

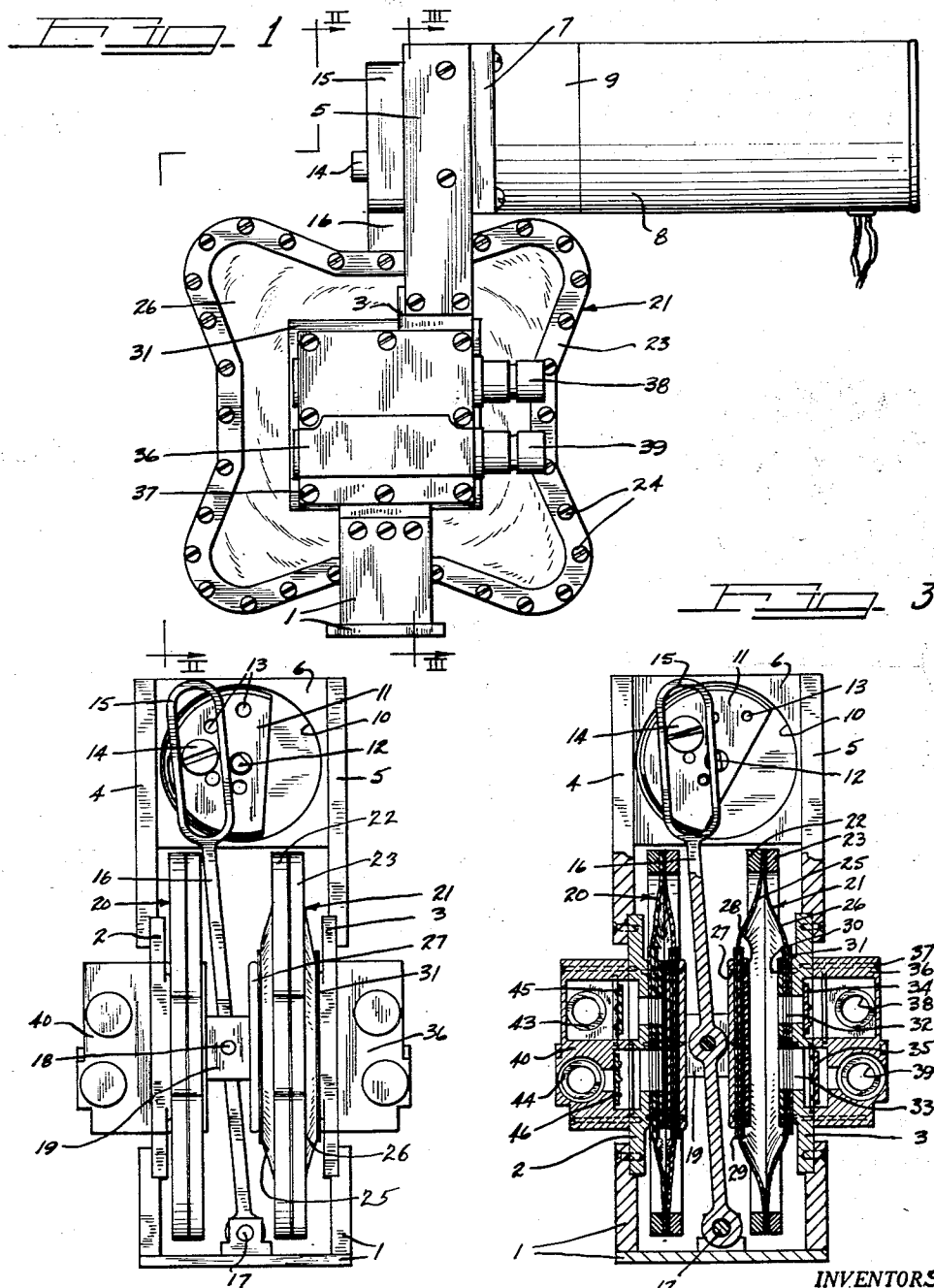
Oct. 13, 1964

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ARTIFICIAL HEART

3,152,340

Filed Nov. 28, 1960

3 Sheets-Sheet 1



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FIG. 4

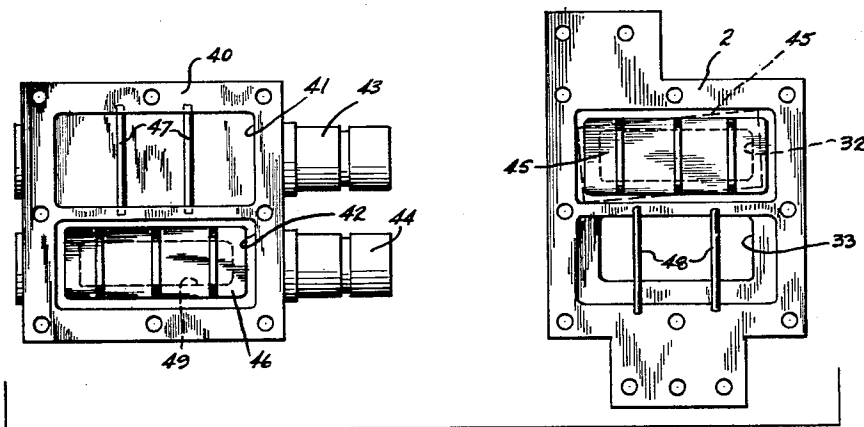


FIG. 5

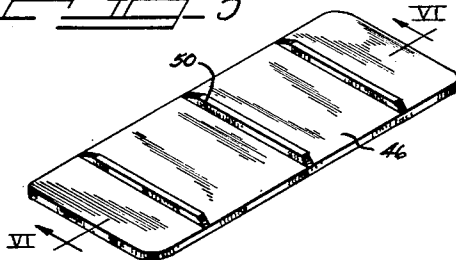


FIG. 6

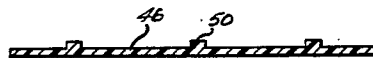
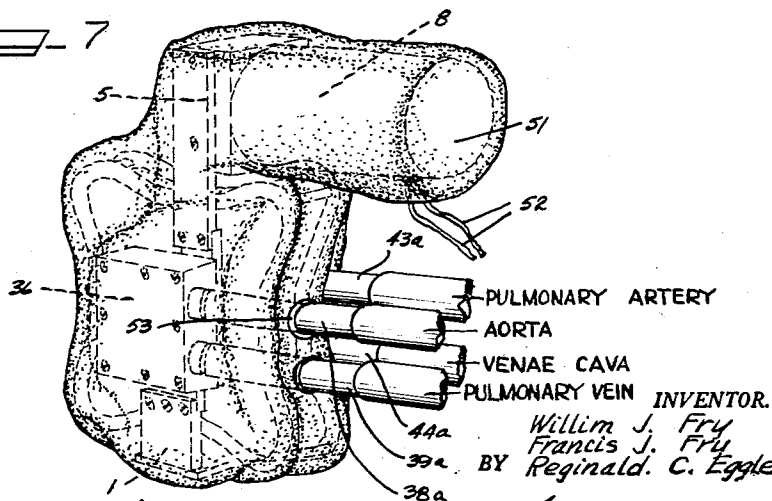


FIG. 7



PULMONARY ARTERY
AORTA
VENAE CAVA
PULMONARY VEIN

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3 Sheets-Sheet 3

FIG. 8

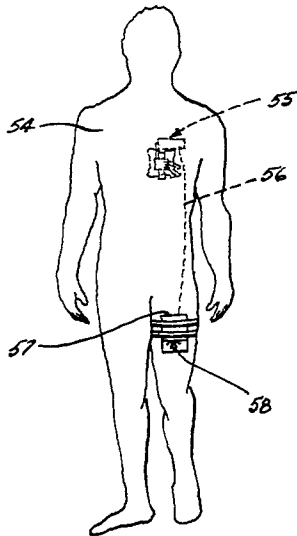


FIG. 10

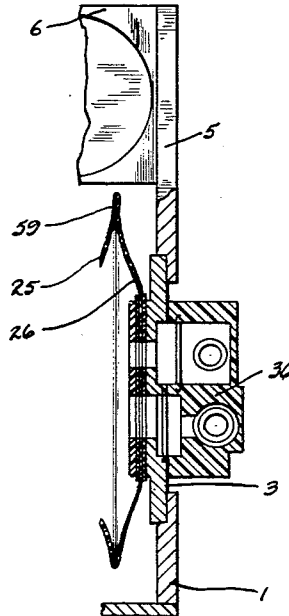
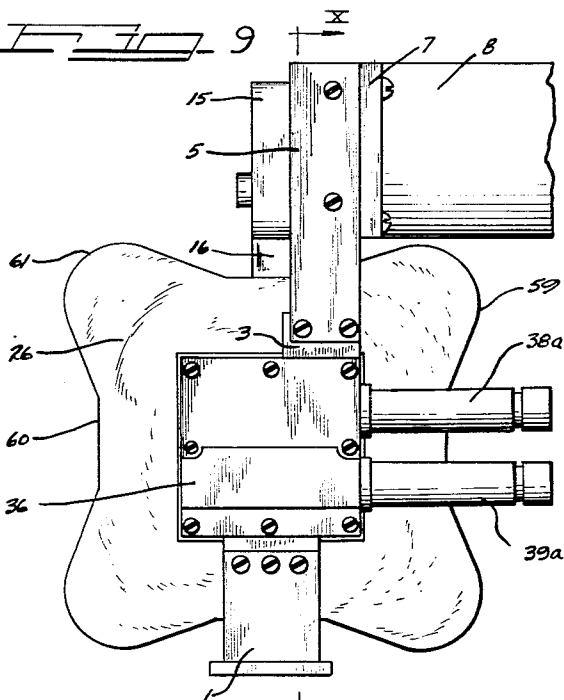


FIG. 9



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3,152,340

ARTIFICIAL HEART

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9 Claims. (Cl. 3—1)

This invention relates to improvements in an artificial heart, and more particularly to a pumping apparatus capable of substituting for the mammalian heart and particularly the human heart, the invention being highly desirable for use externally of the body as a means of providing an adequate blood supply while the real heart is isolated during an operation, and equally as desirable for use internally of the body as a complete substitute for the natural heart which is removed and discarded, although the invention may have other uses and purposes in connection with the pumping of a liquid, as will be apparent to those skilled in the art.

The instant invention is an improvement upon the mechanical heart set forth, described and claimed in William J. Fry et al. Letters Patent No. 2,917,751 dated December 22, 1959, and possesses all of the advantages of the invention in the aforesaid patent, as well as other and additional advantages apparent from the disclosures hereinafter.

Heretofore, blood pumping apparatus of the character utilized externally of the body while the natural heart was isolated was of a cumbersome and unwieldy character embodying many parts requiring separate sterilization and requiring an objectionable amount of time and labor in order to properly prepare or condition the apparatus for use. Also, in the event of a temporary power failure, hand operation of the apparatus would be extremely difficult if not impossible to a satisfactory extent. Further, previously known apparatus of this type could only be used a limited length of time without extreme danger to the patient owing to damage to the blood being circulated apparently caused by the apparatus. In addition, it might be mentioned that with such formerly known apparatus adjustments as to speed and amount of blood flowing per minute could not be varied without considerable effort, and in some cases it was impossible to vary speed or output per minute while the device was in operation.

With such thoughts in mind, it is an important object of the instant invention to provide a pumping apparatus capable of substituting for a natural heart, which is sufficiently small and light in weight as to be held in one hand by an operator should occasion warrant, and which is, in effect, a silent, low pressure and high volume pump.

Another object of the invention is the provision of a simple form of natural heart substitute which may be operated for an indefinite length of time particularly for the pumping of human blood without danger, since tests have shown that the body produces blood elements faster than damage to elements of the blood can occur by virtue of the use of the invention.

It is also a feature of this invention to provide a simple form of substitute for a natural heart which effectively pumps a desired quantity of blood and in which the blood contacts no surface other than a relatively non-reacting or inert plastic surface.

It is also a feature of this invention to provide a pumping apparatus capable of serving as a substitute for a natural heart, and in which the output per minute may be selectively varied at will and while the device is in operation.

A further object of the invention is the provision of a simple device capable of substituting for a natural heart, from which the drive motor may readily be removed and

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the remainder of the apparatus sterilized as a unit with a minimum of time and effort expended.

Also a feature of the invention resides in the provision of a simple pumping apparatus capable of substituting for a natural heart, and from which, in the event of a temporary power failure, or for any other reason, the motor may be very quickly removed and a crank substituted so that the device can be effectively operated by hand.

Up to the advent of the aforesaid Letters Patent No. 2,917,751, a mechanical or artificial heart capable of being mounted permanently in the chest cavity of a patient upon removal of the natural heart had not been developed. In regard to the structure of the aforesaid patent, the instant invention comprises a smaller structure, embodying less moving parts, and which also includes floating valves responsive to pressure differentials and which require no direct mechanical actuation.

It is also an important object of this invention to provide a mechanical or artificial heart having an improved diaphragm structure, which corresponds to the chambers of a natural heart.

Still another important feature of this invention is the provision of an artificial heart having plastic diaphragms therein so arranged that there is no stretch in the material during operation, no sharp creases or bending points where cracking might occur, the entire diaphragm operating merely upon a flexing movement with no damaging strain on the material itself.

While some of the more salient features, characteristics and advantages of the instant invention have been above pointed out, others will become apparent from the following disclosures, taken in conjunction with the accompanying drawings, in which:

FIGURE 1 is a side elevational view of an artificial heart embodying principles of the instant invention;

FIGURE 2 is an end elevational view taken substantially as indicated by the staggered line II—II of FIGURE 1;

FIGURE 3 is a vertical sectional view taken substantially as indicated by the line III—III of FIGURE 1;

FIGURE 4 is an exploded view, enlarged, and showing confronting faces of the valve chamber assembly in elevation;

FIGURE 5 is a perspective view of one of the floating valve elements alone;

FIGURE 6 is a transverse sectional view through a valve element taken substantially as indicated by the line VI—VI of FIGURE 5;

FIGURE 7 is a perspective view of an artificial heart embodying principles of the instant invention enclosed within a casing, for mounting in the human body;

FIGURE 8 is a diagrammatic elevational view indicating the mounting of the structure of FIGURE 7 in the body and the positioning of control connections on the body;

FIGURE 9 is a fragmentary side elevational view of an artificial heart structure lighter in weight than is the structure shown in FIGURE 1; and

FIGURE 10 is a fragmentary vertical sectional view taken substantially as indicated by the line X—X of FIGURE 9.

As shown on the drawings:

Referring now more particularly to FIGURES 1, 2 and 3, we have shown a structure suitable for use both externally and internally of the body. Such device, externally of the body, would of course be utilized when the natural heart was isolated during treatment, adjustment, an operation or the like.

This structure includes a frame comprising a U-shaped base portion 1 to one leg of which is attached a side member 2, and to the other leg of which is attached a

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side member 3, the attachments in both instances being by way of suitable bolts or machine screws as illustrated. Both these side plates 2 and 3 form the inside member of a valve box or housing to be more fully later described. The actual shape of these side plates 2 and 3 is best seen in the right-hand view of FIGURE 4 which shows the outer face of the side plate 2. Upstanding from the side plate 2 is a top piece 4 and upstanding from the side plate 3 is a top piece 5, between the upper ends of which is a bearing plate 6. Attached to one side of the bearing plate 6 and upper edges of the top pieces 4 and 5 by means of a flange 7 and suitable screws or bolts is a motor 8 which may have a gear reduction section 9 if used externally of the body. As seen in FIGURES 2 and 3 the opposite face of the bearing plate 6 is hollowed as at 10 to accommodate an eccentric or crank 11 rotating within the hollow and keyed to the end of the motor shaft 12 which projects through a suitable aperture in the bearing plate. The eccentric 11 is provided with a series of threaded apertures 13 therein at varying distances from the center of the shaft 12 to selectively accommodate a crank pin 14. This crank pin 14 extends into an elongated loop 15 on the upper end of a pitman 16 the lower end of which is pivoted to the bottom of the frame structure as indicated at 17. Pivoted to an intermediate portion of the pitman 16, as indicated at 18, is what might be termed an external double acting piston 19 which reciprocates laterally as the pitman 16 is swung backward and forward around the pivot 17 by the action of the eccentric 11 and crank pin 14.

On each side of the piston 19 is a diaphragm or imitation heart chamber, these being indicated generally by numerals 20 and 21. Each diaphragm comprises a pair of frame members 22 and 23 secured tightly together by screws 24 as seen best in FIGURE 1, and between these frame members is the circumscribing marginal portions of a pair of sheets 25 and 26 of plastic material such as polyethylene, polyvinyl chloride, or a plastic consisting of a tetrafluoroethylene polymer, these substances being relatively inert and minimal damaging to blood, particularly human blood. At least the outermost sheet 26 is preferably transparent so that the contents of the diaphragm are readily visible. The inner sheet 25 of the diaphragm is preferably imperforate except for screw holes through which opposed plates 27 and 28 are joined together, there being a suitable gasket as indicated at 29 between each such plate and the diaphragm wall 25. The inner plate 27 is fixedly connected to the adjacent face of the piston 19 and the plate 28 inside the diaphragm is screwed to the plate 27. The gaskets may be of the same material as the diaphragm sheets and are used to insure that there is no leakage by way of the screws joining the plates.

The outer diaphragm sheet 26 has a plate 30 and a suitable gasket on its inner face, which plate 30 is screwed through the diaphragm sheet to the aforesaid side frame member 2 or 3, there being a gasket 31 between the side frame member and the diaphragm sheet. As seen best in FIGURE 3 there is a common aperture 32 through the plate 30, the diaphragm sheet in both gaskets and the side frame member 3 to form an outlet port from the inside of the diaphragm chamber. There is a similar aperture 33 therebelow which forms an inlet port to the diaphragm chamber.

Flow through the discharge port 32 is controlled by a floating plate valve 34, and flow through the inlet port 33 is controlled by another and similar floating plate valve 35. The valves are maintained in place by a suitable valve box 36 screwed to the side frame member 2 or 3 as indicated at 37. The valve box 36 has upper and lower separated chambers leading to the ports 32 and 33 respectively, as will more fully later appear herein, which chambers are in communication with external nipples 38 and 39 respectively projecting from the valve box for attachment to tubes when the artificial heart is

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used externally of the body, and to certain blood vessels when the artificial heart is located within the body.

Allochiral but otherwise identical structure is associated with the diaphragm chamber 20, including a valve box 40 having upper and lower chambers 41 and 42 therein, as best seen in FIGURE 4, and externally projecting nipples 43 and 44 respectively in communication with these chambers. Flow between the diaphragm chamber and the upper valve box chamber is controlled by a floating valve plate 45, and flow between the diaphragm chamber and the lower valve box chamber is controlled by a floating valve plate 46. As seen best in FIGURE 4, movement of the valve 45 is limited by a pair of bars 47 extending across the upper valve box chamber 41 and by contact with the smaller discharge port 32 leading from the interior of the diaphragm chamber. In the same manner, movement of the valve 46 is limited by a pair of bars 48 over the opening 33 in side frame member 2, and there is an opening 49 of less size than the valve plate 46 establishing communication between the lower valve box chamber 42 and the nipple 44. Both valve plates are floating so as to respond freely to pressure differentials, and they are of such size as to completely cover the respective opening they are designed to close even though they become tilted as indicated by the dotted line showing in the right-hand part of FIGURE 4.

In FIGURES 5 and 6 a valve plate itself is shown, all being identical in construction. It will be seen that the plate is merely a flat sheet of plastic material such as nylon or a plastic consisting of a tetrafluoroethylene polymer reinforced by a plurality of integral transverse ribs 50 to avoid any possible bending of the valve plate.

When the artificial heart is to be used only externally of the body, many of the parts thereof may be made of stainless steel to resist rough handling. Should the side frame plates 2 and 3 and the valve boxes be made of stainless steel, they would also be lined with a suitable plastic so that the blood never comes in contact with metal but only with the non-damaging plastic surface. It might also be desirable to utilize a suitable and inert anti-foam agent particularly inside the diaphragm chambers, and for this purpose a silicon anti-foam agent is satisfactory.

The motor 8 should be an alternating current motor to avoid the use of brushes, particularly when the device is to be mounted within a living body. The motor should also have a constant torque output. For such purpose a synchronous motor is satisfactory and the speed may be varied through a frequency variation obtained by varying the voltage. When the artificial heart is used inside the body, the motor should preferably operate in the speed range around 60 revolutions per minute and would be driven by batteries with known electronic means for converting the direct current of the batteries into the alternating current for the motor. When the device is used externally of the body, the stroke of the piston 19 may be varied by changing the position of the crank pin 14, as well as the speed of the motor.

Where the device is used externally of the body the motor is preferably supplied with power from a suitable or handy convenience power outlet, and the power pack for the motor is designed so that it may be plugged into a convenience power outlet when the device is within the body to relieve the batteries of the load and recharge them.

With extracorporeal use of the artificial heart, it is a simple expedient to remove the motor by releasing the screws through the flange 7, and sterilize the remainder of the apparatus. The apparatus is then connected to the particular blood vessels of the body to isolate the natural heart in some cases, and in other cases to assist the natural heart by a connection in some indicated location such as a femoral vein and artery pair or a connection in the neighborhood of the natural heart, synchronized, if necessary, with the natural heart cycle. To that end, plastic tubes made of a plastic comprising a series of modified halide

polymers, condensation resins, and diene derivatives compounded to produce synthetic rubber-like material is satisfactory for the purpose. By way of example, the outlet nipple 43 would be connected through a tube to the pulmonary artery, the outlet nipple 44 to the superior and inferior venae cava; the nipple 38 to the aorta; and the nipple 39 to the pulmonary vein. Upon starting of the motor, the external piston 19 will be reciprocated laterally by the action of the pitman 16 and alternately compress and expand each of the chambers. Thus, upon a single rotation of the motor shaft, there will be a complete expansion and depression of each diaphragm chamber. Looking at the structure as it is shown in FIGURE 3, a complete compression of the diaphragm chamber 20 is approaching and it will be noted that the valve 45 is in open position while the floating valve 46 is in closed position and at this point blood would be discharged through the nipple 43 to the pulmonary artery. At the same time the diaphragm chamber 21 is nearing full expansion, and the valve 34 is in closed position while the valve 35 is in open position permitting the entry of blood through the nipple 39 from the pulmonary vein. When the crank pin reaches the opposite diametrical position from that seen in FIGURE 2, the diaphragm chamber 21 will be expelling blood through the nipple 38 to the aorta and the diaphragm chamber 20 will be receiving blood through the nipple 44 from the superior and inferior venae cava. With transparent sheets forming the diaphragm chambers, it is a simple expedient to visibly note whether any gas is in the system so that it can be removed. It should also be especially noted that with the structure of the diaphragms the plastic sheets included therein are subject to no movement other than an in and out flexing, there being no appreciable tension or stretch placed upon the material and there are no sharp bends or corners where cracking might ultimately occur.

If a slight leakage to keep the blood pressure of a particular patient down is indicated, a particular floating valve element may be easily adjusted to provide such slight leakage. Further, should there be a temporary power failure, it is a simple expedient to quickly remove the motor, engage a hand crank in the eccentric 11, and operate the device manually.

The artificial heart can be used for an indefinite length of time, as long as any particular occasion may warrant, for human blood particularly without damage to any of the blood elements. The body produces red cells and platelets faster than damage occurs.

The fact that the artificial heart embodies only two chambers whereas the natural heart embodies four chambers makes no essential difference. Nor does it make any difference whatever that the pulmonary system is supplied with blood the equivalent of one-half heart beat out of phase with the supply of blood to the systemic system by the artificial heart, whereas both systems are simultaneously supplied by a natural heart, since each system is supplied at the same rate as it is by the natural heart.

As seen in FIGURE 7, before the artificial heart is placed in the body, it is covered with a casing 51 of reasonably stiff material and this casing is preferably shaped in general accordance with the shape of the artificial heart mechanism so as to occupy a minimum amount of space. The casing may be fastened to the frame of the artificial heart at the bottom, top and to the valve blocks on each side or any other suitable locations. The casing is coated on its outer surface with a substance that is compatible with body tissue and non-toxic. To this end, the casing may be sprayed with a plastic coating. The casing may be attached in a known manner to the transverse processes of the thoracic vertebrae and a bilateral fastening would appear to be most desirable. Added securement may be had by also securing the casing to one or more ribs so that it is held firmly and positively in place. Wires 52 from the

motor extend through the casing, and in this instance the nipples have been lengthened to project well without the casing for the attachment directly thereto of the various blood vessels as seen in FIGURE 7, projecting nipple 43a may connect directly with the pulmonary artery; the projecting nipple 44a with the junction vein from the superior and inferior venae cava; the nipple 38a with the aorta, and the nipple 39a with the pulmonary vein. Obviously there is a close seal as indicated at 53 between the nipples and the casing 51 and the same is true at the point where the wires or conductors 52 pass through the casing.

In addition, it should be noted that the casing preferably is filled interiorly with a liquid such as a light oil which would serve to lubricate any of the movable parts not functioning with a self-lubricating bearing construction, and that liquid is in pressure equilibrium with the body.

In FIGURE 8 there is a diagrammatic showing of a human body 54 with the artificial heart generally indicated by numeral 55 mounted in position therein. The wires to the motor are preferably formed into a single cable indicated at 56 and it is preferable to extend this cable between the layers of mediastinum through the muscles of the chest wall and then between superficial and deep fascia along the lateral aspect of the flank into the inguinal region and emerge the cable preferably below the inguinal line. Strapped around the thigh and connected to the cable is a battery box 57 which not only contains batteries for driving the motor, but also contains a rheostat 58 controlling the voltage from the batteries to selectively vary the speed of the motor. The electronic means of known type which change the direct current of the battery to alternating current for the motor may either be carried in the box 57 on the thigh, or they can be mounted along with a small form of rechargeable battery inside the casing of the artificial heart between the diaphragm structures on either side of the pitman 16.

Where the heart is for use inside the body it is preferable to have the nipples extend through the casing; as much as possible of the frame structure and the valve chamber parts are made of plastic such as nylon or a polymerized tetrafluoroethylene for the sake of lightness in weight, and also for the sake of lightness in weight the frame members 22 and 23 may be eliminated from each diaphragm chamber if desired. In FIGURES 9 and 10 a diaphragm chamber is shown with the frame completely eliminated. This diaphragm chamber consists of an inner wall 25 and an outer wall 26 as above described, but instead of being marginally connected by means of the frame structure, the outer and inner walls of the chamber are connected by either an integral seam 59 or a heat seal seam in the same location. The two sheets forming the outer and inner walls may be heat sealed together around the margins thereof or it might be possible to mold the entire diaphragm structure in one unitary piece embodying both walls.

As mentioned previously herein, it is important that the walls of the diaphragm chamber are subject only to flexing. There is no excessive tension, stretch, or material strain upon either of the walls during operation and there is no sharp bending or mechanical squeezing of the walls in any location. That is deemed highly preferable to avoid possible cracking of the diaphragm chamber or possible rupture due to overstrain. While the particular shape of diaphragm chamber illustrated herein may not be the only one that will accomplish this purpose it is a highly satisfactory shape. As seen in FIGURES 1 and 9 a peripheral contour of each diaphragm chamber might be said to be generally square with widened protruding and rounded corners, a straight side edge portion 60 alternating with a protruding rounded corner 61, and so on entirely around the periphery of the diaphragm. This shape provides a diaphragm of exceptionally long life.

After installation of the artificial heart in the body of the patient, or prior thereto if so desired, the rheostat 58 is preferably fixed so that it is impossible to fully turn off the battery current so that the artificial heart will operate at minimum speed under any circumstances. Also, it is well known that the amount of blood pumped through the body varies for different individuals, so that the rheostat is preferably set to provide a speed of operation for any particular individual to maintain proper blood pressure for that patient. It might also be noted that the speed of operation of the artificial heart should be changed or varied in accordance with the activity of the patient wearing the same. For example, if an adult wearer of the artificial heart is at repose the pumping of 3 to 4 liters of blood per minute should be satisfactory on the average, whereas if that person is active it may be necessary to pump 10 to 12 liters of blood per minute. This change in speed can be accomplished by an adjustment of the control, and in most cases the patient should make the adjustment in anticipation of exertion. In general, diaphragm chambers having a capacity of 70 cubic centimeters each should be satisfactory for most adult human installation and with the illustrated shape of diaphragm chambers this can be accomplished and still maintain the diaphragm chambers relatively small.

From the foregoing, it is apparent that we have provided a silent, low pressure and high volume pumping apparatus, simple in construction, very compact and small in size, and which may function as an artificial heart substituting for a natural heart either externally or internally of the human body.

It will be understood that modifications and variations may be effected without departing from the scope of the novel concepts of the present invention.

We claim as our invention:

1. An artificial heart to act as a substitute for a natural heart both externally and internally of the body, comprising a frame, a motor on said frame, an adjustable amplitude eccentric driven by said motor, a crank pin secured to the adjustable eccentric, a pitman pivoted to said frame and oscillated by said crank pin, a double acting piston on said pitman, a plastic diaphragm defining a chamber on each side of said piston to be successively compressed and expanded by the same, each diaphragm having an inlet and an outlet port therein, a valve casing adjacent each said diaphragm having separate chambers therein each communicating with a different one of said ports, valves in said casings controlling flow through said ports, and a nipple extending from each valve casing chamber for connection to a blood vessel of the body.

2. An artificial heart to act as a substitute for a natural heart both externally and internally of the body, comprising a frame, a motor on said frame, an adjustable amplitude eccentric driven by said motor, a crank pin selectively secured to the adjustable eccentric, a pitman pivoted to said frame and oscillated by said crank pin, a double acting piston on said pitman, a plastic diaphragm defining a chamber on each side of said piston to be successively compressed and expanded by the same, each diaphragm having an inlet and an outlet port therein, a valve casing adjacent each said diaphragm having separate chambers therein each communicating with a different one of said ports, floating valves in said casings controlling flow through said ports, and a nipple extending from each valve casing chamber for connection to a blood vessel of the body, all surfaces of said chambers, valves, and nipples with which blood comes in contact being of plastic inert material non-damaging to blood.

3. An artificial heart to act as a substitute for a natural heart both externally and internally of the body, comprising a frame, a pair of opposed plastic diaphragm chambers, an oscillatory pitman between said chambers, means on said pitman connected to the inner walls of said chambers, the outer walls of said chambers having inlet and outlet ports therein, a valve box over said ports

for each chamber, floating valves controlling flow through said ports, a separate nipple for each port extending from the respective valve box, and means to oscillate said pitman.

4. An artificial heart to act as a substitute for a natural heart both externally and internally of the body, comprising a frame, opposed inner and outer walled diaphragms defining chambers therein in said frame, a double-acting external piston between the inner walls of said diaphragms, means to reciprocate said piston to alternately expand and compress said diaphragms, the outer wall of each diaphragm having inlet and outlet ports therein, a valve box having coincidental ports connected to the outer wall of each diaphragm and forming a part of said frame, valve means in said boxes controlling flow through the diaphragm ports, and a nipple projecting from each valve box for each port.

5. In an artificial heart, a frame, a valve box at each side of said frame having separate ports and passages therein, a nipple projecting from each said box for each said passage, a floating plastic plate valve in each box for controlling flow through each port and passage, a pair of opposed double-walled diaphragms one wall of each of which is connected to the respective valve box and provided with ports coincidental with those of the valve box, and means for alternately compressing and expanding said diaphragms.

6. In an artificial heart, a frame, a valve box at each side of said frame having separate ports and passages therein, a nipple projecting from each said box for each said passage, a floating plastic plate valve in each box for controlling flow through each port and passage, a pair of opposed double-walled diaphragms one wall of each of which is connected to the respective valve box and provided with ports coincidental with those of the valve box, and means for alternately compressing and expanding said diaphragms, said diaphragms each comprising plastic outer and inner walls connected at the peripheries thereof, and at least the outer wall being transparent.

7. In an artificial heart, a frame, a valve box at each side of said frame having separate ports and passages therein, a nipple projecting from each said box for each said passage, a floating plastic plate valve in each box for controlling flow through each port and passage, a pair of opposed double-walled diaphragms one wall of each of which is connected to the respective valve box and provided with ports coincidental with those of the valve box, and means for alternately compressing and expanding said diaphragms, said plate valves being of such size in comparison with the ports controlled thereby that each valve will block flow through the respective port even though the valve is tipped out of parallelism with the port.

8. In an artificial heart for use externally of a body while the natural heart is isolated, a pair of opposed diaphragms each comprising an inner and an outer sheet of flexible plastic material, rigid frame members secured together and tightly clamping the sheets of each diaphragm therebetween around the periphery of the diaphragm, a double-acting piston disposed centrally between said diaphragms to alternately compress and expand the same, a motor to actuate said piston, the outer sheet of each diaphragm having inlet and outlet ports therein, a valve box containing valve means and separate passages leading from said ports mounted over the ported portion of each said outer sheet, means to vary the speed of said motor, and means to vary the stroke of said piston.

9. In a pumping mechanism for use externally of the body as an assist to the natural heart, a pair of opposed diaphragms each comprising an inner and outer sheet of plastic material connected in a leakproof manner at the peripheries thereof, means between the inner walls of said diaphragms to alternately expand and contract the diaphragms, the outer sheet of each diaphragm having an inlet and an outlet port therein, a valve box containing pressure responsive valve means and separate passages

leading from said ports mounted over the ported portion of each outer sheet, a nipple leading from each said passage for connection to a body blood vessel, and a synchronous motor to drive said means.

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