

[54] HEART ASSIST METHOD AND DEVICE

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[58] Field of Search 3/1.7; 23/258.5; 128/1 D, 128/2.05 E, 2.05 R, 419 P, 419 PG, DIG. 3

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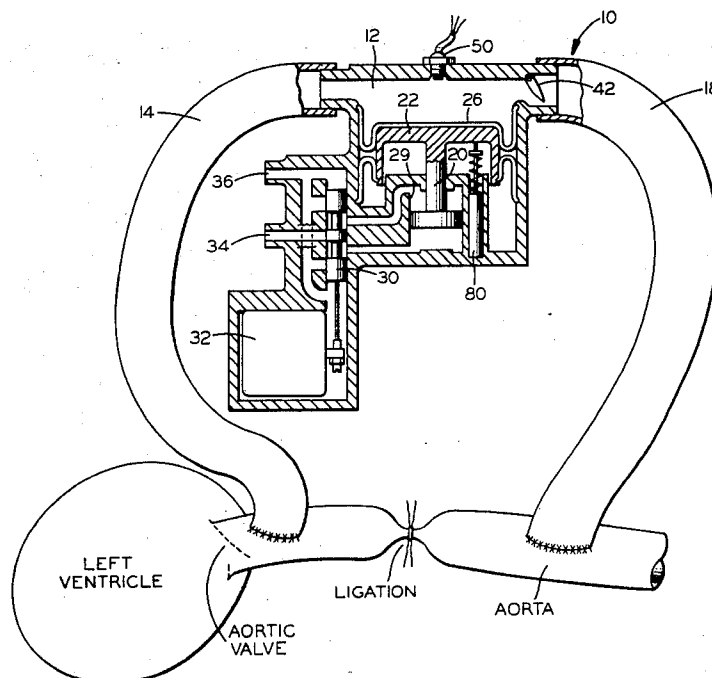
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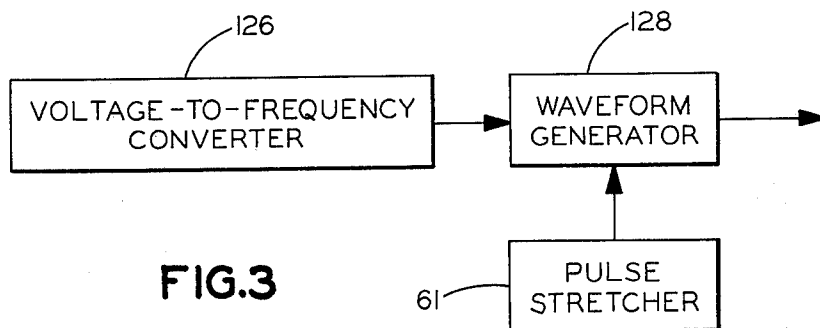
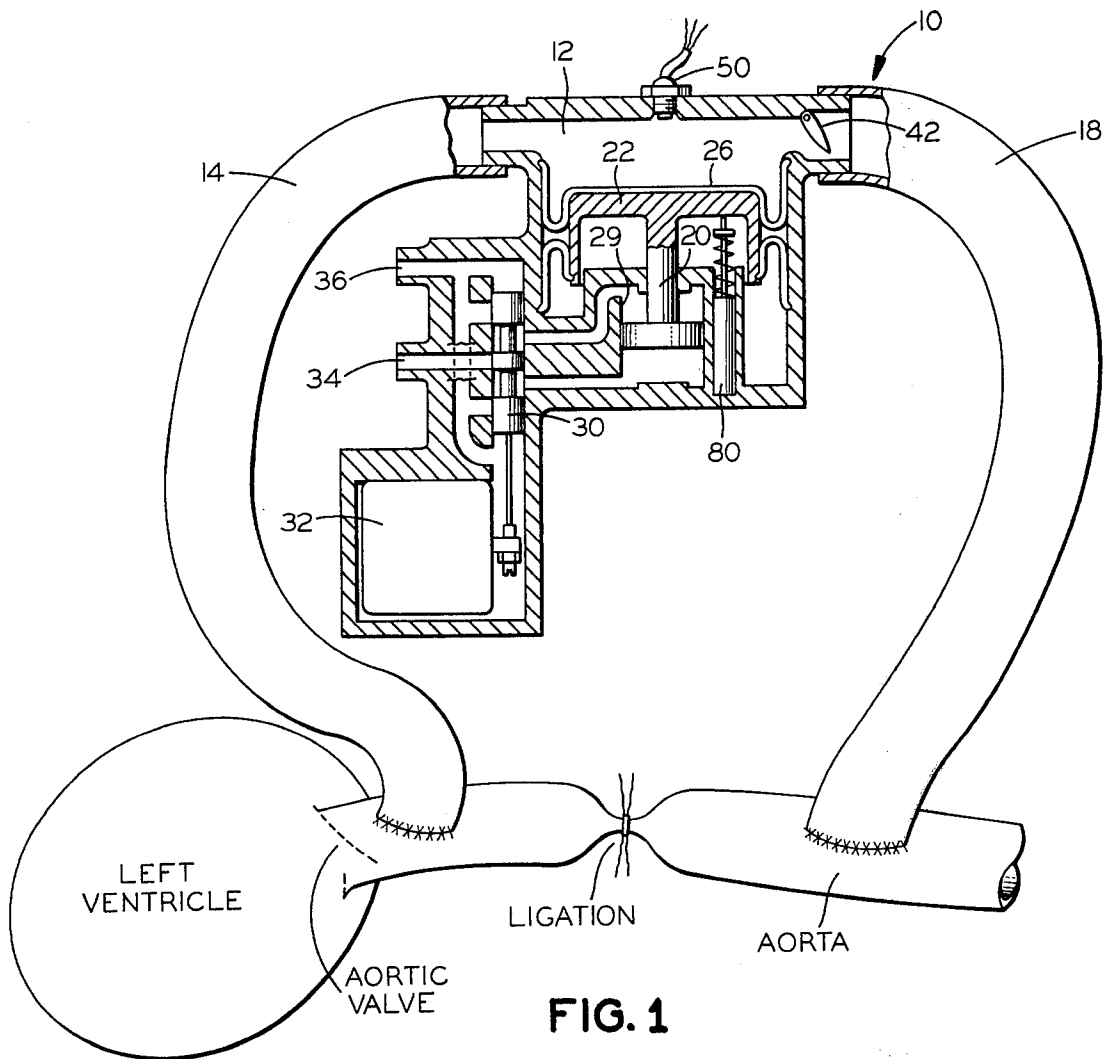
[57] ABSTRACT

A heart assist device is controlled in a normal mode of

operation to counterpulsate with the heart and produce a blood flow waveform corresponding to the flow waveform of the heart being assisted. A blood pump in the device is connected serially between the discharge of a heart ventricle and the vascular system, and during the normal mode of operation, the pump is operated to maintain a programmed pressure at the ventricle discharge during systolic cardiac pulsation. A pressure transducer detects the pressure at the ventricle discharge and a hydraulically powered, closed-loop servomechanism controls the displacement of a piston in an expansible chamber receiving the blood from the ventricle, in such a way that programmed pressure is maintained in the chamber. Means are provided for recording the piston displacement as a function of time during ventricular systole. During diastole, the piston motion is reversed, and servo-controlled to duplicate the recorded displacement waveform while the piston contracts the chamber volume and expels blood into the vascular system. In this way the output blood from wave-form produced by the pump during diastole is the same as the output flow waveform produced by the ventricle during the previous systole. In the event that the heart beat stops or becomes severely arrhythmic, the device switches to an autonomous mode of operation and a waveform generator in the pump controls provides an ideal blood flow waveform independent of cardiac pulsations.

19 Claims, 3 Drawing Figures





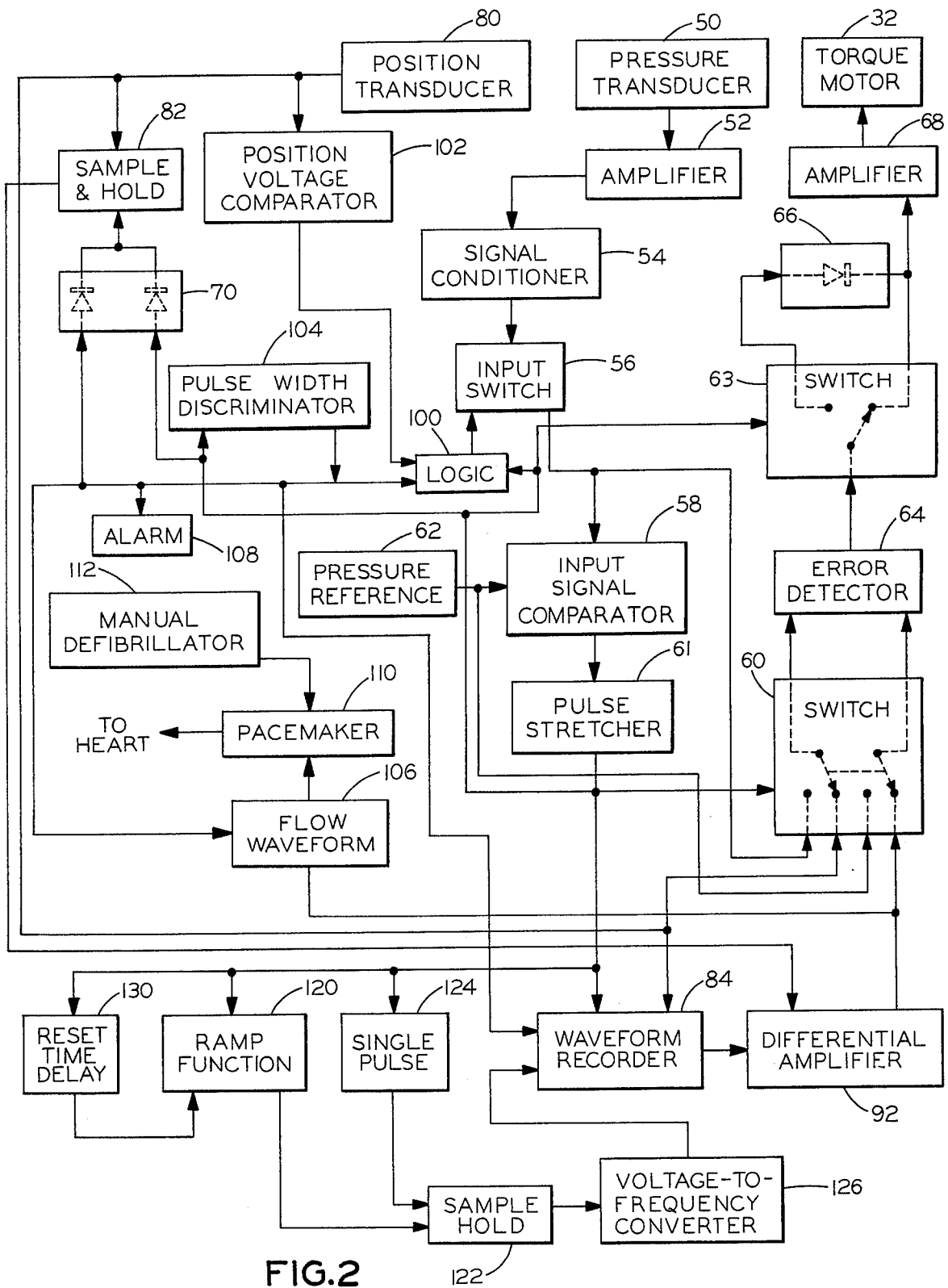


FIG. 2

HEART ASSIST METHOD AND DEVICE

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of copending application Ser. No. 458,535, filed Apr. 5, 1974, entitled HEART ASSIST DEVICE.

BACKGROUND OF THE INVENTION

The present invention relates to prosthetic devices and, more particularly, is concerned with a heart assist device which can operate in counterpulsation with the heart or establish autonomous control of blood flow from the heart.

Several approaches to the problem of providing artificial assistance to a weak or diseased heart have been proposed or developed. A common approach involves the concept of counterpulsation in which a blood pump in series with the heart is operated in synchronism with ventricular contractions to receive blood from the ventricle at low pressure during the systolic phase of heart action, and to expel this blood at arterial pressure during the diastolic phase of heart action. Counterpulsation by itself, however, can be achieved in various manners and does not necessarily result in duplication of the heart pressures and flows that would normally be experienced from a healthy heart. It is desirable that the heart assist device produce a pulsatile flow which the vascular system is accustomed to and in this respect, the blood flow waveform during each pulsation should be such that there is no breakdown or damage to the blood or the vascular system.

The need for an optimum blood flow waveform is apparent from the physical characteristics of the heart and the vascular system into which it empties. The vascular system properly preforms its function only when it transports a needed amount of blood in a given time to the appropriate cells of the body. Examination of blood vessels at different locations in the vascular system reveals that the wall of each vessel has the minimum cellular structure required to withstand the most severe stresses imposed upon it by the circulatory system. Significantly, this minimum structure of the vessels is designed for the particular blood flow waveform produced by the heart. It can be demonstrated that other waveforms delivering the same average blood flow during a given ventricular contraction generate greater arterial wall stresses than the natural heart waveform. Greater stresses applied cyclically over long periods of time produce deleterious effects which the body may not be able to withstand.

A heart assist device which operates in copulsation with the natural heart to produce a blood flow waveform substantially the same as that of the natural heart is disclosed in my copending application Ser. No. 458,535 identified above. In the copulsation device, blood is expelled into the vascular system by the blood pump during systolic contractions of the heart. My present invention relates to a counterpulsation heart assist device which is capable of expelling blood into the vascular system with a blood flow waveform substantially the same as that produced by the heart.

It is, therefore, a general object of this invention to disclose a counterpulsation heart assist device which provides a blood flow waveform that duplicates closely the natural heart output.

SUMMARY OF THE INVENTION

The present invention resides in a heart assist method and device which operates in counterpulsation with the heart and duplicates the blood flow waveform of the natural heart, that is the blood flow versus time function during systolic contraction, as long as the heart beat is not severely arrhythmic.

The heart assist device includes blood pumping means connectible between a ventricle of the natural heart and the associated vascular system of the body, which may include the coronary arteries themselves, to produce a pulsatile blood flow. Pumping control means is connected with the heart and the pumping means for regulating the pumping means in counterpulsation with the heart. The pumping means includes an expansible and contractible pumping chamber connected with the ventricle, and a displaceable piston which controls chamber expansion and contraction is operated by the pumping control means to maintain a programmed systolic pressure or back pressure at the ventricle during systole. Means are provided in the pumping control means for detecting and recording or storing the expansion of the chamber as a function of time during ventricular systole. The stored expansion defines the blood flow waveform produced by the heart, and means for regulating the pumping means reproduces the flow waveform during ventricular diastole by controlling chamber contraction and blood expulsion into the vascular system in a proportional manner. Accordingly, during diastole, blood is expelled from the chamber into the vascular system with a flow waveform which duplicates the flow waveform produced by the contracting ventricle during the previous systole.

By duplicating the blood flow waveform produced by the heart, the vascular system experiences the same stress that would ordinarily be produced by the healthy heart. At the same time, the heart is permitted to operate against a reduced load at the ventricle discharge. Thus, the counterpulsation heart assist device duplicates the flow characteristics of the heart while reducing the heart load.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 schematically illustrates in cross-section the blood pump and the manner in which the pump is connected into the vascular system adjacent to the heart.

FIG. 2 is a schematic diagram showing the controls which regulate the blood pump operation for both counterpulsation and autonomous operation.

FIG. 3 is a schematic diagram of a variable time-base, programmed pressure reference.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 shows the blood pump, generally designated 10, of a heart assist device in one embodiment of the present invention. The pump 10 is surgically connected to the aorta immediately adjacent the aortic valve in the left ventricle and preferably is installed within the body.

The pump 10 includes a cylindrical expansible and contractible pumping chamber 12 which is connected by means of a blood compatible inlet 14 to the aorta between the aortic valve at the left ventricle discharge and a ligation in the aorta a short distance from the discharge. Chamber 12 is fitted with a check valve 42 at

its discharge, and the downstream side of this valve is connected to the aorta at the opposite side of the ligation from the tube 14 by a blood compatible outlet tube 18. The coronary arteries (not shown) are preferably connected to the aorta at the same side of the ligation as the tube 18 discharging blood from the pump 10. With the surgical installation indicated, all blood leaving the left ventricle must pass serially from the heart through the pump 10 and then into the aorta. The pump is operated as explained in greater detail below to maintain programmed pressure or back pressure at the ventricle discharge during systole, and to expel blood into the aorta during diastole with a flow waveform corresponding to that produced by the heart during the previous systolic contraction of the ventricle.

Since the major circulatory load of the heart is borne by the left ventricle, the heart assist device of the present invention is most commonly employed with that ventricle. However, the utility of the device is not so limited and it is also possible to connect the pump to the right ventricle to transmit the venous blood to the lungs through the pulmonary arteries. Within the scope of the present invention, the term "vascular system" is used generally to refer to the arterial system connected to the ventricle supported by the assist device.

Within the pump 10 a displaceable piston 20 is provided with piston head 22 inside chamber 12. The piston head 22 is sealed at the cylindrical wall of the chamber 12 by means of a flexible diaphragm 26 which rolls back and forth along the walls of the chamber as the piston 20 is reciprocated. The piston 20 is mounted within a cylinder 29 and together they form a hydraulic actuator in a servomechanism including a spool valve 30 and an electrical torque motor 32. In conventional fashion, the torque motor 32 receives electrical signals from a pump control and positions the spool valve to regulate the flow of hydraulic fluid between the hydraulic actuator and an inlet port 34 and discharge port 36.

During ventricular contraction, piston head 22 moves from top to bottom in FIG. 1, ingesting blood into chamber 12. During diastole, the aortic valve of the ventricle closes, preventing back-flow of blood, and the piston head 22 moves from bottom to top in FIG. 1, expelling blood through the check valve 42 into the vascular system.

Hydraulic fluid used to operate the actuator including the piston 20 may be derived from a self-contained and battery-operated power source installed within the body of the heart assist recipient or carried externally of the body.

FIG. 2 illustrates the pump control which regulates the blood pump in FIG. 1 to achieve either counterpulsation of the pump and left ventricle or autonomous operation of the pump.

A principal operation of the heart assist device is counterpulsation of the heart ventricle and pump 10 in a manner which causes the blood flow waveform emanating from the pump 10 to duplicate the flow waveform from the ventricle during systolic contractions. The counterpulsation operation of the heart assist device is a cyclic operation synchronized with the heart and it will be assumed that the beginning of each cycle corresponds with the beginning of each heart beat when the ventricle is filled with blood and about to begin a systolic contraction. The first portion of the cycle is substantially coextensive with a systole and

during this portion the displacement of the piston 20 is regulated by a closed-loop servomechanism in the pump control to maintain a programmed pressure at the ventricle discharge. Piston displacement is recorded or memorized as a function of time during systole and the recorded displacement accordingly represents the blood flow waveform produced by the ventricle. The other portion of the counterpulsation cycle is coextensive with the ventricular diastole and during this portion the recorded piston displacement is supplied as an input to the pump control to regulate piston displacement and the expulsion of blood from the chamber 12 with a flow waveform that is a duplicate of that produced by the heart during the previous systole. The recorded piston displacement, therefore, represents a reference waveform that the pump duplicates during diastole.

During the first portion of a counterpulsation operation cycle the piston 20 is controlled to maintain a programmed pressure at the ventricle discharge. A pressure sensor or transducer 50 supplies electrical signals as feedback in the closed-loop servomechanism including the torque motor 32 located in the pump 10 but illustrated separately in FIG. 2. The transducer 50 must be located in a position to detect the blood pressure at the discharge of the left ventricle and in one form of the invention, the transducer is located in the chamber 12 of the pump 10 as illustrated in FIG. 1.

As the systolic contraction begins, pressure at the discharge of the ventricle, and correspondingly in the chamber 12, begins to rise, and an electrical signal from the transducer 50 passes to an input amplifier 52 in FIG. 2 where it is amplified to a maximum level of several volts. The electrical signal produced by the transducer is proportional to the pressure in the chamber and hence, represents an analogue pressure signal. The amplified signal passes through a shaping network or signal conditioner 54, which filters out unwanted noise, and then through an electronic switch 56 into an input signal comparator 58 and a double pole/double throw electronic switch 60. The electronic switch 56 serves as a gate transmitting the analogue pressure signal during the systolic period if the heart is beating properly as explained in greater detail below.

In the signal comparator 58, the analogue pressure signal is compared with an electrical, programmed pressure level signal determined by the setting of the pressure reference 62 which, for example, may be an adjustable potentiometer. The programmed pressure reference signal represents a desired pressure to be maintained at the discharge of the left ventricle and can be adjusted to increase or decrease the load against which the ventricle operates during the systolic period.

If the input pressure detected by the transducer 50 is greater than the programmed reference pressure, the output of the comparator 58 is turned on, and when the input pressure again drops below the reference pressure the output is turned off. Hence, the comparator 58 normally produces a control pulse in synchronism with the coextensive with the systolic period of the left ventricle. This control pulse is used as a mode signal for controlling the servomechanism.

To insure that perturbations of the pressure signal detected by the transducer 50 do not prematurely cut off the mode signal, the control pulse is transmitted through a pulse stretcher 61 which effectively delays the trailing edge of the pulse a few milliseconds to in-

sure that the systolic contraction has in fact ended. The control pulse of the pulse stretcher 61 is transmitted to the electronic switch 60 and a single pole/double throw electronic switch 63 to pull in and set these switches in the positions opposite the deactivated positions illustrated.

The analogue pressure signal from the electronic switch 56 and the pressure reference signal from the reference 62 are then transmitted through parallel circuits in the switch 60 to the differential error detector 64 which produces an error signal representative of the difference between the two signals. That error signal is transmitted through the electronic switch 63, a rectifier 66 and a servo-amplifier 68 to drive the torque motor 32 and piston 20.

The rectifier 66 prevents the servo-amplifier 68 and torque motor 32 from responding to negative error signals which are generated when the pressure sensed by the transducer 50 drops below the reference pressure. Such negative error signals occur, for example, at the end of each systole during the several milliseconds that the control pulse from comparator 58 is extended by the pulse stretcher 61. The error signal during this period could rapidly reverse the movement of the pump piston 20 and interfere with the programmed return of the piston described below.

Control of the piston 20 during systolic contraction displaces the piston head 22 downward in FIG. 1, and increases the volume of chamber 12 at the same instantaneous rate that the volume of the ventricle is decreasing. A position transducer 80, mounted in the pump 10 and cooperating with the piston head 22, produces an electrical piston position signal that represents the ventricle output volume as a function of time. This signal is fed into a waveform recorder 84, which is turned on at the start of systole by the leading edge of the control pulse from pulse stretcher 61. The waveform recorder consists of an analog-to-digital converter, a random access memory (preferably a state-of-the-art semiconductor memory), timing and control circuits for storing and retrieving information from the memory, and a digital-to-analog converter. As the piston head 22 moves during systole, the output from the position transducer 80 is sampled and digitized at closely spaced intervals of time by the analog-to-digital converter within the waveform recorder 84. The digitally encoded data is sequentially addressed and stored in the semiconductor memory by the internal timing and control circuits. Since this data is read in at a constant clock rate, as described below, the information stored in the memory represents the displacement waveform of piston head 22, and hence the volume output waveform of the heart ventricle.

During systole therefore, the torque motor 32 is in a closed servo loop which attempts to hold the ventricle discharge pressure at the level of the reference pressure and causes the piston 20 in the pump 10 to move from top to bottom in FIG. 1 as long as the pressure sensed by the transducer 50, that is the systolic pressure of the left ventricle, does not drop below the programmed pressure established by the reference 62. At the same time, the chamber 12 receives a quantity of blood equal to the quantity expelled from the left ventricle, and as long as the servomechanism including the piston head 22 holds the systolic pressure near its reference value with small error signals, the displacement signals produced by the position transducer 80 and stored in the

waveform recorder 84 will represent the blood flow waveform produced by the ventricle during the systolic period.

The foregoing description of the pump control which causes blood to be ingested into chamber 12 entails a pressure mode of operation which mode is coextensive with the systolic period of the ventricle. During the diastolic period of the ventricle, blood then filling chamber 12 is expelled through the check valve 42 into the aorta. To accomplish this return, the pump control switches to a position mode of operation.

Since it is an object of this invention to supply the vascular system with a blood flow waveform which duplicates the flow waveform produced by the heart ventricle, the piston head 22 in the pump 10 is controlled during its return by the displacement waveform stored in the waveform recorder 84. In pumping, the piston head 22 must displace a volume of blood in each successive time increment of its return stroke equal to that ingested during a corresponding time increment of the previous ingesting stroke when the piston head followed the volume output waveform of the ventricle. This process and the apparatus regulating the pump 10 generate a blood flow waveform in the aorta that duplicates the flow waveform produced by the ventricle during the previous systolic period. The durations of the systole and diastole of the natural heart, of course, vary with physiological demand, but within the range of heart beats that is expected of a recipient of the heart assist device, the systole is shorter than the succeeding diastole so that there is always adequate time to duplicate the blood flow waveform of the previous systole during a diastole. The vascular system, therefore, receives a quantity of blood matching the ventricle output during each systole and experiences a pressure waveform which should be easily tolerated without deleterious effects since the pressure waveform is generated as the vascular system response to a flow waveform produced by the heart. At the same time, the load or pressure against which the left ventricle operates is reduced to a level determined by the pressure reference 62. It is contemplated that the pressure reference may be adjusted upwardly during a recuperative period to permit a damaged or diseased heart to eventually reach a functional level approximating that of a healthy heart.

At the end of a systolic contraction and the beginning of the diastole, the pressure in chamber 12 falls below its reference value and causes the comparator 58 and pulse stretcher 61 outputs to turn off. This pulse transition causes the timing and control circuits in the waveform recorder 84 to retrieve the information stored in its memory, on a first-in-first-out basis. The sequentially addressed digital data is processed by the digital-to-analog converter within waveform recorder 84 and generates a series of output voltage levels which closely approximate the waveform recorded.

Because the semiconductor memory in the waveform recorder 84 can store a limited number of digital words, and the size and cost of the memory increase with increasing word storage capacity, the minimum word capacity required for adequate waveform amplitude resolution should be used. Although the memory must have a capacity capable of storing the number of words necessary to digitize the entire stroke of piston 20 to the required amplitude resolution (even though the full stroke may not be utilized during each beat),

excess memory capacity would be required if a constant clock frequency were used. This is because the heart beat rate and the period of systolic contraction vary widely to meet various physiological demands. If a constant clock rate were used, a digital word would be recorded with each clock pulse after a constant delay between clock pulses had elapsed. The clock rate would be that required to achieve the necessary amplitude resolution for the shortest expected systolic period. If this same clock rate were used while digitizing the waveform with the longest expected period, however, the clock would produce several digital words for each amplitude resolution level selected for the faster waveform. These redundant digital words would waste memory space.

To avoid this, an adjustable clock rate based on the previous systolic period is utilized. A fast clock rate is used for the shortest waveform duration, and this rate is proportionally lowered as the systolic period increases. This assures a more uniform amplitude increment for each clock pulse, so that memory capacity is dictated mostly by amplitude resolution considerations.

The clock rate is derived by sampling and storing a voltage proportional to the previous systolic period, and using this stored voltage as the input to a voltage-to-frequency converter circuit.

To this end, a reset time delay 130 is triggered at the beginning of a systolic period by the leading edge of the control pulse from pulse stretcher 61. After a delay of only several milliseconds, delay 130 triggers a ramp function generator 120 to reset to its initial value, and to begin generating a ramp voltage. This ramp voltage decreases linearly with time and reaches a minimum value only at the end of the longest systole. At the end of a systole, the trailing edge of the control pulse from the pulse stretcher 61 causes the generator 120 to stop and hold its last ramp voltage. At the beginning of the following systole, the leading edge of the control pulse from stretcher 61 triggers a single-pulse generator 124, generating an output pulse that is shorter than the delay generated by circuit 130. A sample-and-hold circuit 122 responds to the pulse from the pulse generator 124, forming a sample time aperture coextensive with the duration of this pulse, and during which the circuit 122 stores the voltage of the ramp generator 120 representing the length of the previous systolic period. It should be noted that the stored voltage representing the systolic period is smaller if the period is longer.

A voltage-to-frequency converter 126 is connected to the output of the sample-and-hold circuit 122, and produces an output pulse train having a pulse rate proportional to its input voltage. This pulse train determines the clock rate for reading and recording information in the waveform recorder 84. Note that although the clock rate is adjusted from heart beat to heart beat on the basis of the previous systolic period, it remains constant during each heart cycle of one systole and diastole, assuring that the waveform is read into and out of the memory at the same rate. The ramp function generator 120, the sample-and-hold circuit 122, the converter 126 and associated control components therefore form an adjustable clock for controlling the read and record rate for the memory in the waveform recorder 84.

During its return stroke, piston 20 is regulated in a closed loop by the pump control to reproduce the position waveform stored in recorder 84. To do this, the

output of the position transducer 80 is compared with the waveform output of recorder 84 and hydraulic control is exercised to minimize the error between these signals. When the position signal is fed into recorder 84, however, the transducer 80 output begins at a zero level when the piston 20 is in its extreme top position, and increases as the piston travels downward in FIG. 1. When the waveform is read out of the memory, however the piston must travel in the opposite direction, that is from bottom to top in FIG. 1. This means that the position transducer 80 output signal cannot be directly compared with the waveform recorder 84 output during the piston return stroke. To be compared with the transducer 80 output, the waveform recorder 84 signal must be subtracted from a constant representing the transducer 80 voltage output when it begins its return stroke.

To achieve this, the trailing edge of the control pulse from the pulse stretcher 61 causes a sample-and-hold circuit 82 to hold the last transducer 80 voltage occurring at the end of systole. This voltage is fed into a differential amplifier 92. Another input of this amplifier receives the output signal from the waveform recorder 84 during diastole. Differential amplifier 92 generates a signal representing the difference between these signals. This difference signal is then compared directly with the position transducer 80 output signal during the piston 20 return stroke, allowing reproduction of the volume displacement waveform, and hence the blood flow waveform produced by the ventricle during systolic contractions. In particular, the output signal from the differential amplifier 92 is applied to an input of the electronic switch 60. Also, the output of the position transducer 80 representing actual piston position is fed back to another input of the electronic switch 60. The two position signals are transmitted through the switch when the trailing edge of the control pulse from pulse stretcher 61 deenergizes the switch and the switch assumes the position illustrated schematically. The error detector 64 compares the position signals and produces a position error signal. At the same time, the electronic switch 63 is de-energized so that the position error signal is applied through the electronic switch 63 to the servoamplifier 68 and torque motor 32 which drives the piston 20 upwardly to the starting position in accordance with the stored waveform in recorder 84.

Accordingly, the servomechanism assumes a position mode of operation in response to the trailing edge of the control pulse from the pulse stretcher 61 and the piston 20 is returned to its starting position by the servomechanism under closed-loop control.

As long as the heart continues to beat in a regular manner, the pump control illustrated in FIG. 2 continues to switch between the pressure and position modes of operation in synchronism with the systolic and diastolic periods of the left ventricle. This synchronism is maintained by utilizing the systolic pressure pulse detected by the transducer 50 as the synchronizing signal.

Since it is the systolic pressure pulse of the ventricle which switches the servomechanism, or more specifically the electronic switches 60 and 63, between the pressure and the position modes of operation, the pressure pulse generated by the piston 20 during its return stroke will also be detected by the transducer 50, and could inadvertently switch the servomechanism into the pressure mode of operation. To prevent inadvertent mode switching in this fashion, the electronic switch 56

serving as a control gate for the pressure signal remains open during diastole and is closed only if the piston is in its starting (extreme top in FIG. 1) position. Furthermore, the switch remains closed thereafter only if a control pulse from the stretcher 61 is present. In other words, the electronic switch 56 is held closed only if the piston is at its extreme top position or if the piston is moving from top to bottom during a systolic contraction of the left ventricle.

To this end, a logic circuit 100 controls the electronic switch 56 in response to signals received from a position voltage comparator 102 and the pulse stretcher 61. The voltage comparator 102 receives information from the position transducer 80 and produces an output to the logic circuit only when the piston 20 is in the starting position. If the logic circuit receives a signal from either the voltage comparator 102 or the pulse stretcher 61, and as long as an additional signal from a pulse discriminator 104 described in greater detail below is absent, the logic circuit 100 closes the electronic switch 56 and analogue pressure signals will pass to the signal comparator 58 and the electronic switch 60.

At the end of a systolic pressure pulse, the logic circuit 100 opens and disables the electronic switch 56 and further pressure pulses sensed by transducer 50 during the return stroke of the piston do not cause the switches 60 or 63 to be positioned in the pressure mode condition.

The pump 10 continues cyclic operation in counterpulsation with the left ventricle as long as a regular heart beat persists. If, however, the heart beat should cease or become severely arrhythmic, that is either too long in the case of severe bradycardia or too short indicating ventricular tachycardia or fibrillation, the pump control switches to an autonomous operation in which the pulsation rates are no longer controlled by the heart. The control for the pump as disclosed includes a secondary control system that automatically provides an artificially generated blood flow waveform from the pump to establish blood circulation completely independent of the natural heart.

The secondary control system includes a pulse width discriminator 104 which monitors the delay between the control pulses received from the pulse stretcher 61. The discriminator produces two delay periods in response to the trailing edge of each pulse, the delay periods representing the maximum and minimum delay periods considered acceptable for the heart. If the leading edge of the subsequent control pulse occurs either before the minimum delay period has elapsed or after the maximum delay period has elapsed, the discriminator produces a latched output signal. This discriminator signal is applied to the logic circuit 100 to disable the electronic switch 56 and prevent further signals from passing through it. These signals could trigger the signal comparator 58 and pull the electronic switches 60 and 63 into the pressure mode positions. The discriminator signal is also transmitted to a flow waveform generator 106 which produces a time-voltage waveform representing the piston position signals that would be generated by the transducer 80 during a normal ventricular contraction and dilation. This waveform signal is applied as the input to the electronic switch 60 along with the feedback signal from the position transducer 80 and is repeated continuously as long as the input from the pulse discriminator 104 is present.

During autonomous operation of the pump 10 the servomechanism drives the piston 20 in a closed-loop positioning mode of operation in accordance with the waveform generator 106. To prevent the output of the sample-and-hold circuit 82 from interfering with the position commands from the waveform generator 106, the signal from the discriminator 104 is applied through a blocking diode of the rectifier 70 in the same manner as the control pulse from the stretcher 61. The sample-and-hold circuit 82 is therefore placed in the sample mode of operation with zero output. A separate input from the pulse width discriminator 104 resets and holds the waveform recorder 84 at zero output. The only signals then received at the operative inputs of the electronic switch 60 are the voltage waveform produced by the generator 106 and the position feedback signal from the position transducer 80. Accordingly, the closed-loop positioning control of the piston 20 continues as long as the discriminator output persists.

The blocking diodes of isolation rectifier 70 prevent the signal from the pulse width discriminator from reaching the electronic switches 60 and 63 during autonomous operation of the pump control and prevent the control pulses from the pulse stretcher 61 from reaching the logic circuit and other components connected with discriminator 104. Since the discriminator signal and control pulses have contradictory effects, the isolation provided by the rectifier 70 is needed.

To warn the individual wearing the heart assist device that the pump control is operating autonomously, the signal from the discriminator 104 is also applied to an alarm 108.

The flow waveform generator 106 can also produce a timing pulse to trigger a pacemaker 110 and cause the heart to receive a mild electrical shock in synchronism with the leading edge of the flow waveform. In this manner, normal contraction may be reinduced in the heart in synchronism with the autonomous operation of the pump 10.

The pulse width discriminator 104 may be manually reset by the user. If the heart has recovered and assumed normal contractions, the alarm 108 remains off and the entire pump control system reverts to counterpulsation rather than autonomous operation. If the alarm turns back on immediately after manual resetting of the discriminator 104, the individual will know that normal heart action has not been resumed. At this point he has the option of remaining on autonomous operation or utilizing the manual defibrillator 112 which raises a single pacemaker pulse to the level of defibrillator action and administers a severe electrical shock to a fibrillating heart in order to return to normal operation. If he elects to utilize the defibrillator, he can again determine whether it has been successful by resetting the pulse width discriminator 104 and listening for the alarm signal.

Although the programmed systolic pressure or back-pressure established by the pressure reference 62 has been described above as being constant throughout systole, it is contemplated that the pressure reference may also generate a variable, programmed analog pressure signal during each ventricular contraction. FIG. 3 discloses one form of the pressure reference 62 and associated components described above that are capable of producing a variable, programmed pressure waveform with an adjustable time base. The time base is derived from the previous systolic period.

The output of the voltage-to-frequency converter 126 is a pulse train having a pulse rate proportional to the input or stored voltage in circuit 122, which in turn is proportional to the previous systolic period. These pulses are applied as an input to the waveform generator 128 in FIG. 3, and serve as clockpulses for reading a pressure program memory. The waveform generator 128 is basically a read-only memory having analogue pressure voltages or signals stored as digital words at sequentially addressed memory sites. The clock pulses cause sequential reading of these digital words. An internal digital-to-analog converter processes these digital words into a sequence of analog voltages, producing a desired systolic pressure or backpressure waveform that becomes the variable pressure program to be maintained by the blood pump during each systole.

Since the frequency of the clock pulses from the converter 126 determines the rate at which the pressure waveform is produced by the generator, and since the frequency depends upon the voltage stored in the sample-and-hold circuit 122, the pressure waveform is produced in a period of time related to the last preceding systolic period. By setting the slope of the ramp produced by the generator 120 in conjunction with the converter 126, the programmed pressure waveform from the generator 128 can be produced in a period of time equal to the last preceding systolic period.

The waveform generator 128 is turned on by the leading edge of the control pulse from pulse stretcher 61, and is reset to the initial value by its trailing edge.

Accordingly, the components producing the pulse train input for the waveform generator 128 form an adjustable time-base generator which derives its time base from the previous systolic period. Either the variable pressure program or the constant pressure program produced by a potentiometer may be selected to most advantageously serve the recipient of the heart assist device.

While the present invention has been described in several embodiments, it will be understood that numerous modifications and substitutions can be had, without departing from the spirit of the invention. Many of the components described and illustrated in the pump control of FIG. 2 may be replaced by other components performing equivalent functions. The waveform recorder 84 may include random or controlled access memory devices which store the ingested blood flow waveform in either analog or digital form. The ramp function generator 120, the sample-and-hold circuits 82 and 122, the flow waveform generator 106 and other components may be digital or analog devices. The specific blood pump shown and described is not the only design available for counterpulsation, and suitable modifications of the servomechanism driving the disclosed pump or other pumps can be made as long as the blood flow waveform produced by the ventricle is matched at the pump output. Accordingly, the present invention has been described in a preferred embodiment by way of illustration rather than limitation.

I claim:

1. A counterpulsation heart assist device comprising: blood pumping means connectible between a ventricle of the natural heart and the associated vascular system of the body, and including an expansible and contractible pumping chamber for ingesting blood from the ventricle and expelling blood into the associated vascular system; and

pumping control means connected with the heart and the pumping means for regulating the pumping means in counterpulsation with the heart and including means for detecting and storing the blood flow waveform produced by the heart during systolic ventricle contractions and means for regulating the expulsion of blood from the pumping chamber to duplicate the stored flow waveform.

2. The heart assist device of claim 1 wherein:

the blood pumping means has a displaceable piston associated with the pumping chamber for expanding and contracting the chamber volume and correspondingly causing blood to be ingested and expelled; and

the pumping control means includes driving means for regulating the piston displacement.

3. A heart assist device as in claim 2 wherein:

the means for detecting and storing is connected to the displaceable piston.

4. A heart assist device as defined in claim 3 wherein: the means for detecting and storing includes a piston position transducer and waveform recorder connected with the transducer for recording piston displacement.

5. A heart assist device as in claim 4 wherein:

the waveform recorder has a memory programmed on a first-in-first-out basis.

6. A heart assist device as in claim 5 wherein:

the waveform recorder includes a clock-controlled, sequentially addressed memory; and

the pumping control also includes an adjustable clock connected to the memory for adjusting the memory access rate.

7. A heart assist device as defined in claim 1 wherein

the pumping control means includes:

pressure responsive means for controlling the expansion of the pumping chamber at a rate establishing a programmed pressure at the ventricle discharge during systole; and

the means for detecting and storing includes memory means for recording the chamber expansion as a function of time.

8. A heart assist device as in claim 7 wherein:

the blood pumping means includes a displaceable piston connected with the pump chamber for causing chamber expansion and contraction;

the pressure responsive means comprises a closed loop servomechanism connected with the piston to control the piston displacement; and

the means for detecting and storing includes a pressure transducer sensing ventricle discharge pressure and providing a pressure signal as an input to the servomechanism.

9. A heart assist device as in claim 7 wherein:

the means for regulating the expulsion of blood from the pumping chamber also includes the closed loop servomechanism connected with the piston in the pumping means.

10. A heart assist device as defined in claim 9 wherein:

the control means includes switching means operated in synchronism with the heart cycle for connecting the input of the servomechanism alternately to receive as inputs the pressure transducer signal and the stored blood flow waveform.

11. A heart assist as defined in claim 1 further including in the pumping control means;

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an autonomous pump control having a waveform generator providing a predetermined flow waveform for regulating the pumping means independently of the heart pulsations; and

discriminator means responsive to systolic pressure for energizing the autonomous pump control in the presence of severely arrhythmic heart pulsations.

12. A heart assist device as defined in claim 1 wherein:

the pump control means includes programmed means defining the programmed systolic pressure as a constant pressure level throughout the systolic period.

13. A heart assist device as defined in claim 1 wherein:

the pump control means includes programmed means defining the programmed systolic pressure as a variable pressure waveform during the systolic period.

14. A heart assist device as defined in claim 13 wherein:

the programmed means includes an adjustable time-base generator responsive to a heart function for producing the variable pressure waveform in periods of time dependent upon the heart function.

15. A method of assisting the heart to produce pulsatile blood flow in the vascular system of the body with the blood flow waveform duplicating that of the heart comprising:

maintaining a programmed pressure at the ventricle discharge of the heart during systole;

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detecting the blood flow waveform from the heart while the programmed pressure is maintained; recording the blood flow waveform from the heart as the waveform is detected; and

pumping blood into the vascular system in a controlled manner to duplicate the recorded blood flow waveform.

16. The method of assisting the heart as in claim 15 wherein:

the step of pumping includes the steps of retrieving the recorded flow waveform and driving a blood pump in accordance with the retrieved waveform.

17. The method of assisting the heart as in claim 15 wherein:

the detecting step includes receiving a volume of blood equal to that discharged by the ventricle during systole in a chamber and wherein,

the step of pumping comprises expelling the received volume of blood from the chamber during diastole.

18. The method of assisting the heart as defined in claim 15 wherein:

the step of pumping is performed during the diastole immediately following the systole in which the blood flow waveform was detected.

19. The method of assisting the heart as defined in claim 15 including the step of:

synchronizing the step of pumping with the systolic and diastolic periods of the heart by sensing the blood pressure emanating from the ventricle.

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