a. a first circuit for gas for driving said gas driven means;
- b. a second circuit for conducting gas pulses transmitted from said gas driven means when said means is in positions for initiating said systolic and diastolic displacement of said piston;
- c. a displaceable main spool interposed in said first and second circuits for directing driving gas to said gas driven means;
- d. a displaceable reversing spool interposed in said first and second circuits for alternately directing said pulses to opposite ends of said main spool for causing reciprocation of same whereby driving gas is alternately directed by said main spool to different portions of said gas driven means for alternately initiating said systolic and diastolic displacement of said piston.

16. The control means of claim 15, including:

24

- e. pressure regulating means for regulating gas pressure in said first circuit such that the pressure of gas applied to said gas driven means during systolic displacement of said piston is higher than the pressure of gas applied during diastolic displacement.

17. The control means of claim 15, including:

- e. adjustable nozzle means in said second circuit for adjusting the duration and pressure of said gas pulses.

18. The control means of claim 15, for use in said implantable heart pump having two variable displacement blood pumping pistons and associated gas driven means, including:

- e. a first portion of said first circuit for gas for driving one of said gas driven means;
- f. a second portion of said first circuit for gas for driving the other one of said gas driven means;
- g. pressure regulating means in said first circuit for separately regulating the pressures of gas in said first and second portions whereby different pressures are applied to each of said gas driven means during systolic displacement of said pistons.

* * * * *