July 7, 1970 J. A. LA RUSSA 3,518,702

IMPLANTABLE BODY ACTUATED ARTIFICIAL HEART SYSTEM

Filed Jan. 23, 1967 8 Sheets-Sheet 1

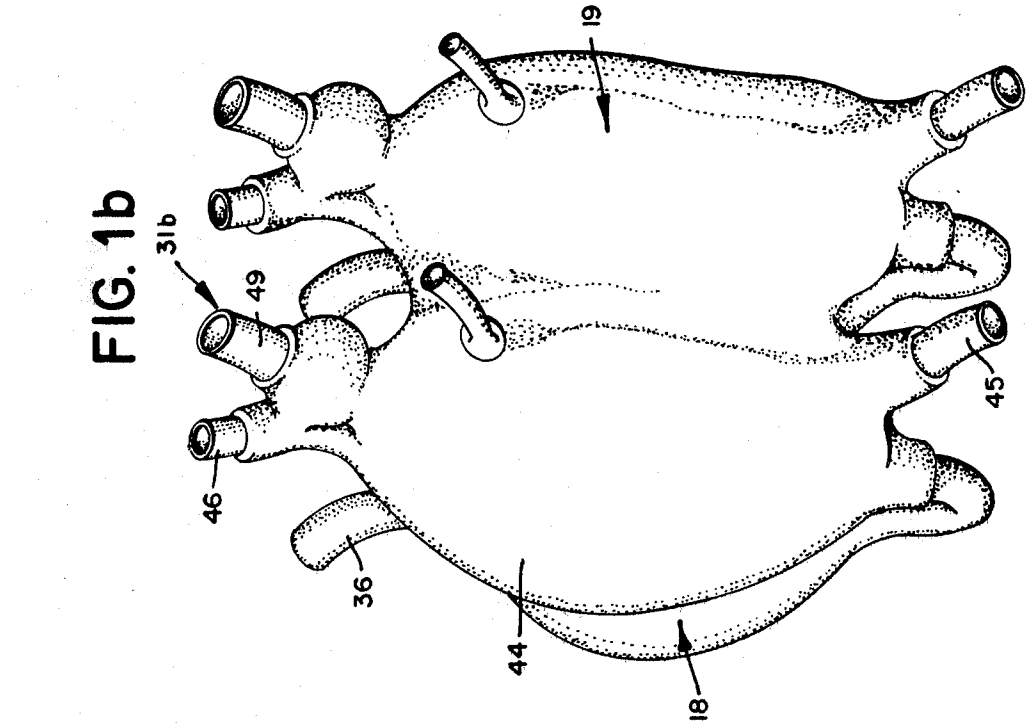

FIG. 1b

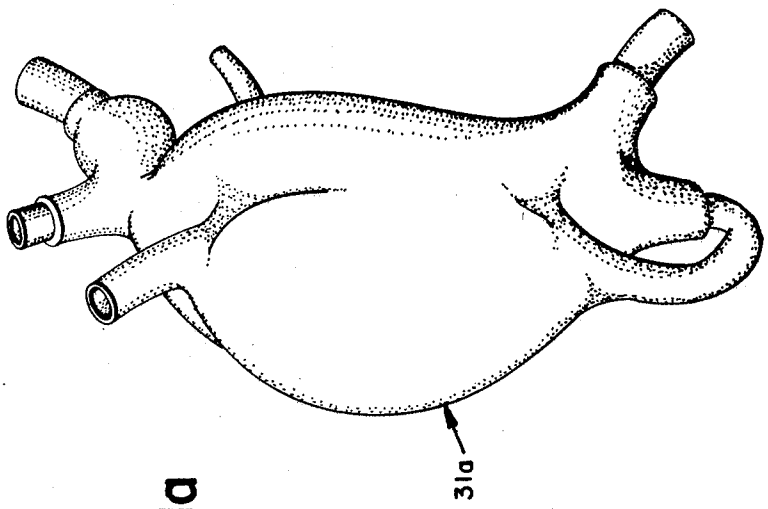

FIG. 1a

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IMPLANTABLE BODY ACTUATED ARTIFICIAL HEART SYSTEM

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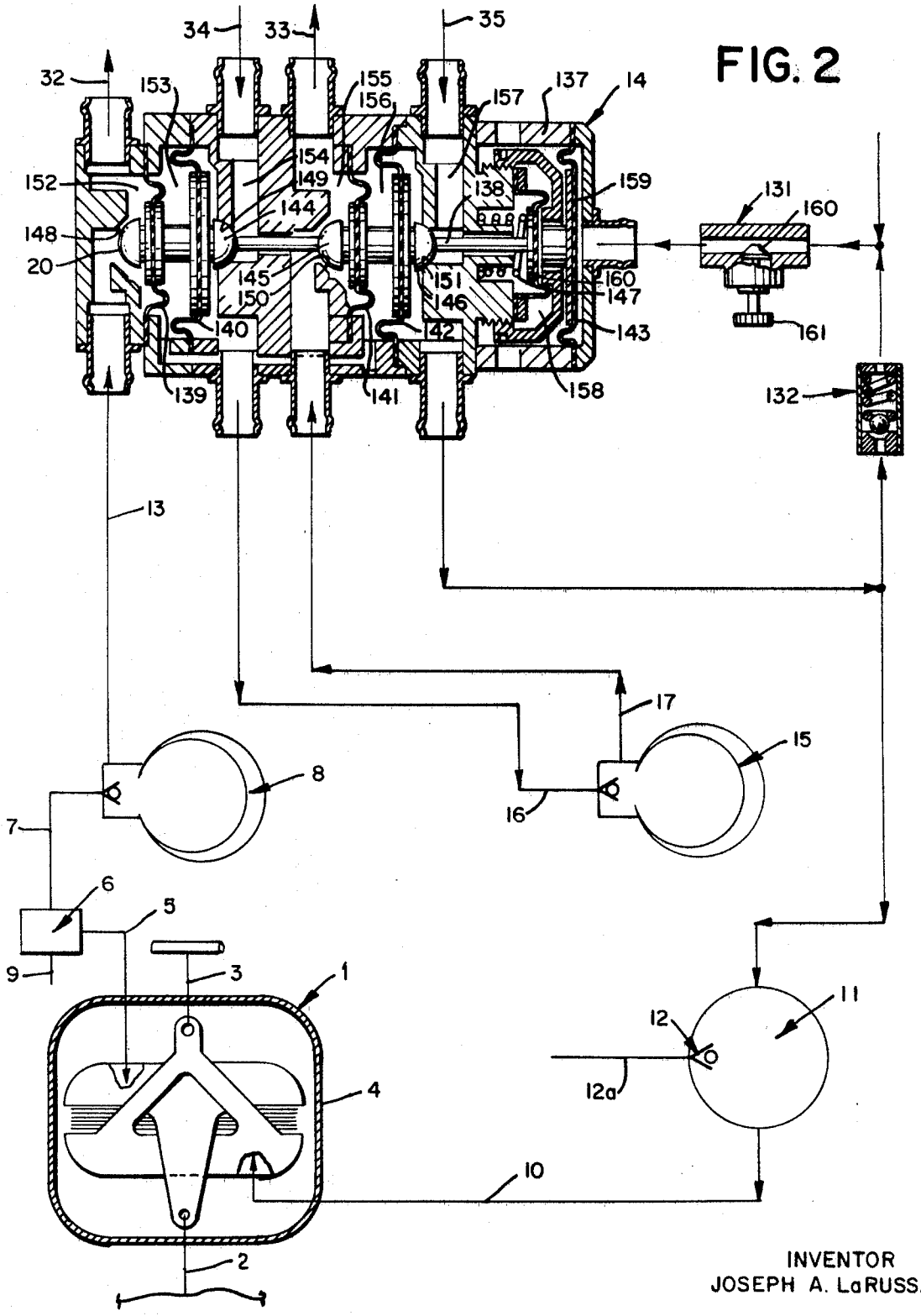
FIG. 2



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IMPLANTABLE BODY ACTUATED ARTIFICIAL HEART SYSTEM

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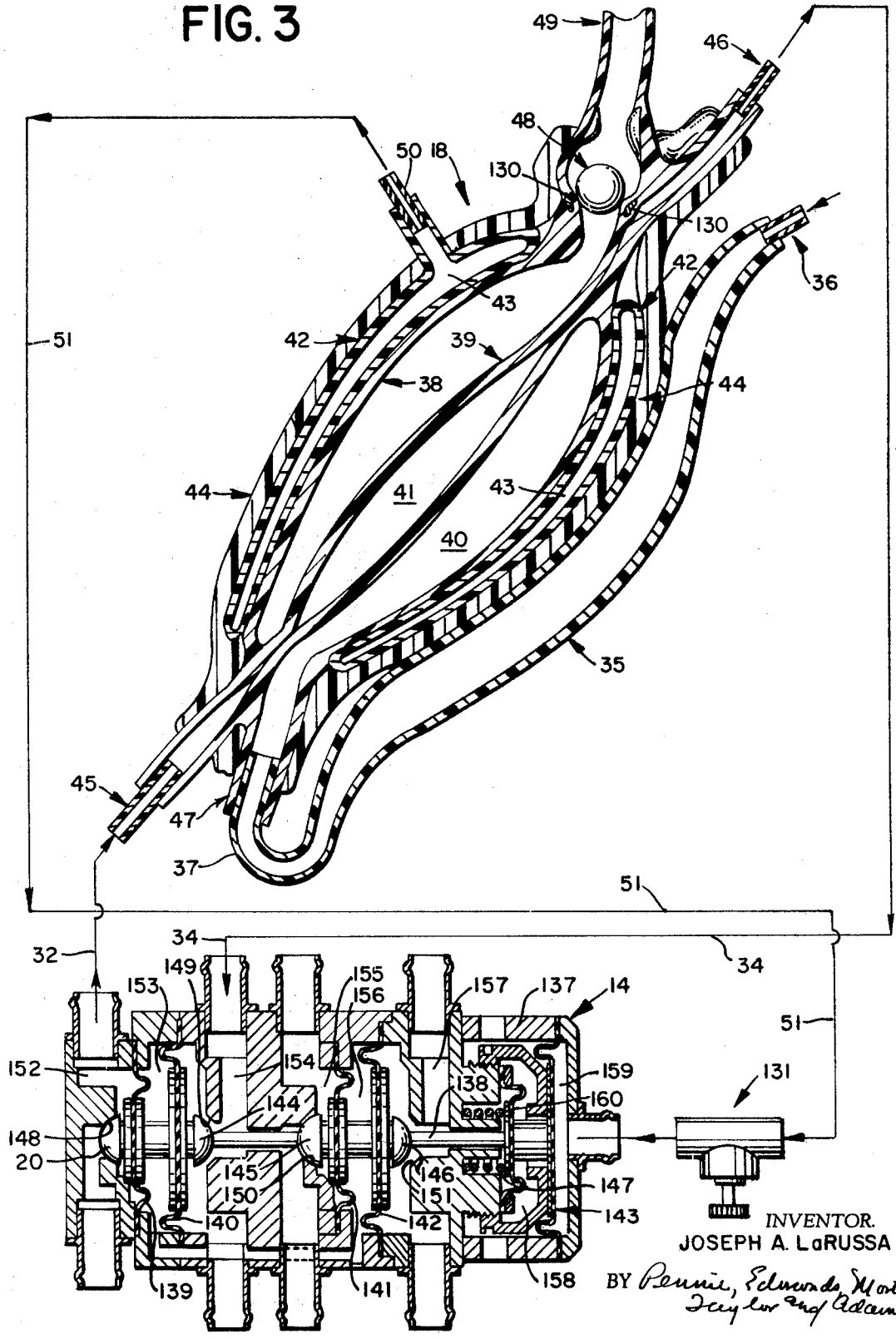
FIG. 3



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IMPLANTABLE BODY ACTUATED ARTIFICIAL HEART SYSTEM

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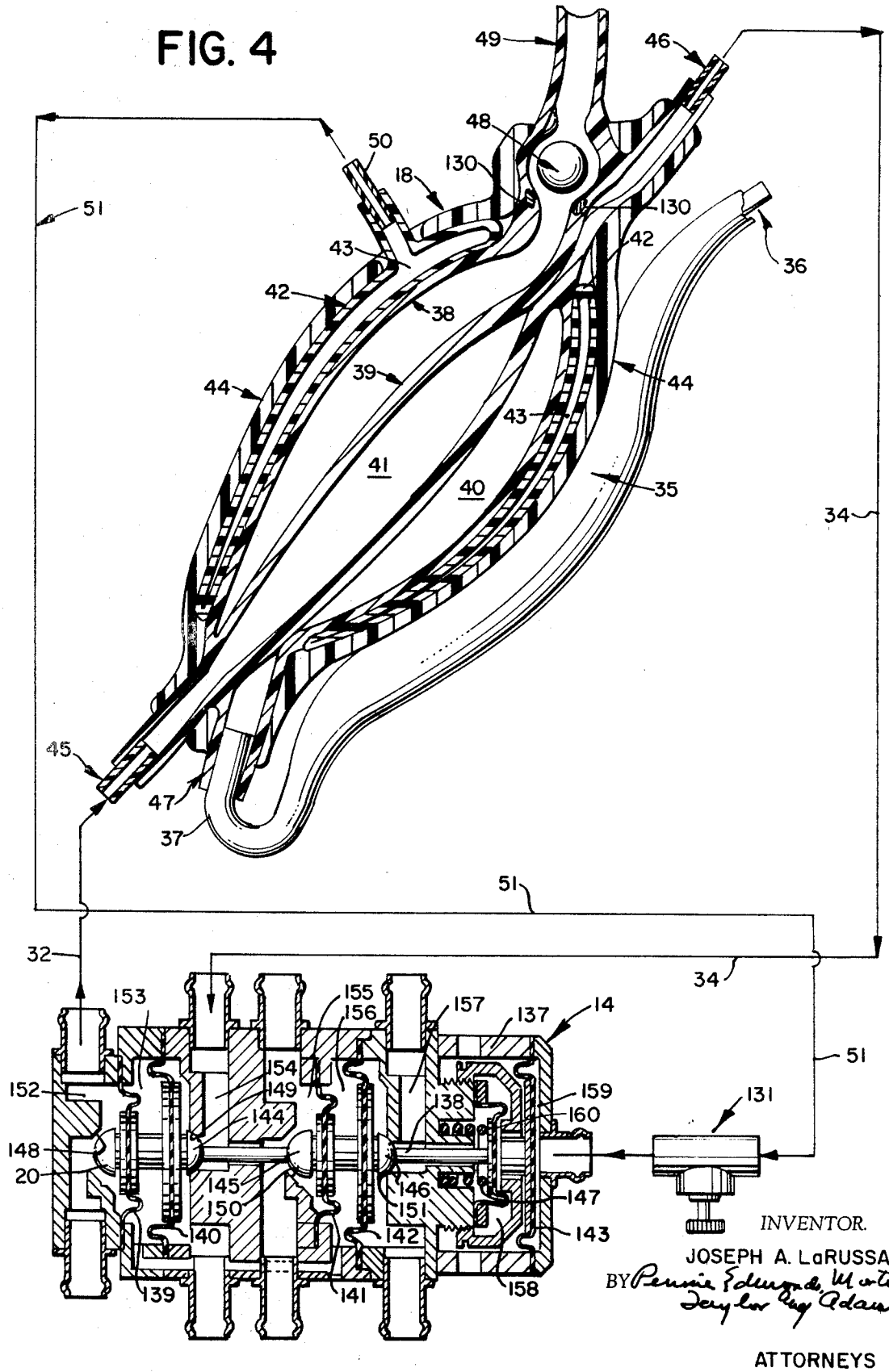
FIG. 4



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IMPLANTABLE BODY ACTUATED ARTIFICIAL HEART SYSTEM

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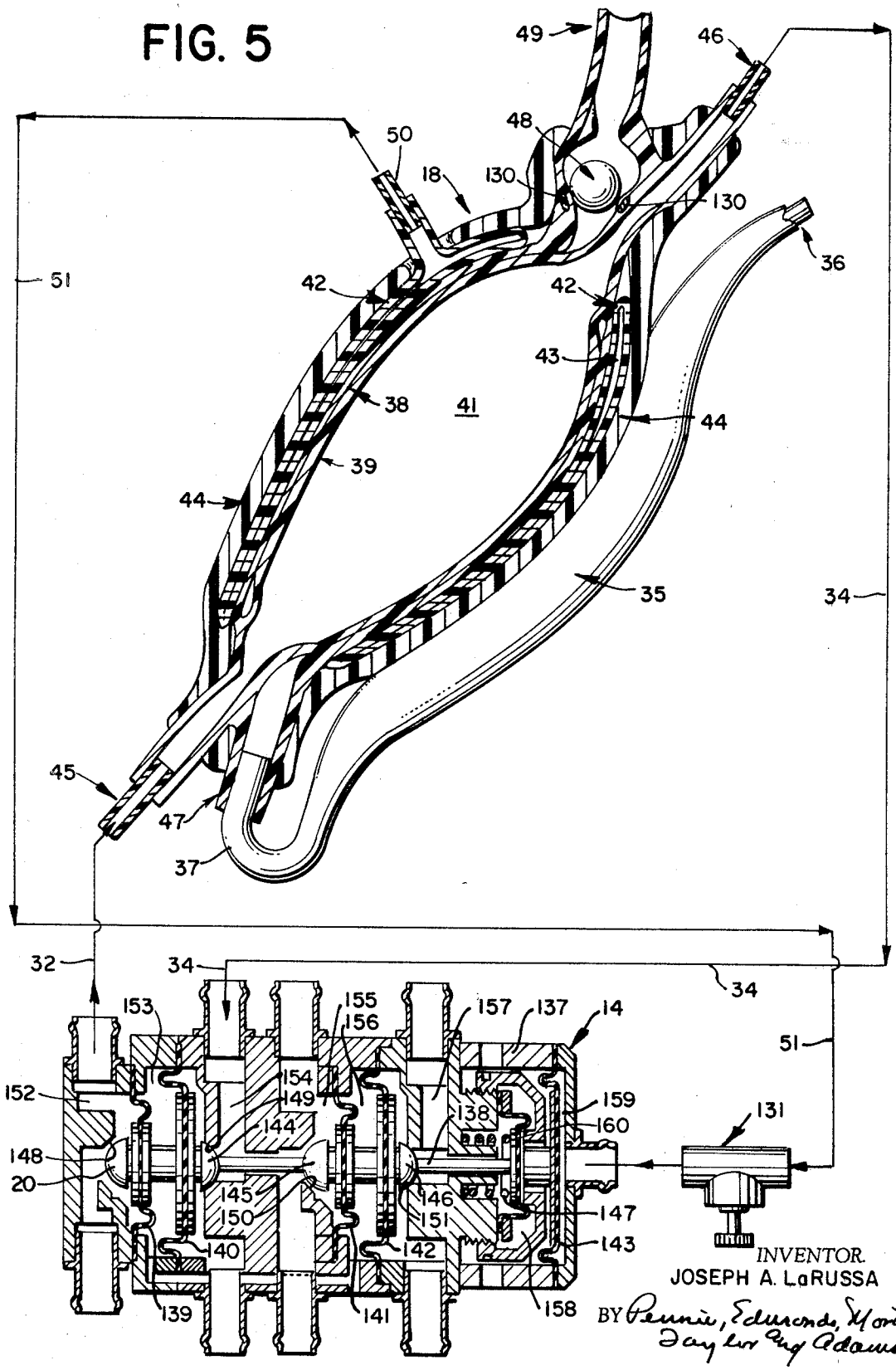
FIG. 5



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IMPLANTABLE BODY ACTUATED ARTIFICIAL HEART SYSTEM

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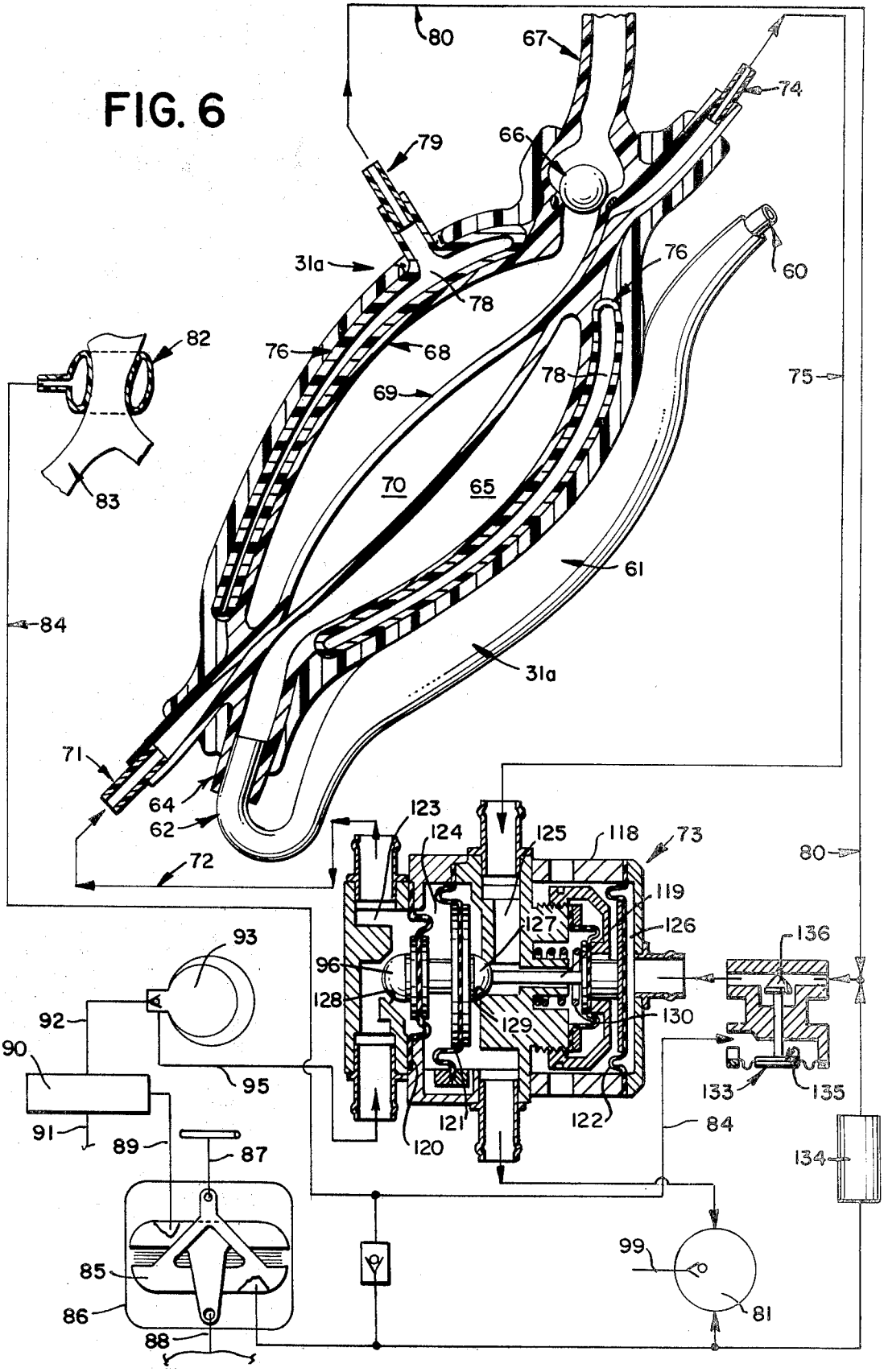
FIG. 6



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IMPLANTABLE BODY ACTUATED ARTIFICIAL HEART SYSTEM

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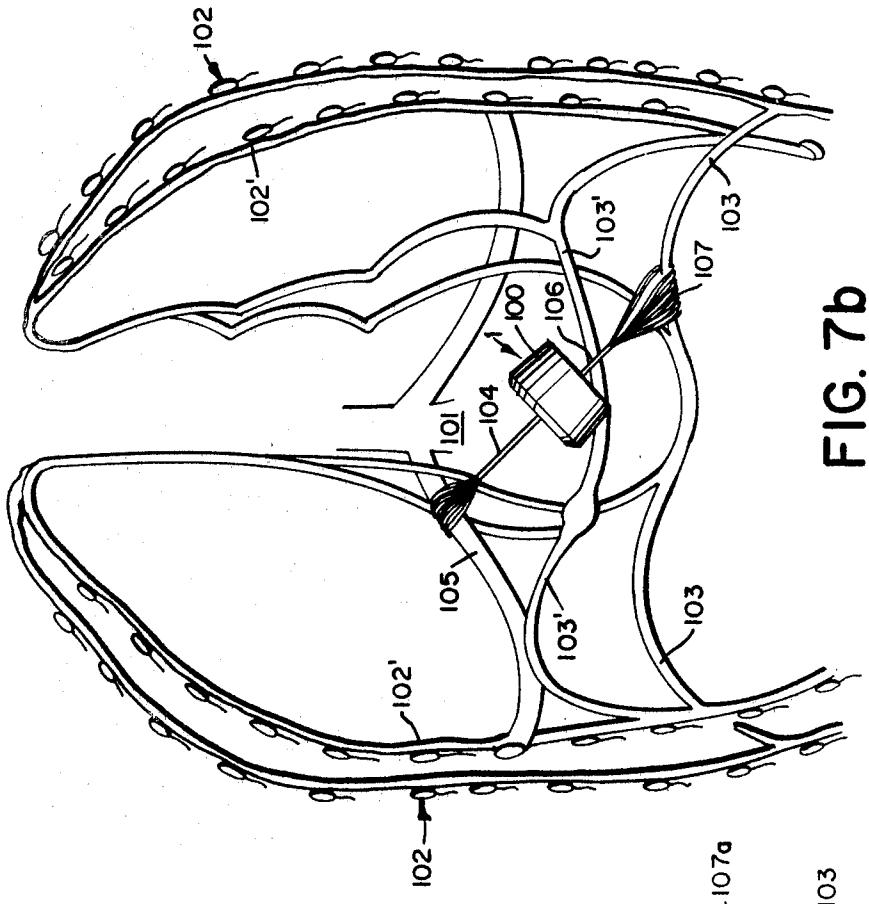

FIG. 7b

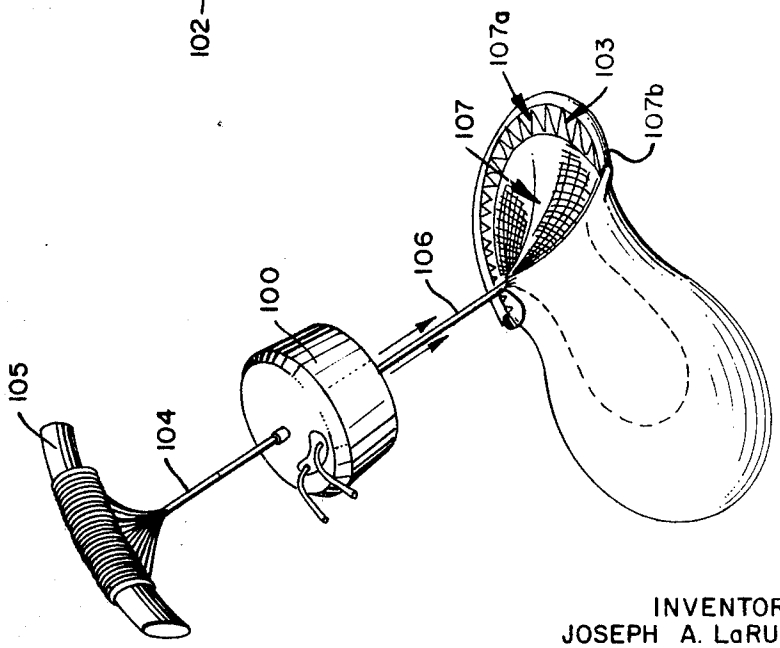

FIG. 7a

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IMPLANTABLE BODY ACTUATED ARTIFICIAL HEART SYSTEM

Filed Jan. 23, 1967 8 Sheets-Sheet 8

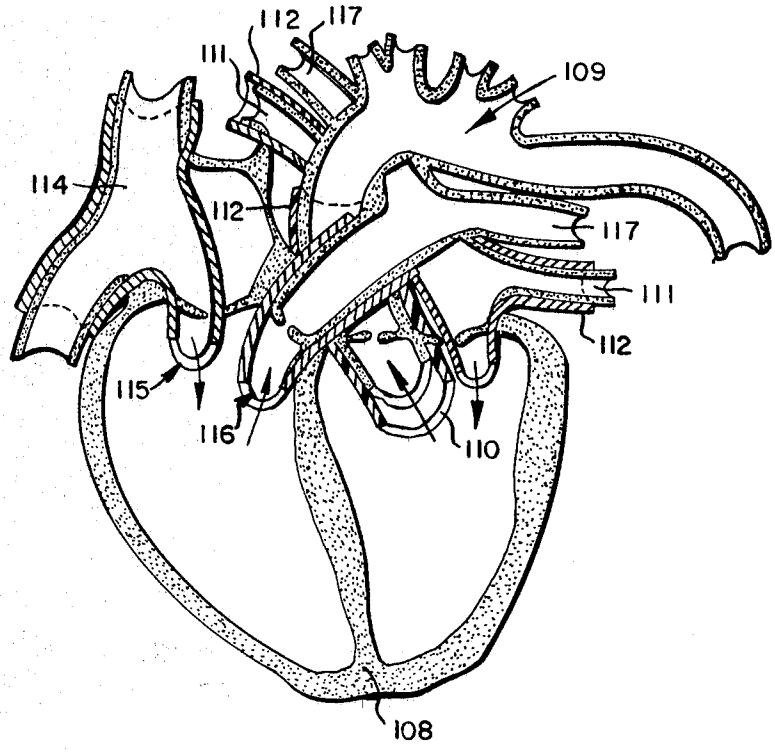

FIG. 8

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United States Patent Office 3,518,702 Patented July 7, 1970

3,518,702

IMPLANTABLE BODY ACTUATED ARTIFICIAL HEART SYSTEM

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Filed Jan. 23, 1967, Ser. No. 611,090
Int. Cl. A61f 1/24
U.S. Cl. 3—1 20 Claims

ABSTRACT OF THE DISCLOSURE

An artificial heart system for maintaining a normal blood circulation within a living, breathing body which is totally implantable within the thoracic and pericardial cavities of the recipient body and which is adapted to be fully powered and regulated by the body's chest and breathing muscles. The components of the artificial heart system comprise a reciprocating pneumatic or fluid pump, an artificial heart, and a control means. The reciprocating pump is adapted to be operably connected to the body chest and breathing muscles to produce pneumatic or fluid pressure in response to the reciprocatory action of the body breathing. The artificial heart is a pneumatic or fluid pressure actuated blood pump which is connected to the reciprocating pump and is adapted to circulate blood in the circulatory system under pneumatic or fluid power supplied by the reciprocating pump. The control means is operably connected between the reciprocating pump and the artificial heart for maintaining a proportion between the body breathing rate and the rate of circulation powered by the artificial heart thereby maintaining a normal blood circulation at a variable rate according to the requirement of the body.

BACKGROUND OF THE INVENTION

Field of the invention

This invention relates to an artificial heart system adapted to be completely implanted within and fully powered by a living, breathing body with no external connections. More specifically, this invention relates to a pneumatically operated artificial heart system comprising a pneumatically operated artificial heart, a reciprocating plural element pneumatic pump for producing pneumatic pressure for the artificial heart, and a control means consisting of pneumatic accumulators for storing and releasing the operating pneumatic pressures and a control valve assembly for supplying pulses of pneumatic pressure to operate the artificial heart. The reciprocating pneumatic pump which powers this system is actuated by the relatively reciprocating movement during body breathing of the rib cage and diaphragm or other breathing muscles to generate pneumatic pressure to supply the pneumatic pressure accumulators. The control valve assembly operates to maintain a proportion between the body breathing rate (12 to 18 breaths a minute) and the pumping rate of the artificial heart (60 to 80 strokes a minute). Since the body breathing rate is governed by the carbon dioxide concentration in the blood and increases or decreases thereby in relation to the bodily oxygen requirement, the artificial heart pumping rate is likewise regulated in accordance with the body demands. The artificial heart systems of this invention are adapted for total implantation within the pericardial and thoracic cavities of the body as either a total replacement for the patient's natural heart or as a means for assisting the natural heart to maintain a normal circulation.

Description of the prior art

Considerable research effort has been directed to the development of a practical, totally implantable artificial heart prosthesis. Especial impetus to this research effort has been provided by the National Heart Institute, a branch of the United States Department of Health, Education and Welfare. The utility of a practical, totally implantable heart replacement or assist device is obvious. It has been estimated that the development of a practical artificial heart would extend the national life span by two years. (Medical World News, Apr. 2, 1965.)

Dr. Samuel A. Levine of the Harvard Medical School and Dr. B. K. Kussero of the University of Vermont in consultation with several other cardiologists have made tentative predictions as to the efficacy of a total implant artificial heart and an implantable heart assist device. It has been predicted that at least 20% of acceptable candidates will survive with the help of a temporary assist device. Of those whose lives are extended by a temporary assist device, it is estimated that 25% will recover satisfactory cardiac function and be able to return to an active, useful life. For others with extensive myocardial fibrous and incipient left ventricle failure the prognosis will be severely restricted physical activity and, for the most part, gainful employment will not be possible. With respect to patients receiving a totally implanted permanent circulatory support, the outlook is more favorable. It is expected that about 60% of all these patients receiving either a permanent left ventricular assist device or a total heart replacement will return to a productive life, including gainful employment. An additional 25% will be limited in their activities to some extent but will not require continued hospitalization. In summary, it is estimated that about 85% of all patients receiving permanent circulatory support will recover sufficiently to resume a normal life.

The practicability of an artificial heart system has been dramatically demonstrated by the recent use of externally powered pneumatic heart assist pumping devices for the post-operative recovery of open heart surgery patients. Such heart assist devices operate as an artificial ventricle which by-passes the patient's left ventricle by pumping blood from the pulmonary vein to the aortic artery. Most noteworthy of these devices are the pneumatic diaphragm blood pump developed by Baylor University, Waco, Tex. and the artificial pneumatic ventricle device developed at Brooklyn Hospital, Brooklyn, N.Y. Both of these devices successfully sustained a patient after open heart surgery for periods up to 48 hours without any evidence of excessive hemolysis or excessive deterioration of the patient's blood cells.

A major problem which must be overcome in a practical artificial heart design is the development of a reliable, long-life, totally implantable power source. The use of an external power source for all but post-operative recovery assist devices is undesirable in at least two respects. The primary disadvantage is that the blood pump would have to be connected by percutaneous leads. The presence of bacteria on the skin surface in close proximity to a tube or wire passing through the skin barrier would make infection a constant hazard to the patient. A second considerable disadvantage is that an external power source would prove cumbersome to the patient and would have the psychological effect of reminding the patient of his dependency upon his prosthesis.

A large number of totally implantable power sources have been proposed, all of which appear to be either impracticable or have serious disadvantages. The more practical power sources which have been proposed for total implantation are as follows: (1) a long-life rechargeable chemical battery, (2) the use of radiofrequency power or magnetic coupling form an external source which transmits power in the form of radiation through the chest wall, (3) a small radioisotope actuated electric battery

and (4) a thermal isotope source for a thermodynamic engine. The use of externally located magnetic or radio-frequency power sources are impractical as they would require the location of the power source at or near the chest wall of the patient and therefore would prove cumbersome. Further, the implantation of chemical or radioactive sources within the patient are undesirable as the energy source would eventually become depleted and require periodic maintenance, possibly surgery, for reactivation or replacement with a new power source. In addition, chemical and radioactive power sources present dangers of radioactive or chemical contamination. Low frequency electro-magnetic energy coupling devices may have a yet unknown deleterious effect on the tissues of the chest wall.

A number of researchers have suggested the use of a thermodynamic engine powered by a thermoisotope source, and a thermonuclear steam engine having a suitable weight and volumetric displacement has reached the design stage (Medical World News, Apr. 2, 1965; Hamilton Standard, Feb. 11, 1966, Final Report to National Heart Institute, pp. 140, 174, 218). However, there is serious doubt as to whether the human body could tolerate the heat dissipation from an implanted thermal source, which in some designs would be dissipated into the blood by means of a heat exchanger.

A second major problem which must be overcome by a practical artificial heart design is a simple and reliable control device for regulating blood flow and pressure in accordance with bodily requirements. Most all of the control designs proposed to date are relatively complicated electrical feedback systems utilizing complex metabolic sensing and monitoring devices. At the present time, all of the physiological parameters involved in the regulation of heart action are not known, and ineed the complexity involved in attempting to duplicate the natural control system is just being recognized. (Such difficulties are discussed in the Hamilton Standard Final Report to the National Heart Institute, Feb. 11, 1966, page 196.)

No proposal to date has been advanced which suggest a practical system which may be powered and regulated by a patient's chest and breathing muscles. Notably, at least one technical report to the National Heart Institute has stated that "the use of skeletal muscle has shown to be infeasible." (Thermo Electron Engineering, Final Report, Artificial Heart Program, March 1966, page 25.) Nevertheless, it is through the use of a recipient's chest and breathing muscles as a power source and means of regulation that the present invention achieves a practical, self regulated artificial heart system with a reliable and safe source of power.

SUMMARY OF THE INVENTION

It is the object of this invention to provide an artificial heart system which may be completely implanted within and fully powered and regulated by a living, breathing body without external connections. This invention provides a pneumatically operated heart system which may totally replace the natural heart function or may be used as an assist device which by-passes all or a part of the natural heart. The artificial heart system disclosed herein requires no artificial source of power either external or internal but rather is fully powered and regulated by the chest and breathing muscles of the recipient body. As the means by which this system is powered will not become depleted, periodic maintenance to replace or reactivate the power source is not required. Surgery or other painful and health injuring procedures is thereby avoided. The artificial heart system provided herein is automatically responsive to the body needs of the patient providing 60 to 80 pumping strokes per minute at an average pumping volume of 5 liters per mintue. The artificial heart of the system is adapted to provide a pressure of 20 to 80 mm. of mercury to the pulmonary portion of the circulatory system and to provide a pressure of 120 to 180 mm. of mercury to the systemic portion of the circulatory system. The artificial heart systems provided herein will generate a negligible amount of heat to be dissipated by the recipient's body, the small amount of heat generated by this system being due to the volumetric inefficiency of the pneumatic pumping system. Further, the artificial heart systems described herein will minimize blood damage through mechanical shock by maintaining laminar flow during pumping and through the use of only two moving parts in the artificial heart, namely two plastic check ball valves. The artificial heart systems of this invention are preferentially provided with a means for introducing make-up air into the pneumatic system to replace gas lost by diffusion through the plastic walls of the pneumatic mechanism, the make-up air being provided thereby by the lungs of the patient or by gas injected into a suitable storage or make-up container located underneath the patient's skin surface. A further advantage of the present invention is that little noise will be generated to remind the patient of his prosthesis. Such noise that is generated will be muffled by the body tissues surrounding the artificial heart system.

Briefly stated, this invention is an artificial heart system for maintaining a normal blood circulation within a living, breathing body. The artificial heart system described herein is comprised of three elements, namely: (a) reciprocating pneumatic pump means for connection to a body for the production of pneumatic pressure in response to relative movements during breathing of the chest and breathing muscles, (b) an artificial heart connected to said pump means and to the circulatory system of the body for circulating blood through the circulatory system under pneumatic power received from said pump, and (c) control means operably connected between the pump means and the artificial heart for maintaining a proportion between the movements of the rib cage and the diaphragm and the rate of circulation powered by the artificial heart.

In one preferred form of this invention, the artificial heart is adapted to totally replace the natural heart of the body. In a second preferred form of this invention, the artificial heart is adapted to assist the natural heart of the body to maintain a normal blood circulation, the artificial heart being synchronized with the pumping action of the natural heart.

BRIEF DESCRIPTION OF THE DRAWINGS

To aid in the understanding of this invention, the design and operation of two preferred forms are explained in detail below in conjunction with the accompanying drawings.

FIG. 1 represents oblique views of the two preferred embodiments of this invention.

FIG. 1*a* depicts an artificial heart comprised of a single blood pump for use as an assist to the left ventricle of the natural heart.

FIG. 1*b* depicts an artificial heart for total replacement of the natural heart. The total replacement heart is comprised of two blood pumps, one for the pulmonary system and the second for the systemic system.

FIG. 2 represents a schematic diagram of the pneumatic system utilized to supply pressure pulses to operate an artificial heart adapted for total replacement of the natural heart.

FIG. 3 represents in cross-section the left half of an artificial heart adapted for total replacement of the natural heart. In this figure, the artificial heart is depicted during the diastole stage of the pumping cycle, i.e. as pneumatic pressure is released from the central pneumatic sac **39** to cause it to contract and thereby induce blood into the surrounding pumping sac **38**. The pneumatic control valve assembly **14**, shown below the artificial heart in cross-section, is depicted in a condition to effect diastole.

FIG. 4 represents in cross-section the left half of the

artificial heart and the control valve assembly **14** at the beginning of systole. During systole pneumatic pressure is introduced into the central pneumatic sac **39** to cause it to expand to fill the surrounding pumping sac **38** thereby expelling blood from the artificial heart.

FIG. 5 represents in cross-section the left half of the artificial heart and the control valve assembly **14** at the end of systole. In the condition depicted the central pneumatic sac **39** has filled the surrounding pumping sac **38** thereby expelling substantially all of the blood from the artificial heart. In this condition, the fully expanded pneumatic sac presses against the outer cushion sac **42** thereby generating a pneumatic pressure pulse which triggers the control valve assembly **14** to begin diastole.

FIG. 6 represents in cross-section one half of an artificial heart for use as an assist to the left ventricle of the natural heart. The artificial heart as well as the pneumatic control valve assembly **73** shown in cross-section below the artificial heart are depicted during the diastole stage of the pumping cycle. A pneumatic sensing collar **82** disposed around the pulmonary artery **83** is actuated by the systolic pulses from the right ventricle of the recipient's natural heart. The sensing collar in turn activates the pneumatic control valve assembly to effect synchronization between the patient's heart and the artificial heart.

FIG. 7 depicts the implantation of the plural element reciprocating pump **1**, its interconnection with the rib cage and diaphragm of the body and the relative positions of the rib cage during inspiration and expiration of breathing.

FIG. 8 illustrates the manner in which the recipient's circulatory system is interconnected with an artificial heart for total replacement of the natural heart.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

First preferred embodiment

Referring to FIGS. 2 and 3, a plural element reciprocating pump assembly, **1** is connected by artificial tendon **2** to the diaphragm of the patient and artificial tendon **3** connects the reciprocating pump to the rib cage. The plural element reciprocating pump is encased in a stainless steel container **4** to prevent growth of tissues in the thoracic cavity from interfering with pumping action. Pneumatic pulses generated by relative movement of the rib cage and diaphragm during breathing is conducted through line **5**, through pump filter and drain **6** and thence through line **7** to a high pressure accumulator **8**. Pump drain **6** filters condensation from the pressurized air from the pneumatic pump **1**, if and when such condensation occurs, and the condensate is drained through a suitable check valve mechanism to line **9**. Air is supplied through line **10** to the intake of the pneumatic pump **1** from the cushion chamber accumulator **11**. Cushion chamber accumulator **11** is provided with a one-way check valve **12** which supplies the cushion chamber accumulator **11** with make-up air from a small tube **12***a* inserted into one of the patient's lungs, if air is used as the pressurizing means. If gas such as CO_2 or O_2 is used because of its ability to dissolve in the blood stream, then the make-up line **12***a* is terminated in a special cavity beneath the chest wall such that additional gas may be supplied by means of an injection through the skin.

High pressure from the high pressure accumulator **8** is supplied through line **13** to valve **20** of the pneumatic control valve assembly **14**. The system is also provided with a low pressure accumulator **15** which is interconnected by lines **16** and **17** with the pneumatic control valve **14**. High pressure accumulator **8** maintains a pressure of from 3.0 to 4.0 p.s.i. Low pressure accumulator **15** maintains a pressure from 2.0 to 3.0 p.s.i. The cushion accumulator **11** maintains a pressure from 1.0 to 2.0 p.s.i. The pneumatic control valve **14** simultaneously provides pneumatic pulses to the left blood pump **18** and the right blood pump **19** of the artificial heart assembly **31***b*. The pneumatic pulses for the left blood pump **18** supplied through line **32** and the pneumatic pulses for the right blood pump **19** being supplied through line **33**. The pneumatic exhaust from the artificial heart assembly **31***b* to the pneumatic control valve **14** is provided by line **34** for the left blood pump **18** and line **35** for the right blood pump **19**. The artificial heart system in effect operates to convert the 12 to 18 strokes per minute of the diaphragm or breathing muscles to 60 to 80 pumping strokes per minute of the artificial heart pump. Pressure generated in pneumatic pump **1** in response to the action of the body breathing muscles develops high pressure in the range of 3 to 4 p.s.i. which is accumulated in the high pressure accumulator **8**. The high pressure accumulator introduces high pressure into pneumatic control valve **14** which distributes the pneumatic pressure to the artificial heart **31***b*. The low pressure accumulator **15** retains pressure at 2 to 3 p.s.i. and the cushion chamber accumulator **11** retains pressure at from 1 to 2 p.s.i. The pneumatic control valve additionally supplies pulses of pneumatic pressure to the left and right blood pumps, the left blood pump **18** being actuated by pressure pulses supplied from the high pressure accumulator **8** and the right pneumatic blood pump **19** being operated by pressure pulses supplied from the low pressure accumulator **15**. The low pressure accumulator **15** is charged by the exhaust pressure of the left blood pump **18**, and the cushion chamber **11** is charged by the exhaust pressure of the right blood pump.

The pumping cycle of the left blood pump **18** of the artificial heart **31***b* is depicted in FIGS. 3, 4 and 5. FIG. 3 depicts the condition of the left blood pump towards the end of diastole; FIG. 4 depicts the beginning of systole; and FIG. 5 depicts the end of systole. Referring to FIG. 3, the left blood pump **18** is depicted at the end of the pumping cycle, i.e. the end of diastole. The left blood pump **18** is supplied by an expandable reservoir sac **35** whose walls are expandable and contractable to prevent underfilling of the artificial ventricles and as well to prevent the formation of vapor bubbles in the blood due to a negative pressure that would be created during diastole of the blood pump. The expandable reservoir sac **35** is adapted for interconnection with a vein at inlet tube **36**. An inlet tube **37** is connected with the fluid chamber **40** of left blood pump **18**. The left blood pump **18** is comprised of a pumping sac **38** defining a pumping chamber **40**. Disposed within the said fluid chamber **40** is a pneumatic sac **39** defining pneumatic chamber **41** which may be expanded to completely fill the fluid chamber **40** and thereby effect the pumping action. The fluid sac **38** is at least partially surrounded by pneumatic cushion sac **42** which defines the pneumatic cushion chamber **43**. Pneumatic cushion sac **42** and fluid sac **38** are surrounded by a semi-rigid housing **44**. Pneumatic chamber **41** is provided with an inlet **45** and an outlet tube **46**. A fluid chamber is provided with inlet tube **47** interconnecting with the outlet tube **37** of the expandable reservoir sac **35**. The pumping sac **38** is additionally supplied with an outlet check valve **48** and outlet tube **49** adapted for interconnection with an artery. The cushion chamber is provided with an outlet tube **50**.

The beginning of the artificial heart pumping cycle, i.e. the beginning of systole is depicted in FIG. 4. At this stage of the cycle, the pneumatic chamber outlet tube **46** is effectively blocked by pneumatic control valve assembly **14** while high pressure air from the high pressure accumulator **8** is introduced into the pneumatic chamber inlet **45**. As the pressure in the pneumatic chamber **41** is increased, the pneumatic sac **39** expands to fill pumping chamber **40**. It should be noted that at this stage of the pumping cycle the pneumatic sac **39** has expanded sufficiently to block off the inlet **47** to fluid chamber **40** and thereby the backward flow of blood into the expandable reservoir chamber **37** is prevented. As depicted in FIG. 4, the outlet ball check valve **48** is forced open during this part of the cycle to allow blood

to be expelled from fluid chamber **40** through outlet **49** and into an interconnected artery.

FIG. 5 represents the stage of the pumping cycle at which pneumatic sac **39** has been completely expanded to fill the pumping chamber **40**, i.e. the end of systole. The pneumatic sac **39** by expanding to completely fill fluid chamber **40** insures that blood is completely exhausted from the pumping chamber **40** during each pumping cycle and that thereby no stagnant blood is entrapped within the pumping mechanisms and allowed to deteriorate therein. At the end of systole, check ball valve **48** becomes seated in the fluid chamber outlet and closes the fluid chamber **40** off from back flow from the circulatory system. The ball check valve seats against the soft plastic material of the fluid chamber outlet **49** and is further cushioned by the air voids **130** in order to prevent damage to the blood by any sudden squeezing effect. Towards the end of systole the expanding pneumatic sac **39** forces itself against the wall of the pumping sac **38** and causes the pneumatic cushion sac **42** to collapse thereby forcing the air contained in cushion chamber **43** out through line **51** to the pneumatic control valve **14**. The pressure introduced by **51** into the pneumatic control valve **14** forces the oscillating valve assembly to reposition itself in such a manner that the inlets to the pneumatic chambers of both the left and right blood pumps **18**, **19** are shut off, the outlets to the pneumatic chambers of boh right and left blood pumps **18**, **19** are opened and pneumatic pressure contained within the pneumatic chambers of both blood pumps are exhausted. The pneumatic pressure from the left blood pump is exhausted through control valve assembly **14** into the low pressure accumulator **15** and the right blood pump is exhausted through control valve assembly **14** into the cushion accumulator **11**.

The flow control unit **131** shown in FIG. 5 serves as a pneumatic time delay to assure total pumping action and complete evacuation of both right and left pneumatic chambers before the increased pressure in pneumatic cushion chamber **43** is transmitted through line **51** to the pneumatic control valve **14**. One-way valve **132** maintains an air supply in the pneumatic cushion sac **43** whenever the pressure in the sac falls below that of the pneumatic cushion chamber **11**. (The lowest ambient pressure that exists in pneumatic cushion chamber **43** throughout its cycle is that of the cushion chamber **11**.)

The regulation and control of the pumping action in this system is provided by virtue of the fact that the body breathing rate varies in accordance with the bodily requirement for oxygen. As the bodily requirement increases the breathing rate also increases thereby developing a greater force to actuate the reciprocating pneumatic pump **1** with the result that the pneumatic pressure supplied to the artificial heart system is increased. The increased pressure in the system increases the pumping rate of the artificial heart and greater power is developed in each pumping stroke. In like manner, as the bodily oxygen demand is decreased, the body breathing rate also decreases causing a reduction in the pumping rate and power developed by the artificial heart. In this manner, the artificial heart system accomplishes self-regulation that is fully responsive to the physiological requirements of the patient.

Second preferred embodiment

FIG. 6 illustrates a second preferred embodiment of this invention in which a single artificial heart pump **31***a* is used as a ventricular assist to assist a weakened natural heart by aiding or wholly replacing the pumping action of the natural heart's left ventricle which performs the majority of the pumping work in the human heart.

The artificial heart assist system depicted in FIG. 6 is similar in construction and function of the system described above for total replacement. Blood is introduced from the pulmonary vein into an inlet tube **60** of an expandable reservoir sac **61**. The function of the expandable reservoir sac **61** is to expand and contract and thereby maintains a pressure at all times upon the blood above its vapor pressure at the ambient temperature. Blood travels from the reservoir sac **61** to the reservoir exit tube **62** and into the inlet of the pumping chamber **65**. Blood is pumped from the inlet **64** through the pumping chamber **65** and exits through the ball check valve **66** to the pumping chamber exit tube **67** which is interconnected with the patient's ascending aorta. In this manner the patient's left ventrical is by-passed and the effort of the patient's heart is directed to pumping blood into the right ventricle of the natural heart.

As is the case in the total implanted system, the ventricle assist blood pump is comprised of a pumping sac **68** defining a fluid chamber **65** in which is located an expandable pneumatic sac **69** defining the pneumatic chamber **70**. The pneumatic chamber **70** is provided with an inlet **71** which connects through line **72** to the pneumatic pressure control valve **73**, said pneumatic control valve functioning in a manner similar to control valve **14** of the total replacement system. The inlet tube is adapted to receive high pressure from the pneumatic control valve **73** which causes the inflation of the pneumatic sac **69**. The inflation of the pneumatic air sac provides the pumping function of the blood pump by expanding to completely fill the fluid chamber **65** and thereby gently forcing the blood content in the fluid chamber out through ball check valve **66** and to the ascending aorta.

The pneumatic air chamber **70** is additionally supplied with an exit tube **74** which connects by line **75** to the pneumatic pressure control valve **75** whereby the pneumatic chamber is exhausted during the diastole portion of the pumping cycle through the pneumatic control valve to cause collapse of the pneumatic sac **69** and thereby places the blood pump **31***a* in condition for another pumping stroke.

As is the case of the total implanted system, the fluid sac is at least partially surrounded by a pneumatic cushion sac **76** defining a pneumatic cushion chamber **78** which has the function of cushioning the shock of the pumping action of the pneumatic sac. The pneumatic cushion chamber **78** connects by means of exit **79** through line **80**, and a one-way valve **134** to cushion chamber accumulator **81**.

The control and regulation of the pumping action is provided by pneumatic sensing collar **82** which fits around the neck of the pulmonary artery **83**. Systole of the patient's natural heart causes the pulmonary artery to expand and thereby constrict the pneumatic sensing collar **82** to generate a pneumatic pulse. The pneumatic pulse from sensing collar **82** is conveyed through line **84** to the flow control valve **133** to actuate diaphragm **135** and thereby cause the conical valve head **136** to become unseated. When the flow control valve **133** is in this condition a pneumatic pressure pulse generated by cushion chamber **78** (as the blood pump **31***a* reaches the end of systole) will freely pass through line **80** and the flow control valve **133** into chamber **126** to trigger the pneumatic control valve **73** to effect diastole of the artificial heart. In this manner, the pumping cycle of blood pump **31***a* is synchronized with the action of the patient's natural right ventricle.

As in the total implanted system, the artifical heart system is powered by a pneumatic pump **85** encased in a stainless steel case **86** which is activated by the relatively reciprocating motion of the patient's rib cage and diaphragm by means of artificial tendon **87** connected to a rib and artificial tendon **88** connected to the patient's diaphragm. High presure pulses from the pneumatic pump **85** are sent through line **89** to filter **90** which filters condensate from the pressurized air, such condensate being led from filter **90** through line **91**. Filtered pressurized pulses travel from filter **90** through line **92** to the high pressure accumulator **93**. The high pressure from the accumulator travels through line **95** to the high pressure inlet valve **96** of the pneumatic control valve **73**. The

exhaust from the pneumatic chamber **70** travels through line **75** to the pneumatic control valve **73** and there to the cushion accumulator chamber **81**. The pneumatic pressure is recycled from cushion chamber **81** to the intake of the pneumatic pump **85**. Make-up air is provided through line **99** which provides make-up air from the patient's lung to replace air which may be lost over long periods by leakage through the pores of the plastic walls of the various components of the artifical heart system.

DESCRIPTION OF THE METHOD OF IMPLANTATION

FIG. 7 illustrates the implantation of the pneumatic pump for both total replacement and assist systems. The pneumatic pump **100** is located within the thoracic cavity **101** defined by the rib cage **102** and diaphragm **103**. The pneumatic pump **100** is connected by means of an artificial tendon **104** to a rib **105** and is also connected by means of a second artifical tendon **106** to the diaphragm **103**. Advantageously, tendon **106** is attached to the diaphragm **103** by means of a stainless steel wire reinforced Dacron web **107** which is sewn to the diaphragm at **107***a*. The junction of the diaphragm to the chest wall is separated by a narrow plastic lining **107***b* to prevent the formation of adhesions. The stainless steel wire reinforced Dacron web **107** used to harness the diaphragm is woven into the small diameter artifical tendon **106**. The same construction is utilized to manufacture the second artifical tendon **104**.

Reference numbers **102** and **102'** represent the relative location of the rib cage during inspiration and expiration, respectively. In like manner, reference numbers **103** and **103'** represent the relative location of the diaphragm during inspiration and expiration, respectively. In FIG 7*b*, the relative location of the artifical tendons **104** and **106** and the pneumatic pump **100** are shown during inspiration.

FIG. 8 represents the manner in which the recipient's circulatory system is interconnected with an artifical heart for total replacement of the natural heart. FIG. 108 represents in cross-section a natural heart which is removed for total implantation of the artifical heart system. FIG. 109 represents in cross-section the aortic arch which is connected by a suitable sleeve **110** of an inert woven plastic such as Dacron for connection to the outlet of the left blood pump **18** of the artifical heart. The pulmonary veins **111** likewise are connected by means of an inert woven plastic sleeve **112** to the expandable reservoir sac of the left blood pump **18**. The superior and vena cava **114** are connected by sleeve **115** to the inlet of the expandable reservoir sac of the right blood pump **19**. The pulmonary arteries are connected by sleeve **116** to the outlet of the right blood pump **19**. By this means, the entire circulatory system of the patient is interconnected with the artifical heart to effect a total replacement of the function of the natural heart.

DESCRIPTION OF THE OPERATION OF THE PNEUMATIC CONTROL VALVES

The operation of the two pneumatic control valve assemblies **14** and **73** described above can be best explained by describing first the operation of the pneumatic control valve assembly **73** for the artifical heart system depicted by FIG. 6. In FIG. 6, the pneumatic control valve **73** is shown to be comprised of a housing **118**, a control rod **119** which is allowed limited horizontal movement, and three pressure sealing diaphragms **120**, **121** and **122**, all operably connected to the control rod **119**. In addition, there are four pneumatically sealed chambers identified by reference number **123**, **124**, **125** and **126** which are defined by the housing **73** and three pneumatically sealed diaphragms **120**, **121** and **122**. The control rod **119** is provided with ball valve heads **96** and **127** which are adapted to seat against valve orifices **128** and **129**. The control rod **119** is spring loaded by spring **130** which tends to force the rod into position as depicted in FIG. 6. In the condition depicted by FIG. 6, valve orifice **128** is open to allow pneumatic pressure from the high pressure accumulator **93** to pass through chamber **123** to line **72** and then to pneumatic chamber **70** of the artifical heart. In the condition depicted by FIG. 6, valve orifice **129** is closed with ball valve head **127** seated thereby blocking exhaust from the exit **74** of the pneumatic chamber **70**. In this condition, the pneumatic control valve assembly **73** effects systole by expanding pneumatic sac **69** under pneumatic pressure supplied from the high pressure accumulator **93**.

As the right ventricle of the natural heart effects systole, the expansion of the pulmonary artery **83** will cause the pneumatic sensing collar **82** to generate a pneumatic pulse which is conveyed through line **84** to flow control valve **133** to actuate diaphragm **135** and thereby cause the conical valve head **136** to become unseated. In this condition, a pneumatic pulse from cushion chamber **78** will freely pass through line **80** and the flow control valve **133** into chamber **126** of the pneumatic control valve **73**. As explained above, when pneumatic sac **69** has expanded to fill pumpng chamber **65** at the end of systole, the pneumatic sac presses against cushion sac **76** and thereby generates a pneumatic pulse. The pneumatic pulse from cushion chamber **78** when synchronized with systole of the right ventricle of the natural heart will be conveyed to pneumatic chamber **126** of the control valve assembly and operate against the pneumatic diaphragm **122** to force the control rod assembly into a position to effect diastole.

When control valve **73** is in condition to effect diastole, the control rod **119** is positioned so that ball valve **96** is seated against valve orifice **128** thereby stopping the flow of high pressure to the pneumatic chamber **70**. Ball valve head **127** is unseated and pneumatic pressure in pneumatic chamber **70** may freely exhaust through valve orifice **129** to cushion chamber **81**.

When in an open condition, conical valve head **136** acts as a pneumatic time delay which delays the build up of pneumatic pressure in pneumatic chamber **126**. By providing this time delay, the pneumatic sac **69** is allowed to fully expand within the pumping chamber **65**. The time delay action of conical valve head **136** also acts to delay the release of pressure from pneumatic chamber **126** as the pneumatic sac **69** contracts and the pressure in the cushion chamber **78** returns to that of the cushion chamber **81**. In this manner, by a careful adjustment of the amount of travel of the conical valve head **136** when it is opened by pressure applied to pneumatic diaphragm **135**, the diastolic and systolic rates of the blood pump may be adjusted.

The control valve assembly **14** for the total replacement artificial heart system operates in essentially the same manner. The major difference between the two control valve assemblies **14** and **73** is that control valve assembly **14** operates two blood pumps **18** and **19** rather than one. Control valve assembly **14** comprises a housing **137**, a control rod **138**, five pneumatically sealed diaphragms **139**, **140**, **141**, **142** and **143**, all connected to control rod **138**, and four ball valve heads **20**, **144**, **145** and **146** disposed along the control rod **138** which are adapted to seat against valve orifices **148**, **149**, **150** and **151**. The five pneumatic diaphragms in the housing **137** define eight pneumatically sealed chambers **152**, **153**, **154**, **155**, **156**, **157**, **158** and **159**. Spring **147** acts against rod **138** to force the control rod into position depicted in FIG. 2. In this position, valve orifices **148** and **150** are open to allow pneumatic pressure to enter the pneumatic chambers of both left and right blood pumps of the artificial heart. Valve heads **144** and **146** are seated against their respective valve orifices **149** and **151** to block the exit tubes of the pneumatic chambers of both right and left blood pumps. In this condition, the control valve **14** affects systole by expanding the pneumatic sacs of both

blood pumps **18** and **19** to fill the pumping chambers and thereby expel blood from the artificial heart to the interconnected arteries.

As the artificial heart **31***b* reaches the end of systole, the cushion chamber **43** of the left blood pump **18** generates a pneumatic pulse which is conveyed through line **51** to flow control valve **131** and then to pneumatic chamber **159** to actuate pneumatic diaphragm **143**. The flow control valve assembly **131** is provided with an adjustable truncated conical valve head **160** which provides for a time delay in the build up of the pneumatic pressure from cushion chamber **43** actuating pneumatic diaphragm **143**. When the left blood pump **18** reaches the end of systole, the pneumatic pressure in chamber **159** reaches a sufficient value to drive the control rod **138** into a position in which valve heads **20** and **145** are seated against valve seat orifices **148** and **150** thereby terminating the flow of pneumatic pressure through both the pneumatic chambers of the artificial heart **31***b*. In this position orifice valves **144** and **146** are open to allow the exhaust of pneumatic pressure from the two pneumatic chambers of the artificial heart **31***b*. As both pneumatic chambers contract and the pressure in cushion chamber **43** of the left blood pump returns to a value equal to the pressure in the cushion chamber **11**, pneumatic pressure in pneumatic pressure chamber **159** passes through flow control valve **131** to the cushion chamber. Flow control valve **131** during this phase of the pumping cycle also acts as a time delay in the release of pneumatic pressure from pneumatic chamber **159** whereby the control valve rod **138** is held in a position for a sufficient length of time to completely effect diastole. The degree of obstruction presented by control valve head **160** is adjustable by means of turn screw **161** whereby the diastolic and systolic rates of the artificial heart system may be adjusted.

VOLUMETRIC AND ENERGY REQUIREMENTS OF THE PREFERRED EMBODIMENTS

The various components of the artificial heart systems described above are sufficiently light and have a sufficiently small volumetric displacement for implantation in the pericardial and thoracic cavities of the recipient body. The artificial heart and the pneumatic control valve assembly are adapted to be implanted in the pericardial cavity. The various pneumatic accumulators, which are adapted to implantation in the thoracic cavity, all have specific gravities less than 1.0 and therefore need not be supported. The volumetric displacement of the high pressure accumulator is approximately 100.0 cubic inches. The low pressure accumulator will displace 75.0 cubic inches, and the cushion chamber accumulator will displace 50 cubic inches.

The energy required to operate the various artificial heart systems described above is provided by the muscular energy of the patient's diaphragm. The human diaphragm develops on the average 21.7 ft.-lbs. of work per stroke during relaxed breathing and 54.4 ft.-lbs. of work per stroke during heaving breathing. For total replacement the artificial heart system will require 6.2 ft.-lbs. of energy per stroke. An artificial heart system to assist or replace the function of the left ventricle of the natural heart will require 2.57 ft.-lbs. of energy per stroke. Therefore, the diaphragm muscles of the recipient will readily adapt to the additional effort required to power an implanted artificial heart system and the interference to normal body breathing will be minor.

The above disclosure and particularly the two preferred embodiments set forth therein are by way of illustration only and are not intended to limit the scope of the invention described herein. Other working media than a compressible pneumatic gas may be used advantageously, for example, a relatively incompressible hydraulic fluid. It should be obvious to one skilled in the art that many modifications and variations may be made upon the artificial heart system disclosed above without departing from the spirit and the scope of the invention.

I claim:

1. An artificial heart system for maintaining a normal blood circulation within a living, breathing body at a variable rate according to the requirement of the body comprising:

(a) reciprocating pneumatic pump means for connection to a body for the production of pneumatic pressure in response to relative movements of the chest and breathing muscles during breathing,

(b) an artificial heart connected to said pump means and adapted to be connected to the circulatory system of the body for circulating blood through the circulatory system under pneumatic power received from said pump, and

(c) control means operably connected between the pump means and the artificial heart for maintaining a proportion between the relative movements of the chest and breathing muscles and the rate of circulation powered by the artificial heart.

2. An artificial heart system described by claim **1** in which:

(a) the artificial heart is comprised of an inert flexible plastic material defining a plurality of chambers adapted to receive blood from at least one interconnected vein and to pump said blood to at least one interconnected artery, said chambers comprising at least one reservoir chamber interconnected with one pumping chamber, said reservoir chamber adapted to receive blood from an interconnected vein and to deliver said blood to the pumping chamber at a pressure sufficiently greater than the vapor pressure of the blood, said pumping chamber operable to alternately receive a quantity of blood from the reservoir chamber and expel said glood to an interconnected artery in response to the alternate receipe and release of pneumatic pressure supplied to the artificial heart from the control means, said pumping chamber expelling blood upon the receipt of pneumatic pressure and receiving blood upon the release of said pneumatic pressure.

(b) the control means comprises a plurality of pneumatic pressure accumulators for supplying pneumatic pressure to the artificial heart and receiving pneumatic pressure released therefrom and a control valve assembly positioned between said pneumatic pressure accumulators and the artificial heart for controlling the supply and release of pneumatic pressure for the artificial heart to thereby operate said pumping chambers, a first and a second of said accumulators being positioned between the reciprocating pneumatic pump means and the control valve assembly, said first accumulator interconnected with the reciprocating pneumatic pump means and the control valve assembly and thereby adapted to be charged with pneumatic pressure produced by the pneumatic pump means and to supply pneumatic pressure to the pneumatic control valve assembly, said second accumulator interconnected with the control valve assembly and the reciprocating pneumatic pump means and thereby adapted to be charged with pneumatic pressure released from the control valve assembly and to supply pneumatic pressure to the pneumatic reciprocating pump means, said pneumatic control valve assembly comprising a plurality of valve means operable in unison at a rate proportional to the value of the pneumatic pressure supplied by said first accumulator, said valve means operating to alternately supply and release pneumatic pressure for the artificial heart and thereby operate the pumping chambers, and

(c) the reciprocating pneumatic pump comprises a plurality of elements, a first element of said recipro-

cating pneumatic pump having means for connection to the rib cage of the body and a second element having means for connection to the diaphragm of the body, said connecting means adapted to reciprocate said pump elements upon relative movement of the rib cage and diaphragm during inspiration and expiration of breathing of the body, said pneumatic pump supplying pneumatic pressure to said first accumulator upon inspiration of the body at a value dependent upon the frequency and force of relative movements of the rib cage and diaphragm during inspiration of breathing,

whereby variable pumping rate of the artificial heart is attained according to the requirement of the body by maintaing a proportion between the rate of body breathing, the value of pneumatic pressure supplied to the high pressure accumulator, and the rate at which the control valve assembly alternately supplies and releases pressure for the pneumatic chambers of the artificial heart.

3. An artificial heart system described in claim 2 in which:

(a) the artificial heart is adapted to generate a pressure pulse as one of the pumping chambers expels blood to an interconnected artery, said artificial heart provided with means to deliver said pneumatic pressure pulse to the control valve assembly, and

(b) the pneumatic pressure control valve assembly is adapted to be actuated by said pneumatic pressure pulse to release pneumatic pressure from the artificial heart to cause the pumping chambers of the artificial heart to receive blood from the interconnected reservoir chambers, said control valve assembly adapted to alternately supply and release pneumatic pressure for the artificial heart and thereby effect variable control of the pumping rate of the artificial heart according to the requirements of the body.

4. An artificial heart system described by claim 3 in which:

(a) a flow control valve is operably connected between the artificial heart and the control valve assembly, said flow control valve operable to control the value of the pneumatic pressure pulse delivered to the control valve assembly from the artificial heart as one of the pumping chambers expels blood to an interconnected artery, and

(b) a pneumatic sensing collar adapted to be disposed around the pulmonary artery of the body and adapted to generate a pneumatic pressure pulse as said pulmonary artery expands during systole of the right ventricle of the natural heart of the body, said pneumatic sensing collar provided with means to deliver said pneumatic pressure pulse to the flow control valve, said flow control valve actuated by a pneumatic pressure pulse from the sensing collar to allow a sufficient value of pneumatic pulses from the artificial heart to be delivered to the control valve assembly which is actuated thereby to release pressure from the artificial heart to cause the pumping chambers of the artificial heart to receive blood from the interconnected reservoir chambers,

whereby the pumping action of the artificial heart is synchronized with the natural heart of the body by means of pneumatic pressure pulses supplied to the flow control valve from the pneumatic sensing collar.

5. An artificial heart system described by claim 3 in which the artificial heart is comprised of a first reservoir chamber interconnected with a first pumping chamber and a second reservoir chamber interconnected with a second pumping chamber, said artificial heart being adapted to be interconnected with the circulatory system of the body with the first reservoir chamber interconnected with the inferior and superior vena cava and the first pumping chamber interconnected with the pulmonary artery, the second reservoir chamber interconnected with the pulmonary vein and the second pumping chamber interconnected with the aortic arch, said artificial heart adapted to generate a pressure pulse when blood is substantially expelled from the pumping chambers, said artificial heart provided with means to deliver said pneumatic pressure pulse to the control valve assembly, whereby the artificial heart totally replaces the natural heart of the body and maintains a normal blood circulation in the circulatory system according to the requirement of the body.

6. An artificial heart system described by claim 4 in which the artificial heart is comprised of a one reservoir chamber interconnected with one pumping chamber, said artificial heart adapted to be interconnected with the circulatory system of the body with said reservoir chamber interconnected with the pulmonary vein and the pumping chamber interconnected with the ascending aorta, whereby the artificial heart assists the natural heart of the body to maintain a normal blood circulation in the circulatory system, said artificial heart being synchronized with the pumping action of the natural heart by means of pneumatic pressure pulses supplied to the control valve assembly from the pneumatic sensing collar.

7. An artificial heart system described by claim 5 in which:

(a) the artificial heart is comprised of:

(i) a first expandable reservoir sac defining a first reservoir chamber interconnected with a first blood pump defining a first pumping chamber, a first pneumatic chamber and a first cushion chamber,

(ii) a second expandable reservoir sac defining a second reservoir chamber interconnected with a second blood pump defining a second pumping chamber, a second pneumatic chamber and a second cushion chamber,

said pneumatic chambers adapted to receive pneumatic pressure from the control valve assembly to expel blood contained within said pumping chambers, said pneumatic chambers further adapted to release pneumatic pressure to the control valve assembly to allow said pumping chambers to receive blood from the interconnected reservoir chambers, said first cushion chamber adapted to generate a pressure pulse when blood is substantially expelled from the pumping chamber, said first cushion chamber provided with means to deliver said pneumatic pressure pulse to the control valve assembly,

said artificial heart being adapted to be interconnected with the circulatory system of the body with the second reservoir chamber interconnected with the inferior and the superior vena cava and the second pumping chamber interconnected with the pulmonary artery, the first reservoir chamber interconnected with the pulmonary vein and the first pumping chamber interconnected with the aortic arch,

(b) the control means is comprised of:

(i) a high pressure accumulator interconnected with the reciprocating pneumatic pump means and the control valve assembly and thereby adapted to be charged with pneumatic pressure produced by the pneumatic pump means and to supply pneumatic pressure to the pneumatic control valve assembly to operate said first pneumatic chamber,

(ii) a low pressure accumulator interconnected with the control valve assembly and thereby adapted to be charged with pneumatic pressure from the first pumping chamber and to supply

pneumatic pressure to the second pneumatic chamber,

(iii) a cushion chamber accumulator interconnected with the reciprocating pneumatic pump means and the control valve assembly and thereby adapted to be charged with pneumatic pressure from the second pneumatic chamber and to supply pneumatic pressure to the pneumatic reciprocating pump means,

(iv) a control valve assembly interconnected with said accumulators, said pneumatic chambers, and the first cushion chamber, said pneumatic control valve assembly comprising a plurality of valve means operable in unison at a rate proportional to the valve of the pneumatic pressure supplied by the high pressure accumulator, said pneumatic pressure control valve assembly adapted to be actuated by a pneumatic pressure pulse from the first cushion accumulator to release pneumatic pressure from the pneumatic chambers, said control valve means operating to alternately supply and release pneumatic pressure for the pneumatic chambers and to thereby operate the pumping chambers, and

(c) the reciprocating pneumatic pump comprises a plurality of elements, a first element of said reciprocating pneumatic pump having means for connection to the rib cage of the body and a second element having means for connection to the diaphragm of the body, said means adapted to reciprocate said pump elements upon relative movement of the rib cage and diaphragm during inspiration and expiration of breathing of the body, said pneumatic pump supplying pneumatic pressure to said first high pressure accumulator upon inspiration of the body at a value dependent upon the frequency and force of relative movements of the rib cage and diaphragm during inspiration of breathing,

whereby variable pumping rate of the artificial heart is attained according to the requirement of the body by maintaining a proportion between the rate of body breathing, the value of pneumatic pressure supplied to the high pressure accumulator, and the rate at which the control valve assembly alternately supplies and releases pressure for the pneumatic chambers of the artificial heart.

8. An artificial heart system described by claim **6** in which:

(a) the artificial heart is comprised of an expandable reservoir sac defining a reservoir chamber interconnected with a blood pump defining a pumping chamber, a pneumatic chamber and a cushion chamber, said pneumatic chamber adapted to received pneumatic pressure from the control valve assembly to expel blood contained within said pumping chamber, said pneumatic chamber further adapted to release pneumatic pressure to the control valve assembly to allow said pumping chamber to receive blood from the interconnected reservoir chamber, said cushion chamber adapted to generate a pressure pulse when blood is substantially expelled from the pumping chamber, said cushion chamber being provided with means to deliver said pneumatic pressure pulse to the control valve assembly, said artificial heart adapted to be interconnected with the circulatory system of the body with said reservoir chamber interconnected with the pulmonary vein and the pumping chamber interconnected with ascending aorta,

(b) the control means comprises:

(i) a high pressure accumulator interconnected with the reciprocating pneumatic pump means and the pneumatic control valve assembly and thereby adapted to be charged with pneumatic pressure produced by the pneumatic pump means and to supply pneumatic pressure to the pneumatic control valve assembly to operate the pnematic chamber,

(ii) a cushion chamber accumulator interconnected with the reciprocating pneumatic pump means and the control valve assembly and thereby adapted to be charged with pneumatic pressure supplied by the control valve assembly from the pneumatic chamber and to supply pneumatic pressure to the pneumatic reciprocating pump means,

(iii) a flow control valve assembly operably connected between the artificial heart and the control valve assembly, said flow control valve operable to control the value of the pneumatic pressure pulses delivered to the control valve assembly from the artificial heart as the pumping chamber exepels blood to the ascending aorta,

(iv) a pneumatic sensing collar adapted to be disposed around the pulmonary artery of the body and adapted to generate a pneumatic pressure pulse as said pulmonary artery expands during systole of the right ventricle of the natural heart of the body, said pneumatic sensing collar provided with means to deliver said pneumatic pressure pulse to the flow control valve, said flow control valve actuated by a pneumatic pressure pulse from the sensing collar to allow a sufficient value of pneumatic pulses from the artificial heart to be delivered to the control valve assembly which is actuated thereby to release pressure from the artificial heart to cause the pumping chambers of the artificial heart to receive blood from the interconnected reservoir chambers,

(v) a control valve assembly interconnected with said accumulators, the artificial heart and the flow control valve, said control valve assembly comprising a plurality of valve means operable in unison at a rate synchronized with the pumping rate of the natural heart, said control valve assembly adapted to be actuated by pneumatic pressure pulses from the cushion chamber of the artificial heart to thereby cause the control valve assembly to release pressure from the pneumatic chamber and thereby allow the pumping chamber to receive blood from the interconnected reservoir chamber, said valve means operating to alternately supply and release pneumatic pressure for the artificial heart and thereby operate the pumping chambers,

(c) the reciprocating pneumatic pump comprises a plurality of elements, a first element of said reciprocating pneumatic pump having means for connection to the rib cage of the body and a second element having means for connection to the diaphragm of the body, said means adapted to reciprocate said pump elements upon relative movement of the rib cage and diaphragm during inspiration and expiration of breathing of the body to thereby supply pneumatic pressure to the high pressure accumulator,

whereby the artificial heart assists the natural heart of the body to maintain a normal blood circulation in the circulatory system, said artificial heart being synchronized with the pumping action of the natural heart by means of pneumatic pressure pulses supplied to the flow control valve from the pneumatic sensing collar.

9. In the artificial heart system described by claim **7**, an artificial heart comprising:

(a) a first expandable reservoir sac defining a first reservoir chamber interconnected with a first blood pump defining a first pumping chamber, a first pneumatic chamber and a first cushion chamber,

(b) a second expandable reservoir sac defining a second reservoir chamber interconnected with a second

blood pump defining a second pumping chamber, a second pneumatic chamber and a second cushion chamber,

(c) each expandable reservoir sac comprising an inert flexible plastic defining a reservoir chamber provided with an inlet tube and an outlet tube, the inlet tube adapted to interconnection with the vein and the outlet tube communicating the reservoir chamber with the pumping chamber of the blood pump, said reservoir chamber adapted to maintaining a pressure upon blood contained therein at a sufficient value so that when pumped by the pneumatic pump the blood will be maintained at a pressure greater than its vapor pressure,

(d) each of said blood pumps comprising:

(i) a pumping sac adapted to receive blood from an interconnected reservoir chamber and to deliver said blood to an interconnected artery, said pumping sac comprising an elongated inert flexible plastic sac defining the pumping chamber and provided at one end with an inlet communicating with the outlet of the interconnected expandable reservoir sac and an outlet at the opposite end provided with an inert plastic ball check valve communicating with an outlet tube adapted to interconnection with an artery,

(ii) an expandable pneumatic sac located within said pumping chamber and adapted to receive and release pneumatic pressure to effect pumping of the blood contained within the pumping chamber, said pneumatic sac comprising an expandable inert plastic sac defining a pneumatic chamber provided with an inlet tube at the inlet end of the pumping sac and an outlet tube at the outlet end of the pumping sac, said inlet and outlet tubes communicating the pneumatic chamber with the control valve assembly, said pneumatic sac adapted to expand to fill the pumping chamber by the introduction of pneumatic pressure into the pneumatic chamber so that blood contained in the pumping chamber is expelled from the pumping chamber through the ball check valve at the pumping chamber outlet, said pneumatic sac adapted to contract from an expanded condition by the release of pneumatic pressure from the pneumatic chamber so that blood contained in the reservoir chamber is induced into the pumping chamber,

(iii) a cushion sac at least partially surrounding said pumping sac and adapted to pneumatically cushion the pumping action of the pneumatic sac, said cushion sac comprising an expandable inert plastic sac defining a cushion chamber and adapted to being compressed to thereby generate a pneumatic pressure pulse as the pneumatic sac expands to fill the pumping chamber, said pneumatic cushion sac provided with an exit tube communicating with the cushion chamber, the cushion chamber exit tube for the second blood pump for interconnection with the cushion chamber accumulator and the cushion chamber exit tube for the first blood pump for interconnection with the pneumatic pressure control valve assembly, the pneumatic pressure pulses from the first cushion chamber controlling the action of the control valve assembly to actuate the control valve assembly to release pneumatic pressure from both pneumatic chambers,

(iv) a housing of inert semi-rigid plastic at least partially surrounding said cushion sac and said pumping sac, said housing adapted to confine the expansion of both the cushion sac and the pumping sac.

10. In the artificial heart system described by claim **8**, an artificial heart comprising:

(a) an expandable reservoir sac defining a reservoir chamber interconnected with a blood pump defining a pumping chamber, a pneumatic chamber and a cushion chamber,

(b) the expandable reservoir sac comprising a flexible inert plastic sac defining a reservoir chamber provided with an inlet tube and an outlet tube, the inlet tube adapted to interconnection with a vein and the outlet tube communicating the reservoir chamber with the pumping chamber of the pneumatic pump, said expandable reservoir sac adapted to maintaining a pressure upon blood contained therein at a sufficient value so that when pumped by the blood pump the blood will be maintained at a pressure greater than its vapor pressure, and

(c) said blood pump comprising:

(i) a pumping sac adapted to receive blood from an interconnected reservoir chamber and to deliver said blood to an interconnected artery, said pumping sac comprising an elongated flexible inert plastic sac defining a pumping chamber provided at one end with an inlet communicating with the outlet of an expandable reservoir sac and an outlet at the opposite end provided with an inert plastic ball check valve communicating with an outlet tube adapted to be interconnected with an artery,

(ii) an expandable pneumatic sac located within said pumping chamber and adapted to receive and release pneumatic pressure to effect pumping of the blood contained within the pumping chamber, said pneumatic sac comprising an expandable inert plastic sac defining a pneumatic chamber provided with an inlet tube at the inlet end of the pumping sac and an outlet tube at the outlet end of the pumping sac, said inlet and outlet tubes communicating the pneumatic chamber with the control valve assembly, said pneumatic sac adapted to expand to fill the pumping chamber by the introduction of pneumatic pressure into the pneumatic chamber so that blood contained in the pumping chamber is driven from the pumping chamber outlet, said pneumatic sac adapted to contract from an expanded condition by the release of pneumatic pressure from the pressure chamber so that blood contained in the reservoir chamber is induced into the pumping chamber,

(iii) a cushion sac at least partially surrounding said pumping sac and adapted to pneumatically cushion the pumping sac and adapted to pneumatically cushion the pumping action of the pneumatic sac, said cushion sac comprising an expandable inert plastic sac defining a pneumatic cushion chamber, said pneumatic cushion sac adapted to being compressed to thereby generate a pneumatic pressure pulse as the pneumatic sac expands to fill the pumping chamber, said pneumatic cushion sac provided with an exit tube adapted to communicate the pneumatic cushion chamber with the flow control valve, the pneumatic pressure pulse from the cushion chamber, when synchronized with a pneumatic pressure pulse from the pneumatic sensing collar, actuating the control valve assembly to release pneumatic pressure from the pneumatic chamber of the artificial heart,

(iv) a housing of semi-rigid plastic at least partially surrounding said cushion sac and said pumping sac, said housing adapted to confine the expansion of both the pneumatic cushion sac and the pumping sac.

11. In an artificial heart system described by claim **1**,

a pneumatic pump for powering a pneumatically operated artificial heart comprising a plurality of elements, a first element of said reciprocating pneumatic pump having means for connection to the rib cage of the body and a second element having means for connection to the diaphragm of the body, said means adapted to reciprocate said pump elements upon relative movement of the rib cage and diaphragm during inspiration and expiration of breathing of the body, said pneumatic pump supplying pneumatic pressure to the artificial heart upon inspiration of the body at a rate dependent upon the frequency and force of relative movements of the rib cage and diaphragm during inspiration of breathing.

12. In an artificial heart system described by claim **1**, a means for powering a pneumatically operated artificial heart comprising:

(a) a control means comprised of a plurality of pneumatic pressure accumulators for supplying pneumatic pressure to the artificial heart and receiving pneumatic pressure released therefrom and a control valve assmebly positioned between said pneumatic pressure accumulators and the artificial heart for controlling the supply and release of pneumatic pressure for the artificial heart to thereby operate said artificial heart, a first and a second of said accumulators being positioned between a reciprocating pneumatic pump and the control valve assembly, said first accumulator interconnected with the reciprocating pneumatic pump means and the control valve assembly and thereby adapted to be charged with pneumatic pressure produced by the pneumatic pump means and to supply pnuematic pressure to the pneumatic control valve assembly, said second accumulator interconnected with the control valve assembly and the reciprocating pneumatic pump means and thereby adapted to be charged with pneumatic pressure released from the control valve assembly and to supply pneumatic pressure to the pneumatic reciprocating pump, said pneumatic control valve assembly comprising a plurality of valve means operable in unison at a rate proportional to the valve of the pneumatic pressure supplied by said first accumulator, said valve means operating to alternately supply and release pneumatic pressure for the artificial heart and thereby operate said artificial heart, and

(b) a reciprocating pneumatic pump comprised of a plurality of elements, a first element of said reciprocating pneumatic pump having means for connection to the rib cage of the body and a second element having means for connection to the diaphragm of the body, said means adapted to reciprocate said pump elements upon relative movement of the rib cage and diaphragm during inspiration and expiration of breathing of the body, said pneumatic pump supplying pneumatic pressure to said first pressure accumulator upon inspiration of the body at a value dependent upon the frequency and force of relative movements of the rib cage and diaphragm during inspiration of breathing,

whereby variable pumping rate of the artificial heart is attained according to the requirement of the body by maintaining a proportion between the rate of the body breathing, the value of pneumatic pressure supplied to the pressure accumulator, and the rate at which the control valve assembly alternately supplies and releases pressure for the pneumatic chambers of the artificial heart.

13. A method of actuating a plural element reciprocating pneumatic pump disposed within a toracic cavity defined by the rib cage and the diaphragm of a living, breathing body which comprises:

(a) connecting a first element of said pump by means to the rib cage,

(b) connecting a second element of said pump by means to the diaphragm, said means adapted to reciprocate said elements of the pneumatic pump upon relative movement of the rib cage and diaphragm, and

(c) reciprocating said elements of the pneumatic pump in accordance with the relative movement of the diaphragm and rib cage during inspiration and expiration of breathing of the body.

14. A method of mechanically circulating blood in the circulatory sysem of a living breathing body which comprises:

(a) operating a reciprocating pneumatic pump implanted within the thoracic cavity of the body and therein connected by means to the rib cage and diaphragm, said pneumatic pump being operated by said means which reciprocate said pneumatic pump to produce pneumatic pressure upon relative movements of the rib cage and diaphragm during inspiration and expiration of breathing of the body,

(b) supplying said pneumatic pressure to a pneumatically operated artificial heart adapted to pumping blood in the circulatory system,

(c) pumping blood within the circulatory system by means of said pneumatically operated artificial heart.

15. A pneumatically operated artificial heart comprising:

(a) a first expandable reservoir sac defining a first reservoir chamber interconnected with a first blood pump defining a first pumping chamber, a first pneumatic chamber and a first cushion chamber,

(b) a second expendable reservoir sac defining a second reservoir chamber interconnected with a second blood pump defining a second pumping chamber, a second pneumatic chamber and a second cushion chamber,

(c) each expandable reservoir sac comprising an inert flexible plastic defining a reservoir chamber provided with an inlet and an outlet, the inlet adapted to interconnection with a vein and the outlet communicating the reservoir chamber with the pumping chamber of the blood pump, said reservoir chamber adapted to maintaining a pressure upon blood contained therein at a sufficient value so that when pumped by the pneumatic pump the blood will be maintained at a pressure greater than its vapor pressure,

(d) each of said blood pumps comprising:

(i) a pumping sac adapted to receive blood from an interconnected reservoir chamber and to deliver said blood to an interconnected artery, said pumping sac comprising an elongated inert flexible plastic sac defining the pumping chamber and provided at one end with an inlet communicating with the outlet of the interconnected expandable reservoir sac and an outlet at the opposite end communicating with an inert plastic ball check valve adapted to interconnection with an artery,

(ii) an expandable pneumatic sac located within said pumping chamber and adapted to receive and release pneumatic pressure to effect pumping of the blood contained within the pumping chamber, said pneumatic sac comprising an expandable inert plastic sac defining a pneumatic chamber provided with an inlet and an outlet, said pneumatic sac adapted to expand to fill the pumping chamber by the introduction of pneumatic pressure into the pneumatic chamber so that blood contained in the pumping chamber is expelled from the pumping chamber through the ball check valve at the pumping chamber outlet, said pneumatic sac adapted to contract from an expanded condition by the release of pneumatic pressure from the pneumatic chamber so that blood contained in the reservoir chamber is induced into the pumping chamber,

(iii) a cushion sac at least partially surrounding said pumping sac and adapted to pneumatically cushion the pumping action of the pneumatic sac, said cushion sac comprising an expandable inert plastic sac defining a cushion chamber and adapted to being compressed to thereby generate a pneumatic pressure pulse as the pneumatic sac expands to fill the pumping chamber, said pneumatic cushion sac provided with an exit to allow the release therefrom of said pneumatic pressure pulse,

(iv) a housing of inert semi-rigid plastic at least partially surrounding said cushion sac and said pumping sac, said housing adapted to confine the expansion of both the cushion sac and the pumping sac.

16. A pneumatically operated artificial heart comprising:

(a) an expandable reservoir sac defining a reservoir chamber interconnected with a blood pump defining a pumping chamber, a pneumatic chamber and a cushion chamber,

(b) the expandable reservoir sac comprising a flexible inert plastic sac defining a reservoir chamber provided with an inlet and an outlet, the inlet adapted to interconnection with a vein and the outlet communicating the reservoir chamber with the pumping chamber of the blood pump, said expandable reservoir sac adapted to maintaining a pressure upon blood contained therein at a sufficient value so that when pumped by the blood pump the blood will be maintained at a pressure greater than its vapor pressure, and

(c) said blood pump comprising:

(i) a pumping sac adapted to receive blood from an interconnected reservoir chamber and to deliver said blood to an interconnected artery, said pumping sac comprising an elongated flexible inert plastic sac defining a pumping chamber provided at one end with an inlet communicating with the outlet of an expandable reservoir sac and an outlet at the opposite end communicating with an inert plastic ball check valve adapted to be interconnected with an artery,

(ii) an expandable pneumatic sac located within said pumping chamber and adapted to receive and release pneumatic pressure to effect pumping of the blood contained within the pumping chamber, said pneumatic sac comprising an expandable inert plastic sac defining a pneumatic chamber provided with an inlet and an outlet, said pneumatic sac adapted to expand to fill the pumping chamber by the introduction of pneumatic pressure into the pneumatic chamber so that blood contained in the pumping chamber is driven from the pumping chamber outlet, said pneumatic sac adapted to contract from an expanded condition by the release of pneumatic pressure from the pumping chamber so that blood contained in the reservoir chamber is induced into the pumping chamber,

(iii) a cushion sac at least partially surrounding said pumping sac and adapted to pneumatically cushion the pumping sac and adapted to pneumatically cushion the pumping action of the pneumatic sac, said cushion sac comprising an expandable inert plastic sac defining a pneumatic cushion chamber, said pneumatic cushion sac adapted to being compressed to thereby generate a pneumatic pressure pulse as the pneumatic sac expands to fill the pumping chamber, said pneumatic cushion sac provided with an exit to allow the release therefrom of said pneumatic pressure pulse,

(iv) a housing of semi-rigid plastic at least partially surrounding said cushion sac and said pumping sac, said housing adapted to confine the expansion of both the pneumatic cushion sac and the pumping sac.

17. A pneumatic pump for powering a pneumatically operated artificial heart comprising a plurality of elements, a first element of said reciprocating pneumatic pump having means for connection to the rib cage of the body and a second element having means for connection to the diaphragm of the body, said means operable to reciprocate said pump elements upon relative movement of the rib cage and diaphragm during inspiration and expiration of breathing of the body, said pneumatic pump adapted to supply pneumatic pressure to a pneumatically operated artificial heart upon inspiration of the body at a rate dependent upon the frequency and force of relative movements of the rib cage and diaphragm during inspiration of breathing.

18. A means for powering a pneumatically operated artificial heart comprising:

(a) a control means comprised of a plurality of pneumatic pressure accumulators for supplying pneumatic pressure to and receiving pneumatic pressure released from a pneumatically operated artificial heart and a control valve assembly interconnected with said pneumatic pressure accumulators and adapted to interconnection with an artificial heart for controlling the supply and release of pneumatic pressure for the artificial heart to thereby operate said artificial heart, a first and a second of said accumulators being positioned between a reciprocating pneumatic pump means and the control valve assembly, said first accumulator interconnected with a reciprocating pneumatic pump means and the control valve assembly and thereby adapted to be charged with pneumatic pressure produced by the pneumatic pump means and to supply pneumatic pressure to the pneumatic control valve assembly, said second accumulator interconnected with the control valve assembly and the reciprocating pneumatic pump means and thereby adapted to be charged with pneumatic pressure released from the control valve assembly and to supply pneumatic pressure to the pneumatic reciprocating pump, said pneumatic control valve assembly comprising a plurality of valve means operable in unison at a rate proportional to the value of the pneumatic pressure supplied by said first accumulator, said valve means operating to alternately supply and release pneumatic pressure for a pneumatically operated artificial heart and thereby operate said artificial heart, and

(b) a reciprocating pneumatic pump means comprised of a plurality of elements, a first element of said reciprocating pneumatic pump having means for connection to the rib cage of the body and a second element having means for connection to the diaphragm of the body, said means adapted to reciprocate said pump elements upon relative movement of the rib cage and diaphragm during inspection and expiration of breathing of the body, said pneumatic pump supplying pneumatic pressure to said first pressure accumulator upon inspiration of the body at a value dependent upon the frequency and force of relative movements of the rib cage and diaphragm during inspection of breathing,

whereby variable pumping rate of an interconnected pneumatically operated artificial heart is attained according to the requirement of the body by maintaining a proportion between the rate of the body breathing, the value of pneumatic pressure supplied to the first pressure accumulator, and the rate at which the control valve assembly alternately supplies and releases pressure for the pneumatic chambers of the artificial heart.

19. In the artificial heart system described in claim **1** a

control means for operating a pneumatically operated artificial heart by the alternate supply and release of pneumatic pressure provided to the control means by a pneumatic pressure source comprising a plurality of pneumatic pressure accumulators for supplying pneumatic pressure to and receiving pneumatic pressure released from a pneumatically operated artificial heart and a control valve assembly interconnected with said pneumatic pressure accumulators and adapted to interconnection with an artificial heart for controlling the supply and release of pneumatic pressure to and from the pneumatic pressure accumulators for the artificial heart, a first of said accumulators adapted to be charged by the pneumatic pressure source and to supply pneumatic pressure to the pneumatic control valve assembly, said pneumatic control valve assembly comprising a plurality of valve means operable in unison at a rate proportional to the valve of the pneumatic pressure supplied by said first accumulator, said pneumatic control valve assembly operating an interconnected artificial heart by the alternate supply and release of pneumatic pressure for the artificial heart.

20. In the artificial heart system described in claim **1** a pneumatic control valve assembly for operating a pneumatically operated artificial heart with pneumatic pressure supplied from a pneumatic pressure source comprising a plurality of valve means operable in unison to receive pneumatic pressure from a pneumatic pressure source and to alternately supply and release said pneumatic pressure to a pneumatically operated artificial heart to thereby operate said artificial heart, said valve means operating to supply and release pneumatic pressure at a rate proportional to the value of the pneumatic pressure supplied by the pneumatic pressure source.

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