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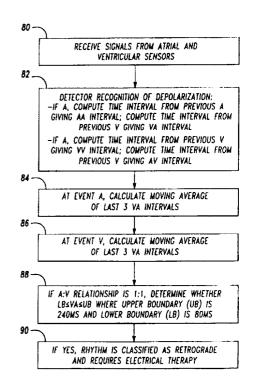
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(54) Title: METHOD FOR CARDIAC ARRHYTHMIA DETECTION

(57) Abstract

Using only ventricular and atrial rate criteria, there is ambiguity in the case of atrial tachycardia (AT) with retrograde conduction. The introduction of dual chamber sensing in anti-tachycardia devices allows for computational inexpensive measurements of VA intervals. The present invention addresses problems arising in tachycardia with confounding 1:1 relationships. According to the present invention, using atrial and ventricular rates only, all 1:1 tachycardia would be classified as VT, resulting in false shocks. Specificity of ambiguous 1:1 tachycardia can be potentially increased using VA interval measurements (82), at the cost of minimum loss in sensitivity for VT detection. The applied algorithm imposes little in additional computation for dual chamber sensing ICDs and greatly reduces the possibility of false shocks in 1:1 atrial tachycardia.



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METHOD FOR CARDIAC ARRHYTHMIA DETECTION

SPONSORSHIP

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CROSS-REFERENCE TO RELATED APPLICATION

This is a continuation-in-part application of a provisional application filed April 19, 1997, and assigned U.S. Serial No. 60/016,370.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to the detection of cardiac arrhythmia. More particularly, the present invention relates to detection of cardiac arrhythmia by ventriculoatrial (VA) internal analysis.

2. Discussion

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The heart may be viewed as a spontaneous current generator whose pumping action is effected by spontaneous generation of an electrical impulse (known as an action potential), conduction of the electrical impulse throughout the heart, and subsequent contraction of the heart muscle (myocardium) in response to the impulse. It is, therefore, electrical activity which initiates and controls muscular contraction of the heart.

The heart's electrical impulse originates in the sino-atrial node and is transmitted (cell-to-cell) to all portions of the atria, resulting in the contraction of the atrial chambers. The electrical impulse continues in its path to reach a cluster of conduction fibrils known as the atrioventricular node, or the A-V node. By delaying conduction for approximately one-tenth of a second, the A-V node acts as a buffer for impulses from the atria to the ventricles. This allows for proper flow of blood from the atria to the ventricles. Following this delay, the A-V node transmits an impulse that reaches another cluster of fibers known as the bundle of His which comprises left and right bundle branches of the His-Purkinjie system. The bundle branches terminate with the Purkinjie fibers which are attached directly to the myocardial cells.

2

A coordinated wave of electrical impulses effects contraction of many myocardial cells simultaneously, thus causing the heart's pumping action. The action begins in the sino-atrial node from which impulses are provided spontaneously and periodically. The impulses travel to the surrounding cardiac tissue and propagate as a wave of depolarization. As noted above, contracting of the cardiac muscle of the atria follows after the depolarization. Subsequent ventricular conduction is initiated via the A-V node and the His-Purkinjie system.

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Normal electrical function provides for continued proper functioning of the heart. However, aberrations in electrical origination or transmission produce concomitant malfunctions of the systemic delivery of blood to the body. The majority of cases of cardiac malfunction may be traced to a failure in the electrical conduction system of the heart. The result of such an electrical failure or change from the normal electrical activity and sequence of cardiac activity is an arrhythmia. Arrhythmias may be atrial, atrioventricular, or ventricular.

Several methods are known to treat arrhythmia. Drugs are occasionally prescribed, and while having significant side effects are often justified because of the severity of the arrhythmia. Drugs, called calcium antagonists, mediate the heart's conduction by halting electrical conduction through blocking of the calcium channels of myocardial cells. Nitrates may be used as treatment in cases of acute myocardial infarction or congestive heart failure. Often times, patients are resistant to such drugs, thereby greatly reducing their therapeutic effect.

Another therapeutic technique is referred to as radio frequency ablation which is directed to neutralizing accessory electrically-conductive pathways of the heart which cause the heart to fail in properly conducting electrical impulses due to some small area of the heart which is skewing the direction of depolarization. In this technique, a catheter is introduced into the heart and high frequency radio waves are delivered to burn away the faulty area of the heart. Following successful radio frequency ablation therapy, normal conduction of the heart will return and the particular arrhythmia associated with the damaged tissue will be eliminated.

One of the most common approaches to the elimination of arrhythmia is electrical therapy in which electrodes are fitted to either the body or the heart for selectively delivering an electrical current or shock to alter the abnormal rhythm of the heart. Implantable cardioverter defibrillator, or "ICDs", stimulate the heart directly using function generators with specific waveforms to respond to and treat arrhythmias on

3

an "as-needed" basis. In the past decade, ICDs have emerged as the treatment of choice for malignant tachyarrhymias unresponsive to antiarrhythmic drugs. In known devices of this type, considerable effort has been devoted to the development of detection circuitry to accurately identify abnormal heart activity which requires defibrillation or cardioversion (i.e., insuring true-positives) and for preventing a "no output" situation when an output is actually needed (i.e., preventing true negatives).

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Implantable cardioverter defibrillator have achieved overwhelming success in salvaging thousands of lives by providing immediate electrical therapy for the treatment of potentially lethal arrhythmias. These rhythms are believed to be responsible for over 80% of cases of sudden cardiac death, which is estimated to annually claim 400,000 victims. The vast number of implants of ICDs is exceptional despite its relative infancy in the medical field.

A remaining area of improvement in ICD technology relates to refinement of detection criteria such that delivery of shock therapy is prevented when none is needed. The application of electrical shock in response to the incorrect identification of ventricular fibrillation (VF) or ventricular tachycardia (VT) (i.e., false positives) presents a three-fold problem. First, false shocks present an unnecessary patient distress. Second, false shocks deplete battery power which renders the device less capable of addressing true urgencies and forces premature explanation. Third, false delivery of therapy can initiate ventricular tachycardia or ventricular fibrillation when none previously existed.

In an effort to overcome these problems, devices offer a multitude of therapies tailored to specific arrhythmias and provide a variety of programmable parameter settings. However, limitations in current detection capabilities remain. The present challenge is to optimize detection in order to direct appropriate therapy without sacrificing sensitivity of VT and VF detection, and without significantly increasing the complexity and power consumption in an implantable battery-operated device.

Most present-generation ICDs rely predominantly on single (ventricular) chamber analysis of arrhythmias. Rate criteria are set such that ventricular tachycardia and ventricular fibrillation are detected with high sensitivity to ensure dangerous arrhythmias are never missed. High sensitivity, however, comes at the cost of limited specificity. Distinction of VT and VF from nonthreatening supraventricular rhythms remains a severe limitation in present ICDs. The ICD may unnecessarily discharge during any arrhythmia in which the ventricular heart rate exceeds a preprogrammed

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threshold value. Unnecessary shocks have been reported to occur in 9-41% of treatments with ICDs.

In an effort to reduce false positives, dual-chamber sensing, implantable cardioverter defibrillator have been heretofore developed. Such ICDs incorporate an atrial sensing lead in addition to a ventricular sensing lead. One type of dual-chamber sensing ICD is commercially available from ELA Medical, Co. of France.

The addition of dual-chamber sensing in antitachycardia devices (e.g. ICDs) permits the measurement of atrioventricular and ventriculoatrial intervals. Most supraventricular arrhythmias and most ventricular arrhythmias can be detected by an n:1 (A:V) relationship, where n does not equal 1. However, when using combined ventricular and atrial rate criteria ambiguity in the vase of atrial tachycardia with anterograde conduction (which doesn't need treatment) versus ventricular tachycardia with retrograde conduction (which needs treatment) still remains.

The state of the art for antitachycardia devices, including implantable cardioverter defibrillator, is described in detail in the references which follow. These references are hereby incorporated by reference as if fully set forth herein.

REFERENCES

- [1] R. Arzbaecher, T. Bump, J.M. Jenkins, K. Glick, F. Munkenbeck, J. Brown, N. Nandhakumar, "Automatic Tachycardia Recognition", *PACE*, vol. 7, pp. 541-547, May-June 1984.
- [2] J.M. Jenkins, T. Bump, F. Munkenbeck, J. Brown, and R. Arzbaecher. "Tachycardia Detection in Implantable Antitachycardia Devices", *PACE*, vol. 7, pp. 1273-1277, November-December 1984.
- [3] F.E. Marchlinski, R.B. Kleiman, B.G. Hook, R. Pachulski, M. Ratcliffe, "Advances in Implantable Cardioverter Defibrillator Therapy", in *Tachycardias: Mechanisms and Management*, M.E. Josephson, Ed., Mount Kisco, NY: Futura Publishing Co. Inc., pp. 405-420, 1993.
 - [4] W. Grimm, B.F. Florers, F.E. Marchlinski, "Electrocardiographically Documented Unnecessary, Spontaneous Shocks in 241 Patients with Implantable Cardioverter Defibrillators", *PACE*, vol. 15, pp. 670-669, November 1992.

- [5] B.G. Hook, D.J. Callans, R.B. Kleiman, B.T. Flores, F.E. Marchlinski, "Implantable Cardioverter-Defibrillator Therapy in the Absence of Significant Symptoms, Rhythm Diagnosis and Management Aided by Stored Electrogram Analysis", *Circulation*, vol. 87, pp. 1897-1906, June 1993.
- 5 [6] S.O. Nunain, M. Roelke, T. Trouton, S. Osswald, Y.H. Kim, G. Sosa-Suarez, D.R. Brooks, B. McGovern, M. Guy, D.F. Torchiana, G.J. Vlahakes, H. Garan, J.N. Ruskin, "Limitations and Late Complications of Third-Generation Automatic Cardioverter-Defibrillators", *Circulation*, vol. 91, pp. 2204-2213, April 15 1995.
- [7] P.J. Troup, S. Nisam, "Complications Associated with the Automatic Implantable Cardioverter Defibrillator", in *The Implantable Cardioverter/Defibrillator*, E Alt, H. Klein, J.C. Griffin, Eds. Berlin: Springer-Verlag, 1992, pp. 253-271.
- [8] G.L. LeCarpentier, J.J. Baga, H. Yang, R.T. Steinman, M.D. Meissner, M.H. Lehmann, "Differentiation of Sinus Tachycardia from Ventricular Tachycardia with 1:1 Ventriculoatrial Conduction in Dual Chamber Implantable Cardioverter Defibrillators: Feasibility of a Criterion Based on the Atrioventricular Interval", PACE, vol. 17, pp. 1818-1831, November 1994.
- [9] C.J. Chiang, J.M. Jenkins, L.A. DiCarlo, "The Value of Rate Regularity and Multiplicity Measures to Detect Ventricular Tachycardia in Atrial Fibrillation of Flutter with a Fast Ventricular Response", *PACE*, vol. 17, pp. 1503-1508, September 1994.
 - [10] S.A. Caswell, L.A. DiCarlo, C.J. Chiang, J.M. Jenkins, "Automated Analysis of Spontaneously Occurring Arrhythmias by Implantable Devices: Limitation of Using Rate and Timing Features Alone", *J Electrocardiol*, vol. 27 (suppl), pp. 151-156, 1994.
 - [11] C.J. Chiang, J.M. Jenkins, L.A. DiCarlo, D. Lin, P.C. Li, "Real-Time Arrhythmia Identification from Automated Analysis of Intraatrial and Intraventricular Electrograms", *PACE*, vol. 16, pp. 223-227, January 1993.

6

- [12] R.M. Schuilenburg, "Patterns of V-A Conduction in the Human Heart in the Presence of Normal and Abnormal A-V Conduction", *The Conduction System of the Heart*, HJJ Wellens, KI Lie, MJ Janse Eds. Philadelphia: Lea and Febiger, 1976, ch 27, pp. 485-503.
- 57 [13] R. Arzbaecher, "A Pill Electrode for the Study of Cardiac Dysrhythmia", *Medical Instrumentation*, vol. 12, pp. 277-281, 1978.
 - [14] J.M. Jenkins, D. Wu, R. Arzbaecher, "Computer Diagnosis of Supraventricular and Ventricular Arrhythmias", *Circulation*, vol. 60, pp. 977-987, 1979.
- [15] S.A. Caswell, K.S. Kluge, C.J. Chiang, J.M. Jenkins, L.A. DiCarlo, "Pattern Recognition of Cardiac Arrhythmias Using Two Intracardiac Channels", *Comp Cardiol*, pp. 181-184, 1993.
 - [16] L.A. DiCarlo, D. Lin, J.M. Jenkins, "Automated Interpretation of Cardiac Arrhythmias", *J Electrocardiol*, vol. 26, pp. 53-67, January 1993.
- [17] R.M. Luceri, P. Zilo, The United States and Canadian Enguard Investigators,
 "Initial Clinical Experience with a Dual Lead Endocardial Defibrillation System with Atrial Pace/Sense Capability", *PACE*, vol. 18, pp. 163-167, January 1995.
 - [18] W.F. Kaemmerer, W.H. Olson, "Dual Chamber Tachyarrhythmia Detection Using Syntactic Pattern Recognition and Contextual Timing Rules for Rhythm". *PACE*, vol. 18, p. 872, April 1995. (abstract)
- 20 [19] J.M. Jenkins, S.A. Caswell, "Detection Algorithms in Implantable Cardioverter Defibrillators", IEEE, vol. 84, No. 3, March 1996.

While the studies identified above demonstrate various advances in the art, all known methods and devices for cardiac arrhythmia detection are subject to improvement. Most significant, a decrease in the identification of false positives, and thereby unnecessary shock therapy is desirable. In this regard, using only ventricular and atrial rate criteria, there is ambiguity in the case of

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atrial tachycardia (AT) with anterograde conduction versus ventricular tachycardia (VT) with retrograde conduction.

SUMMARY OF THE INVENTION

The present invention addresses the above-discussed problems which have heretofore arisen in correctly discerning between atrial tachycardia and ventricular tachycardia with retrograde where the A:V ratio is 1:1. The introduction of dual chamber sensing in antitachycardia devices allows for computationally inexpensive measurements of VA intervals.

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As noted above, using only a ventricular and atrial rate criteria, ambiguity exists in the case of atrial tachycardia with anterograde conduction versus ventricular tachycardia with retrograde conduction. From investigating the relationships between AV and VA intervals, a VA interval analysis has been developed to address the problem arising in tachycardias with confounding 1:1 relationships. Through application of the method of the present invention, dual chamber sensing in ICDs are capable of dramatically improving specificity by reducing the number of false shocks.

It is a principal object of the present invention to provide a method which overcomes the drawbacks associated with the prior art, including but not limited to those discussed above.

It is another object of the present invention to provide a method of cardiac arrhythmia detection which provides reliable protection against the administration of unneeded shock therapy, i.e., which provides protection against a false positive output.

It is a more specific object of the present invention to provide a method for cardiac arrhythmia detection which greatly reduces the possibility of false shocks in 1:1 tachycardias.

The above and other objects are achieved in accordance with the principles of the present invention in a method for cardiac arrhythmia detection which incorporates VA analysis to discern between types of 1:1 atrial and ventricular tachycardias.

8

In one form, the present invention provides a method of classifying a cardiac arrhythmia with a 1:1 confounding relationship as either an atrial tachycardia or a ventricular tachycardia with retrograde. The method includes the steps of measuring a characteristic (e.g., the VA interval) of a tachycardia and comparing the characteristic to an established range of acceptable values. Additionally, the method of the present invention includes the step of classifying the cardiac arrhythmia as a retrograde conduction when the characteristic is between the upper boundary and the lower boundary of the acceptable range and as an anterograde conduction when the characteristic is beyond the range of acceptable values.

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In a more preferred form, the present invention provides a method for reducing unnecessary shock treatments from an anti-tachycardia device by discerning between atrial tachycardias having anterograde and retrograde conductions with confounding 1:1 relationships. The method includes the initial steps of placing a first lead of a dual chamber sensor in operative sensory association with a ventricular chamber of a patient's heart and placing a second lead of the dual chamber sensor in operative sensory association with the atrial chamber of the patient's heart. The dual chamber sensor is operatively associated with the anti-tachycardia device and a plurality of signals provided by the first and second leads of the dual chamber sensor are used to measure the VA interval of the tachycardia. The VA interval of the tachycardia is compared against established upper and lower boundaries. The tachycardia is classified as a retrograde conduction when the VA interval is between the upper and lower boundaries and classified as an anterograde conduction when the VA interval is outside the upper and lower boundaries. The anti-tachycardia device is only activated when the tachycardia is classified as a retrograde conduction.

9

BRIEF DESCRIPTION OF THE DRAWINGS

Additional objects and advantages of the present invention will become apparent from a reading of the following detailed description of the preferred embodiments which makes reference to the drawings of which:

Figure 1 is a schematic diagram of an implantable cardioverter defibrillator embodying the present invention for applying defibrillating electrical energy to a human heart shown in operative association with a human heart.

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Figure 2 is a simplified flow chart showing the general steps of the method of the present invention.

Figure 3 is a flow chart setting forth the establishment of an algorithm using VA interval criterion to classify 1:1 retrograde activation according to the present invention.

Figure 4 is a simplified flow chart showing the general steps involved in applying the algorithm of the present invention for identifying VT with retrograde.

Figure 5 is a graph plotting the mean VA interval of naturally occurring anterograde and retrograde conductions.

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DETAILED DESCRIPTION OF THE INVENTION

Referring first to Figure 1, a schematic diagram of an implantable cardioverter defibrillator 10 is shown in operative association with a human heart 12. The portions of the heart 10 illustrated include the right ventricle 14, the left ventricle 16, the right atrium 18, and the left atrium 20, and the superior vena cava 22.

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The ICD 10 generally includes an enclosure 24 for hermetically sealing the internal circuit elements to be described hereinafter, and first and second leads 26 and 28. The enclosure 24 and first and second leads 26 and 28 are arranged to be implanted beneath the skin of a patient in a conventional manner so as to render the ICD 10 fully implantable.

The first lead 26 generally includes an electrode 30. As illustrated, the first lead 26 is flexible and is passed down the superior vena cava 22, so that the electrode 30 is preferably positioned high in the right atrium 18. The second lead 28 is also flexible and similarly includes an electrode 32. As illustrated, the second lead 28 is fed through the superior vena cava 22, into the right atrium 18, and then into the right ventricle 14. The electrodes 30 and 32 of the first and second leads 34 and 36, respectively, provide dual-chamber sensing of heart activity. The electrode 32 further provides for the delivery of defibrillating electrical energy to the heart 10.

The contents within the enclosure 24 of the ICD 10 is largely convention in nature and is shown to include a pair of amplifiers 36 and 38 for receiving signals from the electrodes 30 and 32. The enclosure further includes a microprocessor 40 which conventionally includes one or more counters, a time stamp, comparators, and in-dwelling software, all of which cooperate in a well known manner to detect tachycardias without a 1:1 confounding relationship. In addition, the otherwise conventional in-dwelling software has been modified to incorporate an algorithm in accordance with the present invention for detecting tachycardias with a 1:1 confounding relationship. The microprocessor 40 is arranged to operate in conjunction with a memory 42.

WO 97/39799

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PCT/US97/06728

The contents within the enclosure 24 of the ICD 10 is further shown to include a discharge circuit 44 coupled to the electrode 32 for applying cardioverting or defibrillating electrical energy to the heart 12. Lastly, the ICD 10 includes a depletable power source 46, such as a lithium battery, for providing power to the electrical components of the ICD 10.

Turning generally to the Figures 2-4, and specifically to Figure 2, the method of the present invention for reducing unnecessary shock treatments from an antitachycardia device will now be described. Figure 2 is a flow chart illustrating the general steps of the present invention. The Start 50 of the application of the present invention begins upon receipt by the ICD of signals from the electrodes 30 and 32. In the general Step 52, the VA interval of the tachycardia is compared with predetermined acceptable boundaries 54 and 56 (shown in Figure 5).

As will become more apparent, the predetermined boundaries 54 and 56 are established such that the tachycardia is classified as a retrograde conduction which requires treatment if the VA interval of the tachycardia is within the boundaries 54 and 56. Conversely, if the VA interval of the tachycardia is beyond the predetermined boundaries 54 and 56, the tachycardia is classified as an anterograde conduction which does not require treatment. Thus, as shown at the Step 58, shock therapy by the ICD is delivered to the patient's heart 12, if and only if, the VA interval of the tachycardia is within the predetermined boundaries 54 and 56. Otherwise, the method of the present invention returns to the Start point 50 for analysis of subsequent tachycardias with confounding 1:1 relationships.

The predetermined boundaries 54 and 56 for acceptable values of the VA interval can be established through cardiac pacing and by analysis of naturally occurring arrhythmias. With specific reference to Figure 3, a flow chart is provided which illustrates the general steps of establishing an algorithm using VA interval analysis to classify 1:1 retrograde activation with paced data.

In the Step 60, 1:1 anterograde pacings and 1:1 retrograde pacings are analyzed. More particularly, 1:1 anterograde conductions from patients during

12

atrial pacing (AP) at predetermined cycle lengths and 1:1 retrograde conductions from patients during ventricular pacing (VP) at similarly cycle lengths are analyzed.

In the Step 62, selected statistical analysis tools are used to calculate the moving averages of successive VA intervals (mean VA intervals) for each passage of 1:1 retrograde and anterograde conductions analyzed.

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In the Step 64, a plurality of the mean VA intervals are randomly selected from the VP passages and are used as a training set.

In the Step 66, the tightest boundaries in which the mean intervals of all randomly selected VP passages are correctly classified are used to establish an upper boundary 54 and a lower boundary 56. In one specific application, which will be addressed below, the paced rhythms were used to establish an upper boundary 54 of 234 msec. and a lower boundary 56 of 132 msec.

In the Step 68, verification is conducted to determine that a certain number of the last-determined moving averages fall within the upper and lower limits 54 and 56 of the boundary criterion to account for premature beats and outliers.

Finally, in the Step 70, the remaining passages of VP and AP are compared with the predetermined boundaries for purposes of verifying the integrity of the established boundaries 54 and 56.

As noted above, the boundaries 54 and 56 for acceptable values of mean VA intervals may also be established through analysis of naturally occurring tachycardias with 1:1 confounding relationships. More particularly, by plotting mean VA intervals for retrograde tachycardias having confounding 1:1 relationships, predetermined boundaries 54 and 56 may be established defining an acceptable range of values. The predetermined boundaries 54 and 56 are preferably chosen to encompass substantially all the retrograde conductions to thereby minimize false negatives and also minimize the false positives. In one particular application which will be described in detail below, naturally occurring rhythms established an upper boundary 14 of 240 msec. and a lower boundary 16 of 80 msec.

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With reference now to Figure 4, general Step 52 of Figure 2 is addressed in greater detail. More specifically, Figure 4 is a simplified flow chart showing the general steps involved in applying the algorithm of the present invention for identifying VT with retrograde.

In Step 80, signals are received by the microprocessor 40 from the electrodes 30 and 32 of the first and second leads 26 and 28.

In Step 82, if an atrial signal (A) is received, the time interval from the previous atrial signal is computed to establish an AA interval and the time interval from the previous (V) is computed to establish a VA interval. If a ventricular signal is received, the time interval from the previous ventrical signal is computed to establish an VV interval and the time interval from the previous atrial signal is computed to establish an AV interval.

In Step 84, the moving average of the last three VA intervals is calculated.

In Step 86, the moving average of the last three AV intervals is calculated.

In Step 88, a determination of whether the VA interval is less than or equal to the upper boundary 54 and greater than or equal to the lower boundary 56. In the exemplary application of the algorithm, the upper boundary 54 is 240 msec. and the lower boundary 56 is 80 msec.

In Step 90, the rhythm is classified as a VT with retrograde which requires electrical therapy if a positive determination is made in Step 88. As with the paced data, verification is made that a certain number of the last-determined moving averages fall within the upper and lower boundaries 54 and 56 to account for premature beats and outliers. In one application, verification requires 9 of 12 of the last-determined moving averages to fall within the boundaries 54 and 56.

Example

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The following example illustrates the application of the above-described method according to the present invention with paced and naturally occurring rhythms.

Initially, thirty-one passages of 1:1 anterograde conduction from 9 patients during atrial pacing (AP) at cycle lengths of 600 to 300 ms, and twentyfour passages of 1:1 retrograde conduction from 8 patients during ventricular pacing (VP) of 600 to 300 ms were analyzed. Interval measurements were extracted using a real-time arrhythmia detection program developed by the University of Michigan Medical Computing Laboratory reported in an article. entitled "Real-Time Arrhythmia Identification From Automated Analysis of Intraatrial and Intraventricular Electrograms," PACE, Vol. 16, pg. 223, 1993. Moving averages were used to develop a criterion to be implemented into an algorithm to reduce ambiguity. Statistical Analysis Tools in MS-Excel were used to calculate the moving averages of three successive VA intervals for each passage of 1:1 conduction analyzed. Five randomly selected VP passages were used as a training set. The upper and lower tightest boundaries 14 and 16 were determined in which all five VP passages were correctly classified. To account for premature beats and outliers, the boundary criterion required 9 of the last 12 moving averages to fall within the upper and lower limits. The 19 remaining passages of VP and the 31 passages of AP were then tested.

Patients with 1:1 retrograde conduction during ventricular pacing had mean VA intervals in the narrow range of 150 msec - 240 msec in 28/29 (96.6%) passages; 9/28 (32.1%) of the passages of 1:1 anterograde conduction during atrial pacing had mean VA intervals in this range. From the training set of the five randomly selected VP passages, the lower and upper boundaries 14 and 16 were determined to be 132 msec and 234 msec, respectively. Eighteen of the 19 (95%) remaining VP passages were correctly classified while 1/19 (5%) were classified as anterograde. Of the 31 AP passages, 24/31 (77%) were correctly classified while 7/31 (23%) were classified as retrograde.

Subsequently, five naturally occurring 1:1 retrograde conductions were analyzed. With reference to Figure 3, mean VA intervals in milliseconds for all

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episodes of anterograde and retrograde conductions were plotted. The open squares represent anterograde conductions. The closed diamonds represent retrograde conductions. Upper and lower boundaries 14 and 16 for classifying the conductions were determined which maximized true positives and minimized false positives. Patients with 1:1 retrograde conductions had mean VA intervals in the narrow range of 80 msec. - 240 msec. in 29/30 (96.7%) occurrences. Patients with 1:1 anterograde conductions had mean VA intervals in this range at a rate of 21/42 (50%).

Provided immediately below is a confusion matrix illustrating the number of patient episodes classified by the algorithm of the present invention. Truth is indicated by column headings, while diagnosis is indicated by row headings. Thus, correct classification occupy the Northwest and Southeast diagonal cells.

Diagnosis/Truth	Retrograde	Anterograde
Retrograde	29 (96.7%)	21 (50%)
Anterograde	1 (3.3%)	21 (50%)
Total	30	42

Table 1
Patient Episodes Classified by VA Interval
Boundaries of 80-240 msec.

One of the 30 (3.3%) retrogrades was incorrectly classified as an anterograde (i.e., false negatives). Of the 42 anterogrades, 21/42 (50%) were correctly classified while 21/42 (50%) were classified as retrogrades. Through the addition of a VA interval feature, the present invention provides a reduction of false shocks by 50% compared to conventional ICD methods, thereby significantly reducing unnecessary patient distress, saving battery power, and avoiding the possible initiation of ventricular tachycardia or ventricular fibrillation when none previously existed.

Accordingly, and as may be understood by reference to the description and specific example set forth above, the algorithm according to the present

invention imposes little in additional computation, which is an important consideration for all implantable devices, and greatly reduces the possibility of false shocks in 1:1 atrial tachycardias.

Using atrial and ventricular rates only, all 1:1 tachycardias would be classified as VT, resulting in false shocks. Specificity of ambiguous 1:1 tachycardias can be potentially increased using VA interval measurements, at the cost of minimum loss of sensitivity for VT detection. This VA interval analysis for the cardiac arrhythmia detection in 1:1 arrhythmias can be practically implemented into dual chamber ICDs and can greatly reduce the possibility of false shocks in 1:1 atrial tachycardias.

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Thus, the present invention provides a method of cardiac arrhythmia detection which has enhanced specificity of diagnosis in ambiguous 1:1 tachycardias. The method uses VA interval measurements at the cost of minimum loss in sensitivity for ventricular tachycardia detection. The present invention imposes little in additional computation for dual-chamber sensing ICDs and greatly reduces the possibility of false shocks in 1:1 supraventricular tachycardias.

While the above description constitutes two preferred embodiments of the invention, it will be appreciated that the invention is susceptible to modification, variation, and change without departing from the proper scope or fair meaning of the accompanying claims. For example, the teachings of the present invention will be understood as having application to various types of antitachycardia devices and are not limited to the specific application of ICDs.

17

CLAIMS

We claim:

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1. A method for classifying a cardiac arrhythmia as one of an atrial tachycardia and a ventricular tachycardia with retrograde, the method comprising the steps of:

measuring a characteristic of the cardiac arrhythmia;

establishing an upper boundary for said characteristic of the cardiac arrhythmia;

establishing a lower boundary for said characteristic of the cardiac arrhythmia;

classifying the cardiac arrhythmia as an atrial tachycardia where
said characteristic is outside said upper boundary and said boundary; and
classifying the cardiac arrhythmia as an ventricular tachycardia
with retrograde conduction atrial tachycardia when said characteristic is
between said upper boundary and said lower boundary.

18

- 2. The method for classifying a cardiac arrhythmia of Claim 10, wherein the step of measuring a characteristic of the cardiac arrhythmia comprises the step of measuring a VA interval of the cardiac arrhythmia.
- 3. The method for classifying a cardiac arrhythmia of Claim 2, wherein said upper boundary is approximately 240 msec.
- 4. The method for classifying a cardiac arrhythmia of Claim 2, wherein said lower boundary is approximately 80 msec.
- 5. The method for classifying a cardiac arrhythmia of Claim 1, wherein the step of establishing an upper boundary and a lower boundary includes the steps of:

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- (a) ventricular pacing a patient's heart to produce a plurality of paced retrograde conductions; and
- (b) forming a training set from said plurality of paced retrograde conductions.
- 6. The method for classifying a cardiac arrhythmia of Claim 5, wherein the step of forming a training set from said plurality of retrograde conductions includes the step of randomly selecting the VA interval of at least two of said plurality of paced retrograde conductions.
- 7. The method for classifying a cardiac arrhythmia of Claim 6, wherein the step of measuring said VA interval includes the step of calculating the moving averages of a plurality of successive VA intervals for the atrial tachycardia.

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8. A method for reducing unnecessary shock treatments from an antitachycardia device by discerning between tachycardias having anterograde and retrograde conductions with confounding 1:1 relationships, the method comprising the steps of:

placing a first lead of a dual chamber sensor in operative sensory association with a ventricular chamber of a patient's heart;

placing a second lead of said dual chamber sensor in operative sensory association with an atrial chamber of said patient's heart;

operatively associating said dual chamber sensor with the antitachycardia device;

establishing an upper boundary and a lower boundary for a VA interval of an atrial tachycardia;

measuring said VA interval based on a plurality of signals provided by said first and second leads;

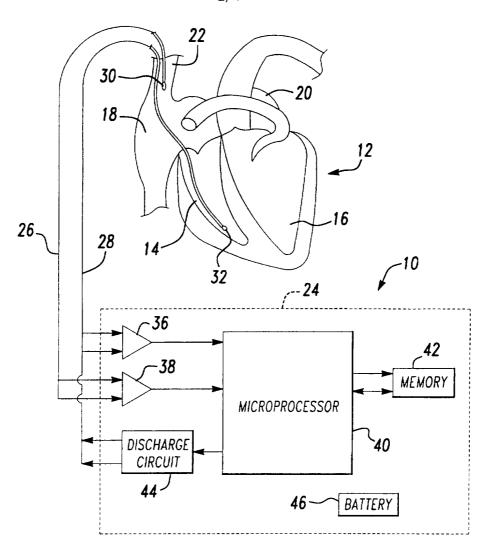
classifying said tachycardia as a retrograde conduction when said VA interval is between said upper and lower boundaries; and

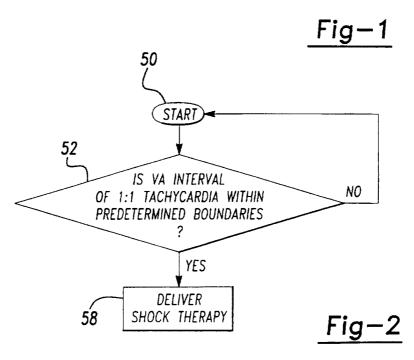
classifying said tachycardia as an anterograde conduction when said VA interval is outside said upper and lower boundaries.

- 9. The method for reducing unnecessary shock treatments from an antitachycardia device of Claim 8, further comprising the step of activating said antitachycardia device only when said tachycardia is classified as a retrograde conduction.
 - 10. The method for reducing unnecessary shock treatments from an antitachycardia device of Claim 9, wherein the step of measuring said VA interval includes the step of calculating a moving average for each of a plurality of successive VA intervals for the tachycardia.

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- 11. The method for reducing unnecessary shock treatments from an antitachycardia device of Claim 10, wherein the step of establishing an upper boundary and a lower boundary includes the steps of:
 - (a) ventricular pacing said patient's heart to produce a plurality of paced retrograde conductions; and
 - (b) forming a training set based on said plurality of paced retrograde conductions.
- 12. The method for reducing unnecessary shock treatments from an antitachycardia device of Claim 11, wherein the step of forming a training set based on said plurality of retrograde conductions includes the steps of randomly selecting a moving average of a plurality of successive VA intervals of at least two of said plurality of paced retrograde conductions.
- 13. The method for reducing unnecessary shock treatments from an antitachycardia device of Claim 8, wherein said upper boundary is approximately 240 msec.
- 14. The method for reducing unnecessary shock treatments from an antitachycardia device of Claim 8, wherein said lower boundary is approximately 80 msec.





SUBSTITUTE SHEET (RULE 26)

ESTABLISHMENT OF AN ALGORITHM USING VA INTERVAL CRITERION TO CLASSIFY 1:1 RETROGRADE ACTIVATION

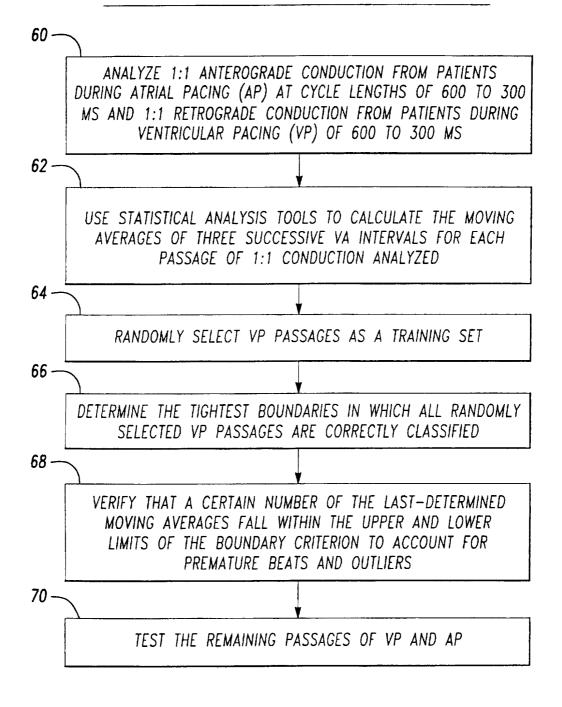


Fig-3

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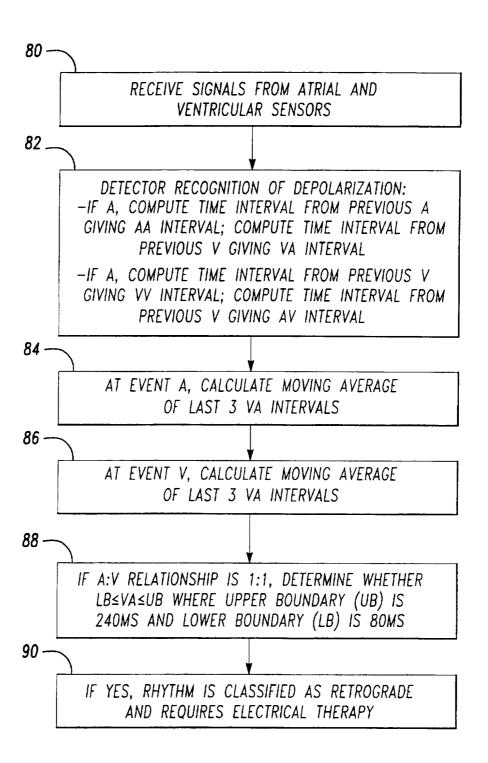
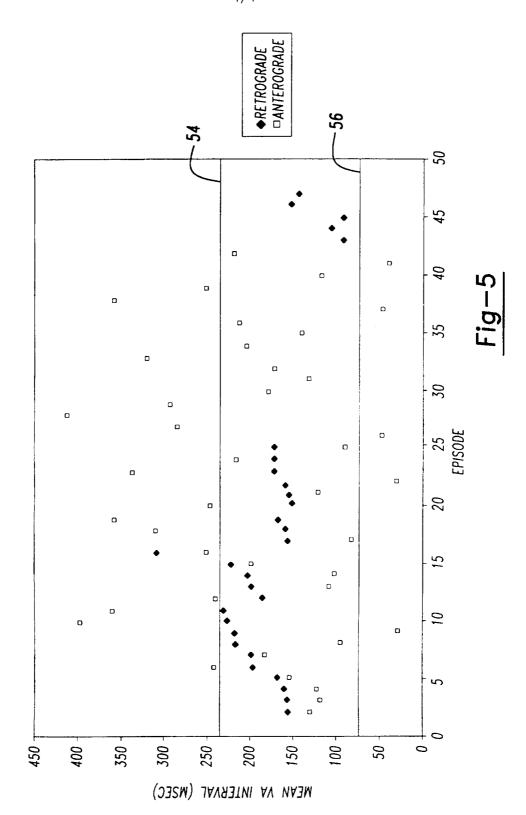


Fig-4



SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/06728

	ASSIFICATION OF SUBJECT MATTER							
IPC(6) :A61N 1/362 US CL :607/14								
According to International Patent Classification (IPC) or to both national classification and IPC								
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Minimum documentation searched (classification system followed by classification symbols)								
U.S. :	128/705; 607/9, 14							
Documentat	tion searched other than minimum documentation to the extent that such documents are included	Air at a Calda and a land						
	and some other dam minimum documentation to the extent that such documents are included	in the tields scarened						
Electronic d	lata base consulted during the international search (name of data base and, where practicable							
	the contract during the manifestation (name of data base and, where practicable	, sealen terms used)						
C. DOC	UMENTS CONSIDERED TO BE RELEVANT							
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.						
A	US 5167224 A (LIMOUSIN et al) 01 December 1992, entire	1-14						
· `	document.	1-14						
	document.							
A	US 5327900 A (MASON et al) 12 July 1994, entire	1-14						
	document.	1-1-4						
	document.							
A I	US 4860749 A (LEHMANN) 29 August 1989, entire	1-14						
	document.	1-14						
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Further documents are listed in the continuation of Box C. See patent family annex.								
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acsumit No	703) 305-3230 // Telephone No. (703) 308-2612 // A/210 (second sheet)(July 1992)★							