



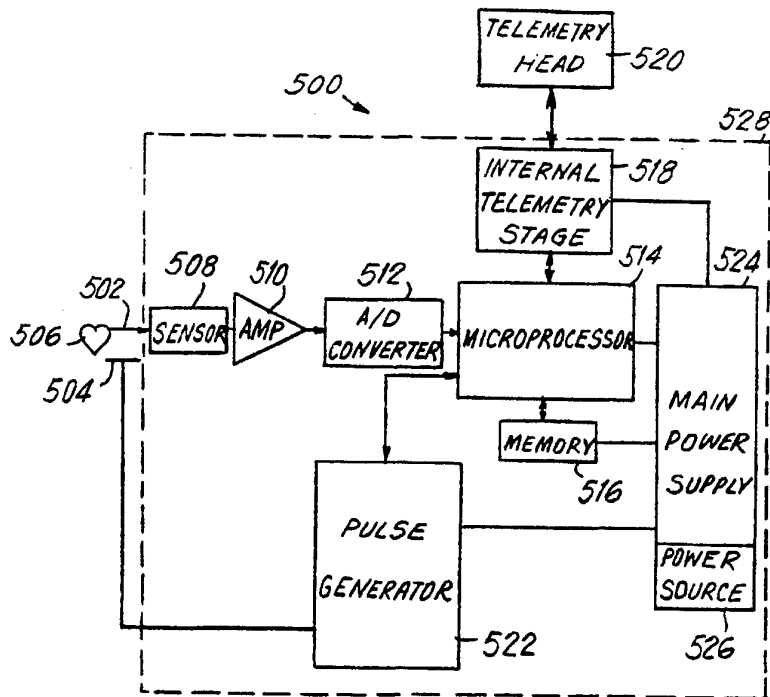
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(54) Title: SYNCHRONIZED CARDIOVERTER SHOCK THERAPY FOR PREEMPTIVE DEPOLARIZATION

(57) Abstract

An implantable cardioversion shock therapy system is provided which delays delivery of a cardioversion shock until late in the cardiac cycle to optimize the chance for the vast majority of ventricular myocardial tissue to be nonrefractory. The system increases efficacy and safety by properly synchronizing the cardioversion shock to the appropriate portion of the cardiac cycles to successfully terminate a tachycardia episode. The timing of the cardioversion shock is programmable as either a percentage of measured tachycardia cycle length or in milliseconds. The system includes a conventional microprocessor (514) for analyzing incoming sensor data, processing a sequence of stored instructions (516), and controlling the generation and delivery of cardioversion shocks, and also includes a telemetry system (518) for transferring control parameters and data between an external programmer and the cardioversion shock therapy system (500).



shocks, and also includes a telemetry system (518) for transferring control parameters and data between an external programmer and the cardioversion shock therapy system (500).

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## SYNCHRONIZED CARDIOVERTER SHOCK THERAPY FOR PREEMPTIVE DEPOLARIZATION

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### Background of the Invention

The present invention relates to implantable cardiac stimulation devices that provide cardioversion shock therapy for interrupting episodes of tachycardia. More particularly, the present invention relates to specific improvements to such devices that (i) reduce the potential for lethal acceleration, (ii) increase the probability that the treatment will safely terminate the arrhythmia, and (iii) allow cardioversion therapy to use a lower energy electrical stimulation pulse, thereby lowering power consumption of the devices and reducing discomfort to patients.

One form of cardiac arrhythmia with serious consequences is tachycardia. Tachycardia is a condition where an abnormally high heart rate severely affects the ability of the heart to pump blood. The higher the heart rate, the more dangerous the condition. In ventricular tachycardia (VT), the QRS complexes defining the heart rate are abnormally broad and occur at a rate in the range from about 100 to about 200 beats per minute. Sustained episodes of VT are particularly dangerous because they may deteriorate into ventricular fibrillation (VF), the most life-threatening cardiac arrhythmia. VF is the result of disordered, rapid stimulation of ventricular cardiac tissue, which prevents the ventricles from contracting in a coordinated fashion. VF may cause a severe drop in cardiac output and death if not quickly reverted.

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Tachycardia is often the result of electrical feedback within the heart -- a natural beat results in the feedback of an electrical stimulus which prematurely triggers another beat. Tachycardia control is usually achieved by applying electrical stimulation to the heart. The application of electrical stimulation disrupts the stability of the feedback loop, thereby returning the heart to normal sinus rhythm.

One type of electrical stimulation therapy that is known for interrupting tachycardia is cardioversion shock therapy. Cardioversion shock therapy is performed by applying an electrical shock to cardiac tissue in order to depolarize the ventricular myocardium. This allows the site of fastest spontaneous discharge, the sinus node, to regain pacing control, thereby terminating the tachycardia episode. In known cardioversion systems, the cardioversion shock is electronically synchronized to fire at the QRS complex following confirmation of the arrhythmia. Because of electronic delays which are the result of device switching and charging requirements, the shock is generally provided shortly after the confirming QRS complex. Nevertheless, the shock is often administered while significant portions of cardiac tissue are still refractory from the confirming depolarization. A cardioversion shock that is administered while significant portions of cardiac tissue are refractory must typically have a higher energy content than would otherwise be the case. Also, an improperly timed cardioversion shock can cause an afterdepolarization which can prolong the arrhythmia and even lead to a lethal acceleration.

Another type of electrical stimulation therapy known for interrupting tachycardia is antitachycardia pacing. This type of therapy is

typically provided by a pacemaker that delivers antitachycardia pacing pulses to cardiac tissue in a manner intended to revert the tachycardia episode. Antitachycardia pacing pulses are of much lower energy than cardioversion shocks, typically between about 25  $\mu$ joules and about 30  $\mu$ joules and accordingly, such pacing pulses should be delivered when the heart is most responsive to external stimulation. More particularly, antitachycardia pacing pulses should be delivered when the heart is nonrefractory.

Unfortunately, there is usually no way of knowing exactly when the relative refractory period associated with the preceding QRS complex ends. In recent years, pacemakers that provide antitachycardia pacing therapy have employed various techniques to attempt to deliver antitachycardia pacing pulses to the portion of the cardiac cycle most likely to lead to termination of the tachycardia episode. For example, U.S. Patent No. 4,280,502 refers to a pacemaker which, after confirmation of a tachycardia episode, automatically initiates a search routine consisting of a sequence of stimulation pulses. The pulses are provided within a predetermined time interval after a confirmation tachycardia beat. The refractory period is estimated from the experimental results of the search routine, and the search is terminated when a normal heartbeat is detected. If the first search routine is unsuccessful at terminating the tachycardia episode, a second pulse is then applied following the previously determined refractory interval by a second interval which is also experimentally determined by a second search routine.

U.S. Patent No. 4,390,021 refers to a pacemaker which generates a sequence of two electrical stimulation pulses to terminate tachycardia. The delay of the first stimulation pulse and the coupled

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delay between the first and the second pulse are each scanned through 16 discrete steps. Successful time delay parameters are permanently stored, and on the next confirmed episode of tachycardia, scanning begins with the most recent successful synchronization parameters.

U.S. Patent No. 4,587,970 refers to a pacemaker which uses experimental data taken from a general sample population to determine a function estimating the relationship between refractory period and heart rate. A sequence of pacing pulses is generated at intervals defined by the predetermined function in an attempt to synchronize the pacing pulses to a time shortly after the end of the refractory period. If the tachycardia episode is not terminated, another sequence of pulses is generated. The rate of the new sequence is decreased or increased depending upon whether an unevoked heartbeat was sensed during the preceding sequence.

U.S. Patent No. 4,398,536 refers to a programmable pacemaker which automatically increases the pulse rate. A burst of pulses is generated after the last heartbeat used to confirm tachycardia. The initial time interval between the last heartbeat used to confirm tachycardia and the first pulse in the sequence is equal to a measured heartbeat cycle less a fixed decrement. If tachycardia persists, another pulse burst is generated at a higher rate. After exceeding the maximum rate, the scanning resumes during the next cycle at the minimum rate. The last burst rate which is successful in terminating tachycardia is stored in the pacemaker and is used for the first burst generated following the next tachycardia confirmation.

The features described above have enabled pacemakers capable of providing antitachycardia pacing

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therapy to interrupt tachycardia. However, similar technology has not been applied to implantable cardiac stimulating devices that provide cardioversion shock therapy. Indeed, the aforescribed approaches taken  
5 with respect to antitachycardia pacing devices would be inappropriate for cardioversion shock therapy systems, because they require the generation and delivery of a "sequence" or "burst" of pulses. A sequence or burst of cardioversion shocks, which are  
10 typically several orders of magnitude greater in energy content than antitachycardia pacing pulses, would rapidly deplete limited energy reserves, and could possibly cause great discomfort to the patient.

Prior art cardioversion shock systems either  
15 provide no synchronization or they synchronize the stimulation pulses to fire immediately after a QRS complex rather than to the period at which the heart is most responsive to external stimulation -- i.e., the supranormal period of the cardiac cycle.  
20 Furthermore, the cardioversion shocks provided by some "synchronized" systems are administered at approximately the same time relative to the confirming QRS complex regardless of the patient's heart rate. Since the timing of the supranormal period relative to  
25 the previous QRS complex is a function of heart rate, these prior art systems that are heart rate independent do not accurately synchronize delivery of cardioversion shocks to the supranormal period. Consequently, these systems may administer shocks that  
30 have higher than necessary energy content, increasing the possibility of discomfort to the patient and reducing the useful life of the implanted cardioverter.

What is needed, therefore, is an implantable  
35 cardiac stimulating device that attempts to administer a cardioversion shock during the supranormal period,

when a lower energy cardioversion shock can effectively interrupt a tachycardia episode. A cardioversion shock properly administered during the supranormal period, when the heart is most responsive to an external stimulus, would optimize the chance of eliciting a heartbeat that preempts the next expected tachycardia beat.

#### Summary of the Invention

The present invention provides an implantable cardiac stimulating device and a method for synchronizing cardioversion shocks to the supranormal period of the cardiac cycle. The implantable cardiac stimulating device of the present invention administers therapy for terminating tachycardia more effectively and safely than known "synchronous" cardioversion shock therapy systems, which simply synchronize the shocks to the end of the QRS complexes that are used to confirm episodes of tachycardia. In general, these improvements delay the shocks until late in the cardiac cycle to optimize the chance for the vast majority of the ventricular myocardium to be nonrefractory.

This invention relates not only to the implantable cardiac stimulating device itself, including the manner in which cardioversion shocks are delivered to the heart, but also to a method of synchronizing the cardioversion shocks to the supranormal period of the cardiac cycle. More particularly, the present invention is directed to providing preemptive cardioversion shock therapy.

In a preferred embodiment of the present invention, a cardioversion shock is synchronized to be administered during the supranormal period at the end of the relative refractory period following a confirmation QRS complex. Such a properly

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synchronized cardioversion shock has a high probability of creating an action potential that is conducted through the heart. If successful in creating an action potential, the cardioversion shock will elicit a heartbeat that preempts the next anticipated tachycardia beat. In this way, the tachycardia episode will be efficiently and safely reverted.

The preferred embodiment of the present invention includes a sensor for monitoring the electrophysiology of the heart; an analog-to-digital converter for converting the analog data from the sensor into conventional digital signals; a microprocessor for analyzing incoming sensor data, processing a sequence of stored instructions, and controlling the generation and delivery of shocks; nonvolatile memory for storing control instructions and program data; an internal telemetry stage for sending and receiving data from an external programmer; and a pulse generator for generating cardioversion shocks under control of the microprocessor. The cardioversion shocks are delivered to cardiac tissue by a shocking lead, which may also be used as part of the electrophysiology sensor. Although the invention is described in the context of an implantable device, the principles disclosed herein may also be applied to external cardioversion shock therapy systems.

The present invention provides numerous advantages over prior art cardioversion systems. Less energy is required to successfully revert the tachycardia to sinus rhythm if the cardioversion shock is properly synchronized to the supranormal period of cardiac cycle. Also, fewer cardioversion shocks may be necessary. In fact, the preferred embodiment of this invention uses only a single cardioversion shock

to interrupt a tachycardia episode. The use of fewer shocks both reduces the discomfort to the patient and increases the useful life of the implantable cardiac stimulating device by using less energy.

5           In the preferred embodiment, the approach to cardioversion therapy described herein is heart rate dependent. More particularly, the patient's tachycardia rate is measured and utilized to synchronize the cardioversion shock to the supranormal  
10           period of the cardiac cycle. This is necessary for proper synchronization, since the timing of the supranormal period is heart rate dependent. The therapy is thus generally applicable to the patient population without the necessity of sophisticated  
15           programming.

          Also, the preferred embodiment of the present invention provides preemptive cardioversion shock therapy. Specifically, the cardioversion shock is synchronized to the supranormal period of the  
20           cardiac cycle, and will thus have a high probability of eliciting a heartbeat that will preempt the next expected tachycardia beat. This is in contrast to the prior art post-arrhythmia systems, which typically synchronize the cardioversion shock to a period of  
25           time immediately after the heartbeat used to confirm the tachycardia episode.

#### Brief Description of the Drawings

          The above and other objects and advantages  
30           of the invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference characters refer to like parts throughout, and in which:

35           FIG. 1 is a graphical representation of refractory periods of a myocyte;

FIG. 2 is a timing waveform illustrating a confirmed tachycardia episode;

FIG. 3 is a timing waveform illustrating prior art synchronization of a cardioversion shock to a QRS complex;

FIG. 4 is a timing waveform illustrating synchronization of a cardioversion shock to provide preemptive depolarization in accordance with the principles of the present invention;

FIG. 5 is a schematic block diagram of a preferred embodiment of an implantable cardiac stimulating device designed to administer cardioversion shock therapy to provide preemptive depolarization in accordance with the principles of the present invention; and

FIG. 6 is a logic flow diagram of software executed by the microprocessor shown in the diagram of FIG. 5.

#### Detailed Description of the Preferred Embodiments

For an understanding of the theory behind the invention, it is useful to describe the refractory periods of a myocyte (i.e., a muscle cell). FIG. 1 graphically depicts the myocyte membrane potential during the refractory period. During an absolute refractory period 102, the myocyte (not shown) is nonresponsive to applied stimulation. Thus if a stimulation pulse 104 is applied during the absolute refractory period 102, it will not revert tachycardia. An effective refractory period 106 includes a brief period beyond the absolute refractory period 102 during which stimulation produces a localized depolarization that does not effectively propagate throughout the myocardium. During a relative refractory period 108, stimulation produces a weak action potential that propagates slowly. During a

supranormal period 110, a relatively small stimulus is capable of triggering an action potential. Ideally, cardioversion shock therapy is most effectively and safely applied when a stimulation pulse 112 is

5 synchronized to the supranormal period 110.

For an understanding of the invention itself, it is useful to begin with the implantable cardiac stimulating device function rather than implementation. For this reason, the timing waveforms

10 of FIGS. 2-4 are described next.

Referring to FIG. 2, a waveform 200 depicts a plurality of heartbeats representing a tachycardia episode in progress starting at a heartbeat 202. If each of a preprogrammed number of heartbeats occurs

15 within a preprogrammed time interval 204 following its respective preceding heartbeat, tachycardia is confirmed and assumed to be in progress. A preprogrammed time interval 204 corresponds to a maximum allowable heart rate. The number of

20 heartbeats and the preprogrammed time interval 204 may be programmed by a physician (not shown). In the waveform 200, the preprogrammed number of beats is five and the preprogrammed time interval 204 is slightly less than one normal heartbeat cycle 206.

25 Here, tachycardia is confirmed to be in progress since each of four successive heartbeats 202, 208, 210, 212 occurred at times less than the preprogrammed time interval 204 of their preceding respective heartbeats and a time interval 214 following the fourth

30 successive heartbeat 212 is less than the preprogrammed time interval 204.

Referring now to FIG. 3, a waveform 300 illustrates the application of a prior art "synchronous" cardioversion therapy to revert the

35 tachycardia shown in the waveform 200 of FIG. 2. The underlying principle of this type of cardioversion

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shock therapy is that if a cardioversion shock is applied to the heart (not shown) at least once shortly after a heartbeat, but before the next naturally occurring heartbeat at the rapid rate, the heart may  
5 revert back to sinus rhythm. A cardioversion shock 302 is electronically synchronized to fire at a QRS complex 304 which is used to confirm tachycardia. Because of an electronic time delay 306 inherent to device (not shown) switching and charging  
10 requirements, the cardioversion shock 302 is generally provided many milliseconds after the QRS complex 304. Typical delays are on the order of between about 20 milliseconds and about 40 milliseconds. The electronic time delay 306 is generally fixed, but can  
15 depend on the state of the pulse generator (not shown). It typically is not programmable by the physician nor does it provide for varying tachycardia rates. Thus, the shocks administered in the prior art "synchronous" cardioversion therapy systems are  
20 independent of heart rate. Despite the electronic time delay 306, the shock is typically administered while significant portions of the heart are still refractory from the detected depolarization. This lack of proper synchronization may produce  
25 afterdepolarizations, and perhaps an acceleration 308.

Referring now to FIG. 4, a waveform 400 illustrates delivery of cardioversion shock therapy in accordance with the principles of the present invention. A single cardioversion shock 402 is  
30 delivered at a time interval 404 following a QRS complex 406 which is used to confirm tachycardia. The time interval 404 can be a fixed time or a percentage of a tachycardia cycle length 408. With proper synchronization, the cardioversion shock 402 will have  
35 a high probability of creating an action potential that is conducted through the heart. Thus, unlike

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prior art "synchronized" systems, which are really post-arrhythmia systems that simply deliver a cardioversion shock after tachycardia is confirmed, the present invention advantageously delays delivery of a cardioversion shock until the supranormal period of the detected tachycardia cycle. By properly synchronizing the cardioversion shock 402 in this manner, the cardioversion shock 402 can arrest the tachycardia episode with much less energy. This provides a significant advantage over the prior art "synchronous" cardioversion therapy systems -- the use of less energy both reduces the discomfort to the patient and increases the useful life of the implantable cardiac stimulating device (not shown). The latter advantage is particularly significant considering the fact that replacing the power source in an implantable cardiac stimulating device requires a surgical procedure.

In accordance with this invention, the time interval 404 is programmable as either a fixed time delay or a percentage of the tachycardia cycle length 408. The preferred embodiment is to use the percentage of the tachycardia cycle length 408. For example, the physician may select to have the cardioversion shock 402 provided at the time interval 404 which is equivalent to 90% of the tachycardia cycle length 408. If tachycardia was measured at 150 beats per minute (400 millisecond cycle length), then the cardioversion shock 402 would be provided 360 milliseconds (90% of 400) after the confirmation QRS complex 406. In this fashion, the cardioversion shock 402 has a greater chance of advantageously preempting the next expected tachycardia beat (not shown) with an elicited beat 410. When this occurs, the heart regains natural pacing control. In this embodiment, the system is

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thus heart rate dependent because the time interval 404 depends on a particular patient's tachycardia cycle length 408.

In an alternative embodiment, a fixed time interval could be selected. For example, the time interval 404 could be selected to be 350 milliseconds, independent of the tachycardia cycle length 406. When this method is used, the physician will typically have historical data from which to base the time interval 404. Regardless of the method of synchronization, the cardioverter is programmed to synchronize the cardioversion shock 402 so that it falls within the supranormal period (i.e., the supranormal period 110 of FIG. 1) after the end of the relative refractory period (i.e., the relative refractory period 108 of FIG. 1) associated with the confirmation QRS complex 406.

Referring now to FIG. 5, a block diagram of an implantable cardioversion shock system 500 designed to provide preemptive cardioversion shock therapy is described. The implantable cardioversion shock system 500 is designed to be implantable and includes a connectable cardiac sensing lead 502 and a shocking electrode 504. The cardiac sensing lead 502 is physically connected to a patient's heart 506, and the implantable cardioversion shock system 500 also includes a sensor 508 which receives electrical signals from the cardiac sensing lead 502 representing cardiac electrical activity. In an alternative embodiment, shocking and sensing functions may be provided by the same physical lead (not shown). The implantable cardioversion shock system 500 further includes an amplifier 510 which amplifies the electrical signal detected by the sensor 508, and an analog-to-digital converter 512 which converts the analog electrical signals provided by the

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amplifier 510 to digital signals suitable for digital logic devices.

5 A microprocessor 514 receives the digital signals from the analog-to-digital converter 512 and performs operations so as to generate different control and data outputs. Alternatively, other customized logic devices (not shown) can be used in place of the microprocessor 514. A memory 516, which is available to the microprocessor 514, stores program  
10 instructions and operating parameters. An internal telemetry stage 518 transmits and receives operating parameters between a telemetry head 520, which communicates with an external programmer (not shown) and the memory 516, via the microprocessor 514.

15 A pulse generator 522, responsive to the microprocessor 514, generates and stores the energy for cardioversion shocks. When the microprocessor 514 determines that it is necessary to administer cardioversion therapy, it sends a command to the pulse  
20 generator 522 causing it to generate and deliver a cardioversion shock to the heart 506 via the shocking electrode 504.

The sensor 508, the amplifier 514, and the analog-to-digital converter 512 may be combined into  
25 one or several integrated circuits (not shown). Similarly, the microprocessor 514 and the memory 516 may be combined into one integrated circuit (not shown).

30 A main power supply 524, including a power source 526, provides a reliable voltage and current source to the following active components within an implantable enclosure 528: the sensor 508 (connection not shown), the amplifier 510 (connection not shown), the analog-to-digital converter 512 (connection not  
35 shown), the microprocessor 514, the memory 516, the internal telemetry stage 518, and the pulse

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generator 522. The main power supply 524 also regulates and distributes appropriate voltage and current levels to all active components of the implantable cardioversion shock system 500. Energy is  
5 supplied to the main power supply 524 by the power source 526. The power source 526 is preferably a long life battery such as a lithium battery or a plurality of lithium batteries.

Many of the aforementioned elements are  
10 conventional and thus, little further description of their operation is necessary. Generally, the sensor 508 measures the electrical activity of the heart 506 from the signals transmitted by the cardiac sensing lead 502. The amplifier 510 conditions the  
15 sensor signal to provide appropriate input to the analog-to-digital converter 512. The analog-to-digital converter 512 converts the analog signals from the amplifier 510 to digital signals suitable for input to the microprocessor 514. The  
20 microprocessor analyzes the data received from the analog-to-digital converter 512 and determines when to instruct the pulse generator 522 to generate and deliver a cardioversion shock to the heart 506 via the shocking electrode 504. The previously discussed  
25 problem associated with charging and switching delays is typically not a problem in the context of the present invention, because such delays are normally of substantially shorter duration than the time between a confirmation QRS complex and the delivery of the  
30 cardioversion shock (i.e., the time interval 404 of FIG. 4).

The telemetry head 520 is provided so that the physician (not shown) can communicate with the microprocessor 514 via the internal telemetry stage  
35 518. Both the telemetry head 520 and the internal telemetry stage 518 may include encoders (not shown),

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decoders (not shown), transmitters (not shown) and receivers (not shown) that are conventional for data communications. The internal telemetry stage 518 and the telemetry head 520 may utilize either radio  
5 frequency or magnetic impulse transmission or other suitable transmission means to allow the external programmer to enter operating parameter data in the memory 516, preferably by coded transmission. This advantageously allows the operating parameters to be  
10 modified over the useful life of the device.

The electronic components of the implantable cardioversion shock system 500 are within the implantable enclosure 528 which is biologically compatible and hermetically sealed, such as one  
15 constructed of titanium. The implantable enclosure 528 itself is implanted at a suitable location in the patient's body (not shown).

Referring now to FIG. 6, a logic flow diagram of a control program for the  
20 microprocessor 514 of FIG. 5 is described, as it may be implemented in suitable microcode or any other higher level language. The preprogrammed number of heartbeats, which is the number of accelerated heartbeats used to confirm tachycardia, the time  
25 interval corresponding to the maximum heart rate (i.e., the time interval 204 of FIG. 2), the percentage of the tachycardia cycle length when the stimulation pulse will be applied (used to compute the time interval 404 of FIG. 4), the energy level of the  
30 stimulation pulse, and possibly other parameters, are set by the physician using an external programmer (not shown) via the internal telemetry stage 518 and the telemetry head 520 of FIG. 5.

The main program begins at start 602, which  
35 is followed by a step 604 at which a counter is set to zero. At a step 606 the time interval between two

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consecutive heartbeats is determined from data received from the analog-to-digital converter 512 (FIG. 5). At a test 608, the microprocessor 514 (FIG. 5) determines whether the interval measured in the step 606 is less than the time interval corresponding to the maximum heart rate (i.e., the preprogrammed time interval 204 of FIG. 2). If the interval measured at the step 606 is not less than the preprogrammed time interval 204 (FIG. 2), the program loops back to the step 604; otherwise, the counter is incremented at a step 610.

The step 610 is followed by a test 612 at which the microprocessor 514 (FIG. 5) determines whether the counter is equal to the preprogrammed number of heartbeats required to confirm tachycardia. If tachycardia is not confirmed, the program loops back to the step 606, where the time interval between the next two consecutive heartbeats is measured. The time required for the program to step through the loop beginning at the step 606, followed by the test 608, the step 610, the test 612, and returning back to the step 606 is insignificant as compared to the time between two successive heartbeats, so that the heartbeat intervals measured in the step 606 are from consecutive heartbeats, and no heartbeat intervals are skipped.

If tachycardia is confirmed at the test 612, the program proceeds to a step 614, where the microprocessor 514 (FIG. 5) directs the pulse generator 522 (FIG. 5) to generate and store the energy necessary for the cardioversion shock 402 (FIG. 4). The program then proceeds to a step 616 where the microprocessor 514 (FIG. 5) computes the time interval 404 (FIG. 4), which determines when the cardioversion shock 402 (FIG. 4) is applied. In the preferred embodiment, the time interval 404 (FIG. 4)

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is computed using the aforementioned preprogrammed percentage and the tachycardia cycle length measured at the step 606. At a step 618, the microprocessor 514 (FIG. 5) instructs the pulse generator 522 (FIG. 5) to administer the cardioversion shock 402 (FIG. 4) to the heart 506 (FIG. 5) via the cardioversion electrode 504 (FIG. 5) after the time interval 404 (FIG. 4) determined at the step 616. The program then loops back to the step 604, where the counter is zeroed in preparation for response to another tachycardia episode.

An example of the operation of the microprocessor control program described with respect to FIG. 6 is now provided by reference to the waveform 200 of FIG. 2. At the heartbeat preceding the heartbeat 202 (FIG. 2), the counter value is zero. The previous normal heartbeats separated by time interval 206 (FIG. 2) would result in program flow proceeding from the step 604, to the step 606, to the test 608, and back to the step 604. The counter value would remain at zero. At the heartbeat 202 (FIG. 2), the interval measured is less than the normal heartbeat cycle 206 (FIG. 2), and the counter is incremented to a value of one at the step 610. At the test 612, it is determined that the counter value is less than the preprogrammed number of heartbeats, and the program loops back to the step 606. Following the heartbeats 208, 210, and 212 (FIG. 2), the counter is incremented to values of two, three, and four respectively. Program flow loops back from the test 612 to the step 606 after each counter increment. On the next heartbeat after the heartbeat 212 (FIG. 2), the counter is incremented to the value five. In this example, five equals the preprogrammed number of rapid heartbeats required to confirm tachycardia. Thus, the test 612 causes the program to proceed to the

steps 614, 616, and 618 to deliver therapy. After therapy is delivered, the program loops back to the step 604 where the counter is set to zero, and subsequent heartbeat intervals are measured.

5                   Thus an implantable cardiac stimulating device and method for administering synchronized cardioversion shock therapy is provided. One skilled in the art will appreciate that the present invention can be practiced by other than the described  
10                   embodiments, which are presented for purposes of illustration and not of limitation, and the present invention is limited only by the claims that follow.

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CLAIMSWhat is Claimed is:

- 5                   1.    An implantable cardioversion shock  
therapy system, comprising:  
                    sensing means, responsive to  
depolarizations of cardiac tissue, for providing a  
signal indicative of intrinsic cardiac activity;  
10                   pulse generating means for generating a  
cardioversion shock and delivering said cardioversion  
shock to said cardiac tissue; and  
                    control means, coupled to said sensing  
means and said pulse generating means, for analyzing  
15                   said signal indicative of intrinsic cardiac activity  
to confirm a tachycardia episode, for determining when  
said cardiac tissue will be substantially  
nonrefractory, and for causing said pulse generating  
means to deliver said cardioversion shock after said  
20                   tachycardia episode is confirmed and when said cardiac  
tissue is substantially nonrefractory.
2.    The system of claim 1, wherein said  
control means determines when a supranormal period  
25                   following confirmation of said tachycardia episode  
will occur and causes said pulse generating means to  
deliver said cardioversion shock when said supranormal  
period occurs.
- 30                   3.    The system of claim 1, wherein said  
control means causes said pulse generating means to  
deliver said cardioversion shock after a predetermined  
fixed time interval has elapsed following confirmation  
of said tachycardia episode.

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4. The system of claim 3 further comprising telemetry means for transmitting system operating parameters, including said predetermined fixed time interval, from an external programmer to  
5 said control means.

5. The system of claim 1, wherein said control means determines a tachycardia cycle length, computes a predetermined percentage of said  
10 tachycardia cycle length, and causes said pulse generating means to deliver said cardioversion shock after a length of time corresponding to said predetermined percentage of said tachycardia cycle length has elapsed following confirmation of said  
15 tachycardia episode.

6. The system of claim 5 further comprising telemetry means for transmitting system operating parameters, including said predetermined  
20 percentage, from an external programmer to said control means.

7. The system of claim 1, wherein said pulse generating means generates said cardioversion  
25 shock with a lower energy content than would be required when cardioversion shock therapy is administered while said cardiac tissue is substantially refractory.

30 8. An implantable system for administering cardioversion shock therapy to cardiac tissue in accordance with a tachycardia rate of a patient to preempt an expected tachycardia beat, said system comprising:

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sensing means, responsive to depolarizations of cardiac tissue, for providing a signal indicative of intrinsic cardiac activity;

pulse generating means for generating a  
5 cardioversion shock and delivering said cardioversion shock to said cardiac tissue; and

control means, coupled to said sensing means and said pulse generating means, for analyzing said signal indicative of intrinsic cardiac activity  
10 to determine said tachycardia rate and for causing said pulse generating means to deliver said cardioversion shock after a length of time, determined as a function of a tachycardia cycle length corresponding to said tachycardia rate, has elapsed  
15 following a preceding tachycardia beat, to elicit a heartbeat that preempts said expected tachycardia beat.

9. The system of claim 8, wherein said  
20 function of said tachycardia cycle length is a predetermined percentage of said tachycardia cycle length.

10. The system of claim 8, wherein said  
25 preceding tachycardia beat is used by said control means to confirm tachycardia, and said control means causes said pulse generating means to deliver said cardioversion shock between confirmation of tachycardia and said expected tachycardia beat.

30

11. The system of claim 10, wherein said  
function of said tachycardia cycle length results in a time delay corresponding to a time interval between said preceding tachycardia beat and a supranormal  
35 period following said preceding tachycardia beat, and said control means causes said pulse generating means

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to deliver said cardioversion shock after said time delay so that said cardioversion shock is delivered during said supranormal period.

5                   12. The system of claim 11, wherein said pulse generating means generates said cardioversion shock with a lower energy content than would be required when cardioversion shock therapy is administered other than during said supranormal  
10 period.

                  13. The system of claim 8 further comprising telemetry means for transmitting system operating parameters, including said function, from an  
15 external programmer to said control means.

                  14. An implantable cardioversion shock therapy system, comprising:  
                  a cardiac activity sensor for providing  
20 an analog signal indicative of intrinsic cardiac activity;  
                  an analog-to-digital converter that converts said analog signal indicative of intrinsic cardiac activity to a digital signal;  
25                   a power supply;  
                  a pulse generator for providing a cardioversion shock of sufficient energy to terminate a tachycardia episode using energy supplied by said power supply;  
30                   a shocking lead, coupled to said pulse generator, for delivering said cardioversion shock to cardiac tissue;  
                  a memory for storing system operating parameters and program instructions; and  
35                   a microprocessor, coupled to said cardiac activity sensor, said analog-to-digital

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converter, said pulse generator, and said memory, for  
executing said program instructions to confirm a  
tachycardia episode from information provided by said  
digital signal and for causing said pulse generator to  
5 provide said cardioversion shock after a predetermined  
time interval following confirmation of said  
tachycardia episode to preempt an expected tachycardia  
beat.

10           15. The system of claim 14, wherein said  
predetermined time interval corresponds to a length of  
time between a preceding tachycardia beat and a  
supranormal period prior to said expected tachycardia  
beat.

15           16. The system of claim 15, wherein said  
predetermined time interval is a predetermined fixed  
time interval following said preceding tachycardia  
beat.

20           17. The system of claim 15, wherein said  
microprocessor determines a tachycardia cycle length  
from said digital signal, and said predetermined time  
interval is a predetermined percentage of said  
25 tachycardia cycle length following said preceding  
tachycardia beat.

          18. The system of claim 15, wherein said  
pulse generator generates said cardioversion shock  
30 with a lower energy content than would be required  
when cardioversion shock therapy is administered other  
than during said supranormal period.

          19. An implantable cardioversion shock  
35 therapy system, comprising:

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means for detecting a tachycardia episode;

means for delivering a cardioversion shock to cardiac tissue in response to said tachycardia episode; and

means for synchronizing delivery of said cardioversion shock to a supranormal period between a preceding tachycardia beat and an expected tachycardia beat.

10

20. A method of providing cardioversion shock therapy to cardiac tissue, comprising the steps of:

detecting a tachycardia episode; and synchronizing delivery of a cardioversion shock to a period between a preceding tachycardia beat and an expected tachycardia beat when said cardiac tissue is substantially nonrefractory following detection of said tachycardia episode.

20

21. The method of claim 20, wherein said synchronizing step comprises the steps of:

determining when a supranormal period following said preceding tachycardia beat will occur; and

delivering said cardioversion shock during said supranormal period.

22. The method of claim 20, wherein said synchronizing step comprises the step of delivering said cardioversion shock after a predetermined fixed time interval following said preceding tachycardia beat has elapsed.

23. The method of claim 20, wherein said synchronizing step comprises the steps of:

35

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determining a tachycardia cycle length;

and

delivering said cardioversion shock  
after a length of time corresponding to a  
5 predetermined percentage of said tachycardia cycle  
length has elapsed following said preceding  
tachycardia beat.

24. A method of administering cardioversion  
10 shock therapy to cardiac tissue to preempt an expected  
tachycardia beat, comprising the steps of:

detecting an occurrence of a  
tachycardia episode;

determining a tachycardia rate defining  
15 said tachycardia episode; and

delivering a cardioversion shock to  
said cardiac tissue after a length of time, determined  
as a function of a tachycardia cycle length  
corresponding to said tachycardia rate, has elapsed  
20 following a preceding tachycardia beat.

25. The method of claim 24, wherein said  
function of said tachycardia cycle length is a  
predetermined percentage of said tachycardia cycle  
25 length.

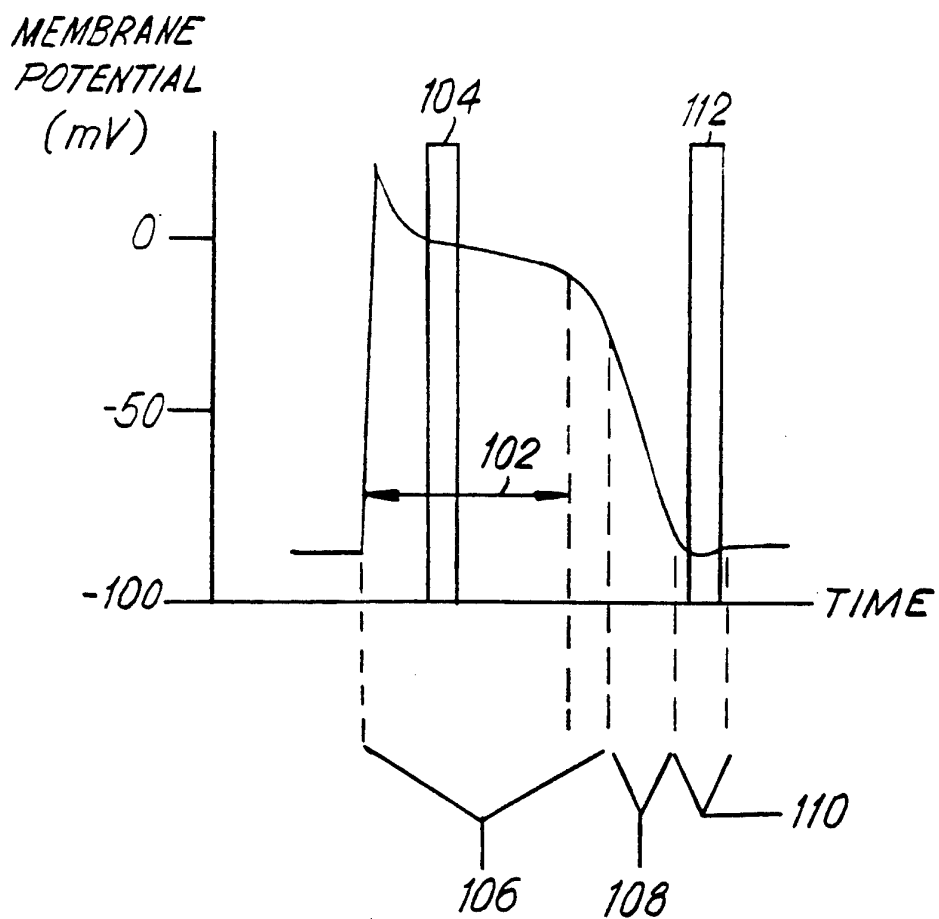
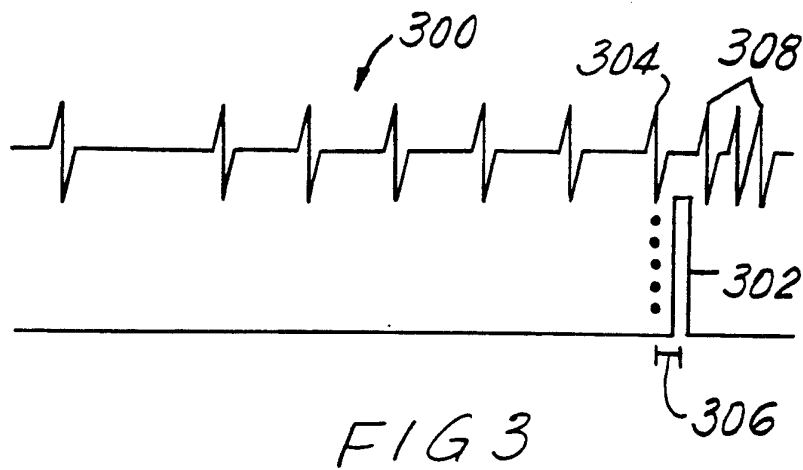
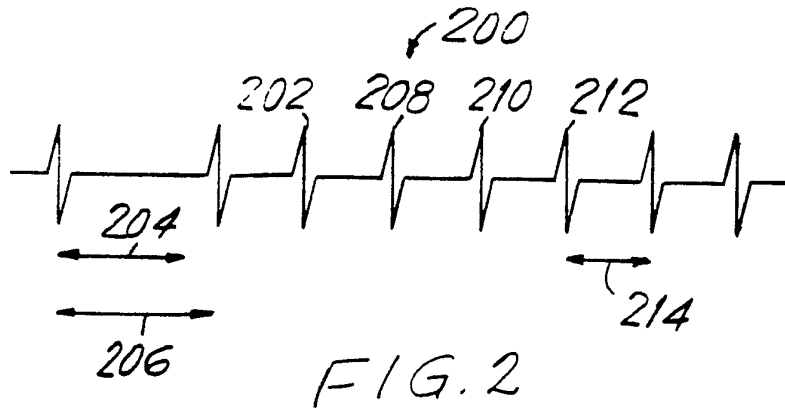
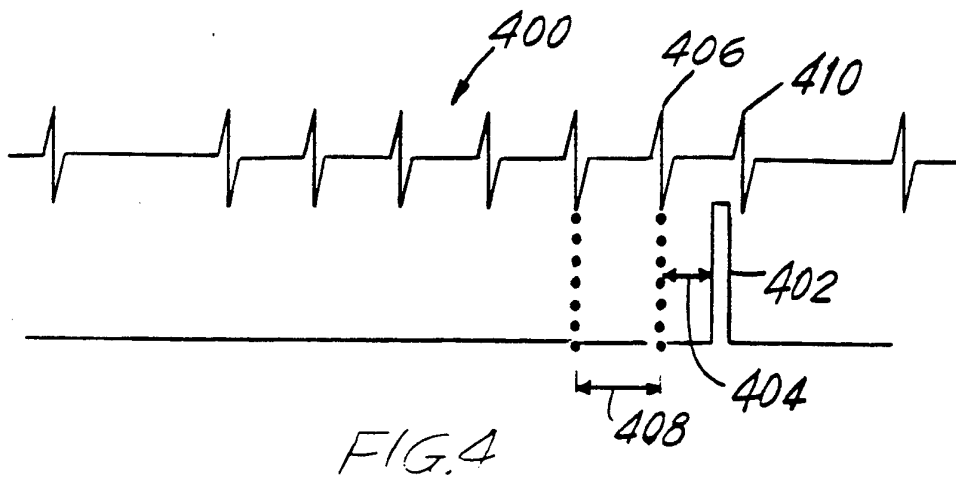


FIG. 1



PRIOR ART



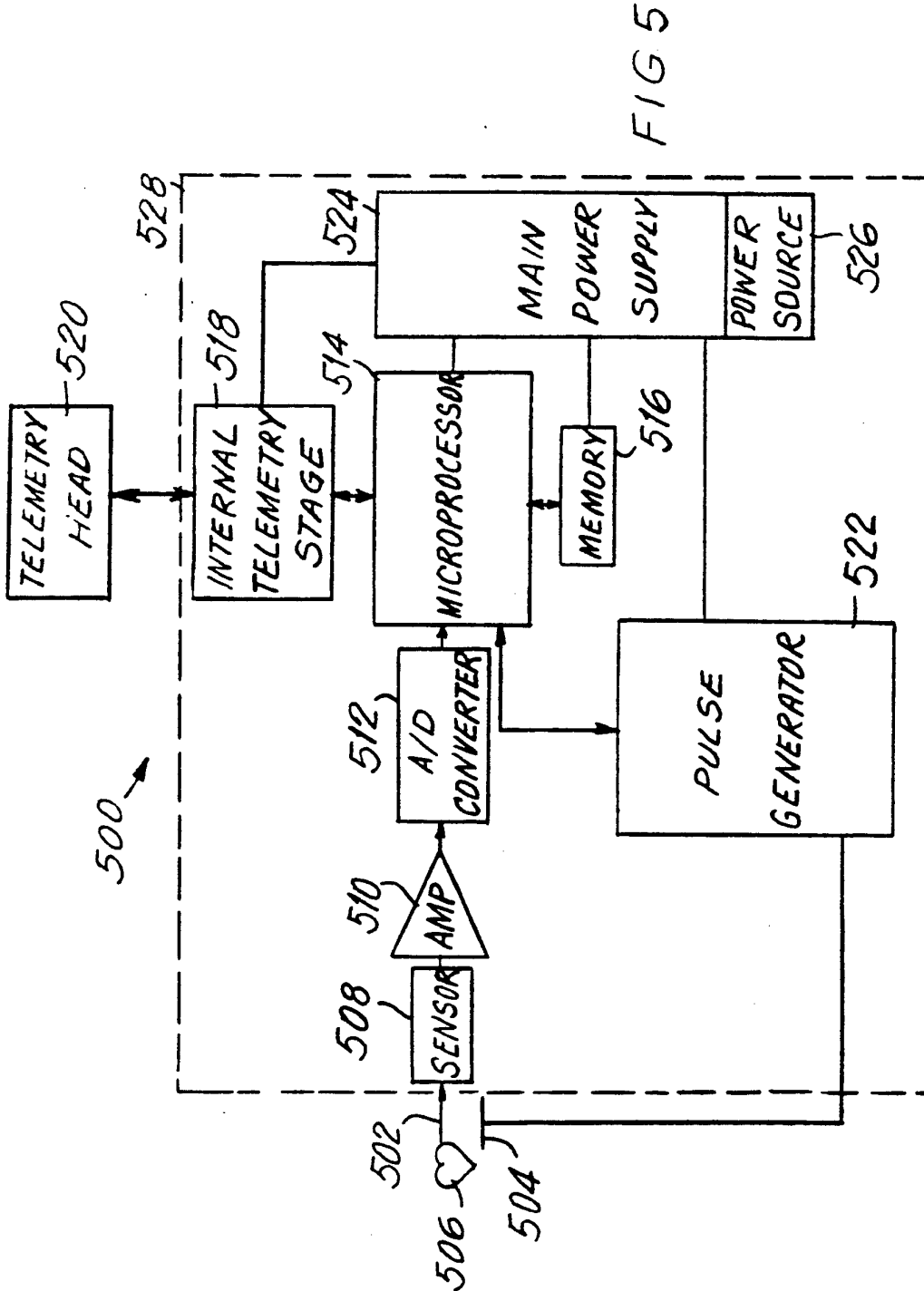


FIG 5

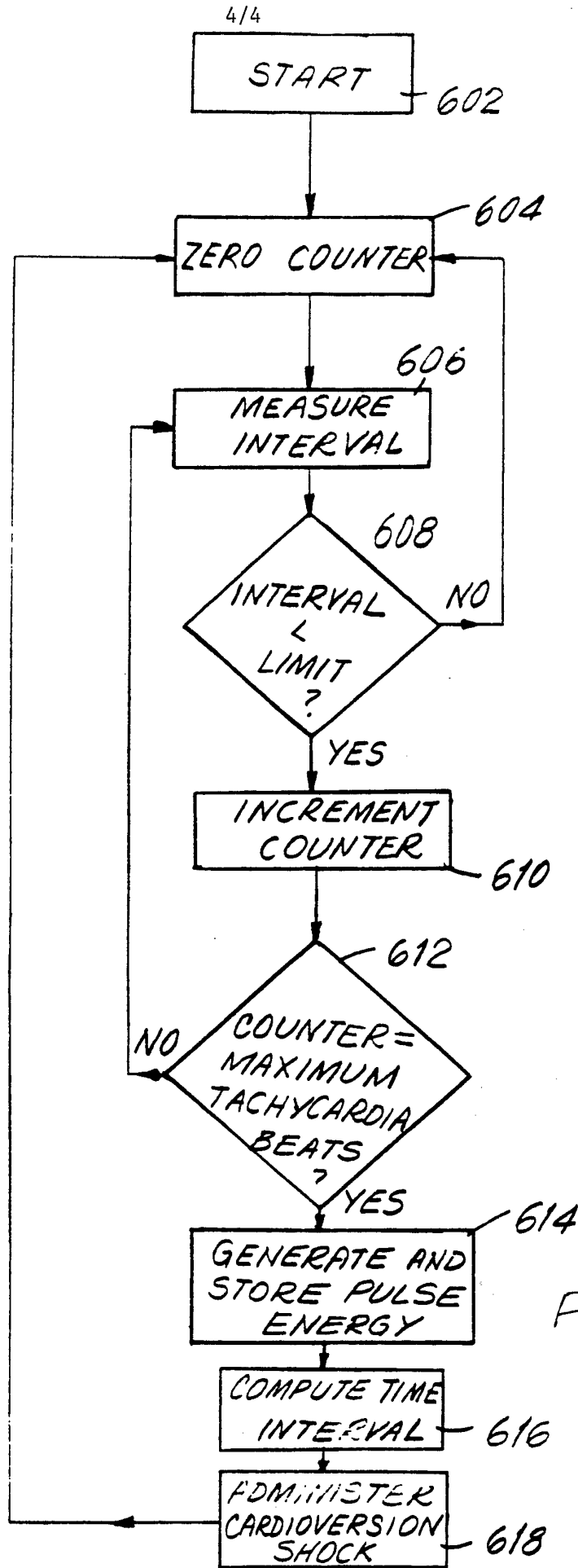


FIG 6

INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US94/10442

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61N 1/39  
US CL :607/005

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 607/005, 014

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,788,980, (MANN ET AL.), 06 December 1988. See entire document.	1-4, 7, 14-22
X --- Y	US, A, 4,587,970, (HOLLEY ET AL.), 13 May 1986. See entire document.	1-3, 5, 7-12, 14-25 ----- 4, 6, 13
X --- Y	US, A, 4,280,502, (BAKER, JR. ET AL.), 28 July 1981. See entire document.	1-3, 5, 7-12, 14-25 ----- 4, 6, 13
Y	US, A, 5,063,928, (GREVIS ET AL.), 12 November 1991. See entire document.	4, 6, 13

Further documents are listed in the continuation of Box C.  See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

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25 OCTOBER 1994

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Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Authorized officer *Jeffrey R. Jastrzab*  
JEFFREY R. JASTRZAB

Facsimile No. (703) 305-3230

Telephone No. (703) 308-2097