

[54] **VENTRICLE ASSEMBLY FOR PULSATILE-TYPE PUMP**

[75] Inventor: **Donald J. Bentley**, Newport Beach, Calif.

[73] Assignee: **Bentley Laboratories, Inc.**, Irvine, Calif.

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[63] Continuation of Ser. No. 171,924, Aug. 16, 1971, abandoned.

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[58] Field of Search **128/1 R**, 1 D, 3, 214 R; 3/DIG. 2; 137/525.1; 417/389, 383, 394, 474, 478, 567

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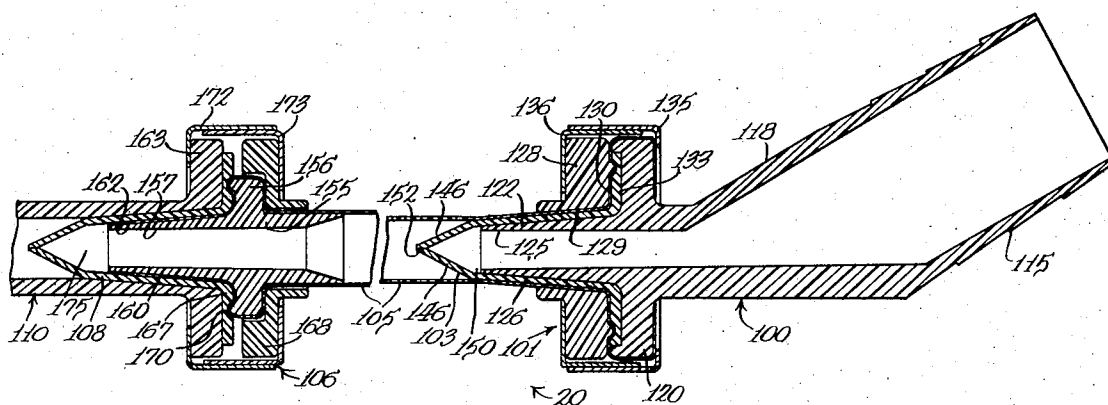
Primary Examiner—Aldrich F. Medbery
Attorney, Agent, or Firm—Lyon & Lyon

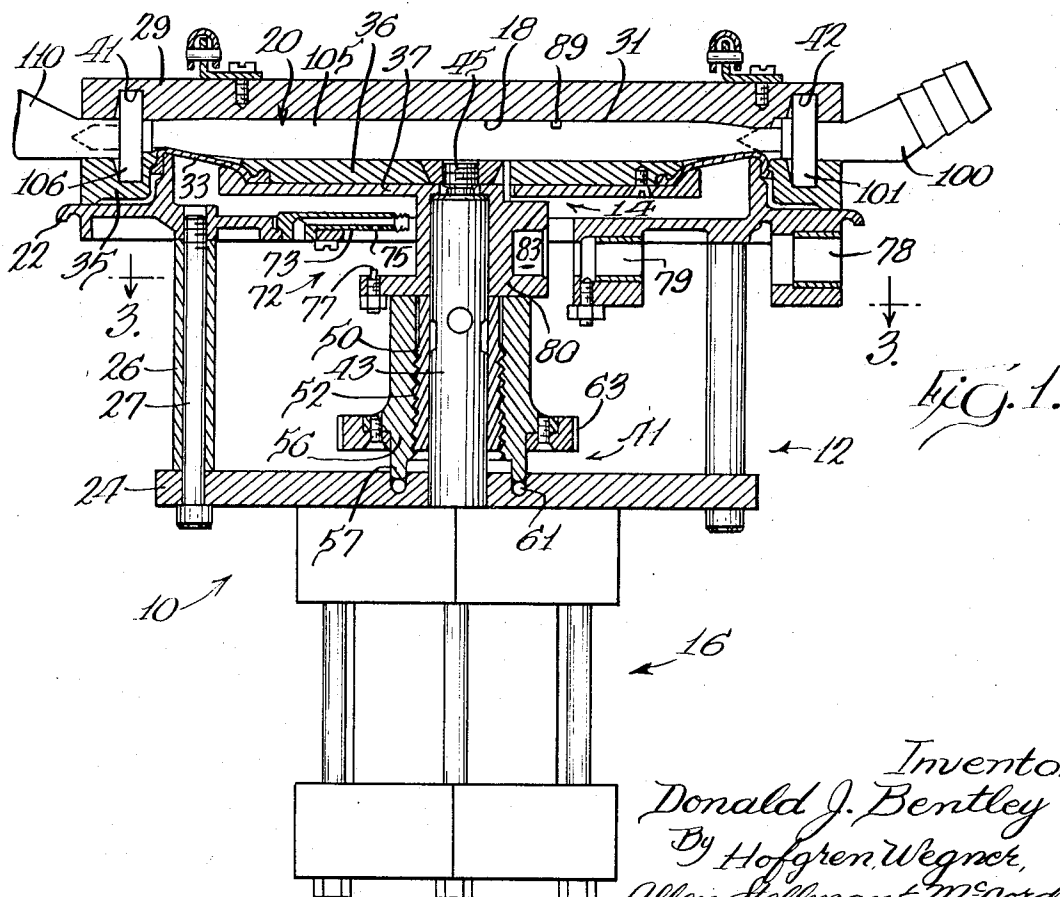
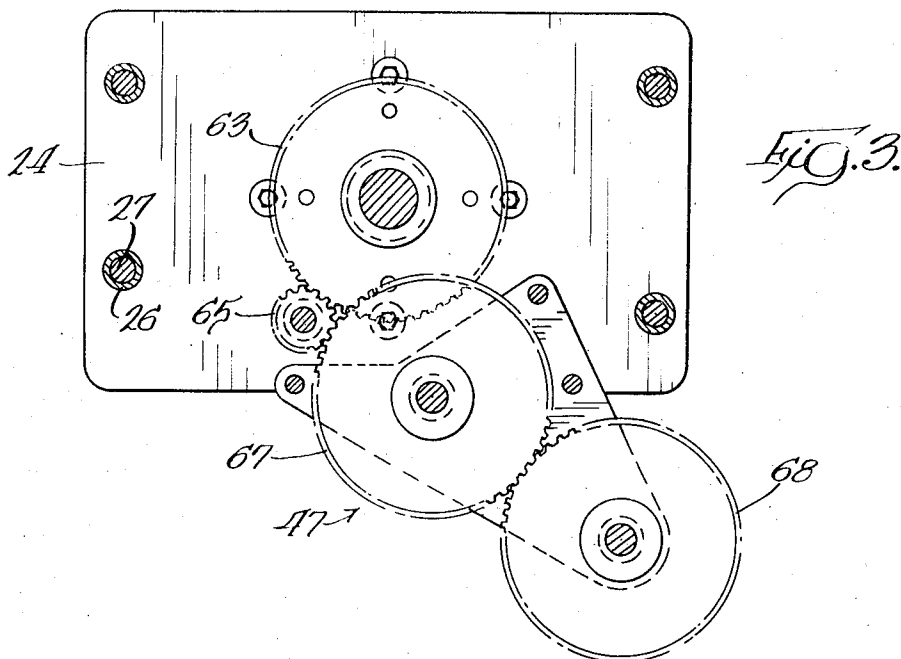
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ABSTRACT

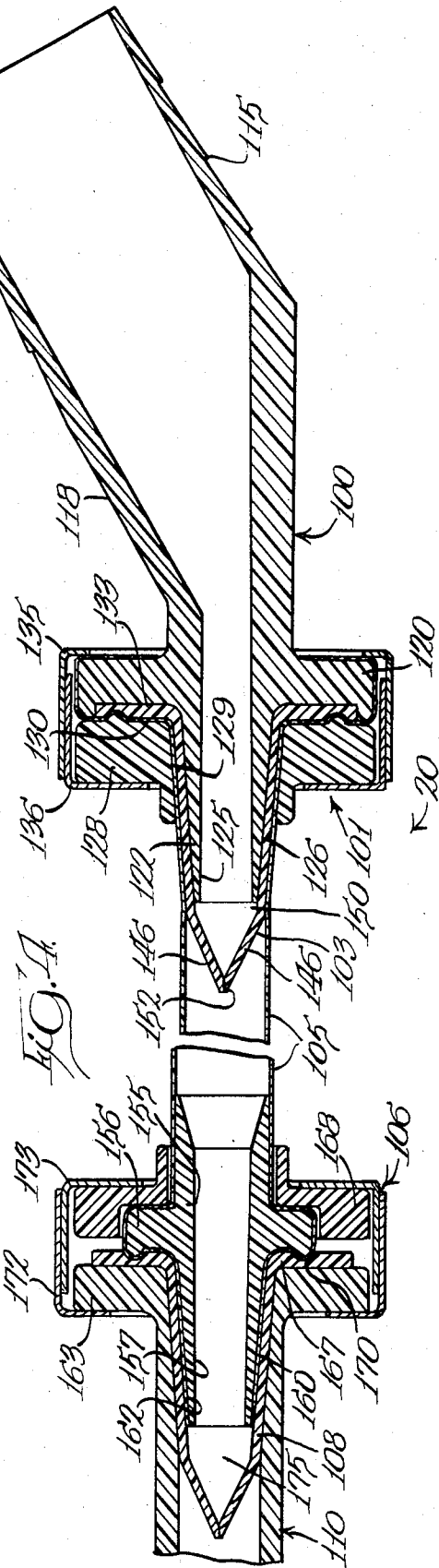
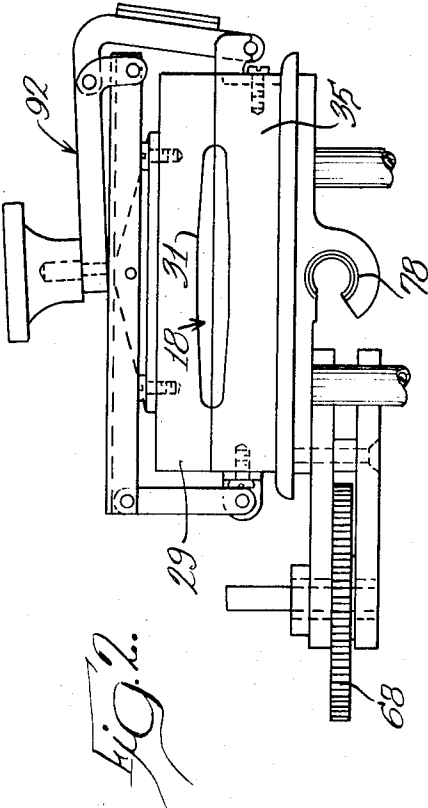
A pulsatile blood pumping assembly having a diaphragm reciprocable in a chamber that receives a disposable ventricle assembly having an inlet fitting that communicates with an elongated leaflet inlet valve having a hydraulic radius approximately equal to the inlet fitting, an extremely flexible ventricle having one end surrounding and closely engaging the inlet valve and the other end communicating with an elongated leaflet outlet valve, both of the valves having a small height compared to their width.

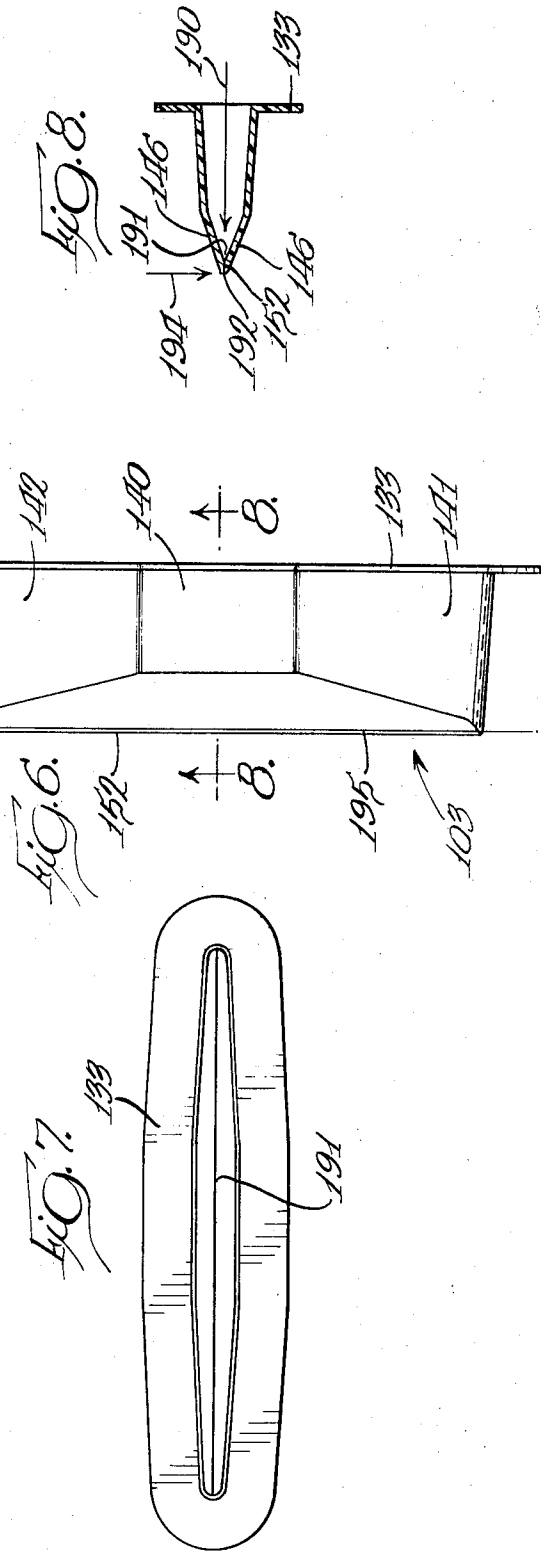
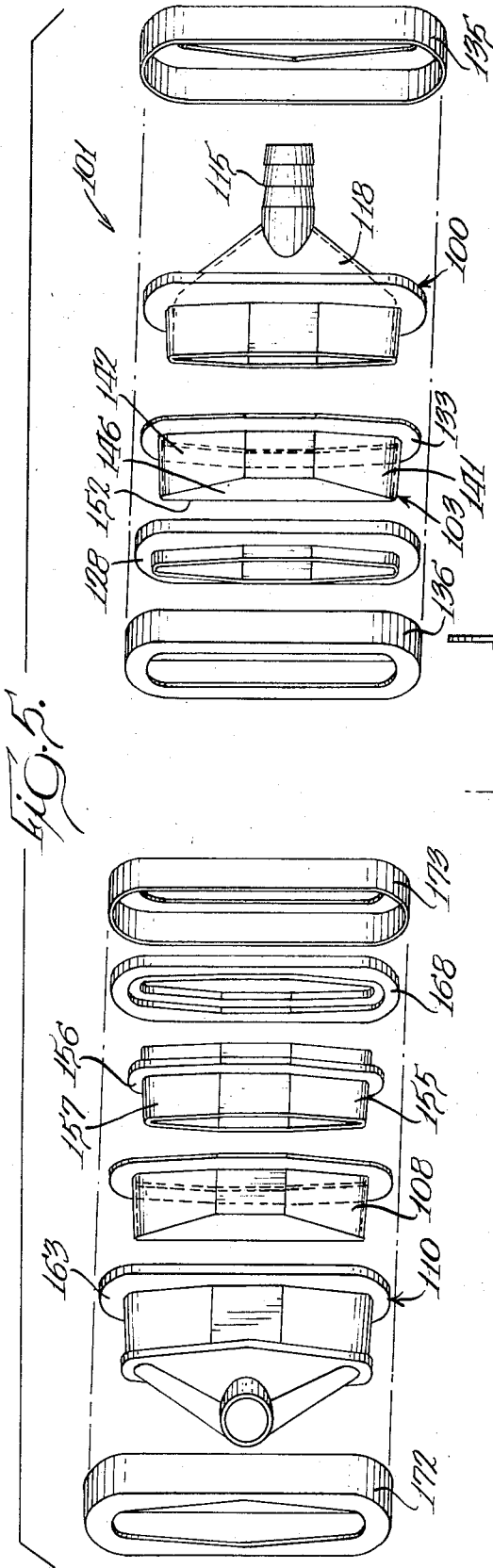
23 Claims, 8 Drawing Figures





Inventor:
 Donald J. Bentley
 By Hofgren, Wegner,
 Allen, Hellman & McCord
 Attys





VENTRICLE ASSEMBLY FOR PULSATILE-TYPE PUMP

This is a continuation, of application Ser. No. 171,924, filed Aug. 16, 1971 and now abandoned.

BACKGROUND OF THE PRESENT INVENTION

Extracorporeal Extracorporeal pumping has achieved a considerable amount of success, particularly in vascular surgery. Until recently the pumping mechanisms have delivered blood by occluding a tube and squeezing the blood in the tube from it, and these devices have come to be known as "finger pumps" which squeeze tubes progressively between an anvil and some movable fingers. This type of pump is no longer in general use.

There were several early attempts to utilize moving diaphragms to pump blood in what has come to be known as a pulsatile-type pump, but for one reason or another these attempts were never successful. In recent years, most extracorporeal blood pumping has been accomplished by a pump known as a roller pump, which consists of a suitable circular raceway in which a piece of flexible plastic tubing is positioned with a roller rotating in such a fashion to squeeze the tube progressively around the circumference of the raceway. The idea of using a piece of tubing as the pumping means has been popular not only because it is a simple method of isolating the blood being pumped from all other portions of the mechanism, but also because the tubing is disposable. In the design of roller pumps there has, however, been little consideration given to the trauma produced by the pump. Moreover, with the exception of the early pulsatile pumps, present day roller pumps produce relatively unvarying pressure and, therefore, are not pulsatile. It has been demonstrated that since the pumping action of the heart itself is pulsatile, there is a disadvantage in non-pulsatile perfusion of the body.

For this reason, pulsatile pumps have just recently achieved some acclaim. There are several reasons for this success, one being that the pulsatile flow is more metabolic. Moreover, with pulsatile flow it appears that peripheral perfusion is vastly improved over a continuous unvarying blood flow system.

However, the valving in these prior pulsatile pumps has continued to produce a significant amount of trauma to the blood, even though less than other forms of blood pumping devices.

Many of the pulsatile pumps that have been constructed have a tightly stretched diaphragm contained between two rigid parts with one side of the diaphragm being the blood side and the other side being the power-operated side. The power supplied to this type of pump has generally been some type of fluid, either gas or liquid. This type of construction leads to several problems. Firstly, any leaks in the diaphragm tend to contaminate the blood and, therefore, its safety is questionable; secondly, the ability to pump is dependent upon the ability of the diaphragm to return to its original position and eject the power fluid from the chamber allowing the blood to fill. Therefore, the pulse rate is very slow and its output limited. Moreover, since the ejection of the power fluid is dependent upon the resiliency of the membrane, it follows that this is a modified sucking-type pump which creates a negative pressure which in itself is not metabolic.

In some of these pumps, the valving, such as ball valves, are quite traumatic to the blood, crushing erythrocytes and causing a significant amount of hemolysis. Moreover, ball valves have a considerable inertia and, therefore, the opening and closing pressures are high. Other types of valves have been tried, but each has had many disadvantages and, therefore, have not been successful.

Leaflet-type valves have been known in the past, but these have been provided with circular inlets or circular tubing with the end of the tube pinched to form the leaflet valve. This simple configuration will act as a valve, but it has many drawbacks, one being because of the length of the first portion at the end of the tube, its resistance to flow is high. Moreover, since a rigid portion must be provided to hold the tube in a round configuration, the inlet has a much larger cross-sectional area than the more or less flat configuration toward the squeezed end and there is a significant pressure drop across the valve. A still further disadvantage is that since there is a considerable amount of volume around the outside of the flat portion of this prior leaf valve, stasis is created when used with blood. Furthermore, the long flat configuration of the valve tends to make the valve resonate at a particular frequency which would be traumatic to blood flow.

SUMMARY OF THE PRESENT INVENTION

In accordance with the present invention, an atraumatic pulsatile blood pumping assembly is provided having a disposable ventricle assembly insertable therein. The ventricle assembly includes inlet and outlet check valves. An inlet fitting is round and merges into a diverging narrow portion which terminates at the inlet of an elongated leaflet valve. The valve has a width considerably greater than its height with the cross-section approximately equal to the cross-section of the circular portion of the inlet fitting to provide a constant hydraulic radius through the ventricle assembly, reducing the pressure drop across the inlet valve. A suitable clamping assembly is provided for affixing the inlet fitting to the inlet valve.

Surrounding and fixed to the inlet valve is a very flexible polyurethane ventricle that is sufficiently nonelastic so that it imposes no negative pressures on the blood and thus the present pumping apparatus relies on the venous blood pressure for passive filling thereof, reducing hemolysis to the blood caused by prior art "sucking" pumps.

The height of the inlet valve is very small compared to its length and thus requires a very small opening and closing force. Moreover, because of the close engagement of the ventricle with the exterior of the inlet valve, there is very little blood surrounding the periphery of the valve and thus very little stasis in the present ventricle assembly.

At the other end of the flexible central ventricle, an outlet valve is positioned that is similar in construction to the inlet valve, with the outlet valve being positioned within an outlet fitting closely surrounding the valve to minimize stasis as with the inlet valve. Moreover, the outlet fitting converges into a circular fitting portion that has a cross-sectional area equal to that of the valve so that again with the outlet valve there is very little pressure drop thereacross, and the valve opens and closes with very little force.

Further, according to the present invention, a pulsatile pump is provided which provides as close to metabolic flow as possible with the minimum blood damage (hemolysis) and platelet deposition with no fibrin or thrombus formation. Moreover, the physician can vary the pulse rate within the metabolic range, vary the stroke volume and the total perfusion rate to accommodate the patient, and limit the pressure against which the pump will function to avoid damage to the patient under certain conditions. It is also possible to trigger the action of the pump from an external signal, such as a timing device, or the R wave of the patient's EKG waveform.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-section of a pulsatile pump according to the present invention;

FIG. 2 is a right-end fragmentary view of FIG. 1;

FIG. 3 is a cross-section taken generally along line 3—3 of FIG. 1;

FIG. 4 is a cross-section of the ventricle assembly according to the present invention;

FIG. 5 is an exploded view of the ventricle assembly shown in FIG. 4;

FIG. 6 is a plan view of one of the leaflet valves;

FIG. 7 is a view from the inlet side of one of the leaflet valves; and

FIG. 8 is a cross-section taken generally along line 8—8 of FIG. 6 illustrating one of the valves.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the drawings and particularly FIGS. 1, 2 and 3, a pulsatile pump 10 is illustrated consisting generally of a central frame member 12, and a diaphragm assembly 14 reciprocated by a pneumatic or hydraulic cylinder 16 in a chamber 18 enclosing a disposable ventricle assembly 20. The chamber 18 is vented and the diaphragm assembly 14 serves to force blood from the ventricle assembly 20 on its upward stroke and subsequent to the downward stroke of the diaphragm assembly 14, the ventricle assembly 20 fills passively, minimizing hemolysis.

The frame assembly 12 consists of spaced, generally horizontal frame members 22 and 24, rigidly held together and spaced by posts 26 and threaded fasteners 27 extending therethrough. The frame member 22 has pivoted thereto a top plate 29 having a recess 31 for receiving part of the ventricle assembly 20 and also defining a portion of the chamber 18.

The diaphragm assembly 14 includes a flexible member 33 fixed between the support 22 and a retaining ring 35 as shown in FIG. 1. The inner periphery of the flexible member 33 is fixed between plates 36 and 37 which define the other side of the ventricle chamber 18. Note that the top plate 29 and the retaining ring 35 are suitably recessed as shown at 41 and 42 for receiving the clamps of the ventricle assembly 20.

For reciprocating the ventricle assembly 14, shaft 43 is provided having a reduced threaded portion 45 threadedly engaging the diaphragm plate 36. Shaft 43 extends into and is fixed to a piston in the actuator 16.

For the purpose of varying the volume of the pump, the lower limit of travel of shaft 43 is controlled. Toward this end, a stroke control mechanism 47 is provided shown clearly in FIGS. 1 and 3. A bushing 50 is

fixed to shaft 43 and has a threaded portion 52 threadedly receiving stop member 56 having a stop flange 57 engageable with an O-ring 59 seated in a recess 61 at the lower limit of travel of the diaphragm assembly 14 as shown in FIG. 1. The threaded engagement between the stop 56 and the rotatably fixed member 50 provides the necessary axial movement of the stop 56 with respect to shaft 43 upon rotary motion of the stop member 56. To accomplish this, the stop member 56 has integrally formed therewith the gear 63 which is driven through interengaging gears 65 (FIG. 3), 67 and 68. Gear 68 has a shaft 70 projecting therefrom that is accessible from the front panel (not shown) of the instrument for the purpose of adjusting the stroke volume within certain limits, e.g., 0 to 120 ml.

For determining the upper limit of travel of the diaphragm assembly 14, a proximity sensor 72 is provided. The proximity sensor 72 provides a fixed upper limit for the diaphragm 14, which upper limit is below the point where any crushing of the blood cells would occur. Toward this end, the proximity sensor includes a horizontally disposed tube 73 having a vertically disposed aperture 75. Air is supplied to the proximity sensor tube 73 from an associated pneumatic circuit (not shown). When a projection 77 on a shaft fixed member 80 closes aperture 75 upon upward movement of the diaphragm assembly 14, back pressure will be created in tube 73 which provides a signal to the associated pneumatic circuit which shifts an appropriate valve to switch the delivery of fluid to the opposite side of the actuator 16 to drive the diaphragm assembly 14 in a downward direction. The actuator 16 is provided with a suitable cushioning element to cushion the upper limit of travel of the diaphragm assembly 14. Thus, the upper limit of the diaphragm assembly is fixed and the lower is adjustable to vary the stroke volume.

A manual crank assembly is provided for the purpose of operating the diaphragm 14 in the event the control circuit fails for one reason or another. Toward this end, spaced bearings 78 and 79 are provided in frame member 22 which receive a crank element. An eccentric on the crank is adapted to be fitted into a recess 83 on the opposite side of the member 80 from the projection 77.

The initiation of each cycle of the pump 10 may be effected in a plurality of ways. As noted above, the proximity sensor 72 provides a signal which reverses the diaphragm at the top of its stroke. However, the diaphragm 14 remains at rest at the top of its stroke, through suitable control circuitry, until the occurrence of a cycle initiation signal. The cycle initiation signal may be provided by a proximity sensor 89 in the top plate 29. When the ventricle assembly 20 is filled with blood, the proximity sensor 89 will be actuated providing a signal to the control circuitry which initiates the upward movement of the diaphragm assembly 14 forcing blood from the ventricle assembly 20. Another alternative to the cycle initiation by ventricle fill, is a periodic timer which initiates each cycle of the pump assembly 10 upon a predetermined time interval. Such timers are conventional in construction and a detailed discussion thereof is not believed necessary.

As seen in FIG. 2 a suitable handle and toggle linkage 92 is provided for clamping the upper frame member 29 closed against lower frame member 35. This arrangement permits the removal and replacement of the

disposable ventricle assembly 20 described in more detail below.

The ventricle assembly 20 is illustrated in FIGS. 4, 5, 6, 7 and 8 and is seen to consist generally of an inlet fitting 100, an inlet clamp 101, an inlet check valve 103, a flexible ventricle 105, an outlet clamp assembly 106, an outlet valve 108 and an outlet fitting 110. Upon relaxation of the flexible ventricle 105, venous blood under its own pressure opens inlet valve 103 filling ventricle 105 in a passive fashion. After filling of the ventricle, the ventricle 105 is squeezed by the diaphragm assembly 14 opening outlet check valve 108 and expelling blood from the ventricle 105.

The inlet fitting 101 may be constructed of a polycarbonate and includes an inlet portion 115 which is cylindrical in construction, a tapered portion 118, a flanged portion 120 and a valve expander portion 122. As seen in FIG. 5, the tapered portion 118 diverges outwardly to present substantially the same flow area as the cylindrical portion 115. The same thing is true of the valve expander portion 122 which has an elongated aperture 125 therein.

The exterior surface 126 of the valve expander 122 is tapered and receives a clamping element 128 having a tapered surface 129 snugly received on the tapered surface 126 of the valve expander in a manner to squeeze both end 130 of the ventricle 105 as well as the base portion 133 of the inlet check valve 103. For the purpose of securely clamping the clamp member 128 against the flange member 122, elongated metal clamping elements 135 and 136 are provided. Suitable adhesives may be used in the clamping assembly where desired.

The valve member 103 is a silicone rubber, but may be constructed of other plastic materials. As seen in FIG. 5, valve member 103 consists of the base portion 133 from which extend inwardly tapering portions 140 as well as inwardly tapering and laterally converging portions 141 and 142. Formed integrally therewith are tapered surfaces 146 which form the actual valving elements for the valve as seen in FIGS. 4 and 5. An important aspect to the present invention is that the flow area at the inlet 150 to the valve member 103 is approximately equal to or even greater than the flow area presented by any portion of the inlet fitting 100 and thus the check valve 103 does not present any significant resistance to flow.

Moreover, the width of the valve member, or more particularly the width of the valving edges 152 as viewed in FIG. 4, is many times greater than the vertical height of the valve inlet 150 as shown in FIG. 4 making the inlet valve extremely easy to open and close under very low differential pressures.

The closed ventricle 105 is a 5 to 10 ml. polyurethane material which is extremely flexible and has no tendency under its own elasticity to expand to an open position, and for this reason there are no negative pressures imposed on the blood in the present pulsatile pump assembly.

The outlet clamp assembly 106 is similar in configuration and is seen to include a valve expander 155 having a flange 156 therearound and an elongated aperture 157 having a tapered outer surface 160 snugly receiving a tapered inner surface 162 on the outlet fitting 110. The tapered surface 162 along with flange 163 squeezes and clamps both the base 167 of the outlet valve 108 as well as end portion 170 of the left end of

the ventricle 105 sealing the same. Suitable adhesives are applied where desired. For the purpose of clamping the flange 163 to the flange 156, an additional ring member 168 is applied around the right end of the valve expander 155 and flange 156 and serves to receive elongated metal clamping members 172 and 173.

The outlet valve 108 is identical in construction to the inlet valve 103 so that a detailed description thereof is not believed necessary. However, it should be understood that the hydraulic radius at valve outlet 175, due to the configuration and elongation or width of the valve 108, is sufficient so that it is at least as great as any restrictive portions of the outlet fitting 110.

As shown in FIGS. 6, 7 and 8, the valve members 103 and 108 are constructed of a one-piece molding with the valving edges 146 uncut. After the initial molding, the valve is placed in a suitable die and a knife edge is driven in the direction of arrow 190 in FIG. 8 making a cut along line 191 in FIG. 7, but with the cut not going all the way through the material and stopping short of point 192 (FIG. 8). Thereafter, another knife edge cut is made in the direction of arrow 194 in FIG. 8 along line 195 intersecting the cut made in the direction of arrow 190 and opening the valve member and thereby defining the valve surfaces 152. This forms clean sharp edges on the valving surfaces and minimizes trauma to the blood.

I claim:

1. A pulsatile heart pump assembly, comprising: a chamber, means reciprocal in the chamber, a ventricle assembly at least partly in the chamber including an inlet fitting, an elongated leaflet valve wider than the inlet fitting and having a hydraulic radius substantially equal to the inlet fitting in the normally open position of the valve, a ventricle surrounding at one end said inlet fitting and adapted to be filled with blood, an outlet valve at the other end of the ventricle, and an outlet fitting communicating with said outlet valve.

2. A pulsatile heart pump assembly, comprising: a chamber, means reciprocal in the chamber, a ventricle assembly disposed at least partly in said chamber including an inlet fitting, an elongated inlet leaflet valve communicating with said inlet fitting and having a cross section substantially equal to the cross section of the inlet fitting in the normally open position of the valve, a ventricle surrounding said inlet valve and extending in said chamber, an elongated outlet leaflet valve at the other end of the ventricle, an outlet fitting communicating with the outlet valve, and said outlet valve having a cross section approximately equal to that of the outlet fitting, whereby the pressure drop across the inlet and outlet valves is at a minimum.

3. A pulsatile heart pump assembly as claimed in claim 2, wherein said ventricle has no elasticity sufficient to return to the open position to prevent negative pressures in the ventricle assembly.

4. A pulsatile heart pump assembly as claimed in claim 3, wherein said ventricle is constructed of 5 to 10 ml. polyurethane.

5. A pulsatile heart pump assembly as claimed in claim 2, wherein said inlet and outlet fittings have a circular portion and laterally diverging and converging portions, respectively, to increase the hydraulic radius of the fitting.

6. A pulsatile heart pump assembly as claimed in claim 2, wherein said inlet fitting has an elongated

valve expander positioned within the inlet leaflet valve.

7. A pulsatile heart pump assembly as claimed in claim 2, including an elongated valve expander positioned within the outlet valve.

8. A pulsatile heart pump assembly as claimed in claim 2, wherein the inlet and outlet valves have widths substantially greater than their inlet heights.

9. A pulsatile heart pump assembly as claimed in claim 2, wherein the inlet valve has a base portion surrounding and clamped to the inlet fitting.

10. A pulsatile heart pump assembly as claimed in claim 2, wherein the outlet valve projects within the outlet fitting and has a base portion clamped thereto.

11. A pulsatile heart pump assembly as claimed in claim 2, wherein each of the inlet and outlet valves have engageable flat valve surfaces.

12. A pulsatile heart pump assembly, comprising: a chamber, a moveable member in said chamber, a ventricle assembly at least partly disposed in said chamber, including an inlet fitting, an elongated inlet valve communicating with said inlet fitting, a flexible ventricle closely and immediately surrounding said inlet valve to reduce stasis, an outlet valve at the other end of the ventricle, and an outlet fitting communicating with said outlet valve.

13. A pulsatile heart pump assembly as claimed in claim 12, wherein said ventricle directly engages the inlet valve completely around the valve.

14. A pulsatile heart pump assembly as claimed in claim 12, wherein said ventricle is sufficiently flexible so that it has no tendency to open under its own elasticity.

15. A pulsatile heart pump as claimed in claim 12, wherein said outlet valve projects into a transversely elongated portion of the outlet fitting, said outlet fitting engaging and surrounding said outlet valve to minimize stasis.

16. A pulsatile heart pump assembly as claimed in claim 12, wherein said leaflet valves are molded plastic with the valve openings molded closed and thereafter opened.

17. In a pulsatile heart pump assembly having a chamber, pressure producing means in communication with the chamber, a ventricle assembly at least partly in the chamber including an inlet fitting and an outlet fitting, wherein the improvement comprises: an inlet valve communicating with said inlet fitting, and a flexi-

ble ventricle closely and immediately surrounding said inlet valve to reduce stasis.

18. A pulsatile heart pump assembly as claimed in claim 17, wherein an outlet valve communicates with said outlet fitting and projects into a portion of said outlet fitting, said outlet fitting engaging and surrounding said outlet valve to minimize stasis.

19. In a pulsatile heart pump assembly having a chamber, pressure producing means in communication with the chamber, a ventricle assembly at least partly in the chamber including an inlet fitting and an outlet fitting, wherein the improvement comprises: a first valve communicating with one of said fittings and having a cross section substantially equal to the cross section of said one fitting in the normally open position of the valve whereby the pressure drop across the valve is at a minimum.

20. A pulsatile heart pump assembly as claimed in claim 19, wherein a second valve communicates with said other fitting and has a cross section substantially equal to the cross section of said other fitting in the normally open position of the valve whereby the pressure drop across the valve is at a minimum.

21. A pulsatile heart pump assembly as claimed in claim 20, wherein said first and second valves comprise elongated leaflet valves.

22. A ventricle assembly for a heart pump, comprising: an inlet fitting, an elongated leaflet valve wider than the inlet fitting and having a hydraulic radius substantially equal to the inlet fitting in the normally open position of the valve, a ventricle surrounding at one end the inlet fitting and adapted to be filled with blood, an outlet valve at the other end of the ventricle and an outlet fitting communicating with said outlet valve.

23. A ventricle assembly for a heart pump, comprising: an inlet fitting, an elongated inlet leaflet valve communicating with said inlet fitting and having a cross section approximately equal to the cross section of the inlet fitting in the normally open position of the valve, a ventricle surrounding said inlet valve and extending in said chamber, an elongated outlet leaflet valve at the other end of the ventricle, an outlet fitting communicating with said outlet valve, and said outlet valve in its normally open position having a cross section substantially equal to that of the outlet fitting so that the pressure drop across the inlet and outlet valves is at a minimum.

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