

Feb. 11, 1969

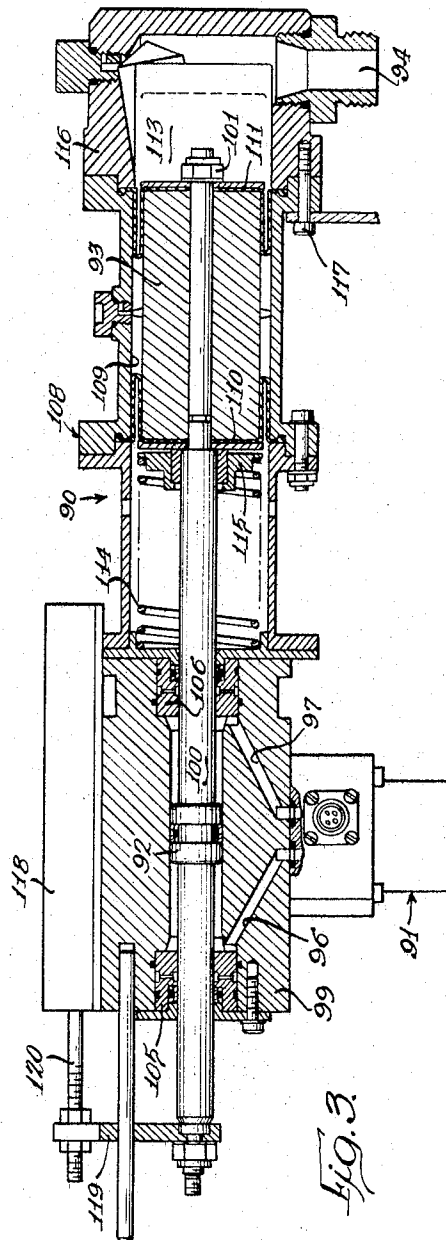
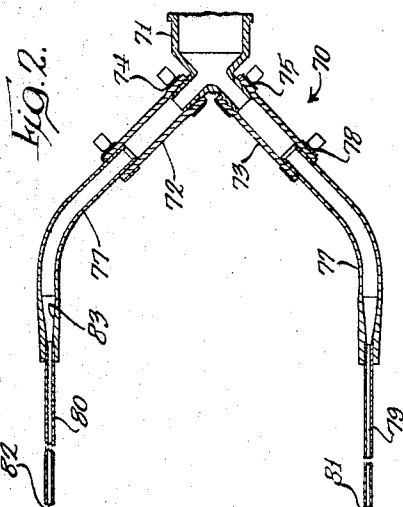
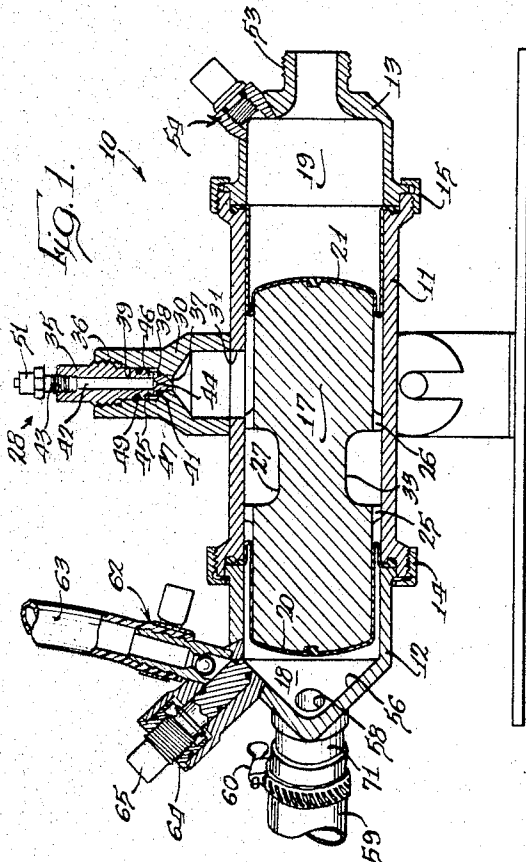
M. G. CHESNUT ET AL

3,426,743

HEART PUMP AUGMENTATION SYSTEM

Filed Oct. 27, 1964

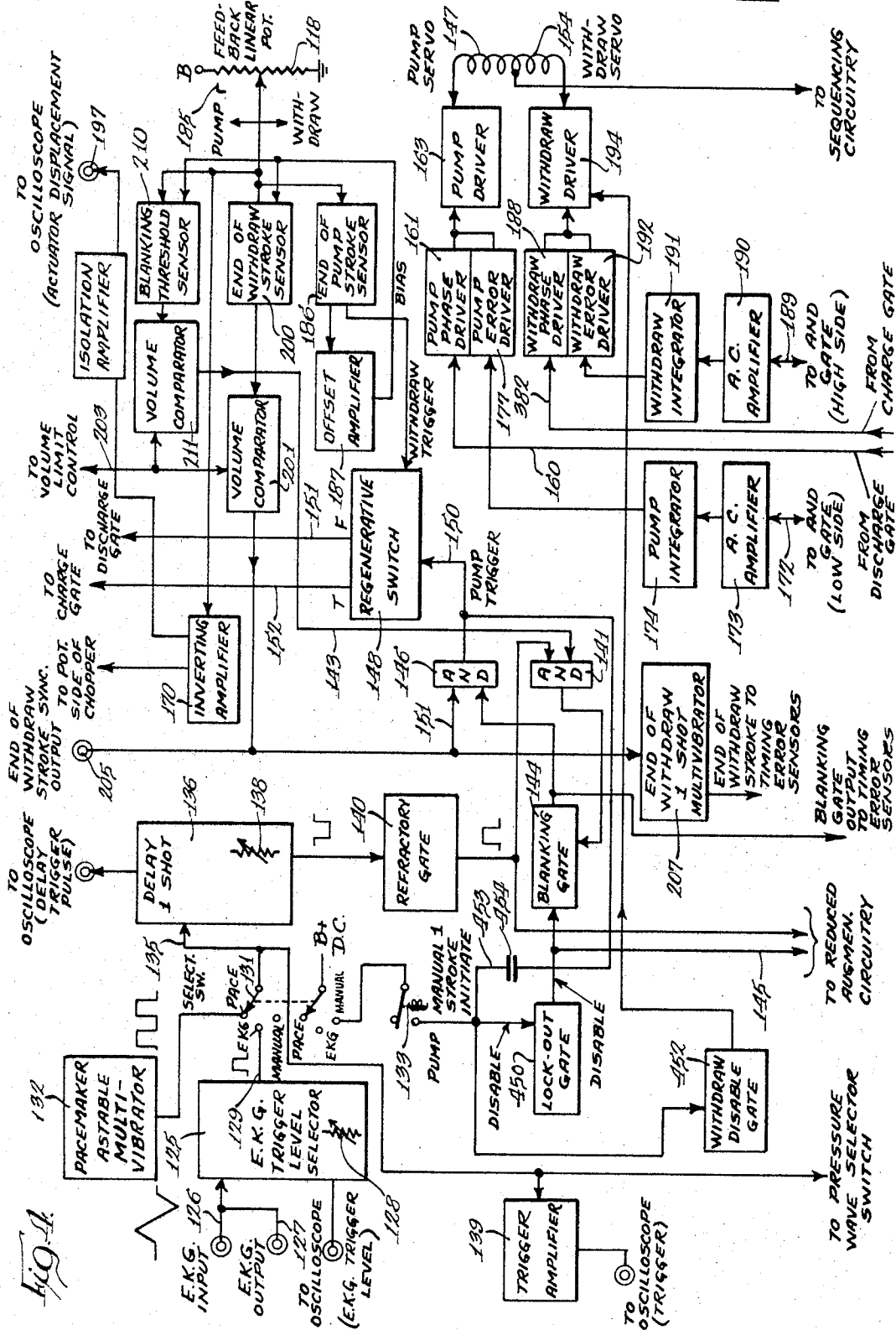
Sheet 1 of 6



M. G. CHESNUT ET AL

HEART PUMP AUGMENTATION SYSTEM

Sheet 2 of 6



Feb. 11, 1969

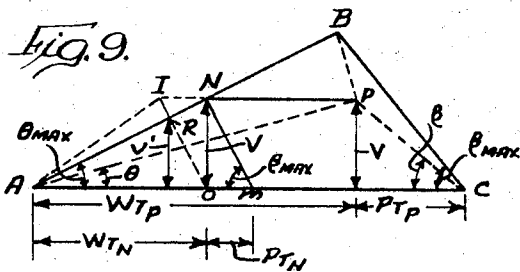
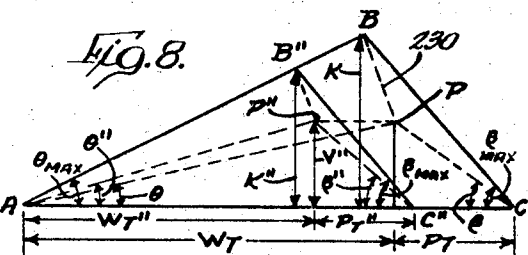
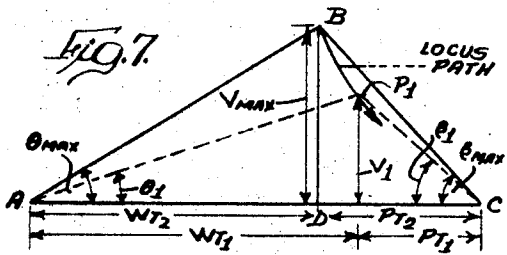
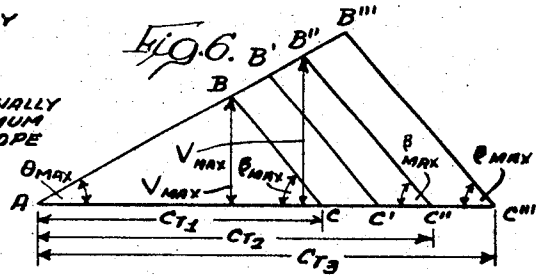
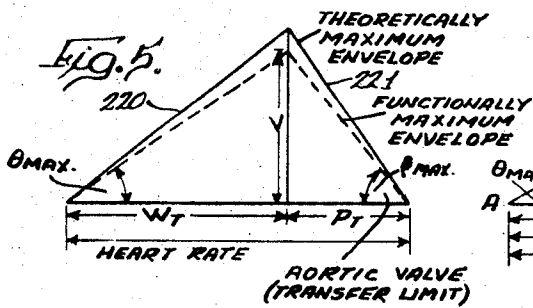
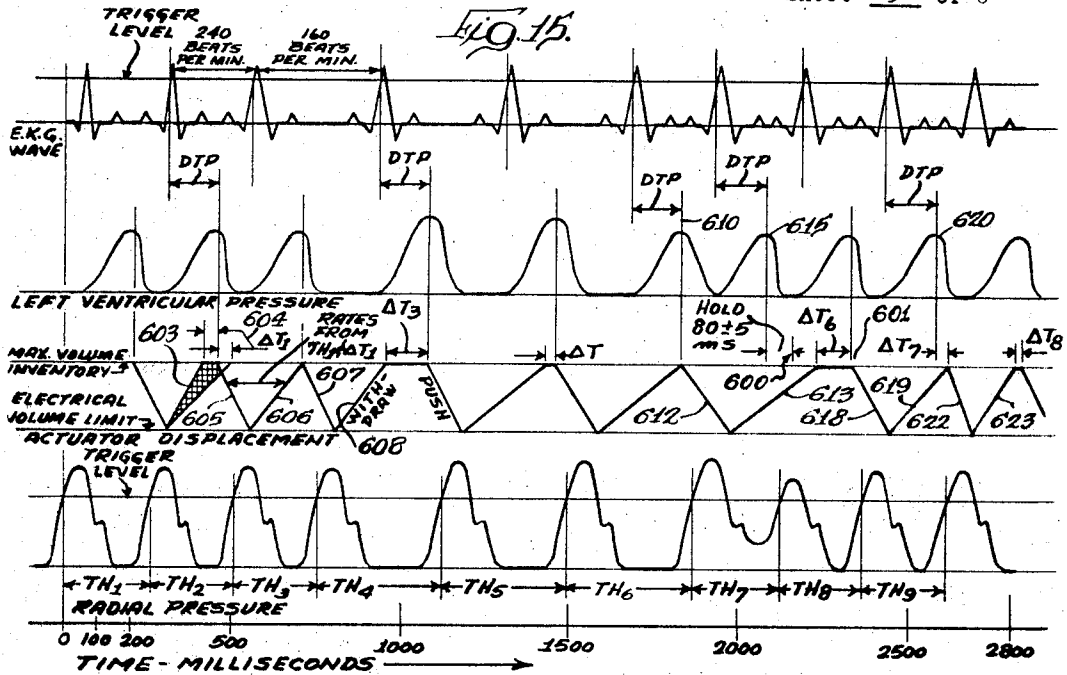
M. G. CHESNUT ET AL

3,426,743

HEART PUMP AUGMENTATION SYSTEM

Filed Oct. 27, 1964

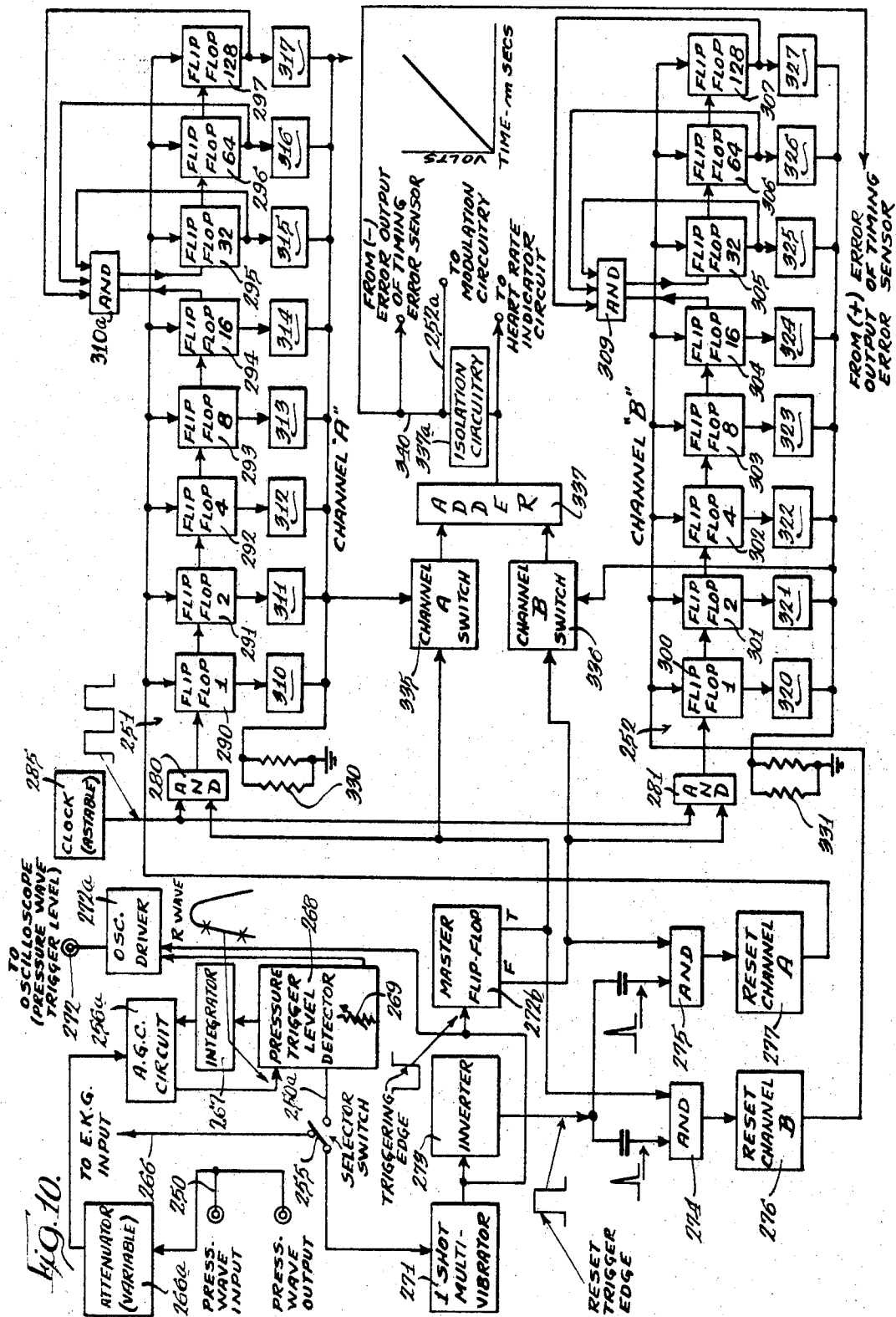
Sheet 3 of 6



M. G. CHESNUT ET AL

HEART PUMP AUGMENTATION SYSTEM

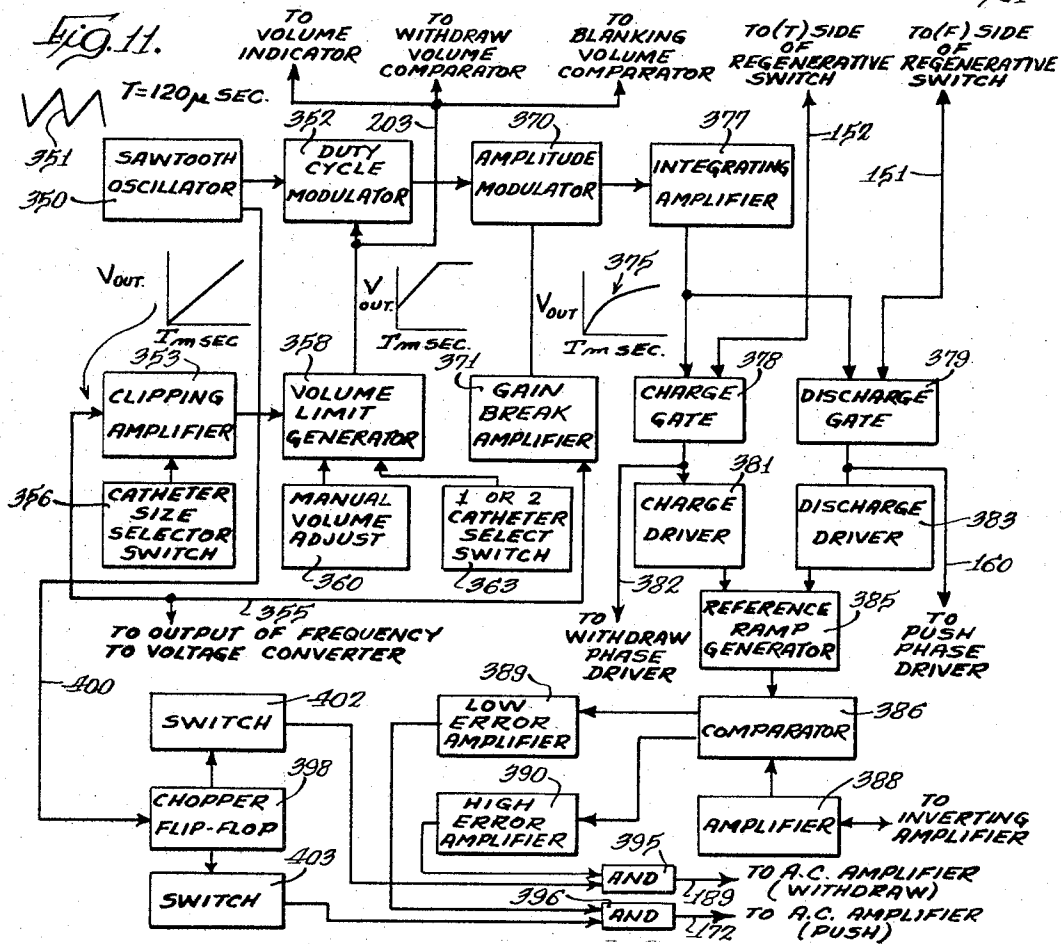
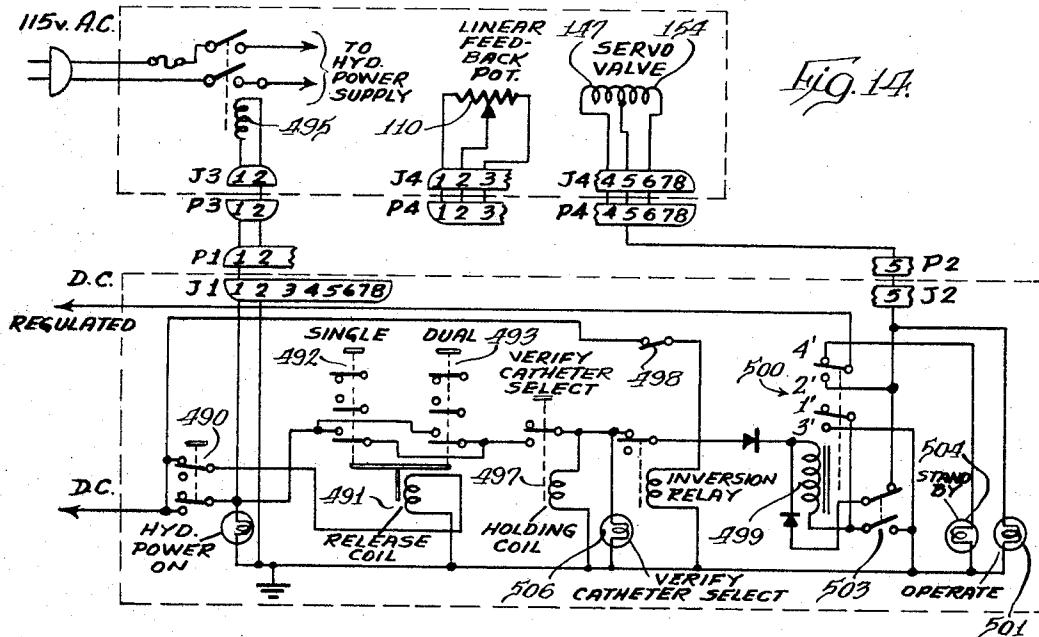
Sheet 4 of 6



M. G. CHESNUT ET AL

HEART PUMP AUGMENTATION SYSTEM

Sheet 5 of 6



Feb. 11, 1969

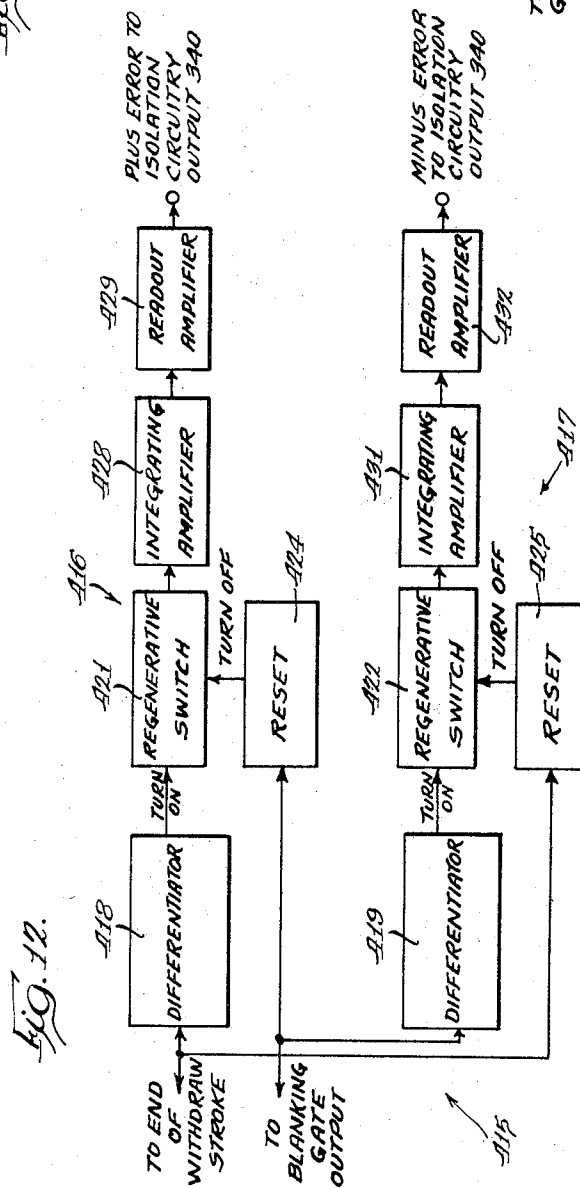
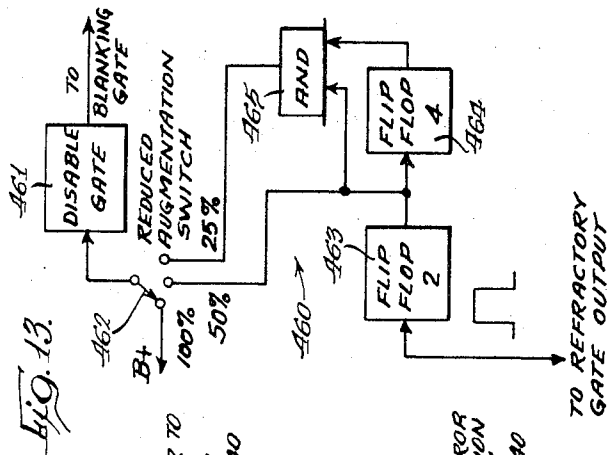
M. G. CHESNUT ET AL

3,426,743

HEART PUMP AUGMENTATION SYSTEM

Filed Oct. 27, 1964

Sheet 6 of 6



1

2

3,426,743

HEART PUMP AUGMENTATION SYSTEM

Merrill Gaines Chesnut, Arvada, and Phillip B. Callaghan,
Westminster, Colo., assignors, by mesne assignments, to
United Aircraft Corporation, a corporation of Delaware

Filed Oct. 27, 1964, Ser. No. 406,722

U.S. Cl. 128—1

30 Claims

Int. Cl. A61h 31/00; A61m 5/14, 29/02

ABSTRACT OF THE DISCLOSURE

A catheter communicates blood with the patient's circulatory system in response to a blood pump which responds in turn to a hydraulic actuator system that is electrically driven in response to electronic control means. The electronic control means are timed to the patient's natural heart action to control the pumping cycle. The electronic control means includes a pair of binary counters for counting timing signals indicative of the time duration of heart cycles of the patient, with a master flip-flop for selecting one counting channel to control the pump while the other counting channel is counting the time of the heart cycle, alternatively. Reduced augmentation, and pump strokes without withdraw strokes are also selectively controlled by the electronic circuits. The pump speed as well as times of initiating the push and withdraw phases are controlled in response to the patient's heart action. Pump rates may be manually selected in dependence upon the size of catheter in use.

Field of invention

This invention relates generally to a device for assisting the natural action of a defective heart. More particularly, it concerns an apparatus for assisting insufficient natural heart action by automatically synthesizing the parameters of the patient's physiological heart waveform.

Description of the prior art

The present invention relates to an improvement over the heart pump system shown in our copending application Ser. No. 347,500, filed Feb. 26, 1964. This copending application relates to a heart assisting system in which a cannula is inserted into the descending aorta and pulsed in timed relation to the patient's natural heart beat as derived from the patient's EKG waveform. In the apparatus disclosed in this prior application, a control system is provided for reciprocating a pulsating pumping element which delivers fluid in two directions through an aorta-inserted cannula. The synthesized pressure waveform produced in the patient's arterial system is manually adjustable, in that the surgeon or technician operating the device can manually vary the volume of blood pumped, the ratio of push and withdrawal rates of the pump, and the delay time of the pumping cycle with respect to the patient's EKG waveform. The present invention automates the control of these parameters and others so that the surgeon may concentrate his efforts in assisting the patient in other ways.

Summary of invention

The present system is of the augmentation type and, in contradistinction to the bypass-type system, operates in series with the heart while the heart is actually beating and supplying blood to the arterial tree. The basic objectives of this type of system are to reduce the work load of the heart by lowering the pressure head against which the ventricle must eject its contained blood, and to aid the coronary circulation by increasing the blood pres-

sure and flow during the correct phase of the natural heart cycle regardless of changes in the natural heart rate. This phase corresponds to the period of time when the resistance to coronary circulation is at a minimum. This phase has been found to be in what is described in this field as the post-systolic period.

More specifically, the present invention relates to a reciprocating blood pump connected in closed circuit fashion to a single or double catheter adapted to be inserted in the patient's femoral arteries. The cycle of the reciprocating blood pump may be divided hemodynamically into a withdrawal time and a push time, corresponding to the reciprocating strokes of the pump, and it is further electrically governed by a third parameter, i.e., the delay time which is the phase lag of the pump cycle with respect to the cardiac cycle. Other variables in the cycle are the volume of blood to be pumped per cycle, the patient's natural heart rate or period, the rate of withdrawal of the blood through the catheter and the rate of injecting blood into the aorta during the push phase. For a given catheter, the maximum negative pressure which can be obtained is theoretically a perfect vacuum minus some small allowance for vapor pressure, and therefore, there is a certain maximum rate at which blood can be removed from the vascular tree through a catheter of given length and bore. A certain volume of blood must be removed from the aorta to produce the desired pressure drop within the aorta, and for this reason there is a minimum withdrawal time to remove that volume. If this is exceeded, cavitation and degassing of the blood will occur with increased hemolysis. Also, there is a limit on maximum rate at which blood may be pushed into the aorta and this limit is determined by the point at which cerebral vessel damage could be caused by excessive pressure. For these reasons, the maximum allowable withdrawal and push rates are never exceeded in the present heart pump system regardless of changes in the patient's natural heart period or rate.

However, for a given heart beat rate or heart cycle period, it is not always desirable to deliver the maximum volume of blood to the patient's aorta. In this event, the present device, in response to the selection of a lower than maximum volume, automatically adjusts the pump and withdrawal rates below their maximum values in accordance with a predetermined complex function to achieve the new desired volume. This complex function reduces the ratio of the pump time to the withdrawal time as it is advisable to increase the withdrawal time as much as possible as the withdrawal rate effects on the blood are more critical than the push rate effects.

During the use of the present heart pump system on a patient, because of the patient's abnormal condition, the patient's natural heart rate changes frequently. The present device automatically compensates for changing heart rates by computing new withdrawal and pumping rates and sometimes effects an automatic change in the volume of blood pumped when the maximum blood pumping rates have been reached. This occurs at a time when the patient's heart rate is extremely fast. Under normal conditions, the circuit logic in the present invention permits the heart rate to change while leaving the volume of blood pumped the same. In extreme conditions where the heart rate increases to the point where the maximum pumping rates would have to be exceeded to pump the desired quantity of blood, the control system computes a new lower volume for this system compatible with the maximum withdrawal and pumping rates so that the pumping cycle equals the patient's heart cycle time. Attention to these boundary conditions or maximum blood pumping rates is very important if destruction to the blood is to be minimized. Means are provided

whereby it is impossible for the operator to increase the volume pumped for a given heart rate above that which would produce the maximum permissible push and withdrawal blood pumping rates, and this is attained automatically in the present device.

Depending upon the individual patient and other conditions, it is desirable to use different sized catheters for insertion within the patient's femoral arteries. Also, it is sometimes desirable to use two catheters rather than one to assist in augmenting the patient's natural heart action. The present invention automatically compensates for changes in catheters and by computer logic makes adjustments in the withdrawal and pumping rates in accordance with the catheter arrangement selected.

It is, therefore, a primary object of the present invention to provide a pulsatile heart augmentation system in which the pumping parameters are automatically computed in response to changes in the patient's physiological parameters. A digital counter is provided for determining the time period of the patient's natural heart cycle which time period is employed in a computer circuit to determine pumping and withdrawal rates necessary to achieve coincidence between the pumping cycle and the patient's natural heart period.

A further object of the present invention is to provide a pulsatile heart pumping system of the character described in which the computer logic circuitry prevents an extremely fast heart rate from producing excessive push and withdrawal blood pumping rates which cause excessive blood damage by limiting the maximum pumping rates to predetermined values. This is achieved by effecting an automatic reduction of the volume of blood pumped below the value preset by the surgeon when the heart rate increases to a rate which would require excessive pumping rates to pump the preset volume.

A still further object of the present invention is to provide a pumping system of the character described in which a manual blood volume selector is provided and a computer control circuit in association therewith limits the maximum volume of blood which may be pumped during any pump cycle regardless of heart rate. As the heart rate decreases, the maximum permissible delivery of blood increases even though the maximum pumping rates stay constant for a given sized catheter. For this reason, the computer logic responds to changing heart rates to set up different maximum blood volume values which in effect limit the rate of blood delivered to the patient during a heart cycle.

Another object of the present invention is to provide a new and improved heart pump system of the character described having a control system which automatically varies the withdrawal and pumping rates of the blood pump in response to changes in the desired volume of blood to be delivered for any given heart beat rate. Changes in the desired volume of blood flow also automatically change the ratio of the push time to the withdrawal time favoring the more severe limitation on the withdrawal time which if too short for a given volume produces hemolysis and other blood damage.

Another object of the present invention is to provide a new and improved heart pumping system of the character described in which a digital counter measures the time duration between the patient's natural heart pulses and from which the pumping parameters are computed. A two-bank digital counter is provided which counts the time duration of each heart cycle and employs the output of the counter to control the pumping parameters on the next succeeding pumping cycle which assists the corresponding natural heart cycle.

A still further object of the present invention is to provide a new and improved heart pumping system in which the heart rate is computed by sensing blood pressure while the pumping cycle is triggered from a selected portion of the patient's EKG waveform. Noise that has a purely electrical origin which may cause false trig-

gering of a pumping cycle may be eliminated and prevented from causing false triggering by placing a rejection band of known width on either side of the base line of the patient's EKG waveform, so that no signals in this range may be accepted to trigger a false pumping cycle. However, the noise that has a physiological origin provides a more difficult problem. If the digital counter was connected to count the time duration between selected EKG pulses there would be a possibility that false physiological pulses would result in a false readout on the counter and adversely affect the functions computed from the natural heart time period. In the present invention, the digital counting counter can be made to respond to the blood pressure wave and only legitimate EKG signals are associated with this wave and therefore, only legitimate EKG signals initiate the triggering circuitry. Thus, the EKG waveform still provides a trigger for the pumping cycle but the interval between the pressure waves represents the true cardiac cycle time and sets the push and withdrawal rates of the pump.

A further object of the present invention is to provide a heart pump of the character described in which circuitry is provided for preventing any EKG or false trigger signal from initiating the pumping cycle except in a certain time zone determined by the absolute refractory of the myocardium.

Another object of the present invention is to provide a new and improved heart pumping system of the character described in which the time differential between the end of the pumping cycle and the receipt of a delayed pump cycle triggering pulse is computed and employed to vary the pumping cycle to achieve coincidence between the pumping cycle and the patient's natural heart period.

A still further object of the present invention is to provide a new and improved reciprocating heart pump having a chamber designed to reduce the damage to the blood or to improve the flow of fluid flowing therein.

Another object of the present invention is to provide a new and improved reciprocating diaphragm type heart pump having an improved mechanism for filling and venting the annular chamber between the diaphragms to produce effective pumping action.

Another object of the present invention is to provide a new and improved catheter arrangement for a heart pumping system in which two catheters are provided and are adapted to be inserted into the patient's femoral arteries through which fluid is pulsed in both directions in timed relation to the patient's natural heart action.

Other objects and advantages will become readily apparent from the following detailed description taken in connection with the accompanying drawings.

Brief description of the drawings

FIG. 1 is a cross sectional elevation of the hemodynamically designed heart pump with a free floating diaphragm sealed piston;

FIG. 2 is a plan view in cross section showing the double catheter assembly which is adapted to be connected to one end of the reciprocating pump shown in FIG. 1;

FIG. 3 is a cross sectional elevation of the hydraulic actuator for the present invention adapted to deliver fluid to and from one end of the heart pump shown in FIG. 1;

FIG. 4 is a schematic diagram of a portion of the control circuit including the EKG input circuitry and the reciprocating pump output servo coils;

FIGS. 5 to 9 are triangles representing the displacement of the reciprocating pump for a predetermined heart rate as computed by the circuit logic;

FIG. 10 is a schematic diagram of another portion of the control circuitry including the blood pressure wave input circuit and the digital counter;

FIG. 11 is a schematic diagram of the computer por-

tion of the control circuit which selects the volume, push and withdrawal rates, and cycle time of the reciprocating pump of FIG. 1;

FIG. 12 is a schematic diagram of the timing error sensors which determine the error in the pumping cycle time;

FIG. 13 is a schematic diagram of the reduced augmentation circuitry which selects only certain heart beats to initiate the pumping cycle;

FIG. 14 is a partial schematic diagram of the power supply for the hydraulic and electric control circuits;

FIG. 15 is a graph showing the physiological and pumping parameters as they would appear on an oscilloscope.

While an illustrative embodiment of the invention is shown in the drawings and will be described in detail herein, the invention is susceptible of embodiment in many different forms and it should be understood 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 embodiment illustrated. The scope of the invention will be pointed out in the appended claims.

Pumping apparatus

Referring to FIG. 1, a reciprocating diaphragm pump, generally indicated by the numeral 10, serves to deliver and withdraw fluid through the catheter assembly shown in FIG. 2 which is adapted to be connected to the left end of the diaphragm pump 10. The housing of the pump 10 consists of a generally cylindrical central cylinder 11 and forward and rear cylinders 12 and 13, respectively, fixed thereto. The forward and rear cylinders 12 and 13 are attached to the central cylinder 11 by threaded rings 14 and 15, respectively. A free floating piston 17 is slidably mounted in the housing and forms a forward chamber 18 and a rear chamber 19 within the housing. Flexible diaphragms 20 and 21 cover and roll on both ends of the pistons and serve to separate and seal the working chamber 18 from the actuating chamber 19. The diaphragm 20 is seated and retained between the mating ends of the housing member 11 and the housing member 12, and the diaphragm 21 is seated and retained between the housing member 11 and the housing member 13. The diaphragms 20 and 21 serve to provide proper sealing of the working chamber 18 and also assure smooth pumping action. Guides 25 and 26 are provided on the piston 17 and are spaced inwardly from the rolling diaphragms 20 and 21 when at their innermost position. The guides 25 and 26 prevent yawing and the consequent buckling of the diaphragms. The guides 25 and 26 are formed integrally with the piston 17 and are annular in shape with grooves therein which permit the escape of air bubbles from between the guide and the ends of the respective rolling diaphragms around the piston 17 to the central recessed portion 27 of the piston 17. The guides are spaced far enough from the end of the piston so they do not foul the diaphragms.

A valve mechanism, generally designated by the numeral 28, is mounted on the central housing member 11 and serves to fill and vent the space between the diaphragms 20 and 21 to assure proper diaphragm rolling action. A cylindrical boss 30 houses the valve mechanism and is fixedly mounted on the housing 11 and communicates with a bore 31 in the housing member 11 located between the diaphragms 20 and 21 and communicating with the annular space 33. A plug member 35 is threaded into the boss 30 at 36 and has a conical seating surface 37 which engages a mating seat 38 formed in one end of a bore 39 in the boss 30. Seal ring 41 provides a tight seal. The plug 35 has a central passage 42 formed therein which is open at its upper end 43 and is closed at its lower end 44. Radial passages 45 and 46 formed in the lower end of the plug 35 above the seal ring 41 communicate with the passage 42 and an annular space 47 around

the lower end of the plug 35. A seal ring 49 spaced above the passages 45 and 46 in plug 35 prevents air from leaking from the outside into the chamber 47. An adapter 51 is threaded into the upper end of the passage 42 in the plug 35 and permits the opening and closing of passage 42.

The evacuation of chamber 33 proceeds by unscrewing the plug 35 from the position shown unseating the surface 37, and filling the chamber 33 with a sterile saline solution through adapter 51, passage 42, passages 45 and 46, chamber 47, and bore 31. A syringe is then attached to the adapter 51 and air is withdrawn from the chamber 33 until a slight negative pressure is produced. Then while a slight negative pressure is held, the plug 35 is rotated downwardly until the seating surface 37 on the plug 35 engages the surface 38 on the boss 30 whereby the chamber 33 is completely shut off and then contains only sterile saline solution under a slight negative pressure.

The actuating chamber 19 receives fluid from a fluid actuator, shown in FIG. 3 and described in more detail below, for reciprocating the piston 17 through suitable hydraulic coupling on the actuator adapted to be connected to the threaded fitting 53 on the rear end of the rear housing cylinder 13. An air vent 54 on the housing member 13 is provided for venting the actuating chamber 19.

The front chamber 18 of the pump 10, which is the working chamber, is hemodynamically designed so that the pressure drops are balanced against the inertial forces. The forward housing member 12 has a conical inside surface 56 to minimize the pressure drops and yet keep the inventory of the blood at a minimum. Blood, or a blood compatible solution, is delivered from the working chamber 18 to the catheter assembly, shown in FIG. 2, through a port 58 in the forward housing member 12. The port 58 communicates with a section of flexible tubing 59 connected to the forward chamber 12 by a suitable clamp 60.

In some cases it is desirable to introduce additional blood into the patient's cardiovascular system, and for this purpose, a fitting assembly 62 is provided and a flexible tube 63 connected therewith is adapted to be connected at its upper end to a suitable reservoir containing blood. A stop plug assembly 64 mounted on the forward housing member 12 has a threaded plug 65 which seats in its closed position flush with the surface 56 of the working chamber 18 so that no stagnant pool of coagulable blood is allowed to exist in a standpipe when blood is not actually being transfused. Of course, when the plug 65 is unthreaded, blood from the reservoir is permitted to flow into the forward chamber 18 through flexible tube 63.

Further, the tube 63 may be employed to conduct a suitable dye into the forward working chamber 18 when it is desired to use the pumping system for the purpose of making an angiogram rather than using it for natural heart augmentation.

Referring to FIG. 2, wherein the catheter assembly generally designated by the numeral 70 is shown, a Y fitting is formed integrally with the forward housing member 12. Short lengths of tubing 72 and 73 are clamped to the fitting 71 by suitable thumb ring clamps 74 and 75, respectively. Central catheter sections 77 are clamped inside the short length of tubing 72 and 73 by suitable clamps 78. The central catheter sections 77 have tapered internal surfaces 83 to improve the characteristics of the flow of fluid therein. The catheters 79 and 80 are of uniform internal and external diameter and are fixed inside the central catheter sections 77. As noted above, the catheters 79 and 80 are adapted to be inserted into the patient's femoral arteries, and are of relatively short length so that they lie within the femoral arteries during heart augmentation. The central catheter sections 77, of course, lie wholly outside the body during the use of the pumping system. The extreme or distal ends 81 and 82 of the catheters 79 and 80 are open, permitting blood or a blood

compatible fluid to flow in either direction into the patient's arterial system.

An actuator, generally designated by the numeral 90 in FIG. 3, is provided for delivering motive fluid to and from the actuating chamber 19 of the reciprocating pump 10 shown in FIG. 1. The actuator 90 consists generally of a servo valve assembly 91 which ports fluid to both sides of an actuating piston 92 to drive a reciprocating plunger 93 and thereby deliver fluid through an outlet port 94 adapted to be connected by a suitable hydraulic coupling to the working chamber 19 of the reciprocating pump 10. The servo valve assembly 91 consists of a pump servo coil and a withdrawal servo coil (not shown in FIG. 3) which control the position of a servo valve (not shown) which selectively distributes fluid through one of the passages 96 or 97 formed in an actuator housing member 99. The servo valve assembly 91 is of the type which delivers fluid in either of two directions as a flow rate proportional to the magnitude of the current in the servo coils. Such a servo valve mechanism is disclosed in our copending application Ser. No. 347,500. Therefore, as the magnitude of the current in the servo coils increases, the rate of movement of the plunger 93 will increase producing a corresponding increase in the rate of movement of the pumping piston 17 which moves with the plunger 93 because of the high bulk modulus of the fluid coupling therebetween. Energization of one of the servo coils is effective to deliver fluid through passage 96 while energization of the other servo coil is effective to deliver fluid through passage 97.

An actuating shaft 100, which fixedly carries the piston 92, is slidably mounted in the housing member 99 and is fixed to plunger 93 at its right end by a nut 101 threaded on the right end of the shaft. Suitable bearing and seal assemblies 105 and 106 are provided in counter bores in both ends of the housing member 99 for supporting the shaft 100 and sealing the working chambers adjacent the actuating piston 92.

A plunger housing assembly, generally designated by the number 108, is fixed to the right end of the actuator housing member 99 and defines a cylinder 109 which slidably receives the plunger 93. Diaphragms 110 and 111 are provided on both ends of the plunger 93 in a similar manner to the diaphragms 20 and 21 on the pump piston 17. A forward housing member 116 is fixed to the housing member 108 by suitable fasteners 117 and defines therewithin an annular working chamber 113. A spring 114 seated within the housing member 108 biases the plunger 93 through a bushing 115 to the right end of the cylinder 109. The plunger, as shown in FIG. 3, is in a central position of its stroke.

A control circuit, described in more detail below, controls the duration and magnitude of the current to each of the servo coils in the servo valve mechanism 91 to control the length of stroke and speed of stroking of the plunger 93 in both directions which produces a corresponding movement in the reciprocating pump piston 17. A potentiometer 118, or any other suitable transducer, is provided for feeding back a signal to the control circuit indicative of the actual position of the plunger 93 and the piston 17. The potentiometer 118 is driven by the actuator shaft 100 through a suitable bracket mechanism 119 attached to the left end of the shaft 100 and a potentiometer rod 120. A suitable supply of hydraulic fluid is provided for the hydraulic actuator 90, such as that disclosed in our copending application Ser. No. 347,500.

In operation, when the withdrawal coil is energized by the control system, fluid is ported by the servo mechanism 91 to conduit 97 at a rate determined by the magnitude of current in that coil, and the fluid acting against the right end of piston 92 drives the actuating rod 100 and the plunger 93 to the left thereby withdrawing fluid from the actuating chamber 19 of the pump 10 producing a rightward movement of the piston 17. Blood is thereby

drawn into the catheters and the intra-aortic pressure is reduced. After a predetermined time, the control circuit de-energizes the withdrawal coil and energizes the push coil in the servo mechanism 91 porting fluid to passage 96 which drives the piston 92 to the right along with plunger 93 and drives pumping piston 17 to the left. This effects a reversal of the flow of fluid or blood in the catheters and the intra-aortic pressure is increased to assist the natural heart action in distributing blood through the arterial system.

Triggering and driving circuit

The triggering and driving circuit which is disclosed in FIG. 4, is generally adapted to receive an input signal from the patient's EKG waveform, delay the signal and after various computer functions, drive the pump and withdrawal servo coils. The triggering circuit is effective to develop and delay a triggering pulse for the reciprocating pump cycle and delay the trigger pulse from a selected trigger level portion of the QRS segment of the patient's EKG waveform. Referring to FIG. 15, an exemplary patient's EKG waveform appears as it would on an oscilloscope. Below the EKG waveform, is a graph of the patient's intraventricular pressure having peaks which are seen to lag behind the associated QRS segment of the patient's EKG wave in accordance with known physiological phenomena. The triggering circuit in FIG. 4 selects a portion of the rising QRS segment of the EKG wave as a predetermined trigger level, for example the level as shown in FIG. 15, and derives and delays a triggering pulse therefrom. The delay time is indicated as D_{tp} in FIG. 15. The triggering pulse derived initiates the push phase of the pumping cycle which effects a delivery of fluid into the patient's aorta increasing the intra-aortic pressure at a time when the work load of the heart is the lowest. This delay time D_{tp} determines the phase relationship of the pumping cycle to the arterial pulse wave. It is determined physiologically as that phase relationship which reduces the intraventricular pressure to a minimum for a given volume pumped and increases the post systolic arterial pressure to an extent which returns the intra-aortic pressure to its prepump level or better so that coronary and peripheral circulation may be assisted. This phasing has been found to be most effective when the push phase of the pumping cycle begins after or at the peak of the intraventricular waveform with the push phase continuing during the post systolic period. In the present system, 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, and continues until the peak of the next intraventricular waveform at which time another pumping or push phase begins in response to another triggering signal.

Referring again to FIG. 4, an EKG trigger level selector 125 is connected to receive the patient's EKG waveform from a conventional electrocardiogram through line 126. Line 127 connected to line 126 is adapted to drive an oscilloscope so that the patient's EKG waveform may be viewed during the use of the heart pumping system by the surgeon or technician. The EKG trigger level selector 125 may consist of a differential comparator, a level detector and trigger level selector circuitry. One side of the comparator is driven from the EKG input 126 and the other side is biased by the manually adjustable trigger level potentiometer 128. This potentiometer also drives the level detector (not shown) which consists of a transistor switch referenced to ground and driving an inverter. If the potentiometer 128 is adjusted to a positive voltage, the switch turns on, whereas a negative voltage turns it off. When the logic of the level detector coincides with the proper logic from the switches driven by the comparator, an active AND gate (not shown) is energized. This AND gate, in the trigger level selector 125, triggers a multivibrator in the selector which consists of

a standard transistor dual PNP configuration with base triggering. The output pulse from the trigger level selector is delivered through line 129.

A selector switch 131, which may be located on a convenient control panel, permits the alternative initiation of the pumping cycle by a pacemaker 132, or by the EKG trigger level 125, or by the manual stroke initiate switch 133. In some cases, the patient's EKG waveform is so weak that it is not suitable for use in initiating the heart pump augmentation system and in this event, the switch 131 is placed in its uppermost position connecting the pacemaker 132, which may be an astable multivibrator, to a delay trigger circuit 136 through line 135. When switch 131 is in its central or middle position, it connects the EKG trigger level selector 125 to the trigger delay circuit 136 through line 135. 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 the power supply which places the pump cycle under manual control. The manual control is useful when the pumping device is used for taking angiograms by inserting or forcing dye through the pumping catheters rather than blood or a saline solution.

The undelayed triggering pulse from the trigger level selector 125 is amplified in trigger amplifier 139 which is used to trigger the sweep of the oscilloscope. The surgeon may view the triggering level along with the other parameters.

The trigger delay circuit 136 delays the actual triggering pulse behind the selected portion of the patient's EKG waveform. It may consist of a standard dual PNP transistor 1-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 D_{tp} shown in FIGURE 15. 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 1-shot multivibrator with base triggering.

The pulse from the refractory gate 140 comprises one of the 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 refractory gate 140 is conducted to the AND gate 141 prior to 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 140 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 and is 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 delivered 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.

By this circuitry the possibility of out of phase pumping is virtually eliminated by combining electronic control features with the physiological phenomena known as the refractory period. Out of phase pumping is the worst possible error in this type of system and it is important that the push stroke initiation occur after the left ventricular pressure peaks. If the stroke begins before the pressure peaks, the heart work is increased. The refractory period of the heart may be explained as follows. The

tissue bundle which conducts signals to the left ventricle acts very much like a capacitor in that it has a definite charge and discharge time. In the typical EKG, the QRS wave complex represents the discharge time which is normally 80 msec. but may be as long as 120 msec. During this 80 to 120 msec. period, the tissue bundle is refractory, and therefore effectively blocks additional signals until the QRS wave complex is completed. In addition, within an 80 msec. period following a QRS wave complex, it is extremely unlikely that another complex will begin because the charge build-up is insufficient. Thus, within approximately 160 msec. period, only one complete QRS wave complex can occur. The AND gate 146 permits the initiation of the push or pumping stroke only after completion of the withdrawal stroke and the receipt of the delayed EKG signal from the blanking gate 144. If the delayed signal from blanking gate 144 is received by the AND gate 146 after the withdrawal stroke is completed, the push stroke is initiated immediately upon receipt of the delayed trigger signal. If the delayed signal from blanking gate 144 is received prior to the withdrawal stroke completion, the signal will be held for 80 msec. as this is the pulse width determined by the refractory gate 140. If the withdrawal stroke is not completed within this 80 msec. time, the triggering signal will be dropped and the push stroke will not occur until the next delayed signal is received from the blanking gate 144. Further, all triggering signals from the refractory gate 140 which occur a predetermined time before the end of the withdrawal stroke are dropped by the AND gate 141.

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 to 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 a 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 off and the second stage on thereby energizing line 151 and de-energizing line 152. Line 151 energizes the pump servo coil 147 through the volume and rate computer circuitry shown in FIGURE 11, 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 FIGURE 11, energizes line 160 in FIGURE 4 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 is directly proportional to the magnitude of the current in the pump coil 147 and the withdraw coil 154.

The piston 17 then begins its push stroke and drives the feedback potentiometer 118. The feedback displacement signal from the potentiometer 118 drives an inverting amplifier 170 whose output is used to determine the error between the actual pump and withdrawal displacement signals and the reference pump and withdrawal displacement signals determined by the computer circuitry in FIGURE 11. Any error is fed back from the computer circuitry to line 172 in FIGURE 4 where it is amplified by an AC amplifier 173 and integrated by a pump integrator 174 which excites a pump error driver 177 which varies 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 NPN transistors which are collector coupled in parallel with the error drivers. The servo 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 reach the end of stroke and a mechanical stop 185, 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 de-energizing line 151. The end of pump stroke sensor 186 may consist of an inverting PNP amplifier which drives a PNP comparator. The PNP amplifier emitter modulates the PNP comparator. The base of the comparator is biased by a potentiometer in the offset amplifier 187. The output of the end of pump stroke sensor 186 immediately initiates the withdrawal stroke at the end of the pumping stroke. The potentiometer in the offset amplifier 187 which provides a vernier adjustment for the length of stroke may also be used to bias the end of withdrawal stroke sensor 200 to eliminate offset errors due to mechanical alignment tolerances between the piston 17 and the feedback potentiometer 118.

The energization of line 152 from the regenerative switch 148 enables the withdrawal phase driver 188. Withdrawal rate errors are impressed in the form of an error signal on line 189 and through the AC amplifier 190, the withdraw 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 driving circuit described above. A withdraw driver 194 energizes the withdraw servo coil 154 to drive the pump piston in its withdraw stroke thereby drawing blood through the catheters and producing a lower intra-aortic pressure.

As the pump proceeds in its withdraw stroke the feedback potentiometer 118 is driven as shown in FIG. 4. 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 by the actuator shaft 100, it drives an end of withdraw stroke sensor 200. The end of withdraw stroke sensor 200 modulated by the volume comparator 201 indicate 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. 11. Suffice it to state at this point that a signal representative of the desired volume is carried in line 203. The end of withdrawal 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 withdraw oscilloscope output 205 as well as the pump trigger AND gate 146 and an end of withdraw 1-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.

During the withdraw stroke, the feedback potentiometer 118 also drives a blanking threshold sensor 210 which provides one of the two inputs to AND gate 141 which prevents triggering pulses occurring earlier than a predetermined time before the completion of the withdraw stroke. The blanking threshold sensor 210 may be iden-

tical 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 211. The output of the volume comparator 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. 10, 11 and 12, is to vary the pump and withdrawn rates and the volume pumped in response to varying heart cycle times and to different desired volumes selected. While the volume adjustment is primarily manual, the output volume pumped decreases as a function of the heart rate as the maximum withdrawal and pump rates are reached. The push and withdrawal rates for each cycle are determined from the heart rate computed in the previous cycle. To eliminate any stacking of errors, a closed loop error detection circuit is provided at the end of the withdraw stroke.

For a clear understanding of the logic in the computer circuitry reference is now made to FIGS. 5 to 9 which show exemplary displacement cycle diagrams plotted against the heart rate. Referring first to FIG. 5 (inverted displacement wave) ramp line 220 represents the withdraw stroke displacement with respect to time and the slope of the line represents the rate of the withdraw stroke. Similarly, line 221 represents the pump stroke displacement with respect to time and its slope is proportional to the pump or push rate. Any vertical line drawn in this triangle, of course, represents the volume or displacement of the pump at a particular time in the displacement cycle. W_T is the withdraw time and P_T is the push time. Now for a given catheter, there is a given internal catheter diameter and a maximum negative pressure which can theoretically be exerted. The angle of the line 220 shown in FIG. 5 has a limiting maximum value for each catheter size shown as $\theta_{\max}$. If this is exceeded, cavitation and degassing of the blood will occur with excessive hemolysis. As discussed above, there is also a theoretical maximum angle, angle beta (β) $_{\max}$, which represents the maximum displacement rate for any given catheter size. The maximum triangle, however, should be modified or reduced slightly to allow for inertial and vibration losses and pressure drops in the system so that a functional envelope, shown as the dotted line in FIG. 5 should be established for pump behavior inside the theoretical maximum. It is seen, therefore, that for a given catheter size and heart cycle time, i.e. the length of the base of the triangle shown in FIG. 5, a maximum envelope and a corresponding maximum volume may be determined. There is, therefore, a maximum volume which can be pumped back and forth through the catheter for a given heart rate, otherwise the maximum $\theta_{\max}$, or maximum beta (β) $_{\max}$, limits would be exceeded. Thus, there can be constructed an entire family of functionally maximum envelopes for different heart rates, as more clearly shown in FIG. 6, where C_t indicates the heart cycle time, and $\theta_{\max}$ represents the maximum permissible withdraw rate, beta (β) $_{\max}$ indicates the maximum permissible pump rate and $V_{\max}$ indicates the maximum permissible volumes for a given heart rate. As described below a computer circuit responsive to changing heart rates varies the maximum permissible push and withdraw rates in accordance with these maximum envelopes.

Referring now to FIG. 7, where the volume variation logic is represented, it is not always desirable to pump the maximum volume of blood permissible into the human patient and, therefore, the computer logic circuitry described below permits a manual volume adjustment below the maximum permissible for any given heart rate. For example, suppose it was desired to pump a volume V_1

indicated in FIG. 7. The computer circuit in response to a manual volume selection of V_1 , automatically computes the withdraw rates proportional to θ_1 and the pump rate proportional to β_1 to achieve the new volume V_1 which is well below the maximum for the envelope corresponding to the heart rate or heart cycle time AC at that time. Note that the locus path BP in FIG. 7, which is the path programmed in the computer for reducing the volume displacement below maximum, is well to the right of line BD in FIG. 7, to assure that the withdraw time W_{T1} increases significantly in proportion to the pump time P_{T1} to minimize the destruction of the blood while maintaining good pulsatile flow. If perhaps the surgeon selects a volume above the indicated V_{max} for a particular heart rate the computer logic limits the volume pumped to that determined by the maximum permissible envelope at that heart beat rate.

Now if the volume setting remains fixed in spite of the heart cycle rate changes, a triangular relationship as shown in FIG. 8 results. Assume that the heart rate changes from a cardiac cycle represented by AC" to one represented by AC as shown in FIG. 8, the maximum permissible volume K" consistent with maximum theta must change to K which defines another maximum envelope. In this event the computer effectively determines a new maximum envelope having a base AC and a volume K but reduces the volume automatically along line 230 to point P where new pump and withdrawal rates are determined to maintain the same volume displacement.

Another condition is provided for in the computer logic and is illustrated in FIG. 9. Assuming initially that the cardiac cycle has a length AC and that the pumping system is operating at a volume P which must necessarily produce a withdraw angle of theta (θ) and a pump angle of beta (β). If the period of the cardiac cycle changes from AC to AM, the computer logic computes a new maximum envelope ANM and a volume V which corresponds to the manually set volume. Now if the cardiac cycle further shortens to AO, the volume would theoretically have to approach point I. However, the maximum withdrawal angle would be exceeded and for this reason the computer logic automatically reduces the volume to point R where the maximum permissible volume is pumped, V', compatible with the maximum withdraw and pump rates for the cardiac cycle time.

The computer logic described theoretically above is based upon the cardiac cycle time as a variable input parameter. From the cardiac cycle time the withdraw and pump rates may be computed for a selected or desired volume of blood to be pumped.

While the heart rate may be determined or computed from the patient's EKG input waveform, 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 waveform. Although this heart pump produces a post systolic pressure in addition to the patient's wave, provision is made so that the counter sees only the patient's portion of the total waveform.

Referring to FIG. 10, wherein the digital cardiac cycle counting circuit is shown in schematic form, a pressure input signal from a suitable transducer attached to the patient is impressed on input line 250. The interval between the 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 patient's heart cycle time is delivered to the modulation circuitry in FIG. 11 by output line 252A. The digital counting circuitry in FIG. 10 produces a linear output voltage with time as shown in the graph in FIG. 10. Referring to the schematic circuit diagram of FIG. 10 in more detail, a selector switch 255 permits the counting circuitry to be initiated from either the EKG input 266 or the pressure wave input 250a. The pressure wave input is at-

tenuated by a variable attenuator 266a which includes a voltage divider adjustable from a suitable control panel. This waveform drives an A.G.C. circuit 256a which consists of dual cascaded field effect transistors. This waveform is impressed on a pressure trigger level detector 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 A.G.C. circuitry 256a to maintain a constant amplitude at the AC amplifier output. A 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 a 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 272a 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 or the pacemaker signals when suitably connected by switch 255. The one shot multivibrator 271 triggers a master flip-flop 272b and an inverter 273. The master flip-flop 272b 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 272b 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 rests. 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 272b also enables 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 272b 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 272b 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 and 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 of 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

15

been triggered once. A similar circuit is provided for bank 251 (channel A).

The false side of each of the counter flip-flops 290 is 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 read-out 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 associated 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 272b through either line F or T. An adder 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 actual cardiac cycle time. This error, if it is negative, is delivered to the isolation circuitry output 337a through line 340 where it subtracts from the counted heart cycle time to provide a new effective heart cycle time. If it is positive it is also delivered to the isolation circuitry output 337a where it adds to the counted cycle time. As the heart cycle time is the controlling parameter for the computer modulating circuitry it is possible to correct errors in the displacement cycle time merely by varying the effective cardiac time signal to the modulation circuitry through line 252a.

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

Referring to FIG. 11, wherein the modulating circuitry for determining the push and withdrawal rates is schematically shown, a sawtooth oscillator 350 produces a sawtooth waveform as shown at 351 with a rising ramp voltage and a very steep retrace. The sawtooth oscillator 350 may consist of a unijunction relaxation oscillator driven by a constant current source. Its 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 withdrawal rates, for a given heart cycle period. 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 from the theoretical discussion of FIG. 6 that there is a maximum volume which may be pumped, or should be pumped, for every heart cycle period. The clipping amplifier 353 prevents a greater volume from being pumped than the maximum computed in accordance with the logic shown in

16

FIG. 6. 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. 10. The clipping amplifier 353 may consist of a two-stage DC amplifier, having an NPN transistor driving a PNP transistor, with gain and 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 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 is a complex function of the flow characteristics of the particular catheter used. The catheter size selector switch 356 is basically an eight position switch corresponding to eight different catheter sizes. The 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. The emitter resistor for the PNP stage in the clipping amplifier 353 is selected from one of eight resistors which correspond to the 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 heart period 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 so that any lesser volume, selected by the surgeon, will control the pump 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. The catheter select switch 363 divides the bias to the PNP limiting emitter follower from 2:1. While it is usually desirable to use the two-catheter construction as shown in FIG. 2, in certain instances it may be more desirable to use only one catheter. 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 in this heart pumping system, such as the catheter mechanism shown in FIG. 2, the two-catheter switch in the catheter select switch 363 approximately doubles the maximum voltage that the volume 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 and hence 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 in excess of the maximum volumes dictated by these components.

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. 4, 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 which is limited by the computed maximum volume for each heart cycle time for the catheter number and size used. As the heart rate varies, it is apparent that the withdrawal and pump rates must change to maintain the same volume of blood delivered and to achieve a time coincidence between the displacement cycle with the cardiac cycle in accordance with the logic shown and described in FIGS. 8 and 9. 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 heart cycle period determined by the digital counter in FIG. 10. The voltage at line 355 is linear with respect to time. Since the withdrawal and pump rates must be proportional to the frequency of the patient's heart, as discussed above with respect to FIGS. 8 and 9, the linear voltage at 355, must be converted to an exponential voltage representing frequency. Hence, the patient's heart 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.

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 ex-

ponential 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, the gain break amplifier 371 effectively provides an exponential voltage output proportional to the frequency of the cardiac cycle.

The amplitude modulator 370 may consist of a single PNP transistor inverting amplifier driven by the pulse width modulated 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 cardiac cycle.

An integrating amplifier 377 is provided for integrating the pulse train which is modulated both with volume and with heart 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 heart 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 patient's heart beat 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 patient's heart beat increases, so does the push and withdrawal rates to achieve coincidence between the patient's cardiac cycle and the displacement cycle. Similarly, as the desired volume increases, represented by the output voltage from the volume limit generator 358, the pulse width of 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. As discussed above with respect to FIG. 6, for a given cardiac cycle, the volume of blood delivered on each cycle is correspondingly controlled.

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. 4. 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. 11 and the actual displacement waveform produced by the feedback potentiometer 118. Referring to FIG. 11, 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. 4. It is amplified by a two-stage, noninverting DC amplifier 388, shown in FIG. 11. 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, respectively. 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. 11 from the heart rate counted in the previous cycle by the digital counter described in FIG. 10. Referring now to FIG. 12, 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 the next delayed push trigger signal. The resulting error signal is used to vary the pump and withdraw rates during the next cycle in closed loop fashion. This closed loop approach to error correction compensates for hydraulic 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 withdrawal stroke and the pump triggering signal. Channel 416 determines the error when the pumping cycle is completed before the next delayed triggering pulse is received by the blanking gate 144, and channel 417 determines the error when the pump triggering signal from the blanking gate 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 cardiac period and channel 417 determines the error when the pump and withdraw rates are too slow for a particular 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 of the 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 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 amplifiers 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 read out amplifier 429. The read out amplifier 429 may consist of a PNP transistor DC amplifier. Channel 417 has a similar NPN transistor read out amplifier 432.

If the displacement cycle is too fast compared with the 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 read out amplifier 429. The error signal from the read out amplifier 429 increases the current in the isolation circuit summing resistor in the digital counting circuit shown in FIG. 10. Since this current represents the time period of the cardiac cycle, the read out amplifier 429 effectively lengthens the counted cardiac cycle time, producing a new, effective cardiac cycle time. Since the cardiac cycle time has been effectively increased, the modulating circuitry, shown in FIG. 11, views an effectively longer cycle time than it would view without the addition of the error signal. Since an increase in the cardiac cycle count produces a reduction in the withdrawal and push rates determined by the modulating circuitry in FIG. 11, the displacement wave slows down on the next cardiac cycle to correct for this error. Conversely, if the pump cycle is too slow compared with the 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 read out 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. 10, to effectively reduce the counted cardiac cycle time computed by the digital counter circuit. The modulating circuitry shown in FIG. 11 will view a reduced cardiac cycle time and will increase the pump and withdrawal rates on the next cardiac cycle to correct for this error.

If 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 dyes in the cardio vascular system and/or to obtain coronary angiograms. Referring to FIG. 4, 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 lock-out 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 activated 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 de-energized 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. 13, 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 beats of the patient's heart and give only partial circulatory assistance. 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 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 cardiac cycles. Flip-flop 463 is tripped to either state by refractory gate 140 and therefore responds to the EKG triggering pulses. 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 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 25% reduced augmentation. Now on every fourth beat of the patient's heart the binary flip-flop 464 which is the fourth binary stage activates AND gate 465 and the disable gate 461 permitting a pulse to pass through the blanking gate 144. In this manner three cardiac cycles may be skipped regardless of variations in the patient's cardiac cycle time.

Power supply

Referring to FIG. 14, 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.

Operation

The working chamber 18 of the reciprocating pump 10 is initially filled with a blood compatible fluid such as physiological saline or "Dextran." Catheters 81 and 82 are inserted into the patient's femoral arteries. The power supply circuit, shown in FIG. 14, is placed in the standby position. The surgeon 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 17 at this time is at the end of the pump stroke. The various oscilloscope outputs are connected so that the surgeon views the various parameters as shown in FIG. 15 and the start switch 503 is tripped preparing the control circuitry for the receipt of the pump triggering signal from the patient's EKG waveform. The EKG trigger level selector 125 may be adjusted to select a portion of the QR rising ramp of the patient's EKG waveform and the delay 1-shot trigger 136 in turn produces a triggering pulse to initiate the pump stroke a predetermined time after the selected portion of the patient's QR segment of the EKG wave. The delayed time is set by the surgeon by the adjustment of the potentiometer 138. If a triggering pulse occurs before the end of the withdrawal stroke the AND gate 146 will hold the triggering pulse for approximately 80 milliseconds and if the withdraw stroke has not been completed in that time the triggering pulse will be dropped as shown at 600 in FIG. 15. AND gate 146 will then wait for another triggering pulse as indicated at 601 in FIG. 15 before initiating the push phase of the heart pumping cycle. Of course on the first stroke of the pump a triggering pulse will not be dropped because the pump piston is at the end of the withdrawal stroke at that time. Upon triggering the regenerative switch 148 the pump proceeds through its pump and then its withdrawal stroke driving the feedback potentiometer 118. During a time period from shortly before the initiation of the first pump stroke, and during a portion of the push phase, the digital counting circuit, shown in FIG. 10, counts the cardiac cycle time TH₁ shown in FIG. 15 on the patient's pressure wave. Assuming that the withdraw phase proceeds along the line 603 there will be an error 604 between the end of the withdraw stroke and the receipt of the next triggering pulse. This error is determined by the timing error sensor in

FIG. 14 and is added to the cardiac cycle time counted by the digital counter. The new cycle time which is TH_1 plus ΔT_1 is the controlling input parameter for the modulating circuitry of FIG. 11 which computes new pump and withdraw rates 605 and 606 on the next pumping cycle.

Now assuming the heart rate decreases from 240 to 160 beats per minute, the digital counting circuitry of FIG. 10 will count the cycle time TH_2 and the modulating circuitry of FIG. 10 will compute new push and withdraw rates which on the next pumping cycle produce a push and withdrawal waveform shown at 607 and 608. The timing error sensors will then compute the error ΔT_3 and make a correction in the pumping rates on the next cycle.

Now assuming the heart rate again increases rapidly at line 610 shown on the intraventricular pressure waveform. At this time the push rate 612 and the withdrawal rate 613 are computed by the time cycle TH_6 , which is much too slow for the actual heart rate at that time. The triggering pulse on the intraventricular peak 615 will be dropped by AND gate 146 and the timing error sensors will determine the error time ΔT_6 . On the next cardiac counting cycle TH_7 , the radial pressure parameter has increased significantly in rate over the previous counting cycle TH_6 , but the timing error sensors subtract the error time ΔT_6 from the counted cardiac cycle time TH_7 , so that the modulating circuitry in FIG. 11 views a much shorter cardiac cycle and then in response thereto increases the push and withdrawal rates on the next cardiac cycle indicated at 618 and 619 respectively so that the pumping cycle then closely coincides to the patient's cardiac cycle time.

If the triggering pulse indicated at 620 on the intraventricular waveform occurs some 50 milliseconds before the end of the withdrawal phase indicated at 619 the AND gate 146 will hold the triggering pulse for 80 milliseconds which is sufficient to permit pump stroke triggering when the withdraw stroke is completed and in this case the triggering pulse is not dropped. However the time differential ΔT_7 between the triggering pulse and the initiation of the push phase of the pumping cycle is determined by the timing error sensors and used to increase the push and withdrawal rates on the next pumping cycle as shown at 622 and 623.

Now if the patient's heart rate is so fast that the maximum permissible push or withdraw rates would have to be exceeded to pump the preset volume of blood, the clipper amplifier 353 and the volume limit generator 358 automatically reduce the volume of blood pumped to that volume which corresponds with the maximum permissible withdraw and pump rates to produce a pumping cycle equal to the very short cardiac cycle at that time. Similarly, at a given heart rate, if the surgeon selects a volume to be pumped which would produce excessive withdrawal and pump rates, the clipper amplifier 353 and the volume limit generator 358 automatically prevent increase of the manual volume adjustment above that which would produce the maximum permissible push and withdraw rates.

So long as the cardiac cycle is long enough with respect to the desired volume to be pumped, the gain break amplifier 371 which is responsive to cardiac cycle time, varies the push and withdrawal rates as described with respect to FIG. 15 to achieve coincidence between the pumping cycle and the patient's natural cardiac cycle.

We claim:

1. A heart augmentation system, comprising: a reciprocating pump for supplying blood to the patient's arterial system, means for initiating the cyclical operation of said pump in timed relation to one of the patient's physiological parameters, and control circuit means for varying the velocity of the stroke of the reciprocating pump in response to changes in said one physiological parameter, whereby the pumping cycle coincides with the patient's physiological cycle.

2. A heart pumping system, comprising: a recip-

rocating pump for supplying blood to the patient's arterial system, means to initiate the pump and a pumping cycle in timed relation to one of the patient's cyclical physiological parameters, control circuit means for varying the velocity of the stroke of the reciprocating pump in response to changes in the cycle time of the patient's physiological parameter, and means for normally maintaining the volume of blood supplied by the reciprocating pump constant regardless of changes in the cycle time of the patient's physiological parameter, whereby a constant volume of blood is normally delivered and the pumping cycle time changes with the changes in the cycle time of the patient's physiological parameter.

3. A heart pumping system, comprising: a reciprocating pump for supplying blood to the patient's circulatory system, control means for initiating a pumping cycle in timed relation to one of the patient's cyclical physiological parameters, and control circuit means for selecting a desired volume of blood supplied by the reciprocating pump, said control circuit means including means for automatically limiting the selected volume of blood to a predetermined maximum value to minimize damage to the blood.

4. A heart pumping system, comprising: a reciprocating blood pump for supplying blood to the patient's arterial tree, control means for initiating a pumping cycle in timed relationship to one of the patient's physiological parameters, control circuit means for varying the rate of movement of the push and withdraw phases of the reciprocating pump in response to changes in the cycle time of the patient's selected parameter whereby the pumping cycle coincides with the patient's selected parameter cycle, said control circuit means including means for limiting the rates of movement of said pump to a predetermined value to prevent excessive hemolysis.

5. A heart pumping system, comprising: means adapted to be inserted into the patient's circulatory system, a reciprocating blood pump for delivering fluid through said means for supplying blood to the patient's circulatory system, first control means for initiating a pumping cycle in timed relationship to one of the patient's physiological parameters, and second control means for varying the rate of movement of said reciprocating pump in response to changes in the cycle time of one of the patient's physiological parameters, said second control means including means for limiting the rate of movement of said pump to a predetermined value to prevent excessive hemolysis of the blood, said rate limiting means including computer means responsive to the patient's parameter cycle time for converting said predetermined value to a function of the maximum volume of blood that may be pumped, and said rate limiting means including means for limiting the maximum volume of blood that may be pumped on a cycle.

6. A heart pumping system, comprising: means adapted to be inserted into the patient's circulatory system, a reciprocating pump for supplying fluid through said means to supply blood to the patient's circulatory system, control means for initiating a pumping cycle in timed relationship with one of the patient's physiological parameters; and control circuit means for varying the time duration of the pumping cycle including input means for determining the time duration of one of patient's selected parameters, means for varying the pumping cycle time in response to changes in said input means, means for determining the error between the patient's physiological cycle times and the pumping cycle times, and means for correcting the pumping cycle time in response to said error, whereby substantial coincidence is achieved between the patient's physiological cycle and the pumping cycle.

7. A heart pumping system, comprising: means adapted to be inserted into the patient's circulatory system, a reciprocating blood pump for supplying fluid through said means for supplying blood to the patient's circulatory systems, control means for initiating a cycle of said pump

in timed relationship with one of the patient's physiological parameters, and control circuit means for varying the pumping cycle time including a digital counter for determining the cycle time of one of the patient's selected parameters, and means for computing a new pumping cycle time in response to the output of said digital counter.

8. A heart augmentation system, comprising: catheter means adapted to be inserted in the patient's circulatory system, a reciprocating pump connected to deliver fluid through said catheter means, control means for initiating a pumping cycle in timed relationship with one of the patient's physiological parameters, control circuit means for varying the pumping cycle time including a digital counter for determining the time duration of one of the patient's cyclical parameters, means for converting the resulting time duration parameter to a function of the frequency of the patient's parameter, and means for increasing the pumping rate and for decreasing the pumping rate in response to increases and decreases in said function.

9. A heart augmentation system, comprising: catheter means for insertion into the patient's circulatory system, a reciprocating pump having a push and a withdraw phase defining a pumping cycle connected to said catheter to deliver fluid therethrough, means for determining the push and withdraw rates of movement and the volume of fluid to be pumped, means for driving the pump in response to said determining means, means for deriving a continuous reference signal representing the desired displacement of the pump with respect to time, transducer means for continuously deriving a feedback signal proportional to the actual position of the pump with respect to time, comparator means for continuously comparing the reference signal to the feedback signal to produce an error signal, and a chopper circuit for periodically applying said error signal to correct the movement of said pump.

10. A heart pumping system, comprising: catheter means for insertion with the patient's circulatory system, a reciprocating pump having a push and a withdraw phase defining a pumping cycle connected to said catheter means to deliver fluid therethrough, means for deriving a pump cycle triggering signal in timed relationship with one of the patient's physiological parameters, driving means for actuating said reciprocating pump, means for producing a signal at the end of said pumping cycle, means for initiating said driving means in response to the presence of both said triggering signal and said end of pumping cycle signal, and means for holding said triggering signal for a predetermined time and then dropping said triggering signal whereby if the triggering signal occurs before the end of the pumping cycle but within said predetermined time another pumping cycle will be initiated but if the triggering signal occurs earlier than said predetermined time before the end of the pumping cycle a new pumping cycle will not be initiated, and in this manner the system prevents out of phase pumping.

11. A heart pump system, comprising: catheter means adapted to be inserted into the patient's circulatory system, a reciprocating pump connected to said catheter means and having push and withdraw phases defining a pumping cycle, means for initiating the pumping cycle in timed relationship with one of the patient's physiological parameters, control means for varying the volume of fluid delivered in a pumping cycle including means for varying the push and withdraw rates of movement without varying the pumping cycle time, and means for changing the pumping cycle time including means responsive to the frequency of one of the patient's physiological parameters for varying the push and withdraw rates of movement of the pump.

12. A heart pump system, comprising: catheter means adapted to be inserted into the patient's circulatory system, a reciprocating pump connected to said catheter

means and having a push and a withdraw phase defining a pumping cycle, an input circuit for receiving the EKG waveform of the patient and selecting a portion thereof as the triggering level, means for initiating a pumping cycle in response to said input circuit, a second input circuit for receiving another of the patient's physiological waveforms, a counting circuit responsive to said second input circuit for determining the frequency of said physiological waveform, and control means responsive to said counting circuit for varying the duration of the pumping cycle to achieve coincidence between the pumping cycle and the patient's parameter cycle while preventing false triggering of the pumping cycle.

13. A heart pump system, comprising: catheter means adapted to be inserted into the patient's circulatory system, a reciprocating pump connected to said catheter means and having a push and a withdraw phase defining a pumping cycle, control means for initiating the pumping cycle in timed relationship with one of the patient's physiological parameters, control circuit means for varying the push and withdraw rates of movement of the pump, means for limiting the push and withdraw rates to a predetermined maximum value to prevent excessive blood damage, and catheter select means for changing said predetermined limit upon the selection of different catheter sizes.

14. A heart pump system as defined in claim 13, and further including second catheter select means for changing said predetermined limit upon the selection of different numbers of catheters.

15. A heart pumping system, comprising: catheter mean adapted to be inserted into the patient's circulatory system, a reciprocating pump connected to said catheter means and having a push and a withdraw phase defining a pump cycle, control means for initiating the pump cycle in timed relationship with one of the patient's physiological parameters, control means for driving said pump in the push and withdraw phases and for varying the rate of movement of said pump, a control circuit connected to said driving means for varying the rate of movement of said pump including a pulse train generator, means for modulating the width of the pulse in accordance with the desired volume of blood to be pumped, amplifier means responsive to the frequency of one of the patient's physiological parameters for limiting the pulse width to some maximum value to prevent excessive pump cycle rates, amplitude modulating means for varying the amplitude of the pulses in said pulse train in response to changes in the cycle time of said one physiological parameter to achieve coincidence between the pumping cycle and the patient's parameter cycle, an integrating amplifier for integrating said pulses, said driving means being connected to said integrating amplifier to vary the rate of movement of said pump in response thereto on the push and withdraw phases thereof.

16. A heart pumping system as defined in claim 15, and further including a reference generator for deriving a reference signal for the pump displacement with respect to time in response to the output of said integrating amplifier, transducer means for deriving a signal proportional to the actual pump displacement with respect to time, comparator means for continuously computing the error signal between said reference and transducer signals, and a chopper circuit connected to said driving means and responsive to said error signal for making a plurality of compensating corrections during each pumping cycle.

17. A heart pump system as defined in claim 15, and further including second means for producing triggering signals in response to one of the patient's physiological parameters, a two channel binary counter, each of said channels being connected to be activated on alternate triggering signals from said second triggering means, a pulse generator for providing pulses to be counted in each of said channels, summing means for determining the count on each of said channels, and means for reading out

said summing means upon the presence of a triggering signal from said second means, said readout means being connected to control said control circuit for varying the push and withdraw rates.

18. A heart pump system as defined in claim 15, and further including means responsive to the actual position of the pump for deriving a signal indicating the desired end of a pumping cycle, and control means for initiating the pump cycle including means for producing a pump cycle triggering signal, a timing error sensor for determining the time duration between the end of the pumping cycle signal and the occurrence of the triggering pulse, the output of the timing error sensor being connected to said amplitude modulating means to vary the time duration of the pumping cycle.

19. A heart pumping system, comprising: a catheter adapted to be inserted into the patient's circulatory system, a reciprocating pump connected to said catheter and having a push and a withdraw phase defining a pumping cycle, driving means for moving said pump, a trigger level selector for selecting a portion of the patient's EKG waveform, means responsive to said selector for producing a pump cycle trigger signal a predetermined delay time after the selected portion of the patient's EKG waveform, means for sensing the desired end of a pumping cycle responsive to the actual position of the reciprocating pump, an AND gate for energizing said driving means in response to the presence of a delayed triggering signal and an end of pumping cycle signal, and means for holding said delayed triggering signal in said AND gate a predetermined time if the delayed triggering signal occurs before the desired end of the pumping cycle, whereby the triggering pulse will be dropped if it occurs earlier in the pumping cycle before said predetermined time.

20. A heart pump system as defined in claim 19, and further including a reduced augmentation circuit for permitting only selected triggering signals to initiate pumping cycles whereby the pump operates only on certain heart beats, said augmentation circuit including a blanking gate for blanking said triggering signals, a disable gate for disabling the blanking gate on selected triggering signals, a digital counter for counting said triggering pulses, and selective switch means for energizing said disable gate in response to a predetermined count in said digital counter.

21. A heart pump system as defined in claim 19, and further including manual stroke means including switch means connected to said driving means and by passing said AND gate to initiate a single push phase, and means disabling the withdraw phase responsive to said switch means whereby the pump will proceed only through the push phase of the pumping cycle.

22. A heart pump system as defined in claim 19, wherein said reciprocating pump includes a generally cylindrical housing member having a cylindrical inner surface defining a cylinder, one end of said housing having a substantially conical inner surface to improve the hydraulic flow characteristics, a piston slidable in said cylinder, rolling diaphragms on each end of said piston and fixed to said housing to assure proper pumping action, said diaphragm defining a working chamber in said housing adjacent said one end thereof and an actuating chamber adjacent the other end thereof, and guide means on said piston for preventing tilting thereof in said housing.

23. A heart pump system as defined in claim 19, wherein said catheter means includes a Y fitting on said pump, two intermediate tube sections connected at one end to said Y fitting, said intermediate sections having decreasing internal diameters from said Y fitting, and two catheters each connected to one of said intermediate sections, said catheters being of uniform internal and external diameters and having their distal ends open to deliver and withdraw blood therethrough.

24. A heart pump system as defined in claim 22, and further including evacuating means for evacuating the space between said diaphragms, said evacuating means in-

cluding a stationary valve member having a conical seat mounted on said housing member and communicating with said space, a movable valve member having a conical end selectively engageable with said conical seat, passage means disposed centrally in said movable valve element and communicating with the exterior of said movable valve member above said conical seat, whereby said space may be evacuated when the movable valve member is spaced from said seat in the stationary valve member and said space may be sealed when the movable valve member is seated on said stationary valve member seat.

25. A heart pump system, comprising: a catheter adapted to be inserted into the patient's circulatory system, a reciprocating pump connected to said catheter having a push and a withdraw phase defining a pumping cycle, means for initiating a pumping cycle in timed relationship with the patient's natural heart action, driving means for the pump, and control circuit means connected to said driving means to control the pumping cycle, said control circuit being responsive to a digital counting circuit, said counting circuit being responsive to the patient's natural heart action, and including two binary counting channels, a master flip-flop for selecting one of the channels on alternate heart cycles of the patient, pulse generating means for delivering pulses to be counted to the channel selected by the master flip-flop, readout means responsive to said master flip-flop for reading out the count in each of said channels at the end of alternate heart cycles, and means connecting said readout means to said control circuit whereby the pumping cycle is controlled by the patient's heart cycle time.

26. A heart augmentation system, comprising: a reciprocating pump for supplying blood to the patient's arterial system, means for receiving a cyclical signal, means for initiating the cyclical operation of said pump in timed relation to said signal, and control circuit means for varying the velocity of the stroke of the reciprocating pump in response to changes in said signal, whereby the pumping cycle coincides with the signal cycle.

27. A heart pumping system, comprising: a reciprocating blood pump for supplying blood to the patient's arterial tree, signal receiving means for receiving a cyclical signal, control means for initiating a pumping cycle in response to said receiving means, control circuit means for varying the rate of movement of the pump during the push and withdraw phases thereof in response to changes in the cycle time of the received signal whereby the pumping cycle coincides with the signal cycle, said control circuit including means for limiting the rate of movement of said pump to a predetermined value to prevent excessive hemolysis.

28. A heart pumping system, comprising: catheter means adapted to be inserted into the patient's circulatory system, a reciprocating pump connected to said catheter means and having push and withdraw phases defining a pumping cycle, means for receiving a cyclical input signal, means for initiating the pumping cycle in timed relationship with said received signal, control means for varying the volume of fluid delivered in a pumping cycle including means for varying the push and withdraw rates of movement without varying the pumping cycle time, and means for changing the pumping cycle time including means responsive to the frequency of said received signal for varying the push and withdraw rates of movement of the pump.

29. A heart pumping system, comprising: catheter means adapted to be inserted into the patient's circulatory system, a reciprocating pump connected to said catheter means and having push and withdraw phases defining a pumping cycle, means for initiating the pumping cycle in timed relationship with a cyclical input signal, control means for varying the volume of fluid delivered in a pumping cycle including means for varying the push and withdraw rates of movement without varying the pumping cycle time, and means for changing the pump-

ing cycle time including means responsive to the frequency of said cyclical input signal for varying the push and withdraw rates of movement of the pump.

30. A heart pumping system comprising: catheter means for insertion within a patient's circulatory system, a pump having a push and a withdraw phase defining a pumping cycle and connected to said catheter means to direct fluid therethrough, means for deriving a pump cycle triggering signal in timed relationship with one of the patient's physiological parameters, driving means for said pump, means for producing a signal at the end of said pumping cycle, means for initiating said driving means in response to the presence of both said triggering signal and said end of pumping cycle signal, means for holding said triggering signal for a predetermined time and then dropping said triggering signal so that if the triggering signal occurs prior to the end of the pumping cycle but within said predetermined time, another pumping cycle will be initiated but if the triggering signal occurs earlier than said predetermined time before the end of the pumping cycle a new pumping cycle will not be initiated, means for holding said pumping cycle signal after the completion of a pumping cycle so that if a triggering signal occurs after the completion of a pumping cycle the next pumping cycle will be initiated immediately upon the occurrence of a triggering signal, means for determining the time difference between the triggering signal and the end of the pumping cycle, and means

5
10
15
20
25

responsive to said time difference means for synchronizing the pump cycle time with the cycle time of the patient's physiological parameter.

References Cited

UNITED STATES PATENTS

986,263	3/1911	Bevill	128—276	X
2,935,068	5/1960	Donaldson	128—348	
3,039,399	6/1962	Everett	103—150	
3,094,124	6/1963	Birtwell	128—348	
3,099,260	7/1963	Birtwell	128—1	
3,266,487	8/1966	Watkins et al.	128—1	

OTHER REFERENCES

Murphy: "The Cardiac Programmer to Trigger an Arterial Pump," Am. Soc. Artificial Inter. Organs, vol. 7, 1961, pages 361-366.
Goldfarb et al.: Surgery, vol. 56, #3, September 1964, pages 547-555.
Hiller et al.: "A Servomechanism to Drive an Artificial Heart Inside the Chest," vol. 8, 1962, Am. Soc. Artificial Organs, pages 125-130.

DALTON L. TRULUCK, *Primary Examiner.*

U.S. Cl. X.R.

128—214