

March 4, 1969

W. J. FLANAGAN ET AL

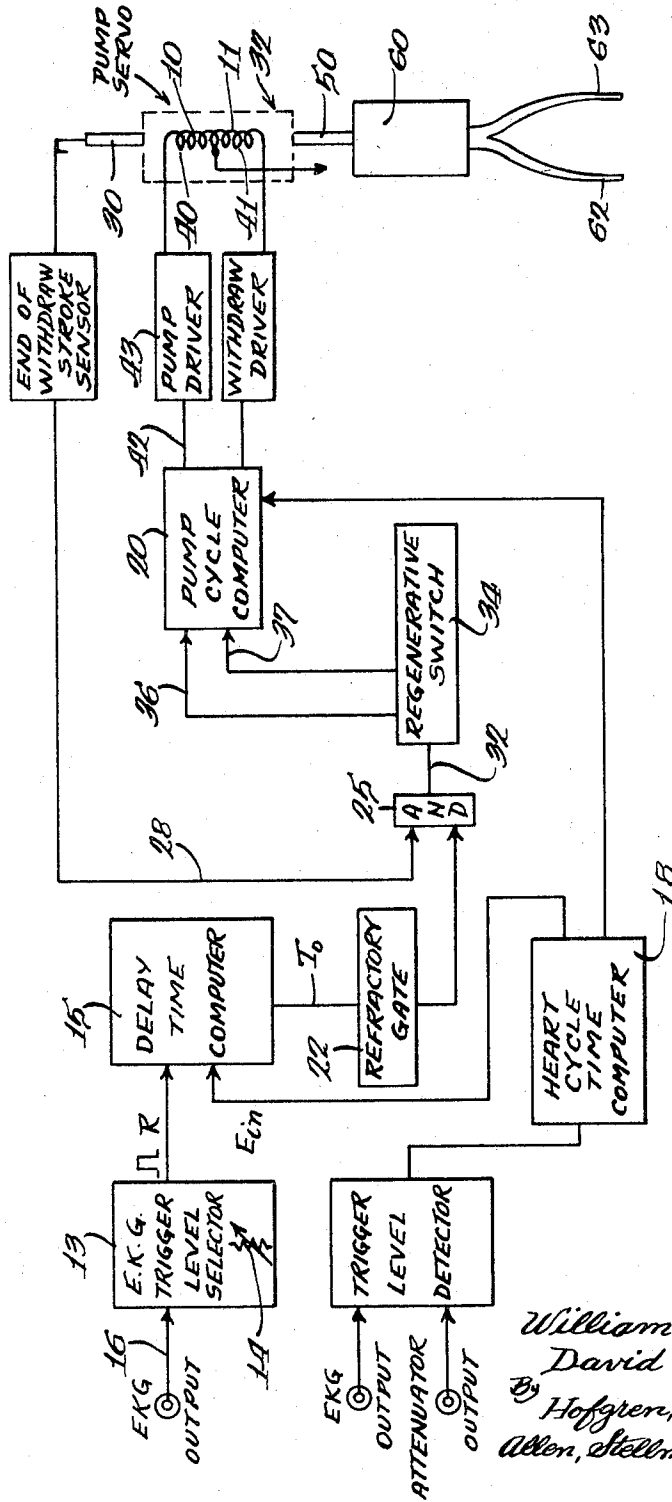
3,430,624

DELAY TIME COMPUTER FOR HEART PUMP SYSTEM

Filed Sept. 7, 1966

Sheet 1 of 3

Fig. 1.



Inventors:
 William J. Flanagan
 David Q. Lee
 By Hofgren, Wegner,
 Allen, Stellman & McCord
 Attys

March 4, 1969

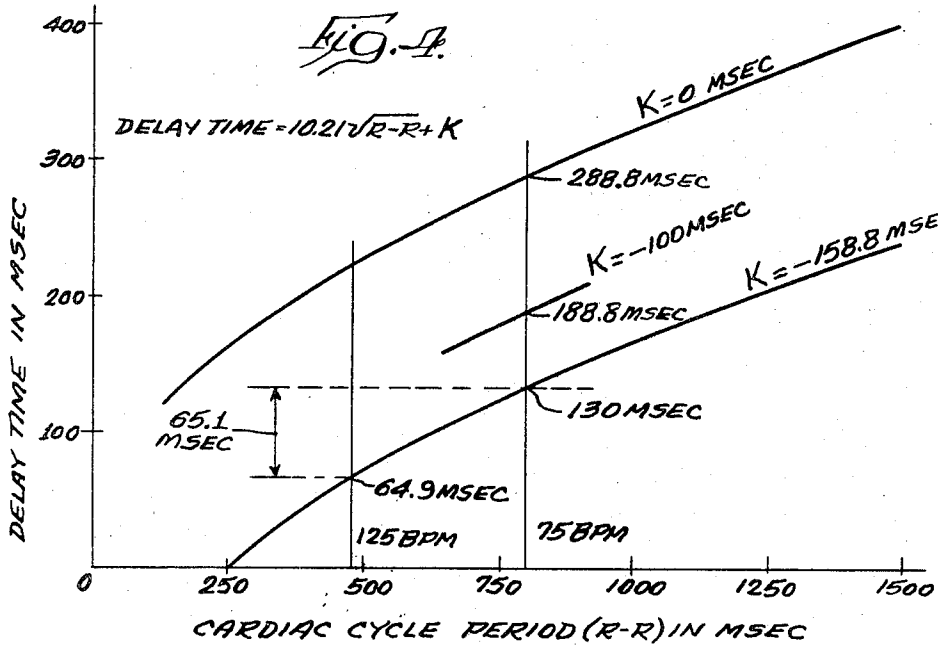
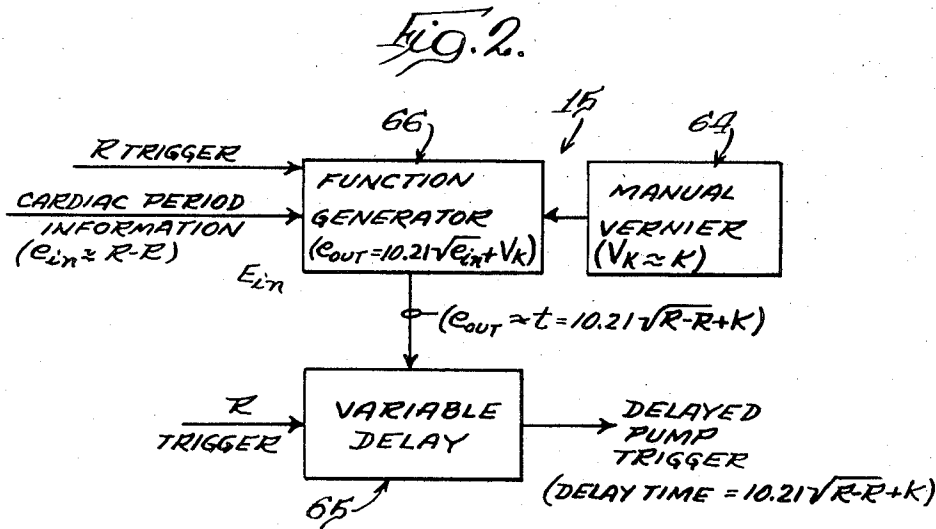
W. J. FLANAGAN ET AL

3,430,624

DELAY TIME COMPUTER FOR HEART PUMP SYSTEM

Filed Sept. 7, 1966

Sheet 2 of 3



March 4, 1969

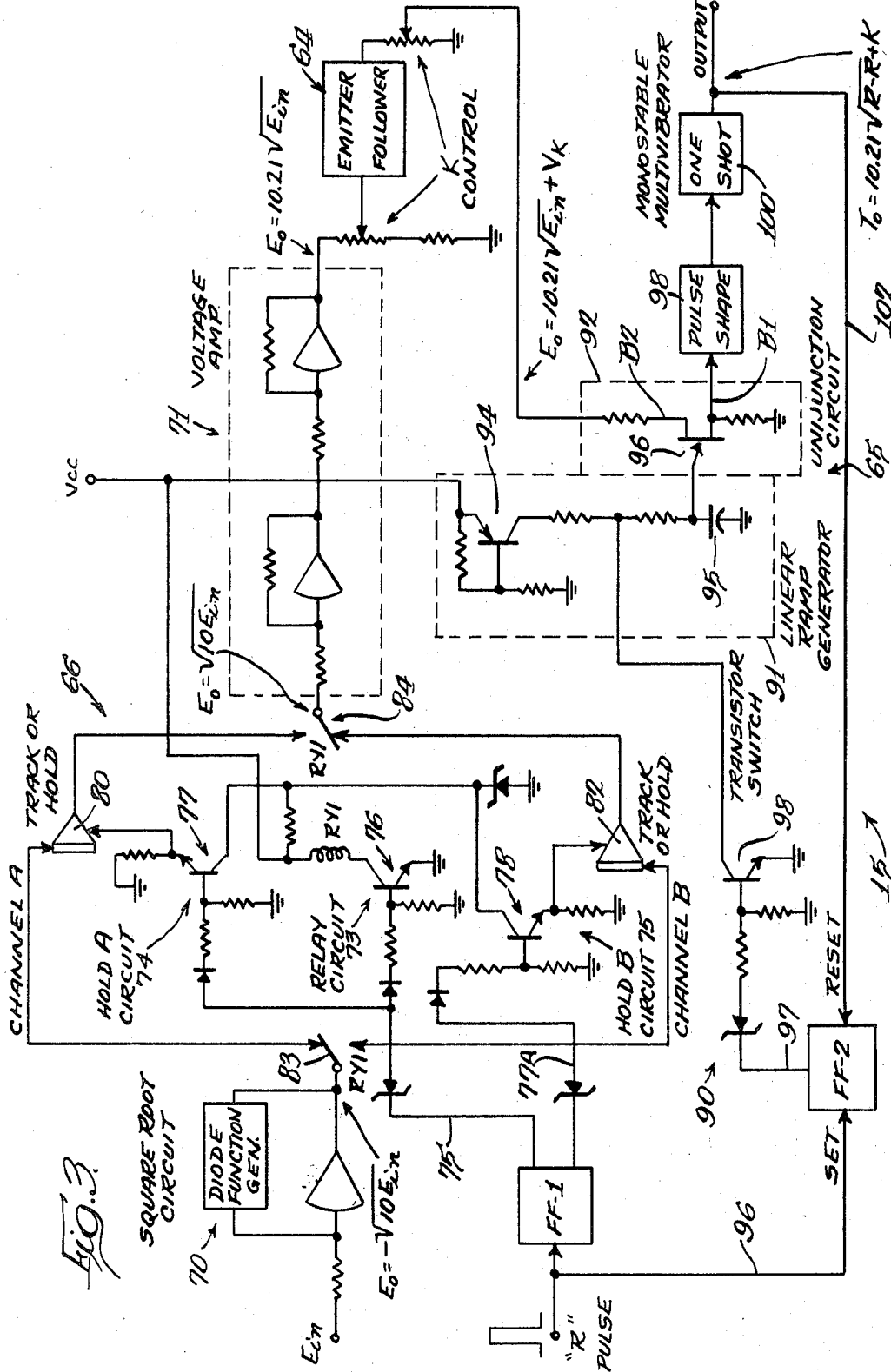
W. J. FLANAGAN ET AL

3,430,624

DELAY TIME COMPUTER FOR HEART PUMP SYSTEM

Filed Sept. 7, 1966

Sheet 3 of 3



1

3,430,624

DELAY TIME COMPUTER FOR HEART
PUMP SYSTEM

William J. Flanagan, Denver, Colo., and David Q. Lee,
Rockford, Ill., assignors, by mesne assignments, to
United Aircraft Corporation, a corporation of Del-
aware

Filed Sept. 7, 1966, Ser. No. 577,680

U.S. Cl. 128—1

Int. Cl. A61m 5/14; A61h 31/00

9 Claims

ABSTRACT OF THE DISCLOSURE

A heart pump system includes a triggered function generator for generating a variable delay which defines the time that a heart pump stroke should be delayed from the R wave of a patient's EKG waveform. The delayed time is computed from the function $10.21 \sqrt{R-R} + K$, where $R-R$ is the cardiac period, and K is a manually set constant. The system includes a two-channel cycle time computer for counting time between R waves, in each of two channels, alternatively. The cycle time computer controls a pump cycle computer along with the output of the delayed time computer. A withdraw stroke sensor prevents the delay time computer from operating the pump cycle computer sporadically, by means of a gate. The pump cycle computer is controlled by a regenerative switch to operate the pumped stroke driver of a blood pump during one portion of the cycle, and operate the withdraw stroke driver of the blood pump in another part of the cycle.

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

It relates to an improvement over the heart pump system shown in the copending application of Merrill G. Chesnut et al., Ser. No. 406,722, filed Oct. 27, 1964, and assigned to the assignee of the present invention. This prior system has the basic objective of reducing 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 pressure 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 and has been found to be in what is described as the post-systolic period.

This prior system includes a reciprocating blood pump connected in closed circuit fashion to a single or double catheter adapted to be inserted into the patient's femoral arteries. The cycle of the reciprocating 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 of the patient's natural heart 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 amount for vapor pressure, and therefore, there is a certain maximum rate at which blood can be removed from the vascular tree through a catheter

2

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 the 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 above mentioned prior 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 device described in the above application in response to the selection of a lower than maximum volume automatically adjusts 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 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.

In addition to automatically varying the above pump cycle parameters, this prior 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. With normal variations in heart rate the device has no effect on the volume of blood pumped. However, when the heart rate varies widely 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 compatible with the maximum withdrawal and pump rates so that the pumping cycle equals the patient's heart cycle time.

The above described system, and other heart pump systems known in the prior art have what may be termed as a fixed delay time. The delay time may be defined as that interval of time between a selected portion of the "R" wave of the patient's EKG waveform (which is used as the input parameter to the system) and the actual initiation of the pumping cycle. This delay time is extremely important to achieve proper phasing of the pump with the patient's natural heart action. It has been determined physiologically that a phase relationship exists 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 systolic period, and 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 with the withdrawal phase continuing until the peak of the next intraventricular waveform at which time another pumping or push phase begins in response to another triggering signal.

It is apparent from the above that the proper phasing of the pumping cycle with the cardiac cycle is dependent to a large extent upon the time between the selected portion of the R wave of the patient's EKG waveform and the peak of the intraventricular waveform. However,

the duration of the intraventricular waveform has been found to vary as a function of heart rate, and therefore, the delay required for proper phasing should also vary. Prior known systems are not capable of any automatic variation in this delay time.

As a result of physiological experimentation now of general knowledge, it has been determined that the variation in duration of the intraventricular waveform with the heart rate can be predicted with some confidence. This experimentation has indicated that the $Q-II-A$ interval between the onset of the electrocardiogram's QRS complex and the onset of the second heart sound of aortic origin may be approximated by the equation $Q-II-A = 10.21\sqrt{R-R} + K$, where $R-R$ is the cardiac cycle period in milliseconds, and K is a constant number of milliseconds for a specific individual.

Since the pump trigger pulse is initiated by the R portion of the patient's EKG wave, which bears a relatively fixed relationship to the onset of the $Q-R-S$ complex, and since the desired arrival time of the pump pulse at or after the peak of the intraventricular waveform is in the close vicinity of aortic incisura, which is intimately associated with the second heart sound of aortic origin, proper phasing of the pump pulse with heart rate variations may be achieved by variation of the pump trigger delay directly with the function $10.21\sqrt{R-R}$.

It is therefore a primary object of the present invention to provide a new and improved heart pump system of the type having each pumping cycle phased with respect to a sensed physiological parameter of the patient with means for automatically varying the delay of the pumping cycle with respect to the sensed parameter.

Another object of the present invention is to provide a new and improved heart pump system of the type described above which computes in response to changes in the patient's heart rate the proper delay of each pumping cycle with respect to the QRS complex of the patient's EKG waveform.

A further object of the present invention is to provide a delay time computer circuit for a heart pump of the type described above having a dual channel circuit which computes a signal representing the desired delay time in one channel while reading out of the other channel during one heart cycle and thereafter reverses so that on the next heart cycle the first channel will be read out and the second channel will compute a new delay time so that the circuit has a memory function.

A still further object of the present invention is to provide a heart pumping system of the type described above with a delay time computer circuit which converts a voltage representing the computed function into a time base with a resettable linear ramp generator and a uni-junction transistor circuit.

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

FIGURE 1 is a block diagram of a heart pump system according to the present invention;

FIGURE 2 is a block diagram of the automatic delay time computer circuit shown in FIGURE 1;

FIGURE 3 is a schematic drawing of the delay time computer circuit; and

FIGURE 4 is a graph showing the computed relationship between delay time and the cardiac cycle period.

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.

Referring now to FIGURE 1, a block diagram of a heart pumping system is shown generally similar to that

disclosed in the above mentioned copending application of Chesnut et al. For this reason only the general function and operation of the overall system will be described in order to clearly illustrate the environment for the present delay time computer circuitry, but it should be understood that reference should be made to the copending application of Chesnut et al. for the details of components.

As shown, the circuit is generally adapted to receive as an input signal the patient's EKG waveform, delay the signal, and after various computer functions drive the pump and withdraw servo coils 10 and 11 in an associated pump servo motor. A triggering circuit is provided effective to develop and delay a triggering pulse for a reciprocating pump and delay the triggering pulse from a selected trigger level portion of the QRS segment of the patient's EKG waveform. For this purpose, a trigger level selector 13 is connected to receive the patient's EKG waveform from a conventional electrocardiogram through line 16. Suitable provision may be made for driving an oscilloscope from the EKG signal so that the patient's waveform may be viewed during the use of the heart pumping system by the surgeon or technician. The trigger level selector 13 includes a manually adjustable trigger level potentiometer 14 to select the proper or desired triggering level on the QRS waveform.

As noted in the above mentioned copending application, pump cycle triggering may be alternatively provided by a pacemaker, or by a manual initiation switch.

The undelayed triggering pulse (synchronous with the selected portion of the patient's R wave) from the trigger level selector 13 is delayed by a delay time computer circuit 15 so that the actual triggering pulse lags the selected portion of the patient's EKG waveform. In addition to receiving the triggering signal as an input, the delay time computer receives a signal, designated E_{in} from a heart cycle time computer 18.

The heart cycle time computer 18 may be similar to the digital cardiac cycle counting circuit shown in the above copending application, which circuit responds to an arterial pump pressure signal, or the patient's EKG signal, to digitally count in either of two channels the time period between arterial pulses or R waves depending on whether pressure or EKG is used as the input parameter. The digital counting circuit provides a linear output voltage with time proportional to the cardiac interval. This is represented by E_{in} in FIG. 1. The counted heart cycle time from the computer 18 is also applied to a pump cycle computer 20 as input parameter for determining the duration, speed, and magnitude of each pumping cycle.

The output from the delay time computer 15, which is properly phased with respect to the trigger signals from the trigger level selector 13, triggers a refractory gate 22 which produces an 80 millisecond pulse when triggered.

The pulse from the refractory gate 22 comprises one of two inputs to AND gate 25. AND gate 25 prevents any erroneous triggering signal from the refractory gate 22 from initiating a pumping cycle. That is, if the triggering pulse from the refractory gate 22 is conducted to the AND gate 25 prior to the receipt of a signal from the other input to AND gate 25, i.e., line 28, which indicates completion of the withdrawal stroke, the 80 millisecond pulse will be held by the AND gate for 80 milliseconds and if line 28 is not energized by that time, the triggering pulse will be dropped. Line 28 is energized by suitable transducer 30 connected to pump servo mechanism 32 indicating that the withdrawal stroke of the pump has been completed.

A pulse in line 32 from AND gate 25 initiates the push phase of the pumping cycle by turning on a regenerative switch 34. The presence of the high voltage in line 32 turns the first stage of the regenerative switch on and the second stage off thereby energizing line 36 and deenergizing line 37. Line 36 energizes a pump servo coil 40 through the pump cycle computer 20 (volume and rate computer circuitry); while the energization of line 37 energizes the

time represented by the time between initiation of a ramp voltage and the firing of the unijunction transistor 96.

In an exemplary operation of the present device, and viewing the graph of FIG. 4, assume that a patient's heart rate is 75 beats per minute (a cardiac cycle period of 800 milliseconds), and that the initial setting of the manual vernier 64 corresponds to a K of minus 100 milliseconds. The function generator 66 will then compute a time delay of 188.8 milliseconds for the variable delay circuit 65. Further assume that for this particular patient and heart rate the proper pump trigger delay is 130 milliseconds. When the pump is activated, the operator will observe that the intraventricular waveform display on an oscilloscope indicates late pump phasing by 58.8 milliseconds. He, therefore, would then adjust the manual vernier 64 for proper pump phasing and thereby automatically adjusting K to the proper value of minus 158.8 milliseconds for a 130 millisecond delay at 75 beats per minute. If the patient's heart rate should then change to, for example, 125 beats per minute (a cardiac period of 480 milliseconds) the position of the heart pressure waves dichrotic notch will advance in time by 65.1 milliseconds. The function generator 63, however, will automatically compute the proper delay time as follows:

$$\text{Delay time} = 10.21\sqrt{480} - 158.8 = 64.9$$

milliseconds which of course is 65.1 milliseconds less than the original delay of 130 milliseconds.

We claim:

1. In a heart pump system, the combination comprising: pump means having pumping cycles, means connected to the pump adapted to convey fluid relative to the patient's circulatory system, control means for said pump means including means for initiating the pumping cycles in timed relationship with a physiological parameter, said means for initiating pumping cycles including means for delaying the initiation of a pumping cycle relative to a portion of the physiological parameter, and means for automatically varying the time of said delay with variations in said physiological parameter.

2. In a heart pump system, the combination comprising: a pump having pumping cycles, means connecting the pump for conveying fluid relative to the patient's circulatory system, control means for said pump including means for initiating each pumping cycle in timed relationship with one of the patient's cyclical circulatory parameters, means responsive to the period of said cyclical parameter for computing the duration of each pumping cycle, control means responsive to said computing means for varying each pumping cycle, means for delaying each pumping cycle with respect to a selected portion of said cyclical parameter, means for computing the proper time of said delay with variations in the period of said cyclical parameter, and control means responsive to said means for computing delay for varying said delay time, whereby each pumping cycle will be initiated at a predetermined point relative to the patient's intraventricular waveform regardless of the repetition rate of said cyclical parameter.

3. The combination defined in claim 2, wherein said means for initiating each pumping cycle includes means for receiving a signal representing the patient's EKG waveform, means for selecting a portion of the R wave thereof and deriving triggering signals therefrom, said means for delaying being responsive to said triggering signals, means for computing the time duration of one of the patient's cyclical circulatory parameters and deriving a signal representing the same to determine the cardiac period, said delay computer being responsive to said signal representing the time duration of said circulatory parameter for deriving a signal as a nonlinear function thereof representing the desired variation in delay time with cardiac period, said means for delaying being responsive to said

delay computer for producing pump triggering signals delayed from said "R" wave.

4. The combination defined in claim 3, wherein said delay computer includes a function generator for generating the nonlinear function as a function of the duration of the intraventricular waveform with cardiac cycle time.

5. The combination as defined in claim 4, wherein said function generator includes means to generate a signal proportional to the function $X\sqrt{R-R}+K$, where X and K are constants and R-R is the cardiac period.

6. The combination as defined in claim 5 wherein parameters of said function generator are chosen so as to derive a signal proportional to a function in which said constant X is approximately 10.21 so that each pumping cycle is initiated approximately at aortic valve closure.

7. The combination defined in claim 4 wherein said delay computer includes a function generator responsive to said signal representing the cardiac period, two selectively operable track and hold channels for following and storing the output of said function generator, sequencing means for alternately activating said track and hold channels so that one channel and the other holds during each cardiac period, said sequencing means effecting alternate readout of said channels, manually variable means for adding a signal to the output of said channels to apply a patient constant factor to said delay time, and means responsive to said adding means for converting its output signal to a time base, said converting means being activated by said triggering signals so that the pump triggering signals are delayed therefrom.

8. In a heart pump system of the type in which each pumping cycle is initiated by a signal derived from the patient's EKG waveform, a computing circuit for properly delaying triggering of the pumping cycle from a predetermined portion of the EKG waveform to compensate for variations in the duration of the intraventricular waveform with cardiac rate, comprising: means for receiving a signal representing the cardiac period, means for receiving a triggering signal representing a selected portion of the patient's EKG waveform, means responsive to said receiving means for the cardiac period signal for deriving a signal having a nonlinear relationship with said cardiac period signal, and time conversion means responsive to said derived signal and said triggering signal for producing a pump triggering signal delayed from said triggering signal in accordance with said nonlinear relationship.

9. The combination as defined in claim 8, wherein said means for deriving said nonlinear signal includes a square root circuit, two hold and track channels, means responsive to said triggering signal receiving means for alternately connecting said channels to said square root circuit, amplifier means alternately connectable with said track and hold channels for amplifying the output therefrom, variable emitter follower means for adding a fixed signal to the output of said amplifying means, said time conversion means including a unijunction circuit responsive to said emitter follower, a resettable linear ramp generator for firing said unijunction circuit at a time determined by the emitter follower means, and means responsive to the output of said unijunction circuit and said triggering signal receiving means for resetting said ramp generator.

References Cited

UNITED STATES PATENTS

3,099,260	7/1963	Birtwell	128—1
3,266,487	8/1966	Watkins et al.	128—1

DALTON L. TRULUCK, *Primary Examiner.*

U.S. Cl. X.R.

128—214

withdrawal servo coil 41 through the same volume and rate computer circuit.

A pump phase signal, modulated by the volume and rate computer circuitry in line 42, drives the pump phase driver 43. The magnitude of the current in line 42 determines the bias of the pump driver 43 and thereby the magnitude of excitation of the pump servo coil 40. The rate of travel of the pump actuator shaft 50 is directly proportional to the magnitude of the current in the coils 40 and 41.

Pump 60 may be of the reciprocating piston type and is connected to deliver fluid in both directions through catheters 62 and 63. For arterio-arterial heart assist the catheters 62 and 63 are inserted into the patient's femoral arteries. Then fluid is delivered to the aorta and withdrawn therefrom in the above described phase relationship with the patient's natural cardiac action.

As shown in FIG. 2, the delay time computer 15 consists generally of a function generator 66 for deriving an output voltage from the input voltage E_{in} (heart cycle period), a manual vernier 64 for adding a patient constant voltage to the voltage derived by the function generator 66, and a variable delay circuit 65 which converts the output voltage from the function generator to a time base relative to the trigger pulses R from the trigger level selector 13.

As noted above, the desired delay time between the onset of the QRS complex of the patient's EKG waveform and the peak of the intraventricular wave where the pump cycle is to be initiated for proper phasing is defined by the equation $10.21\sqrt{R-R+K}$, where $R-R$ is the cardiac period in milliseconds, and K is a constant number of milliseconds for a specific patient.

Referring to FIG. 3 for a more detailed description of the delay time computer circuit 15, the equation for the desired delay time $T_D = 10.21\sqrt{R-R+K}$ is solved electronically by converting K and the R to R period to a function of voltage magnitude. Toward this end, a square root circuit 70 is provided consisting of an operational amplifier with a diode squaring module as the feedback element. With E_{in} (the applied voltage from the heart cycle time computer 18 representing the cardiac interval) the square root circuit 70 is constructed to provide an output $E_0 = \sqrt{10E_{in}}$.

The function generator 66 consists generally of the square root circuit 70, track and hold channel A and channel B, and voltage amplifier 71. The dual channels A and B are necessary to provide a memory capability so that during one heart cycle channel A is computing the voltage magnitude from the square root module 70 and channel B is reading out into the voltage amplifier 71, and during the next heart cycle channel A will be read out into the voltage amplifier 71 and channel B will compute the voltage magnitude from the square root circuit 70. To effect this timing of the operation of channels A and B a flip-flop FF-1 is provided, which may be a bistable multivibrator, for driving a relay circuit 73 and hold circuits 74 and 75.

When the flip-flop FF-1 is turned on by an R pulse from the trigger level selector circuit 13, the voltage in line 77A rises to a higher potential than line 75, turning transistors 76 and 77 "off" and transistor 78 "on." Transistor 77 places track or hold module 80 in channel A in its track state preparatory to following the output signal from the square root circuit 70. Transistor 78, now "on," places track or hold module 82 in its hold state so that it stores the signal computed from the square root generator circuit 70 on the previous cycle. The track and hold modules 80 and 82 are of conventional design as will be apparent to those skilled in this art.

The transistor 76 in the relay circuit 73 being "off" de-energizes relay RY1 moving contacts 83 to connect channel A with the square root circuit 70 and moving contacts 84 to connect channel B with the amplifier 71. In this man-

ner, during the heart cycle under consideration, channel A tracks the output voltage from the square root circuit 70 and channel B, which stores the output from the square root circuit on the previous cycle is read out into the operational amplifier 71.

The next succeeding R pulse from the EKG trigger level selector 13 changes the state of flip-flop FF-1 raising line 75 to a higher potential than line 77A, thereby turning "on" transistors 76 and 77 and turning "off" transistor 78. With transistor 77 "on," the track or hold module 80 changes to its hold state, storing the output from the square root circuit 70, and transistor 76 energizes relay RY-1 so its contacts 83 connect the square root generator 70 to channel B and its contacts 84 connect channel A to the amplifier 71. During this heart cycle channel A is read out into the amplifier 71 and channel B tracks the voltage output from the square root circuit 70.

The voltage amplifier 71 amplifies the voltage magnitude from the track or hold modules, and produces an output in accordance with the equation $E_0 = 10.21\sqrt{E_{in}}$.

The manual vernier circuit 64 consists of an adjustable emitter follower circuit arranged so that the voltage V_k is added to the voltage from the operational amplifier 71 as desired by the operator.

The conversion of the output voltage from the emitter follower 64 into a period of time is accomplished by the variable delay circuit 65 which includes a switching circuit 90, a linear ramp generator 91, and a unijunction circuit 92.

A transistor 94 in the linear ramp generator circuit 91 charges a capacitor 95 linearly, which capacitor is connected to the emitter of a unijunction transistor 96. When the ramp voltage across capacitor 95 exceeds a certain fraction (η) of the voltage across the bases B2 and B1, the unijunction transistor fires. Since the base B2 voltage of the unijunction transistor 96 is the voltage which has been computed according to the equation $10.21\sqrt{E_{in}} + V_k$, the unijunction transistor 96 fires when the voltage at the emitter exceeds a value which is proportional to the instantaneous computed voltage on B2.

The transistor switch circuit 90 is provided for synchronizing the ramp voltage in the linear ramp generator with each R pulse. Toward this end the flip-flop FF-2, which may be a bistable multivibrator, is connected to be set by an R pulse on line 96, lowering the potential on line 97 to turn off transistor 98. When transistor 98 is turned off, i.e., nonconductive, capacitor 95 is permitted to charge until the ramp voltage formed thereacross exceeds a fraction η of the instantaneous base voltage across the unijunction transistor 96, at which time an output pulse occurs at the base B1 of the unijunction transistor 96. This pulse is shaped by a pulse shaper 98 and coupled to a monostable multivibrator 100 thereby producing a properly delayed pump cycle triggering pulse to be applied to the refractory gate 22 for initiation of the push phase of the cycle of pump 60.

The output of the monostable multivibrator 100 is also used for resetting the flip-flop FF-2 (line 102). The appearance of the output pulse from multivibrator 100 resets the flip-flop FF-2, raising the potential on line 97, and driving the transistor 98 into saturation. This prevents the linear ramp generator from charging capacitor 95 until the receipt of another triggering pulse on line 96. When the next triggering pulse on line 96 sets flip-flop FF-2 and turns transistor switch 98 off, capacitor 95 will again begin charging to provide a ramp voltage at the emitter of transistor 96, and another cycle is repeated.

Thus, it is apparent that the variable delay circuit 65 converts a D.C. voltage representing the desired time delay from the emitter follower 64 into a pulse delayed from the triggering R pulse by a desired time, by initiating a ramp voltage with each R pulse at the emitter of a unijunction transistor and by varying the base voltage of the unijunction transistor with the voltage representing the desired delay time, so that the latter voltage is converted into a