An implanted pacemaker system includes a resettable oscillator for generating a train of pulses having a period slightly greater than the period of a natural heartbeat. The pulses generated in the oscillator are coupled to a pulse-shaping network which stabilizes the pulses to an electrode contacting the heart. If no natural heartbeat is sensed, the oscillator operates at its natural frequency and the shaping network transmits heart-stimulating pulses to the electrodes. If a natural heartbeat is detected, the oscillator is reset and timing circuitry in the shaping network is modified so that a non-stimulating pulse is transmitted to the electrode. The non-stimulating pulses are detectable by a receiver outside the body to permit an examining physician to ascertain whether the pacemaker is functioning normally even though the system is non-competing. Further, the non-stimulating pulses do not produce an artifact on an EKG machine monitoring the patient's heartbeat, and negligible energy is dissipated in the non-stimulating pulses.
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CARDIAC PACER SYSTEM

BACKGROUND AND SUMMARY

The present invention relates to an artificial system which is implanted in a body for stimulating the heart in the absence of a natural heartbeat; such systems are commonly referred to as cardiac pacers.

For purposes of understanding the present invention, the heart may be thought of as including two upper chambers (the left and right auricles), and two lower chambers (the left and right ventricles). The two auricles together form the atrium. Blood is pumped from the atrium to the ventricles and thence into either the lungs (from the right ventricle) or the aorta (from the left ventricle).

The contraction of the atrium is accompanied by a depolarization of the muscle cells in the atrium which coincides with a small but detectable electrical pulse referred to as the P wave. The ventricular contraction which accompanies ventricular pumping action is accompanied by a depolarization of the muscle cells of the ventricles, referred to as the QRS complex, or simply the R wave. In a properly functioning heart, the R wave follows the P wave by a fixed and constant time period (usually about 0.2 sec. in man) because blood is pumped from the atrium to the ventricles and then through the body. For a period of about 0.1 second after the contraction of the ventricle, the heart remains insensitive to electrical pulses; and this is sometimes referred to as the "refractory" period of the heart. After the refractory period, there is a short period of the order of a few milliseconds during which an electrical impulse transmitted to the heart and capable of stimulating it, may cause damage to the heart by sending it into a state of fibrillation.

The constant period of time between the successive occurrences of a P wave and an R wave (signaling respectively the contraction of the atrium and ventricles) is provided by a conductive nerve system extending from the atrium to the ventricles and commonly referred to as the AV conduction system. In some types of heart disorders the AV conduction system becomes intermittently discontinuous whereby ventricular pumping action does not follow contraction of the atrium by the fixed delay period. Cardiac pacer systems are employed to insure stimulation of the ventricles in these cases.

Cardiac pacer systems may be divided into two broad categories, fixed-rate or competing pacers and non-competing pacers. In a fixed-rate pacer, a main oscillator establishes a time base for generating a train of pulses having a constant repetition rate. It can be seen that a fixed-rate pacer can operate in modes wherein it "competes" (i.e., generates pulses not timed with the occurrence of an R wave) with a natural heartbeat. A non-competing pacer is one in which the stimulating pulses are always synchronized with the natural R wave if there is one; and there are two broad subclasses here. The first is referred to as the synchronous pacer, and the second is referred to as a demand or standby pacer.

Early cardiac pacer systems of the so-called "synchronous" type employed two separate electrodes, a sensing electrode contacting the atrium and an exciting electrode contacting the ventricle. In a synchronous pacemaker, the sensing electrode detects an atrial P wave, delays it for a predetermined and fixed time, then uses that pulse to initiate or generate a stimulating pulse which is transmitted to the ventricle coincident with the time that a natural R wave should occur. That is, a stimulating pulse is transmitted to the exciting electrode in the ventricle in timed relation with a natural heartbeat. If a natural heartbeat occurs, the stimulating pulse merely reinforces it; whereas, if the AV conduction system is not functioning normally, the pulse stimulates the ventricle.

A demand or standby pacer provides an electrical discharge into the ventricle only on demand—i.e., a main oscillator circuit is reset so as not to provide a stimulating pulse if a natural QRS complex is detected before the end of the fixed period of the oscillator, which fixed period is set to be slightly longer than the natural period between heartbeats.

Pacer systems currently available are permanently implanted in the patient's body so as to avoid the psychological effect of having any part of the system in the patient's view. The power supply will normally operate reliably for a period of 18 to 30 months; and a patient having an implanted cardiac pacer periodically visits a physician for check-ups on the operability of the system. However, the predominant use of implanted pacers presents a problem to the physician in that with competing pacers the stimulating pulses discharged into the ventricle normally have energy comparable to the naturally occurring R wave so that the artificial pulse alters the appearance of a natural QRS complex. Hence, although an examining physician may determine that the cardiac pacer is operable by detecting the magnitude of the stimulus, he is not easily able to determine with certainty whether the AV conduction system is functioning normally, or whether the heart is being artificially stimulated.

Conversely, in the case of an implanted non-competing demand or standby cardiac pacer if the patient's heart is acting normally during his periodic check-up, an examining physician has no way of telling whether the dormant pacer is functioning properly because the occurrence of each natural heartbeat suppresses the generation of a stimulating pulse by the pacer.

In the inventive system, a main oscillator generates pulses to establish a time base; and the oscillator circuit energizes a pulse shaping circuit which transmits output pulses to the ventricle whether or not a natural heartbeat is sensed. In the absence of a natural heartbeat, the pulse shaping circuit generates a stimulating electrical pulse to cause the ventricle to contract. However, if a natural heartbeat is detected, the oscillator is reset, and at the same time, timing circuitry in the pulse shaping network is modified so that the pulse transmitted to the heart is very narrow—of the order of less than ten microseconds. This narrow pulse is transmitted in synchronism with the occurrence of an R wave; but its energy content is such that it is non-stimulating so that the narrow pulse has no effect on the heart. However, because the pulse is so narrow, it has a substantial high frequency content and may be externally detected by separate receiving means. Thus, during a routine examination, an examining physician may determine whether the heart is functioning naturally and, if so, whether the implanted pacer is also fully operative. The non-stimulating high frequency pulse is not apparent on the standard EKG record but is used to analyze the electrical functioning of the heart. The oscillator has a built-in refractory time which inhibits re-triggering of the pulse shaping circuit by a pacer-generated pulse and filters out noise frequencies outside the physiologic range.

Other features and advantages of the present invention will be apparent to persons skilled in the art from the following detailed description of a preferred embodiment accompanied by the attached drawing wherein identical reference numerals will refer to like components or elements in the various views.

THE DRAWING

FIG. 1 is a functional block diagram of a cardiac pacer system according to the present invention; FIGS. 2A and 2B comprise a detailed circuit schematic diagram for the system of FIG. 1; FIG. 3 is a diagrammatic illustration of a detection system; and FIG. 4 is a diagram illustrating the time relationship between various idealized voltage wave forms in the inventive system.

DETAILED DESCRIPTION

Referring first to FIG. 1, reference numeral 10 generally denotes an electrode in contact with the ventricle of the patient's heart. A lead connects the electrode 10 to a junction 10a within the pacer housing. Preferably the housing encloses the circuitry and may be located in the abdomen of the patient
and a current return is provided through the body fluids to the pacer circuitry. A conductive wire or lead 11 connects the junction 10a to the signal input of a protective network 12 which clips or limits the amplitude of the voltages fed to the system. The output of the protective network 12 then feeds an input amplifier 13 which amplifies the signals detected at the ventricle electrode. The input amplifier 13 feeds a pulse rectifier circuit 14. The pulse rectifier 14 generates output pulses of one polarity regardless of the polarity of an input pulse; and the output pulses from the pulse rectifier circuit 14 trigger a monostable multivibrator circuit 15. The monostable multivibrator circuit 15 has two outputs designated respectively 16 and 17. The former feeding an oscillator circuit 18 for resetting it. The output 17 of the monostable circuit 15 triggers a second monostable (or "one-shot") circuit 19. The oscillator circuit 18 feeds a first input A to a pulse shaping circuit 20; and the output of the monostable multivibrator 19 feeds a second input B to the pulse shaping circuit 20. The output pulse of the pulse shaping circuit 20 is coupled to an output amplifier 21 which, in turn, is connected to the junction 10u to energize the ventricle electrode 10.

Referring to FIG. 4, there is shown on line 4 an idealized illustration of the electrochemical pulses occurring in the heart, namely, the above described F, G, R, S and T waves. For simplification of the illustration, there are two sets of waveforms shown in FIG. 4. The left side are those waveforms generated when a natural heartbeat is detected (the heartbeat waveform being identified as the solid line 22); this may be referred to as the demand mode of system operation. The right side shows those waveforms occurring when no natural heartbeat occurs (but the dashed line 23 indicates a natural heartbeat to show the time relation); and this may be called the fixed rate mode.

The period of oscillation of the oscillator circuit 18 is set to be slightly greater than the time between successive beats of a normally functioning heart. Typically, the period of the output train of pulses generated by the oscillator 18 is 0.85 sec. In the absence of a natural heartbeat, the oscillator 18 acts as a free-running oscillator to trigger the input A of the pulse shaping circuit 20 which, in turn, generates an output pulse having a duration of about 1 millisecond. This output pulse, when amplified by the output amplifier 21 is sufficient to stimulate the heart.

If, on the other hand, a natural heartbeat is detected, it is fed through the protective network 12, the input amplifier 13, and the pulse rectifier circuit 14 to trigger the monostable multivibrator 15. The monostable multivibrator 15 transmits a first pulse along the line 16 to reset the oscillator 18. At the same time, the monostable multivibrator circuit 15 transmits a pulse along the line 17 to trigger the monostable multivibrator 19. When reset, oscillator 18 produces an output pulse which is transmitted to input A of the pulse shaping circuit 20. At the same time, multivibrator 19, when triggered, produces an output pulse transmitted to input B. Thus, both inputs A and B of the pulse shaping circuit 20 are energized when a natural heartbeat occurs; and the function of the pulse shaping circuit under these circumstances is to generate a much narrower, non-stimulating output pulse of the same amplitude. This non-stimulating output pulse has a duration of the order of 10 microseconds or less; and it is coupled through the output amplifier directly to the heart and in timed relation with the occurrence of the QRS complex that generates it.

The narrow, 10 microsecond pulse contains sufficient high frequency energy so that it may be easily detected by a detector means held in proximity to the pacer system. One detector means is shown in FIG. 3 and includes a pick-up coil generally designated by reference numeral 25. The terminals of the coil 25 are connected to an amplifier 26 which amplifies the high frequency detected pulse and energizes an indicator 27 (preferably to generate an audible signal) to indicate the presence of such pulse. Although the illustrated embodiment employs a non-stimulating pulse which is of much shorter duration than the stimulating pulse and of equal amplitude, persons skilled in the art will realize that other forms of non-stimulating pulses may be used although it is preferred that these pulses have the following characteristics in addition to being incapable of stimulating the heart: (1) they should be easily externally detectable; (2) they should not produce an artifact on an EKG machine monitoring the patient; and they should dissipate only a negligible amount of electrical energy from the storage batteries. Further detection means other than the one illustrated may be used. For example, it has been found that a portable transistor radio receiver, tuned to a frequency between broadcasting stations, will produce an audible signal (in the form of a "blip") for each pulse when its antenna is placed near the patient.

Turning now to FIGS. 2A and 2B, the protective network is enclosed within a dashed line again designated 12; and it includes a resistor 30 for limiting the input current, and diodes 31 and 32 which are connected anode-to-cathode and in parallel between the resistor 30 and the negative terminal of a supply battery 33 via a negative supply bus 33b. It will be appreciated that the battery 33 may include a plurality of individual 1/2 volt cells connected in series to generate the desired bias voltage; and its positive terminal is connected to a positive supply bus 33a.

The other terminal of the resistor 30 is directly connected to the previously described line 11 connected to the electrode 10. The output signal from the protective network 12 is coupled to the base of a transistor Q1 through a capacitor 34. Unless indicated differently, all transistors are of the NPN type. The transistor Q1 is biased in the linear amplifying region as a common emitter amplifier with feedback resistor in the emitter circuit. Since the biasing and feedback circuitry is conventional, it need not be further described here. The transistor Q1 comprises the first stage of the three-stage input amplifier 13. Thus, a second transistor Q2 receives the collector signal of the transistor Q1, and the transistor Q2 is similarly biased in the active region in a common-emitter configuration. The input amplifier 13 also includes a third stage—an amplifier Q3. The transistor Q3 is biased in the forward-biasing region, and emitter follower Q4 is connected to the negative power bus 33a.

The output of the collector terminal of resistor Q3 is also coupled to the base of a transistor Q5 through a capacitor 40 in series with diode 41 connected to transmit only positive pulses. The collector is connected to the common junction between the base of transistor Q4 and the negative bus 33a.

Transistors Q4 and Q5 are feedback amplifiers connected between the negative power bus 33b and the base of transistor Q3. The output of the transistor Q3 is connected to the common junction between the base of transistor Q4, and the negative power bus 33a.

Transistors Q4 and Q5 are feedback amplifiers connected between the negative power bus 33b and the base of transistor Q3. The output of the transistor Q3 is connected to the common junction between the base of transistor Q4, and the negative power bus 33a. The output of the second transistor Q2 is connected to the common junction between the base of transistor Q3 and the negative power bus 33a.

Transistor Q5 is biased in the common-emitter configuration with the feedback resistor in the emitter circuit. Since the biasing and feedback circuitry is conventional, it need not be further described here. The transistor Q2 comprises the third stage of the three-stage input amplifier 13. The input amplifier 13 also includes a second stage—a common-emitter amplifier including, as the active element, transistor Q3. The output signal (see pulse 34a on line 2 of FIG. 4) from the collector of transistor Q3 is coupled by means of a first capacitor 35 and a first diode 36 to the base of a PNP transistor Q4. The diode 36 is arranged to permit the passage of negative pulses only. A first resistor 37 connects the cathode of the diode 36 to the positive power bus 33a; and a resistor 38 connects the common junction between the base of transistor Q4 and the anode of diode 33 to the positive power bus 33a. The emitter of transistor Q4 is connected directly to the positive power bus 33a; and its collector terminal is connected to the negative power bus 33b through a series resistor 39.

The output of the collector terminal of transistor Q3 is also coupled to the base of a transistor Q5 through a capacitor 40 in series with a diode 41 connected to transmit only positive pulses. The junction between the anode of the diode 41 and capacitor 40 is connected to the negative power bus 33b by means of a resistor 42; and the cathode of the diode 41 is connected directly to the common junction between the base of transistor Q4 and resistor 39. Transistors Q4 and Q5 comprise active elements of the circuit previously described as the pulse rectifying circuit identified by reference numeral 14. In operation of the circuitry thus far described, an R wave detected by the ventricle electrode 10 is fed to the input of the protective network 12. Although line 1 of FIG. 4 shows the R wave as positive-going, the present system is designed to accommodate either polarity. That is, the protective diodes 31 and 32 provide a means for clipping or limiting input pulses of both polarities; and the input amplifier comprising the three-stage amplifier for including transistors Q1-Q3 will amplify both positive and negative voltage polarities.

Normally, transistors Q4 and Q5 are biased in the cut off region. If the output pulse from the collector of transistor Q3 is negative-going, it will be blocked by diode 41 and transmitted through the capacitor 35 and the diode 36 to forward-bias the
emitter-base junction of transistor Q4 and drive that transistor into saturation. Collector current from transistor Q4 will then flow into the base of transistor Q5 to forward-bias that transistor and drive it into saturation. If, on the other hand, the output pulse from the collector of transistor Q5 is positive-going, it will be blocked by the diode 36, be transmitted through capacitor 40 and diode 41 to forward-bias the base-emitter junction of transistor Q5 directly. Thus, whether the output pulse from the input amplifier section is positive or negative, the pulse rectifier 14 will draw collector current at transistor Q5.

Transistors Q6 and Q7 comprise the active elements of monostable circuit 15. The emitter of PNP transistor Q6 is connected to the positive supply bus 33a by means of a resistor 43, and its base is connected to the positive bus by means of resistor 44. The collector of transistor Q5 is connected by means of a resistor 45 to the cathode of a diode 46, the anode of which is connected by means of a resistor 47 to the common junction between the base of transistor Q6 and the resistor 44. The collector of transistor Q7 is connected to the positive supply bus 33a by means of a resistor 48 and to the cathode of diode 46 by means of a coupling capacitor 49. The base of transistor Q7 is connected to the collector of transistor Q6 through resistor 50, and it is connected to the negative power bus 33b through resistor 51. The resistors 45 and 51 thus form a voltage divider network; and that series circuit is shunted by a resistor 52. A diode 53 is connected in the emitter circuit of the transistor Q7 with its cathode connected to the negative supply bus 33b.

As already mentioned, normally the transistor Q5 of the pulse rectifying circuit 14 is cut off; but either polarity pulse from the input amplifier 13 will cause it to conduct thus drawing collector current through the diode 46 and causing the junction between the voltage divider network of resistors 44 and 47 to go relatively negative. This, in turn, will draw base current from transistor Q6 causing it to conduct. When transistor Q6 conducts, base current will flow to transistor Q7; and it will saturate. The diode 53 in the emitter circuit of transistor Q7 insures that under normal circumstances, transistor Q7 will be biased at cut off. Thus, at the occurrence of an input pulse to the monostable circuit 15, transistors Q6 and Q7 will conduct; and the right terminal of capacitor 49 will be clamped to a potential slightly above the potential of the negative terminal of the supply battery 33. As current flows through resistors 44 and 47 to charge the capacitor 49, the left terminal thereof will become positively charged until it reaches a point at which transistor Q5 will be biased again at cut off; and both transistors Q6 and Q7 will thereafter be non-conducting. The time constant of the output pulses from the monostable circuit 15 is determined by the values of the resistor 44 and capacitor 49, the value of resistor 47 being very much smaller than that of the resistor 44. In practice, the output pulses of the monostable circuit 15 are 100 milliseconds; and they are seen in FIG. 4 on the left section of lines 3 and 4, identified respectively by reference numerals 55a and 55b. The output of the collector of transistor Q6 is the positive pulse 55c on line 3; and it is coupled through a capacitor 57 to the line 16 which, as already disclosed, feeds the input of the oscillator 18, the detailed circuitry of which is illustrated in FIG. 2B and will be described in detail after a description of the monostable circuit 19. The output pulse 55b of the collector of transistor Q7 is seen on line 4 of FIG. 4.

The monostable circuit 19 includes a PNP transistor Q8 and an NPN transistor Q9. The emitter of transistor Q9 is connected directly to the negative bus 33b; and the collector of transistor Q9 is connected to the base of transistor Q8 through a resistor 61. The collector of transistor Q8 is also connected to a line 63 which feeds the input B of the pulse shaping circuit 20 of FIG. 1 and to the positive power bus 33a by means of a resistor 65. The emitter of transistor Q8 is directly connected to the bus 33a, the collector is connected to line 33b by means of a resistor 66, and the base is connected to line 33a by means of resistor 67. The collector of transistor Q8 is also connected through capacitor 68 and resistor 69 to the base of transistor Q9; and a resistor 70 connects line 33b with the junction between the base of transistor Q9 and the resistor 69. The base of transistor Q8 is also connected to the collector of transistor Q7 by means of a coupling capacitor 71. It will be remembered that the monostable multivibrator circuit 15, when it is triggered, will produce a positive pulse (reference numeral 55a, line 3 of FIG. 4) along the line 16 which is fed to the oscillator 18 as well as a negative pulse (reference numeral 55b, line 4 of FIG. 4) which is coupled along the line 17 and through capacitor 71 to the base of transistor Q8.

Normally, both transistors Q8 and Q9 are cut off so there is no net change across capacitor 66. When a negative pulse is transmitted along line 17 through capacitor 71, it causes transistor Q8 to conduct and the resulting positive pulse at the collector of transistor Q8 is coupled through capacitor 68 to the base of transistor Q9 to cause it to conduct. When transistor Q8 saturates, the right terminal of capacitor 68 is clamped to the positive potential of the power supply 33; and the left terminal thereof begins to charge to the potential of the negative terminal of the power supply 33 through resistors 69 and 70. When the left terminal of capacitor 68 reaches a sufficiently low voltage, transistor Q9 will again cut off; and its collector, which is coupled directly to the line 63 which feeds the input B of the pulse shaping circuit 20, goes positive, ending the negative output pulse.

This negative pulse is shown on line 5 of the left section of the timing diagram of FIG. 4; and it is denoted by reference numeral 73. The width of the pulse 73 is normally about 30 milliseconds.

Turning now to FIG. 2B, and in particular to the left-hand side, the lines 11, 16, 33c, 33b, and 63 are repeated. These lines represent respectively the sense line from the ventricile electrode, the positive power bus, the output of transistor Q6 of the monostable circuit 15, the negative power bus, and the output of the collector of transistor Q9 of the multivibrator circuit 19.

The oscillator 18 includes first and second transistors Q10 and Q11, the latter being a PNP transistor. The collector of transistor Q11 is directly connected to the base of transistor 10 and to the line 16 through a diode 74 arranged to conduct positive pulses to the base of transistor Q10. The collector of transistor Q10 is directly connected to the base of transistor Q11. The emitter of transistor Q10 is connected to line 33b through a resistor 75 and to line 33a through a capacitor 76. The emitter of transistor Q11 is directly connected to the bus 33a, and the base of transistor Q11 is connected to the bus 33a by means of a parallel circuit comprising a resistor 78 and a capacitor 79. The base of transistor Q10 is connected to a bias network including the resistors 80 in series with a resistor 81; both are connected between the power bus 33a and ground. The junction of the bias resistors is connected directly to the base of transistor Q10 and to the movable contact of a single pole, single throw switch S. The fixed contact of the switch S is connected to the positive power bus 33a through a resistor 82. When switch S is open, the oscillator 18 generates a train of pulses at the rate of 70 per minute. When the switch S is closed, the oscillator 18 generates pulses at the rate of 90-95 per minute.

In operation, the bias network including resistors 80 and 81 (and resistor 82 if switch S is closed) bias the transistor Q10 to a conducting state by causing its base to be positive relative to its emitter. When the transistor Q10 conducts, however, its collector draws current through the base of transistor Q11 which saturates immediately; and the lower terminal of capacitor 76 is thereupon directly connected to the positive power bus 33a through the saturated transistors Q10 and Q11. Thus, the charge on capacitor 76 will dissipate very rapidly through the saturated transistors Q10 and Q11. However, as the lower terminal of capacitor 76 rises to a potential sufficient to reverse-bias the emitter-base junction of transistor Q10, both transistors in the oscillator circuit will cut off; and the capacitor 76 will again begin to charge. The cycle is repeti-
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tive for as the lower terminal of capacitor 76 reaches a sufficiently low potential (depending upon the base bias established by the resistors 80 and 81) the transistor Q10 will again conduct.

The output pulse of the oscillator circuit 18 is taken from the collector of transistor Q11; and it is diagrammatically illustrated on line 6 of the timing diagram of FIG. 4 as the positive pulse 85. The duration of the pulse 85 is 20-30 milliseconds; and as already mentioned, the period between pulses is approximately 850 milliseconds. It will be observed that when the transistor Q10 is cut off by depletion of the charge on capacitor 76, its base voltage is slightly less than the voltage on the positive power bus 33b because transistor Q11 is saturated at that time. However, when the transistors Q10 and Q11 are cut off, the base bias voltage for transistor Q10 is very much lower—i.e., it is more nearly that of the negative power bus 33b. Hence, at the instant at which the transistor Q10 is turned off, the lower terminal of the capacitor 76 is at a relatively high potential; and it must recover down to a relatively low potential before the transistor Q10 can be re-triggered. This action provides a built-in refractory time for the operation of the oscillator 18. That is, for a definite period of time after the triggering of the oscillator 18, it may not be re-triggered.

In a preferred design, this refractory period extends for 300 milliseconds, sufficient to extend beyond the critical period when a pacemaker-produced pulse could stimulate the pacemaker detection circuit, and lead to an additional pulse. This refractory period further renders the system insensitive to external noise sources—a primary problem with implanted cardiac pacers. Thus, the refractory period has the effect of rendering the system incapable of response at repetition rates above the physiological range of interest (i.e., repetition rates above 180 per minute). Beyond the refractory period, however, the oscillator 18 may be reset by a positive pulse transmitted from the monostable circuit 15 along the line 16 through the diode 74 to cause the transistor Q10 to conduct.

It will be observed that any such advance triggering automatically establishes a set of initial conditions in the oscillator 18 so that it continues to operate in the same mode, but will have a new triggering time. As already mentioned, if a natural heartbeat is detected, it will be amplified by the input amplifier and fed through the pulse rectifier circuit 14 to trigger the one-shot monostable circuit 15. This will advance the output pulse of the oscillator circuit 18 as indicated by the solid pulse 85 in line 6 of FIG. 6. The dashed pulse 85a representing the naturally occurring pulse if a natural heartbeat had not been detected.

If the switch S is closed, the resistor 82 is coupled in parallel with the resistor 89, and the bias voltage at the base of transistor Q10 is raised, thereby raising to a relatively more positive level the voltage to which the capacitor 76 must charge in order to cause the transistor Q10 to conduct and decreasing the time between pulses even in the absence of a detected heartbeat.

The collector of transistor Q11 thus forms the input A to the pulse shaping circuit 20 which includes three transistors, Q12, Q13, and Q14. The base of transistor Q12 is connected to the input terminal A by means of a capacitor 85 and a diode 86 which is arranged to pass positive pulses. The transistors Q13 and Q14 are PNP transistors. The junction between the capacitor for the anode of diode 86 is connected to the negative bus 33b by means of a resistor 87; and the cathode of diode 86 is connected to the negative bus 33b through a resistor 88. The base of transistor Q12 is connected to the collector of transistor Q13 by means of a series circuit comprising a resistor 89 and a capacitor 90. The collector of transistor Q12 is connected to the positive power bus 33a through the collector-base junction of transistor Q12 and is connected to the negative power bus 33b by means of a resistor 92. The output signal of transistor Q12 is taken from its collector and fed directly to the base of transistor Q13. The emitter of transistor Q13 is directly connected to the positive power bus 33a; and the collector of transistor Q13 is directly connected to the emitter of transistor Q14. The collector of transistor Q14 is connected to the emitter of transistor Q12 through a resistor 94; and a resistor 95 is connected between the emitter and collector of transistor Q14. The base of transistor Q14 is connected to the input B of the pulse shaping circuit 20 through a resistor 96. It will be recalled that the pulse shaping circuit 20 was received from the monostable circuit 19 along the line 63 which is connected to the collector of transistor Q9. The pulse transmitted to the input B when a natural heartbeat is detected is shown on the left side of line 7 of the timing diagram of FIG. 4 as the negative pulse 97, there being no corresponding pulse when the system is operating in the fixed rate mode.

The pulse shaper circuit 20 is a complementary single-shot multivibrator circuit in which normally all of the transistors Q12-Q14 are biased in the cut off region. In the fixed rate mode of operation when there is no detected heartbeat (see the right side of the timing diagram of FIG. 4) so that the oscillator 18 is not advanced, a positive pulse (denoted 85b on line 6) is transmitted from the oscillator 18 to the input A, but no pulse (right side of line 7) is transmitted from the monostable multivibrator 19 to the input B of the pulse shaping circuit. Since all of the transistors in the pulse shaping circuit 20 are normally off, there is no net change on the capacitor 90 when the positive pulse is transmitted, so that if transistor Q12 is transmitted through the diode 86, it causes transistor Q12 to conduct; and this will, in turn, cause transistor Q13 to conduct and saturate. Thus, current will flow through the capacitor 90 in a regenerative action to saturate the transistor Q12 because the right terminal of the capacitor 90 is directly connected to the positive bus 33a through the saturated transistor Q13. The RC network including the input capacitor 85 and resistor 87 differentiates the positive input pulse so that it supplies only a triggering action; and when the current flowing through the capacitor 90 into the base of transistor Q12 subsides to a point at which it is incapable of sustaining conduction of transistor Q12, transistor Q12 will become nonconducting and shut off the transistor Q13. Under these conditions, the output pulse transmitted to the output amplifier 21 has a duration of 1 millisecond. It will be observed that in this mode of operation, the transistor Q14 remains nonconducting so that the resistor 95 (which is very much larger than the resistance 94) in effect isolates the collector of transistor Q13 from the emitter of transistor Q12. The width of the output pulse is determined primarily by the time constant established by the values of the resistor 89 at the capacitor 90. Under these circumstances, the output pulse generated by the output amplifier 21 is the negative pulse 98 in the right side of line 8 of FIG. 4. The output pulse received from the base of amplifier Q15 and Q16 as the active elements. Transistor Q15 is connected in a conventional common emitter arrangement. Transistor Q16, normally in a non-conducting state, allows capacitor 100 to charge thru resistor 99, and discharges capacitor 100 thru the heart during the 1 millisecond on-time of a stimulating pulse, or the 10 microsecond on-time of a non-stimulating pulse. The line 11 is connected to the junction between the power supply 101 and the heart electrode 10.

It will be appreciated that the output pulse caused by the pulse 98 of the pulse shaping circuit 20 when the pacemaker is operating in the fixed rate mode is also detected along line 11 and fed to the input amplifier 13 through the protective network 12, resulting in pulse 34b on the right side of line 2 of FIG. 4. Pulses 55c and 55d on lines 3 and 4 will also result from the monostable circuit 15. However, these pulses do not affect the remainder of the operation because there is a slight delay through the three-stage input amplifier and the pulse relay circuit. At delays such as this pulse pulse received at the oscillator 18 is received while the oscillator is in its refractory period and insensitive to any received input pulses. Hence, there is no effect on the pulse shaping circuit 20.

Turning now to the case in which a natural heartbeat is detected by the input amplifier along the line 11 (the left side of
FIG. 4). signal inputs are received at both the input A and the input B of the pulse shaping circuit 20. The negative pulse received from the collector of transistor Q9 is fed along the line 23 and causes the transistor Q14 to conduct thereby shutting the resistor 95 and connecting the collector of transistor Q13 to the emitter of transistor Q12 via resistor 94 which, it will be remembered, has a relatively low resistance. Simultaneously, the pulse received at the input A causes the transistor Q12 to conduct; and this, in turn, causes the transistor Q13 to conduct and again feed regenerative current through the capacitor 90 into the base of transistor Q12. However, since transistor Q14 is saturated, the voltage at the emitter of transistor Q12 is approximately the same (less the drops through resistor 94 and across the emitter-collector junction of transistor Q14) as the voltage at the right terminal of the capacitor 90. Thus, almost immediately as soon as the capacitor 90 begins to charge, the emitter-base junction of transistor Q12 is reverse-biased thereby cutting it off and terminating the pulse at the collector of transistor Q13 in a very short time—namely 10 microseconds. This output pulse is shown as the narrow pulse 105 on the left side of line 8 of FIG. 4.

It will be realized that in FIG. 4, the waveforms shown are idealized for the purposes of explanation, exaggeration being made in amplitude and in time in certain instances to illustrate the operation of the inventive system.

This narrow pulse 105 is also amplified by transistors Q15 and Q16, and coupled to the heart through the capacitor 100 and inductor 101. However, since there is so little energy involved it is non-stimulating and, therefore, non-competitive. At the same time, it provides an examining physician with an indication that the entire implanted cardiac pacemaker system is in an operative condition since it is capable of being picked up by the coil 25 of FIG. 3, amplified, and detected.

As already mentioned, it is convenient to have the detection means generate an audible "blip" when the narrow, non-stimulating pulse occurs. This means audible detection means may be used in conjunction with a standard EKG machine which typically has a single recording channel. When a patient is examined who has an implanted pacemaker whose AV conduction system is functioning properly, the standard EKG recording is made. It will show no pacemaker artifact; thus it is immediately obvious to the physician that the patient is pacing himself, i.e., does not have heart block. The physician then wants to know whether the pacemaker will be functional in the event of a later episode of heart block. He places a transistor radio on the pacemaker generator bulge and listens for the "blip." By watching the recorder at the same time, he can see that the non-stimulating pulse he hears is synchronized with the QRS complex; and he therefore can conclude that the pacemaker generator is functioning and the lead system is intact and sensing the natural QRS complex.

Having thus described in detail a preferred embodiment of the present invention, persons skilled in the art will be able to substitute elements for those disclosed to perform the same or similar functions, or to otherwise modify the illustrated embodiment while continuing to practice the inventive principle; and it is, therefore, intended that all such modifications and substitutions be covered as they are embraced within the spirit and scope of the invention. As used in the claims, the word "pulse" is intended to describe any electrical signal other than a non-varying signal (such as zero voltage or any other dc level) or a continuous wave signal such as a continuous sine wave.

I claim:

1. In a cardiac pacer system adapted to be implanted in a body, the combination comprising electrode means adapted to contact the heart, excitation means for generating a continuous train of electrical pulses to energize said electrode means, and a generator means for generating a control signal in timed relation with a natural heartbeat, said excitation means including circuit means for generating either a first electrical pulse in said train to stimulate the heart in the absence of said control signal or a second electrical pulse in said train incapable of stimulating said heart in the presence of said control signal.

2. In combination with the system of claim 1, detector means adapted for use external to said pacer system and responsive to said second electrical pulses for detecting the occurrence of said non-stimulating pulses whereby when said pacer system is implanted said system is non-competitive and an examining physician may ascertain that the pacer system is operative in the presence of a normally functioning heart.

3. The system of claim 1 wherein said excitation means includes an oscillator for generating a train of electrical pulses at a repetition rate slightly less than the normal repetition rate of the heart, pulse shaping circuit means receiving the output signal of said oscillator means for generating a heart-stimulating first pulse for each received pulse from said oscillator means in the absence of said control signal, and conductive means coupling said control signal to said pulse shaping circuit means for generating said non-stimulating second pulse in timed relation with the occurrence of said natural heartbeat.

4. The system of claim 3 further comprising means for resetting said oscillator means in the presence of a natural heartbeat whereby said oscillator means operates in a fixed rate mode to generate said first pulses in the absence of a natural heartbeat and generates said second electrical output pulses in synchronism with a naturally occurring heartbeat.

5. The system of claim 4 wherein said oscillator means has a refractory period of about 300 milliseconds after it is reset wherein it is not capable of forever continuing to oscillate within said refractory period, thereby to reduce the sensitivity of said system to external noise sources having a repetition rate greater than about 3 cycles per second.

6. The system of claim 1 wherein said generator means includes sensor means adapted to contact the vestibule of the heart to sense a QRS complex therein.

7. A non-competitive pacemaker system capable of either a fixed rate or a demand mode of operation comprising electrode means for contacting the heart of a patient, first pulse generator means for generating a train of heart-stimulating signals and coupling the same to said electrode means at an interval greater than the natural heartbeat interval only when said natural heartbeat does not occur within said interval, whereby said system operates in a fixed rate mode in the absence of a natural heartbeat, and sensing means including circuit means for generating externally detectable, non-stimulating pulses in timed relation with natural heartbeats and for coupling said non-stimulating pulses to said electrode means only when said natural heartbeat occurs whereby said pacer operates in a demand mode.

8. In combination with the system of claim 7 wherein said non-stimulating pulses extend for a duration of about 10 microseconds and further comprising detection means exterior of said patient for selectively detecting the occurrence of said non-stimulating pulses whereby an examining physician may ascertain the operativeness of said system when said system is operating in said non-competing mode and the heart of the patient is functioning normally.

9. The combination of claim 8 wherein said detection means further includes means for generating an audible signal when said non-stimulating pulses occur.

10. The system of claim 8 wherein said first signal generator means includes a fixed-rate oscillator for generating a train of pulses at intervals greater than the natural heartbeat interval and shaping circuitry for coupling a heart-stimulating pulse to said electrode means from said oscillator means only after said natural heartbeat interval has lapsed.

11. The system of claim 10 wherein said sensing means comprises means adapted to sense the occurrence of a natural QRS complex in a heart for generating a control signal in response thereto, means for resetting said oscillator to generate a non-stimulating pulse immediately in timed relation with said control means thereby coupling said control signal to said shaping means for modifying the time constant thereof to generate said non-stimulating pulse immediately and in timed relation with the occurrence of a natural heartbeat.
12. The system of claim 7 characterized in that said stimulating pulses occur for about one millisecond and said non-stimulating pulses occur for about 10 microseconds.

13. A method of pacing a heart comprising sensing a natural QRS complex, generating an electrical control signal in response to said sensed QRS complex, generating a non-stimulating, externally detectable pulse in response to said control signal, and stimulating said heart in the absence of said control signal at a predetermined time after a natural heartbeat should have occurred.

14. The method of claim 13 further comprising coupling said non-stimulating pulse to said heart.

15. In combination, an implantable, non-competing demand cardiac pacer system for generating heart stimulating pulses and transmitting said stimulating pulses to the heart only in the absence of a natural heartbeat; and means responsive to the presence of a natural heartbeat for generating externally detectable, non-stimulating pulses in mutually exclusive relation with said stimulating pulses and for transmitting said non-stimulating pulses to said heart, whereby the detection of said non-stimulating pulses is indicative that the pacer is operating in a demand mode and that said system is operational.