May 26, 1970 M. G. CHESNUT ET AL 3,513,845

BYPASS HEART PUMP AND OXYGENATOR SYSTEM

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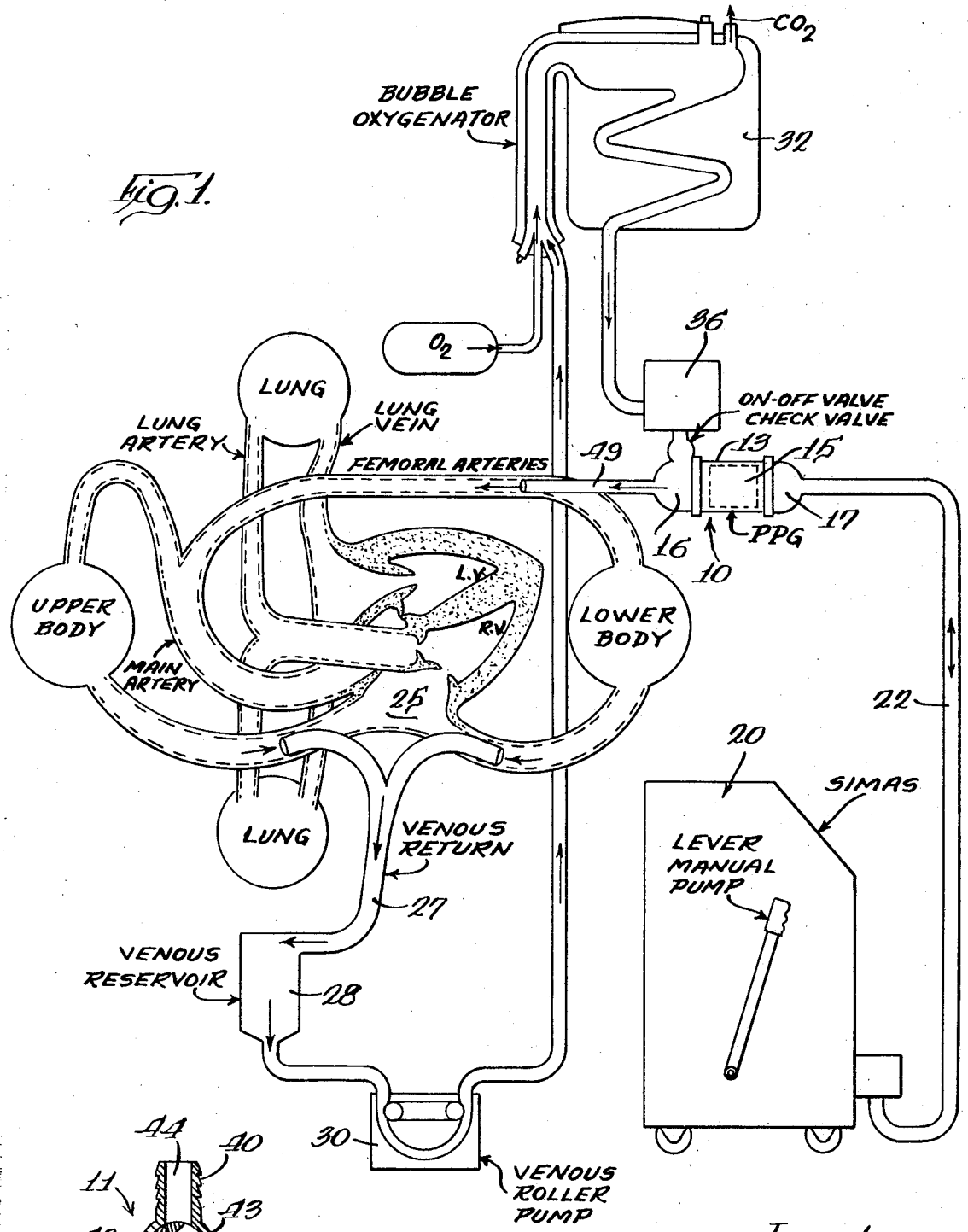
Fig. 1.



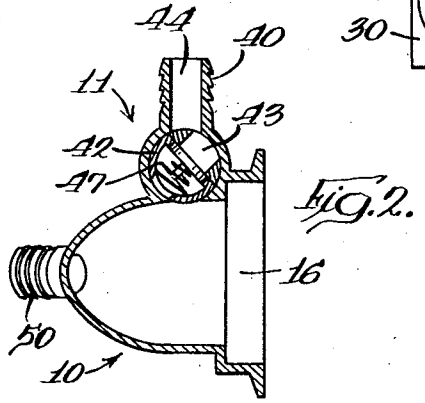




Fig. 2.

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Fig. 3.

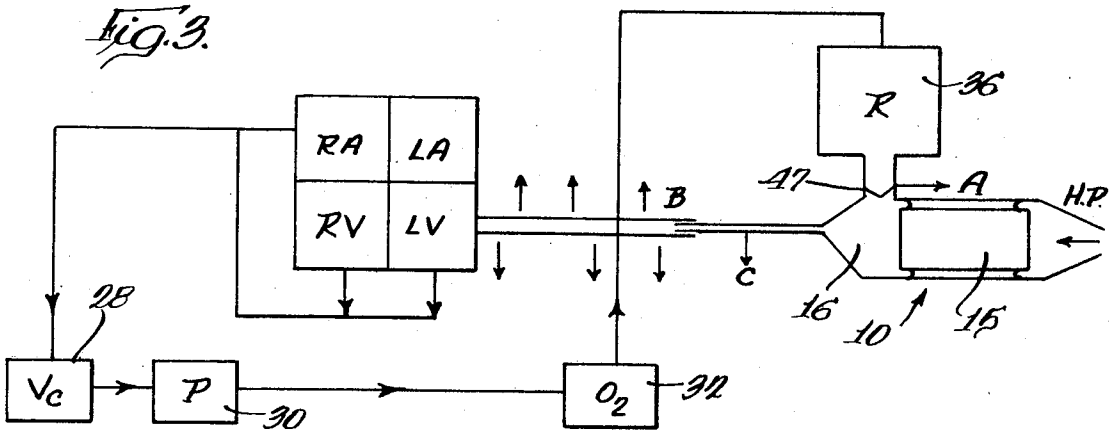



Fig. 4.

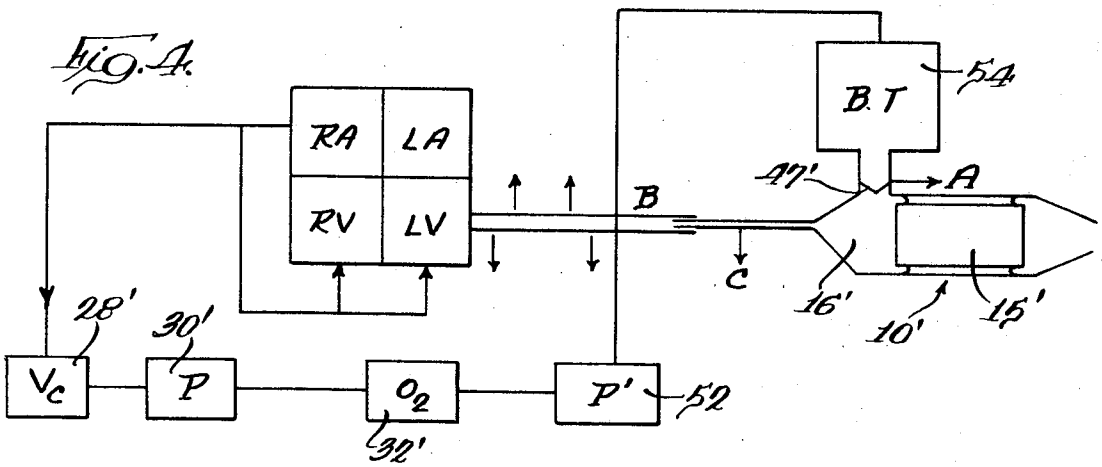
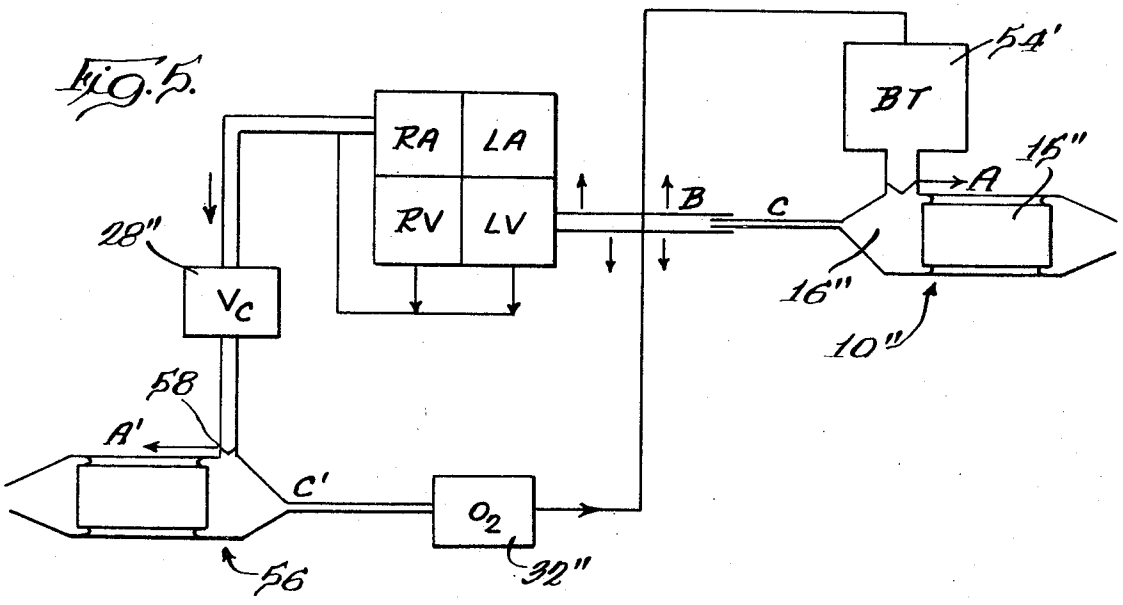



Fig. 5.



BYPASS HEART PUMP AND OXYGENATOR SYSTEM

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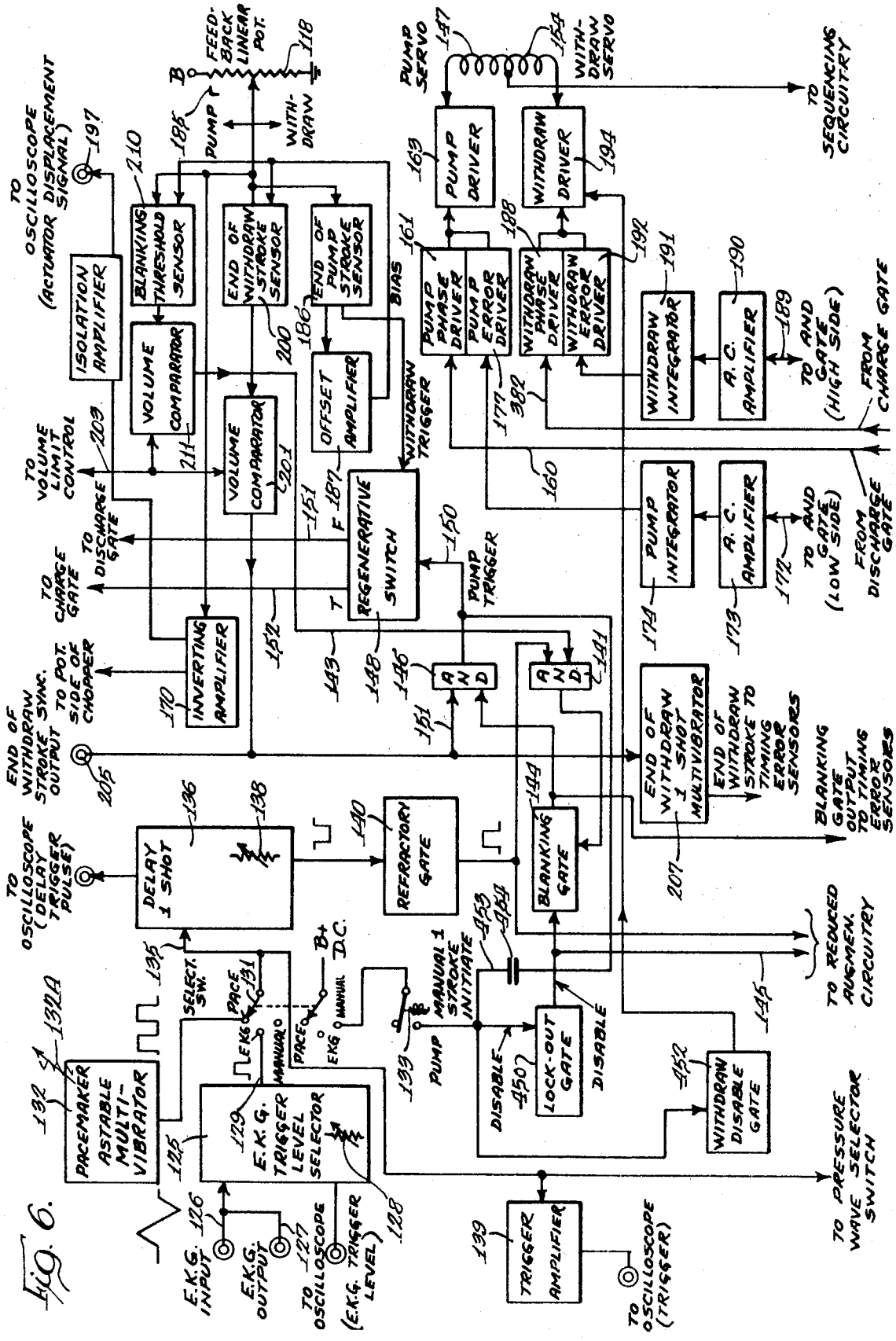


Fig. 6.

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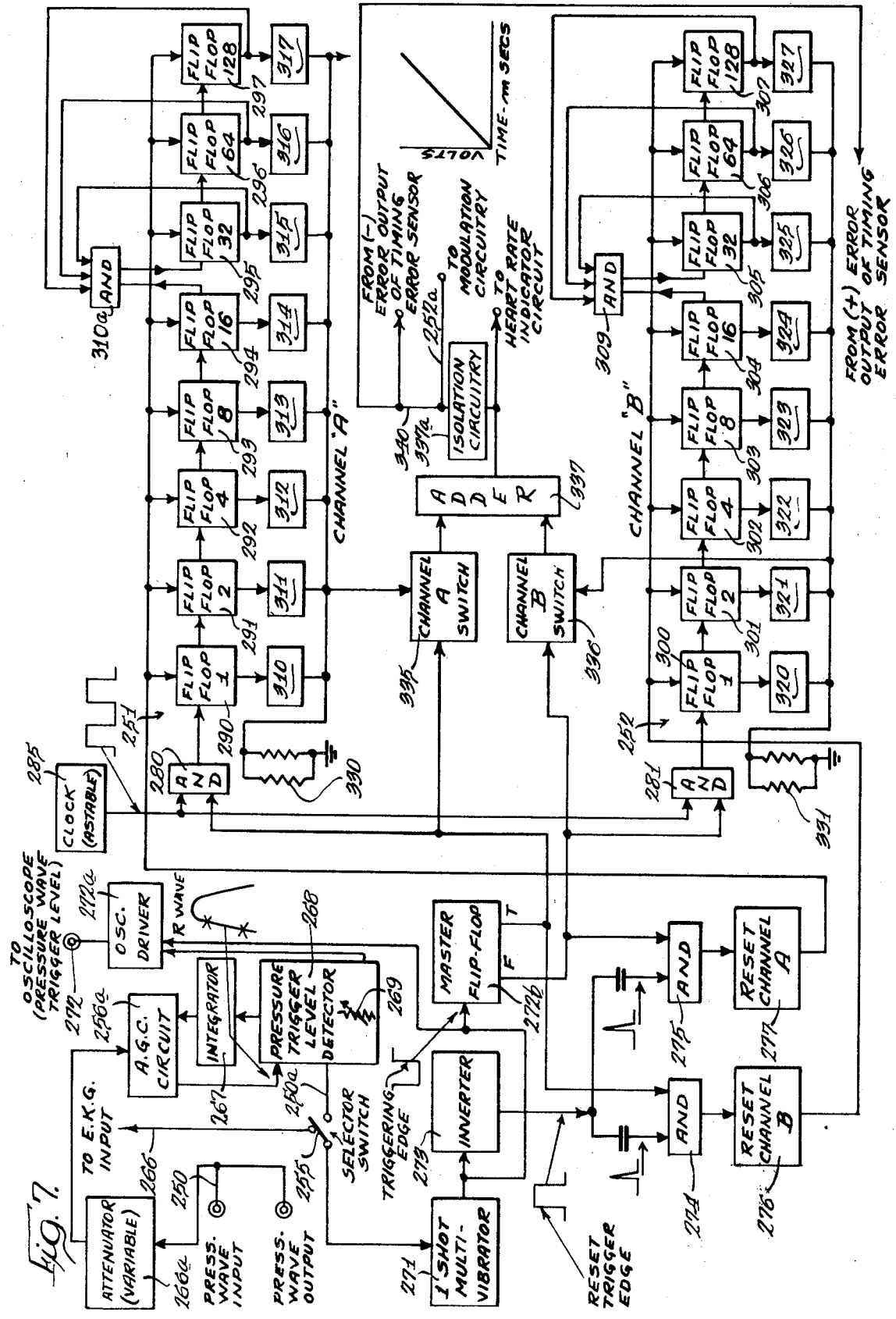


Fig. 7.

BYPASS HEART PUMP AND OXYGENATOR SYSTEM

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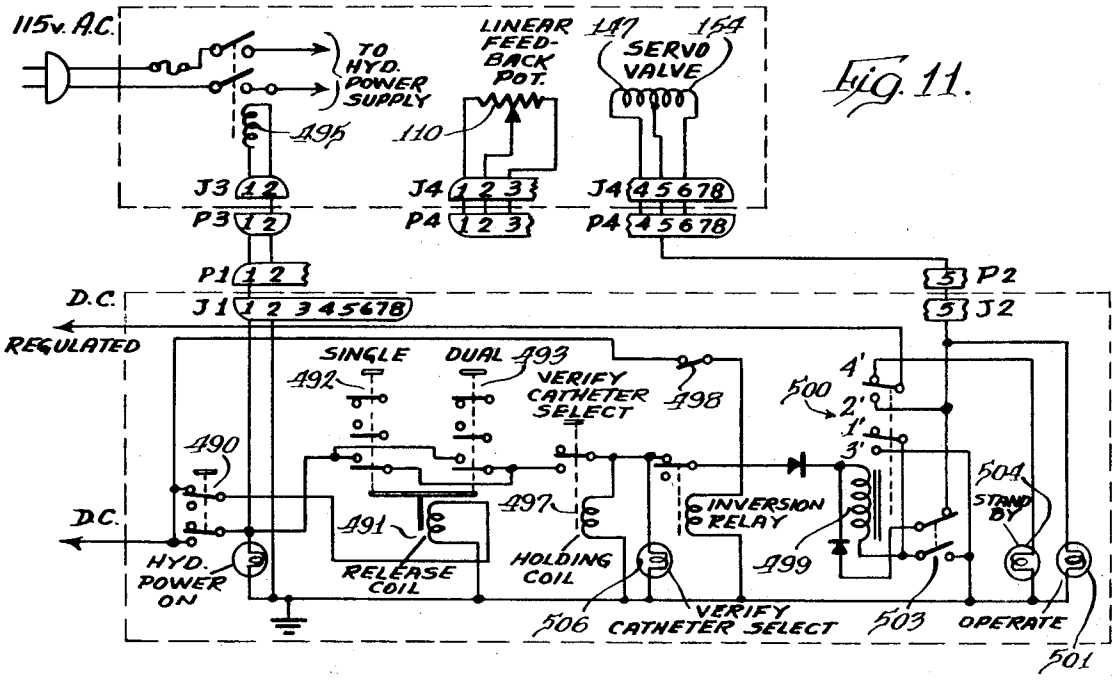
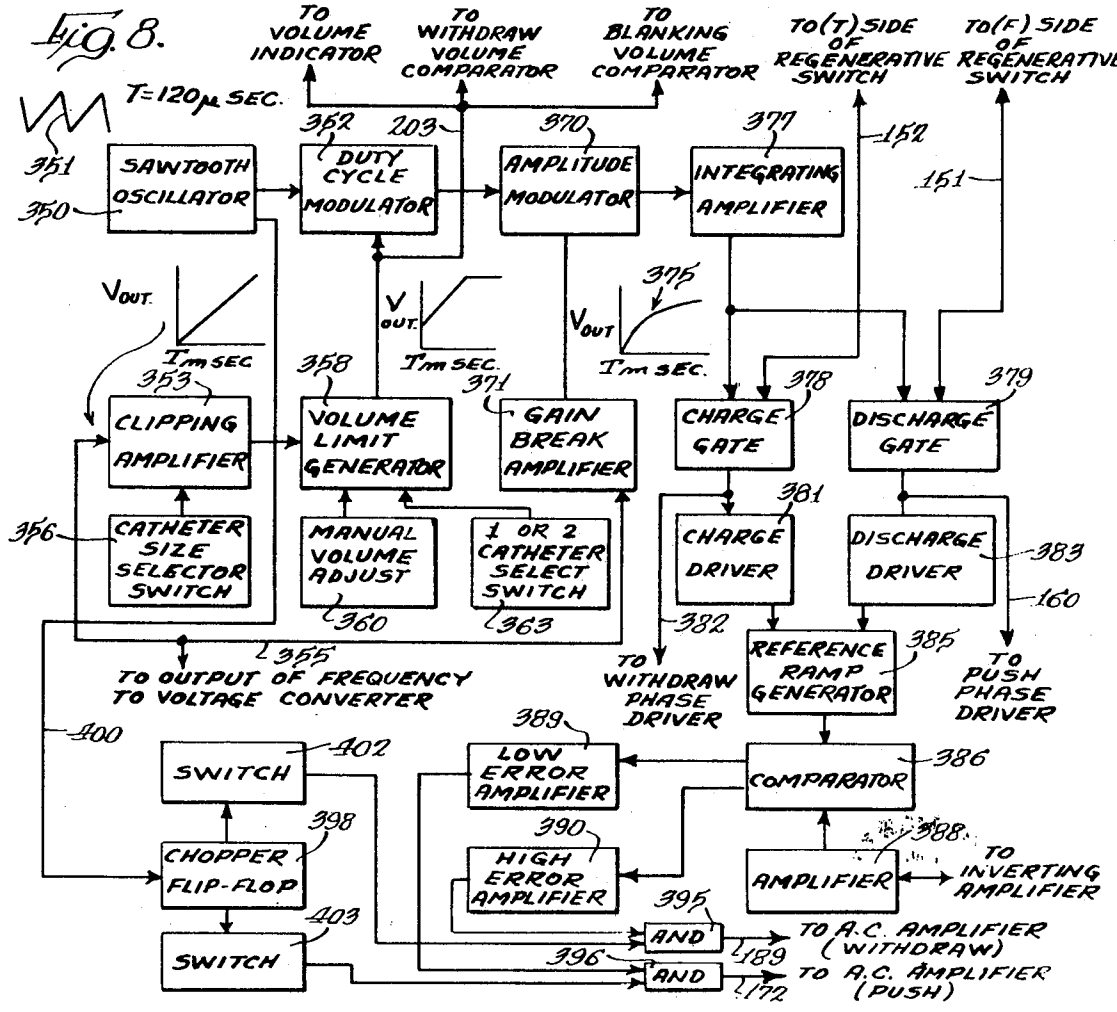



Fig. 11.

Fig. 8.



BYPASS HEART PUMP AND OXYGENATOR SYSTEM

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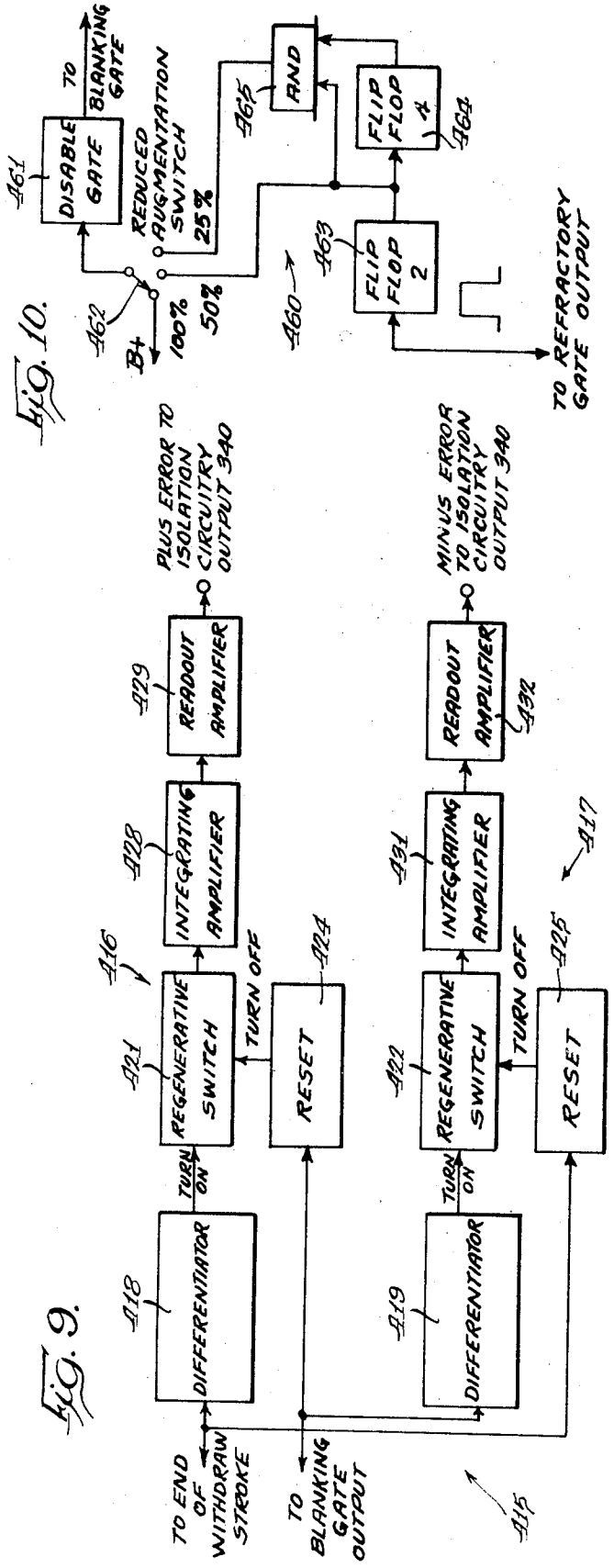


Fig. 9.

Fig. 10.

United States Patent Office 3,513,845 Patented May 26, 1970



3,513,845

# BYPASS HEART PUMP AND OXYGENATOR SYSTEM

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Filed Sept. 15, 1966, Ser. No. 579,565
Int. Cl. A61m 1/03
U.S. Cl. 128—214 5 Claims

## ABSTRACT OF THE DISCLOSURE

A cardiopulmonary bypass includes a reciprocating pump to deliver blood from a reservoir fed by an oxygenator to the femoral arteries. The oxygenator receives blood from either a venous roller pump or a reciprocable pump which draws the blood from a venous reservoir that in turn is fed by catheters placed into the superior and inferior vena cavae. The pumps are controlled by computer circuitry which provides the rate, the volume and the speed of blood flow under various controls. The system includes controls to permit utilization of an arterio-arterial assist device rather than as a complete cardiopulmonary bypass device. This includes the elimination of a check valve by utilizing differential flow cross-sections. In one embodiment, a second roller pump delivers blood from a reservoir of the oxygenator to a bubble trap, the output of which is returned to the patient through a reciprocating pump.

This invention relates generally to heart pump systems for replacing the function of a patient's heart, and more particularly to a heart pumping system for complete cardiopulmonary bypass.

In complete or total cardiopulmonary bypass, the total blood flow from the venous side of the patient's circulatory system is withdrawn, oxygenated, and returned to the arterial side of the system under sufficient pressure to perfuse the peripheral arterial tree. In systems of this type, in contradistinction to partial veno-arterial bypass, bypass of the right heart, and bypass of the left heart, the entire oxygenating function is effected by an extra corporeal oxygenator rather than the patient's lungs.

A primary limitation in prior known cardiopulmonary bypass systems is that they have not had long-term capabilities due to the development of metabolic acidosis after extended perfusions. Metabolic acidosis may be defined as the acid products released in the circulatory system resulting from a lack of oxygen in the blood causing the incomplete combustion of carbohydrates, fats and proteins. The tissue hypoxia resulting from metabolic acidosis is most prevalent in the use of steady state heart pump systems, such as those employing roller pumps, but also appears to result from the use of known pulsatile systems.

The peripheral pooling of blood during long perfusions with resulting hypoxia has been relieved somewhat using presently known techniques of hemodilution. Further, operative respiration of the lungs with helium and drainage of the left ventricle during bypass have obviated some of the alveolar collapse and interstitial hemorrhage encountered with prior known systems and techniques. However, from the circulation standpoint the high rates of flow necessary in these prior systems have produced excessive damage to the blood and overloading of the reticluoendothelial system, plugging of the renal tubules and acute renal failure. In prior systems these high rates of flow have been necessary because low flow rates lead to the development of metabolic



acidosis, often times during fairly short time intervals of perfusion. However, as the length of perfusion has increased, three has been found to develop a paradoxical metabolic acidosis even when the perfusion rate matches the normal cardiac output. Many authors explain this development as due to a sludging of the blood in the peripheral arterial tree.

Attempts have been made by various investigators to avoid the metabolic acidosis by lowering the oxygen requirement of the tissues by hypothermia. However, hypothermia produces its own problems, e.g., at ten degrees centigrade (despite the great reduction in oxygen requirement) the temperature of the blood limits circulation profoundly.

It is therefore a primary object of the present invention to provide a new and improved total cardiopulmonary bypass system in which microcircultaion is better perfused without employing flow rate rates high enough to rupture coronary vessels, thus enabling the system to maintain artificial circulation for longer periods of time and permitting more complicated surgical procedures to be attempted on the patient.

A further object of the present invention is to provide a new and improved pulsatile cardiopulmonary bypass system which in general will eliminate the patient's tendency toward metabolic acidosis even over long-term perfusions.

A further object of the present invention is to provide a new and improved pulsatile cardiopulmonary bypass system of the type described in which the arterial flow rate may be controlled by the surgeon as desired by simultaneously varying the speed and stroke length of a pulsatile pump in the system.

A more specific object of the present invention is to provide a new and improved bypass system of the type described above in which triggering signals from a variable rate pacemaker initiate each cycle of the pulsatile pump, and an automatic computer circuitry maintains coincidence between each pumping cycle and the period of the triggering signals and also varies the flow rate by automatically varying the speed of stroking of the pump in response to changes in the selected volume by the surgeon.

Another object of the present invention is to provide a new and improved cardiopulmonary bypass system of the type described above in which a roller pump is provided for withdrawing blood from the venous side of the patient's circulatory system and delivering it to an oxygenator, and including a reservoir for receiving blood from the oxygenator prior to entry into a blood pumping chamber in the pulsatile pump.

A still further object of the present invention is to provide an improved cardiopulmonary bypass system, somewhat modified from that described immediately above, in which two roller pumps are provided, one for pumping blood into the oxygenator and the other for withdrawing blood from the oxygenator and delivering it to the blood pumping chamber in the pulsatile pump.

Another object of the present invention is to provide a cardiopulmonary bypass system of the type described generally above, but in somewhat modified form in that a second pusatile pump is provided for withdrawing blood from the venous side of the system and delivering it through the oxygenator in place of the roller pumps, thereby more nearly simulating the physiological function of the human heart.

Still another object of the present invention is to provide a heart pumping system which may be used as a complete cardiopulmonary bypass during an operation and as a circulation assist postoperatively.

In accordance with the present invention, a reciprocat-

ing piston pulsatile pump is provided in which each pumping cycle is initiated by triggering signals from a pacemaker in the form of an oscillator in an associated control circuit. A pumping cycle as defined herein is one complete reciprocation of the pumping piston within the pulsatile pump, i.e., a push and a withdraw stroke. The reciprocating piston defines an expanding and contracting fluid chamber within the pump connected to receive oxygenated blood and deliver it in pulsatile fashion to the arterial side of the patient's circulatory system. Several means are disclosed for withdrawing the blood from the patient's vena cavae, oxygenating the venous blood, and delivering it to the blood pumping chamber in the pulsatile pump.

While each pumping cycle is initiated by the pump triggering signal referred to above, a computerized control circuit is provided for varying the time base of each pumping cycle so that it coincides with the period of the triggering signal by normally maintaining the length of stroke selected by the surgeon and varying the rate of travel of the pumping piston to achieve this coincidence. However in complete cardiopulmonary bypass, as there is no essential relationship between pulsatile flow initiation and the patient's natural heart action, the pacemaker may be adjusted by the surgeon to the desired rate. The present computer circuitry does permit the surgeon to select the desired rate and volume and the computer circuitry automatically initially computes the proper pumping or stroke speed to eliminate dwell or overlap between the pumping cycles.

The regulation of arterial flow rate, which is one of the important aspects of the present invention, is effected in the present computerized control by the rate and volume control circuitry. The volume circuitry permits the surgeon to merely select the desired volume of blood to be pumped per cycle and the system automatically computes the correct pump speed and stroke length to achieve the selected volume without varying the time base for the pumping cycle dictated by the repetition rate of the triggering signal described above. It is this interrelationship between pumping speed, stroke length and cycle time that provides the capability of the present device of long-term perfusions and the elimination of metabolic acidosis produced by prior known systems.

The present system when used in complete bypass fashion provides adequate blood pressure profiles with low blood flow rates. These low flow rates are sufficient to avoid metabolic acidosis but are low enough not to rupture the coronary arteries.

Other objects and advantages will be readily apparent from the following detailed description taken in connection with the accompanying drawings in which:

FIG. 1 is a diagrammatic view of the present bypass system shown with its connections into the patient's circulatory system;

FIG. 2 is a sub-assembly view of a portion of the pump shown in FIG. 1;

FIG. 3 is a simplified diagrammatic view of the system shown in FIG. 1;

FIG. 4 is a diagrammatic view of a system similar to that in FIG. 1 employing two roller pumps in addition to a pressure pulse generator;

FIG. 5 is a diagrammatic view of a somewhat modified system employing two reciprocating piston pumps;

FIG. 6 is a schematic diagram of a portion of the control circuit including the pacemaker input circuitry and the reciprocating pump servo coils;

FIG. 7 is a schematic diagram of another portion of the control circuitry including a digital counter;

FIG. 8 is a schematic diagram of the computer portion of the control circuit which selects the volume, push and withdraw rates, and cycle time of the reciprocating pump of FIG. 1;

FIG. 9 is a schematic diagram of timing error sensors which determine the error in the pumping cycle time;

FIG. 10 is a schematic diagram of a reduced augmentation circuit which selects only certain heartbeats to initiate the pumping cycles; and

FIG. 11 is a partial schematic diagram of the power supply for the control circuits.

While this invention is susceptible of embodiment in many different forms, there is shown in the drawings and will herein be described in detail embodiments of the invention with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the invention to the embodiments illustrated. The scope of the invention will be pointed out in the appended claims.

Referring to the system shown in FIG. 1 of the drawings, a pressure pulse generator **10** is provided generally similar to the pump shown in our copending application, Ser. No. 406,722 filed Oct. 27, 1964, assigned to the assignee of the present invention. Reference should be made to this application for a more detailed description of the pump **10**. It will only briefly be described herein with particular reference to a combined on and off check valve **11** shown in FIG. 2 which permits both complete bypass operation and arterio-arterial circulation assist.

The pump **10** includes a multi-member housing **13** having a cylinder formed therein which slidably receives a reciprocating piston **15** defining in the housing **13** a pumping chamber **16** and an actuating chamber **17**.

A controller **20** described in more detail below delivers fluid in two directions through the fluid coupling **22** to the actuating chamber **17** thereby reciprocating the piston **15** in forward and reverse strokes, sometimes referred to herein as push and withdraw phases, respectively.

As shown in FIGS. 1 and 3, the pump **10** is connected in complete cardiopulmonary bypass so that blood flow from the heart and through the lungs is terminated and circulation and oxygenation is effected extracorporeally by the artificial system. Toward this end venous blood is drained by catheter assembly **27** from the superior and inferior vena cavae which normally drain into the right atrim **25**. This blood is drained by gravity into a venous collecting chamber **28**. The chamber **28** should be placed below the level of the operating table for this gravity feed.

Venous blood in the reservoir **28** is pumped by a roller pump **30** through an oxygenator **32**. The roller pump **30** may be any one of a number of commercially available units of this type. The oxygenator **32** may take several forms including the bubble type, disc, screen, or even membrane type.

Blood in the oxygenator drains by gravity into a reservoir **36**. No bubble trap is required in this embodiment as any bubbles in the blood will rise to the top of the reservoir.

The reservoir **36** is connected to fitting **40** shown in FIG. 2 communicating through check valve **11** with the pumping chamber **16** in the pump **10**.

The valve **11** may be manually operated to either block flow from the reservoir **36** into the chamber **16**, or to permit flow from the reservoir but prevent back flow from the chamber **16** into the reservoir. For this purpose a manually rotatable valve member **42** is provided with a large diameter through passage **43** therein. When valve member **42** is rotated so that passage **43** is aligned with bore **44** in the fitting, fluid may flow from the reservoir **36** into the chamber **16**. This is the valve open position, and is so placed when the system is used in complete bypass. During postoperative circulation assist the valve **42** may be rotated 90 degrees from its valve open position closing bore **44**. The function of this is described in more detail below.

A check valve assembly **47** is mounted within a passage **43** and permits flow from the reservoir **36** into the chamber **16**, but prevents flow from the chamber into the reservoir. In this manner during the push stroke of the piston **15** blood will flow from chamber **16** into the patient's arterial system rather than back into the reservoir **36**.

The pumping chamber **16** is connected into the circulatory system through a catheter assembly **49** connected to fitting **50** (FIG. 2). The catheter assembly may be similar to that shown in our copending application, which includes branched catheters adapted for insertion into the femoral arteries up into the patient's descending aorta.

It should be noted that there are no check valves in the catheter assembly **49** preventing flow from the arterial side of the patient's circulatory system into the pumping chamber **16** as the piston **15** withdraws. To prevent any significant amount of blood from being removed from the arterial tree during this withdrawal action, the diameters of the bore **44** and passage **43** are large compared with the smallest diameter of the catheter assembly **49** so that the catheters offer much greater resistance to flow during the withdrawal of piston **15** than the passages connected with the reservoir **36**.

As the piston **15** moves in its push phase forcing blood into the arterial tree, the check valve **47** prevents reverse flow into the reservoir **36**.

As the controller and actuator **20** delivers fluid through the coupling **22**, piston **15** reciprocates drawing blood into chamber **16** through check valve **47** (with valve member **42** open), and in the opposite phase forcing blood from the chamber **16** through catheter assembly **49** into the arterial tree. This action provides pulsatile perfusion of the blood in the arterial tree.

In FIG. 4 a cardiopulmonary bypass system is shown generally similar to that shown in FIGS. 1 to 3 except that the reservoir **36** is replaced by a combination of a second roller pump **52** and a bubble trap **54**. With this arrangement blood is forced into the pumping chamber **16'** rather than being fed by gravity from a reservoir such as noted with respect to FIGS. 1 to 3. When piston **15'** withdraws during the withdrawal phase, both the pressure from roller pump **52** and the withdrawal action of the piston **15'** cooperate in filling the chamber **16'**. There is only minimal leakage through the valve **47'** during the push phase of the pump **10'** as the pressure in chamber **16'** is above the output pressure from pump **52**, although the valve **47'** closes somewhat slower in this embodiment than in the embodiment of FIGS. 1 to 3.

Since the system shown in FIG. 4 is essentially closed from the oxygenator to the arterial side of the patient's circulatory system, the bubble trap **54** is required to removed gases entrained in the blood.

The minute flow in the system shown in FIG. 4 is somewhat higher than that shown in FIG. 3 due to the additional filling assist of chamber **16'** by the pump **52**.

In the FIG. 5 embodiment, a cardiopulmonary bypass system is disclosed generally similar to those described above with reference to FIGS. 1 to 4 except that an additional pulsatile pump **56** is provided for withdrawing blood through valve **58** from the reservoir **28''**. Valve **58** is a check valve and may be similar in construction and operation to the valve **11** shown in FIG. 2. Pump **56** during its withdraw phase draws fluid from reservoir **28''**, and during its push phase pumps blood into oxygenator **32''**. The withdrawal of blood from the oxygenator **32''** is effected by the withdrawal action of piston **15''** in pump **10''**. A bubble trap **54'** is also necessary as the system is a closed one from the oxygenator **32''**. Suitable circuitry is provided (not shown) to balance the output of the pumps **56** and **10''** so that they may operate under different load situations preventing the oxygenator **32''** from being either flooded with too much blood or being drained dry.

In all the above systems the intermittent infusion of blood into the arterial tree produces a pulsatile arterial pressure wave. The height or amplitude of this wave may be increased by increasing the travel of the piston **15** and for this purpose a suitable volume dial is provided on the controller **20** in FIG. 1 which permits the surgeon to select the desired volume per cycle of the pump. In addition, the relative time duration of the positive pressure wave in comparison to the total cycle time of the pump may be altered by changing the relative time duration of the push and withdraw phases of the piston **15**. Furthermore, the length of cycle is also governed from the controller **20** by changing the rate of pacemaker which provides triggering signals for each cycle of the pump. During complete cardiopulmonary bypass the phase relationships between the patient's natural heart action and the synthesized wave produced by the pump **10**, important in assisted circulation, are of no importance.

The control circuitry described below, contained in the controller **20**, exercises control over the pumping parameters of stroke length, speed of stroking during both push and withdraw phases, and pump cycle duration. It should be understood at this point that only portions of the described circuitry are operative during complete cardiopulmonary bpyass, the other portions being operative during arterio-arterial assist as a postoperative circulation aid.

Triggering and driving circuit

The triggering and driving circuit disclosed in FIG. 6 is generally adapted to develop triggering signals for initiating each cycle of the reciprocating pump **10**. For complete cardiopulmonary bypass, a pacemaker **132**, which may take the form of an astable multivibrator, provides triggering pulses for the pumping cycles. A suitable control **132***a* is provided for varying the repetition rate of the triggering signals from the pacemaker so that the surgeon may select the cyclical rate he desires. For arterio-arterial assist, which is employed as a postoperative measure in the present device, an EKG trigger level selector **125** is provided for initiating the pumping cycles in timed relationship with the patient's EKG waveform. It should be understood that the pacemaker **132** and the trigger level selector **125** are used selectively.

In the arterio-arterial mode, the triggering circuit is effective to develop triggering pulses and delay them from a selected trigger level portion of the QRS segment of the EKG wave at a predetermined trigger level, and derives and delays a triggering pulse therefrom. The triggering pulse derived initiates the push phase of the pumping cycle and effects delivery of fluid into the patient's aorta increasing intra-aorta pressure at a time when the workload of the heart is the lowest. As noted above, during postoperative arterio-arterial assist the valve **11** would be closed. The delay time for the triggering pulse determines the phase relationship of the pumping cycle to the arterial pulse wave, and is determined physiologically as the phase relationship, which reduces the intraventricular pressure to a minimum for a given volume pumped and increases the postsystolic arterial pressure to an extent which returns the intra-aortic pressure to its pre-pump level or better so that coronary and peripheral circulation may be assisted. The withdrawal phase begins immediately upon completion of the pumping phase and continues during aortic valve opening thereby aspirating the left ventricle into the aorta. The withdrawal phase continues until the peak of the next intraventricular waveform at which time another pumping or push phase begins in response to another triggering signal. This phase relationship is not of any significance in the complete cardiopulmonary bypass as there is no load on the patient's heart.

As shown in FIG. 6, an EKG trigger level selector **125** is connected to receive the patient's EKG waveform from a conventional electrocardiogram through line **126**. Line **126** connected to line **127** is adapted to drive an oscilloscope so that the patient's EKG waveform may be viewed during the use of the heart pumping system in the arterio-arterial mode by the surgeon or technician. Reference should be made to the copending application Chesnut et al. for the details of construction of the trigger level selector **125**.

A selector switch **131**, which may be located on a convenient control panel, permits the alternate initiation of

the pumping cycles by the pacemaker **132**, by the EKG trigger level selector **125**, or by the manual stroke initiate switch **133**. As noted above, during complete cardiopulmonary bypass, with which the present invention is mainly concerned, the switch **131** is placed in its uppermost position connecting the pacemager **132** to a trigger delay circuit **136** through line **135**. With switch **131** in its central or middle position, it connects the trigger level selector **125** to the trigger delay circuit **136** through line **135**. And when switch **131** is in its lowermost position, the manual position, the upper half of switch **131** is ineffective but the lower half of the switch is connected to a power supply which places the pump cycle under manual control.

The trigger delay circuit **136** delays the actual triggering pulse behind the selected portion of the patient's EKG waveform during arterio-arterial assist. It may consist of a standard dual PNP transistor one shot multivibrator with base triggering. Its RC time constant is manually adjustable with a potentiometer **138** which may be mounted on the control panel. The potentiometer **138** provides an adjustment of the delay time. The output triggering pulse from the trigger delay circuit **136** triggers a refractory gate **140** which produces an 80 msec. pulse when triggered. The refractory gate **140** may be a standard dual PNP transistor one shot multivibrator with base triggering. The delay provided by the delay circuit **136** is unnecessary during complete cardiopulmonary bypass.

The pulse from the refractory gate **140** comprises one of two inputs to AND gate **141**. The AND gate **141** prevents any erroneous triggering signal from the refractory gate **140** from initiating the pumping cycle. If a triggering pulse from the refractory gate **140** is conducted to the AND gate **141** prior to the receipt of a signal from the other input to the AND gate **141**, i.e., line **143**, which indicates a partial completion of the withdrawal stroke, the 80 msec. pulse will be held by the AND gate for 80 msec. and if line **143** is not energized by that time, the triggering pulse will be dropped. If a triggering pulse from the refractory gate **141** and a signal from line **143** are received by the AND gate **141** simultaneously, blanking gate **144** passes a signal. The blanking gate **144** consists of a dual PNP transistor switch normally deactivated by the lock-out gate **450**. A signal in line **145** to the blanking gate **144** blanks out selected triggering pulses in response to the reduced augmentation circuitry described in more detail below. A pulse derived from the blanking gate **144** is one of the two required enabling signals to the AND gate **146**. The AND gate **146** will not trigger the pumping cycle, however, until a signal is received in line **151** which is the other input to the AND gate **146** indicating that the pump has completed its withdrawal stroke. This circuitry eliminates out-of-phase pumping during arterio-arterial assist by combining electronic control features with the physiological phenomenon known as the refractory period.

A pulse in line **150** from the AND gate **146** initiates the push phase of the pumping cycle by turning on a regenerative switch **148**.

The regenerative switch **148** may consist of two transistor stages connected so that the output is fed back into the input. In addition, another NPN transistor switch shunts the first stage of the regenerative switch. A high voltage at the first stage turns on the regenerative switch, whereas the high voltage at the shunting NPN transistor turns it off regeneratively. The presence of a high voltage in line **150** turns the first stage of the regenerative switch on and the second stage off thereby energizing line **151** and deenergizing line **152**. Line **151** energizes the pump servo coil **147** through the volume and rate computer circuitry shown in FIG. 8, while the energization of line **152** energizes the withdrawal servo coil **154** through the same volume and rate computer circuit.

A pump phase signal, modulated by the volume and rate computer circuitry described in more detail below with reference to FIG. 8, energizes line **160** in FIG. 6 which drives the pump phase driver **161**. The magnitude of the current in line **160** determines the bias on the pump driver **163** and thereby the magnitude of excitation of the pump servo coil **147**. The rate of travel of the piston **15** is directly proportional to the magnitude of the current in the pump coil **147** and the withdraw coil **154**.

The servo coils **147** and **154** drive a servo valve (not shown) which ports fluid to a reciprocating hydraulic actuator. The hydraulic actuator drives fluid in two directions through coupling **22** shown in FIG. 1 which in turn reciprocates the piston **15**. Such a system is shown in our above mentioned copending application. Alternatively, the coils **147** and **154** may be arranged to drive an electromagnetic actuator eliminating the need for a hydraulic servo valve and the associated hydraulic circuitry. Connected to the actuator is a linear feedback potentiometer **118** for indicating the actual position of the pumping piston **15**.

As the piston **17** begins its push stroke driving the potentiometer **118**, a feedback displacement signal from the potentiometer drives an inverting amplifier **170**, the output of which is used to determine the error between the actual pump and withdrawal displacement and the reference pump and withdrawal displacement signals determined by the computer circuitry shown in FIG. 8. Any error is fed back from the computer circuitry to line **172** in FIG. 6 whereby it is amplified by an AC amplifier **173** and integrated by a pump integrator **174** which excites a pump error driver **177** for varying the bias on the pump driver **163**.

An identical closed loop feedback circuit is provided as shown for the withdrawal stroke and consists of line **189**, AC amplifier **190**, withdraw integrator **191**, a withdraw error driver **192**, a withdraw phase driver **188**, and a withdraw driver **194**. The error drivers are two-stage DC amplifiers which are collector coupled to the base of the NPN servo drivers for isolation purposes. The phase drivers **161** and **188** are PNP transistors which are collector coupled in parallel with the error drivers. The sevo drivers **163** and **194** may each be an NPN transistor which is connected in push-pull fashion to the associated servo coil. The servo drivers **163** and **194** are driven from an isolated source and are collector coupled to the servo valve coils **147** and **154** for isolation purposes.

As the feedback potentiometer **118** and the actuator shaft (connected with the actuator described above) reach the end of the push stroke and a suitable mechanical stop (not shown), an end of pump stroke sensor **186** provides a high voltage to the regenerative switch **148** to turn the switch off, thereby energizing line **152** and deenergizing line **151**. The end of pump stroke sensor **186** may consist of an inverting PNP amplifier which drives the PNP comparator. The PNP amplifier emitter modulates the PNP comparator. The base of the comparator is biased by a potentiometer offset amplifier **187**. The output of the end stroke sensor **186** immediately initiates the withdrawal stroke at the end of the pump stroke. The potentiometer and the offset amplifier **187** which provides a vernier adjustment for the length of stroke may also be used to bias an end of withdrawal stroke sensor **200** to eliminate offset errors due to mechanical alignment tolerances between the piston **15** and the feedback potentiometer **118**.

The energization of line **152** by the regenerative switch **148** enables the withdrawal phase driver **188**. The withdrawal rate errors are impressed in the form of an error signal on line **189** and through the AC amplifier **190**, the withdrawal integrator **191** and the withdraw error driver **192** providing a closed loop feedback on the withdrawal rate in the same manner as the corresponding components in the pump error driver circuit described above. A withdraw driver **194** energizes the withdraw servo coil **154** to drive the pump piston **15** in its withdraw stroke thereby drawing blood from the reservoir **36** through valve **11** into the fluid chamber **16**.

As the pump proceeds in its withdrawal stroke, the feedback potentiometer **118** is driven as shown in FIG. 6. An isolated oscilloscope jack **197** is provided so that the inverted pump displacement wave may be viewed by the surgeon during heart augmentation.

As the feedback potentiometer **118** is driven toward ground, it drives the end of withdraw stroke sensor **200**. This sensor, modulated by the volume comparator **201**, indicates when the pump has reached the end of the desired withdraw stroke. The length of stroke is determined by a volume limit generator described in more detail below with respect to FIG. 8. Suffice it to state at this point that a signal representative of the desired volume is carried in line **203**. The end of withdraw stroke sensor **200** and the volume comparator **201** may consist of an inverting PNP amplifier which drives one-half of an NPN differential amplifier. The other side of this comparator is driven by the signal representing the desired volume in line **203** so that a suitable switch (not shown) is turned on whenever the displacement wave amplitude from the potentiometer **118** exceeds the volume amplitude in line **203**. This switch drives an end of withdrawal oscilloscope output **205** as well as the pump trigger AND gate **146** and an end of withdraw one shot multivibrator **207** for purposes described in more detail below. Line **151** is then energized and awaits a new pump triggering signal from the blanking gate **144** to initiate another pumping cycle as described above. In this manner the volume of blood pumped by the reciprocating pump may be accurately controlled and selected by the surgeon as desired.

During the withdraw stroke, the feedback potentiometer **118** also drives a blanking threshold sensor **210** which provides one of two inputs to AND gate **141** preventing triggering pulses occurring earlier than a predetermined time before the completion of the withdraw stroke. This portion of the circuit is usually only operative during arterio-arterial assist when the EKG trigger level selector **125** is operative. The blanking threshold sensor **210** may be identical to the end of withdraw sensor **200** except that the input volume signal in line **203** is divided by a ratio of .9 in a volume comparator to **211**. The output of the volume comparator to **211** which occurs a predetermined time before the end of the withdrawal stroke enables AND gate **141**. Upon receipt of the refractory gate output signal AND gate **141** enables in turn the AND gate **146** through the normally inactive blanking gate **144**.

## Rate and volume computer circuitry

The purpose of the rate and volume computer circuitry shown in FIGS. 7, 8 and 9 is, generally speaking, to vary the pump and withdraw rates in response to changes in the triggering signal rate from the pacemaker **132** selected by the surgeon, and to vary the pump and withdraw rates in response to the desired volume per cycle selected by the surgeon. Thus, during complete cardiopulmonary bypass, the surgeon need only select the desired repetition rate for the pumping cycles by adjusting control **132***a* on the pacemaker and the computer circuitry will automatically vary the speed of the pumping piston **15** so that the duration of each pumping cycle coincides with the period of the signal from pacemaker **132**. Further, in response to the selection of a certain volume per cycle by the surgeon, the computer circuitry varies the length of stroke of piston **15** and automatically corrects the speed or rate of stroke of the piston so that the pump cycle duration remains constant with that determined by the period of the signal from pacemaker **132**.

When used in arterio-arterial assist, the rate and volume computer circuitry is used to vary the pump and withdraw rates and the volume pumped in response to varying heart cycle times and also in response to different desired volumes selected. Further, the output volume pumped decreases as a function of the heart rate as the maximum withdrawal and pumping rates are reached. These maximum rates are determined by blood hemolysis and catheter size. The push and withdrawal rates for each cycle are determined from the heart rate computed on the previous cycle. To eliminate any stacking errors, a closed loop error detection circuit is provided at the end of the withdraw stroke.

The computer logic described briefly above is based upon the selected rate of pacemaker **132** (or the cardiac cycle time during postoperative assist) and the selected volume per stroke as variable input parameters. From these the pump and withdraw rates are computed and the pump controlled.

During arterio-arterial assist it is sometimes more desirable to determine the cardiac cycle time from a pressure wave which is sensed from the patient. False triggering of the counting circuitry can be eliminated to a great extent by counting the time interval between the patient's pressure waveforms rather than his EKG wave.

Referring to FIG. 7 wherein the digital counting circuit is shown in schematic form, a pacemaker input signal is received in line **266** from pacemaker **132**. With switch **255** connecting line **266** to one shot multivibrator **271** the digital counting circuitry counts each period of the pacemaker pulses and provides an output voltage to the modulation circuitry shown in FIG. 8 which in turn computes the proper speed of the pumping piston **15**. Thus, during complete cardiopulmonary bypass, the digital counting circuitry shown in FIG. 7 determines the period or rate of the pulses from pacemaker **132**.

Alternatively, during arterio-arterial assist the digital counting circuitry in FIG. 7 may be employed to determine the patient's cardiac cycle time as represented either by the patien's EKG wave or a pressure signal. Toward this end, if switch **131** is placed in its intermediate position connecting trigger level selector **125** to line **266** the digital counter in FIG. 7 will determine the period between the patient's R wave. Alternatively, if switch **255** connects the one shot multivibrator **271** with line **250***a* the counting circuit will determine the cardiac cycle time from a pressure input circuit driven by a suitable transducer attached to the patient and impressed on input line **250**.

Regardless of the input to the counting circuit, the interval between successive waveforms is counted by one of the digital counting banks **251**, channel A, or **252**, channel B, and the resulting signal proportional to the interval between waves or pulses is delivered to the modulation circuitry in FIG. 8 through output line **250***a*. The digital counting circuitry produces a linear output voltage with time as shown in the graph in FIG. 7.

When the pressure wave is used as an input, it is attenuated by variable attenuator **266***a* which includes a voltage divider adjustable from a suitable control panel. This waveform drives an AGC circuit **256***a* which consists of dual cascaded field effect transistors. This waveform is impressed on a pressure trigger level selector **268** which consists of an integrator, an AC amplifier, an AC signal detector, and a Schmitt trigger. The integrator **267** is provided to prevent the digital counter from viewing the portion of the synthesized pressure waveform produced by the pump as a separate triggering wave. The output of the AC amplifier (not shown) is integrated by the integrator **267** and biases the AGC circuitry **256***a* to maintain a constant amplitude at the AC amplifier output. Potentiometer **269** in the pressure trigger level detector **268** provides an adjustable bias for the detector so that a selected portion of the patient's pressure wave may be employed to initiate the counting circuitry. With this circuitry, false signals may be filtered and prevented from initiating the digital counting circuit. The Schmitt trigger (not shown) in the pressure trigger level detector **268** triggers the one shot multivibrator **271** through selector switch **255**. The trigger level of the pressure wave may be viewed on the oscilloscope through an isolation oscilloscope driver **272***a* to output **272**. The one shot

multivibrator 271 generates a 100 microsecond wide pulse.

Of course, the one shot multivibrator 271 may also be triggered by the EKG waveform. It should be remembered that during cardiopulmonary bypass the one shot multivibrator 271 is triggered only by pulses from the pacemaker 132.

The one shot multivibrator 271 triggers a master flip-flop 272*b* and an inverter 273. The master flip-flop 272*b* selects either channel A or channel B for counting on alternatively successive cardiac cycles. The master flip-flop may be a standard dual PNP transistor flip-flop with base steering. The inverter 273 resets the digital counting banks 251 and 252 to "erase" the count held by the counting banks at the beginning of every other cycle by providing a reset pulse to each of the AND gates 274 and 275 upon receipt of each triggering pulse. The master flip-flop 272*b* provides an enabling pulse to each of the AND gates 274 and 275 on alternate triggering pulses so that after a first triggering pulse channel A resets and after a second triggering pulse channel B resets. The reset circuits 276 and 277 are conventional transistor switches which reset each appropriate channel by simultaneously base triggering its associated flip-flops.

The master flip-flop 272*b* also enable the AND gates 280 and 281 selectively on alternate cardiac cycles, so that the first signal from the master flip-flop through line T enables AND gate 280 allowing counting bank 251 to count, while the second signal from the master flip-flop 272*b* disables the AND gate 280 and enables the AND gate 281 through line F so that the flip-flop bank 252 is activated and ready to count.

The digital pulses for the counting channels A and B are provided by an astable clock 285 which may be a multivibrator or a standard unijunction transistor oscillator which triggers a driver flip-flop. When the trigger pulse from the patient's pressure wave energizes the master flip-flop 272*b* which activates one of channels A or B, clock 285 delivers digital pulses to it.

Each of the counting banks 251 and 252 consists of a plurality of series connected flip-flops which count pulses from the astable clock 285 in binary coded fashion. Flip-flops 290 to 297 in bank 251 and flip-flops 300 to 307 in bank 252 are standard dual PNP transistor flip-flops with base steering. Each flip-flop divides the frequency of its input signal by 2, successively. Each bank is capable of counting 256 pulses. A three input AND gate 309 is provided between the flip-flops 304 and 305 so that counter circuitry output may not indicate less than a count of 224 if it has been inadvertently allowed to exceed a count of 256. The inputs to the AND gate 309 are driven from the false side of the flip-flops 305 and 306 and 307 so that the trigger pulse to flip-flop 305 from 304 is inhibited after each of these three flip-flops has been triggered once. A similar circuit is provided for bank 251 (channel A).

The false side of each of the counter flip-flops 290 to 297 and 300 to 307 may be diode coupled to constant current switches 310 to 317 and 320 to 327. Each of the constant current switches is composed of a single PNP transistor stage which delivers a current flow proportional to its corresponding count when its associated flip-flop is triggered. For example, constant current switch 321 will produce a current proportional to a count of two, while constant current switch 325 will produce a constant current proportional to a count of 32 so that the sum total of the currents in the constant current switches associated with the triggered flip-flops represents the time duration of the cardiac cycle. A composite analog readout of the constant current switches is obtained by summing the currents through a precision resistor 330 associated with channel A or a precision resistor 331 asociated with channel B. Channel switches 335 and 336 are single transistor stages which alternatively shunt the precision output resistors 330 and 331. The channel which is counting is always shunted by the channel switches which are driven by master flip-flop 272*b* through either line F or T. An added 337 receives a constant DC voltage at its input from one or the other of channel switches 335 or 336.

As described in more detail below, a timing error sensor circuit is provided for correcting any error between the actual displacement cycle time and the period of the input signal from the pacemaker, or the actual cardiac cycle time (in arterio-arterial assist). This error, if it is negative, is delivered to the isolation circuitry output 337*a* through line 340 where it subtracts from the counted input signal period to provide a new effective period. If it is positive it is also delivered to the isolation circuitry output 337*a* where it adds to the counted period. As the period of the input signal delivered to the one shot multivibrator 271 is the controlling parameter for the computer modulating circuitry it is possible to correct errors in the displacement cycle time by varying the effective period signal to the modulation circuitry through line 252*a*.

It is apparent that each of the channels 251 and 252 count on alternate input signals so that upon completion of any one cycle channel A will read out to the modulating circuitry in response to a change in state of master flip-flop 272*b*, while at the same time channel B counts. Upon the initiation of the counting circuitry by the next input signal pulse which changes the state of master flip-flop 272*b* again, channel B reads out to the modulating circuitry and channel A counts.

Referring to FIG. 8 wherein the modulating circuitry for determining the push and withdrawal rates is schematically shown, a saw toothed oscillator 350 produces a saw tooth waveform as shown at 351 with a rising ramp voltage and a very steep retrace. The saw tooth oscillator 350 may consist of a unijunction relaxation oscillator driven by a constant current source. The output may be capacitively coupled to a variable voltage divider which is internally adjusted to compensate for the voltage gain tolerance of the unijunction oscillator.

A duty cycle modulator 352 is provided for relating the desired or limited blood displacement volume to a time base. The output of the duty cycle modulator 352 is a pulse having a width modulated proportionally to the desired or limited volume of blood to be displaced.

A clipping amplifier 353 is provided for setting the maximum volume, and hence the maximum pump and withdraw rates, for given heart cycle period. This circuit is only operative during arterio-arterial assist when the system responds to the patient's EKG wave. To achieve this, the linear voltage which represents the heart period is impressed on line 355 and constitutes an input to the clipping amplifier 353. It will be recalled that there is a maximum volume which may be pumped or should be pumped for every heart cycle period. In this regard, the clipping amplifier 353 prevents excessive withdrawal and pump rates caused by an extremely fast heart beat rate counted by the digital counter in FIG. 7. The clipping amplifier 353 may consist of a two stage DC amplifier having an NPN transistor driving a PNP transistor, with gain quiescent bias adjustment provided by the patient's computed cardiac cycle time.

A catheter size selector switch 356 is provided for varying the maximum volume limitation determined by the clipping amplifier 353 for different catheter sizes.

The relationship of heart rate or pacemaker rate to the maximum permissible volume may be drawn as exponential curves based upon the transfer characteristics of each individual catheter size. Therefore, the maximum permissible volume for any catheter size is a complex function of the flow characteristics of the particular catheter used. The catheter size selector switch 356 in response to the selection of any of the catheter sizes biases the clipping amplifier 353 to vary the gain thereof

and hence the maximum permissible volume in accordance with calculated data. An emitter resistor for the PNP stage in the clipping amplifier **353** is selected from one of eight resistors which correspond to eight catheter sizes. Hence, the gain of the clipping amplifier **353** is selected by the selector switch **356**. In addition an output resistive voltage divider is connected to the collector of the PNP transistor and one of eight resistors is simultaneously selected to adjust the output quiescent level of the DC amplifier. By this circuitry the clipping amplifier **353** produces output voltages varying with the heart period, or pacemaker, for each catheter size.

It should be noted that the clipping amplifier **353** merely sets the maximum limit of the volume pumped during any cycle and that for any lesser volume selected by the surgeon will normally determine the push and withdrawal rates.

A volume limit generator **358** biases the duty cycle modulator **352** to achieve a pulse output from the duty cycle modulator having a width proportional to either the maximum permissible volume or the manual volume selected, if it is less than the maximum permissible volume which is determined by the clipping amplifier **353**.

The duty cycle modulator **352** may consist of a two-transistor stage DC amplifier, followed by a regenerative switch and an NPN reset transistor. The sawtooth oscillator output is amplified and provides a forward bias to the first stage of the regenerative switch. Simultaneously, a back bias is provided by the volume generator circuitry. When the sawtooth amplitude exceeds the volume amplitude, the regenerative switch turns on. When the sawtooth waveform retraces to start another ramp, the NPN reset transistor turns on, resetting the regenerative switch to its normally off condition. The DC amplifier gain is manually adjustable to accurately match the volume generator output.

A manual volume adjust **360** is provided which normally controls the level of the bias of the volume limit generator on the duty cycle modulator **352**. Therefore, the width of the pulse from the duty cycle modulator **352** is normally proportional to the manually adjusted volume unless the maximum volume limit for a particular heart rate is exceeded. The output of the clipping amplifier **353**, which is discussed above, is a signal proportional to the maximum permissible volume and hence the maximum permissible pump and withdraw rates. It drives an emitter follower in the volume limit generator **358** which limits the output of the volume adjust potentiometer in the manual volume adjust **360** to a value proportional to the maximum permissible volume. The emitter of the emitter follower is diode coupled to the wiper of the volume adjust potentiometer and hence the low driving point impedance of the emitter follower effectively modulates the relatively high impedance of the circuit associated with the volume potentiometer. The volume adjust potentiometer is connected in series with a voltage divider wherein its wiper is the output of the volume limit generator **358**. The potentiometer in the manual volume adjust **360** may be on the control panel so that the surgeon may select the desired volume.

A catheter select switch **363** is provided which selects either one or two catheters. The catheter select switch **363** selects the range of the voltage divider in the volume limit generator **358**. Switch **363** divides the bias to the PNP limiting emitter follower from 2:1. Thus, catheter assembly **49** shown in FIG. 1 may consist of either one or two catheters. When one catheter is used instead of two, the catheter select switch **363** approximately halves the maximum permissible volume limit, which controls or limits the output of the volume adjust potentiometer **360**. When two catheters are used, the two catheter switch in the catheter select switch **363** approximately doubles the maximum voltage the voltage adjust potentiometer **360** may produce over the single catheter select switch position. It should be noted again that the catheter select switch **363**, the catheter size selector switch **356** and the clipping amplifier **353** limit only the maximum volume which may be pumped without exceeding the maximum withdrawal and pump rates. They do not affect the width of the output pulse from the duty cycle modulator **352** unless the potentiometer in the manual volume adjust circuit **360** attempts to produce a voltage representing a volume which would produce excessive rates.

The volume limit generator **358** drives an output line **203** for delivering a signal representing the desired volume to: (1) a volume indicator (not shown) for visual representation, (2) to the withdrawal volume comparator **201** which enables the pump trigger AND gate **146** as described above with respect to FIG. **6**, and (3) to the blanking volume comparator **211** which enables the AND gate **141** which transfers the delayed pump triggering signal to blanking gate **144**.

The above circuitry produces a pulse width modulated pulse train from the duty cycle modulator **352** proportional to the desired volume of blood to be pumped. As the heart rate varies or the pacemaker rate is varied by the surgeon, it is apparent that the withdrawal or the pump rate must change to maintain the same volume of blood delivered and to achieve a time coincidence between the displacement cycle and the period of the pacemaker signal (or the cardiac cycle). For this purpose, an amplitude modulator **370** and a gain break amplifier **371** are provided for amplitude modulating the pulse train from the duty cycle modulator **352**. The input to the gain break amplifier **371** (line **355**) is a voltage proportional to the period of the pacemaker signal (or the heart cycle) determined by the digital counter in FIG. 7. The voltage in line **355** is linear with respect to time. Since the withdrawal and pump rates must be proportional to the frequency of the pacemaker signal or the patient's heart, linear voltage at **355** must be converted to an exponential voltage representing frequency. Hence, the patient's heart period or pacemaker period which is on a time base must be converted to a frequency base so that the amplitude modulator **370** produces a pulse train having an amplitude proportional to the frequency of the heart signal or pacemaker signal.

For this purpose the gain break amplifier **371** produces an exponential output voltage as shown in graph **375** in response to a linear voltage input from line **355**. The gain break amplifier **371** consists of an emitter follower which drives a voltage divider. The impedance of the voltage divider is a function of the divider output voltage. As the voltage increases diodes in the circuit become forward biased, coupling successive resistive loads to the output. There are six of these gain breaks which generate an exponential output curve from the linear input voltage at line **355**. The gain break output is amplified by a single NPN stage which modulates the amplitude modulator. Since heart frequency is an exponential reciprocal function of the heart period or pacemaker period, the gain break amplifier **371** effectively provides an exponential voltage output proportional to the frequency of the pacemaker signal or cardiac cycle.

The amplitude modulator **370** may consist of a single PNP transistor inverting amplifier driven by the pulse width modulator pulse train from the duty cycle modulator **352**. The emitter of this PNP inverter amplifier in the amplitude modulator **370** is back biased by the output of the gain break amplifier **371**. The net collector current flow in the amplitude modulator **370** is therefore directly proportional to the differential of these two biases. In this manner the pulse train output from the amplitude modulator **370** has an amplitude proportional to the frequency of the pacemaker signal or cardiac cycle.

An integrating amplifier **377** is provided for integrating the pulse train which is modulated both with volume and with pacemaker frequency. The integrating amplifier **377** is a conventional RC integrator which drives two NPN DC amplifiers in parallel. The integrating amplifier **377** produces a DC analog voltage equal to the duty cycle

times the peak output voltage which is actually proportional to the desired volume times the pacemaker frequency. Therefore, the DC voltage output has a level proportional to the desired pump and withdraw rates. It is apparent that as the frequency of the pacemaker increases, as computed by the gain break amplifier **371**, the pulse amplitude from the amplitude modulator **370** will increase as will the DC level from the integrating amplifier **377**. Therefore, as the pacemaker frequency increases, so do the push and withdraw rates to achieve coincidence between the pacemaker signal period and the displacement cycle. Similarly, as the desired volume increases, represented by the output voltage from the volume limit generator the pulses from the duty cycle modulator **352** will increase also producing an increase in the DC level voltage output from the integrating amplifier **377** resulting in an increase in pump and withdrawal rates.

The DC voltage output from the integrating amplifier **377** biases a charge gate **378** and a discharge gate **379**. The gates **378** and **379** may each consist of an NPN transistor, the collector of which modulates a pair of PNP transistor drivers. The PNP transistors are forward biased, in parallel, by the integrating amplifier. If the NPN gating transistor is turned on, both PNP transistors are back biased. It will be recalled that during the withdraw stroke, line **152** is energized by the regenerative switch **148** and during the pump phase line **151** is energized by the regenerative switch. During the withdrawal phase, line **151** turns on the NPN gating transistor in the discharge gate **379** back biasing the PNP transistors in the discharge gate **379**. The absence of a signal on line **152** produces an output to charge driver **381** and line **382** which energizes the withdraw phase driver **188** as shown in FIG. **6**. The withdraw phase then proceeds at a rate corresponding to the magnitude of the current in line **382**.

When the regenerative switch **148** deenergizes line **151** and energizes line **152**, the charge gate **378** turns on ending the withdrawal stroke and the discharge gate **379** turns off initiating the pump stroke by energizing the push phase driver through line **160**. The pump stroke rate is determined by the integrating amplifier **377** similar to the withdraw stroke. A charge driver **381** is associated with the charge gate **378** in the same manner as the discharge driver **383** is driven by the discharge gate **379**.

A closed loop error feedback circuit is provided for achieving coincidence between the reference waveform produced by the modulating circuitry in FIG. 8 and the actual displacement waveform produced by the feedback potentiometer **118**. Referring to FIG. 8, the charge driver **381** and the discharge driver **383** drive a reference ramp generator **385**. The ramp generator **385** may be a low leakage wet tantalytic capacitor with a minimum voltage clamping circuit. The clamping circuit may be a resistor voltage divider which is diode coupled to the reference capacitor. The reference ramp generator **385** produces a triangular waveform proportional to the desired displacement of the reciprocating heart pump piston with respect to time. Thus, the reference ramp generator produces a reference signal which biases one side of a comparator **386**. The sense of the reference signal is determined by the regenerative switch **148**.

The comparator **386** may be simple NPN transistor comparator forward biased by the reference ramp generator **385**. The back bias for this transistor is provided by the feedback voltage from the potentiometer **118** which is inverted by the inverting amplifier **170** shown in FIG. **6**. It is amplified by a two stage, non-inverting DC amplifier **388**, shown in FIG. 8. As long as the reference ramp waveform from the reference generator **385** coincides with the inverted displacement waveform from the amplifier **388**, a fixed quiescent voltage drives both the low error amplifier **389** and high error amplifier **390**. The low error amplifier **389** may consist of a dual PNP inverter which drives a resistive voltage divider, and amplifies the negative error voltage between the reference and displacement wave voltages. The high error amplifier **390** may consist of a PNP transistor stage which drives a resistor voltage divider, and amplifies the positive error between the reference and displacement wave voltages. The outputs of the low error amplifier **389** and the high error amplifier **390** are connected to their associated AC amplifiers, **173** and **190**, respectively, through AND gates **395** and **396**.

The AND gates **395** and **396** along with an associated chopper flip-flop **398** provide continuous repetitive error correction during the withdraw and pump phases. The chopper flip-flop **398** is driven by the sawtooth oscillator **350** through line **400** and provides alternate enabling pulses to AND gates **395** and **396** through switches **402** and **403**, respectievly. It is apparent that if the sawtooth oscillator provides sawtooth pulses on the order of 120 microseconds that AND gates **395** and **396** will be enabled many times during each pumping cycle and therefore provide a virtually continuous error correction of the pump and withdraw rates. The pump and withdraw rates determine the volume delivered.

As discussed above, the push and withdraw rates for each cycle are determined by the modulating circuitry of FIG. 8 from the pacemaker rate counted in the previous period of the pacemaker signal by the digital counter described in FIG. 7.

Referring now to FIG. 9, a timing error sensor circuit generally designated by the numeral **415** is provided for computing the time difference between the completion of the withdrawal stroke and the receipt of a pump cycle trigger signal. The resulting error signal is used to vary the pump and withdrawal rates during the next cycle in closed looped fashion. This closed loop approach to error correction compensates for actuator gain variations and counting errors. The timing error sensors **415** are essentially two channels which integrate the error defined by the "on" time of a regenerative switch which is a pulse proportional to the time error between the end of withdraw stroke and the pump triggering signal. Channel **416** determines the error when the pumping cycle is completed before the next triggering pulse is received by the blank gate **144**, and channel **417** determines the error when the pump triggering signal from the blanking rate is received before the end of the cycle. Therefore, channel **416** determines the error when the pump and withdraw rates are too fast for a particular pacemaker period and channel **417** determines the error when the pump and withdrawal rates are too slow for a particular pacemaker period (or cardiac cycle).

Each of the timing error sensor channels **416** and **417** are substantially identical except for having cross connected inputs. Differentiators **418** and **419** receive input pulses respectively from the end of withdraw stroke one shot multivibrator **207** and the blanking gate **144**. The differentiators **418** and **419** may be typical RC type. The differentiated input signal from the differentiators **418** and **419** turn on regenerative switches **421** and **422**. The regenerative switches **421** and **422** may each be standard two PNP transistor cascaded switches with the output fed back to the input. Reset stages **424** and **425** are provided for turning off their respective regenerative switches **421** and **422**. The input to the reset stage **424** is the blanking gate output **144**, while the input to the reset stage **425** is the end of withdraw multivibrator **207**. The reset stages **424** and **425** may each be diode coupled resistor logic which biases the regenerative switch off upon receipt of the appropriate logic command. The time duration that each of the regenerative switches **421** and **422** are on represents the positive or negative error between the pumping cycle and the period of the pacemaker signal (or patient's cardiac cycle). The regenerative switches **421** and **422** drive integrating amplifiers **428** and **431** which produce a DC voltage proportional to the pulse time duration of their associated regenerative

switch outputs. The integrating amplifier **428** and **431** may each consist of a two stage transistor switch, followed by an RC integrator and a single NPN transistor DC amplifier. The output pulse of integrating amplifier **428** drives a readout amplifier **429**. The readout amplifier **529** may consist of a PNP transistor DC amplifier. Channel **417** has a similar NPN transistor readout amplifier **432**.

If the displacement cycle is too fast compared with the pacemaker period or cardiac cycle, the end of withdraw stroke multivibrator **207** will turn on regenerative switch **421** before an output pulse from the blanking gate **144** initiates the reset stage **424** producing a DC error output from readout amplifier **429**. The error signal from the readout amplifer **429** increases the current in the isolation circuit summing resistor in the digital counting circuit shown in FIG. 7. Since this current represents the time period of the pacemaker wave or cardiac cycle, the readout amplifier **429** effectively lengthens the counted pacemaker cycle or cardiac cycle time, producing a new, effective cycle time. Since the cycle time has been effectively increased, the modulating circuitry, shown in FIG. 8, views an effectively longer cycle time than it would view without the addition of the error signal. Since an increase in the pacemaker or cardiac cycle count produces a reduction in the withdrawal and push rates determined by the modulating circuitry in FIG. 8, the displacement wave slows down on the next pump cycle to correct for this error. Conversely, if the pump cycle is too slow compared with the pacemaker or cardiac cycle, a triggering pulse from the blanking gate **144** will turn the regenerative switch **422** on before the end of withdraw stroke multivibrator **207** resets the regenerative switch **422** so that readout amplifier **432** produces an output voltage proportional to the time error. This error signal decreases the current in the isolation circuit summing resistor in the counting circuitry shown in FIG. 7, to effectively reduce the counted pacemaker or cardiac cycle time computed by the digital counter circuit. The modulating circuitry shown in FIG. 8 will view a reduced cycle time and will increase the pump and withdrawal rates on the next pump cycle to correct for this error.

During arterior-arterial assist, the pump triggering pulse occurs very early in the cardiac cycle, i.e., a predetermined time before the end of the withdrawal stroke as determined by the blanking threshold sensor **210** and the volume comparator **211**, the AND gate **141** will drop the triggering signal so that there is no output from the blanking gate **144** and therefore no error output from the channel **417** timing error sensor which normally indicates that the pumping cycle is too slow. In this case, the pump and withdrawal rates are determined by the cardiac cycle time counted by the digital counting circuit on the previous cardiac cycle without the modulation of any error from the timing error sensors.

### Single stroke initiation

The present device is provided with means for initiating a single pump stroke. The purpose of providing this capability is to enable the system to be used for injecting radio-opaque dies in the cardio vascular system and/or to obtain coronary angiograms. Referring to FIG. 6, when the select switch **131** is placed in its manual position a suitable circuit is provided for withdrawing the actuating shaft to the end of the withdraw stroke. In this mode the triggering pulses from the EKG trigger selector **125** and the pacemaker **132** are disconnected from the control system so that repetitive pumping action is prevented. Upon the closure of the spring loaded manual stroke initiate switch **133** lockout gate **450** disables the blanking gate **144**. This prevents the initiation of a triggering pulse from AND gate **141**. At the same time, a withdraw disable gate **452** is activtaed which disables the withdraw driver **194** and prevents any initiation of the withdraw stroke. Actuation of switch **133** also energizes line **453** charging capacitor **454** which initiates a pump triggering signal to line **150** turning the regenerative switch **148** on energizing line **151** and thereby initiating a single pump stroke of the reciprocating pump piston. When switch **133** is deenergized the piston is automatically withdrawn setting up the device for the initiation of a second pump stroke by switch **133**.

### Reduced augmentation circuit

Referring to FIG. 10, a reduced augmentation circuit **460** is provided for skipping one or three cardiac cycles. In this manner the heart pump system will operate only on selected pacemaker pulses or selected beats of the patient's heart, if desired. A disable gate **461** is provided for disabling the blanking gate **144** except when selected triggering pulses are received by blanking gate **144**. A switch **462** is provided for selecting one hundred percent augmentation, fifty percent augmentation and twenty-five percent augmentation as shown. With the switch in the one hundred percent augmentation position, the disable gate **461** completely disables the blanking gate **144** and permits all triggering pulses from the AND gate **141** to be coupled to AND gate **146**. In this event all normal triggering pulses from refractory gate **140** initiate a pump cycle on each pacemaker pulse or cardiac cycle. When switch **462** is in the fifty percent augmentation position, a flip-flop **463** enables the disable gate **461** to blank alternate triggering signals from AND gate **141** and effect a pump cycle only on alternate pacemaker pulses or cardiac cycles. Flip-flop **463** is tripped to either state by refractory gate **140**. This is important because if reduced augmentation were responsive to a time type blanking gate, an increase in the heart rate may produce the blanking gate, an increase in the heart rate may produce the blanking of more than one triggering pulse even if fifty percent augmentation was desired. Another flip-flop **464** cascaded with flip-flop **463**, and an AND gate **465** are provided to drive the twenty-five percent augmentation. Now on every fourth beat of the patient's heart (or pulse from the pacemaker **132**) the binary flip-flop **464** which is the fourth binary stage activates AND gate **465** and the disabled gate **461** permitting a pulse to pass through the blanking gate **144**. In this manner three cardiac cycles or pacemaker pulses may be skipped regardless of variations in the repetition rate of the input signal to the system.

### Power supply

Referring to FIG. 11, a two contact switch **490** is provided connected to a 30 volt DC power supply. When switch **490** is in its upper position, a release coil **491** is energized deactivating the single catheter select switch **492** and a dual catheter select switch **493**. This assures that each of the catheter select switches will be placed in their off positions when the system is turned on assuring the correct catheter selection on the next use of the pumping system. When switch **490** is placed in the lower position, i.e., the on position, release coil **491** is deenergized permitting the manual selection of either the single or dual catheter switches **492** and **493**. At this time the coil **495** is energized connecting the hydraulic power supply to a source of electric power. At the same time, the electric control circuitry is energized with the exception of the pump and withdraw servo coils **147** and **154** respectively.

Before pump and withdraw servo coils **147** and **154** may be energized, it is necessary that the surgeon perform the following functions; (1) select either the single or the dual catheter switches **492** or **493**, (2) choose a catheter size by actuating the catheter size selection switch which energizes a holding coil **497**, (3) and set the manual volume adjust potentiometer **360** to zero volume which by suitable circuitry closes switch **498**. After the surgeon has made all these selections, relay **499** may be energized by closing switch **503** so that contacts **2** and **3** are made, placing the circuit in the operate position indicated by

the energization of an operate lamp **501** on the control panel. If the surgeon has failed to make one of the parameter selections, no current will flow through the coil **499** and even if the surgeon actuates the start switch **503**, power will not be supplied to the pump and withdraw servo coils **147** and **154**. In this case, coil **499** will not be energized and contacts **4** and **1** of relay **500** will be closed lighting a standby lamp **504** on the control panel indicating to the surgeon that he has failed to make a parameter selection. A lamp **506** is also provided on the control panel for indicating when the catheter size select switch **363** has been closed.

The operation

With the components and catheters connected and arranged according to FIGS. 1 and 2, or alternatively according to FIGS. 4 or 5, the power supply circuit shown in FIG. 11 is placed in the standby position. The surgeon then makes the various catheter selections and adjusts the volume potentiometer to place the power supply circuit in the operate position indicated by the operate lamp **501**. The piston **15** at this time is at the end of the pump stroke. The various oscilloscope outlets are connected so that the surgeon views the various parameters and the start switch **503** is tripped preparing the control circuitry for the receipt of a pump triggering signal. Switch **131** is placed in the pacemaker position and switch **255** is moved to a position connecting line **266** with the one shot multivibrator **271**. The surgeon then adjusts the pacemaker **132** to the desired repetition rate of the pumping cycles.

The delay one shot **136** may be adjusted so that the output pulses to the refractory gate are in phase with the pulses from the pacemaker **132** as no delay time is necessary in complete cardiopulmonary bypass.

Pulses from the refractory gate **140** trigger the regenerative switch **148** and the pump proceeds through its pump stroke forcing blood into the patient's arterial tree through catheter assembly **49**. Then the piston **15** proceeds through a stroke dictated by the volume potentiometer **360** associated with the volume limit generator **358**, the regenerative switch **148** is turned off reversing the piston **15** causing blood to be drawn from reservoir **36** into pump chamber **16**. This cycle is repeated with each triggering pulse from the pacemaker **132**.

If the surgeon desires to increase the arterial flow rate, the frequency or repetition rate of the pacemaker **132** may be increased. In response to an increase in the rate of pulses from pacemaker **132**, the modulating circuitry shown in FIG. 8 will increase the speed of stroking of piston **15** so that the pump cycle corresponds with the newly selected period of the pacemaker signal. Further, the arterial flow rate may also be increased by increasing the selected volume on the manual volume adjust **360**. In response to this change the volume comparator **201** (controlled by the volume limit generator **358**) increases the length of stroke of the piston **15**, and the duty cycle modulator **352** at the same time increases the speed of stroke of the piston **15** so that the newly selected volume per cycle will be achieved without variation in the time duration of the pumping cycle.

The proper operation of the present system in complete cardiopulmonary bypass depends upon the proper balance of the manually controlled parameters of volume per stroke and pacemaker rate. If the pacemaker rate is too high, the speed of stroking of the piston **15** will produce blood damage. If the pacemaker rate is too slow, the selected volume per stroke must be increased and this may rupture the small vessels. Thus, the volume adjustment and rate control must be varied to obtain optimum physiological results between these two limits.

As noted above, the present system may be used postoperatively as an arterio-arterial circulation assist after complete cardiopulmonary bypass. To place the system in this mode it is merely necessity to close valve **11** and connected the various inputs to the computing and triggering circuitry so that the patient's EKG wave triggers the pumping cycles. The phasing in this mode is described in detail in our above mentioned copending application.

Thus far, tests on animals have indicated no tendency toward metabolic acidosis with the present complete cardipulmonary bypass system even after extended perfusion. With one exemplary test animal complete cardiopulmonary bypass proceeded as follows. The dog was not allowed to cool, but to warm slowly from 37 degrees centigrade to 39.5 degrees centigrade for one hour, then allowed to cool to 34 degrees centigrade over 45 minutes, and then warm to a normal 37 degrees over the next 30 minutes, the latter temperature being maintained for a further 30 minutes.

At the beginning of the perfusion the peak flow rate was 1,720 ccs. per minute or 62 ccs./kg./min. i.e., peak flow per pump cycle. The flow rates used herein are the peak flow rates attained at the top of the flow curves, the actual flow per cycle being much lower. A pulsed-field electromagnetic flow probe was placed around the common iliac artery, from which the adventitia had been stripped to avoid interference with the readings, for the purpose of sensing the blood flow rate in the animal. It was placed far enough away from the pump catheter so that variations in its diameter with the withdrawal and pump stroke would not affect the electrical fit for the flow probe.

The pressures attained at the initial flow rate were 150/100 which appeared adequate. After 45 minutes the flow rate was readjusted to 1,380 ccs. per minute peak flow, or 49.5 ccs./kg./min. peak flow per cycle. Pressure was then an acceptable 140/70. Only 350 ccs. of saline were added during the first hour and this was less than the loss. The perfusion continued for 3 hrs. The animal was acidotic (respiratory) at the outset of the perfusion with arterial pH being 7.18 and the venous pH being 7.15. After two hours of pulsatile perfusion the arterial pH had risen. Both the arterial and venous pH's increased toward normal during the third hour of perfusion. There was no tendency toward metabolic acidosis. The arterial and venous carbon dioxide contents and the $pCO_2$ levels all declined during the third hour of perfusion. The lactate pyruvate levels rose, but the lactate pyruvate ratios remained stationary or declined slightly during the perfusion. Thus, the perfusion of the arterial tree seemed adequate enough to prevent pooling of blood with resultant tissue hypoxia. Similar biochemical results were found in the other animals.

We claim:

**1.** A heart pump system for complete cardio-pulmonary bypass, comprising: a pulsatile pump having a pumping chamber, a piston reciprocable within said pumping chamber having push and withdraw phases defining a pumping cycle, catheter means for receiving blood from the venous side of a patient's circulatory system, oxygenator means connected to receive and oxygenate blood from said catheter means, means for conveying blood from said oxygenator means to said pumping chamber, second catheter means connecting said pumping chamber with the arterial side of the patient's circulating system, means for reciprocating said piston so that oxygenated blood flows into the patient's circulatory system in pulsatile fashion; and control means for said reciprocating means including means for deriving pump triggering signals corresponding with the desired repetition rate of the pumping cycle, means for initiating the pumping cycles in timed relationship with said pump triggering signals, manually controlled means for varying the volume of blood pumped on each pumping cycle, and means responsive to said manually controlled means for automatically increasing the blood flow rate through said second catheter means as the selected volume of blood is increased, said manually controlled means including means for varying the length of stroke of said piston, said means for automatically increasing the blood

flow rate including means for increasing the rate of movement of said pumping piston.

2. A heart pump system for complete cardio-pulmonary bypass, comprising: a pulsatile pump having a pumping chamber, a piston reciprocable within said pumping chamber having push and withdraw phases defining a pumping cycle, catheter means for receiving blood from the venous side of a patient's circulatory system, oxygenator means connected to receive and oxygenate blood from said catheter means, means for conveying blood from said oxygenator means to said pumping chamber, second catheter means connecting said pumping chamber with the arterial side of the patient's circulating system, means for reciprocating said piston so that oxygenated blood flows into the patient's circulatory system in pulsatile fashion; and control means for said reciprocating means including means for deriving pump triggering signals corresponding with the desired repetition rate of the pumping cycle, means for initiating the pumping cycles in timed relationship with said pump triggering signals, manually controlled means for varying the volume of blood pumped on each pumping cycle, and means responsive to said manually controlled means for automatically increasing the blood flow rate through said second catheter means as the selected volume of blood is increased; and means for preselecting the repetition rate of said triggering signals as desired, said manually controlled means including computer means responsive to the period of said triggering signals for providing substantial coincidence between said triggering signal period and said pumping cycle, said computer means being reponsive to a change in the selected volume for varying the speed of said piston to achieve said coincidence, whereby the speed of said piston will increase and decrease with the selected blood volume.

3. A heart pump system for complete cardio-pulmonary bypass, comprising: a pulsatile pump having a pumping chamber, a piston reciprocable within said pumping chamber having push and withdraw phases defining a pumping cycle, catheter means for receiving blood from the venous side of a patient's circulatory system, oxygenator means connected to receive and oxygenate blood from said catheter means, means for conveying blood from said oxygenator means to said pumping chamber, second catheter means connecting said pumping chamber with the arterial side of the patient's circulating system, wherein said second catheter means permitting blood flow in either direction, said second catheter means and said conveying means having a relative resistance to flow such that during the withdraw stroke of said piston a substantial portion of the blood will be withdrawn from said conveying means rather than from said second catheter means, means for reciprocating said piston so that oxygenated blood flows into the patient's circulatory system in pulsatile fashion; and control means for said reciprocating means including means for deriving pump triggering signals corresponding with the desired repetition rate of the pumping cycle, means for initiating the pumping cycles in timed relationship with said pump triggering signals, manually controlled means for varying the volume of blood pumped on each pumping cycle, and means responsive to said manually controlled means for automatically increasing the blood flow rate through said second catheter means as the selected volume of blood is increased.

4. A heart pump system for cardiopulmonary bypass and postoperative arterio-arterial assist, comprising: a pulsatile pump having a reciprocating piston the push and withdraw strokes of which define a pumping cycle, said piston defining a fluid chamber in said pump, means for receiving and modifying a signal representing one of the patient's physiological parameters and producing pump cycle triggering signals for circulatory assist, pacemaker means for deriving pump cycle triggering signals for bypass operation, control means for initiating each pumping cycle, selectively operable means for connecting the output of said producing means or said deriving means to said control means, catheter means connecting said fluid chamber into the patient's circulatory system so that fluid is delivered thereto during the push stroke of said piston, means for conveying fluid into said fluid chamber during bypass operation, said conveying means having a check valve for preventing the flow of fluid from the fluid chamber into the conveying means, said catheter means being unrestricted so that fluid may flow in either direction therethrough during arterio-arterial assist, and valve means for closing said conveying means during arterio-arterial assist.

5. A heart pump system as defined in claim 4, wherein said check valve is mounted within said valve means.

**References Cited**

UNITED STATES PATENTS

| | | | |
|---|---|---|---|
| 2,847,008 | 8/1958 | Taylor et al. | 23—258.5 |
| 2,927,582 | 3/1960 | Berkman et al. | 23—258.5 |
| 3,099,260 | 7/1963 | Birtwell | 128—1 |
| 3,183,908 | 5/1965 | Collins et al. | 23—258.5 |
| 3,266,487 | 8/1966 | Watkins et al. | 128—1 |

OTHER REFERENCES

Murphy: Trans. Amer. Soc. Artificial Inter. Organs, 1961, vol. VII, pp. 361–68.

DALTON L. TRULUCK, Primary Examiner

U.S. Cl. X.R.

23—258.5