

- [54] **CARDIAC PROGRAMMER FOR A CORONARY BLOOD PUMP**
[75] Inventor: Charles W. Ragsdale, Laramie, Wyo.
[73] Assignee: The United States of America as represented by the Secretary of the Army
[22] Filed: Sept. 9, 1971
[21] Appl. No.: 179,122
[52] U.S. Cl. 128/1 D, 128/2.06 R
[51] Int. Cl. A61b 5/04
[58] Field of Search 128/1 D, 1 R, 2.06 A, 128/2.06 B, 2.06 R, 2.06 F, 2.05 T

[56] **References Cited**
UNITED STATES PATENTS

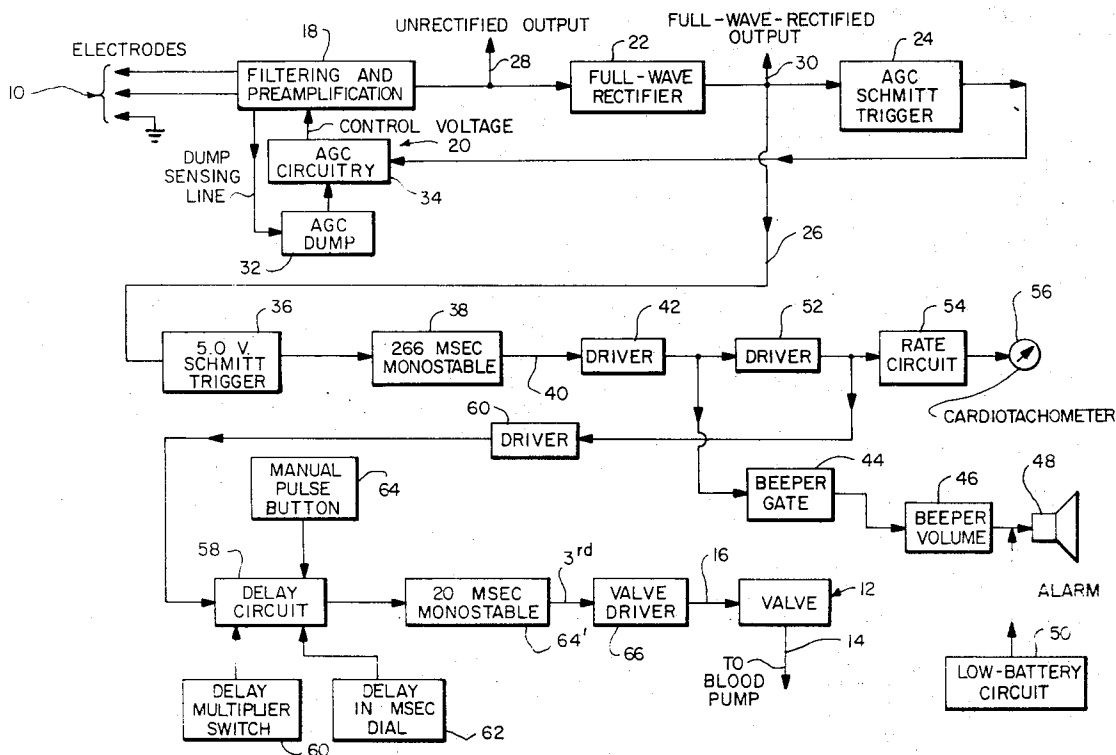
3,465,746	9/1969	Guarino	128/1 D
3,599,628	8/1971	Abbenante et al.	128/2.06 F
3,144,019	8/1964	Haber	128/2.06 A
3,498,288	3/1970	Max et al.	128/2.06 B
3,129,704	4/1964	Burt, Jr.	128/2.06 R
3,266,487	8/1966	Watkins et al.	128/1 D

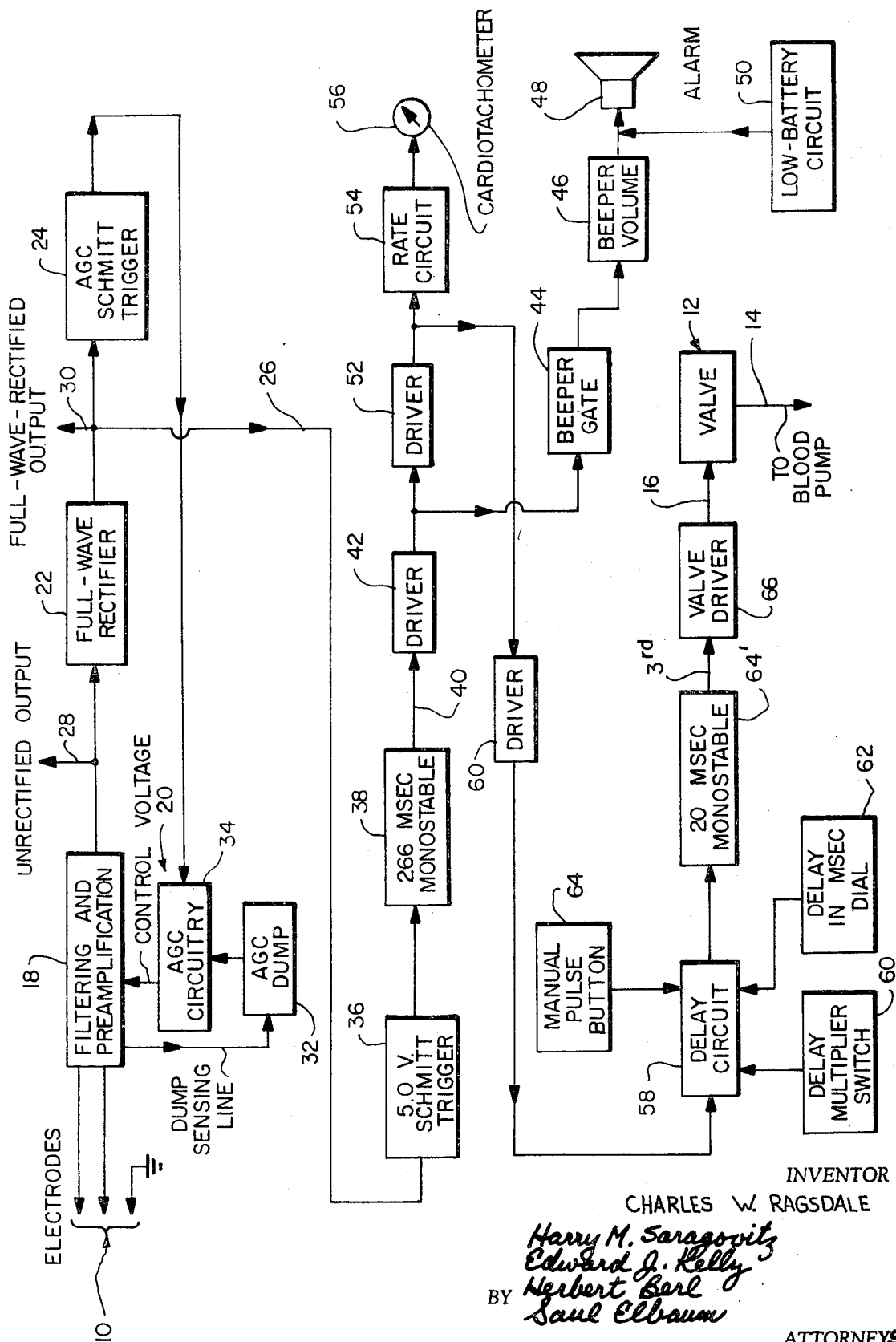
Primary Examiner—William E. Kamm
Attorney—Harry M. Saragovitz, Edward J. Kelly and Herbert Berl et al.

[57] **ABSTRACT**

A programmer system is disclosed for driving a complementary coronary blood pump disposed at a non-thoracic location in delayed synchronism with the electrocardiogram waveform of a subject. Selected characteristics of the electrocardiogram signal are utilized to provide a control pulse, which control pulse actuates a valve mechanism to effect operation of the blood pump. The control pulse is generated by the system after a predetermined time period from the occurrence of the selected electrocardiogram characteristics, the time delay being substantially equal to the propagation time of a coronary ventricular pressure pulse from the thorax region of the subject to the remote blood pump location. In this manner, synchronous cardiac assistance can be effected at any suitable point in the arterial system of the subject.

5 Claims, 1 Drawing Figure





INVENTOR

CHARLES W. RAGSDALE

BY *Harry M. Saragovitz*
Edward J. Kelly
Herbert Berl
Saul Elbaum

ATTORNEYS

CARDIAC PROGRAMMER FOR A CORONARY BLOOD PUMP

The invention described herein may be manufactured, used and licensed by or for the United States Government for governmental purposes without the payment to me of any royalty thereon.

This invention generally relates to the medical arts and particularly concerns a programmer system for use with a complementary coronary blood pump so as to effect synchronous cardiac assistance.

As is known in the art, synchronous cardiac assistance is a technique wherein the heart of a subject is relieved of at least a portion of its work load by means of an external blood pump, or complementary coronary blood pump, which pump operates in synchronism, though not necessarily concurrently, with the heart itself. By so relieving at least a portion of the work requirement of the heart, recovery of the heart from various conditions such as myocardial infarction is facilitated.

The manner in which synchronous cardiac assistance is effected has taken a variety of forms in the prior art. For example, a counterpulsation or post-systolic or diastolic augmentation mode can be achieved by removing blood from some portion of the arterial system of the subject during one part of the cardiac cycle and then returning blood to the arterial system during another part of the cardiac cycle. The reduction of work load on the heart with synchronous cardiac assistance occurring in this mode is achieved by reducing the pressure against which the heart pumps, this pressure being known as the systolic pressure. For example, the blood pump could be connected to the aorta, the blood removed just at the time as the heart ejects or pumps the blood so as to reduce systolic pressure, the pump returning the blood after the aortic valve closes, i.e. when the diastolic period begins. Not only would the systolic pressure be reduced in this fashion, but the diastolic or post-systolic pressure would be increased, this increase being utilized to complement the normal coronary blood flow. As will be appreciated, however, directly connecting the external blood pump to the aorta usually requires an opening of the chest cavity, i.e. a thoracotomy, which may not always be feasible particularly as concerns a patient or subject who is already a poor medical risk due to myocardial damage or other similar factors.

The instant invention contemplates to provide a cardiac programmer system which can effect synchronous cardiac assistance and particularly effect counterpulsation by removing and returning blood at some other point in the arterial system of the subject which requires less surgery to reach than is the case in the thorax region.

To achieve this object, the instant inventive system contemplates to compensate and adjust for the propagation delay time of the ventricular pressure pulse from the thorax region of the patient to the remote location in the arterial system of the subject at which the external blood pump is placed. In this respect, the instant invention takes into account a propagation velocity for the pressure pulse of about 6M/sec in the case of young adults and a velocity of about 8M/sec in aged persons and serves to delay operation of the external pump with the delay adjustment being made with reference to the QRS complex of the electrocardiogram of the subject,

which complex would depict the time of ventricular contraction.

If the triggering or actuation of the external complementary coronary blood pump is delayed for the proper amount of time after a QRS complex occurs, the negative pressure pulse associated with the external pumps removal of blood from the system will arrive at the real heart, though in a later cycle, when the heart is ejecting blood to thereby reduce the work load of the heart. Correct timing adjustment of the system of the instant invention can be ascertained by means of monitoring the aortic pressure utilizing a catheter. Additionally, the positive pressure pulse associated with operation of the external blood pump and specifically return of blood to the system would thereby reach the real heart during the time that the aortic valve is closed. In this respect, it has been found that the time delay of the cardiac programmer system can be adjusted such that the arrival of the positive pressure pulse occurs just after the dicrotic notch in the electrocardiogram, i.e. a slight pressure increase and then decrease in the falling phase of the aortic pressure curve, which increase indicates that the aortic valve has closed.

Utilizing the above principles and with particular consideration being given to the controlled time-delayed operation of the external blood pump, attachment of the external pump to the subject can be effected at such remote arterial locations such as the iliac or femoral arteries in both legs of the patient or subject. Actual attachment of the external blood pump, as is known, can be effected by means of a single cannula or tapered tube, which cannula is inserted into one of the arteries. Alternatively, a double cannula may be utilized which is inserted in an artery in the right and in the left legs. As will be appreciated, such remote sites require relatively little surgery and the arteries of interest can quickly be exposed with relative ease by competent medical personnel.

Other, more specific objectives of the instant invention are also contemplated, such objectives including the provision of a cardiac programmer system for driving a complementary coronary blood pump in the above-described delayed synchronous fashion, which system is physically small and thus portable and which is constructed so as to provide accurate operation over relatively large temperature ranges such as from about -40°C. to $+54.4^{\circ}\text{C.}$

Yet another object of the instant invention concerns the provision of a cardiac programmer system of the type described wherein the time delay operation is adjustable and can range from about 10 to 2,000 msec, or, alternatively, can be operated with zero delay if desired.

Yet another object of the instant invention concerns the provision of a cardiac programmer system of the type described wherein signal input protection against electric cautery and defibrillator signals is achieved.

A further object of the instant invention contemplates the provision of a cardiac programmer system which can operate on self-contained batteries, with the capability of recharging the batteries at either a trickle or a full-charge rate so as to thereby provide isolation and patient safety from perturbations appearing on conventional power lines.

Yet another object of the instant invention contemplates the provision of a cardiac programmer system wherein audible alarm means serve to indicate each

heart beat with a cardi tachometer utilized in conjunction therewith, the alarm means further serving to indicate low charge condition of the batteries.

A further objective of the instant invention concerns the provision of a cardiac programmer which is relatively inexpensive to manufacture and is easy to operate.

These objects as well as others which will become apparent as the description proceeds are implemented by the instant invention which, as aforesaid, comprises a cardiac programmer system for driving a complementary coronary blood pump disposed at a non-thoracic location in delayed synchronism with the electrocardiogram wave form of a patient or subject.

In the preferred inventive embodiment, electrode means are provided, these electrode means being adapted for connection to the subject so as to detect the electrocardiogram signal. Wave-shaping means are coupled to the electrode means for generating a control pulse in response to selected characteristics of the electrocardiogram signal, such as the occurrence of the QRS complex, the wave-shaping means including adjustable time delay means for the purpose of delaying generation of the control pulse for a predetermined time period following the occurrence of the selected electrocardiogram characteristics.

In the preferred inventive embodiment, the wave shaping means will be seen to include a filtering and clipping circuit for removing certain selected components of the electrocardiogram signal and for providing a first periodic signal of substantially constant peak amplitude in response to the electrocardiogram signal. The filtering and clipping circuit preferably comprises a filter and an automatic gain controlled preamplifier coupled to a rectifier, the output of the rectifier defining the first signal with a Schmitt trigger responding to the peak magnitude of the rectifier output, the Schmitt trigger being connected in a feedback loop to the automatic gain controlled preamplifier to thereby adjust the gain. With this circuitry, input protection is provided as above-discussed, and proper operation of the cardiac programmer system is assured through a wide range of input signal magnitudes.

The wave shaping means of the preferred inventive embodiment further includes a trigger circuit which responds to the first periodic signal generated by the filter and clipping circuit so as to provide a second periodic signal which has a preselected duration. The adjustable time delay means of the invention includes a timing circuit which is responsive to this second periodic signal so as to produce the control pulse above-discussed after an adjustable period of time.

This control pulse is then fed to a controllable valve means, such as a solenoid, which valve means is adapted for connection to the external blood pump. The valve means is responsive to and is actuated by the control pulse so as to effect operation of the external blood pump.

The time delay effected by the system, i.e. the delay between application of the control pulse to the blood pump controllable valve means and the occurrence of the selected QRS complex of the electrocardiogram assures that the complementary coronary blood pump operates in proper, though delayed, synchronism with the electrocardiogram wave form of the patient. As briefly mentioned at the outset of this specification, this controlled delay is preferably made substantially equal

to the propagation time of a coronary ventricular pressure pulse from the thorax region of the subject to the remote pump location in the arterial system of the subject.

The invention itself will be better understood and further advantageous features and operational advantages thereof will become apparent from the following detailed description of a preferred inventive embodiment, such description making reference to the appended sheet of drawings, wherein the single Figure schematically depicts an electrical block diagram of the novel circuitry of the instant invention.

Referring to the drawing, the cardiac programmer system therein disclosed will be seen to include electrode means generally designated 10 which are adapted for connection to a subject or patient so as to detect an electrocardiogram signal. The output from the electrode means 10 is sensed by a wave shaping means to be discussed in detail hereinbelow, which wave shaping means consistent with the objectives of the instant invention serves to generate a control pulse to a controllable valve means generally designated 12, the valve means 12 being responsive to and actuable by a control pulse applied thereto so as to effect operation of an external blood pump. In this respect, the output of valve means 12 which, in the preferred inventive embodiment is contemplated to comprise a solenoid valve, is indicated by reference numeral 14, this output leading to a non-illustrated external complementary coronary blood pump of conventional construction.

The control pulse which actuates the valve means is applied to an input 16 of the valve means 12 and, as aforesaid, is generated by the wave shaping means at a predetermined time period following the occurrence of selected electrocardiogram characteristics as sensed by the electrode means 10, these characteristics preferably though not necessarily comprising the so-called QRS complex.

The wave-shaping means of the instant invention structurally will be seen to comprise a filtering and preamplification device 18 having automatic gain control circuitry generally designated by reference numeral 20. High and low frequency filtering of the input signal produced by the electrode means 10 is achieved, preferably at $\frac{1}{2}$ power points at 75 and 3.5Hz, respectively, and with about a 60dB/decade roll-off above and below these points. The high-frequency filtering provided by the filter circuit of device 18 serves to reject 120Hz interference and some muscle potentials, while the low-frequency filtering rejects some slowly changing portions of the electrocardiogram such as S-T segments and some T-waves, as well as slow electrode potential shifts. The preamplifier circuit of the device 18 is constructed to provide input protection against defibrillator pulses, and the differential input contemplated serves to provide some rejection of such typically common-mode signals as 60 and 120Hz interference.

The output from the preamplification portion of the device 18 is full-wave rectified by the full-wave rectifier 22 so that the remainder of the cardiac programmer circuitry is relatively unaffected by input signal polarity changes. The output of the full-wave rectifier 22, which output will be defined as the "first signal" in the following description, is utilized to automatically control the gain of the preamplification portion of device 18.

In this respect, the output from the full-wave rectifier 22 is coupled to an automatic gain control Schmitt trig-

ger 24, device 24 changing state whenever the output from full-wave rectifier 22 exceeds about 6.0V in the preferred inventive embodiment. When the change in state occurs, the automatic gain control circuitry generally designated by reference numeral 20 causes the control voltage applied to the preamplification portion of device 18 to decrease linearly with time such as about 0.5 seconds maximum adjustment time, to thereby decrease the preamplifier gain. When the output from rectifier 22 drops below about 6.0 volts, the control voltage applied to the preamplification portion of device 18 linearly rises with time so as to increase preamplifier gain, this rise or adjustment time having about a 15 second maximum. The automatic control effected over the gain of the preamplifier serves to maintain the rectifier peak output relatively constant with respect to input signal changes. As stated, the rectifier output comprises a "first signal" on line 26. The adjustment is such that the preamplifier gain with respect to the programmer input signals is maintained in a 0.1 to 5.0 mV peak range. Furthermore, this initial filtering and preamplification circuitry contains protection against electric cautery and defibrillator signals having peaks in excess of $\pm 3,000V$.

For purposes of flexibility, both an unrectified output as well as the full-wave rectified output from the preamplification portion of device 18 can be utilized as indicated on lines 28 and 30, respectively, to supply signals to some non-illustrated external device.

The automatic gain control circuitry as above discussed incorporates an automatic gain control dump 32 coupled to the control circuitry per se indicated by reference numeral 34, the automatic gain control dump serving to reset the circuitry 34 so as to give maximum preamplifier gain about 2.0 seconds after an input signal from the electrodes 10 of over ± 5.0 mV peak has been removed. This feature of the instant invention reduces the long waiting time for preamplifier and automatic gain control readjustment that might occur after defibrillation, electrical cauterization, or electrode/battery test.

Conceptually, the above-discussed circuitry of the wave-shaping means of the instant invention can be considered to comprise a filtering and clipping circuit for removing selected components of the electrocardiogram signal and for providing a first periodic signal of substantially constant peak amplitude in response thereto. As described, the filtering and clipping circuitry comprises the filter and an automatic gain control preamplifier 18 coupled to the full-wave rectifier 22, the output 26 of the rectifier defining a "first signal," the filtering and clipping circuit further including the Schmitt trigger 24 responsive to the peak magnitude of the rectifier output, the Schmitt trigger 24 being connected in a feedback loop to the automatic gain control circuitry 20 of the preamplifier so as to adjust the gain.

Continuing, the wave-shaping means of the instant invention will further be seen to comprise a trigger circuit including a Schmitt trigger 36 and a monostable multi-vibrator 38, this trigger circuit being responsive to the first periodic signal on line 26 for providing a second periodic signal on line 40, this second periodic signal having a preselected pulse duration. The Schmitt trigger 36 serves to change state when the rectifier output or the "first signal" on line 26 exceeds approximately 5.0V in the preferred inventive embodiment.

This lower threshold allows some variation in the electrocardiogram or ECG amplitude with each cardiac cycle. Schmitt trigger 36 serves to trigger or actuate the monostable multi-vibrator 38 and cause same to emit a pulse of preferably 266msec duration. This particular pulse width has been found to allow maximum heart rates of 225 beats per minute to be individually indicated and further help the cardiac programmer of the instant invention to reject most T-waves.

A driver amplifier 42 is provided which responds to the pulse output of monostable multi-vibrator 38 to supply a pulse to a beeper or audible signal mechanism gate 44, the output from gate 44 passing through a beeper volume control 46 to a solid state alarm 48, for example. These components of the instant invention serve to provide an audible alarm means which is coupled to the trigger circuit above-described and is responsive to the second periodic signal thereby produced so as to effect a periodic audible tone.

The instant invention is contemplated to be battery operated as above-discussed and, in this respect, an internal self-contained battery pack (not illustrated) is provided with connection being made from the battery to each of the electrical circuit elements of the system. In the preferred inventive embodiment, a low-battery circuit means 50 is further contemplated to be provided which senses the output voltage of the battery pack and, if the voltage is below a selected value, serves to additionally trigger the audible alarm and particularly serves to generate a continuous tone over solid state alarm 48.

An indication of the beverage heart rate of the subject or patient is further contemplated to be provided by the novel inventive cardiac programmer system and, in this respect, a driver amplifier 52 further inverts the second periodic signal produced at the output of monostable multi-vibrator 38 so as to supply a regulated constant-amplitude pulse to rate circuitry means 54 which, in turn, produces a voltage output for a cardiometer 56. The voltage produced by the rate circuitry 54 is linearly proportional to the average rate, and the meter on the cardiometer 56 thus gives the rate indication.

The wave-shaping means of the instant invention is effective to generate the control pulse to the valve means 12 after a predetermined time delay following detection of selected characteristics of the electrocardiogram signal. This time delay is achieved by a delay circuit 58 which receives, as its input, the periodic "second signal" generated by monostable multi-vibrator 38 through driver amplifiers 42 and 52, and driver amplifier 60 which inverts the output from amplifier 52 and operates to provide the triggering pulses for the delay circuit 58. Delay circuit 58, in the preferred inventive embodiment, is contemplated to comprise a monostable multi-vibrator so as to produce a pulse of variable width under control of the operator. Such control is effected by the provision of a delay multiplier switch 60 and a msec delay dial 62. As initially discussed, such delay is contemplated to substantially equal the propagation time of a coronary ventricular pressure pulse from the thorax region of the subject or patient to the utilized remote blood pump location within the arterial system of the subject. If desired, a zero time delay can be achieved to utilize the novel device for other objectives and, for purposes of testing and manual control, a manual pulse button switch 64

is contemplated to be connected to the delay circuit 58.

At the end of the delay circuit pulse produced by delay circuit 58, a monostable multi-vibrator 64' is triggered. Monostable multi-vibrator 64' preferably provides a 20 msec pulse as its output, this pulse defining a "third periodic signal" as utilized throughout the description and the appended claims.

This third periodic pulse is amplified by a valve driver 66 which is contemplated to have output transistor protection against back emf of the solenoid valve means 12 as above-discussed. The valve driver 66 serves to drive or actuate the valve means 12 which, in turn, serves to operate the external complementary coronary blood pump.

Accordingly, the external blood pump will be triggered through operation of the novel cardiac programmer system of the instant invention after a set delay period which preferably follows the peak of the ECG complex.

It should be understood that the invention is not limited to the exact details of construction shown and described herein for obvious modifications will occur to persons skilled in the art. As should now be apparent, the objectives initially set forth at the outset to this specification have been successfully achieved. ACCORDINGLY,

What is claimed is:

1. A cardiac programmer system for driving a complementary coronary blood pump disposed at a non-thoractive location in delayed synchronism with the electrocardiogram waveform of a subject, said system comprising:

1. electrode means adapted for connection to the subject to detect an electrocardiogram signal and for providing an input signal representative thereof;
2. wave-shaping means coupled to said electrode means for generating a control pulse in response to selected characteristics of the electrocardiogram input signal after a predetermined time period following the occurrence of the selected electrocardiogram characteristics, said wave-shaping means including
 - a. filtering and clipping circuit means for removing selected components of the electrocardiogram input signal and for providing a first periodic signal responsive thereto having a substantially constant peak amplitude and being substantially unaffected by spurious changes in the input signal,
 - b. a trigger circuit means responsive to said first periodic signal for providing a second periodic signal having a preselected pulse duration represen-

tative of a desired maximum operational rate of the system, and

c. an adjustable time delay means including a timing circuit means responsive to said second periodic signal for producing a third periodic signal of preselected duration an adjustable periodic of time after occurrence of said second periodic signal, said third periodic signal defining said control pulse and wherein said preselected duration of said adjustable time delay prior to generation of said third periodic signal is substantially equal to the propagation time of a coronary ventricular pressure pulse from the thorax region of the subject to the remote pump location;

3. controllable valve means adapted for connection to an external blood pump, said valve means being responsive to and actuatable by said control pulse to effect operation of the blood pump;

whereby synchronous cardiac assistance is effected at a blood pump location remote from the thorax region in the arterial system of the subject.

2. A system as defined in claim 1, further including a rate circuit means and cardiometer coupled to said trigger circuit means and being responsive to said second periodic signal to indicate cardiac rate.

3. A system as defined in claim 2, further including an audible alarm means coupled to said trigger circuit means and being responsive to said second periodic signal to effect a periodic audible tone, said system further including battery power means for the system with the battery additionally being coupled to said alarm means, and wherein a low battery circuit means is provided such that said alarm means emits a continuous tone when the battery voltage drops below a predetermined level.

4. A system as defined in claim 1, wherein said filtering and clipping circuit means comprises a rectifier a filter and an automatic gain control preamplifier coupled to said rectifier, the output of said rectifier defining said first periodic signal, and a Schmitt trigger responsive to the peak magnitude of the rectifier output, said Schmitt trigger being connected in a feedback loop to said automatic gain controlled preamplifier to adjust the gain thereof.

5. A system as defined in claim 4, wherein said trigger circuit means comprises a Schmitt trigger responsive to said first periodic signal, a monostable multi-vibrator, said Schmitt trigger being coupled to said monostable multi-vibrator for generating a pulse of preselected duration in synchronism with said first periodic signal, said pulse defining said second periodic signal.

* * * * *