

[54] **CONTROLLED ENERGY OUTPUT PACER**
[75] Inventor: **Sherwood S. Thaler**, Lexington, Mass.
[73] Assignee: **American Optical Corporation**, Southbridge, Mass.
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[51] Int. Cl. **A01n 1/36**
[58] Field of Search..... **128/419 P, 419 R, 128/421-423; 307/265**

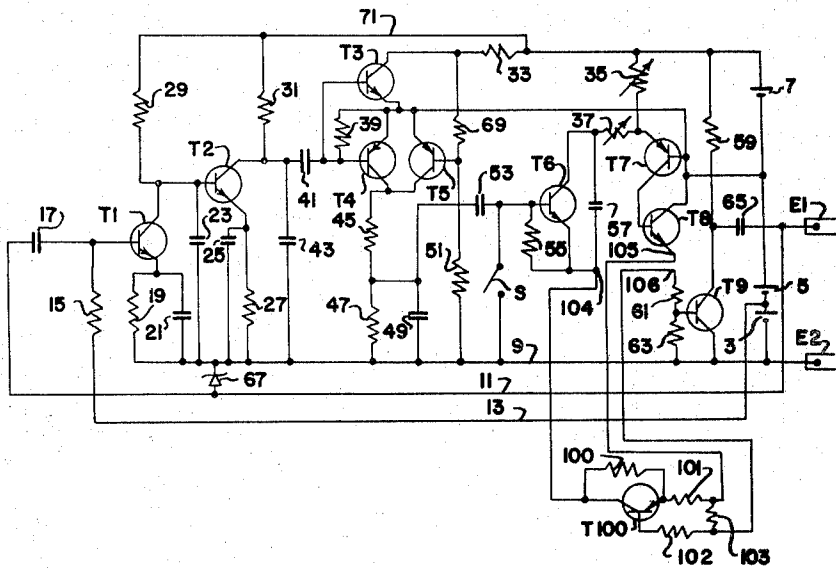
[56] **References Cited**

UNITED STATES PATENTS			
3,127,895	4/1964	Kendall	128/422
3,454,012	7/1969	Raddi	128/419 P
3,523,539	8/1970	Lavezzo et al.	128/419 P

Primary Examiner—William E. Kamm
Attorney—William C. Nealon et al.

[57] **ABSTRACT**
A controlled energy output pacer. The apparatus includes an electrical power supply and a pulser for generating stimulation pulses on terminals connected to a patient's heart. An integral control is provided for automatically controlling the stimulation pulses as a function of power supply (energy source) value to maintain the energy output above a predetermined level. The present invention can be used with many types of heart stimulating devices including extra-corporeal pacers, but is particularly useful when utilized with non-accessible or implanted pacers. In an illustrative embodiment, a circuit is provided for indicating the approximate amount of remaining power supply life and for controlling energy supplied to the heart with each stimulation pulse to above a minimum required value regardless of energy source variation.

5 Claims, 2 Drawing Figures



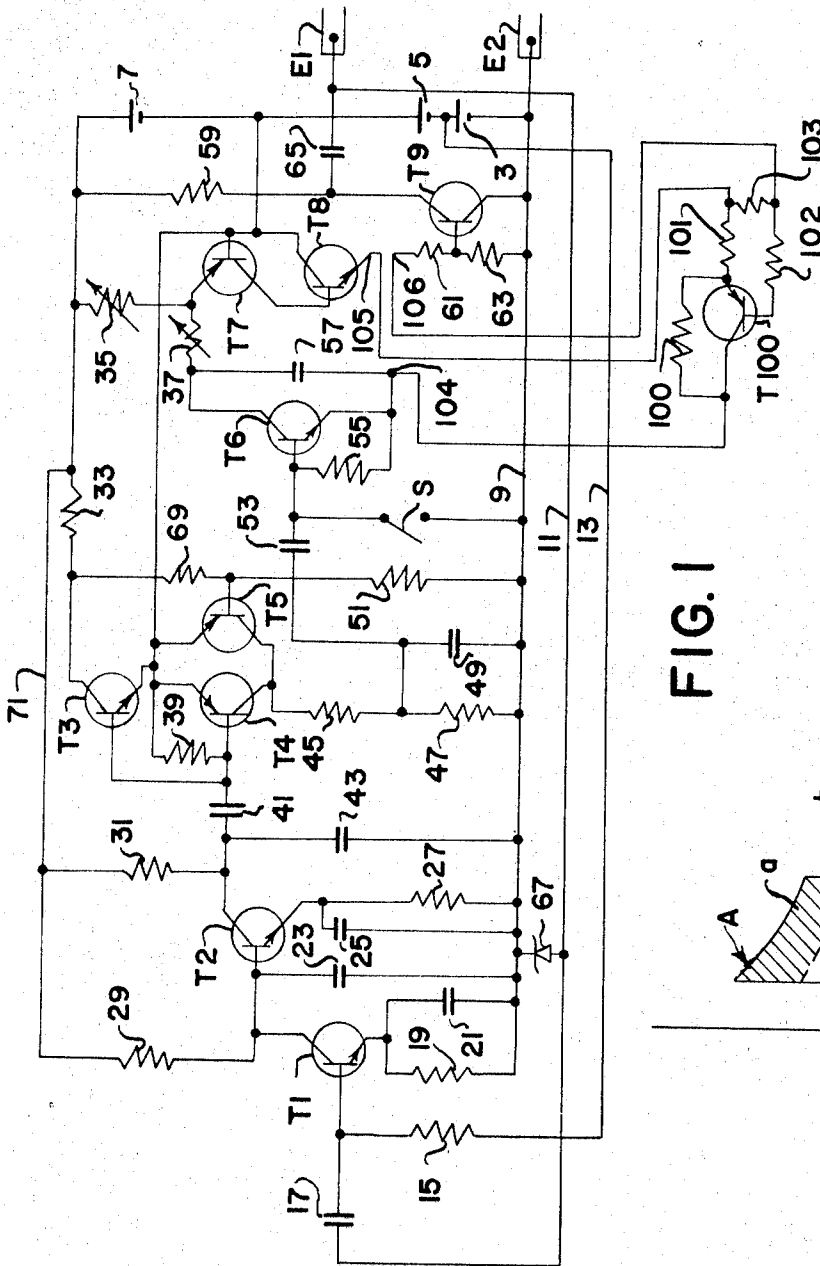


FIG. 1

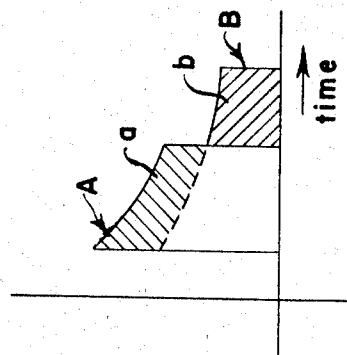


FIG. 2

INVENTOR.
SHERWOOD S. THALER
BY *Joel Wall*
Agent

CONTROLLED ENERGY OUTPUT PACER**BACKGROUND OF THE INVENTION****1. Field of the Invention**

The present invention relates generally to electronic heartbeat-stimulating apparatus. More particularly, the present invention relates to a system for automatically controlling the energy in each heartbeat-stimulating pulse and to a system for indicating the remaining useful life of the battery power supply.

2. Description of the Prior Art

In the burgeoning field of medical-electronics, electronic pacer devices for providing stimulation to a patient's heart to induce a heartbeat have been developed over the past 10 years or so. Stimulating devices of the demand type, wherein stimulation is provided only in the absence of natural heartbeats have been developed. More recently, devices of the type which will stimulate the atrium and the ventricle separately have been developed. The present invention is yet another improvement in the growing family of improvements to heart-stimulating devices.

In the implantable variety of pacers, batteries in a series string are commonly employed as a power supply. Batteries, of course, run down and fail individually after periods of time. One of the problems with most heart stimulating devices to date, and particularly with the implantable variety, results from battery deterioration combined with fixed pulse-width of the heartbeat stimulation pulse. A problem is that energy of the stimulation pulse (related to the voltage-time area of the pulse) will decrease as the battery voltage decreases. This will eventually cause malfunction of the pacer.

A certain quantity of energy is required to stimulate a heartbeat. This energy varies from person to person and is herein termed "capture energy". Initially after implantation of a particular pacer, battery voltages are maximum. To provide capture energy initially after implantation, one requires a relatively narrow pulse. The pulse area is sufficiently large due to relatively large pulse height. By comparison, to provide capture energy at a later point in time (for example, 1 year after implantation when battery voltages have diminished) a sufficiently large pulse width must have been provided at the time of implantation.

Thus, on the one hand, if the pulse width is preset to be "large" a great deal of the battery's energy is not used efficiently, since it is an excess over the required energy. On the other hand, consider the pulse width set exactly at the minimum width required to provide capture energy immediately after implantation. After a period of time when battery voltages diminish or when a battery fails, pulse height will correspondingly diminish and there will be insufficient energy associated with the pulse to cause capture.

This "capture energy" and efficiency problem is solved by the present invention. Applicant provides a device for maintaining the energy of each stimulation pulse approximately constant (equal to or greater than the required capture energy) for the duration of heart stimulator use.

Another problem associated with inaccessible pacers is the lack of information relating to battery usage and/or to remaining battery life. The inaccessibility of implanted pacers makes direct measurement of the batteries impractical. Patients and physicians were not

certain as to when the batteries would deteriorate to the extent that the pacer would malfunction. This uncertainty created unnecessary anguish for the patient. The present invention provides a solution to this problem with an external monitoring/indicating system for indicating the remaining useful life of the implanted pacer batteries.

SUMMARY OF THE INVENTION

The present invention relates to a system for controlling the width of pulses used for heartbeat stimulation. The invention includes a device for sensing variations in the power supply. It controls the width of stimulation pulses in response to variations in the power supply in such a manner as to maintain energy of the stimulation pulses approximately constant. The pulse width control includes a device for automatically varying a time constant circuit in accordance with variations of power supply voltage.

The present invention also relates to a system for monitoring the power supply or batteries of the heartbeat stimulating apparatus. This system provides an indication of the remaining life of the batteries. This information is particularly useful in connection with an implantable pacer. An ex-vivo (external) indication of battery life of an implanted heart pacer is obtained on a simple oscilloscope with the use of ordinary ECG leads. The ECG leads sense the stimulation pulse and it is displayed on the oscilloscope. The width of the displayed pulse provides information from which the remaining useful life (or the amount of life used up) of the battery or batteries is determined.

There are several advantages of the present invention. One salient feature or advantage of the present invention is its ability to allow a physician to determine useful remaining battery life without resorting to a surgical procedure in order to remove the batteries and have the batteries checked.

A second distinct advantage of the present invention is that it permits efficient presetting of the stimulation pulse width for maximum utilization of the supply batteries. This extends battery life and extends the time between implanted pacer replacement surgical operations.

It is thus an object of the present invention to provide a heartbeat-stimulating device which has an approximately constant stimulation-pulse energy.

It is yet another object of the present invention to provide a monitoring system for indicating remaining useful life of the pacer power source.

Other objects and advantages of the present invention will become apparent to one having reasonable skill in the art after referring to the detailed descriptions of the appended drawings in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a circuit diagram of a type of demand pacer that is disclosed in U.S. Pat. No. 3,528,428, incorporating the improvement of the present invention; and,

FIG. 2 is a graph of two superimposed stimulation pulses plotting amplitude vs. time.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 is a circuit schematic diagram of a demand pacer of the type disclosed in U.S. Pat. No. 3,528,428. Subject matter disclosed in that patent is incorporated

herein by reference. Thus, only partial operation of this circuitry will be described below. The reader is referred to U.S. Pat. No. 3,528,428 for complete description of the circuitry. For purposes of simplifying the discussion, consider switch S to be closed thereby rendering transistor T6 non-conductive. (The present invention is operative with switch S open as well.)

In U.S. Pat. No. 3,528,428, capacitor 57 is a timing capacitor. It charges from the series arrangement of batteries 3, 5, and 7, (hereafter referred to sometimes as the energy source or as the battery) through potentiometers 35 and 37 and resistors 61 and 63. The voltage on capacitor 57 charges to a threshold voltage determined by the voltage on the base of transistor T7 established in this embodiment by batteries 3 and 5. When the voltage on capacitor 57 exceeds the voltage on the base of transistor T7 by the base-emitter voltage drop, transistor T7 is rendered conductive, which renders transistor T8 conductive. Transistor T7 and T8 conduct and capacitor 57 discharges through both transistors and only potentiometer 37 (in 3,528,428).

The improvement depicted in a particular illustrative embodiment comprises resistors 100, 101, 102, and 103, and transistor T100. These components are arranged in an integral control circuit to sense fluctuations in battery voltage and to automatically vary its effective circuit resistance value in accordance therewith. (In U.S. Pat. No. 3,528,428, junctions 104, 105 and 106 are a common, unnumbered junction.)

In the control circuit, resistor 100 is in parallel connection with the emitter-collector of transistor T100. The collector of transistor T100 is connected to junction 104. The emitter of transistor T100 is connected to one end of resistor 101, the other end being connected to junction 105. The base of transistor T100 is connected to resistor 102, the other end being connected to junction 106. Resistor 103 is connected between junctions 105 and 106.

In the present invention the charge path of capacitor 57 still includes resistors 61 and 63 since capacitor 57 is charged from batteries through that circuitry, and the discharge path of capacitor 57 still does not involve resistors 61 and 63. But now, capacitor 57 discharges not only through potentiometer 37, but also through resistor 101 and the parallel combination of resistor 100 and transistor T100. (Potentiometer 37 is still used to preset the pulse width but otherwise can be considered as series resistance in the discharge path of capacitor 57. Functionally, it can be considered to be lumped in with the resistance value of resistor 101.)

Resistor 103 can be considered to be one resistor of a resistive voltage divider across batteries 3, 5, and 7. The resistive voltage divider comprises resistors 61 and 63, potentiometer 35 and resistor 103.

In operation, the voltage developed across resistor 103 acts as the biasing source of transistor T100. The higher the voltage developed across resistor 103, the greater the voltage applied to the circuitry to its left. The voltage developed across resistor 103 is due to current flow therethrough only from the series of batteries, and not from capacitor 57. Thus, resistor 103 is a battery voltage sensing resistor. It can also be considered as an energy-source sensing or battery-current sensing resistor.

The voltage developed across resistor 103 causes a base current to flow from emitter to base in transistor T100 (in the direction of the emitter arrow). The

greater the base current, the more transistor T100 turns on and the more readily it conducts capacitor 57 discharge current from its emitter to its collector. Thus, transistor T100 acts like a variable resistor automatically controlled by its base current which is proportional to voltage developed across sampling or sensing resistor 103.

If the pacer were recently implanted, the battery voltage is high or at a peak; transistor T100 is strongly turned on, and its effective resistance to flow of emitter-collector current is relatively low. Thus, capacitor 57 will discharge with ease in a relatively short time through this low resistance path. This is what is expected when the battery potential is high or at a maximum.

By comparison, consider a period of time after implantation (i.e. perhaps a year or so) during which the batteries have individually failed or diminished by virtue of their use. For this situation, after capacitor 57 charges sufficiently to overcome the threshold established on the base of transistor T7, transistors T7 and T8 conduct current as usual. However, when the transistors conduct (and provide a discharge path for capacitor 57 through them and through resistors 101 and 100, and transistor T100), a lower battery voltage is impressed across the resistive voltage divider than described in the previous paragraph.

Resistor 103 now develops smaller voltage than before and voltage applied to base-emitter terminals of transistor T100 and base current of transistor T100 are proportionately reduced. The usual effect of reducing base current of a transistor is to decrease the ability with which it can conduct current between its emitter and collector. Transistor T100 thus conducts less current and acts like an increased resistance in the discharge path of capacitor 57. Accordingly, for lower battery voltages, capacitor 57 requires a greater time to discharge completely than it required in the previous example. Thus, discharge time of capacitor 57 is automatically controlled by battery voltage in this integral pulse control.

The effect of the discharge time control circuit may best be illustrated by reference to FIG. 2. FIG. 2 represents two pulses that are used for stimulation of a heartbeat. Pulse A is generated when the battery voltage is high or at its maximum. The pulse amplitude is correspondingly high or maximum, and the pulse width is low or minimum. Conversely, pulse B represents the heart stimulation pulse generated after a period of use. The pulse amplitude is substantially reduced and the pulse width is substantially increased. Shaded area "a" is approximately equal to shaded area "b". Thus, area of pulse A is approximately equal to area of pulse B. This is the situation in which the energy supplied to the heart remains approximately constant over a period of time even though the supply voltage varies. Pulse area is preset with potentiometer 37 to the capture energy required by the particular patient being stimulated.

But, if area of pulse A is initially preset to the minimum energy necessary to provide capture, and if the present invention is not used, the pulse width does not increase as amplitude decreases. There would be insufficient energy associated with future pulses to cause capture (to stimulate a heartbeat). Therefore, to ensure capture at a future time, an excessive amount of energy would initially have to be used, and thus some would be wasted. For example, the width of pulse A

would have to be made at least as large as the width of pulse B to ensure capture at the amplitude of pulse B when not using the present invention.

According to the present invention, the width of the heart stimulation pulse is inversely related to the amplitude of the battery supply. This relationship may be of the form where the product of battery voltage and pulse width is a constant. Thus, one can monitor the failure of an individual battery or deterioration of the entire battery supply voltage by monitoring the heart stimulation pulse. By using electrocardiogram leads operatively connected to an oscilloscope to externally sense and display the stimulation pulse width, one can monitor the batteries and provide an indication of remaining battery life. The pulse width indicates battery usage. Quantitative measurements can be made. Thus, the present invention includes an implantable pacerbattery external monitoring-system.

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. For example, any point in the circuitry which varies as a function of the energy supply can be used to control at least one transistor switch which in turn can control stimulation pulse width in a discrete fashion. Thus, the present embodiments are to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

What is claimed is:

1. An implantable pacer including at least one battery, said pacer comprising terminals for connection to the heart of a patient, a pulse generator connected to said at least one battery and operatively associated with said terminals including a variable RC timing circuit for generating stimulation pulses on said terminals, sensing circuitry operatively arranged to sense decreasing

value of said at least one battery, and variable circuit means responsive to operation of said sensing circuitry for varying the time constant of said RC timing circuitry in a manner to make the energy of each of said stimulation pulses approximately equal.

2. A pacer as recited in claim 1 and wherein said sensing circuitry comprises a sensing resistor.

3. A pacer as recited in claim 1 and wherein said variable circuit means comprises a transistor.

4. A pacer as recited in claim 1 further including means for sensing beating action of said heart, means responsive to the operation of said sensing means sensing a heartbeat within a predetermined time from a previous heartbeat for inhibiting said pulse generator from generating only the next otherwise generated pulse and responsive to the operation of said sensing means not sensing a heartbeat within said predetermined time from said previous heartbeat for causing said pulse generator to generate only the next otherwise generated pulse at said predetermined time.

5. In an improved pacer including a battery, a pulse generator, connected to said battery and terminal for connection to the heart of a patient said generator operatively associated with said terminals, said pacer having means for demand operation and being adapted to be implanted within the body of a patient, the improvement comprising constant capture energy output means for providing a repetitive approximately minimum energy that stimulates the heart of said patient, said means including a sensing resistor for sensing voltage decrease of said battery, a parallel combination of a transistor circuit and a second resistor conductively connected to said sensing resistor, the effective resistance of said parallel combination being controlled by the operation of said sensing resistor, and a timing capacitor arranged in series connection with said parallel combination and controlled by said effective resistance.

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