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Wall et al.

[11] **3,807,410**

[45] **Apr. 30, 1974**

[54] **ADAPTIVE DEMAND PACER**

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[73] Assignee: **American Optical Corporation,** Southbridge, Mass.

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[52] **U.S. Cl.** .... **128/419 P,** 128/422
[51] **Int. Cl.** **A61n 1/36**
[58] **Field of Search**. 128/419 P, 421, 422, 12.06 A, 128/12.06 F, 12.06 R

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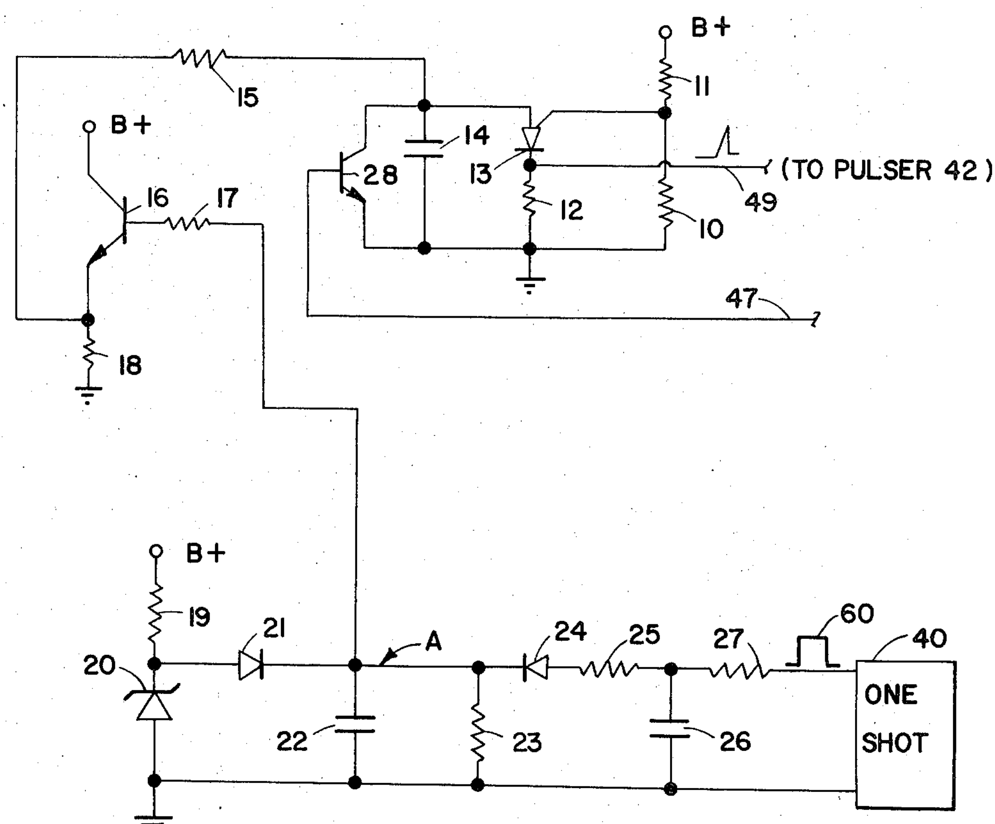
Attorney, Agent, or Firm—Joel Wall; William C. Nealon

[57] **ABSTRACT**

A rate-adaptive demand pacer for stimulating the heart of a patient. The pacer senses or monitors the patient's varying natural heartbeat rate and varying natural escape interval of the heart. The pacer controls generation of heart stimulating impulses at a rate which conforms to the patient's last sensed natural heartbeat rate and escape interval. The initial rate of stimulation applied to the heart is controlled to be within a small predetermined rate difference from the last sensed natural heartbeat rate. Thus, sudden large variations in heartbeat rate are avoided when changing from a natural heartbeat condition to a stimulated heartbeat condition.

2 Claims, 4 Drawing Figures



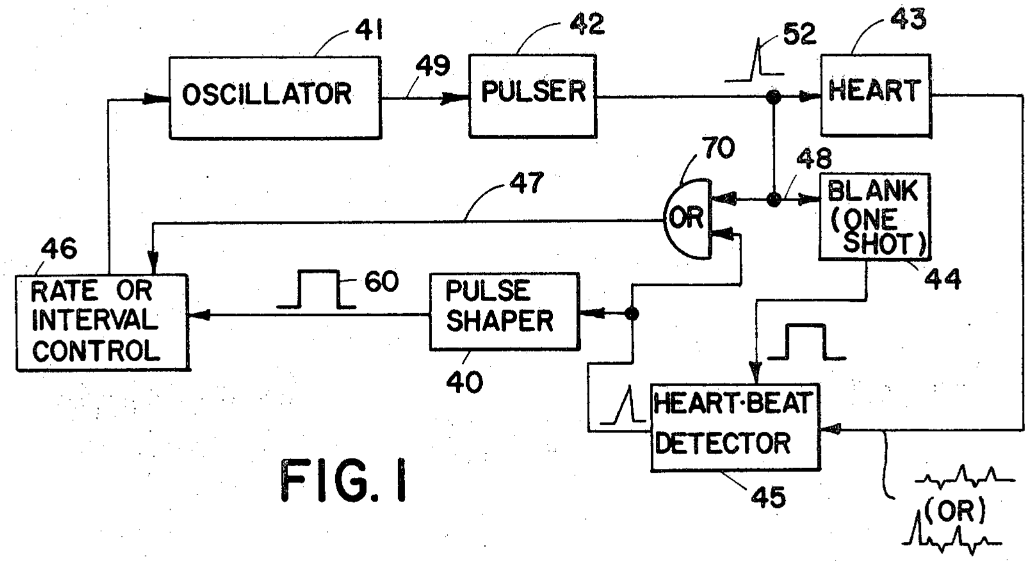

41
OSCILLATOR
49
42
PULSER
52
43
HEART
70
OR
48
BLANK (ONE SHOT)
47
46
RATE OR INTERVAL CONTROL
60
PULSE SHAPER
40
44
HEART-BEAT DETECTOR
45
(OR)

FIG. 1

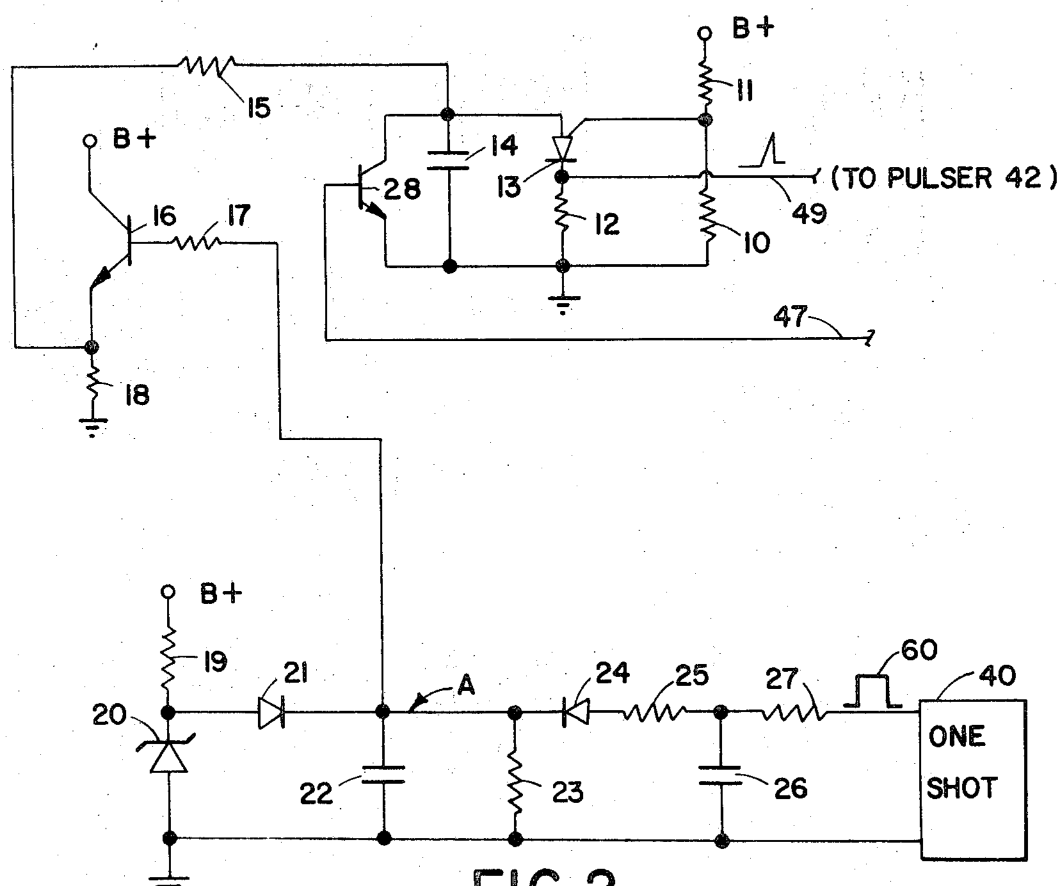

B+
15
11
14
13
28
(TO PULSER 42)
49
B+
16
17
12
10
47
18
B+
19
21
A
24
25
27
60
40
20
ONE SHOT
22
23
26

FIG. 2

(PRIOR ART)

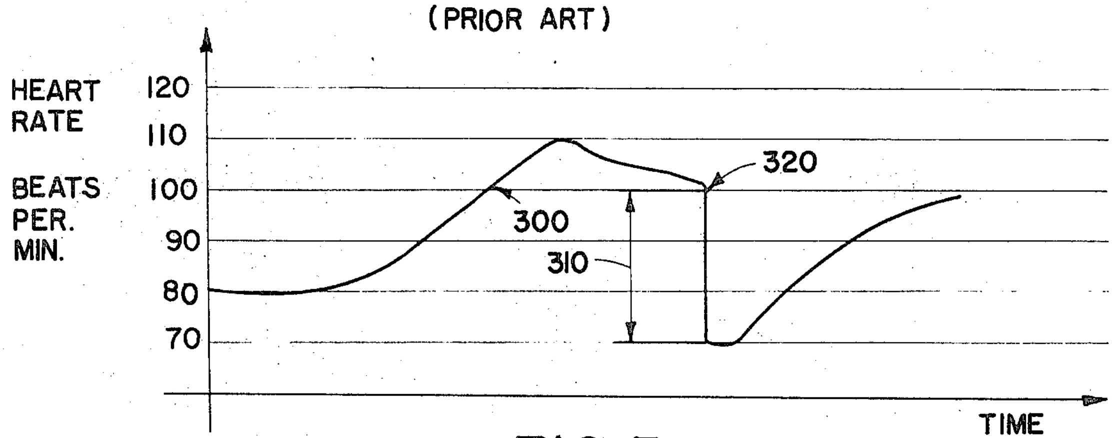


FIG. 3

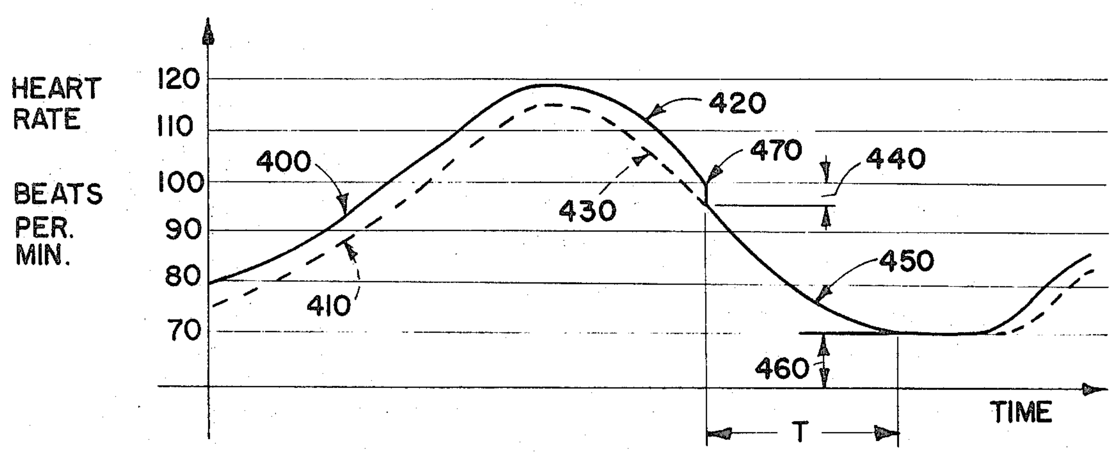


FIG. 4

ADAPTIVE DEMAND PACER

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to heart stimulating devices commonly known as heart pacers. More particularly, the present invention relates to an adaptive rate-control pacer which provides heartbeat stimulation on demand at a rate that conforms to the last natural heartbeat rate of the patient.

2. Description of the Prior Art

In various demand pacers currently available, a relatively fixed or predetermined time interval is employed as a waiting period (known in the medical art as an escape interval). If a natural heartbeat does not occur during this interval, the pacer immediately provides a stimulation inpulse to the heart. In the so called "rate-hysteresis" demand pacer, the time interval from the last naturally occurring heartbeat to the first stimulation impulse is longer than the time between successive stimulating impulses. However, the time between successive stimulation impulses is usually fixed or it varies only slightly.

In all currently available demand pacers, the change from natural heartbeat rate to stimulation rate may be appreciable. For example, consider a person with a prior art type of implanted demand pacer temporarily having a natural heartbeat rate of 100 beats per minute because of some external stimulii (physical movement, fright, etc.). If the patient's heart stops beating, the demand pacer will supply stimulation at whatever predetermined rate was established. This predetermined rate is usually in the neighborhood of 70 beats per minute, and may vary approximately 5 beats per minute for a given pacer. In any event, there is a sharp change in heart stimulation, and in this case, approximately a 25 percent rate change occurs.

By comparison, applicants' invention provides stimulation at near, and in conformance with the 100 beat per minute (in this example) rate. The rate is then automatically and gradually decreased towards a minimum stimulation rate. The minimum rate could be 70 beats per minute. The minimum rate may not be reached in the event that a natural heartbeat occurs during one of the variable-length, pacer-generated, escape intervals, followed by succeeding natural heartbeats during succeeding escape intervals.

SUMMARY OF THE INVENTION

The present invention provides a demand pacer which utilizes a variable frequency oscillator controlled by natural heartbeat rate of the patient. As the natural heartbeat rate of the patient increases, the frequency of the oscillator proportionately increases. As the natural heartbeat rate of the patient decreases, (with the rate of rate decrease being within a selectable limit) the oscillator frequency also proportionately decreases. When the rate of rate decrease tends to exceed this limit, the pacer provides heart stimulation which slows down the rate of rate decrease to that limit. Thus, when demanded, the heart is stimulated at an initial rate which is in conformance with the last previous occurring natural heartbeat rate. There is minimum oscillator frequency provided so that if a patient's heart stops naturally beating indefinitely, the stimulation to that heart will not go below a fixed rate.

The above description using heartbeat rate as a parameter can also be described in terms of its reciprocal parameter — heartbeat interval. If a first pacer-generated escape interval passes without a natural heartbeat occurring therein, a stimulation impulse is generated within a small, fixed, delay time after the expected, but absent natural heartbeat. The next or second pacer-generated escape interval, measured from the stimulated heartbeat, is automically larger than the first interval. During this longer second interval a natural heartbeat may occur; if so, the pacer timing mechanism is reset upon that occurrence and yet a new escape interval is generated. The duration of this new interval, which may be different from all previous durations, depends upon and conforms to the durations of previous intervals.

Assuming that no natural heartbeats occur during any of these progressively increasing intervals, then an upper limit to the interval durations is reached. This corresponds to the lower rate limit described above.

Thus it is an advantage of the present invention to avoid possible physiological distress to the patient by providing heart stimulation at an initial rate that is close to the last natural heartbeat rate of the patient, rather than at a substantially different rate.

OBJECTS OF THE INVENTION

It is thus an object of the invention to provide an improved demand pacer.

It is a further object of this invention to provide a demand pacer with a natural heartbeat rate adaptive stimulation-rate feature.

It is a still further object of this invention to provide a demand pacer that will supply stimulation to a patient on demand at a constant or decreasing rate, where the stimulation rate is initially less than the last occurring value of the natural heartbeat rate by a small predetermined amount.

It is another object of this invention to provide a demand pacer that will supply stimulation to a patient on demand at constant or increasing intervals.

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

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a functional block diagram of an illustrative embodiment of the present invention;

FIG. **2** is a circuit schematic of certain functions of the illustrative embodiment of FIG. **1**;

FIG. **3** is a graphical illustration of heartbeat rate vs. time based on prior art pacers; and

FIG. **4** is an illustration comparable with FIG. **3**, where FIG. **4** uses the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In FIG. **1**, the frequency of oscillator **41** is controlled by rate (or interval) control **46.** The output of oscillator **41** feeds pulser **42** via conductor **49.** Pulser **42** may provide at least one stimulation impulse **52** to heart **43** and will simultaneously provide inputs to both blanking circuitry **44** via conductor **48,** and to rate control **46** via conductor **47** and via "or" gate **70.** The output of blanking circuitry **44** is fed to heartbeat detector **45** to prevent detection of pacer-stimulated heartbeats. The output (P-Q-R-S-T) of heart 43 is fed to heartbeat detector 45 which could otherwise detect all heartbeats whether stimulated or naturally generated. Thus, blanking function 44 is used to prevent heartbeat detector 45 from providing an input to pulse shaper 40 when a pacer stimulated heartbeat occurs. Heartbeat detector 45 provides an input to rate control 46 also, via "or" gate 70. This resets the timing circuitry in control 46 with every occurring heartbeat; it will be discussed later in detail. Pulse shaper 40 shapes the natural occurring heartbeat output of heartbeat detector 45 and provides a precision rectangularly shaped pulse of constant width to rate/interval control 46 the detail of which is discussed later.

Pulser 42 may be comprised of a large capacitor which stores an amount of charge sufficient to cause the heart to beat upon discharge therethrough utilizing transistor switches similar to that found in U.S. Pat. No. 3,528,428 to Berkovits. Heartbeat detector 45 may be comprised of transistorized amplifier and filter circuitry similar to that found in that patent also. Pulse shaper 40 and blanking circuitry 44 may both be ordinary one-shot multivibrator circuits found in the electronics art. Or gate 70 is standard circuitry.

Rate control 46 and oscillator 41 are shown in circuit detail in FIG. 2. Their component interconnection is as follows. The output of pulse shaper (one shot multivibrator) 40 is connected to one end of resistor 27 the other end of which is connected to one end of capacitor 26 and to one end of resistor 25. The other end of capacitor 26 is connected to ground, and the other end of resistor 25 is connected to the anode of diode 24. The cathode of diode 24 is connected to one end of the parallel combination of capacitor 22 and resistor 23 (junction A). The other end of that parallel combination is connected to ground. Junction A is also connected to the cathode of diode 21, the anode of which is connected to the junction of one end of resistor 19 and the cathode of zener diode 20. The anode of zener diode 20 is connected to ground and the other end of resistor 19 is connected to a positive supply voltage.

Junction A is connected to one end of resistor 17, the other end of which is connected to the base of transistor 16. The collector of transistor 16 is connected to a positive supply voltage; the emitter is connected to one end of resistor 18, the other end of which resistor is connected to ground. The emitter of transistor 16 is also connected to one end of resistor 15.

The other end of resistor 15 is connected to a junction comprised of the collector of transistor 28, one end of capacitor 14, and the anode terminal of unijunction transistor 13. The base of transistor 28 is connected to conductor 27. The other end of capacitor 14 and the emitter of transistor 28 are connected to ground. The cathode electrode of unijunction 13 is connected to one end of resistor 12 the other end of which is connected to ground. Also, the cathode electrode is connected to conductor 49 which provides an output to pulser 42. The gate electrode of transistor 13 is connected to the junction of resistors 10 and 11, the other end of resistor 11 being connected to a positive supply voltage and the other end of resistor 10 being connected to ground.

In operation, consider the heart 43 to be beating normally. One shot multivibrator 40 repetitively provides precise rectangularly shaped pulses 60 in a pulse train. One pulse is provided for each heartbeat detected. This

pulse train is averaged by capacitor 26 and resistor 27. Since pulse 60 is a constant width and height, the average DC voltage on capacitor 26 is directly proportional to duty cycle of the pulse train. The average voltage is a DC voltage on capacitor 26 which thus varies with rate of pulses 60.

The voltage on capacitor 22 will be influenced by either (1) breakdown voltage of zener diode 20 minus a small forward voltage drop across diode 21, or (2) voltage of capacitor 26 minus the small voltage drop across resistor 25 and diode 24. (Resistor 25 functions similarly to resistor 27 in causing averaging.) Voltage on capacitor 22 will charge towards the larger of these two voltages. Diodes 21 and 24 are mutually exclusive blocking diodes. For example, if DC voltage on capacitor 26 is higher than breakdown voltage of zener diode 20, diode 24 will be conducting and diode 21 will be blocking or reversed biased. Diodes 24 and 21 reverse their conducting and blocking roles for the other voltage condition.

The voltage of zener diode 20 is selected to provide an acceptable minimum limit to the rate or frequency of oscillator 41. This will be discussed in detail in paragraphs to follow. Voltage on capacitor 26 represents average natural heartbeating rate of the patient. If the natural heartbeat rate of the patient fails the voltage on capacitor 26 will discharge to the zener diode voltage through resistor 23 in response to no further pulses 60 being produced. For that situation, diode 24 would be in the reverse biased condition and diode 21 would be forward conducting.

For example, if capacitor 26 was charged to a high voltage in response to a high natural heartbeating rate, perhaps 100 beats per minute, and if the natural heartbeat stops, capacitor 22 will discharge through resistor 23 to a minimum allowed value supplied by zener diode 20. The zener diode voltage may correspond to a rate of 70 beats per minute. Resistor 23 can be selected over a wide range of values to provide different preset rates of discharge to the minimum 70 beats per minute rate.

Voltage on capacitor 22 is fed to buffer amplifier comprised of transistor 16 and resistors 17 and 18. This amplifier is used to prevent excessive current drain from capacitor 22. Output of the buffer amplifier is a control voltage which is fed to oscillator 41 in general and is connected to resistor 15 in particular. This voltage controls the varying stimulation rate of the present invention.

Resistor 15 and capacitor 14 in combination with unijunction transistor 13 and resistors 10, 11 and 12 form an ordinary unijunction relaxation oscillator. When voltage on capacitor 14 reaches or exceeds voltage established on the gate terminal by voltage divider action of resistors 10 and 11, unijunction 13 conducts and capacitor 14 discharges through unijunction 13 and resistor 12. Current flow through resistor 12 provides a voltage pulse output to pulser 42 on conductor 49.

The rate at which capacitor 14 charges is determined, in this case, by control voltage supplied to resistor 15. If capacitor 22 provides a high control voltage, then capacitor 14 will charge more quickly to a threshold level established by resistors 10 and 11 than if voltage supplied from capacitor 22 was lower. Thus, the higher the voltage on capacitor 22 representing a higher average natural heartbeat rate, the quicker capacitor 14 charges to a threshold level providing a higher possible stimulation rate to be supplied only on demand.

The demand nature of the invention is related to transistor 28. Transistor 28 is in parallel with timing capacitor 14. It provides a discharge path for capacitor 14 in response to each heartbeat occurrence, whether it be a natural or pacer-stimulated heartbeat. If pacer-stimulated, a pulse output of pulser 42 is conducted through or-gate 70 to the base of transistor 28 turning it on. Likewise, if a natural heartbeat occurs, a pulse output of heartbeat detector 45 is conducted through or-gate 70 to the base of transistor 28 turning it on. When transistor 28 conducts in response to naturally generated heartbeats, capacitor 14 discharges prior to its reaching the threshold level established by resistors 10 and 11. Thus, the heart is not stimulated with an impulse when not needed and the demand nature of the invention is demonstrated.

The demand nature of the invention can also be described in terms of pacer-generated escape intervals that are made to vary in duration to conform to the varying natural escape interval between natural heartbeats. The possibly unique duration of each pacer-generated escape interval is determined by the varying charging rate of capacitor 14. A single impulse is generated on demand when no natural heartbeat occurs during a first pacer-generated escape interval, and when a natural heartbeat occurs within the next, longer, pacer-generated escape interval, and when a natural heartbeat occurs within each succeeding pacer-generated escape interval.

Consider once again the example of the heart beating at a natural rate of 100 per minute when the heart stops naturally beating. (It is to be understood that there is no special significance to the rates of 100 per minute, and 70 per minute, and that these numbers are chosen merely for ease of illustration. Applicants' invention is intended to function with all compatible upper and lower heartbeat rate limits.) In applicants' invention, circuit components have been chosen to initially provide stimulation to the heart at slightly less than the last natural rate or in this case at about 98 beats per minute. At this point in time, when the heart fails, capacitor 22 was charged to and was maintained at a control voltage that caused capacitor 14 to charge toward the trigger threshold established by resistors 10 and 11 slowly enough to be pre-empted by a natural heartbeat occurring at a 100 beat per minute natural heart rate. However, capacitor 22 starts to discharge from this last established control voltage through resistor 23 at this time in response to no further current supplied from capacitor 26. The control voltage supplied to resistor 15 is decreasing, and the threshold established by resistors 10 and 11 is reached in a longer and longer time as capacitor 14 successively charges. The rate changes from about 98 beats per minute down to a minimum acceptable value established by the voltage on zener diode 20. This can be selected to be any rate and could be 70 beats per minute. The variation from 100 beats per minute to 70 beats per minute can be made relatively quickly or slowly and is dependent on the rate of discharge of capacitor 22 through resistor 23. For certain patients, it may be desireable to have such a variation and heart rate take place over a period of five minutes. There would be no problem in establishing such a discharge time constant situation. On the other hand, it may be desirable for other patients to have such a variation in heart rate take place in less than a minute; again, it would be no problem to establish this discharge time constant condition.

This operation can be graphically depicted in FIG. 4. Curve portion 400 represents a rising natural heart rate and curve portion 410 represents a rising variable stimulation rate threshold proportional to the voltage on capacitor 22. These curves are separated by about 2 beats per minute, but could be set for almost any differential rate.

At curve portion 420, the natural heartbeat rate decreases slowly enough for the decreasing stimulation rate threshold 430 to follow. Here, the discharge of current from capacitor 22 through resistor 23 is faster than the current being supplied to the capacitor from averaging capacitor 26.

At point 470, natural heartbeating ceases, and the rate falls (by only 2 beats as indicated by constant rate differential 440) to the stimulation rate threshold 430. At this point in time, control voltage "maintaining current" is no longer supplied by capacitor 26 which discharges along with capacitor 22 through resistor 23. The variation from about 100 beats per minute to about 70 beats per minute is made over period of time T. Time T can be selected to be long or short as previously mentioned. Note that rate curve portion 450 may have the outline of a discharging capacitive voltage. Level 460 represents 70 beats per minute established by zener diode 20.

By comparison, FIG. 3 shows cessation of natural heartbeating at curve point 320 at about 100 beats per minute. The stimulation rate which causes the heart to continue to beat is shown to be set for 70 beats per minute. Note the sharp decrease in rate from 100 to 70 as indicated by rate difference 310 compared with the controllably gradual slope at 450 in FIG. 4.

Finally, at this juncture, it should be mentioned that there may be a situation where the natural heartbeat rate rapidly decreases and the natural heartbeat does not fail. But the rate adaptive demand pacer responds as if the heart has failed. In this situation, the natural heartbeat rate attempts to decrease more rapidly than the discharge time constant for capacitor 22. The pacer will thus provide a stimulation pulse when it was not truly demanded (a natural heartbeat would have occured). Past experience with demand pacers shows that this situation is not harmful. In fact, this may have physiological benefits for certain patients since this places an absolute limit on how rapidly the heartbeat rate can decrease. However, this limit can be selected. By a judicious choice of component values, one can provide a limit that is compatible with a given patient's requirements.

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. For example, the oscillator need not be that shown. Also, other means of obtaining averages of natural heartbeat rate including digital circuitry utilizing summations and subtractions, and other means for providing a lower level rate limit may be used.

The present embodiments are therefore to be considered in all aspects as illustrative and 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 ranges of equivalency of the claims are therefore intended to be embraced therein.

What is claimed is:

1. In an improved demand pacer, which can provide repetitive pacer-generated escape intervals each of said intervals being measured from the last previous heartbeat, said pacer comprising means for detecting natural heartbeats and for causing the heart of a patient to beat only in the absence of a natural heartbeat by providing at least one stimulation impulse to said heart of said patient, the improvement comprising:

means for varying duration of said each of said intervals to conform to durations of recent natural escape intervals, said duration varying means including means responsive to the operation of said detecting means for providing a pulse of predetermined amplitude and width with the occurrence of each detected natural heartbeat, means for continuously averaging the voltage of each said pulse, means responsive to said averaging means for providing a control voltage corresponding to the most recent average natural escape interval; and

oscillator means for generating said stimulation impulse when a natural heartbeat does not occur within said pacer-generated escape interval, the frequency of said oscillator means being controlled by said control voltage.

2. The improvement of claim 1 and wherein said averaging means includes capacitive means for operating on each said pulse to provide a varying DC voltage, and means for continuously discharging said capacitive means.

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