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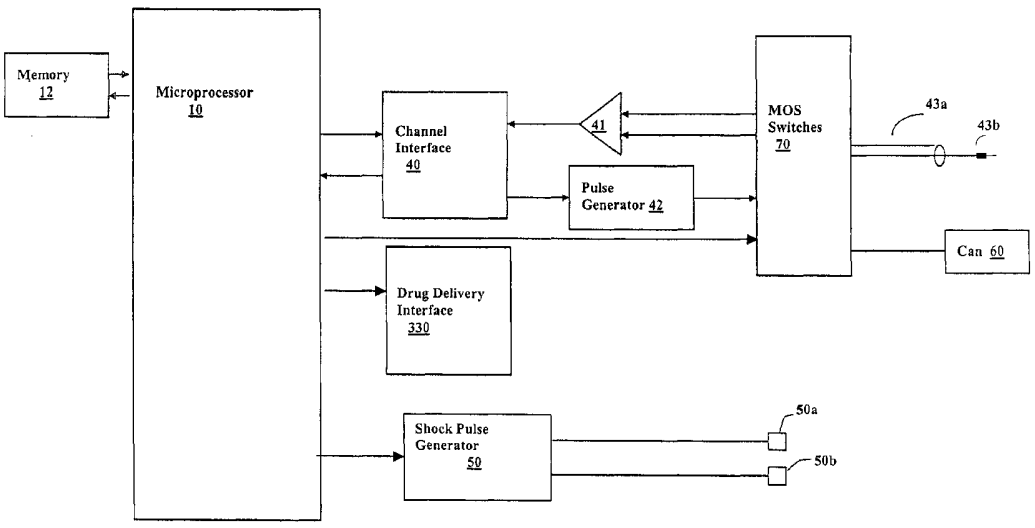
(54) Title: METHOD AND APPARATUS FOR DELIVERING PRE-SHOCK DEFIBRILLATION THERAPY



(57) Abstract: An apparatus and method is presented for improving cardiac function after successful termination of a tachyarrhythmia such as ventricular fibrillation. A series of electrical stimulation pulses are delivered prior to a defibrillation shock if one or more specific criteria are met.

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DEFIBRILLATION THERAPY

Field of the Invention

This invention pertains to apparatus and methods for treating cardiac arrhythmias and improving cardiac function.

Background

Tachyarrhythmias are abnormal heart rhythms characterized by a rapid heart rate. Examples of ventricular tachyarrhythmias include ventricular tachycardia (VT) and ventricular fibrillation (VF). Both ventricular tachycardia and ventricular fibrillation can be hemodynamically compromising, and both can be life-threatening. Ventricular fibrillation, however, causes circulatory arrest within seconds and is the most common cause of sudden cardiac death. Cardioversion (an electrical shock delivered to the heart synchronously with an intrinsic depolarization) and defibrillation (an electrical shock delivered without such synchronization) can be used to terminate most tachyarrhythmias, including VT and VF. As used herein, the term defibrillation and cardioversion should be taken to mean an electrical shock delivered either synchronously or not in order to terminate a fibrillation. In electrical defibrillation, a current depolarizes a critical mass of myocardial cells so that the remaining myocardial cells are not sufficient to sustain the fibrillation.

Implantable cardioverter/defibrillators (ICDs) provide electro-therapy by delivering a shock pulse to the heart when fibrillation is detected by the device. The ICD is a computerized device containing a pulse generator that is usually implanted into the chest or abdominal wall. Electrodes connected by leads to the ICD are placed on the heart, or passed transvenously into the heart, to sense cardiac activity and to conduct the impulses from the shock pulse generator. The device delivers a defibrillation shock pulse to the heart in response to a detected tachyarrhythmia by impressing a voltage between shock electrodes in contact with the heart.

Summary of the Invention

The present invention relates to an apparatus and method for preventing post-shock hypotension after termination of ventricular fibrillation. The invention may be incorporated in an ICD or an external defibrillation device. Post-shock cardiac function is improved by delivering a series of electrical stimulation pulses prior to a defibrillation shock while the heart is in fibrillation. In order to avoid delaying an initial defibrillation shock, such pre-shock stimulation therapy is only applied after one or more failed defibrillation attempts, according to the duration of the tachyarrhythmia, or according to the energy level of the defibrillation shock.

Brief Description of the Drawings

Fig. 1 is a system diagram of an exemplary cardiac rhythm management device in which may be incorporated the present invention.

Figs. 2A through 2D illustrate exemplary algorithms for delivering stimulation pulses to improve cardiac function.

Detailed Description

It has been found that transient hypotension often occurs following defibrillation shocks. This hypotension may last for seconds, minutes, or even hours and can result in post-shock fatigue in some patients. Some evidence suggests that the likelihood of post-shock hypotension is related to the duration of the fibrillation, and that arterial pressure will quickly return to normal if successful cardioversion occurs within approximately thirty seconds in most patients. Patients who remain in VF for a longer period of time, especially after repeated defibrillation attempts, are more likely to experience transient hypotension after successful cardioversion.

In order to improve post-shock cardiac function, and in some cases increase the likelihood of successful cardioversion, a series of electrical stimulation pulses can be delivered prior to the defibrillation shock. By way of example but not by way of limitation, such pulses may be delivered as a pulse train at a frequency range between 10 and 100 Hz, at an amplitude between 15 and 200 volts, and for a duration of between 100 milliseconds and 2 seconds.

Delivering such stimulation pulses while the heart is in fibrillation allows the pulses to be delivered without regard to the intrinsic heart rhythm. Since a patient in VF is in circulatory arrest, however, it is normally considered desirable to delivery defibrillation therapy as soon as possible. In accordance with the present invention, therefore, a series of stimulation pulses are delivered during VF and before a defibrillation shock only after an initial defibrillation shock has failed to cardiovert the patient. In other embodiments, decision algorithms may use additional criteria before delivering pre-shock stimulation therapy such as the duration of the VF, the number of failed defibrillation attempts, and the energy level of defibrillation shock in cases where shocks of increasing magnitude are delivered. By invoking pre-shock stimulation therapy in only these situations, no delay of initial therapy occurs, and the therapy is applied only when it is needed most.

1. Hardware platform

The present invention may be incorporated into either an external defibrillator or an ICD. The description that follows, however, will principally refer to an ICD configured and programmed to carry out the method of delivering pre-shock stimulation therapy described above. Cardiac rhythm management devices such as ICDs are typically implanted subcutaneously on a patient's chest and have leads threaded intravenously into the heart to connect the device to electrodes used for sensing and delivery of defibrillation shocks. A programmable electronic controller causes defibrillation shocks to be delivered when an arrhythmia is detected. The controller also controls the output of pacing pulses in the case of an ICD with pacemaker functionality. The present invention may be incorporated into an ICD or incorporated into an external defibrillation device. For illustrative purposes, however, a block diagram of an implantable device with cardioversion/defibrillation capability is shown in Fig. 1. The controller of the device is made up of a microprocessor 10 communicating with a memory 12, where the memory 12 may comprise a ROM (read-only memory) for program storage and a RAM (random-access memory) for data storage. The controller could be implemented by other types of logic

circuitry (e.g., discrete components or programmable logic arrays) using a state machine type of design, but a microprocessor-based system is preferable.

The device has a sensing channel for sensing cardiac electrical activity and a stimulation channel for delivering stimulation pulses. The device would normally be implanted such that the ventricles are sensed and stimulated by the respective channels. Each channel in this embodiment utilizes a single lead connected to the device that includes a ring electrode 43a and tip electrode 43b for bipolar sensing and stimulation. In certain embodiments, the device may incorporate a pacemaker functionality in which case the stimulation channel may also be used for delivering paces to the heart in accordance with a pacing algorithm. A MOS switching network 70 controlled by the microprocessor is used to switch the electrodes to the input of a sense amplifier 41 for the sensing channel or to the output of a pulse generator 42 for the stimulation channel. The switching network may also be used to connect only one of either the ring or tip electrode to the pulse generator 42 or sensing amplifier 41 for unipolar sensing or stimulation, in which case the conductive case of the device or can 60 is used as the other electrode. A channel interface 40 which communicates bidirectionally with a port of microprocessor 10 may include an analog-to-digital converter for digitizing sensing signal inputs from the sensing amplifier, registers that can be written to for adjusting the gain and threshold values of the sensing amplifier, and registers for controlling the output of stimulation pulses and/or changing the stimulation pulse amplitude or frequency. A defibrillation shock pulse generator 50 with shock leads 50a and 50b for delivering cardioversion/defibrillation shocks to the ventricles is also interfaced to the controller. In an alternative embodiment, the stimulation channel may use the shock leads rather than the sensing lead for delivering stimulation pulses.

The microprocessor 10 controls the overall operation of the device in accordance with programmed instructions stored in memory. The sensing channel detects a chamber sense, either an atrial sense or ventricular sense, when an electrogram signal (i.e., a voltage sensed by an electrode representing cardiac electrical activity) generated by the channel exceeds a specified detection threshold. The time intervals between such senses are measured in order to detect tachyarrhythmias so that appropriate therapy can be delivered by the

device. Upon detection of a tachyarrhythmia warranting intervention (e.g., ventricular fibrillation), the controller causes the delivery of a shock pulse to the heart. As described below with reference to different embodiments, the controller is also programmed to deliver pre-shock stimulation pulses via the stimulation channel when certain criteria are met.

2. Exemplary decision algorithms

Figs. 2A through 2D illustrate decision algorithms for delivering pre-shock stimulation therapy as could be implemented in the programming of the device in Fig. 1. Referring first to Fig. 2A, the cardiac rhythm is monitored at step A1 by detecting ventricular senses (R waves) and determining if a ventricular tachyarrhythmia such as VF exists. If a ventricular tachyarrhythmia has been detected, a defibrillation shock is delivered at step A2. This defibrillation shock is delivered without delay and not preceded by stimulation pulses. At step A3, it is determined whether the tachyarrhythmia is still present. If the patient has been successfully cardioverted, the device returns to step A1. If the tachyarrhythmia is still present, a series of stimulation pulses at a specified frequency, magnitude, and duration is delivered at step A4 before the next defibrillation shock is delivered at step A5. The device then returns to step A3 to see if the defibrillation shock was successful. Thus, in this embodiment, pre-shock stimulation therapy for improving cardiac function is delivered prior to each defibrillation shock only after an initial failure of a defibrillation shock delivered immediately after detection of the tachyarrhythmia.

Fig. 2B shows an alternative embodiment in which an additional step A33 is performed after it is determined that a tachyarrhythmia is still present at step A3. Step A33 adds the requirement that at least N previous unsuccessful defibrillation shocks must have been applied before pre-shock stimulation therapy is delivered at step A4. Fig. 2C shows another embodiment in which step A34 is added after step A3 in order to test the duration of the tachyarrhythmia. In this case, pre-shock stimulation therapy is delivered at step A4 only if it is determined that the tachyarrhythmia has been present for at least M seconds.

Fig. 2D shows an embodiment in which pre-shock stimulation therapy is applied or not in accordance with the energy level of the defibrillation shock. Ventricular fibrillation is a phenomena that exhibits a threshold with respect to the shock magnitude and duration needed to terminate the fibrillation by changing the transmembrane potential in a critical mass of myocardial cells. The ventricular defibrillation threshold (VDFT), for example, is defined the smallest amount of energy that can be delivered to the heart to reliably convert ventricular fibrillation to normal sinus rhythm. The larger the magnitude of the shocks delivered by an ICD, the more the battery is drained, thus decreasing the longevity of the device, and the more discomfort is inflicted upon the patient. It is desirable, therefore, for defibrillation shocks to be as small and close to the VDFT as possible. When a defibrillation shock is unsuccessful in terminating a tachyarrhythmia, however, an ICD may be programmed to increase the energy of the defibrillation shock. The magnitude of the defibrillation shock may be increased after each successive failed shock or after a specified number of failed shocks to implement a kind of tiered therapy with respect to shocking energy level. The embodiment of Fig. 2D adds step A31 to increase the energy level of the defibrillation shock up to a specified maximum after each failed defibrillation attempt. Step A35 then determines if the energy level of the defibrillation shock is at least K joules before pre-shock stimulation therapy is delivered at step A34.

In an alternative embodiment, once the controller 10 detects a tachyarrhythmia warranting intervention, a command may also be issued to the drug delivery interface 330. The drug delivery interface then actuates a drug delivery apparatus 331 incorporated into the device that delivers a quantity of a pharmacological or neurohumoral agent for improving post-shock cardiac function. (e.g., epinephrine or norepinephrine). The drug delivery apparatus may take a number of forms. One example of such an apparatus is a pump and a drug reservoir located within a header portion of the device, where the pump communicates with an intravenously disposed catheter. The drug delivery interface within the housing communicates with the pump by control wires that pass into the header through a feedthrough. Upon actuation by the drug delivery

interface 330, the pump pumps a quantity of drug from a reservoir into the lumen of the catheter.

Although the invention has been described in conjunction with the foregoing specific embodiment, many alternatives, variations, and modifications will be apparent to those of ordinary skill in the art. Such alternatives, variations, and modifications are intended to fall within the scope of the following appended claims.

What is claimed is:

1. A cardiac rhythm management device, comprising:

a sensing channel for generating electrograms reflecting cardiac electrical activity;

a defibrillation shocking channel for delivering a defibrillation shock pulse to the heart;

a stimulation channel for delivering stimulation pulses to improve post-shock cardiac function; and

a controller for causing the defibrillation shocking channel to deliver a first defibrillation shock with no preceding stimulation pulses upon detection of a tachyarrhythmia from the sensed electrogram;

wherein the controller is programmed to cause the delivery of a series of stimulation pulses to the heart prior to delivery of a subsequent defibrillation shock if the first defibrillation shock was unsuccessful in terminating the tachyarrhythmia.

2. The device of claim 1 wherein the stimulation channel may additionally be utilized as a pacing channel by the controller.

3. The device of claim 1 wherein the defibrillation shocking channel includes a pair of shock electrodes and further wherein the stimulation channel utilizes the shock electrodes for delivering stimulation pulses.

4. The device of claim 1 wherein the stimulation pulses are in a frequency range approximately between 10 and 100 Hz.

5. The device of claim 1 wherein the series of stimulation pulses delivered to the heart prior to delivery of a subsequent defibrillation shock if the first defibrillation shock was unsuccessful in terminating the tachyarrhythmia is a pulse train of a duration on the order of 100 milliseconds to 2 seconds.

6. The device of claim 1 wherein the stimulation pulses are of a magnitude on the order of 15 to 200 volts.

7. The device of claim 1 wherein the controller is programmed to cause the delivery of a series of stimulation pulses to the heart prior to delivery of a subsequent defibrillation shock if the first defibrillation shock was unsuccessful in terminating the tachyarrhythmia.

8. The device of claim 1 wherein the controller is programmed to cause the delivery of a series of stimulation pulses to the heart prior to delivery of a subsequent defibrillation shock if a specified number of previous defibrillation shocks were unsuccessful in terminating the tachyarrhythmia.

9. The device of claim 1 wherein the controller is programmed to cause the delivery of a series of stimulation pulses to the heart prior to delivery of a subsequent defibrillation shock if the first defibrillation shock was unsuccessful in terminating the tachyarrhythmia and the tachyarrhythmia has been present for a minimum specified time.

10. The device of claim 1 wherein the controller is programmed to deliver subsequent defibrillation shocks with a greater magnitude than the first defibrillation shock if the latter was unsuccessful in terminating the tachyarrhythmia.

11. The device of claim 7 wherein the controller is programmed to cause the delivery of a series of stimulation pulses to the heart prior to delivery of a subsequent defibrillation shock if the first defibrillation shock was unsuccessful in terminating the tachyarrhythmia and the subsequent defibrillation shock is of a minimum specified magnitude.

12. A cardiac rhythm management device, comprising:

a sensing channel for generating electrograms reflecting cardiac electrical activity;

a defibrillation shocking channel for delivering a defibrillation shock pulse to the heart;

a drug delivery device having contained therein a quantity of a pharmacological or neurohumoral agent for improving post-shock cardiac function; and

a controller for causing the defibrillation shocking channel to deliver a first defibrillation shock upon detection of a tachyarrhythmia from the sensed electrogram;

wherein the controller is programmed to cause the delivery of the pharmacological or neurohumoral agent upon detection of a tachyarrhythmia.

13. A method for operating a cardiac rhythm management device, comprising:

generating electrograms reflecting cardiac electrical activity;

delivering a first defibrillation shock upon detection of a tachyarrhythmia from a sensed electrogram; and

delivering a series of stimulation pulses for improving post-shock cardiac function prior to delivery of a subsequent defibrillation shock if the first defibrillation shock was unsuccessful in terminating the tachyarrhythmia, wherein the first defibrillation shock is not preceded by stimulation pulses.

14. The method of claim 13 wherein the stimulation pulses are in a frequency range approximately between 10 and 100 Hz.

15. The method of claim 13 wherein the series of stimulation pulses delivered prior to delivery of a subsequent defibrillation shock if the first defibrillation shock was unsuccessful in terminating the tachyarrhythmia is a pulse train having a duration between 10 and 100 milliseconds.

16. The method of claim 13 wherein the stimulation pulses have an amplitude between 15 and 200 volts.

17. The method of claim 13 wherein the controller is programmed to cause the delivery of a series of stimulation pulses prior to delivery of a subsequent defibrillation shock if the first defibrillation shock was unsuccessful in terminating the tachyarrhythmia.

18. The method of claim 13 further comprising delivering a series of stimulation pulses to the heart prior to delivery of a subsequent defibrillation shock if a specified number of previous defibrillation shocks were unsuccessful in terminating the tachyarrhythmia.

19. The method of claim 13 further comprising delivering a series of stimulation pulses to the heart prior to delivery of a subsequent defibrillation shock if the first defibrillation shock was unsuccessful in terminating the tachyarrhythmia and the tachyarrhythmia has been present for a minimum specified time.

20. The method of claim 13 further comprising delivering a series of stimulation pulses to the heart prior to delivery of a subsequent defibrillation shock if the first defibrillation shock was unsuccessful in terminating the tachyarrhythmia and the subsequent defibrillation shock is of a minimum specified magnitude.

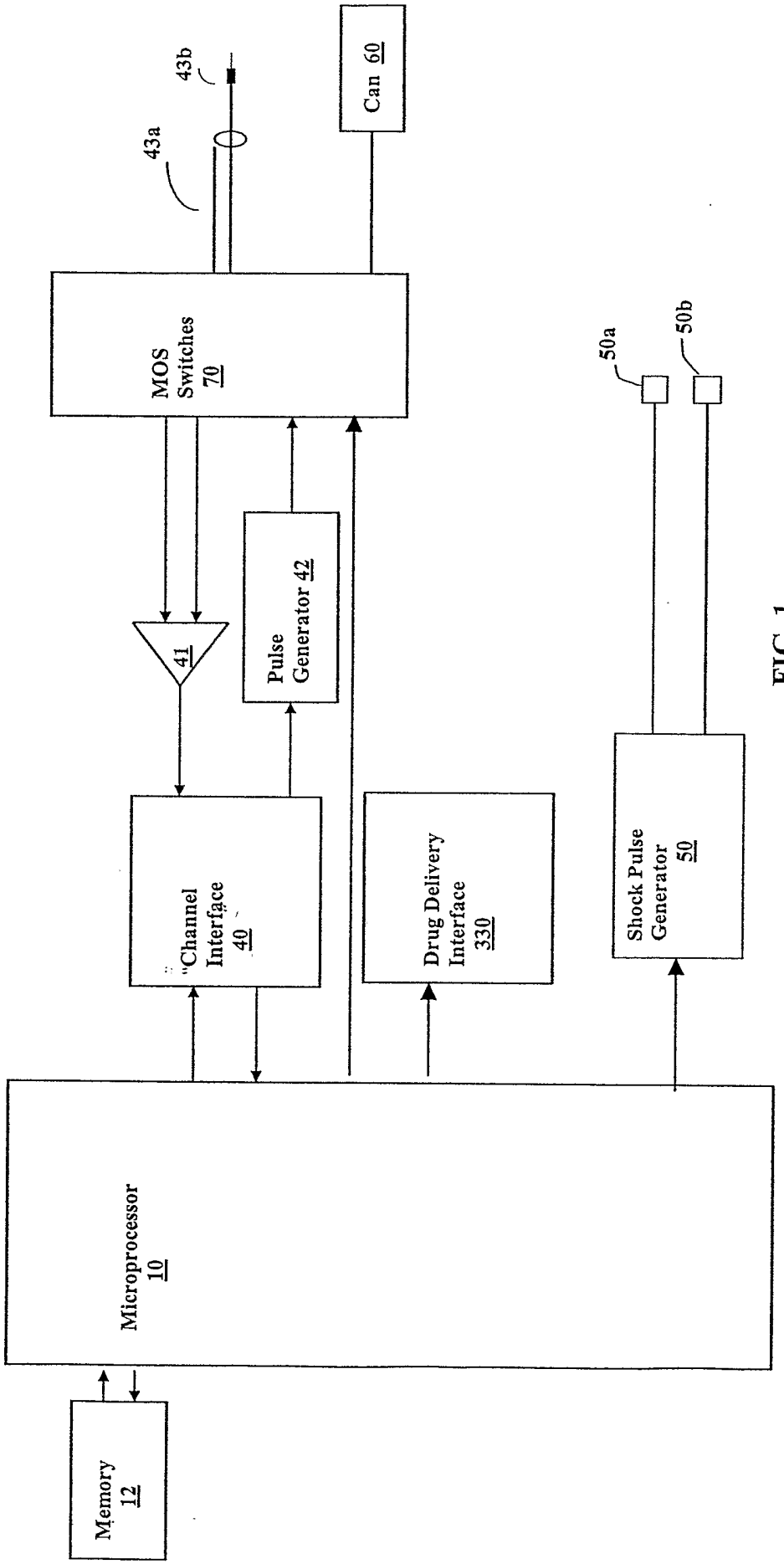
Can 60
43b
43a
MOS Switches 70
50a
50b
41
Pulse Generator 42
"Channel Interface 40
Drug Delivery Interface 330
Shock Pulse Generator 50
Microprocessor 10
Memory 12

FIG. 1

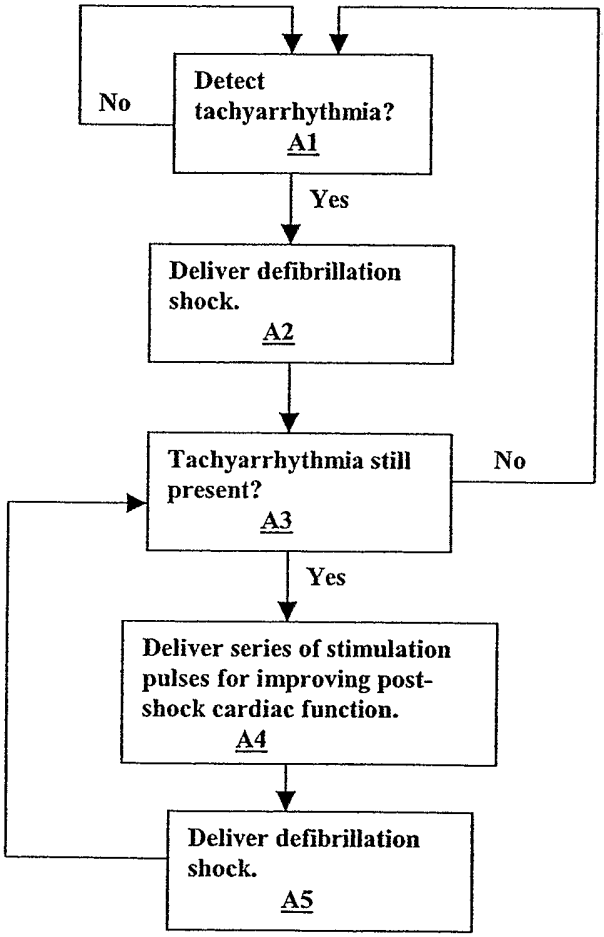
Detect tachyarrhythmia?
A1
No
Yes
Deliver defibrillation shock.
A2
Tachyarrhythmia still present?
A3
No
Yes
Deliver series of stimulation pulses for improving post-shock cardiac function.
A4
Deliver defibrillation shock.
A5

Fig. 2A

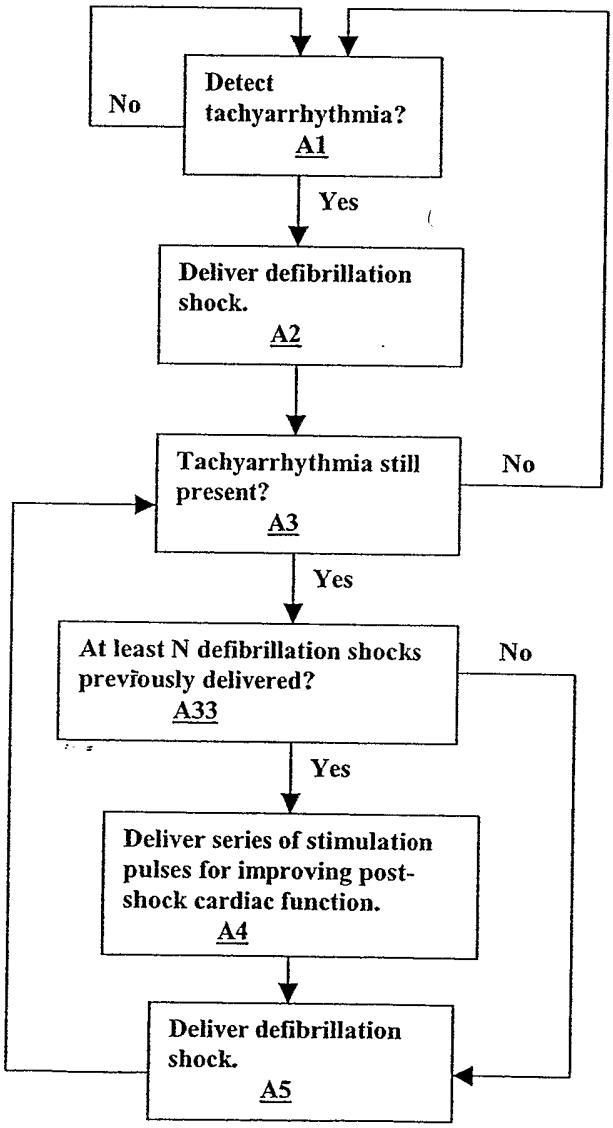
Detect tachyarrhythmia?
A1
No
Yes
Deliver defibrillation shock.
A2
Tachyarrhythmia still present?
A3
No
Yes
At least N defibrillation shocks previously delivered?
A33
No
Yes
Deliver series of stimulation pulses for improving post-shock cardiac function.
A4
Deliver defibrillation shock.
A5

Fig. 2B

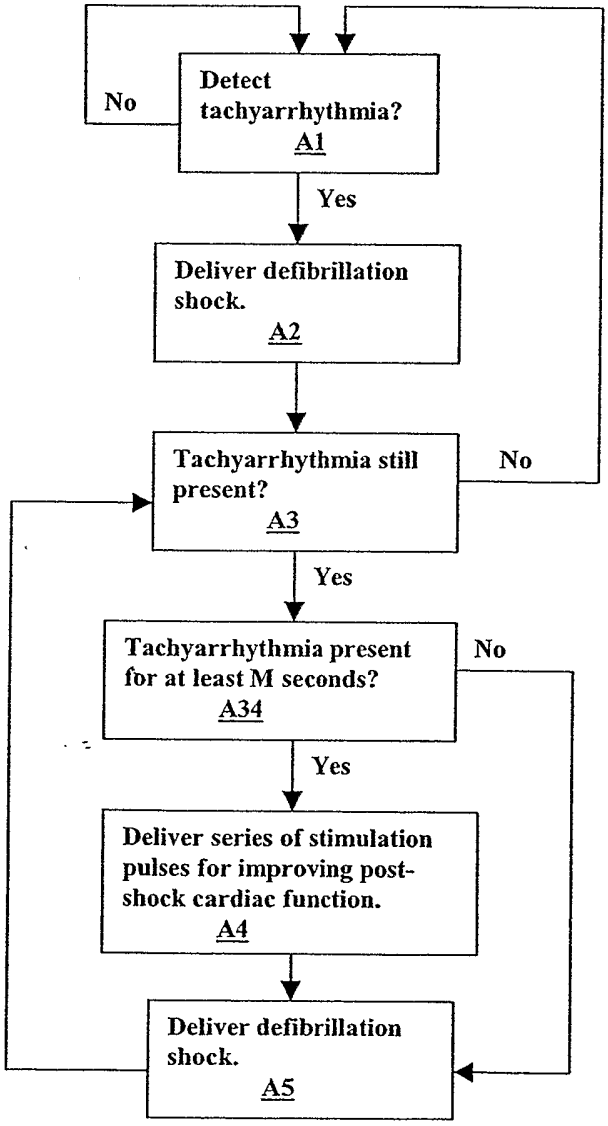
Detect tachyarrhythmia?
A1
No
Yes
Deliver defibrillation shock.
A2
Tachyarrhythmia still present?
A3
No
Yes
Tachyarrhythmia present for at least M seconds?
A34
No
Yes
Deliver series of stimulation pulses for improving post-shock cardiac function.
A4
Deliver defibrillation shock.
A5

Fig. 2C

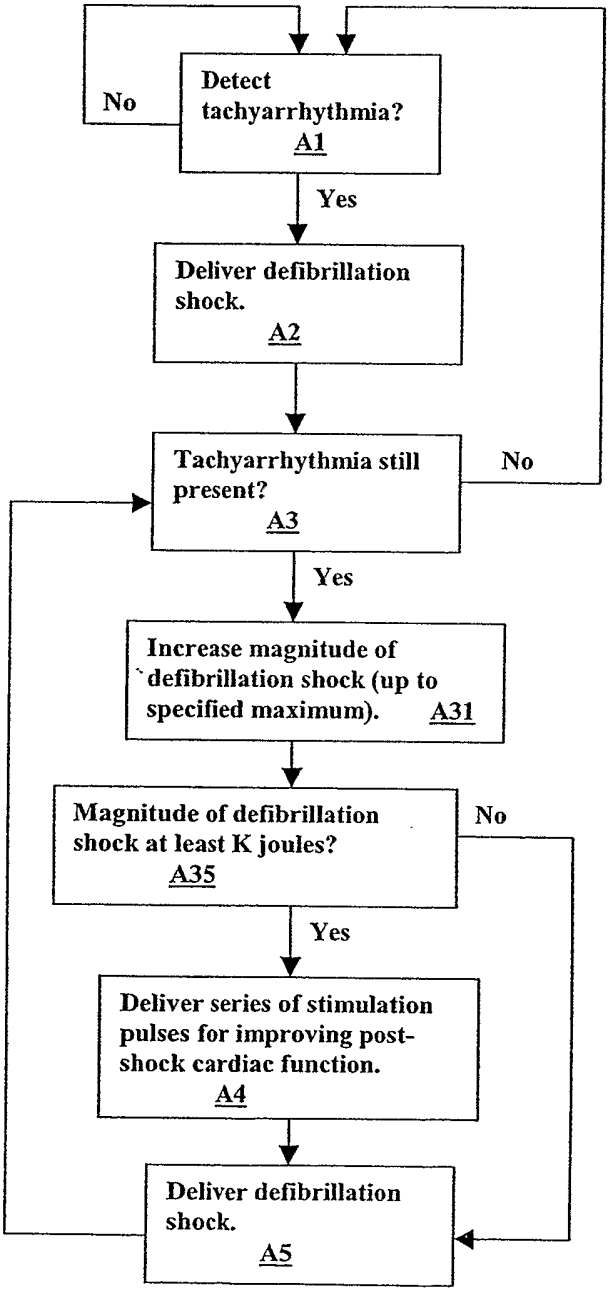
Detect tachyarrhythmia? A1
No
Yes
Deliver defibrillation shock. A2
Tachyarrhythmia still present? A3
No
Yes
Increase magnitude of defibrillation shock (up to specified maximum). A31
Magnitude of defibrillation shock at least K joules? A35
No
Yes
Deliver series of stimulation pulses for improving post-shock cardiac function. A4
Deliver defibrillation shock. A5

Fig. 2D