In the implantable cardiac pacer disclosed herein, various operating parameters are determined or controlled by the information held in a digital storage register such as a binary counter. The information so held may be varied by means of pulse signals transmitted through the body of a patient within whom the pacer is implanted. Rate-sensing and count threshold control circuits are provided to prevent unintended changes in operating parameters.
IMPLANTABLE CARDIAC PACER HAVING ADJUSTABLE OPERATING PARAMETERS

This is a continuation of application Ser. No. 141,694 filed May 10, 1971, now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to fully implantable prosthetic or therapeutic devices and more particularly to cardiac pacers in which various operating parameters may be adjusted or varied without surgically obtaining access to the pacer itself.

Various means have been proposed for altering the operating parameters of an implanted cardiac pacer without requiring surgery as such. For example, it has been proposed to utilize needle-like adjusting tools to select resistance values and to use bistable magnetic reed switches for performing various switching functions. However, each of these prior art adjustment means has heretofore typically been rather limited in application. A serious drawback in most of these prior art systems is that the range of adjustment or the number of adjustments which can be made is highly limited. Further, there may be a problem in retaining the desired value after the adjustment procedure per se is complete. In the case of bistable magnetic reed switches, transient magnetic fields may cause the switch to reverse state. The switch will then remain in that state indefinitely and thereby cause an undesired mode of operation. In the case of needle-like adjusting tools, the danger of infection due to penetrating the patient’s epidermis remains even though that danger is reduced by the needle-like character of the tool.

Among the several objects of the present invention may be noted that provision of apparatus which permits the adjustment or variation of several operating parameters of an implanted prosthetic device such as a cardiac pacer without requiring surgical access to the device; the provision of such apparatus in which a parameter may be adjusted over a wide range and to any one of a wide variety of preselected values within the range; the provision of such apparatus in which predetermined combinations of different operating parameters may be selected simultaneously; the provision of such a system which provides for the reliable storage of the parameter-determining information; the provision of such apparatus which is relatively immune to electrical noise and transient magnetic fields; and the provision of such apparatus which is highly reliable and which is relatively simple and inexpensive. Other objects and features will be in part apparent and in part pointed out hereinafter.

SUMMARY OF THE INVENTION

Briefly, an implantable pacer constructed in accordance with the present invention employs means for detecting pulse signals having predetermined characteristics which are applied externally of a patient within whom the pacer is implanted. A counter is interconnected with the detecting means and is advanced by the detected pulse signals. A cardiac stimulation pulse generator is provided in which at least one output parameter is adjustable. Decoding means are interconnected between the counter and the pulse generator for setting the adjustable parameter to a value corresponding to the particular count accumulated by the counter. Accordingly, the output parameter may be adjusted by means of pulse signals applied externally of the patient.

BRIEF DESCRIPTION OF THE DRAWING

The single drawing is a schematic block diagram of an implantable cardiac pacer having operating parameters which are adjustable in accordance with the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawing, an essentially conventional cardiac stimulation pulse-generating circuit is indicated generally at 11. Appropriate supply potentials are provided as indicated. An NPN transistor Q1 and a PNP transistor Q2 are interconnected in a so-called complementary-symmetry type of relaxation oscillator. The voltage at the base terminal of PNP transistor Q2 is controlled by a voltage divider comprising resistors R12 and R14, this voltage being filtered by a capacitor C4 with the filter source impedance being determined by a resistor R11.

The collector of transistor Q2 is connected to the base of transistor Q1 through a capacitor C5 and a resistor R17 connected in series therewith. As will be understood by those skilled in the art, this connection provides regenerative feedback during the pulse output portion of the oscillator’s cycle of operation. The oscillator output signal, taken from the collector of transistor Q2, is applied, through a pair of resistors R15 and R16, to the base terminal of an NPN output transistor Q3. This transistor is normally biased off by means of a resistor R13. The collector terminal of output transistor Q3 is provided with a load resistor R10 and is coupled, through a capacitor C3, to the pacer output terminal 13. As is understood, the output terminal 13 will be coupled to a patient’s cardiac tissue through an appropriate lead system, as is conventional. The lead system also establishes a common ground potential. The output circuit is protected by a zener diode Z1 in conventional manner.

As is understood, the repetition rate of the complementary symmetry oscillator depends upon the bias current provided to the base terminal of transistor Q1. This current serves to recharge the capacitor 5 between output pulses. This bias current is provided from the positive supply voltage through a series of timing resistors R4–R8 which are graded in value according to a predetermined sequence. Selected ones of the resistors R4–R8 may be shunted by the operation of a quadrilateral switch 15. As will be understood by those skilled in the use of integrated circuits in digital applications, the quadrilateral switch 15 will typically comprise a plurality of active semiconductor elements formed in a single semiconducting wafer or chip. However, for the purpose of facilitating the description of the present invention, the switching function performed by this circuitry is conveniently represented in the drawing by four conventional switch symbols. Each such switch is under the control of a respective input signal, as indicated. As will be understood, 16 values of total series resistance may be obtained by closing the individual switches in various combinations. Correspondingly, 16 different pulse repetition rates will be available from the oscillator comprising transistors Q1 and Q2.
The junction between resistors R15 and R16 can selectively be shunted to ground through a resistor R9 and a semiconductor switch or gate 17. Again, this function is indicated by a conventional switch symbol although semiconductor switching elements are preferred in actual practice. The operation of the switch is under the control of a respective input signal, as indicated. When the gate or switch 17 is closed, a portion of the drive or output current from the oscillator transistors Q1 and Q2 is shunted away from the base circuit of the output transistor Q3 through resistor R9. The stimulation pulse output current is correspondingly reduced. Thus, the gate 17 provides a means for selecting between two output current levels. In other words, means are provided for adjusting the value of a second operating parameter of the stimulation pulse generating circuitry. Since the number of available states double with each further stage added to the binary counter, it can be seen that the number of combinations of several different parameters may easily be expanded. For example, selected count bits may be used to control whether the pacer operates in a synchronous or non-synchronous mode or in a standby or continuous mode.

In accordance with the present invention, the pulse repetition rate and the output current of this stimulation pulse generator 11 may be adjusted or controlled while the pacer is implanted, without surgically entering the patient's body. In the embodiment illustrated, pulse signals for transmitting the information used in determining these output parameters is transmitted into the patient's body by means of a magnetic field which is sensed by a magnetic reed switch 21. Reed switch 21 is interconnected with the positive supply so as to provide a source of input pulses to one of the input terminals of a NOR gate 23. This input terminal is normally biased negatively through a resistor R1. The output signal from NOR gate 23 is coupled, through a capacitor C1, to both input terminals of a second NOR gate 25, which thus functions as an inverter. These input terminals are normally biased in the positive sense through a resistor R2. The output signal from NOR gate 25 is, in turn, applied back to the other input terminal of the first NOR gate 23.

As will be understood by those skilled in the art, this interconnection of the NOR gates 23 and 25 provides the mode of operation of a one-shot multivibrator. The time constant or period of the multivibrator is determined by the relative values of capacitor C1 and resistor R2 and is selected so as to provide, for each triggering pulse, a square-wave output pulse of longer duration than any contact bounce which might be expected from the magnetic reed switch 21. This operation thus provides a pulse shaping so that the resultant electrical pulses are suitable for use with digital circuitry in conventional manner.

While magnetic pulse signals are presently preferred as a method of communicating information to the implanted device, other types of signals, appropriately selected to avoid interference from ambient interference, may also be used. For example, bursts of acoustic energy at preselected frequency can be transmitted through tissue and detected. Likewise, bursts of electromagnetic energy at relatively low r.f. frequencies can be detected and used to advance the counters or registers of the present invention. Relatively low r.f. frequencies, e.g., 15,000-150,000 Hz, have the advantage that they can penetrate a shield around the implanted device which would protect the circuitry from high frequency transients which might affect the logic circuitry.

The pulse signals obtained from the multivibrator are applied, through a diode D1, to a timing capacitor C2 which is shunted by a resistor R3. The voltage on capacitor C2 is, in turn, applied to an inverting gate 27. Gate 27 functions essentially as a voltage threshold device, the output signal from gate 27 being positive or a digital "one," except when the voltage on capacitor C2 is above a predetermined voltage level or threshold which is the level of actuation of the gate. Together with the capacitor C2 and resistor R3, gate 27 thus operates as a rate detector. When pulses from the one-shot multivibrator are applied through diode D1 to capacitor C2 so as to re-charge the capacitor faster than it is discharged by the resistor R3, the output signal from gate 27 will remain negative so as to constitute a logic "zero."

The output signal from gate 27 is applied as a reset signal to a decade counter 31. Decade counter 31 is assumed to be of the integrated digital circuit type having an integral decoder so that separate output signals corresponding respectively to each of the ten successive states of the counter are available without external matrixing. In the embodiment illustrated, only the "6" and "7" output signals are utilized.

The shaped input pulses obtained from the one-shot multivibrator are applied to the input terminal of counter 31, through a NOR gate 35. The "7" output signal from the decade counter 31 is applied as a second input to NOR gate 35 so as to selectively control the application of these input pulses. As will be understood, this connection will allow the counter to count up to its seventh state. At this point, the "7" output signal becomes a digital "one." Accordingly, the output signal from gate 35 will be held at a digital "zero" and further counting is prevented.

The "7" signal from the decade counter 31 is also applied, through an inverting gate 37, to a NOR gate 39. NOR gate 39 is connected so as to control the application of the input pulses, obtained from the one-shot multivibrator, to a binary counter 43. Since the "7" output signal from the decade counter 31 is inverted prior to its application to the NOR gate 39, it will be seen that the binary counter 43 is inhibited from counting until the decade counter 31 reaches its seventh state. The "6" output signal from the decade counter 31 is applied as the reset signal to the binary counter 43.

Thus, when the decade counter 31 passes through its sixth state, the binary counter 43 will be reset. Then, when the decimal counter 31 reaches its seventh state, it will stop counting and the binary counter 43 will begin to count upwards from its reset or "zero" state in response to any pulse input signals applied thereto by the multivibrator circuit.

Counter 43 is a five-stage binary counter, an output signal being provided from each stage. The output signals from the first four stages, i.e., the "1", "2", "4", and "8" signals, are applied to control the quadrant-bilateral switch 15. Thus, the value of the repetition rate-controlling resistance will be a function of the count held by the first four stages of binary counter 43. The "16" output signal from binary counter 43, i.e., the signal from the fifth stage, controls the gate 17 which, as noted previously, affects the output current level of
the stimulation pulse-generating circuit 11. The counter 43 has 32 possible states, 16 of which the "16" signal is a logic "one" and 16 in which that signal is a logic "zero." Accordingly, it will be seen that any of the 16 different pulse repetition rates can be provided at either of the two output current levels. In other words, there are 32 output parameter combinations which can be applied to the stimulation pulse generator 11 and the selection of which of these 32 exists at any one time is under the control of the count accumulated in the binary counter 43.

Summary of Operation

Briefly then, the operation of the embodiment illustrated is as follows. The output parameters of the stimulation pulse generator 11 are determined in correspondence with the count held in the binary counter 43. The existing parameter values persist until the counter 43 is set to some different value. Pulse signals for changing the count held in counter 43 are introduced by applying, through the patient's body, bursts or trains of magnetic pulses which will actuate the magnetic reed switch 21. Each operation of the reed switch triggers the one-shot multivibrator comprising gates 23 and 25 so that a squarewave pulse, suitable for use with digital circuitry, is generated. If successive pulses follow at a rate which is within the time constant determined by capacitor C2 and resistor R3, the gate 27 resets the counter 31 and this counter begins to count the shaped input pulses. After the counter 31 receives six of the succeeding pulses, the binary counter 43 is reset. When the decade counter reaches its seventh state, it is stopped from further counting and subsequent shaped input pulses are applied to the binary counter 43 so that this counter is then advanced from its initial or all "zero" state. The total length of the pulse train is selected so that the new count introduced into the binary counter 43 corresponds to that state of the counter which will produce the desired output parameters, i.e., through the quad bilateral switch 15 and the gate 17. For example, if it is desired to set the stimulation pulse generator output parameters to values corresponding to the seventh state of the binary counter 43, the applied pulse train should produce fifteen activations of the magnetic reed switch 21. The first activation causes the gate 27 to release the reset signal from the counter 31, the next seven counts advance the decade counter 31 and the last seven counts advance the binary counter 43 to the desired state. Since magnetic reed switches can operate at frequencies of several hundred Hz and the digital counting circuitry will operate much faster, a complete resetting cycle can be accomplished in less than a typical heartbeat period. If even faster parameter resetting is sought, semiconductor magnetic or electric sensing devices may be used.

In addition to providing timed resetting of the output control counter 43, the count threshold established by the decade counter 31 also provides the additional desirable function of establishing a count threshold which must be exceeded before any change in output parameter will be effected. Thus, a short burst of electrical noise pulses which might find their way into the circuitry at the proper repetition rate to actuate the ratessensitive circuitry, still would not typically advance the counter 31 sufficiently far to erase the output parameter information previously stored in the binary counter.

Accordingly, a very high degree of noise immunity is provided.

Apparatus in accordance with the embodiment illustrated was constructed using components having the values and/or manufacturer's part designation as given in the following table and this apparatus operated in the manner described.

<table>
<thead>
<tr>
<th>TABLE</th>
<th>Ohms</th>
<th>Microseconds</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1</td>
<td>100,000</td>
<td></td>
</tr>
<tr>
<td>R2</td>
<td>1,000,000</td>
<td></td>
</tr>
<tr>
<td>R3</td>
<td>1,000,000</td>
<td></td>
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<tr>
<td>R4</td>
<td>176,000</td>
<td></td>
</tr>
<tr>
<td>R5</td>
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</tr>
<tr>
<td>R6</td>
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<tr>
<td>R7</td>
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<tr>
<td>R8</td>
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<td>R9</td>
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<td>10,000</td>
<td></td>
</tr>
<tr>
<td>R17</td>
<td>1,000</td>
<td></td>
</tr>
</tbody>
</table>

NOR Gates

RCA CD 4001

23, 25, 35 and 39

Decade Counter

RCA CD 4017

Binary Counter

RCA CD 4004

Quad Bilateral Switch

RCA CD 4016

Gates 27, 37 and 17

RCA CD 4007

With regard to the inverting gates 27 and 37, it may be noted that these gates, in the RCA integrated circuit designated, are in fact pairs of separable field-effect transistors on the same chip and a remaining one of the transistors on the same integrated circuit chip is employed as the switching gate 17. While this particular embodiment was made up using commercially available integrated circuit devices, it should be understood that essentially the same circuitry can be formed as a single special purpose integrated circuit using so-called large scale integrated circuit (LSI) techniques, as can other embodiments falling within the scope of the appended claims. The particular integrated circuits designated are of the complementary MOSFET (metal oxide semiconductor, field-effect transistor) type. An advantage of this type of circuitry in implantable stimulation devices is that the logic gates employed draw very little current except in actual switching and thus average current drain is very low.

While the parameter-controlling apparatus of the present invention has been illustrated in conjunction with stimulation pulse generating circuitry using analog timing and output current control, it should be understood that, the functional parameters of other types of stimulation pulse-generating circuitry may also be controlled in accordance with the count held in a digital storage register such as the binary counter 43. For example, apparatus of the present invention might also be used in conjunction with a digitally timed implantable cardiac pacemaker, e.g., of the type disclosed in U.S. Pat. No. 3,557,796 Keller et al. Similarly, the operating parameters of other types of tissue stimulators, e.g., bladder, phrenic nerve, or carotid sinus, may also be controlled in accordance with the present invention.
In view of the foregoing, it may be seen that several objects of the present invention are achieved and other advantageous results have been attained.

As various changes could be made in the above constructions without departing from the scope of the invention, it should be understood that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

What is claimed is:

1. An implantable cardiac pacemaker comprising:
   means for detecting pulse signals having predetermined characteristics, which pulse signals can be applied externally of a patient within whom said pacemaker is adapted to be implanted;
   a first counter interconnected with said detecting means for selectively counting detected pulse signals;
   a second counter, controlled by said first counter and also responsive to said pulse signal detecting means for counting detected pulse signals occurring after the count held by said first counter reaches a preselected threshold value;
   a cardiac stimulation pulse generator having at least one changeable output parameter; and
   decoding means interconnected with said second counter for controlling said output parameter in predetermined correspondence with the value of the count held by said second counter.

2. In a fully implantable therapeutic device providing an electrically controlled physiological function, apparatus for adjusting the operating parameters of the device while implanted, said apparatus comprising:
   means for detecting pulse signals having predetermined characteristics, which pulse signals can be applied externally of a patient within whom said device is adapted to be implanted;
   a first counter interconnected with said detecting means for selectively counting detected pulse signals;
   a second counter, controlled by said first counter and also responsive to said pulse signal detecting means for counting detected pulse signals occurring after the count held by said first counter reaches a predetermined threshold value;
   decoding means interconnected with said second counter for controlling operating parameters of said device in accordance with the count held by said second counter; and
   means for resetting said first counter if no pulse signals are received for a predetermined period.

3. In a fully implantable device for automatically providing an electrically controlled physiological function, apparatus for adjusting the operating parameters of the device while the device is implanted, said apparatus comprising:
   a magnetically operable switch for detecting magnetic pulse signals, which pulse signals can be applied externally of a patient within whom said device is adapted to be implanted;
   a first counter interconnected with said switch for selectively counting operations of said switch;
   means for resetting said first counter if no pulse signals are received for a preselected period;
   a second counter, controlled by said first counter and selectively responsive to the operation of said switch;
   means controlled by said first counter for resetting said second counter when the count held by said first counter reaches a preselected threshold level and for subsequently enabling said second counter to count switch operations; and
   decoding means interconnected with said second counter for controlling the operating parameters of said device in accordance with the count held by said second counter.

4. A device as set forth in claim 3 including a one-shot multivibrator which is triggered by the operation of said switch and which generates square-wave output pulses of predetermined duration, said counters being responsive to the multivibrator output pulse to count operations of said switch.

5. A device as set forth in claim 3 wherein said first and second counters comprise complementary MOSFET integrated logic circuits.

6. An implantable cardiac pacemaker comprising:
   a magnetically operable switch for detecting magnetic pulse signals, which pulse signals can be applied externally of a patient within whom said pacemaker is adapted to be implanted;
   a first counter interconnected with said switch for selectively counting operations of said switch;
   means for resetting said first counter if no pulse signals are received for a preselected period;
   a second counter, controlled by said first counter and selectively responsive to the operation of said switch;
   means controlled by said first counter for resetting said second counter when the count held by said first counter reaches a preselected threshold level and for subsequently enabling said second counter to count switch operations;
   a cardiac stimulation pulse generator having at least one adjustable output parameter; and
   means interconnected with said second counter for setting said output parameter to a value corresponding to the count held by said second counter.

7. In a fully implantable device for providing an electrically controlled physiological function, apparatus for adjusting the operating parameters of the device while the device is implanted, said apparatus comprising:
   means for detecting pulse signals having predetermined characteristics, which pulse signals can be applied externally of a patient within whom said device is adapted to be implanted;
   means responsive to a first predetermined grouping of detected pulse signals for providing a control signal;
   a parameter control register having a multiplicity of states;
   means for controlling the operating parameters of said device in accordance with the existing state of said control register; and
   means responsive to said control signal for changing the state of said register in accordance with predetermined groupings of detected pulse signals following said first grouping of pulse signals, thereby to vary the operating parameters of said device.

8. In a fully implantable device for automatically providing electrical stimulation of tissue, apparatus for adjusting the operating parameters of the device while the device is implanted, said apparatus comprising:
means for detecting pulse signals having predetermined characteristics, which pulse signals can be applied externally of a patient within whom said device is adapted to be implanted; means including a counter responsive to a first predetermined sequence of detected pulse signals for providing a control signal; a parameter control counter having a multiplicity of sequential states; means for controlling the operating parameters of said device in accordance with the existing state of said control counter; and means enabled by said control signal for advancing the state of said control counter in response to detected pulse signals following said first sequence of pulse signals, thereby to vary the operating parameters of said device.

9. Apparatus as set forth in claim 8 wherein said control counter is responsive to said control signal and is reset thereby to a preselected state.

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