United States Patent
Cole

[15] **3,693,626**

[45] **Sept. 26, 1972**

[54] **DEMAND PACER WITH HEART RATE MEMORY**

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[22] Filed: **Nov. 2, 1970**

[21] Appl. No.: **86,107**

[52] **U.S. Cl.** ....**128/419 P**

[51] **Int. Cl.** **A61n 1/36**

[58] **Field of Search**........128/2.06 A, 2.06 F, 2.06 R, 128/419 P, 420–424

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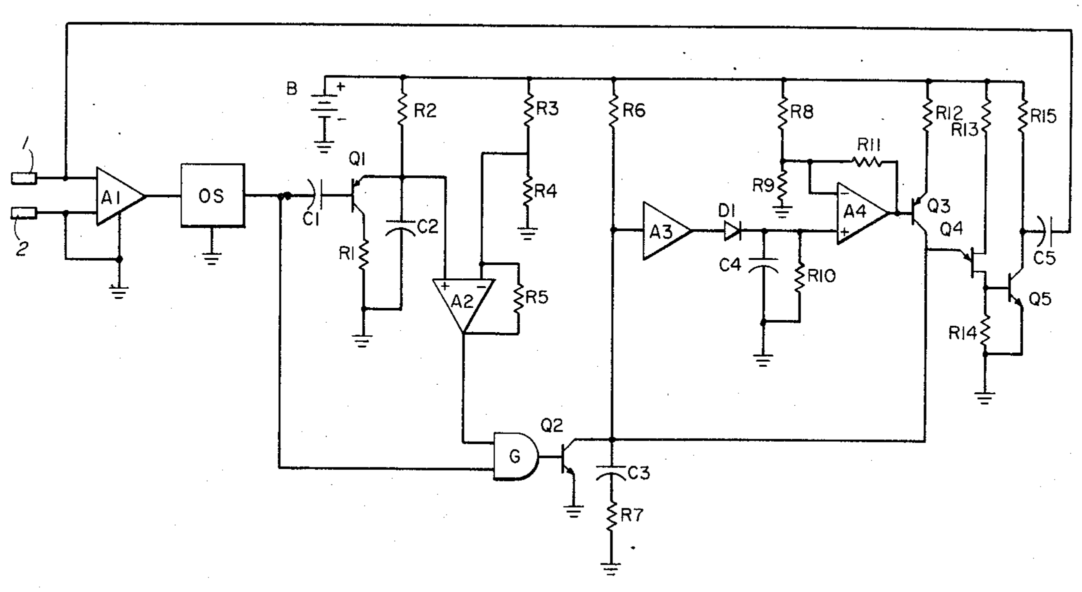
[57] **ABSTRACT**

A demand controlled cardiac pacer including a pair of electrodes for connection with the heart, a variable frequency relaxation oscillator connected to the electrodes, a resetting circuit for disabling the oscillator when heart pulses are produced at a normal rate, and a circuit responsive to the rate of reset for modifying the frequency of the oscillator so that upon heart failure stimulating pulses will be applied to the electrodes at a rate that begins somewhat below the last rate of production of natural pulses and gradually decreases to a fixed minimum rate.

11 Claims, 4 Drawing Figures



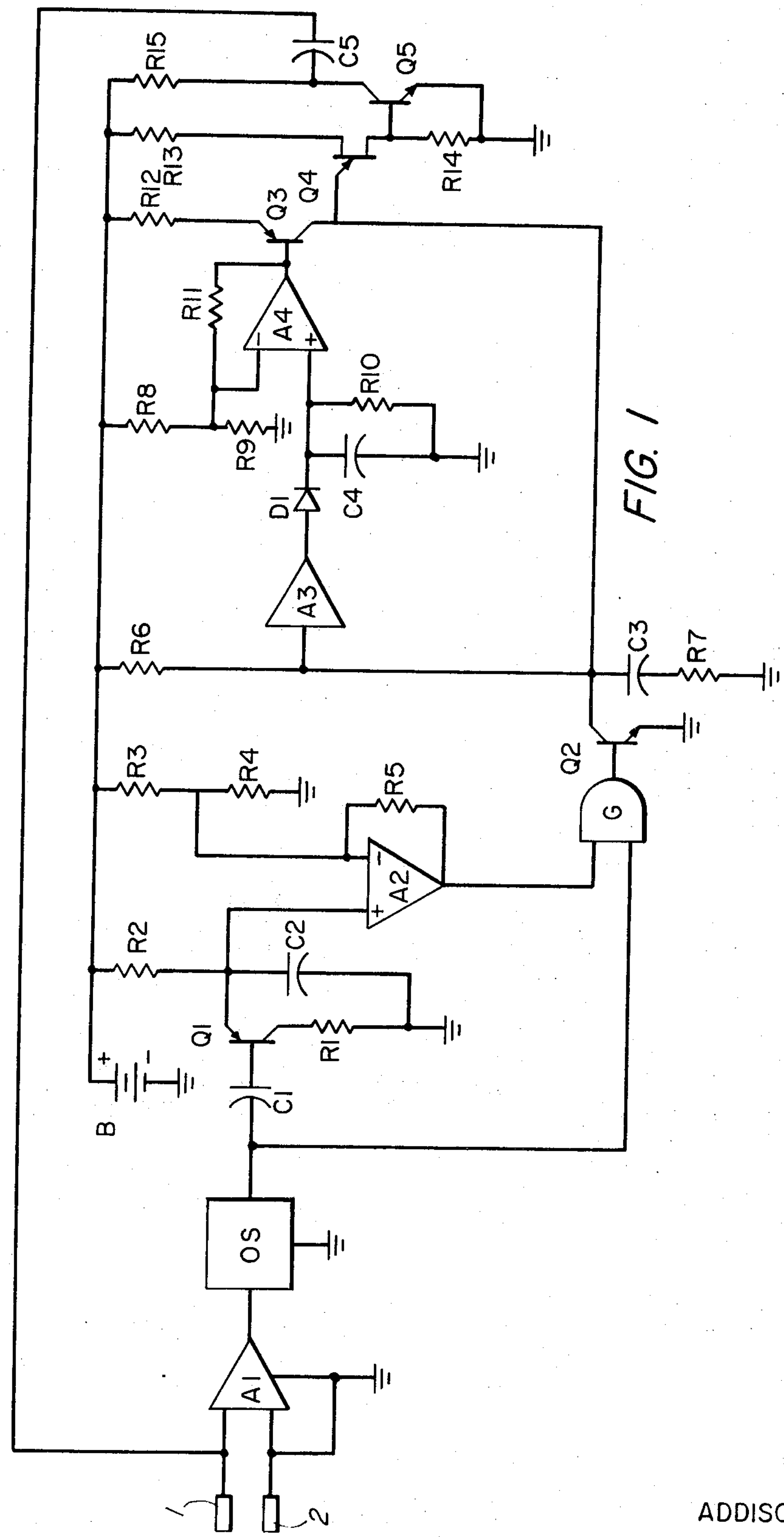


FIG. 1

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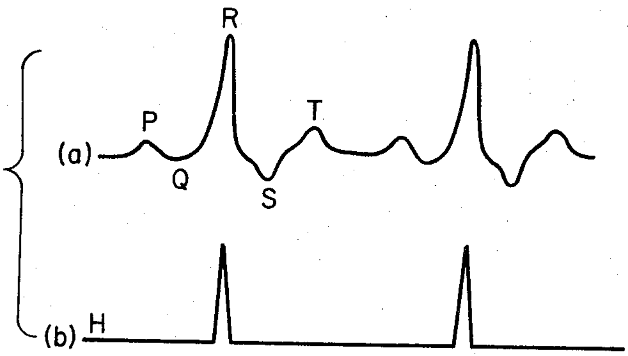

FIG. 2

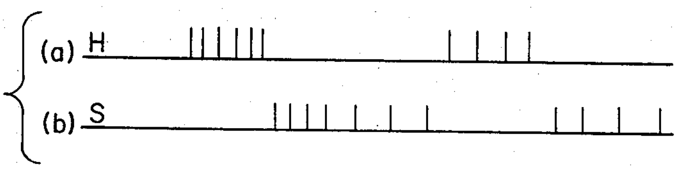

FIG. 3

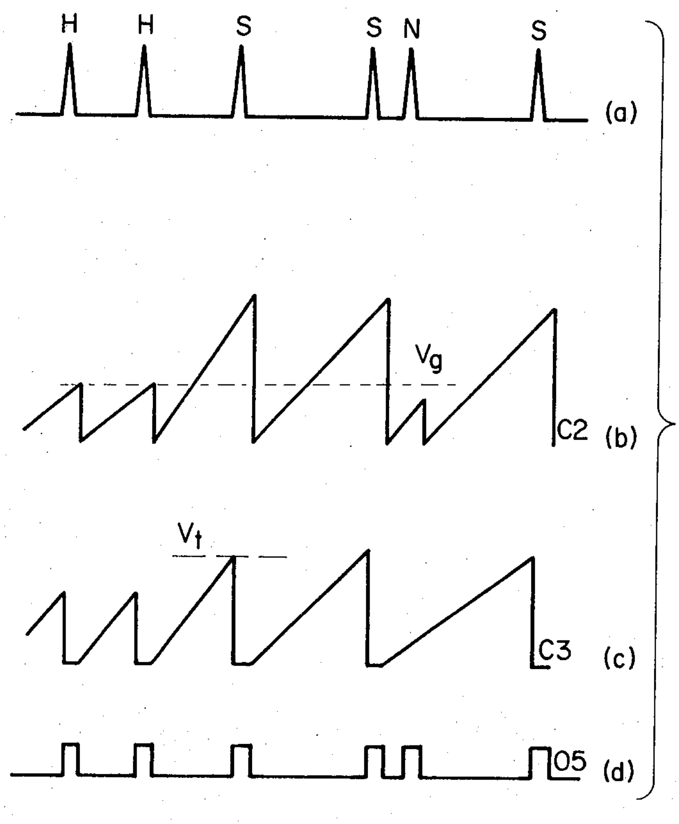

FIG. 4

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DEMAND PACER WITH HEART RATE MEMORY

My invention relates to cardiac pacers, and particularly to a novel cardiac pacer with which the rate at which stimulating pulses is produced is determined by the user so long as natural pulses are at least intermittently produced. The term stimulating pulses as used herein is in accordance with well-known terminology meaning that the stimulating pulse functions as a stimulus to evoke the characteristic physiologic activity of a nerve or muscle, more particularly as used herein, to the heart. The stimulating pulse may be either naturally derived or artificially produced.

Implantable cardiac pacers have been developed for the purpose of supplying stimulating pulses to actuate the heart when the body mechanism fails to provide such pulses. One such pacer comprises a pair of electrodes adapted to be connected in electrical circuit with the myocardium, and a fixed rate relaxation oscillator connected to the electrodes to supply stimulating pulses to the heart at a rate lower than the normally expected rate of natural R waves. The apparatus generally comprises means responsive to the signals appearing on the electrodes for resetting the oscillator to inhibit its operation when natural pulses occur at a normal rate. Such apparatus is reasonably well suited for bed patients whose heart rates may be expected to be more or less constant. However, for ambulatory patients, there is the problem that the normal heart rate varies considerably depending upon the level of activity of the patient, as well as on emotional and digestive factors. Should an episode of heart block occur in a patient whose heart was beaking rapidly, the transition to the relatively low rate necessary with a fixed rate pacer could have unpleasant and possibly dangerous consequences. The object of my invention is to improve the fidelity with which pacers supplement the action of the natural heart.

Briefly, the above and other objects of my invention are attained by a novel pacer in which a variable frequency, resettable relaxation oscillator is employed. Heart sensing and stimulating electrodes are provided for connection to the body of the host. The output terminals of the oscillator are connected to these electrodes. A pulse generator is connected to the electrodes to produce a control pulse each time an electrical signal of sufficient magnitude appears across the electrodes. Preferably, a pulse rate measuring circuit is provided that is controlled by the pulse generator to produce a signal indicative of the rate at which such pulses occur on the electrodes. The oscillator is reset by signals produced when both the pulse generator produces an output pulse and the pulse rate measuring circuit indicates that the rate of pulse production is within a predetermined range. A timing circuit is provided which measures the rate at which the oscillator is reset, and adjusts the frequency of the oscillator to correspond with that rate. If natural heart pulses fail to occur over a relatively long period, the oscillator rate falls to a minimum rate that is selected to be below the rate at which normal pulses would occur. The pulse rate measuring circuit is provided to protect against interference from stray signals that may be coupled into the circuits. Thus, in the absence of any pulses, either of noise or of natural physiological origin, the apparatus of my invention functions as a conventional demand pacer. However, in the presence of intermittent pulses or only occasional stoppages, the pacer acts to supplement the natural heart at a rate determined by the patient's needs.

The manner in which the apparatus of my invention is constructed, and its mode of operation, will best be understood in the light of the following detailed description, together with the accompanying drawings, of a preferred embodiment thereof. In the drawings;

FIG. **1** is a schematic wiring diagram of a variable rate pacer in accordance with my invention;

FIG. **2** comprises a composite graph of waveforms encountered in the operation of my invention;

FIG. **3** is a composite graph illustrating other waveforms encountered in the operation of the apparatus of my invention; and

FIG. **4** is a composite graph of waveforms illustrating still further features of the operation of the apparatus of my invention.

Referring now to FIG. **1**, I have shown a cardiac pacer incorporating a pair of electrodes **1** and **2**. One of the electrodes is to be connected to the myocardium of the patient. The other may be connected to any convenient location elsewhere in the body to serve as a reference and return electrode. The electrode **2** has been shown at a reference ground potential, for convenience of exposition, and not to imply any particular requirement of the circuit. The electrodes **1** and **2** serve to detect naturally occurring heart waves, and at times to apply stimulating electrical pulses to the heart to substitute for missing natural heart signals.

Referring to FIGS. **2***a*, naturally occurring heart waves have the general waveform shown, and are divided for purposes of description and analysis into the P, Q, R, S and T components familiar to those skilled in the art. Of these, the R wave is normally of considerably higher amplitude, and is selected for purposes of marking the interval between beats and to time the application of stimulating substitute pulses.

Returning to FIG. **1**, the electrodes **1** and **2** are connected to the input terminals of a conventional amplifying and limiting network **A1** which may comprise conventional circuits for detecting the R waves selectively, and producing corresponding pulses H as indicated in FIG. **2***b*.

Referring again to FIG. **1**, the pulse produced by the amplifier **A1** serves to trigger a conventional one-shot multivibrator OS and cause it to produce an output pulse of predetermined duration. The pulse so produced is assumed to be a positive, rectangular pulse.

The active output terminal of the one-shot multivibrator OS is connected to one input terminal of a conventional AND gate G that is arranged to produce a positive output signal when and only when two positive signals are applied to its input terminals. The output terminal of the multivibrator OS is also connected through a capacitor **C1** to the base of a conventional pnp transistor **Q1** that serves as an electronic switch.

The collector of the transistor **Q1** is returned to ground through a resistor **R1**. The emitter of the transistor **Q1** is connected to ground through a capacitor **C2**, and through a resistor **R2** to the positive terminal of battery B.

The resistor **R2** and the capacitor **C2** comprise a timing circuit producing a maximum voltage across the capacitor C2 that is a function of the time between discharges of that capacitor. When the transistor Q1 is biased into conduction, the capacitor C2 is discharged through the transistor Q1 and the resistor R1. The resistor R1 is selected to be small relative to the resistor R2; it is included merely to protect the transistor Q1 against excessive currents. As indicated, the transistor Q1 is turned on at the trailing edge of each pulse produced by the multivibrator OS.

The voltage across the capacitor C2 is compared with a reference voltage developed across a resistor R4. The resistor R4 is connected between ground and one terminal of a resistor R3 that has its other terminal connected to the positive terminal of the battery B.

The junction between the resistor R2 and the capacitor C2 is connected to the non-inverting input terminal of a conventional operational amplifier A2. The junction of the resistors R3 and R4 is connected to the inverting input terminal of the amplifier A2. The amplifier A2 is provided with a conventional feedback resistor R5.

The output terminal of the amplifier A2 is connected to the second input terminal of the AND gate G. The amplifier A2 will produce a positive output signal to enable the gate G when the voltage across the capacitor C2 has reached a predetermined value.

The output terminal of the gate G is connected to the base of an npn transistor Q2 that serves as an electronic switch. The emitter of the transistor Q2 is connected to ground. The collector of the transistor Q2 is returned to the positive terminal of the battery B through a transistor R6. The collector of the transistor Q2 is returned to ground through capacitor C3 and a resistor R7 connected in series. The resistor R7 is selected to be small with respect to the resistor R6, and serves primarily to protect the transistor Q2 against excessive currents when it is biased into conduction to discharge capacitor C3.

The collector of the transistor Q2 is connected to the emitter of a unijunction transistor Q4 connected as a relaxation oscillator. The base of the transistor Q4 that is more remote from the emitter, commonly termed "-base one" is returned to ground through a resistor R14. The other base, commonly termed "base two," is connected to the positive terminal of the battery B through a resistor R13.

The minimum rate of oscillation of the relaxation oscillator comprising the transistor Q4 is determined by the time constant of the resistor R6 and the capacitor C3. The resistor R6 is connected in shunt with a second circuit for modifying the period of the oscillator. That circuit extends from the emitter of the unijunction transistor Q4 through the collector-to-emitter path of a pnp transistor Q3, and thence through a resistor R12 of the positive terminal of the battery B. When the transistor Q3 is cut off, the relaxation oscillator comprising the unijunction transistor Q4 oscillates at the rate set by the resistor R6 and the capacitor C3. When the transistor C3 is biased into conduction, depending on the extent of the bias, more or less current flows through the resistor R12 and increases the frequency of oscillation.

A control circuit for adjusting the extent of conduction of the transistor Q3 is responsive to the rate at which the transistor Q2 is turned on to discharge the capacitor C3. For that purpose, a non-inverting amplifier A3 has its active input terminal connected to the collector of the transistor Q2. The active output terminal of the amplifier A3 is connected to a peak detecting circuit comprising diode D1, and a capacitor C4 connected in parallel with a resistor R10 between the cathode of the diode D1 and ground.

The cathode of the diode D1 is also connected to the non-inverting input terminal of a conventional operational amplifier A4. The inverting input terminal of the amplifier A4 is connected to the junction of a pair of resistors R8 and R9. The other terminal of the resistor R9 is connected to ground, and the other terminal of the resistor R8 is connected to the positive terminal of the battery B. The amplifier A4 is provided with a conventional feedback resistor R11.

The active output terminal of the amplifier A4 is connected to the base of the pnp transistor Q3. The positive potential across the resistor R9 tends to produce a negative potential biasing the transistor Q3 into conduction. A positive potential across the capacitor C4 tends to resist this reference potential, and turn off the transistor Q3. Thus, if the capacitor C4 is charged to a sufficiently high voltage, the transistor Q3 will be cut off.

The voltage across the capacitor C4 will depend upon the period between discharges of the capacitor C3. If it is discharged at the minimum rate; i.e., under conditions when the transistor Q3 remains cut off and the oscillator comprising the unijunction transistor Q4 oscillates at the minimum rate, the peak voltage reached across the capacitor C3 will be relatively high, and the voltage across the capacitor C4 will be high enough to keep the transistor Q3 turned off. On the other hand, if the capacitor C3 is more frequently discharged, a lower voltage will be reached across the capacitor C4, and the transistor Q3 will conduct more heavily, increasing the frequency of oscillation of the oscillator comprising the transistor Q4.

Base one of the transistor Q4 is connected to the base of a npn transistor Q5 that serves as an electronic switch. The emitter of the transistor Q5 is connected to ground. The collector of the transistor Q5 is returned to the positive terminal of the battery B through a resistor R15. The collector of the transistor Q5 is connected to the stimulating electrode 1 through a capacitor C5. Thus, during the period between the time when the unijunction transistor Q4 is fired, and the time that the capacitor C3 has discharged sufficiently to cut off the transistor Q4, the collector of the transistor Q5 will go essentially to ground potential and thereby apply a rectangular negative pulse to the electrode 1.

The polarity of natural electrical waves produced in the myocardium with respect to the ground connection provided elsewhere in the body will determine whether it is the electrode 1, connected to the collector of the transistor Q5, or the electrode 3, that is actually connected to the myocardium. As that matter of polarity will not trouble the myocardium. As that matter of polarity will not trouble the artisan, it will be ignored in the following discussion, and in the graphs of FIG. 2 through 4, where all pulses have been indicated as positive to simplify the discussion.

The apparatus of FIG. 1 is preferably enclosed in a suitable biologically compatible container for implantation. As will be apparent to those skilled in the art, the circuits of FIG. 1 are well adapted to construction by miniature circuit techniques familiar to those skilled in the art. Thus, the pacer need occupy but little space.

Having thus described the construction of the apparatus of my invention, its operation will next be described in connection with the diagrams of FIG. 2 through 4. As noted above in connection with FIG. 2, the pulses H are produced by the amplifier A1 in response to each naturally occurring R wave. Fig. 3*a* shows a series of such pulses H, followed by a heart block episode in which no pulses are produced. As illustrated in FIG. 3*b*, when a pulse H fails to occur, a pulse S is produced a short time after it should have occurred. Pulses S continue to be produced at a rate that is initially slightly below the rate at which H pulses had been produced. That rate gradually tapers to a minimum rate below the rate at which natural pulses should be produced. When heart beats are resumed, the pulses S will cease.

The details of the manner in which the apparatus in FIG. 1 functions to produce the operation illustrated in FIG. 3, together with its mode of operation in the presence of noise, will next be described in connection with FIG. 4.

Referring to FIG. 4*a*, I have shown two initial naturally produced pulses H that are assumed to be at the end of a train of such pulses occurring over a sufficiently long interval that the operation of the apparatus in FIG. 1 has become stabilized. Prior to the first of the pulses H shown in FIG. 4, the capacitor C2 has been charging, as illustrated in FIG. 4*b*. When the first pulse H occurs, the one-shot multivibrator OS is triggered to produce a pulse as illustrated in FIG. 4*d*.

It is assumed that the capacitor C2 has charged to a value that will overcome the reference voltage appearing across the resistor R4, and thereby enable the gate G to produce a positive signal in response to the pulse from the one-shot multivibrator OS. That pulse will turn on the transistor Q2 and discharge the capacitor C3 through the resistor R7. The capacitor C3 will remain discharged during the pulse produced by the multivibrator OS. At the trailing edge of that pulse, the capacitor C2 will be discharged, as shown in FIG. 4*b*. That capacitor will begin to charge again, and the cycle will be repeated when the next pulse H is produced.

Next, it is assumed that a heart block episode occurs in which an R wave does not occur within the current period of oscillation of the multivibrator comprising the unijunction transistor Q3. The capacitor C2 will continue to charge, and the capacitor C3 will be charged until it reaches the unijunction firing potential, shown as Vt in FIG. 4*c*.

During the charging of the capacitor C3, the time constant is determined both by the resistor R6 and by the resistor R12 in series with the conducting transistor Q3. The discharge of the capacitor C3 thus occurs more rapidly than it would if the transistor Q3 was cut off, and a stimulating pulse S is produced after an interval longer than but close to the interval between previously appearing pulses H. When the pulse thus is produced, it will retrigger the one-shot multivibrator OS. At the trailing edge of the multivibrator pulse, the capacitor C2 will be discharged.

Since the interval between the last pulse H and the stimulating pulse S was longer than the interval between the previous pulses H, the peak detecting circuit, comprising the diode D1, the capacitor C4 and the resistor R10, will apply a higher voltage to the amplifier A4, reducing the current in the emitter-to-collector path of the transistor Q3, and thereby lowering the rate at which the capacitor C3 will charge. Accordingly, assuming no intervening pulse H, the next pulse S produced by the circuit in FIG. 1 will follow the previous pulse S by a somewhat longer interval than that pulse followed the last H pulse. If succeeding pulses S continue to be produced in the absence of pulses H, the interval would gradually increase until the transistor Q3 was completely cut off, whereupon the pulses S would continue to be produced at a fixed rate.

FIG. 4*a* illustrates a noise pulse N occurring shortly after the second pulse S. That pulse will trigger the one-shot multivibrator OS and cause the capacitor C2 to be discharged before it reaches the voltage Vg at which the gate G could be enabled. Accordingly, the transistor Q2 will remain cut off the capacitor C3 will continue to charge until it reaches the unijunction firing potential Vt. Thus, the oscillator comprising the unijunction transistor Q3 will continue to produce pulses at a rate declining towards the minimum rate so long as either natural pulses H or noise pulses N are produced at a rate greater than the maximum expected rate for natural pulses.

While I have described my invention with respect to the details of the preferred embodiment thereof, many changes and variations will occur to those skilled in the art upon reading my description, and such can obviously be made without departing from the scope of my invention.

Having thus described my invention, what I claim is;

1. A variable rate demand pacer, comprising:

a pair of electrodes adapted to be connected in electrical circuit with living tissue;

pulse generating means connected to said electrodes for producing a first pulse each time an electrical signal above a predetermined magnitude appears on said electrodes;

pulse rate measuring means controlled by said pulse generating means for producing an output signal when said first pulses are produced at a rate below a predetermined maximum rate;

a relaxation oscillator, comprising:

output terminals connected to said electrodes,

a timing circuit including a variable impedance,

a source of voltage, and

a capacitor connected in series, and

means responsive to the voltage across said capacitor for discharging the capacitor and producing a pulse across said output terminals when the voltage across the capacitor reaches a predetermined value;

an electronic switch connected in parallel with said capacitor;

gate means controlled by said pulse generating means and said pulse rate measuring means for closing said switch when said first pulse and said output signal are both produced;

voltage detecting means connected to said capacitor to produce a control signal in accordance with the peak voltage developed across said capacitor; and means responsive to said control signal for adjusting said variable impedance to adjust the period of said oscillator to a rate approximating the rate at which said electronic switch is closed.

2. In combination with a pair of sensing and stimulating electrodes adapted to be connected in electrical circuit with living tissue,

a resettable variable frequency oscillator comprising

a resistor, a capacitor and a source of voltage connected in series;

a voltage responsive electron discharge device connected to said capacitor and responsive to a predetermined voltage across the capacitor to discharge it;

said resistor and capacitor having a time constant selected to actuate said discharge device at intervals greater than the intervals between normal heartbeats;

means connected to said discharge device and responsive to discharge of said capacitor therethrough to apply a pulse to said electrodes;

a variable impedance connected in parallel with said resistor;

means responsive to the average voltage across said capacitor for adjusting said impedance in accordance with said average voltage;

an electronic switch connected across said capacitor and effective when closed to discharge said capacitor independently of the voltage across it; and

means responsive to a pulse across said electrodes for closing said switch.

3. The apparatus of claim 2, in which said variable impedance comprises:

a second resistor, and a transistor having an emitter and a collector connected in series with said second resistor, and a base;

and in which said average voltage responsive means comprises peak detecting means connected between said capacitor and said base for controlling the impedance between said emitter and said collector.

4. A demand pacer, comprising:

a pair of electrodes adapted to be connected in electrical circuit with a heart,

amplifying means connected to said electrodes to produce an output signal in response to a voltage on said electrodes having an amplitude characteristic of an R wave,

a pulse generator connected to said amplifying means to produce a pulse in response to each signal,

a first timing circuit comprising a first resistor, a battery, and a first capacitor connected in series;

a first electronic switch connected across said first capacitor to discharge it when said first switch is closed;

means responsive to the trailing edge of each pulse for closing said switch to discharge said first capacitor;

voltage sensing means controlled by said capacitor for producing a first control signal when the voltage across said capacitor reaches a predetermined value;

gate means responsive to said pulses and said first control signals to produce a second control signal when said first control signal occurs during a pulse;

a second electronic switch controlled by said gate means and closed by said second control signal;

a second capacitor connected across said switch;

a second resistor and a source of voltage connected in series with said capacitor;

an electrically variable impedance connected in parallel with said second resistor;

means responsive to the peak voltage developed across said second capacitor for adjusting said variable impedance;

a voltage responsive electronic discharge device connected across said capacitor to discharge it in response to a predetermined voltage across the capacitor, and means responsive to the discharge of said capacitor to apply a pulse to said electrodes of sufficient amplitude to cause said amplifying means to produce an output signal.

5. A variable rate demand pacer, comprising:

a pair of electrodes adapted to be connected in electrical circuit with living tissue;

pulse generating means connected to said electrodes for producing a pulse each time a signal above a predetermined amplitude appears on said electrodes;

a resettable relaxation oscillator having an adjustable period connected to said electrodes;

means controlled by said pulse generating means and responsive to said pulses to reset said oscillator;

means responsive to the rate at which said pulses are produced for adjusting the period of said oscillator;

said oscillator comprising:

a source of voltage, a resistor, and a capacitor connected in series;

an electron discharge device connected across said capacitor and responsive to a predetermined voltage across the capacitor to discharge the capacitor;

an electronic switch connected across said capacitor and effective when closed to discharge the capacitor and thereby reset the oscillator; and

a variable impedance connected in parallel with said resistor; and

in which said rate responsive means comprises peak detecting means responsive to the peak voltage reached by said capacitor prior to discharge for producing a control signal, and means responsive to said control signal for adjusting said variable impedance.

6. A cardiac pacer normally responsive to natural heart stimulating pulses in its operation and adapted to provide artificial heart stimulating pulses in the event of the absence of a natural pulse, comprising:

means for receiving natural heart stimulating pulses;

means for generating an artificial heart stimulating pulse;

means responsive to said stimulating pulses for controlling said artificial pulse generating means to produce an artificial pulse only after a variable time interval, after the last said stimulating pulse;

means responsive to a plurality of previously naturally occurring pulses for defining said variable time interval as a function of said plurality of previously occurring natural pulses; and

means for coupling artificial stimulating pulses to a natural heart.

7. The The pacer of claim 6, wherein:
said previously naturally occurring pulses responsive means includes means for storing a selected number of the last received natural pulses and producing a signal which is a function of the average interval between said selected pulses.

8. The pacer of claim 6, wherein:
said artificial pulse generating means tends to provide artificial pulses in sequence and said means for controlling said artificial pulse generating means includes means inhibiting said artificial pulse generating means from producing an artificial pulse during said variable time interval after a received natural pulse.

9. The pacer of claim 6, wherein:
said artificial pulse generating means includes a resettable, variable rate, pulse generator.

10. The pacer of claim 7, wherein:
said artificial pulse generator is operative selectively to supply artificial pulses in sequence at controllable intervals, said controllable intervals, at least initially, being determined as a function of the most recent of a predetermined sequence of natural heart stimulating pulses.

11. The pacer of claim 6, wherein:
said artificial pulse generator includes a resettable variable frequency relaxation oscillator, comprising:
a source of voltage, a variable impedance and a capacitor connected in series;
an electronic switch connected in parallel with said capacitor and effective to discharge said capacitor when closed;
means responsive to the rate of discharge of said capacitor for adjusting said variable impedance; and
a voltage responsive electron discharge device connected in parallel with said capacitor and responsive to a predetermined voltage across the capacitor to discharge it.

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