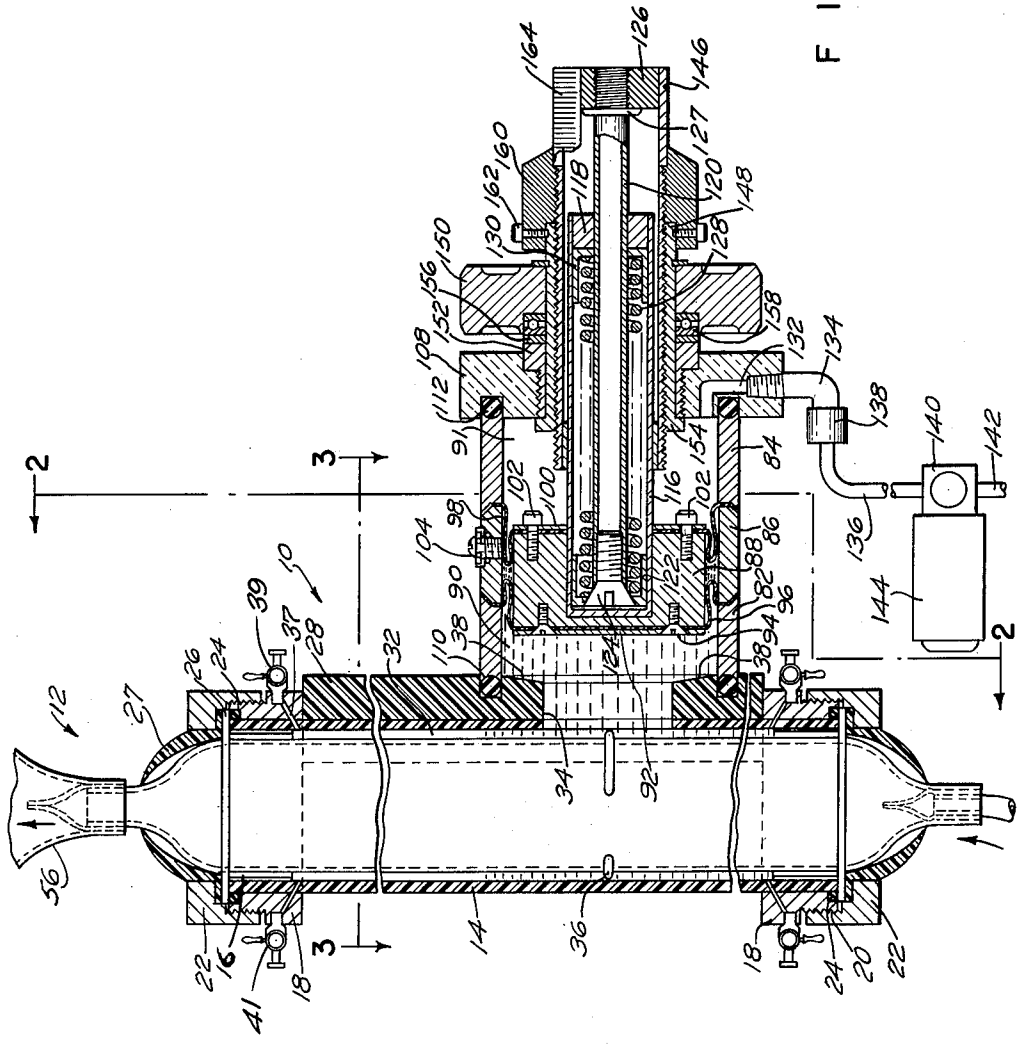
July 30, 1963 W. C. BIRTWELL 3,099,260

HEART PUMP APPARATUS

Filed Feb. 9, 1960 4 Sheets-Sheet 1

FIG. 1



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HEART PUMP APPARATUS

Filed Feb. 9, 1960 4 Sheets-Sheet 2

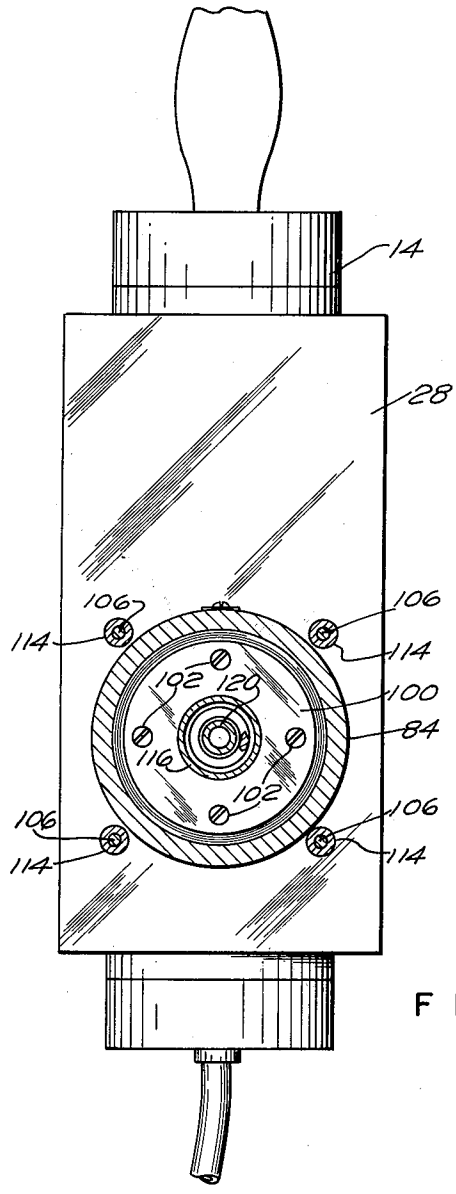

FIG. 2

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HEART PUMP APPARATUS

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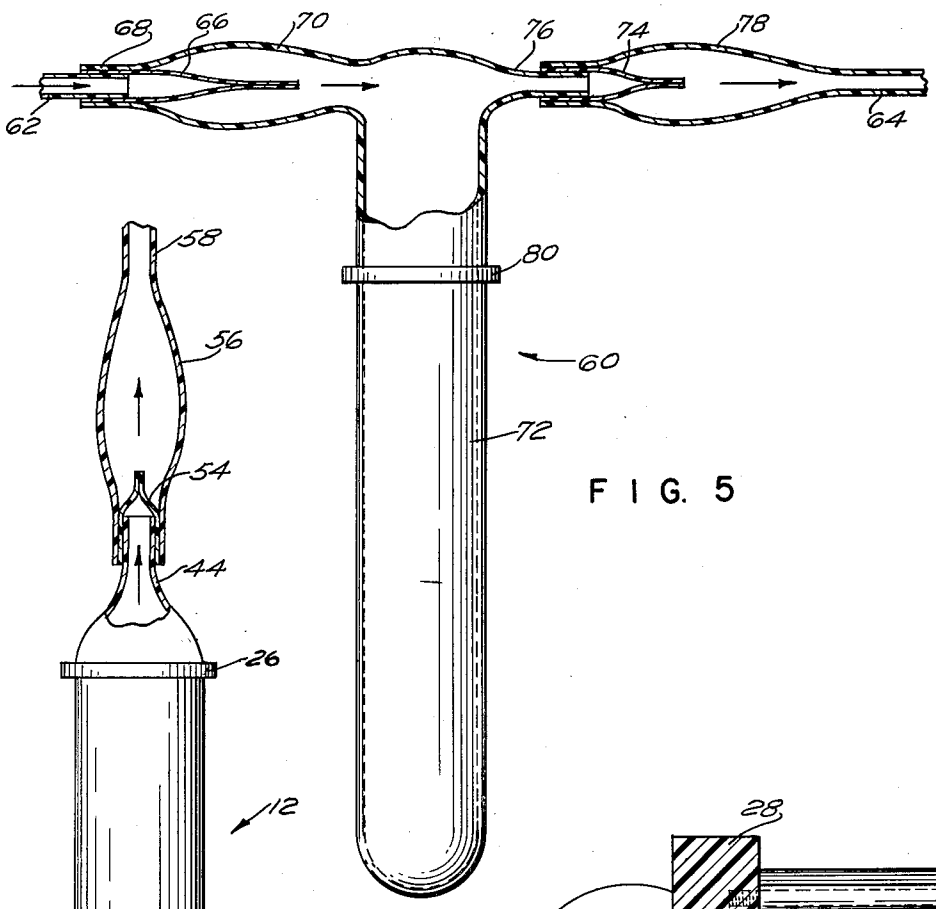

FIG. 5

FIG. 4

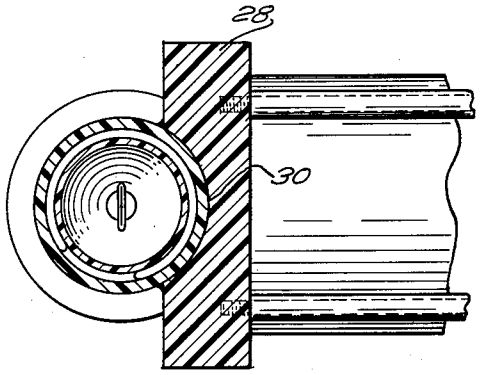

FIG. 3

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July 30, 1963 W. C. BIRTWELL 3,099,260

HEART PUMP APPARATUS

Filed Feb. 9, 1960 4 Sheets-Sheet 4

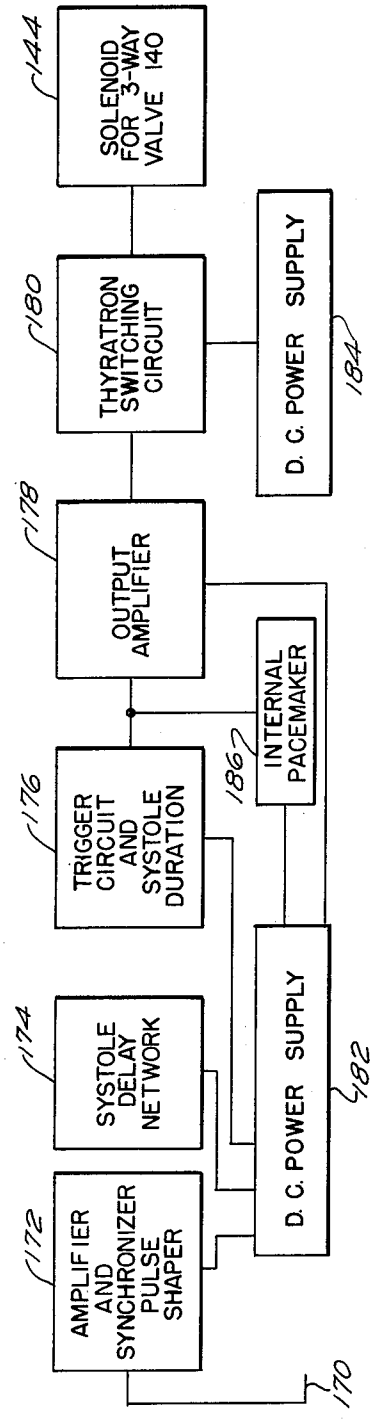

FIG. 6

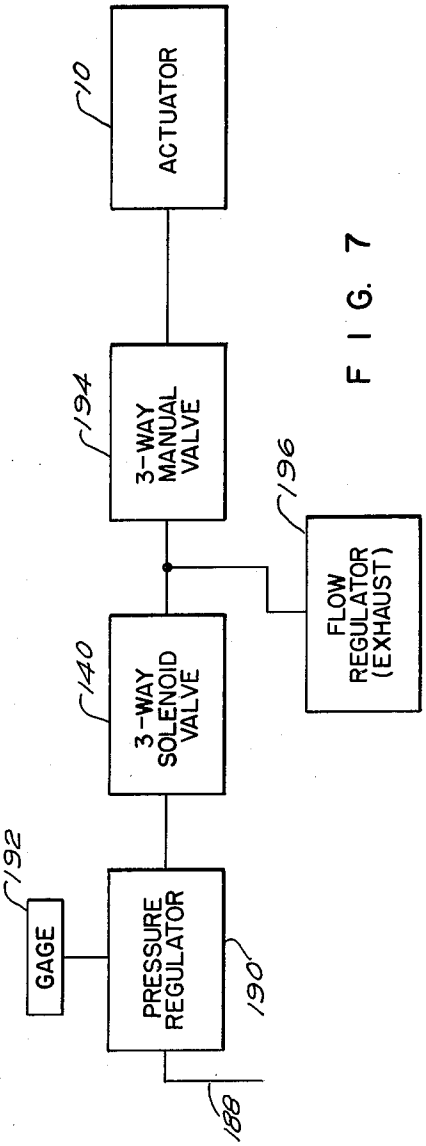

FIG. 7

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3,099,260

HEART PUMP APPARATUS

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Filed Feb. 9, 1960, Ser. No. 7,721
7 Claims. (Cl. 128—1)

The present invention relates to apparatus for maintaining systemic circulation extracorporeally under a wide variety of conditions. More particularly, the present invention relates to a pumping system for use in pumping blood that is designed to operate in conjunction with or without an oxygenator in such a way that circulation in a patient may be maintained extracorporeally.

The description of the apparatus embodied herein will be confined to the problem of circulating blood. However, it is understood that the apparatus, and particularly the pumping unit described hereinafter, has application in other related fields. The development of new surgical techniques in recent years has revolutionized cardiac surgery and has resulted in a demand for apparatus that will aid this type of surgery. In cardiac surgery, it is usually necessary or desirable to bypass that portion of the patient's heart on which the surgeon intends to operate. Accordingly, in order for the patient to survive an operation, the blood flow must be shunted through an artifical system, that will maintain the patient's blood circulation while the patient's heart is temporarily immobilized. It is obvious that a pump through which the patient's blood is shunted must be capable of variations in flow rate and furthermore must be so constructed as to properly influence blood flow without causing breakdown of the various components of the blood.

Heretofore, cardiac surgeons have been performing open-heart surgery with the use of equipment known as pump-oxygenators. A pump-oxygenator is a device that will function in place of the patient's lungs and heart while surgery is being performed on the heart. A pump-oxygenator is usually a combination of pumps and other devices necessary for the proper functioning of the complete system. In the prior known devices used in cardiac surgery, the pump-oxygenators may have included a venous reservoir, a coronary sinus reservoir, various types of pumps, bubble traps, filters and other similar instruments. Thus, in a typical system utilized in cardiac surgery heretofore, the following units may have been employed: a pump for maintaining the arterial circulation; a pump for pumping from a venous reservoir into an oxygenator; a pump for maintaining coronary circulation during the operation; a coronary sinus pump together with one or another of the various types of oxygenators; a suitable venous reservoir; a suitable filter and bubble trap; and means for maintaining constant temperatures or for reducing the temperature of the blood if necessary.

Even with all of the heretofore known equipment in operation, the function of the complete system was to provide means for maintaining systemic circulation for only a short-term basis while open cardiac surgery was being performed. It has become increasingly apparent in recent years that equipment for assisting in extracorporeal circulation may be utilized in another important manner. This important application of a heart pump is in the assisting of the heart for therapeutic application thereof. When used in this manner, a system similar to the manner in which the equipment is used in cardiac surgery may be required. When using a heart pump in a therapeutic manner it may be necessary under certain circumstances to oxygenate the blood, while in other circumstances, an oxygenator may not be necessary. However, in all applications of the equipment when utilized in a therapeutic manner it will be necessary to operate the equipment for

extended periods of time, and it is estimated that the equipment may be in operation for many hours or days. This is in comparison to the limited period of approximately 1½ hours for which the heretofore known apparatus is utilized. By using heart pump equipment for extended periods of time it is contemplated that the equipment may be utilized for regional perfusions in the therapeutic treatment of localized cancers. Still another use of the equipment will be to provide circulation of blood through an artificial organ such as an external artificial kidney. In connection with this function of the apparatus, it should be noted that many research institutions at this time are concentrating their research activities on providing artificial counterparts of other organs, and whenever such application requires extracorporeal circulation, the equipment embodied in the present invention may be utilized.

Although open-heart cardiac surgery has been performed successfully with the equipment known heretofore and mentioned hereinabove, it is well accepted in the medical profession that long-term perfusions with such equipment cannot be performed. The present invention is designed to facilitate long-term perfusions which will be necessary for successful assisted circulation and for therapeutic partial and regional perfusions. Furthermore, for total perfusion certain requirements are necessary and it has been found that the heretofore known heart pump equipment could not satisfy these requirements. The present invention is designed to satisfy all requirements necessary for the successful functioning of a heart pump in total, partial or regional perfusions. Thus, the heart pump embodied herein is simple in construction and atraumatic. The pump produces a minimum or no fibrin during the pumping operation and the pumping element may be disposable if necessary. The pump is capable of being autoclaved or sterilized in some fashion and is capable of having a maximum capacity of not less than five liters a minute. The flow from the pump is calibratable and unvariable with back pressures. The stroke of the pump is adjustable in a simple manner and the stroke volume is also adjustable through a physiologic range. The pump is not only capable of hand operation in emergencies, but furthermore is capable of assisting the patient's heart post-operatively.

It is contemplated that the heart pump and equipment embodied in the present invention will also be utilized in assisted partial perfusions in which the prior known equipment has been found to be unsuccessful. Therefore, in addition to satisfying the above characteristics for total perfusions, the equipment embodied herein may be successfully utilized in assisted partial perfusions and includes a system that is capable of being synchronized with the patient's heart. Furthermore, the pump is capable of being phased with the patient's heart, and the duration of systole or diastole is adjustable. In long periods of use, the pump has been found to be atraumatic and the destruction of the platelets of the blood has been maintained at an even lower minimum than in total perfusions thereby inhibiting the production of fibrin in the pump. The pump is simple to set up and adjust and is capable of being placed in operation in an absolute minimum of time. The pump embodied herein is also designed to be portable for regional perfusion, and in addition to the above characteristics that aid in assisted partial perfusion and which are also necessary in regional perfusion, the pump is also capable of considerably smaller flow rates. As mentioned, the heart pump embodied herein is designed to be synchronized with the demands of the patient, and for this purpose a power supply is provided that is in effect the control center for the heart pump. The power supply, in order to afford the desired flexibility, is capable of facilitating synchronization of the heart pump with the

output of an EKG machine. The power supply also provides means for delaying the systolic pulse of the pump behind the systolic pulse of the heart or the R-wave. The power supply further provides means for controlling the duration of systole and moreover provides means for arbitrarily pacing the pump when synchronization is not desired. Central means are also provided that control the supply of air or gas under pressure to the actuator and also provides means for hand operation in cases of emergency, such as a power failure.

The pump embodied in the present invention satisfies all the requirements for a heart pump set forth above that in clinical tests has been proved to be successful in carrying out the difficult task of pumping blood under various types of conditions.

Accordingly, it is an object of the present invention to provide a pump that is used primarily for the extracorporeal circulation of blood.

Another object of the present invention is to provide a heart pump that is simple in construction and that is atraumatic.

Still another object is to provide an automatically operated heart pump that is also capable of hand operation should any unforeseen development immobilize the pumping equipment.

Still another object is to provide a heart pump that is employed in partial as well as total perfusions.

Still another object is to synchronize the operation of the pumping unit with the patient's demands.

Still another object is to provide a pumping apparatus that is capable of being synchronized with the patient's heart.

Still another object is to provide a pumping apparatus that is capable of being phased with the patient's heart, the diastolic and systolic stroke of the pumping unit being adjustable as desired.

Still another object is to provide an actuator for operating a heart pump wherein the actuator is adapted to control a hydraulic pulse for deforming a pumping unit or ventricle to move an equal volume of blood through the ventricle valve system.

Still another object is to provide a ventricle for use in heart pump that has a stroke volume that is controllable and calibrated.

Still another object is to provide an actuator that provides for easy mounting of a pumping unit therein, that is simple in construction and that is non-susceptible to breakdown.

Still another object is to provide a pumping element that is atraumatic and that minimizes platelet damage.

Still another object is to provide a pumping element for use in assisted circulation that has a stroke displacement adjustable to a physiologic range and that may be either disposable or capable of being cleaned effectively without destroying the general characteristics thereof.

Still another object is to provide a pumping unit for use in assisted circulation that is capable of being sterilized or provided at the outset in a sterile condition ready for use.

Still another object is to provide a ventricle or pumping unit for use in assisted circulation that is capable of emergency operation by hand in the event of immobilization of the automatic equipment.

Still another object is to provide a heart pump which may be adjusted to pump a known volume of blood and which remains substantially constant over a range of back pressures which may be encountered during the pumping operation.

Still another object is to provide an actuator for use in a heart pump that is pneumatically operated for transferring the actuating fluid to the operating ventricles.

Other objects, features and advantages of the invention will become apparent as the description thereof proceeds when considered in connection with the accompanying illustrative drawings.

In the drawings which illustrate the best mode presently contemplated by me for carrying out my invention:

FIG. 1 is a vertical sectional view of the pumping system embodied herein that is utilized for maintaining systemic circulation extracorporeally;

FIG. 2 is a sectional view taken along line 2—2 in FIG. 1;

FIG. 3 is a sectional view taken along line 3—3 in FIG. 1;

FIG. 4 is an elevational view of one form of an operating ventricle with parts shown in section;

FIG. 5 is an elevational view of a modified form of an operating ventricle with parts shown in section;

FIG. 6 is a block diagram of the electrical circuit that is employed for operating the actuator unit and which includes means for synchronizing the operation of the pumping unit with the demands of the patient; and

FIG. 7 is a block diagram of the pneumatic system that supplies gas under pressure to the actuator unit.

The invention embodied herein is adapted to assist in extracorporeal circulation and has application primarily as a heart pump for use in cardiac surgery. It is understood that the pumping equipment may be utilized to assist circulation of blood in regional areas and thus is applicable in total, partial or regional perfusions. It is further understood that the structural embodiments of the heart pump to be described hereinafter, or those specifically disclosed as relating to problems of circulating blood, may nevertheless be utilized in other applications wherein the specific advantages of the instant pump will be applicable. As hereinafter referred to, the pumping ventricles relate to the pumping units and, as such, define the basic unit of the artificial heart of the present invention.

The heart pump embodied herein is adapted to be operated in conjunction with an oxygenator when total perfusion is necessary in maintaining extracorporeal circulation, and is also adapted for use in assisted partial perfusions. In such instances, the heart pump must be capable of being synchronized with the patient's heart. Thus, the heart pump embodied herein is completely flexible in the operation thereof, and in carrying out the intended objects, the device is constructed in three basic units, that is, the power supply illustrated in FIG. 6, the actuator illustrated in FIG. 1, and the pumping unit or ventricle illustrated in FIGS. 4 and 5.

Referring now to FIG. 1, the actuator which is generally indicated at 10 is shown with a ventricle or pumping unit generally indicated at 12 combined therewith. In order to accommodate the pumping unit or ventricle 12, the actuator 10 includes an elongated, cylindrical tube 14 formed of a transparent plastic material. Pressed into the plastic tube 14 at the ends thereof in order to provide for rigidity and further defining a more secure assembly are stainless steel cylinders 16. Fixed to the outer surface of each end of the transparent tube 14 are fittings 18 that are provided with threaded sections 20 for receiving end caps 22 in threaded engagement therewith. Formed in the outer end of each fitting 18 is an annular groove that receives an O-ring 24 therein. The ventricle 12 is firmly retained in position in the assembly by flanges 26 integrally formed on the body thereof and that engage the O-ring 24. A nylon insert 27 having a flange coextensive with the flange 26 of the ventricle 12 is positioned in each end of the tube and cooperates with the adjacent O-ring 24 to lock the flange 26 in sealing relation in the assembly. The inner surface of the nylon insert 27 is shaped to accommodate the outer end of the ventricle, which will be described in detail heerinafter. It is seen that with the elements located in the assembly as shown, tightening of the end cap 22 will force the insert 27 into firm contact with the flange 26, which is in turn sealed on the O-ring 24. The elements are thus not only locked in position, but the interior of the tube 14 is effectively sealed.

As shown in FIG. 3, the elongated tube **14** is mounted in position by securing it in a semi-circular groove **30** formed in a clear plastic block **28**. The outer surface of the ventricle **12** is adapted to be spaced from the inner surface of the tube **14**, thereby defining an annular chamber **32** when the ventricle **12** is mounted in position within the tube **14**. In order to provide for communication of an actuating fluid between the annular chamber **32** and the operating chamber of the actuator **10**, an opening **34** is formed in the block **28** and extends through the elongated tube **14**. In operation of the pumping unit, spring **36** is secured around the body of the ventricle **12** and is adapted to prevent the ventricle from sealing across the opening **34** in the suction stroke of the actuator piston. Grooves **38** are also provided on either side of the opening **34** and are further adapted to prevent the ventricle **12** from sealing on the suction stroke of the actuator piston, as will be described hereinafter.

In order to fill the operating chamber of the actuator with actuating liquid, an opening **37** is formed in the upper end of the tube **14**, the opening **37** communicating with a petcock **39** through which the actuating liquid is directed. A similar petcock **41** is further provided and communicates with the chamber **32** through a suitable opening for releasing any air that may be entrapped within the chamber **32** or the operating chamber of the actuator. It is also contemplated to fill the chambers with the actuating liquid by lifting the upper flange **26** as seen in FIG. 1, clear of the tube and then pouring the actuating liquid into the chamber **32**. In this event, the petccoks **39** and **41** may be eliminated.

Referring now to FIG. 4, the ventricle **12** is illustrated in detail and represents one form of a pumping unit that may be employed with the actuator **10**. The ventricle **12** and the modified form thereof illustrated in FIG. 5, define pumping units that when coordinated with the venous or arterial system of the patient make possible the simulation of the pumping effects of the left ventricle of the patient's heart. The pumping unit **12** has been found to satisfy the requirements necessary in assisted circulation, because of the particular characteristics thereof and not only aids in producing proper performance in total extracorporeal assisted circulation as required for open-heart surgery, but also acts to produce the required pumping effect in assisted circulation and regional circulation necessary for the therapeutic assistance for the patient's heart in cancer therapy. Heretofore, there have been many different kinds of pumping units available for assisting extracorporeal circulation. However, all of these pumping units have fallen far short of accomplishing the desired end result. The pumping units most commonly known heretofore may be grouped in two classes, that is, the Sigma pump and the roller pump. Both of these pumps use a simple piece of tubing, such as rubber or plastic, as the pumping element. In the Sigma pump, the pumping effect is achieved by means of a series of fingers which are cam operated to squeeze against a tubular member that defines the pumping element. These fingers are disposed essentially sinusoidally of the tubular member and their actuation produces a wave-like action. Unidirection flow is achieved by setting the pump to one degree or another of occlusiveness. That is to say, the end position of any one of the fingers squeezing the tubular member may or may not completely occlude the tubing depending on the type of action required. The valving action is accomplished by means of the external squeezing of the tubular member. Similarly, in the roller pump a set of rollers is revolved around a rubber tubing, thereby producing a squeezing action, the setting of the rollers determining the degree of occlusivity. In each case, the valve action and the unidirectional flow is achieved by externally squeezing a tubular member and thereby preventing or minimizing reverse flow or regurgitation.

Each of these heretofore known pumps possessed a certain simplicity in its pumping action which is desirable; however, in many other respects they failed to produce the desired end result. Thus, the flow obtained by the Sigma and roller pumps was not physiologic but was rather continuous even though they were pulsatile in their action, and therefore, neither of these pumps could be effectively synchronized with the action of the patient's heart.

Referring now to FIG. 4, the ventricle **12** is shown in detail and includes a body **40** that is preferably formed of a plastic material such as polyvinylchloride. However, it is understood that the ventricle body may be formed of rubber or any other type of plastic that is capable of being produced in a flexible tube. The ventricle body **40** is basically cylindrical in form, the ends thereof being smoothly reduced in diameter to form reduced end sections **42** and **44**. The gradual reduction in the tubular body to the sections **42** and **44** is necessary in order to provide for a smooth entrance and exit for the blood being pumped. The flanges **26** are formed integral with the body **40** and permit the securing of the pumping unit or ventricle **12** in the actuator tube **14** as described hereinabove. The flanges **26** further provide a seal between the annular chamber **32** and the outer reduced sections **42** and **44** of the ventricle **12**, thereby preventing exterior leakage of the actuating medium disposed in the chamber **32** when the medium is exerting pressure on the body **40**. It is understood that the smooth characteristics of the surfaces of the body **40** and the reduced sections **42** and **44** are produced by a proper choice of material and molding techniques.

In order to provide for smooth flow of blood into the body **40** of the ventricle **12**, an inlet tube **50** is provided. The inlet tube **50** is of sufficient length to reach to the oxygenator or the reservoir from which the blood is to be pumped. The diameter and length of the tube **50** are consistent with the requirements for minimum suction pressures to produce the necessary stroke volume in the actuator **10**. Preferably a half-inch inside diameter tube is utilized since most systems employ such fittings on their oxygenators and reservoirs. The end of the tube **50** extends within the reduced end section **42** and engages the inside surface of a one-way or uni-flow valve indicated at **52**. The normally closed opening of the valve **52** extends inwardly of the body **40** and is adapted to be opened under pressure of the blood flowing through the inlet tube **50**. As shown in FIG. 4, the valve **52** is a simple bicuspid type sometimes referred to as a flutter valve. The valve **52** may be made of any flexible material, such as silicone rubber, latex and various types of plastics, including polyvinylchloride. The polyvinylchloride valve is preferable since all the components of the ventricle are made of this material, and heat sealing thereof is faciliated.

A similar type of uni-flow or uni-direction valve indicated at **54** is provided at the discharge end of the ventricle **12** and is secured or joined to the outer surface of the reduced section **44**, projecting outwardly of the reduced section in order to promote proper flow therethrough. The valve **54** is enclosed in a valve housing **56** and which has a bulbous appearance to provide an expanded region in which the valve **54** can operate unimpeded. The valve housing **56** and valve **54** are also heat sealed to the reduced section **44** to form a unitary construction therewith. Integrally joined to the housing **56** is an exhaust tube **58** that is of sufficient length to reach a bubble trap in the system, thus eliminating any extraneous or unnecessary connections. Thus it is seen that the ventricle **12** may be formed in a unitary construction that includes the inlet and exhaust valves **52**, **54** and the connections thereto. It is further seen that the entire unit may be placed in a sterilized package so that it will be available for immediate use when required.

Referring to FIG. 5, a modified form of a ventricle is illustrated and includes a single-ended unit generally in-

dicated at 60. The single-ended unit 60 includes a suction tube 62 that enters the ventricle 60 at the same end as a discharge tube 64. The suction or inlet tube 62 is joined to the inside surface of a flutter valve 66 in the manner described above. The flutter valve 66, however, is secured to the reduced section 68 of a housing 70 that is joined directly to the main body 72 of the ventricle 60, the housing 70 extending generally at right angles with respect to the body 72. The flutter valve 74 is secured to a reduced section 76 that is joined directly to the body 72, while a housing 78 encloses the valve 74. The discharge tube 64 is joined directly to the housing 78 and is of sufficient length to reach a bubble trap as described hereinabove. The ventricle 60 requires only one flange indicated at 80 for sealing the ventricle into the actuator 10, and it is understood that the end of the tube 14 adjacent the closed end of the ventricle 60 will be blanked and sealed if this ventricle were used in the system. One of the advantages of the ventricle 60 is that in emergencies, it may be more readily removed from the actuator and operated by hand if it is so required. The ventricle 60 may also be formed of a plastic material, such as polyvinylchloride, and the valves as described may be of the bicuspid or flutter type. It is also contemplated, to use tricuspid valves made of rubber and polyvinylchloride and other plastics, although any valve which in its operation offers a minimum of regurgitation and a soft action to minimize trauma will serve the purpose of the present invention.

Both ventricles 12 and 60 must be capable of being operated manually should an emergency occur, such as in a power failure. Since the materials from which the ventricles are made are flexible, the ventricle may be removed from the actuator tube 14 and operated or squeezed mechanically either by hand or by other mechanical means. It is understood, of course, that mechanical operation is less desirable that the automatic operation to be described hereinafter. Both the ventricles 12 and 60 are atraumatic, that is to say, the action thereof produces a minimum of damage to the red cells in the blood. These ventricles also minimize platelet damage and the subsequent end development of fibrin through the coagulating process. The priming required for the ventricles is at a minimum consistent with the required stroke displacement. The ventricles also have a stroke displacement that is adjustable to a physiologic range, that is, up to approximately 50 or 60 cc. per stroke. The ventricles are capable of being disposed of or being cleaned effectively and are capable of being sterilized so that at the outset of the operation thereof they are sterile and ready for use. The ventricles further have a minimum of connections thereby minimizing the possibility of dangerous leaks and breaks in the system while in use, and as shown, are formed in a one-piece unit adapted for immediate use in the actuator 10. The smooth construction of the valves and inlet and exhaust tubes eliminates shoulders, which if located in the direction of flow of the blood would result in sharp breaks in the tubular walls and would produce turbulence, that in turn would tend to produce fibrin by the coagulating process. Finally, the ventricles in their normal operation require only a minimum of negative pressures in the suction stroke of the actuator. If excessive, such negative pressures are traumatic causing destruction of the red cells of the blood.

Referring now to FIGS. 1, 2 and 3, the operating mechanism of the actuator 10 will be described and as shown includes a cylinder defined by end sections 82 and 84 and an intermediate section 86. Disposed within the cylinder defined by the sections 82, 84 and 86 is a piston 88 that is spaced from the inner surfaces of the cylinder and divides the cylinder into a forward actuating chamber 90 and a rear operating chamber 91. The actuating chamber 90 communicates with the opening 34 in the block 28 and has an incompressible fluid disposed therein that is adapted to be utilized as the operating medium for deforming the body 40 of the ventricle 12. Secured to the piston 88 by a plate 92 and screws 94 is a flexible diphragm or bellofram seal 96 that is adapted to seal the operating medium within the chamber 90. The bellofram seal 96 is locked between the end section 82 and the intermediate section 86 of the cylinder and is folded to provide for free movement of the piston 88 during the operation of the actuator. A similar flexible diaphragm or bellofram seal 98 is secured between the end section 84 and intermediate section 86 by a plate 100 and screws 102. Since the flanges of the bellofram seals 96 and 98 are trapped between the sections of the cylinder as illustrated and described, an effective seal is formed between the chambers 90 and 91. The bellofram seals 96 and 98 are not capable of supporting negative pressures to any extent, and therefore the two seals are utilized in back-to-back relation as shown. In order to eliminate any excess pressures between the bellofram seals 96 and 98, the space therebetween is filled with a liquid having a high flash point, such as glycerine, the glycerine being introduced into the space between the seals 96, 98 through a filler plug 104 that is threaded in an opening formed in the intermediate cylinder section 86. The liquid in the space between the bellofram seals 96, 98 also acts as a seal. Since there is a tendency for some air to bleed therethrough thereby creating a small bubble in this zone. Consequently, it is desirable from time to time to remove the bubble by putting the actuator under pressure and tensioning the bellofram seals. The filler plug 104 is then released to allow the air to escape.

As shown in FIGS. 2 and 3, the actuator cylinder is secured to the block 28 by spaced bolts 106 that extend through a rear cap 108 and into the block 28, the rear cap 108 defining the rear wall of the chamber 91. The end section 82 is effectively locked in sealed relation against an O-ring 110 that is positioned in an annular recess formed in the block 28, the annular recess being concentric with the opening 34. The end section 84 similarly engages an O-ring 112 positioned in an annular recess that is formed in the rear cap 108. Spacers 114 encircle the bolts 106 and engage the face of the block 28 and the cap 108, thereby properly aligning the cylinder sections. It is seen therefore that upon tightening the bolts 106, the end cap 108 together with the cylinder sections will be locked to the block 28 and that proper alignment and spacing thereof is assured by the spacers 114.

Fixed to the plate 100 and extending into a central opening formed in the piston 88 is a hollow housing 116. The housing 116 which is movable with the piston 88 extends through the chamber 91 and through an enlarged opening formed in the end cap 108, the outer end of the housing having a bearing 118 secured therein, through which a tubular member 120 extends. The tubular member 120 is normally fixed with respect to the movable housing 116 and projects within the shaft to substantially the inner end thereof. An end cap 122 is secured to the inner end of the tubular member 120 by a screw 124, while the outer end of the tubular member 120 is threaded for engagement with a plug 126. A flange 127 is formed on the tubular member adjacent the threaded outer end thereof and acts as a stop for the plug 126. A spring 128 encircles the tubular member 120 and is positioned within the housing 116, bearing against the end cap 122 and an end cap 130, the rear surface of which engages the bearing 118. It is seen that upon introduction of an operating gas into the chamber 91, the piston 88 will be moved to the left, as seen in FIG. 1, carrying the plate 100, housing 116 and bearing 118 therewith and thereby compressing the spring 128. Upon release of the operating gas from the chamber 91, the spring 128 causes the piston to return to the right as seen in FIG. 1.

The piston 88 is operatively moved within the actuator cylinder by introducing a gas or air under pressure into the chamber 91 through a passage 132 that is formed in

the end cap **108**. A threaded connector **134** communicates with the passage **132** and is joined to a hose **136** through a coupling **138**. The hose **136** extends from a solenoid operated 3-way valve **140** to which a line **142** is connected, the line **142** communicating with a pressure regulator and a source of air or gas under pressure, as described hereinafter. A solenoid **144** operates the valve **140** and is controlled to periodically move the valve **140** to the open position thereof whereby gas under pressure is directed into the chamber **91** to move the piston **88** to the left as seen in FIG. 1.

In order to provide for flexibility of the pumping system so that various stroke volumes may be simulated, the stroke of the piston **88** is adapted to be adjusted. For this purpose a stroke adjustment member **146** is provided and extends through the end cap **108** in concentric relation with respect to the housing **116**. The stroke adjustment member **146** is secured to the plug **126** and has external threads formed thereon. A sleeve **148** threadably engages the member **146** and has a hand wheel **150** secured thereto that is adapted to be rotated for adjusting the stroke of the piston **88**. Thus it is seen that when the sleeve **148** is rotated by the hand wheel **150**, the stroke adjustment member **146** is caused to move in an axial direction. The sleeve **148** is rotatable within a bushing **152** which is pressed into a recess formed in the end cap **108**. The bushing **152** is adapted to reduce wear and furthermore enables close tolerances to be effected which minimize leakage through this zone. An annular flange **154** formed on the sleeve **148** abuts the inner end of the bushing **152** in sealing relation therewith and a thrust washer **156** engages the outer end of the bushing. The thrust worker **156** is formed as part of a ball bearing **158** that is adapted to minimize the friction between the hand wheel **150** and the bushing **152** when the system is under pressure. The bearing **118** that is pressed into the end of the housing **116** is formed of a nylon material and is adapted to minimize the friction that results with the sliding of the housing **116** on the tubular member **120** in a forwardly and rearwardly direction.

In order to calibrate the unit, a spool **160** is provided and is attached to the sleeve **148** by screws **162**. The spool **160** which is formed with a tapered outer edge also threadably engages the stroke adjustment member **146** so that the axial movement of the member **146** by the hand wheel **150** will also be relative with respect to the spool **160**. Thus the tapered outer edge of the spool **160** indicates the stroke adjustment on calibrations **164** that are formed on the outer end of the member **146**. It is seen that the stroke adjustment is effected by turning the hand wheel **150** which in turn rotates the sleeve **148**. Rotation of the sleeve **148** causes the stroke adjustment member **146** to move in an axial direction. The tubular member **120** is then moved axially and relocates the stop or end cap **122**.

In order to provide for flexibility of operation, the actuator piston **88** is formed of aluminum and all the actuator operating components are formed of a stainless steel. The cylinder sections are formed of a clear plastic, such as plexiglass, to afford visibility thereby enabling the components of the actuating unit and ventricle to be surveyed at all times during the operation of the system.

In operation of the actuating unit **10**, gas under pressure is introduced into the operating chamber **91** through the passage **132** formed in the end cap **108** by energization of the solenoid **144** which operates the valve **140**. The gas under pressure admitted into the chamber **91** forces the piston **88** to the left as seen in FIG. 1, thereby compressing the spring **128** between the end cap **130** and end cap **122**. As the piston slides forwardly, the actuating liquid located in the actuating chamber **90** is ejected through the opening **34** and into the annular chamber **32** defined by the inner surface of the tube **14** and the outer surface of the ventricle **12**. The pressure of the actuating fluid causes the flexible body of the ventricle **12** to be deformed, thereby decreasing the internal volume thereof. In response to an external control that is operated in a predetermined sequence as described hereinafter, the solenoid **144** will be deenergized to close off communication of the source of gas with the chamber **91**. The gas in the chamber **91** is then bled out thereby reducing the pressure therein. The spring **128** returns the piston **88** to its original position and the actuating fluid is then withdrawn into the chamber **90**, the flexible body of the ventricle **14** returning to the original position thereof. It is seen that by energizing the solenoid **144** in a predetermined sequence, the flexible body of the ventricle **14** will be periodically and sequentially deformed to produce a pumping action.

As discussed hereinabove, the pumping unit or ventricle must be capable of being synchronized with the patient's heart and this is so particularly during assisted partial perfusion. The pumping unit must also be capable of being phased with the patient's heart, while the duration of the systole and diastole strokes should be adjustable. In order to properly synchronize the operation of the solenoid **144** for admitting the operating air into chamber **91** in accordance with the demands of the patient, an electrically operated control circuit is provided. The control circuit illustrated in FIG. 6 is shown in block diagram form, the individual electrical units including circuitry that is well known in the art. Not shown in the block diagram is an electrocardiograph unit (EKG), the scope output of which is connected to a cable indicated at **170**. The cable **170** feeds the output of the EKG unit into an amplifier and synchronizer pulse shaper **172** that is adapted to amplify the sync pulse or electrical signal used for synchronizing purposes as taken from the scope jack of the EKG machine. The amplifier and synchronizer pulse shaper **172** is also designed not only to limit the magnitude of the sync pulse but to also shape it. The pumping unit is designed to be synchronized on the R-wave of the sync pulse and accordingly all other portions of the wave are either reduced or removed in the amplifier and synchronizer pulse shaper **172**, thereby leaving only the R-wave. Since the hydraulic events in the patient's heart are not simultaneous with the EKG unit or the R-wave, and furthermore since the hydraulic events in the patient's arterial system are delayed behind the systolic pulse of the heart by varying amounts and depending upon the distance of the artery from the ventricle, it is necessary to provide means for phasing the systolic pulse of the pumping unit with the systolic pulse of the heart in order to accommodate these time delays. For this purpose, a systole delay network indicated at **174** is provided. The systole delay network **174** is triggered by the R-wave and creates a sync pulse delayed behind the R-wave by a controlled amount and enables the systolic pulse of the pumping unit to be delayed behind the systolic pulse of the patient's heart by a time interval which can be controlled from approximately .04 of a second to .4 of a second. By providing this time delay interval, the pumping unit may be adjusted so that the pressure reflections from the systolic pulse of the pump will be properly phased with the pressure reflections from the systolic pulse of the patient's heart and in such a way as to physiologically aid the patient's heart. The sync pulse produced by the systolic delay network **174** triggers a trigger circuit indicated at **176**, which is a one shot multivibrator. The trigger circuit is stable in one direction and is tripped by the sync pulse into its other mode of operation. Combined with the trigger circuit **176** is a systole duration control which is provided for controlling the duration of the tripped condition of the trigger circuit. The output of the trigger circuit **176** is fed directly into an output amplifier indicated at **178**, the function of which is to create a suitable signal for firing the thyratron **180**, in the plate circuit of which the solenoid **144** is located. A D.C. power supply indicated at **182** is electrically connected to the amplifier and synchronizer pulse shaper **172**, the

systole delay network 174, the trigger circuit and systole duration 175 and the output amplifier 178 and provides the plate voltages thereto. The D.C. power supply 182 is a typical full-wave rectifier with capacitive filtering and voltage regulators to provide steady voltages in order to maintain calibration of the pumping unit. A D.C. power supply 184 is also provided and is electrically connected to the thyratron switching circuit 180, thereby supplying the proper voltage thereto. The D.C. power supply 184 is a full wave bridge circuit using silicone diodes.

By means of the circuitry illustrated in FIG. 6, the cable 170 is connected to the scope output of a typical EKG unit, and the R-waves present in the signal represented by the sync pulse are amplified by the amplifier 172, delayed by the systole delay network 174 which triggers the trigger circuit 176. The trigger circuit through the rest of the circuitry causes the solenoid 144 to be energized, thereby opening the three-way valve 140 to admit gas under pressure into the actuator chamber 91. Movement of the piston by the gas under pressure causes the systolic pulse of the pump. The system is sufficiently accurate such that pulse rates in excess of 200 a minute can be followed even though these pulse rates may be erratic, as would be encountered in an arrythmic heart. It is pointed out that the synchronized operation as described above will be utilized primarily for partial perfusions and assists. However, it is also contemplated to utilize the equipment in regional perfusions wherein synchronous pulsatile flow may be more effective than continuous flow.

Although the circuit described hereinabove is primarily for the purpose of synchronizing the signal from the patient for operating the pump, it may be desirable to arbitrarily operate the pump without the synchronizing signal. For this purpose, a separate control means 186 indicated as an internal pacemaker is provided, and it is understood that switching means would be available to enable the operator of the device to switch from synchronous to internal control as desired. The internal pacemaker 186 is a free running multivibrator, although it is also contemplated to use a blocking oscillator or gas-trigger circuit in the same manner as the freerunning multivibrator. The frequency range of the internal pacemaker 186 is from approximately 10 strokes a minute to 150 strokes a minute, although it is understood that this range may be changed as desired. Thus, the internal pacemaker will be arbitrarily set to produce a pulse which will operate the solenoid 144 at predetermined intervals notwithstanding the pulse of the patient.

Referring now to FIG. 7, a block diagram of the gas supply system is illustrated. This system provides a quick disconnect for an air hose 188 which is connected to a suitable source of air pressure, the air hose 188 feeding into a pressure regulator 190, the maximum pressure of which is approximately 100 pounds per square inch. A gauge 192 connected to the pressure regulator 190 indicates the actual pressure in the system while the output of the pressure regulator is fed into the three-way solenoid valve 140. The valve 140 is adapted to be operated to allow the compressed gas to be fed to the chamber 91 through a normally open three-way manual valve 194. The valve 140 is controlled by the solenoid 144 in such a manner to allow the gas to be exhausted from the chamber 91 through the three-way manual valve and a flow regulator 196. The three-way manual valve 194 is also utilized to facilitate hand operation for emergency use and also for priming the pump. It is seen that the output from the solenoid valve 140 is fed through the normally open manual valve 194 so that when the unit is operating automatically, the manual valve does not move. However, when the manual valve is operated, the actuator 10 responds regardless of whether the power supply is in the "on" position so long as air pressure or gas pressure is available. The single line feeding the operating chamber 91 exhausts through the three-way manual valve 194 and the flow regulator 196 which acts to regulate the exhaust. The flow regulator 196 also acts to control the rate at which the piston 88 in the actuator makes its return or diastolic stroke and cooperates with the spring 128 to completely control the return stroke of the piston. The regulator 196, although not essential in the operation of the device, is desirable since a less traumatic pumping operation will be produced when the diastolic stroke of the pump is made at the slowest possible rate.

While there is shown and described herein certain specific structure embodying the invention, it will be manifest to those skilled in the art that various modifications and rearrangements of the parts may be made without departing from the spirit and scope of the underlying inventive concept and that the same is not limited to the particular forms herein shown and described except insofar as indicated by the scope of the appended claims.

What is claimed is:

1. In a pumping system for use in maintaining extracorporeal circuation, a pumping unit including a flexible body having an inlet and outlet communicating with the interior thereof and further communicating with the circulation system of the patient, means for sequentially deforming said flexible body to produce a pumping action therein, said deforming means including an incompressible liquid that is confined within an enclosure and is adapted to contact the exterior surfaces of said body under pressure to cause deformation thereof, and means responsive to the pumping action of the patient's heart for sequentially controlling the operation of said deforming means whereby said pumping unit is caused to produce a pumping action in synchronization with the pumping action of the patient's heart, said controlling means including means for delaying the systolic pulse of the pumping unit behind the systolic pulse of the patient's heart, wherein the systolic pulse of the pump is phased with the systolic pulse of the patient's heart in accordance with the normal time delays existing therebetween.

2. In a pumping system for use in maintaining systemic extracorporeal circulation, a pumping unit including a flexible body having an inlet and outlet that communicates with the circulation system of the patient, means for enclosing an incompressible liquid, means for directing said incompressible liquid into contact with the exterior surfaces of said body at predetermined intervals to cause sequential deformation thereof, means responsive to the pulse of the patient's heart for controlling the operation of said directing means whereby said pumping unit is caused to produce a pumping action that is synchronized with the pumping action of the patient's heart, and means for phasing the systolic pulse of the pumping unit with the systolic pulse of the patient's heart in accordance with the normal time delays existing therebetween.

3. In a system for maintaining extracorporeal circulation, an actuating unit, a pumping unit associated with said actuating unit and responsive to the operation thereof to produce a systolic and diastolic stroke, means for operating said actuating unit, means for producing an electrical signal that is a direct function of the pumping action of the patient's heart, and means for controlling the operation of said operating means in response to said electrical signal for synchronizing the operation of said pumping unit with the pumping action of the patient's heart, said controlling means including means for controlling the duration of the systolic stroke of said pumping unit so as to coordinate the time delay of said pumping unit with respect to the pumping action of the patient's heart.

4. In a system for maintaining extracorporeal circulation, an actuating unit, a pumping unit associated with said actuating unit and responsive to the operation there-

of to produce a diastolic and systolic stroke, said pumping unit including a tubular body formed of a flexible material that is adapted to be deformed for producing a pumping action, said actuating unit including a tubular member and a cylinder communicating with said tubular member, said tubular body being positioned in said tubular member and defining an annular chamber therewith, and a piston disposed in said cylinder and adapted to periodically eject an operating fluid into said annular chamber to deform said tubular body thereby producing the pumping action thereof, and means for controlling the duration of the systolic stroke of said pumping unit, wherein the pumping action of said pumping unit is synchronized with the pumping action of the patient's heart, said controlling means being automatically responsive to an amplified signal of the patient's pulse.

5. In a system as set forth in claim 4, means for adjusting the stroke of said piston thereby adjusting the pumping action of said pumping unit.

6. In an artificial heart for use in maintaining extracorporeal circulation, a pumping unit communicating with the circulation system of a patient, an actuating unit communicating with said pumping unit for periodically producing a pumping action therein, means for operating said actuating unit, means for automatically controlling the operation of said actuating unit, means for phasing the systolic pulse of the pumping unit with the systolic pulse of the patient's heart in order to compensate for time delays therebetween, and means responsive to an amplified signal of the patient's pulse for operating said controlling means, wherein the pumping action of said pumping unit is synchronized with the pumping action of the patient's heart.

7. In an artificial heart as set forth in claim 6, said controlling means including a solenoid that is responsive to the aforesaid amplified signal of the pulse of the patient to control a valve, said valve directing an operating medium into said actuating unit for causing the operation thereof.

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