(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
16 December 2004 (16.12.2004)

PCT

(10) International Publication Number
WO 2004/108212 A2

(51) International Patent Classification[7]: A61N 1/365

(21) International Application Number: PCT/US2004/017094

(22) International Filing Date: 2 June 2004 (02.06.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/475,279 2 June 2003 (02.06.2003) US
10/858,598 1 June 2004 (01.06.2004) US

(71) Applicant *(for all designated States except US)*: **CAMERON HEALTH, INC.** [US/US]; 905 Calle Amanecer, Suite 300, San Clemente, CA 92673 (US).

(72) Inventors; and

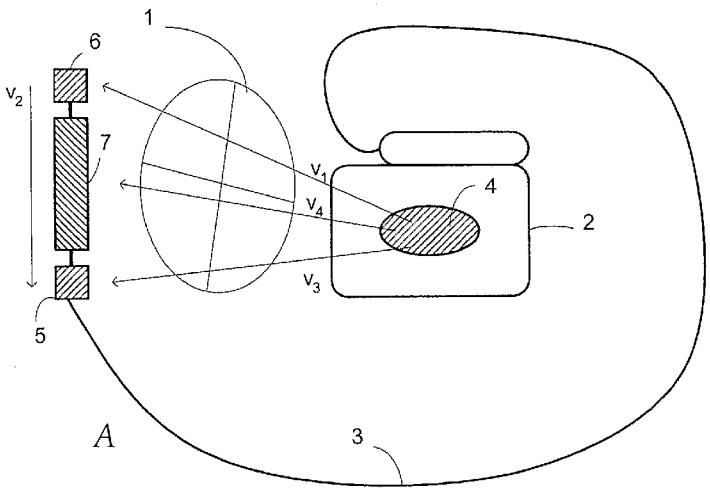
(75) Inventors/Applicants *(for US only)*: **PALREDDY, Surekha** [US/US]; 25952 Miramonte Drive, Mission Viejo, CA 92692 (US). **WARREN, Jay, A.** [US/US]; 30522 Via Andulucia, San Juan Capistrano, CA 92675 (US). **PHILLIPS, James, William** [US/US]; 18424 Santa Veronica Circle, Fountain Valley, CA 92708 (US).

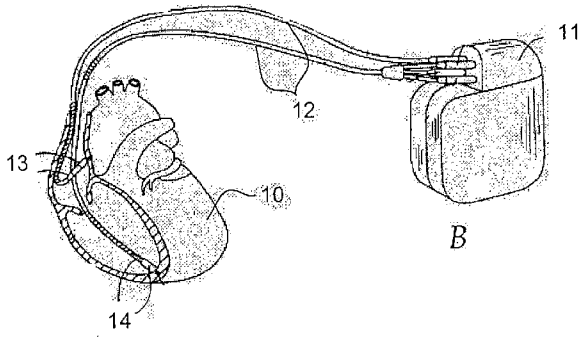
(74) Agent: **CROMPTON, David, M.**; CROMPTON, SEAGER & TUFTE, LLC, 1221 Nicollet Avenue, Suite 800, Minneapolis, MN 55403 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

*[Continued on next page]*

(54) Title: METHOD AND DEVICES FOR PERFORMING CARDIAC WAVEFORM APPRAISAL




(57) Abstract: The present invention is directed toward a sensing architecture for use in cardiac rhythm management devices. The sensing architecture of the present invention provides a method and means for certifying detected events by the cardiac rhythm management device. Moreover, by exploiting the enhanced capability to accurately identifying only those sensed events that are desirable, and preventing the use of events marked as suspect, the sensing architecture of the present invention can better discriminate between rhythms appropriate for device therapy and those that are not.

WO 2004/108212 A2

**(84) Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— *without international search report and to be republished upon receipt of that report*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# METHOD AND DEVICES FOR PERFORMING CARDIAC WAVEFORM APPRAISAL

## Cross-Reference of Co-Pending Applications

This application claims the benefit of U.S. Provisional Application Serial No. 60/475,279, filed June 2, 2003, the disclosure of which is incorporated herein by reference.

## Field

The present invention is related to the field of implantable cardiac treatment devices. More particularly, the present invention is related to methods of electrically sensing cardiac events and confirming the accuracy in detecting a cardiac event prior to determining whether treatment is needed.

## Background

Implantable cardiac rhythm management devices are an effective treatment in managing irregular cardiac rhythms in particular patients. Implantable cardiac rhythm management devices are capable of recognizing and treating arrhythmias with a variety of therapies. These therapies range from providing anti-bradycardia pacing for treating bradycardia, anti-tachycardia pacing or cardioversion energy for treating ventricular tachycardia, to high energy shock for treating ventricular fibrillation. Frequently, the cardiac rhythm management device delivers these therapies for the treatment of tachyarrhythmias in sequence; starting with anti-tachycardia pacing and then proceeding to low energy shocks, and then, finally, to high energy shocks. Sometimes, however, only one of these therapies is selected depending upon the tachyarrhythmia detected.

To effectively deliver these treatments, cardiac rhythm management devices must first accurately detect and classify an episode. Through accurate determination and quantification of sensed cardiac events, these cardiac rhythm management devices are able to classify the type of arrhythmia that is occurring and assess the appropriate therapy to provide to the heart, if any. A problem arises, however, when the cardiac rhythm management device senses noise, and mistakenly declares an episode. As a result, in particular instances, the cardiac rhythm management device may inappropriately deliver therapy.

Extra-cardiac noise may cause a cardiac rhythm management device to misclassify noise events as a tachyarrhythmia. In illustration, by incorporating skeletal muscle noise artifact, or other noise, into a cardiac rate calculation, the

cardiac rhythm management device might inaccurately calculate the ventricular rate as one that is elevated. If the ventricular rate is mistakenly calculated to be elevated over a threshold rate boundary, a frequent determiner of tachyarrhythmias, the cardiac rhythm management device may inappropriately deliver therapy to a patient.

Additionally, problems arise when the cardiac therapy device withholds therapy after mischaracterizing a sensed event. For example, anti-bradycardia devices deliver a pacing pulse based on whether a cardiac event is sensed within a particular time frame. If the sensing architecture fails to sense a cardiac event within a preset time period, the cardiac rhythm management device will deliver a pacing pulse to the heart. This pacing pulse is timed in a preset sequence to induce the patient's heart to contract in a proper rhythm. This therapy, however, may be compromised by having the cardiac rhythm management device sense and characterize an extraneous event as a "true" cardiac event. If the sensing architecture erroneously classifies noise (such as skeletal muscle artifact or other noise) as a "true" cardiac event, then a pacing pulse may be incorrectly withheld. This is particularly problematic when a pacing pulse is required to maintain a physiologically necessary rate of the patient's heart.

Besides being noticeable and sometimes physically painful to the patient, when a cardiac rhythm management device delivers inappropriate treatment, it can be extremely disconcerting to the patient. Moreover, delivery of an inappropriate therapy can intensify the malignancy of the cardiac arrhythmia. Therefore, the accuracy of a sensing architecture is an important factor in ensuring that appropriate therapy is delivered to a patient.

Current implantable cardiac rhythm management devices incorporate a sensing architecture that detects likely cardiac events and renders a decision regardless of the accuracy of those originally detected events. As such, current implantable cardiac rhythm management devices must include painstakingly designed sensing architectures to try and avoid erroneous detections. Prior art devices have been developed with rudimentary systems and methods in an attempt to determine whether noise is present on a sampled cardiac signal. If noise is detected in these devices, the manner in which the cardiac signal is acquired, or the manner in which the device operates in response to the acquired signal, is altered. This reduces the impact of erroneously detecting noise and, therefore, inappropriately triggering or withholding therapy. This methodology, however, leaves the cardiac rhythm

management device open to significant sensing drawbacks, one of which is that it continually perturbates the sensing architecture.

Certain prior art implantable cardiac rhythm management devices continuously adjust parameters such as amplifier gain in response to extra-cardiac noise, which allows for the possibility that the sensing architecture may miss cardiac events. When adjusting the gain control to lessen sensitivity by raising the sensing floor to avoid noise, it is possible to miss actual cardiac events especially during polymorphic rhythms including ventricular fibrillation. In particular, the sensing architecture may miss discrete cardiac beats, or otherwise stated, miss true positives. By missing a cardiac event, rhythm and beat sensitivity is diminished.

Other implantable cardiac rhythm management devices in the prior art repeatedly extend a noise window during continuous noise. When these window extensions either reach a specific number, or more commonly reach the end of a predetermined interval, the device reverts to a non-sensing or asynchronous behavior for a limited period of time. This type of reversion behavior can miss a cardiac event, therefore reducing rhythm and beat sensitivity. Additionally, these reversion approaches to noise are generally only useful for continuous noise. Noise is most frequently burst in nature, for which most reversion schemes are not effective. This often results in overdetection and a potential for inappropriate therapy. Prior art cardiac rhythm management devices frequently utilize these methodologies contiguously.

## Summary

The present invention, in an illustrative embodiment, is directed toward a sensing architecture for use in cardiac rhythm management devices. The sensing architecture of the present invention provides a method and means for certifying detected events by the cardiac rhythm management device. Moreover, by exploiting the enhanced capability for accurately identifying and using information from only those sensed events that are certified, the sensing architecture of the present invention can better discriminate between rhythms appropriate for device therapy and those that are not.

In an illustrative method embodiment, the present invention includes a method of signal detection enhancement for a cardiac rhythm device comprising receiving a signal from electrodes implanted for cardiac observation, observing characteristic

features of the signal, counting the characteristic features, and comparing the number of characteristic features to a threshold either to certify the signal for use in characterizing a cardiac complex, or to determine the signal is unsuitable for use in characterizing a cardiac complex. In some embodiments, the characteristic features may include a number of significant maximum slope points in the sensed signal. In some embodiments, the characteristic features may include a number of monotonic segments in the sensed signal, or may include a number of sample groups within the sensed signal that are monotonic. Additional embodiments include systems and devices suited for performing such methods.

## Brief Description

Figures 1A-1B illustrate, respectively, representative subcutaneous and intravenous ICD systems;

Figure 2 illustrates a block diagram of a sensing architecture in accordance with an illustrative embodiment of the present invention;

Figure 3 shows an electrocardiogram having a plurality of certified cardiac complexes used in classification and a plurality of cardiac complexes being marked suspect by the sensing architecture and not used in classification;

Figure 4 shows an electrocardiogram sample having no waveform appraisal phase implemented by the sensing architecture;

Figure 5 shows the same electrocardiogram sample as that depicted in Figure 3, but with the waveform appraisal phase implemented;

Figure 6 shows a block diagram illustrating the steps employed in some embodiments of the present invention for waveform appraisal;

Figure 7 shows a block diagram illustrating the steps employed in another embodiment of the present invention for waveform appraisal;

Figure 8 shows a block diagram illustrating the steps employed in another embodiment of the present invention for waveform appraisal;

Figures 9A-9B illustrate, graphically, operation of the waveform appraisal methods of Figures 7 and 8 on a clean QRS signal;

Figures 10A-10B illustrate, graphically, operation of the waveform appraisal methods of Figures 7 and 8 on a noisy signal that is not suitable for beat classification;

Figure 11 illustrates, graphically, operation of another waveform appraisal method further illustrated in Figure 12; and

Figure 12 shows a block diagram illustrating the steps employed in a maximum slope point method of waveform appraisal.

## Detailed Description

The following detailed description should be read with reference to the drawings, in which like elements in different drawings are numbered identically. The drawings, which are not necessarily to scale, depict selected embodiments and are not intended to limit the scope of the invention. Those skilled in the art will recognize that many of the examples provided have suitable alternatives that may be utilized.

The present invention is generally related to cardiac rhythm management devices (e.g., an Implantable Cardioverter/Defibrillator (ICD) system) that provide therapy for patients experiencing particular arrhythmias. The present invention is directed toward sensing architectures for use in cardiac rhythm management devices. In particular, the present invention is suited for ICD systems capable of detecting and defibrillating harmful arrhythmias. Although the sensing architecture is intended primarily for use in an implantable medical device that provides defibrillation therapy, the invention is also applicable to cardiac rhythm management devices directed toward anti-tachyarrhythmia pacing (ATP) therapy, pacing, and other cardiac rhythm devices capable of performing a combination of therapies to treat rhythm disorders, including external devices.

To date, ICD systems have been epicardial systems or transvenous systems implanted generally as shown in Figure 1B, however, as further explained herein, the present invention is also adapted to function with a subcutaneous ICD system as shown in Figure 1A.

Figure 1A illustrates a subcutaneously placed ICD system. In this illustrative embodiment, the heart 1 is monitored using a canister 2 coupled to a lead system 3. The canister 2 may include an electrode 4 thereon, while the lead system 3 connects to sensing electrodes 5, 6, and a coil electrode 7 that may serve as a shock or stimulus delivery electrode as well as a sensing electrode. The various electrodes define a number of sensing vectors V1, V2, V3, V4. It can be seen that each vector provides a different vector "view" of the heart's 1 electrical activity. The system may be implanted subcutaneously as illustrated, for example, in U.S. Patent Nos. 6,647,292 and 6,721,597, the disclosures of which are both incorporated herein by reference. By subcutaneous placement, it is meant that electrode placement does not require

insertion of an electrode into a heart chamber, the heart muscle, or the patient's vasculature.

Figure 1B illustrates a transvenous ICD system. The heart 10 is monitored and treated by a system including a canister 11 coupled to a lead system 12 including atrial electrodes 13 and ventricular electrodes 14. A number of configurations for the electrodes may be used, including placement within the heart, adherence to the heart, or disposition within the patient's vasculature. For example, Olson et al., in U.S. Patent No. 6,731,978, illustrate electrodes disposed in each chamber of the heart for sensing, as well as shocking electrodes in addition to the sensing electrodes.

The present invention, in some embodiments, is also embodied by operational circuitry including select electrical components provided within the canister 2 (Figure 1A) or canister 11 (Figure 1B). In such embodiments, the operational circuitry may be configured to enable the methods to be performed. In some similar embodiments, the present invention may be embodied in readable instruction sets such as a program encoded in machine or controller readable media, wherein the readable instruction sets are provided to enable the operational circuitry to perform the analysis discussed in the above embodiments. Further embodiments may include a controller or microcontroller adapted to read and execute the above methods.

Figure 2 illustrates a sensing architecture embodiment 20 of the present invention. The sensing architecture 20 is separated into three distinct and autonomous phases. The three phases are (1) the detection phase 21, (2) the waveform appraisal phase 22 and (3) the classification phase 23. Decisions are made in each of the three phases. Moreover, decisions made in each phase may affect the decision-making process in subsequent phases. However, it is not necessarily the case that decisions made in an individual phase will affect the decision-making process in preceding phases. In illustration, a decision made in the waveform appraisal phase 22 may affect the decision-making process in the classification phase 23, but it may have no effect on the detection phase 21, or in any future decisions made in the detection phase 21.

The first phase of the sensing architecture 20 is the detection phase 21. Within the detection phase 21 of the sensing architecture 20, data is collected by a cardiac rhythm management device. The manner in which the data is collected and the type of data collected is dependent on the cardiac rhythm management device being used. Moreover, the cardiac rhythm management device can be programmed to, or may

automatically adapt to, optimally detect a particular form of data which is sought by the cardiac rhythm management device. In a subcutaneous ICD system, subcutaneous electrodes are used to detect cardiac signals emitted from the patient's heart.

Once the raw detected signal data is received by the cardiac rhythm management device, the detected data is then preprocessed, if required or desired. Preprocessing steps may include smoothing of the detected data, differentiation, filtering and other preprocessing methodologies known in the art. Finally, the detected data, whether preprocessed or raw, is initially classified as being either an event or not an event – indicated in the block diagram at 24. More specifically, a determination is made that an event was detected by the sensing architecture 20. An illustrative determination that an event was detected may include, for example, a determination that a signal has been received having at least a certain amplitude likely indicating an R-wave from a cardiac complex or noise. The result is that the detection phase 21 provides a sensed event to the waveform appraisal phase 22.

Following the detection phase 21 of the sensing architecture 20, sensed events are appraised in the second phase, the waveform appraisal phase 22. In the illustrative embodiment, the waveform appraisal phase 22 is a separate and independent phase in the sensing architecture 20. It is within the waveform appraisal phase 22 where an analysis is performed on the sensed event 24 recognized in the detection phase 21 of the sensing architecture 20. In the waveform appraisal phase 22, an operation is performed on the sensed event. More specifically, the appraisal operator 25 evaluates and certifies that what is sensed during the detection phase 21 is a high quality sensed event. A high quality sensed event is a sensed event that can be used in classifying a cardiac rhythm, such as a sensed event that closely represents a cardiac "beat" without excessive noise. In contrast, a low quality event may be a noise signal that does not represent the desired cardiac signal, or may represent a sensed cardiac beat but the beat is superimposed with a noise artifact sufficient to render the sensed event unsuitable for classification.

In particular embodiments of the present invention, the sensed event being certified in the waveform appraisal phase 22 is the detection of a cardiac ventricular depolarization. In the art, a cardiac ventricular depolarization is often referred to as a QRS complex or R-wave. In this embodiment, the waveform appraisal phase 22 evaluates and certifies that the sensed event is a high quality R-wave that can be used for further decision making. In alternative embodiments of the present invention, the

events being certified may be the detection of a P-wave (cardiac atrial depolarization), T-wave (cardiac ventricular repolarization), a pacing artifact, or any other sensed signal that may be utilized within a rhythm classification architecture. The present invention may also evaluate whether the sensed event was not an R-wave, P-wave, T-wave, pacing artifact, or any other sensed signal that could be misidentified as the sensed event of particular interest.

In particularly noisy conditions, certain noise may appear as a cardiac event, and thus be mistakenly sensed as such. Examples of noise that may create a low quality electrocardiogram signal include extra-cardiac (skeletal) muscle artifact, 50/60 Hertz interference, electromagnetic interference, electrocautery, or any other passing or intermittent electrical occurrence.

Assuming that the detection phase 21 does sense noise as an event, this sensed event is then processed through the waveform appraisal phase 22 so that the sensed event may be certified. For the illustrative embodiment, at least some, but preferably all sensed events are processed through the waveform appraisal phase 22. In the waveform appraisal phase 22, the appraisal operator 25 examines the sensed event through various methods and procedures (described below). In this example, noise may diminish the quality of the sensed event. Thus, the sensed event would be determined by the appraisal operator 25 to be something other than a certifiable event. A non-certifiable event is one that is "suspect". Once the appraisal operator 25 has determined that the sensed event cannot be a certifiable event, the appraisal operator 25 further makes the determination to refrain from presenting the suspect event to the third phase of the sensing architecture 20, the classification phase 23. Specifically, the appraisal operator 25 prevents information from suspect event 26 from proceeding any further in the decision making process of the sensing architecture 20. As such, the waveform appraisal phase 25 greatly reduces the likelihood that suspect events will inappropriately direct treatment.

In further illustration, the appraisal operator 25 also confirms accurately sensed events. When an accurately sensed event is presented to the appraisal operator 25 of the sensing architecture 20, it will be certified. After the appraisal operator 25 has confirmed that the sensed event is certifiable, the appraisal operator 25 then presents the sensed event to the classification phase 23 for its consideration. Thus, again, only sensed events that have been processed through the waveform appraisal phase 22 will be presented to the classification phase 23 of the sensing architecture

20. All suspect events are prevented 26 by the appraisal operator 25 from being available to the classification phase 23.

The third and final phase of the sensing architecture 20 is the classification phase 23. The classification phase 23 receives data corresponding to events certified by the appraisal operator 25 and performs certain mathematical operations to this certified data. Through these mathematical operations, the classification phase 23 examines attributes such as rate, template comparisons and morphological characteristics, among others. Some illustrative classification phase 23 operations are further discussed in co-pending U.S. Patent Application No. _____ entitled METHOD FOR DISCRIMINATING BETWEEN VENTRICULAR AND SUPRAVENTRICULAR ARRHYTHMIAS, filed May 27, 2004, (Atty. File No. 1201.1140101), the disclosure of which is incorporated herein by reference. Any other suitable classification or analytical methods may also be used, as desired. These analyses aid the sensing architecture 20 in determining whether the certified events are associated with a particular class of rhythms. The classification phase 23 preferably accumulates a sufficient amount of data to render a determination which directs the cardiac rhythm management device to either withhold or deliver therapy to a patient.

The incorporation of a waveform appraisal phase 22 into a sensing architecture 20 enables the present invention to possess enhanced positive predictivity values. The mathematical formula for positive predictivity is as follows:

Positive Predictivity = (True Positives)/(True Positives + False Positives)

In several illustrative embodiments, only certified events, and therefore only the highest quality, accurate and representative data, are designed to be sent to the classification phase 23 for evaluation. As such, even legitimate cardiac signals possessing poor quality may not be sent to the classification phase 23 for evaluation. The waveform appraisal phase 22, therefore, is designed to eliminate the preponderance of false positives from consideration by the classification phase. By reducing the number of false positives observed in a classification scheme, the positive predictivity increases and the system benefits from the reduction in inappropriate therapies delivered to a patient.

This heightened positive predictivity is directly observable in counting schemes used within the classification phase 23 employed by cardiac rhythm management devices. For example, the sensing architecture 20 of an embodiment of

the present invention may utilize an X out of Y parameter requiring the classification of eighteen malignant cardiac events out of twenty-four total detected and certified events to declare an episode. The present invention can utilize this classic X out of Y filter; however, the Y input in the present invention will only comprise those events that have been certified. Suspect events, which will include the preponderance of false positives, will have been rejected by the appraisal operator 25 and would not be included in the Y input. Similarly, the X input comprises only those events that are appraised as being certified events through the waveform appraisal phase 22 and classified as dysrhythmic events through the classification phase 23. Thus, a preponderance of false positives are removed by the present invention, dramatically improving the system's positive predictivity.

In contrast, the inclusion of false positive events in the X out of Y filter will result in the reduction of positive predictivity. Therefore, in systems without a waveform appraisal phase 22, the positive predictivity of the counting scheme may be compromised during low quality electrocardiograms. If the positive predictivity is compromised, this may decreases the system's ability to accurately and reliably direct therapy to a patient.

Figure 3 shows an approximately nine second segment of a patient's electrocardiogram 30 that is of low quality. Referring both to Figures 2 and 3, the electrocardiogram in Figure 3 was processed through the sensing architecture 20; including the waveform appraisal phase 22 of the illustrative embodiment. The electrocardiogram 30 shows seven certified events (depicted by the symbol of an inverted triangle) and ten suspect events that were attributed as possessing low quality (depicted by the symbol of a dotted upright triangle). In this particular example, the low quality of the electrocardiogram is attributable to muscle artifact noise.

The first five sensed events 32 in the electrocardiogram were sensed by the detection phase 21, certified through the waveform appraisal phase 22, and presented to the classification phase 23 of the sensing architecture 20 as true cardiac complexes. In contrast, the ten subsequently following sensed events 34 in time were sensed by the detection phase 21, and evaluated and rejected through the waveform appraisal phase 22 as being suspect. Thus, these ten suspect events were not presented to the classification phase 23 – as noted illustratively by the placement of a solid dot in an upright triangle. The last two sensed events 36 in time in the electrocardiogram,

however, are depicted as being sensed and certified, and were presented to the classification phase 23.

If the overall system makes use of a counter or register to determine when to provide therapy to a patient, the occurrence of suspect events 34-34 need not necessarily reset or undermine the counting scheme to any great extent. In the illustrative example, counting during a low-quality signal is suspended during the occurrence of one, or a series of suspect events – such as those sensed events 34 graphically illustrated in Figure 3. Embodiments of the classification phase 23 of the present invention could suspend the count through the low quality signal detection, and again continue the count where it left off following the passage of the low quality signal detection. Thus, in the above described example, the classification phase 23 of the present invention would detect the non-continuity of the stream of sensed data, but could still attribute the first certified event following the interruption, the count of eleven and not one. This feature permits the sensing architecture 20 of the present embodiment to greatly reduce any delay in detection. More specifically, the counting requirement could be fulfilled more quickly by the present invention's ability to hold a count as non-certifiable (suspect) events are rejected by the waveform appraisal phase 22, and therefore, would be quicker to declare an episode than a prior art device that must restart the count following the detection of noise. Thus, the present invention is capable of swift and accurate episode detection, which significantly increases the success of therapy delivered to a patient.

Certain embodiments of the present invention and counting operations may also limit the ability to suspend a count. For example, it would be less desirable to have a counting operation, requiring a preset number of events before declaring an episode, be one event shy of the required number, experience a considerable low-quality signal detection period, and then declare an episode on the first certified event following the low-quality signal detection. In this last example, the present invention may hold the count out longer to assure that the most recently sensed events are part of the trend observed prior to the low-quality signal detection. Similarly, if a lengthy low-quality signal is observed by the present invention (one that far outnumbers the previously certified events) or the continuity of the sensed signal is extremely poor, the present invention could also restart a count to assure that the declaration is accurate.

Figures 4 and 5 show how the application of an illustrative embodiment can enhance ICD operation in directing therapy to a patient. The rate threshold for arrhythmia declaration in both Figures 4 and 5 is approximately 180 BPM, and is depicted as a solid line 48. The running average cardiac rate is depicted generally as line 47.

The electrocardiogram in Figure 4 illustrates a scenario where the calculated rate is the only determinative factor in deciding whether to apply or withhold therapy. Therefore, the analytical method applied to the electrocardiogram in Figure 4 does not include a waveform appraisal phase. In the electrocardiogram of Figure 4, a normal sinus rhythm interspersed with low quality cardiac events is depicted as segment 40, and a high quality segment of normal sinus rhythm is shown as segment 42.

The upward excursions of the running cardiac rate 47 during segment 40 are caused by the inappropriate counting of low-quality events. As a result of this inappropriate rate counting, the patient would have been delivered at least one inappropriate shock, because the only determinative factor for therapy is rate. The points in the electrocardiogram where an event is declared using a prior art algorithm is shown as lines 44 and 46.

The electrocardiogram in Figure 5 illustrates a scenario where a sensing architecture such as sensing architecture 20 in Figure 2 is used, including a waveform appraisal phase 22, as discussed above with reference to Figure 2. The inclusion of the waveform appraisal phase 22 greatly reduces the instances of inappropriate rate counting, and, therefore, inappropriate shocks, such as the ones declared in Figure 4. When the illustrative sensing architecture 20 evaluates the same electrocardiogram signal as Figure 4, it rejects the non-certifiable events as suspect. After the appraisal operator phase 22 rejects the suspect events, it is observed that the illustrative embodiment does not include those suspect events in calculating the running average cardiac rate, and therefore does not deliver therapy. Specifically, when the appraisal operator 20 is presented with the low-quality segment 40, the waveform appraisal phase 14 evaluates the low-quality segment 40, and finds it to be of insufficient quality to use for declaring an event. Thus, in striking comparison to an industry standard sensing architecture as used for the evaluation shown in Figure 4, the illustrative embodiment does not deliver therapy based on the low-quality signals observed in segment 40.

In preferred embodiments of the present invention, whether a cardiac event is accurately detected by the detection phase 21 of the sensing architecture 20, the detection phase 21 is not adjusted by the waveform appraisal phase's determinations. The detection phase 21 continues to operate independently of the remaining portions of the sensing architecture 20. Thus, although the waveform appraisal phase 22 may be evaluating detected events as suspect beats, the detection phase 21 of the sensing architecture 20 continues to sense such events in its customary manner. In alternative embodiments of the present invention, the detection phase 21 may adjust its sensing parameters to compensate for the frequency and number of mischaracterized, and therefore, suspect events.

Although the present invention has been described with relation to an ICD, a pacing device such as a pacemaker may utilize the present invention when in an ATP state. Thus, when a pacemaker is pacing a heart out of a tachyarrhythmia, the pacemaker may utilize the multi-phase sensing architecture of the present invention to certify whether sensed events have high quality or whether they are of low quality such that they may cause a mischaracterized detection. Additionally, there are other cardiac rhythm management devices that may have applicable states where the sensing architecture of the present invention is particularly suited and beneficial.

Referring again to Figure 2, the sensing architecture 20 of the illustrative embodiment is capable of implementing several appraisal operators 25, and mechanisms necessary for the performance of the waveform appraisal phase 22. As described above, the events sensed are highly dependent on the type of cardiac rhythm management device used. Likewise, the appraisal operator 25, and the mechanics behinds its operation, is highly dependent on both the cardiac rhythm management device used and the type of events sensed and requiring certification. The present invention, therefore, is not limited in terms of the particular mechanics used during the waveform appraisal phase of the sensing architecture 20. The following descriptions are to illustrate an exemplary mode or configuration chosen from numerous plausible examples.

Figure 6 shows a block diagram illustrating the steps employed in some embodiments of the present invention for waveform appraisal. From a start block 50, the waveform appraisal is triggered when an event is sensed, as noted at 52. Next, characteristic features of the sensed event are observed, as shown at 54. As noted, the "characteristic features" may take many forms. In illustrative embodiments, the

characteristic features concern the shape of the sensed event. Some characteristic features that relate to the event's shape include the inclusion of monotonic segments, monotonic sample groups, or significant maximum slope points (example methods incorporating each are shown, respectively, in Figures 7, 8, and 12). Those skilled in the art will recognize that many of the characteristic features provided have suitable alternatives that may be utilized.

The waveform appraisal method in Figure 6 continues with the step of counting the characteristic features, as shown at 56. The number of characteristic features is then compared to a threshold, as noted at 58. If the threshold is met, the event is certified as shown at 60, and the waveform appraisal is complete 62. The system then submits the certified event to the classification phase for further analysis. If the threshold is not met, the event is found to be a suspect event that is unsuitable for further analysis, as shown at 64. Then, the system is directed to return to the event sensing module or step until a next event is sensed, as shown at 66.

Figure 7 shows a block diagram illustrating the steps employed in another embodiment of the present invention for waveform appraisal. From a start block 70, the system senses an event 72. Once the event is sensed 72, the system then implements the waveform appraisal phase, including at least some of steps 74-86. First, a collection of Z samples is taken from the sensed event, as shown at 74. This collection of Z samples is analyzed to count the monotonic groups therein, as noted at 76.

The step of counting monotonic groups 76 may be performed, for example, by comparing each successive sample to its predecessor. First a value for a group counter (typically stored in a counter, register or other memory location) is set to zero. Starting with a first sample, the next sample is compared. If the second sample has a value that is greater than the first sample, a direction register can be set to indicate that the samples are increasing in amplitude with time; alternatively, if the second sample has a value that is less than the first sample, the direction register may be set to indicate that the samples are decreasing. If the second sample has the same amplitude as the first sample, then the direction register may be left at its previous value (which is irrelevant until set). If desired, there may be a minimum change in amplitude required to cause a change in the direction register. Each successive sample is then compared in turn. Whenever the direction register is set to a new

value, indicating a change in direction of sensed amplitude change over time, the group counter is incremented to indicate that a new monotonic segment has started.

After the step of counting monotonic groups shown at 76, the number of monotonic groups is compared to a threshold Y, as noted at 78. If there are less than Y monotonic groups in the Z samples, this indicates a high quality sensed event. A YES result 80 calls for certifying the event, and the system goes to an end 82 that directs the certified event to the classification phase. If a NO result 84 occurs, the system rejects the set of Z samples as a suspect event, discarding the samples from memory, and returns to the sensing step as shown at 86.

Figure 8 is a block diagram of another illustrative embodiment of an appraisal system 80 including a waveform appraisal phase. The system begins at start block 90 by the system detecting an event. This illustrative embodiment is adapted to work with a sensing architecture that operates in terms of blocks of samples that are received and then sent forward in the analysis structure. As shown at step 92, a set of Z samples are received by the system. The Z samples are then divided into groups of n samples at shown at 94. Each group of samples is evaluated to determine whether it is monotonic or not, and these groups are counted as shown at 96. The system next checks whether at least a threshold value, Y, of the groups are monotonic, as shown at 98. For example, given thirty-two samples, the system may divide the set into eight groups of four samples and determine how many of the groups are monotonic. For such an example, a value of Y=5 could be used, such that five or more of the groups of samples would have to be monotonic to indicate a certified event.

If there are at least Y monotonic groups, the event is certified as a high-quality sensed event, as shown at 100. The waveform appraisal phase then ends and the system directs the certified event to the classification phase, as shown at 102. Otherwise, if there are less than Y monotonic groups in the set of Z samples, the method rejects the set of samples as a suspect event, as shown at 104, and returns to the sensing block as shown at 106.

Figures 9A-9B show operation of an illustrative waveform appraisal system on a sensed event. The sensed event 110, as shown in its continuous time analog representation in Figure 9A, is rather idealized and includes only that portion of the cardiac signal including the QRS complex. The T wave, in particular, has been excluded by keeping the time window of sensing narrow. For example, the time window of sensing may be less than one second, less than six-hundred milliseconds,

or in the range of about fifty to two-hundred-fifty milliseconds. Figure 9B illustrates a sampled, discrete time representation of the sensed event 110, with the signal including thirty-two samples. The representation of Figure 9B, as can be appreciated by looking at Figure 9A, is a temporally ordered set of samples. The numbers illustrate the number of monotonic segments and when they start by a method similar to the method of Figure 7. The brackets with Y and N letters placed above illustrate whether grouped samples are monotonic by the method of Figure 8, with the thirty-two samples placed in groups of four.

As can be seen, the event in Figure 9B includes six monotonic segments as counted in the manner illustrated in Figure 7. If a further refinement is included where a segment illustrating no change is not considered a separate monotonic segment, segments 1-2 and 5-6 would each count as a single monotonic segment such that the beat would have only four monotonic segments. If a maximum number of segments is set at six, then the sensed event 110 of Figures 9A-9B would be certified.

For the method of Figure 8, the results of the group checks yields six monotonic groups and two groups that are not monotonic. If a threshold of 5/8 groups being monotonic is used, then the sensed event 110 of Figures 9A-9B would be certified.

Figures 10A-10B show operation of an illustrative appraisal operation on a sensed event 120, however, in this example, the sensed event 120 is a low quality event that does not resemble a typical cardiac event. Again, Figure 10A illustrates the sensed event 120 in continuous, analog form. Figure 10B is a sampled (and, if desired, digitized), temporally ordered form of the event, and again indicates analytical results with numbers, brackets, and letters. Using the method of Figure 7, the sensed event 120 includes sixteen monotonic segments. Again using the threshold of six, this sensed event 120 fails to meet the threshold and would be considered suspect. As a result, the method of Figure 7 would not certify the sensed event 120.

Applying the method of Figure 8, the sensed event 120 has four groups that are monotonic segments. Again, using a threshold of five monotonic segments to be certifiable, the sensed event 120 would be found suspect. Application of the method of Figure 7 would, again, not certify the sensed event 120.

In another illustrative embodiment, the present invention includes a method of waveform appraisal that includes counting certain maximum slope points in a cardiac signal. The purpose of the maximum slope counter is to capture slope variation in the

signal during the generated set of data. Low quality signals tend to have much more first derivative variation than a clean high quality cardiac signal. To capture the variation of the first derivative, the second derivative of the generated set is computed and checked for zero crossings. For an illustrative embodiment, a zero crossing of the second derivative is defined as one where the second derivative crosses from a non-zero negative to a non-zero positive value and vice versa. Preferably, simply reaching zero is not considered a zero crossing point. Zero crossings of the second derivative of a single generally correspond to the points of local maximum slope (either positive or negative) of the original signal.

For the illustrative embodiment, the first second derivative zero crossing is accepted as a significant maximum slope point. After that, as each maximum slope point is encountered, it is checked to see if it is significant by applying two rules based on path length. The path length is defined as an accumulation of the magnitude of amplitude changes in the original signal. The rules for the illustrative embodiment are as follows:

1. The path length of the signal between the last significant maximum slope point and the current maximum slope point must be greater than the amplitude difference between the two points.

2. The path length of the signal between the last significant maximum slope point and the current maximum slope point must be greater than a programmed threshold value, derived as a percentage (50%) of the average peak amplitudes of the beats recorded prior to the current detection. If desired, a maximum or minimum for the threshold value may be set. In an illustrative example, using an 8 bit ADC, if the derived threshold value is less than 7 ADC units, the threshold is set at 7 ADC units. If the derived threshold value is greater than 20 ADC units, the threshold is set at 20 ADC units.

Figure 11 illustrates a method of signal analysis for counting significant maximum slope points. In the illustrative example, a number of signal sample points are shown along with a corresponding analog signal 130. The method includes determining where the second derivative of the sampled signal crosses zero, indicating a maximum magnitude for the slope of the signal at each point. Points A, B, C, D, E and F indicate these points.

Next, the method includes the step of determining which of points A-F are significant for the purpose of appraising the signal. The magnitude of amplitude

change from point to point is determined, including the magnitude of such changes for the intermediate points between points A-F. These amplitude changes are indicated as segments $\Delta_0$-$\Delta_7$ in Figure 11. A path length value is then determined. The path length value, as noted above, is the accumulation of the magnitude of amplitude changes in the sampled signal occurring between two points. Thus, the sum of the magnitudes of segments $\Delta_0$ to $\Delta_2$ is the path length from C to D, the sum of the magnitudes of segments $\Delta_0$ to $\Delta_7$ is the path length from C to E, and the sum of the magnitudes of segments $\Delta_3$ to $\Delta_7$ is the path length from D to E.

Next, the actual change in signal amplitude between the points is measured. With these values, the two rules noted above are applied to determine which maximum slope points are significant for appraising the signal. For illustrative purposes, point C is assumed to be certified (C would in fact be certified in the Figure). Using point C as a reference point, from point C to point D, the path length is the same as the amplitude change, therefore, point D is not a significant maximum slope point under Rule 1. Therefore, point D is rejected.

The next step is to go to the next identified maximum slope point, point E, to determine if it is significant for the appraisal method. In this case, the path length from point C to point E exceeds the amplitude change between these two points. Rule 2 is passed because the path length exceeds the illustrated threshold path length minimum. Because the requirements of both rules are met, point E is a significant maximum slope point for the appraisal method.

In further illustration, it can be seen that point B is not a significant maximum slope point because the path length from point A to point B does not exceed the threshold path length minimum. This fails Rule 1, above, and point B would be rejected.

The above analysis yields three significant maximum slope points in the signal shown in Figure 11. If, for example, the threshold maximum number of significant maximum slope points is set at six, then the illustrated signal is considered a certified signal.

Figure 12 shows in block form steps of an illustrative maximum slope point counting method for appraising a received signal. The method begins by receiving a signal, as shown at 140. Next, the maximum slope points are identified, as noted at 142. The first maximum slope point is identified as a significant maximum slope point, as noted at 144. As illustrated in block 146, the rest of the significant

maximum slope points are identified by taking a next maximum slope point as shown at 148, and applying the first rule as shown at 150 and the second rule as shown at 152. After the significant maximum slope points are identified in block 148, the number of significant maximum slope points is compared to a threshold, as shown at 154. If the threshold is not exceeded, the signal is certified, as noted at 156. If the threshold is exceeded, then the signal is marked as suspect, as noted at 158. In some embodiments, after the signal is marked as suspect, it may be subjected to further analysis, for example, to determine if changes in the event detection architecture are needed. In other embodiments, suspect signals are discarded.

The following illustrative embodiments are explained in terms of operational circuitry. The operational circuitry may be configured to include such controllers, microcontrollers, logic devices, memory, and the like, as selected, needed, or desired, for performing the steps for which each is configured.

An illustrative embodiment includes an implantable cardioverter/defibrillator comprising a lead electrode assembly including a number of electrodes, and a canister housing operational circuitry. For the illustrative embodiment, the lead electrode assembly is coupled to the canister; and the operational circuitry is configured to receive a cardiac signal from implanted electrodes, observe characteristic features of the shape of the signal, count the characteristic features, and compare the number of characteristic features to a threshold. With the comparison to the threshold, the operational circuitry is further configured to certify the signal for use in characterizing a cardiac complex, or determine the signal is unsuitable for use in characterizing a cardiac complex. In another embodiment, the operational circuitry is configured such that the step of receiving a signal includes sensing electrical activity and using an event detector to determine the parameters of the signal. In yet a further embodiment, the operational circuitry is configured such that the step of observing characteristic features includes identifying a number of points in the signal where the signal slope reaches a local maximum magnitude.

For a related illustrative embodiment, the implantable cardioverter/defibrillator includes operational circuitry configured such that the step of identifying a number of points in the signal includes identifying zero crossings of the second derivative of the signal. In another embodiment, the operational circuitry is configured such that the step of observing characteristic features includes selecting a first zero crossing as a significant maximum slope point, and characterizing

subsequent zero crossings as either significant maximum slope points or not significant maximum slope points, wherein the significant maximum slope points are observed to be the characteristic features. In a related embodiment, the operational circuitry is configured such that the step of characterizing subsequent zero crossings includes application of a rule related to a threshold for consideration of separate points in the signal. In yet another embodiment, the operational circuitry is configured such that the rule calls for determining whether the path length from a most recent significant maximum slope point to the zero crossing under consideration exceeds a path length threshold. A further related embodiment includes operational circuitry configured such that the path length threshold is related to a selected percentage of the maximum signal amplitude for a chosen cardiac complex.

In another embodiment, the operational circuitry is configured such that the step of characterizing subsequent zero crossings includes application of a rule related to the signal shape between two points in the signal. In a further, related embodiment, the operational circuitry is configured such that the rule calls for determining whether the path length from a most recent significant maximum slope point to the zero crossing under consideration exceeds the magnitude of the difference in amplitude between the signal at the time of the most recent significant maximum slope point, and the signal at the time of the zero crossing under consideration.

In another embodiment, the operational circuitry is configured such that a step of characterizing subsequent zero crossings includes analysis using a first rule and a second rule, the first rule being related to a threshold for consideration of separate points in the signal, the second rule being related to the signal shape between two points in the signal. In a further embodiment, the operational circuitry is configured such that the first rule calls for determining whether the path length from a most recent significant maximum slope point to the zero crossing under consideration exceeds a path length threshold, and the second rule calls for determining whether the path length from a most recent significant maximum slope point to the zero crossing under consideration exceeds the magnitude of the difference in amplitude between, the signal at the time of the most recent significant maximum slope point, and the signal at the time of the zero crossing under consideration. In another related embodiment, the operational circuitry is configured such that the step of observing characteristic features of the signal includes assessment of the degree of monotonicity of the signal.

In another embodiment, the operational circuitry is configured such that the step of observing characteristic features of the signal includes counting a number of monotonic segments of the signal. Yet another embodiment includes operational circuitry configured such that the signal has a duration of less than one second. In several embodiments, the implantable cardioverter/defibrillator includes operational circuitry comprising a controller and a controller readable memory.

An illustrative embodiment includes an implantable cardioverter/defibrillator comprising a lead electrode assembly including a number of electrodes, and a canister housing operational circuitry, wherein the lead electrode assembly is coupled to the canister, and the operational circuitry is configured to: sample a signal from an implanted electrode; identify maximum slope points in the sample signal corresponding to local signal slope maximums; analyze the sample signal to determine which of the maximum slope points are significant; and compare the number of significant maximum slope points to a threshold.

Another illustrative embodiment includes an implantable cardioverter/defibrillator comprising a lead electrode assembly including a number of electrodes, and a canister housing operational circuitry, wherein the lead electrode assembly is coupled to the canister, and the operational circuitry is configured to: receive a signal from a pair of implanted electrodes; sense whether a likely cardiac event has occurred; observe the monotonic characteristics of the signal during a time period corresponding to the likely cardiac event; and determine whether the signal during the time period is sufficiently monotonic to indicate the cardiac signal can be certified for classifying a cardiac rhythm. In a further embodiment, the operational circuitry is configured such that the step of observing the monotonic characteristics includes grouping together samples of the cardiac signal from the time period into sample groups, and observing whether each sample group is monotonic. In yet another embodiment, the operational circuitry is configured such that the step of observing the monotonic characteristics includes counting the number of times that an ordered set of samples of the cardiac signal corresponding to the time period changes its direction of amplitude change. Another illustrative embodiment includes operational circuitry is configured such that the step of observing the monotonic characteristics includes counting a number of monotonic segments found in a sampling of the cardiac signal corresponding to the time period. An illustrative embodiment further includes operational circuitry configured to classify the event to

determine whether the event indicates treatment. In another embodiment, the operational circuitry is further configured to determine whether a cardiac signal appears to indicate a patient's heart is beating at a rate above a rate threshold before performing the receive, sense, observe, and determine steps. In yet another embodiment, the operational circuitry comprises a controller and a controller readable memory.

An illustrative embodiment includes an implantable cardioverter/defibrillator comprising a lead electrode assembly including a number of electrodes, and a canister housing operational circuitry, wherein the lead electrode assembly is coupled to the canister, and the operational circuitry is configured to: sample a cardiac signal from a pair of implanted electrodes; define a number of groups of samples from a portion of the signal; determine how many of the groups of samples are monotonic; and, if the number of monotonic groups does not exceed a threshold, discard the portion of the signal.

Another illustrative embodiment includes an implantable cardioverter/defibrillator comprising a lead electrode assembly including a number of electrodes, and a canister housing operational circuitry, wherein the lead electrode assembly is coupled to the canister, and the operational circuitry is configured to determine whether a heart is pumping at a rate exceeding a threshold, and, if so, perform the following steps: sample a cardiac signal from a pair of implanted electrodes; define a number of groups of samples from a portion of the signal; determine how many of the groups of samples are monotonic; and if the number of monotonic groups does not exceed a threshold, discard the portion of the signal. In another embodiment, the operational circuitry is further configured to classify the signal by analyzing non-discarded portions of the signal, wherein the step of classifying the signal includes classifying portions of the signal as either indicating treatment or not indicating treatment. In yet another illustrative embodiment, the operational circuitry is further configured such that the step of classifying the signal includes keeping a count of classified portions until a threshold number of portions are classified; wherein, when the threshold number of portions are classified, the method further includes determining whether to provide treatment based upon whether a predetermined number of classified portions indicate treatment.

Another illustrative embodiment includes an implantable cardioverter/defibrillator comprising a lead electrode assembly including a number of

electrodes, and a canister housing operational circuitry, wherein the lead electrode assembly is coupled to the canister, and the operational circuitry is configured to: sample a signal from first and second implanted electrodes; set a threshold for the monotonicity of a sensed signal; determine whether the sampled signal meets the threshold; and if the sampled signal does not meet the threshold, discard the signal.

Yet another illustrative embodiment includes an implantable cardioverter/defibrillator comprising a lead electrode assembly including a number of electrodes, and a canister housing operational circuitry, wherein the lead electrode assembly is coupled to the canister, and the operational circuitry is configured to: receive a signal from first and second implanted electrodes; observe a point in the signal; observe a number of samples of the signal following the point; group the samples into a number of groups; observe which of the groups are monotonic; count the monotonic groups; determine whether the number of monotonic groups exceeds a threshold; and, if the number of monotonic groups does not exceed the threshold, discard the portion of the signal from which the number of signals following the point were taken.

An illustrative embodiment includes an implantable cardioverter/defibrillator comprising a lead electrode assembly including a number of electrodes, and a canister housing operational circuitry, wherein the lead electrode assembly is coupled to the canister, and the operational circuitry is configured to: receive a signal from first and second implanted electrodes; observe a monotonic segment of the signal; measure the length of the monotonic segment; compare the length to a threshold; and, if the length is less than the threshold, determine that the monotonic segment does not correspond to a certifiable cardiac event. In a related embodiment, the operational circuitry is further configured to observe a portion of the signal around the monotonic segment, determine whether the monotonic segment ends in a highest signal strength for the portion, and, if the monotonic segment does not end in a highest signal strength for the portion, determining that the monotonic segment does not correspond to a certifiable cardiac event. In another embodiment, the operational circuitry is further configured such that the portion corresponds to time window around the monotonic segment, at least a portion of the time window occurring before the monotonic segment begins, and at least a portion of the time window occurring after the monotonic segment ends, the window having a duration in the range of 50-250 milliseconds.

Another embodiment includes an implantable cardiac treatment system comprising first and second electrodes, and circuitry contained in a housing, the circuitry electrically coupled to the first and second electrodes, wherein the circuitry is adapted to perform the following steps: sampling a signal from first and second implanted electrodes; setting a threshold for the monotonicity of a sensed signal; determining whether the sampled signal meets the threshold; and, if the sampled signal does not meet the threshold, discarding the signal. In a further embodiment, the circuitry includes a controller and a controller readable medium, the controller readable medium containing instructions thereon for performing the steps of sampling, setting, determining and discarding.

Yet another embodiment includes an implantable cardioverter/defibrillator comprising a lead electrode assembly including a number of electrodes, and a canister housing operational circuitry, wherein the lead electrode assembly is coupled to the canister, and the operational circuitry is configured to monitor a signal produced between implanted electrodes to observe an event, observe an event and gathering a signal corresponding to the event, observe characteristic features of the shape of the signal, count the characteristic features, and compare the number of characteristic features to a threshold to certify the signal for use in characterizing a cardiac complex, or determine the signal is unsuitable for use in characterizing a cardiac complex. In the illustrative embodiment, if the signal is certified, the operational circuitry is also configured to use the signal to determine whether a malignant cardiac rhythm is likely occurring.

An illustrative embodiment includes an implantable cardioverter/defibrillator comprising a lead electrode assembly including a number of electrodes, and a canister housing operational circuitry, wherein the lead electrode assembly is coupled to the canister, and the operational circuitry is configured to capture a signal using implanted electrodes placed for observing electrical cardiac activity, analyze the signal to determine whether the signal is suitable for characterizing a cardiac rhythm, and, if the signal is suitable, use the signal to determine whether a malignant cardiac rhythm is likely occurring, or, if the signal is not suitable, reject the signal.

Numerous characteristics and advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many aspects, only illustrative. Changes may be made in details, particularly in matters of shape, size and arrangement of parts without

exceeding the scope of the invention. The invention's scope is defined, of course, in the language in which the claims are expressed.

What is claimed is:

1. A method of signal detection enhancement for a cardiac rhythm device comprising:

receiving a signal from electrodes implanted for cardiac observation;

observing characteristic features of the signal;

counting the characteristic features;

comparing the number of characteristic features to a threshold to:

certify the signal for use in characterizing a cardiac complex; or

determine the signal is unsuitable for use in characterizing a cardiac complex.

2. The method of claim 1, wherein the step of receiving a signal includes sensing electrical activity and using an event detector to determine the parameters of the signal.

3. The method of claim 1, wherein the step of observing characteristic features includes identifying a number of points in the signal where the signal slope reaches a local maximum magnitude.

4. The method of claim 3, wherein the step of identifying a number of points in the signal includes identifying zero crossings of the second derivative of the signal.

5. The method of claim 4, wherein the step of observing characteristic features includes:

selecting a first zero crossing as a significant maximum slope point; and

characterizing subsequent zero crossings as either significant maximum slope points or not significant maximum slope points;

wherein the significant maximum slope points are observed to be the characteristic features.

6. The method of claim 5, wherein the step of characterizing subsequent zero crossings includes application of a rule related to a threshold for consideration of separate points in the signal.

7. The method of claim 6, wherein the rule calls for determining whether the path length from a most recent significant maximum slope point to the zero crossing under consideration exceeds a path length threshold.

8. The method of claim 7, wherein the path length threshold is related to a selected percentage of the maximum signal amplitude for a chosen cardiac complex.

9. The method of claim 5, wherein the step of characterizing subsequent zero crossings includes application of a rule related to the signal shape between two points in the signal.

10. The method of claim 9, wherein the rule calls for determining whether the path length from a most recent significant maximum slope point to the zero crossing under consideration exceeds the magnitude of the difference in amplitude between:

the signal at the time of the most recent significant maximum slope point; and

the signal at the time of the zero crossing under consideration.

11. The method of claim 5, wherein the step of characterizing subsequent zero crossings includes analysis using a first rule and a second rule, the first rule being related to a threshold for consideration of separate points in the signal, the second rule being related to the signal shape between two points in the signal.

12. The method of claim 11, wherein:

the first rule calls for determining whether the path length from a most recent significant maximum slope point to the zero crossing under consideration exceeds a path length threshold; and

the second rule calls for determining whether the path length from a most recent significant maximum slope point to the zero crossing under consideration exceeds the magnitude of the difference in amplitude between:

the signal at the time of the most recent significant maximum slope point; and

the signal at the time of the zero crossing under consideration.

13. The method of claim 1, wherein the step of observing characteristic features of the signal includes assessment of the degree of monotonicity of the signal.

14. The method of claim 1, wherein the step of observing characteristic features of the signal includes counting a number of monotonic segments of the signal.

15. The method of claim 1, wherein the signal has a duration of less than one second.

16. A method of signal detection enhancement for a cardiac rhythm device comprising:

sampling a signal from an implanted electrode;

identifying maximum slope points in the sampled signal corresponding to local signal slope maximums;

analyzing the sampled signal to determine which of the maximum slope points are significant; and

comparing the number of significant maximum slope points to a threshold.

17. A method for evaluating cardiac events comprising:

receiving a signal from a pair of implanted electrodes;

sensing whether a likely cardiac event has occurred;

observing the monotonic characteristics of the signal during a time period corresponding to the likely cardiac event; and

determining whether the signal, during the time period, is sufficiently monotonic to indicate the cardiac signal can be certified for classifying a cardiac rhythm.

18. The method of claim 17, wherein the step of observing the monotonic characteristics includes:

grouping together samples of the cardiac signal from the time period into sample groups; and

observing whether each sample group is monotonic.

19. The method of claim 17, wherein the step of observing the monotonic characteristics includes counting the number of times that an ordered set of samples of the cardiac signal corresponding to the time period changes its direction of amplitude change.

20. The method of claim 17, wherein the step of observing the monotonic characteristics includes counting a number of monotonic segments found in a sampling of the cardiac signal corresponding to the time period.

21. A method of directing cardiac treatment comprising:
performing the method of claim 17; and, if the event is found to be certified,
classifying the event to determine whether the event indicates treatment.

22. A method for observing cardiac function comprising:
determining whether a cardiac signal appears to indicate a patient's heart is beating at a rate above a rate threshold; and, if so,
performing the method steps of claim 17.

23. A method of certifying cardiac events comprising:
sampling a cardiac signal from a pair of implanted electrodes;
defining a number of groups of samples from a portion of the signal;
determining how many of the groups of samples are monotonic;
if the number of monotonic groups does not exceed a threshold, discarding the portion of the signal.

24. A method of cardiac function analysis comprising:
determining whether a heart is pumping at a rate exceeding a threshold; and
if so, performing the method of claim 23.

25. The method of claim 24, further comprising:
classifying the signal by analyzing non-discarded portions of the signal;
wherein the step of classifying the signal includes classifying portions of the signal as either indicating treatment or not indicating treatment.

26. The method of claim 25, wherein the step of classifying the signal includes keeping a count of classified portions until a threshold number of portions are classified; wherein, when the threshold number of portions are classified, the method further includes determining whether to provide treatment based upon whether a predetermined number of classified portions indicate treatment.

27. A method of appraising cardiac events comprising:
sampling a signal from first and second implanted electrodes;
setting a threshold for the monotonicity of a sensed signal;
determining whether the sampled signal meets the threshold; and
if the sampled signal does not meet the threshold, discarding the signal.

28. A method of monitoring a patient's cardiac function comprising:
receiving a signal from first and second implanted electrodes;
observing a point in the signal;
observing a number of samples of the signal following the point;
grouping the samples into a number of groups;
observing which of the groups are monotonic;
counting the monotonic groups;
determining whether the number of monotonic groups exceeds a threshold; and
if the number of monotonic groups does not exceed the threshold, discarding the portion of the signal from which the number of signals following the point were taken.

29. A method of monitoring a patient's cardiac function comprising:
receiving a signal from first and second implanted electrodes;
observing a monotonic segment of the signal;
measuring the length of the monotonic segment;
comparing the length to a threshold; and
if the length is less than the threshold, determining that the monotonic segment does not correspond to a certifiable cardiac event.

30. The method of claim 29, further comprising:

observing a portion of the signal around the monotonic segment;

determining whether the monotonic segment ends in a highest signal strength for the portion;

if the monotonic segment does not end in a highest signal strength for the portion, determining that the monotonic segment does not correspond to a certifiable cardiac event.

31. The method of claim 30, wherein the portion corresponds to time window around the monotonic segment, at least a portion of the time window occurring before the monotonic segment begins, and at least a portion of the time window occurring after the monotonic segment ends, the window having a duration in the range of 50-250 milliseconds.

32. A method of monitoring cardiac function in an implanted cardiac rhythm device comprising:

monitoring a signal produced between implanted electrodes to observe an event;

observing an event and gathering a signal corresponding to the event;

observing characteristic features of the slope of the signal;

counting the characteristic features;

comparing the number of characteristic features to a threshold to:

certify the signal for use in characterizing a cardiac complex; or

determine the signal is unsuitable for use in characterizing a cardiac complex;

and, if the signal is certified, using the signal to determine whether a malignant cardiac rhythm is likely occurring.

33. A method of cardiac rhythm management using an implanted cardiac rhythm management device, the method comprising:

capturing a signal using implanted electrodes placed for observing electrical cardiac activity;

analyzing the signal to determine whether the signal is suitable for characterizing a cardiac rhythm; and

if the signal is suitable, using the signal to determine whether a malignant cardiac rhythm is likely occurring;

if the signal is not suitable, rejecting the signal.

34. An implantable cardioverter/defibrillator comprising:

a lead electrode assembly including a number of electrodes; and

a canister housing operational circuitry;

wherein:

the lead electrode assembly is coupled to the canister; and

the operational circuitry is configured to:

receive a cardiac signal from implanted electrodes;

observe characteristic features of the shape of the signal;

count the characteristic features; and

compare the number of characteristic features to a threshold to:

certify the signal for use in characterizing a cardiac complex; or

determine the signal is unsuitable for use in characterizing a cardiac complex.

35. The implantable cardioverter/defibrillator of claim 34, wherein the operational circuitry is configured such that the step of receiving a signal includes sensing electrical activity and using an event detector to determine the parameters of the signal.

36. The implantable cardioverter/defibrillator of claim 34, wherein the operational circuitry is configured such that the step of observing characteristic features includes identifying a number of points in the signal where the signal slope reaches a local maximum magnitude.

37. The implantable cardioverter/defibrillator of claim 36, wherein the operational circuitry is configured such that the step of identifying a number of points in the signal includes identifying zero crossings of the second derivative of the signal.

38. The implantable cardioverter/defibrillator of claim 37, wherein the operational circuitry is configured such that the step of observing characteristic features includes:

selecting a first zero crossing as a significant maximum slope point; and

characterizing subsequent zero crossings as either significant maximum slope points or not significant maximum slope points;

wherein the significant maximum slope points are observed to be the characteristic features.

39. The implantable cardioverter/defibrillator of claim 38, wherein the operational circuitry is configured such that the step of characterizing subsequent zero crossings includes application of a rule related to a threshold for consideration of separate points in the signal.

40. The implantable cardioverter/defibrillator of claim 39, wherein the operational circuitry is configured such that the rule calls for determining whether the path length from a most recent significant maximum slope point to the zero crossing under consideration exceeds a path length threshold.

41. The implantable cardioverter/defibrillator of claim 40, wherein the operational circuitry is configured such that the path length threshold is related to a selected percentage of the maximum signal amplitude for a chosen cardiac complex.

42. The implantable cardioverter/defibrillator of claim 38, wherein the operational circuitry is configured such that the step of characterizing subsequent zero crossings includes application of a rule related to the signal shape between two points in the signal.

43. The implantable cardioverter/defibrillator of claim 42, wherein the operational circuitry is configured such that the rule calls for determining whether the path length from a most recent significant maximum slope point to the zero crossing under consideration exceeds the magnitude of the difference in amplitude between:

the signal at the time of the most recent significant maximum slope point; and

the signal at the time of the zero crossing under consideration.

44. The implantable cardioverter/defibrillator of claim 38, wherein the operational circuitry is configured such that the step of characterizing subsequent zero

crossings includes analysis using a first rule and a second rule, the first rule being related to a threshold for consideration of separate points in the signal, the second rule being related to the signal shape between two points in the signal.

45. The implantable cardioverter/defibrillator of claim 44, wherein the operational circuitry is configured such that:

the first rule calls for determining whether the path length from a most recent significant maximum slope point to the zero crossing under consideration exceeds a path length threshold; and

the second rule calls for determining whether the path length from a most recent significant maximum slope point to the zero crossing under consideration exceeds the magnitude of the difference in amplitude between:

the signal at the time of the most recent significant maximum slope point; and

the signal at the time of the zero crossing under consideration.

46. The implantable cardioverter/defibrillator of claim 44, wherein the operational circuitry is configured such that the step of observing characteristic features of the signal includes assessment of the degree of monotonicity of the signal.

47. The implantable cardioverter/defibrillator of claim 34, wherein the operational circuitry is configured such that the step of observing characteristic features of the signal includes counting a number of monotonic segments of the signal.

48. The implantable cardioverter/defibrillator of claim 34, wherein the operational circuitry is configured such that the signal has a duration of less than one second.

49. The implantable cardioverter/defibrillator of claim 34, wherein the operational circuitry comprises a controller and a controller readable memory.

50. An implantable cardioverter/defibrillator comprising:

a lead electrode assembly including a number of electrodes; and

a canister housing operational circuitry;

wherein:

the lead electrode assembly is coupled to the canister; and

the operational circuitry is configured to:

sample a signal from an implanted electrode;

identify maximum slope points in the sample signal corresponding to local signal slope maximums;

analyze the sample signal to determine which of the maximum slope points are significant; and

compare the number of significant maximum slope points to a threshold.

51. An implantable cardioverter/defibrillator comprising:

a lead electrode assembly including a number of electrodes; and

a canister housing operational circuitry;

wherein:

the lead electrode assembly is coupled to the canister; and

the operational circuitry is configured to:

receive a signal from a pair of implanted electrodes;

sense whether a likely cardiac event has occurred;

observe the monotonic characteristics of the signal during a time period corresponding to the likely cardiac event; and

determine whether the signal during the time period is sufficiently monotonic to indicate the cardiac signal can be certified for classifying a cardiac rhythm.

52. The implantable cardioverter/defibrillator of claim 51, wherein the operational circuitry is configured such that the step of observing the monotonic characteristics includes:

grouping together samples of the cardiac signal from the time period into sample groups; and

observing whether each sample group is monotonic.

53. The implantable cardioverter/defibrillator of claim 51, wherein the operational circuitry is configured such that the step of observing the monotonic

characteristics includes counting the number of times that an ordered set of samples of the cardiac signal corresponding to the time period changes its direction of amplitude change.

54. The implantable cardioverter/defibrillator of claim 51, wherein the operational circuitry is configured such that the step of observing the monotonic characteristics includes counting a number of monotonic segments found in a sampling of the cardiac signal corresponding to the time period.

55. The implantable cardioverter/defibrillator of claim 51, wherein the operational circuitry is further configured to classify the event to determine whether the event indicates treatment.

56. The implantable cardioverter/defibrillator of claim 51, wherein the operational circuitry is further configured to determine whether a cardiac signal appears to indicate a patient's heart is beating at a rate above a rate threshold before performing the receive, sense, observe, and determine steps.

57. The implantable cardioverter/defibrillator of claim 51, wherein the operational circuitry comprises a controller and a controller readable memory.

58. An implantable cardioverter/defibrillator comprising:
a lead electrode assembly including a number of electrodes; and
a canister housing operational circuitry;
wherein:
the lead electrode assembly is coupled to the canister; and
the operational circuitry is configured to:
sample a cardiac signal from a pair of implanted electrodes;
define a number of groups of samples from a portion of the signal;
determine how many of the groups of samples are monotonic; and
if the number of monotonic groups does not exceed a threshold, discard the portion of the signal.

59. An implantable cardioverter/defibrillator comprising:

a lead electrode assembly including a number of electrodes; and

a canister housing operational circuitry;

wherein:

the lead electrode assembly is coupled to the canister; and

the operational circuitry is configured to:

determine whether a heart is pumping at a rate exceeding a threshold; and,

if so, performing the following steps:

sample a cardiac signal from a pair of implanted electrodes;

define a number of groups of samples from a portion of the signal;

determine how many of the groups of samples are monotonic; and

if the number of monotonic groups does not exceed a threshold, discard the portion of the signal.

60. The implantable cardioverter/defibrillator of claim 59, wherein the operational circuitry is further configured to classify the signal by analyzing non-discarded portions of the signal, wherein the step of classifying the signal includes classifying portions of the signal as either indicating treatment or not indicating treatment.

61. The implantable cardioverter/defibrillator of claim 60, wherein the operational circuitry is further configured such that the step of classifying the signal includes keeping a count of classified portions until a threshold number of portions are classified; wherein, when the threshold number of portions are classified, the method further includes determining whether to provide treatment based upon whether a predetermined number of classified portions indicate treatment.

62. An implantable cardioverter/defibrillator comprising:

a lead electrode assembly including a number of electrodes; and

a canister housing operational circuitry;

wherein:

the lead electrode assembly is coupled to the canister; and

the operational circuitry is configured to:

sample a signal from first and second implanted electrodes;

set a threshold for the monotonicity of a sensed signal;

determine whether the sampled signal meets the threshold; and

if the sampled signal does not meet the threshold, discard the signal.

63. An implantable cardioverter/defibrillator comprising:

a lead electrode assembly including a number of electrodes; and

a canister housing operational circuitry;

wherein:

the lead electrode assembly is coupled to the canister; and

the operational circuitry is configured to:

receive a signal from first and second implanted electrodes;

observe a point in the signal;

observe a number of samples of the signal following the point;

group the samples into a number of groups;

observe which of the groups are monotonic;

count the monotonic groups;

determine whether the number of monotonic groups exceeds a threshold; and

if the number of monotonic groups does not exceed the threshold, discard the portion of the signal from which the number of signals following the point were taken.

64. An implantable cardioverter/defibrillator comprising:

a lead electrode assembly including a number of electrodes; and

a canister housing operational circuitry;

wherein:

the lead electrode assembly is coupled to the canister; and

the operational circuitry is configured to:

receive a signal from first and second implanted electrodes;

observe a monotonic segment of the signal;

measure the length of the monotonic segment;

compare the length to a threshold; and

if the length is less than the threshold, determine that the monotonic segment does not correspond to a certifiable cardiac event.

65. The implantable cardioverter/defibrillator of claim 64, wherein the operational circuitry is further configured to:

observe a portion of the signal around the monotonic segment;

determine whether the monotonic segment ends in a highest signal strength for the portion;

if the monotonic segment does not end in a highest signal strength for the portion, determining that the monotonic segment does not correspond to a certifiable cardiac event.

66. The implantable cardioverter/defibrillator of claim 64, wherein the operational circuitry is further configured such that the portion corresponds to time window around the monotonic segment, at least a portion of the time window occurring before the monotonic segment begins, and at least a portion of the time window occurring after the monotonic segment ends, the window having a duration in the range of 50-250 milliseconds.

67. An implantable cardiac treatment system comprising:

first and second electrodes; and

circuitry contained in a housing, the circuitry electrically coupled to the first and second electrodes;

wherein the circuitry is adapted to perform the following steps:

sampling a signal from first and second implanted electrodes;

setting a threshold for the monotonicity of a sensed signal;

determining whether the sampled signal meets the threshold; and

if the sampled signal does not meet the threshold, discarding the signal.

68. The system of claim 67, wherein the circuitry includes a controller and a controller readable medium, the controller readable medium containing instructions thereon for performing the steps of sampling, setting, determining and discarding.

69. An implantable cardioverter/defibrillator comprising:

a lead electrode assembly including a number of electrodes; and

a canister housing operational circuitry;

wherein:

the lead electrode assembly is coupled to the canister; and

the operational circuitry is configured to:

monitor a signal produced between implanted electrodes to observe an event;

observe an event and gathering a signal corresponding to the event;

observe characteristic features of the shape of the signal;

count the characteristic features;

compare the number of characteristic features to a threshold to:

certify the signal for use in characterizing a cardiac complex; or

determine the signal is unsuitable for use in characterizing a cardiac complex;

and, if the signal is certified, use the signal to determine whether a malignant cardiac rhythm is likely occurring.

70. An implantable cardioverter/defibrillator comprising:

a lead electrode assembly including a number of electrodes; and

a canister housing operational circuitry;

wherein:

the lead electrode assembly is coupled to the canister; and

the operational circuitry is configured to:

capture a signal using implanted electrodes placed for observing electrical cardiac activity;

analyze the signal to determine whether the signal is suitable for characterizing a cardiac rhythm; and

if the signal is suitable, use the signal to determine whether a malignant cardiac rhythm is likely occurring;

if the signal is not suitable, reject the signal.

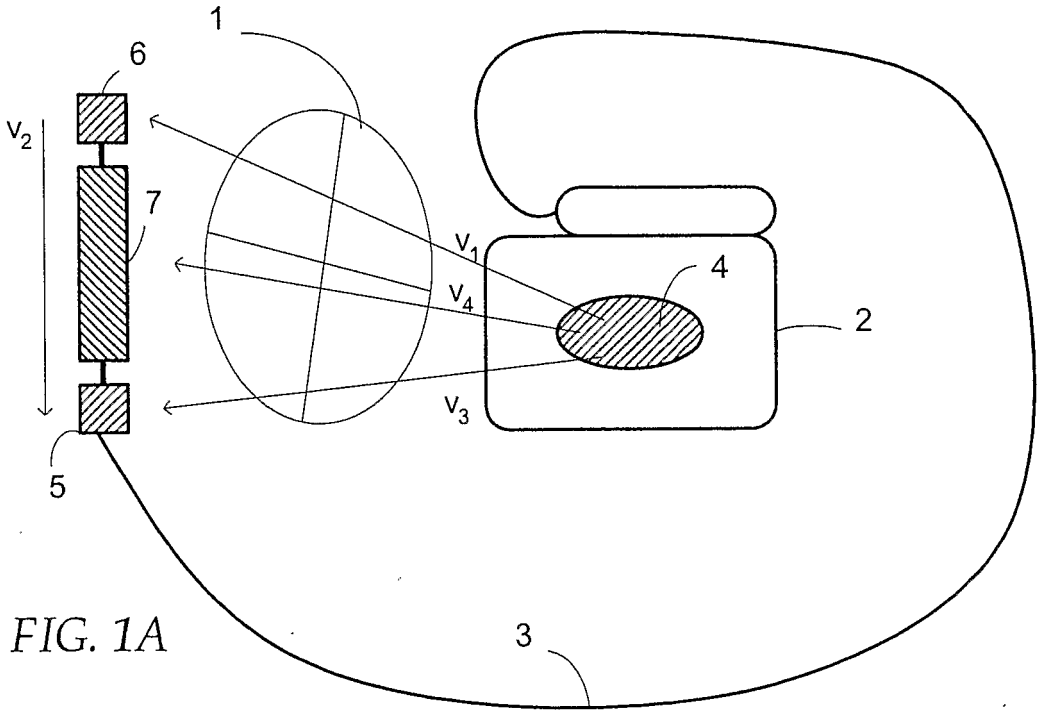



FIG. 1A

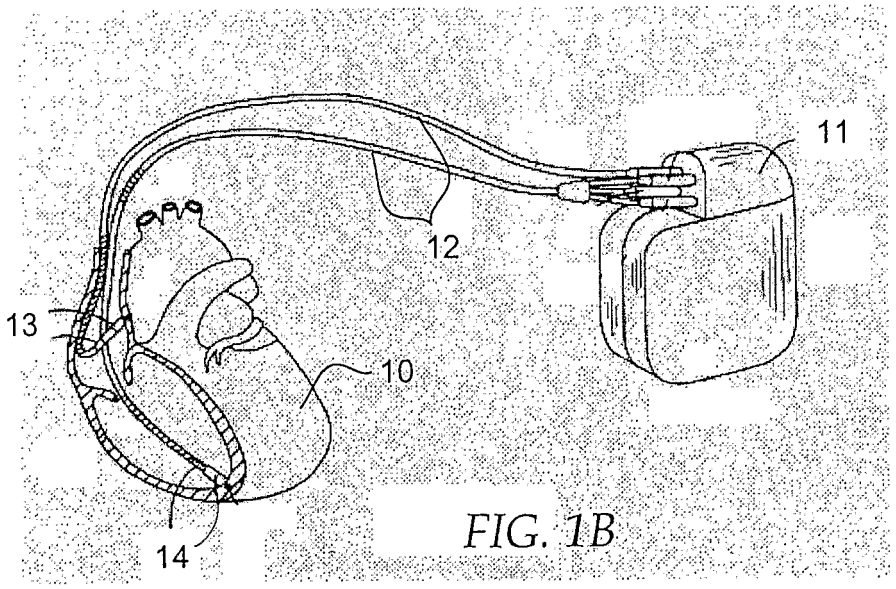



FIG. 1B

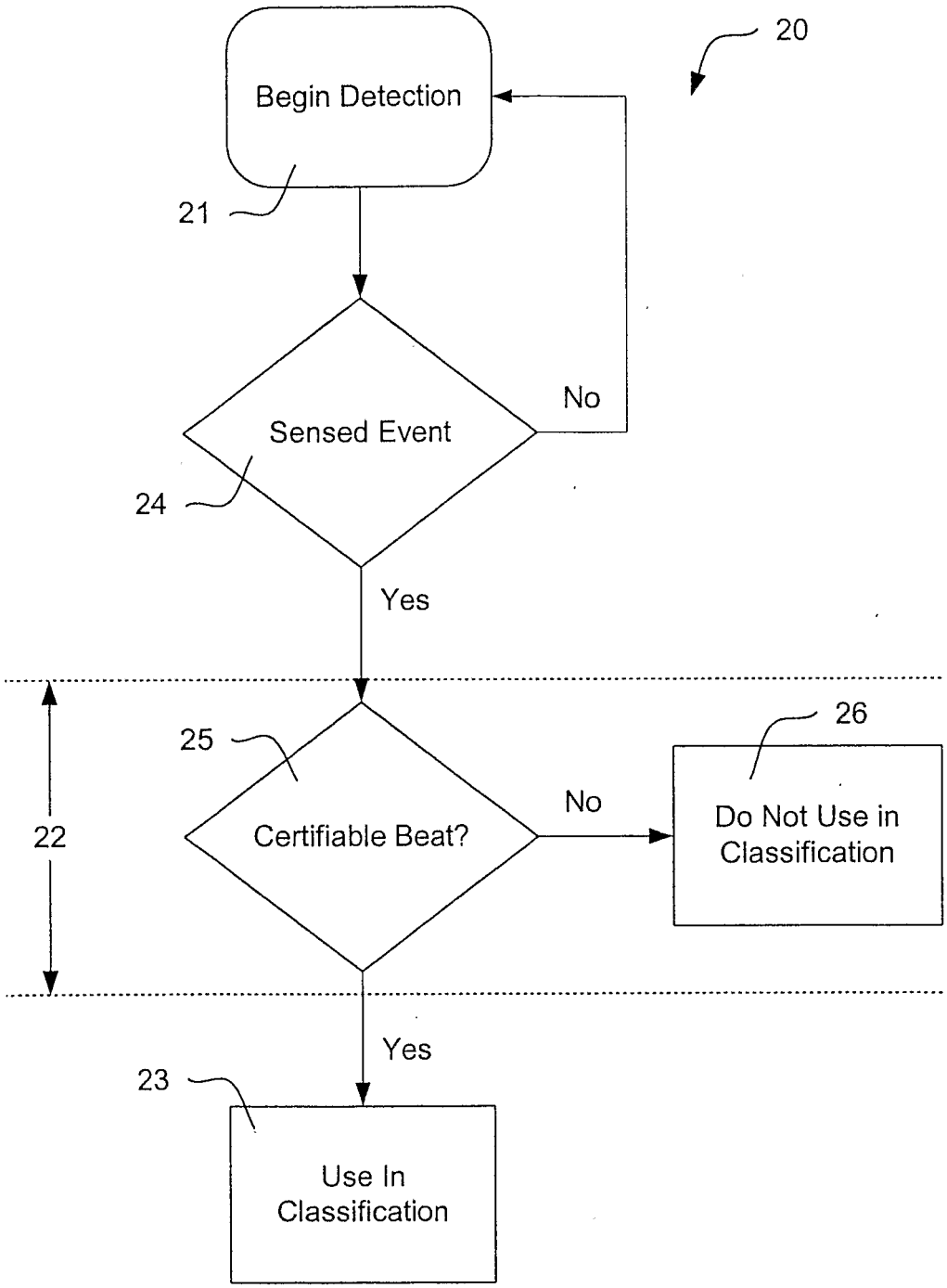

20
Begin Detection
21
Sensed Event
24
No
Yes
22
25
Certifiable Beat?
No
26
Do Not Use in Classification
Yes
23
Use In Classification

FIG. 2

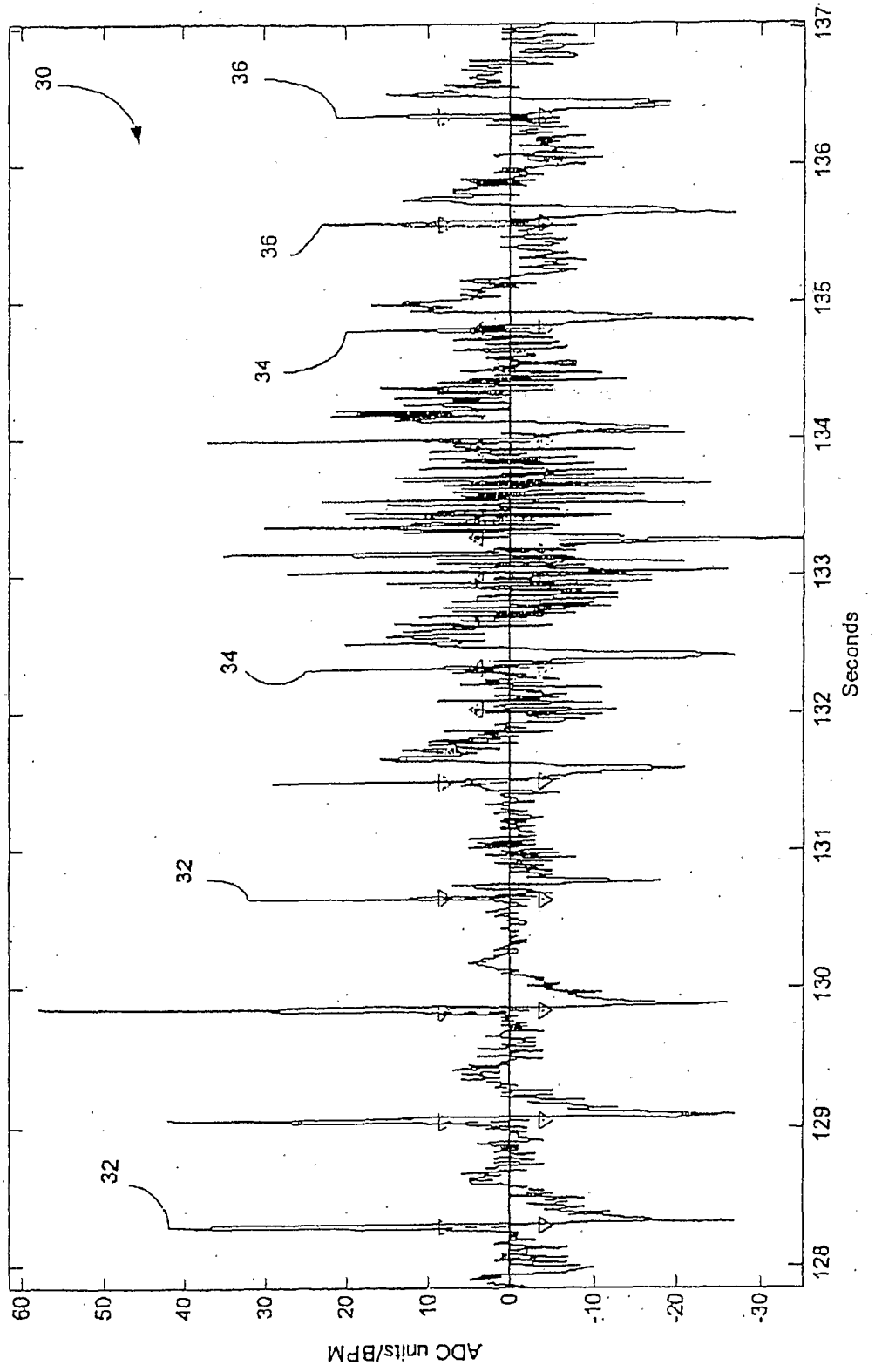

30
36
36
34
34
32
32
ADC units/BPM
60
50
40
30
20
10
0
-10
-20
-30
128
129
130
131
132
133
134
135
136
137
Seconds

FIG. 3

FIG. 4

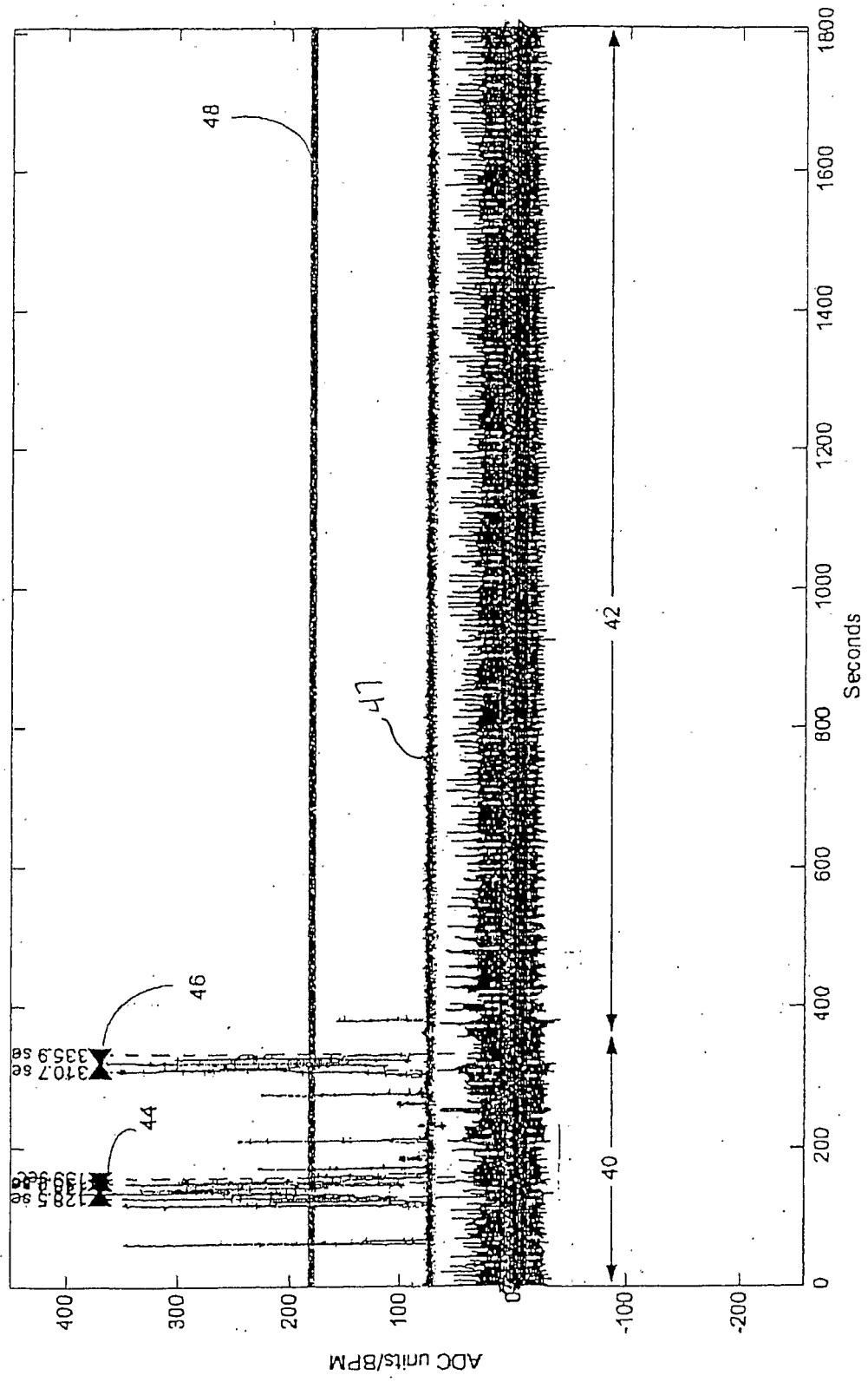
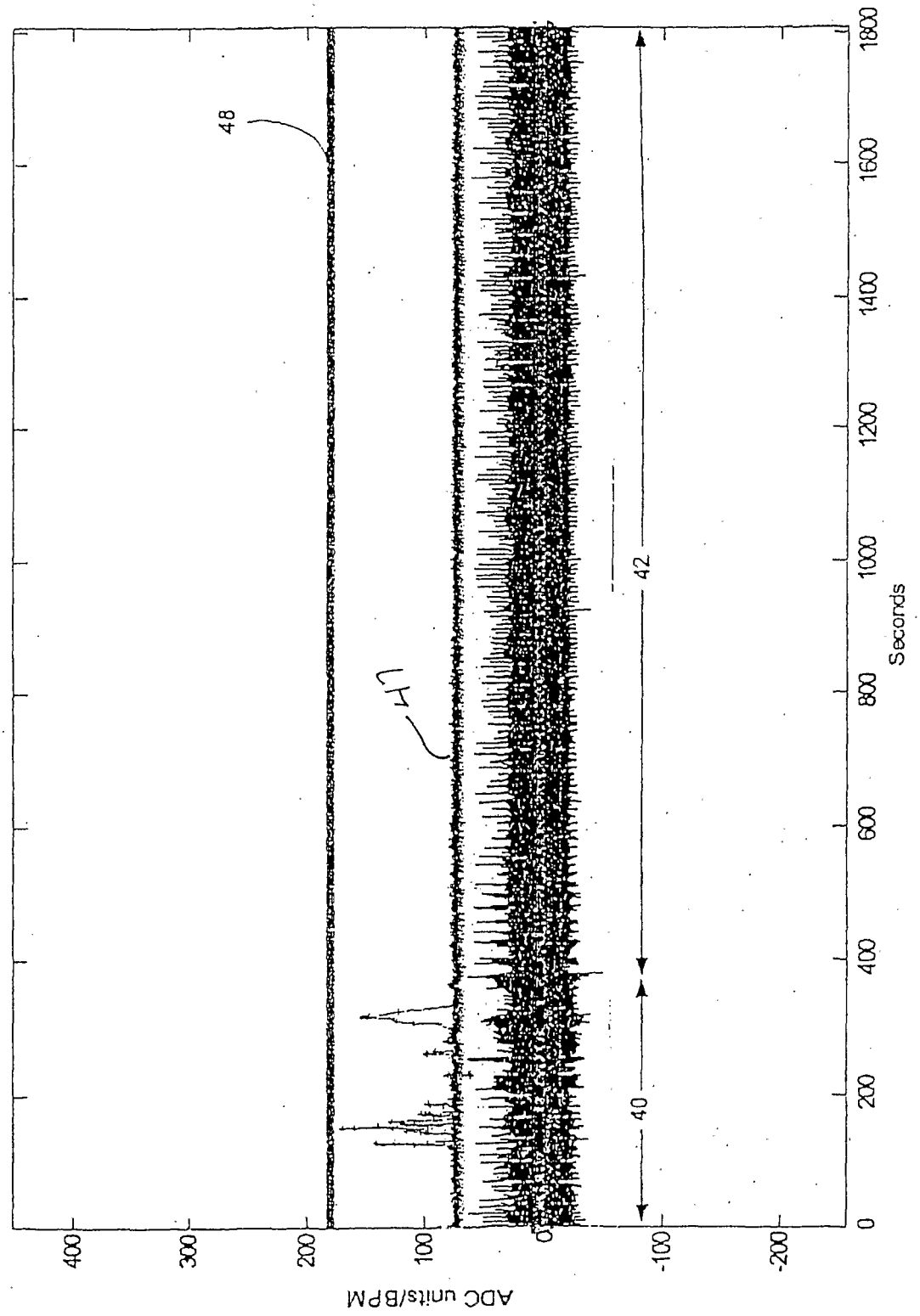

48
47
46
44
42
40
310.7 se
335.9 se
ADC units/BPM
Seconds
400
300
200
100
0
-100
-200
0
200
400
600
800
1000
1200
1400
1600
1800

FIG. 5


48
44
42
40
ADC units/BPM
Seconds
400
300
200
100
0
-100
-200
0
200
400
600
800
1000
1200
1400
1600
1800

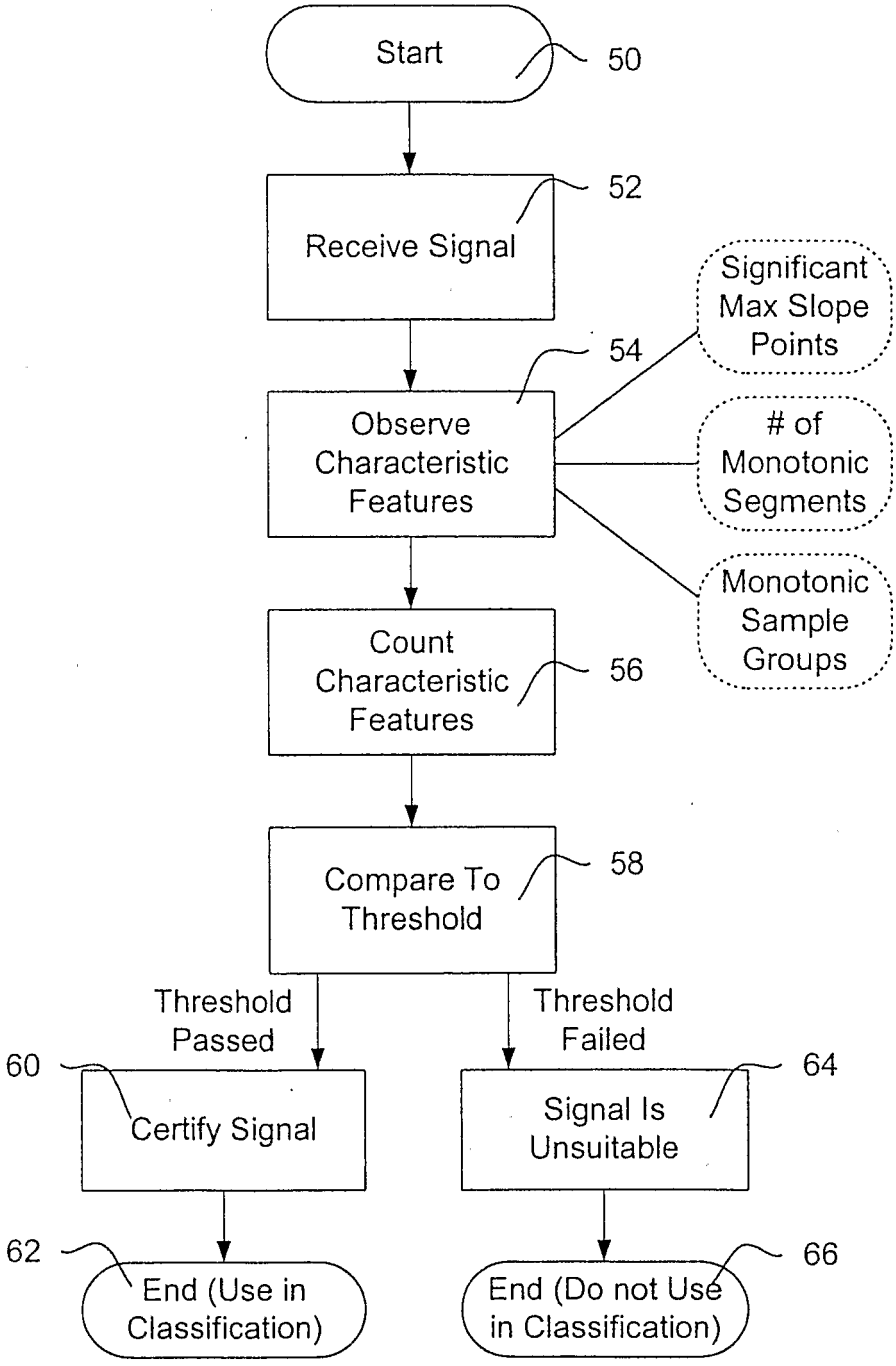

Start
50
Receive Signal
52
Observe Characteristic Features
54
Significant Max Slope Points
# of Monotonic Segments
Monotonic Sample Groups
Count Characteristic Features
56
Compare To Threshold
58
Threshold Passed
Threshold Failed
60
Certify Signal
64
Signal Is Unsuitable
62
End (Use in Classification)
66
End (Do not Use in Classification)

FIG. 6

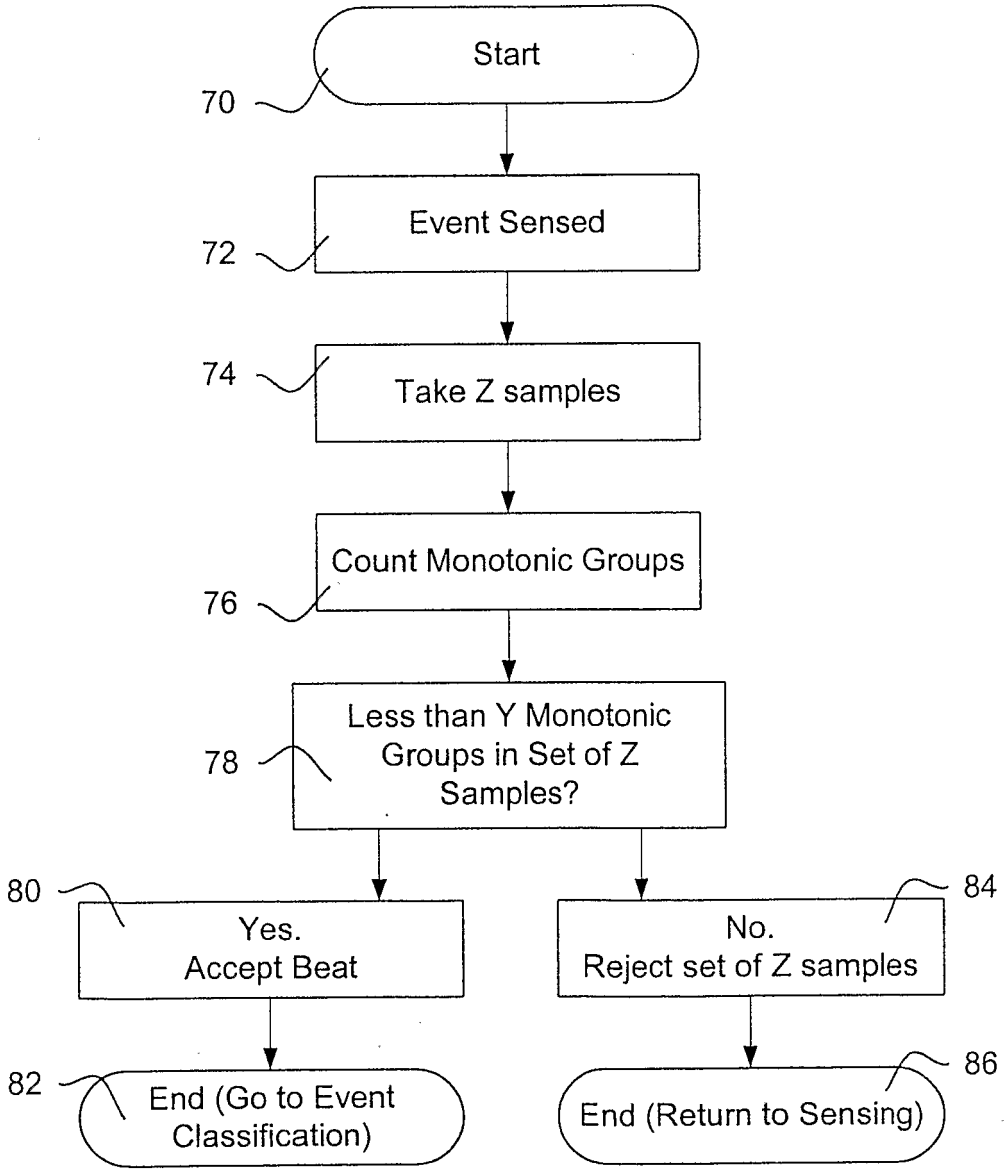

Start
70
Event Sensed
72
Take Z samples
74
Count Monotonic Groups
76
Less than Y Monotonic Groups in Set of Z Samples?
78
80
Yes.
Accept Beat
84
No.
Reject set of Z samples
82
End (Go to Event Classification)
86
End (Return to Sensing)

FIG. 7

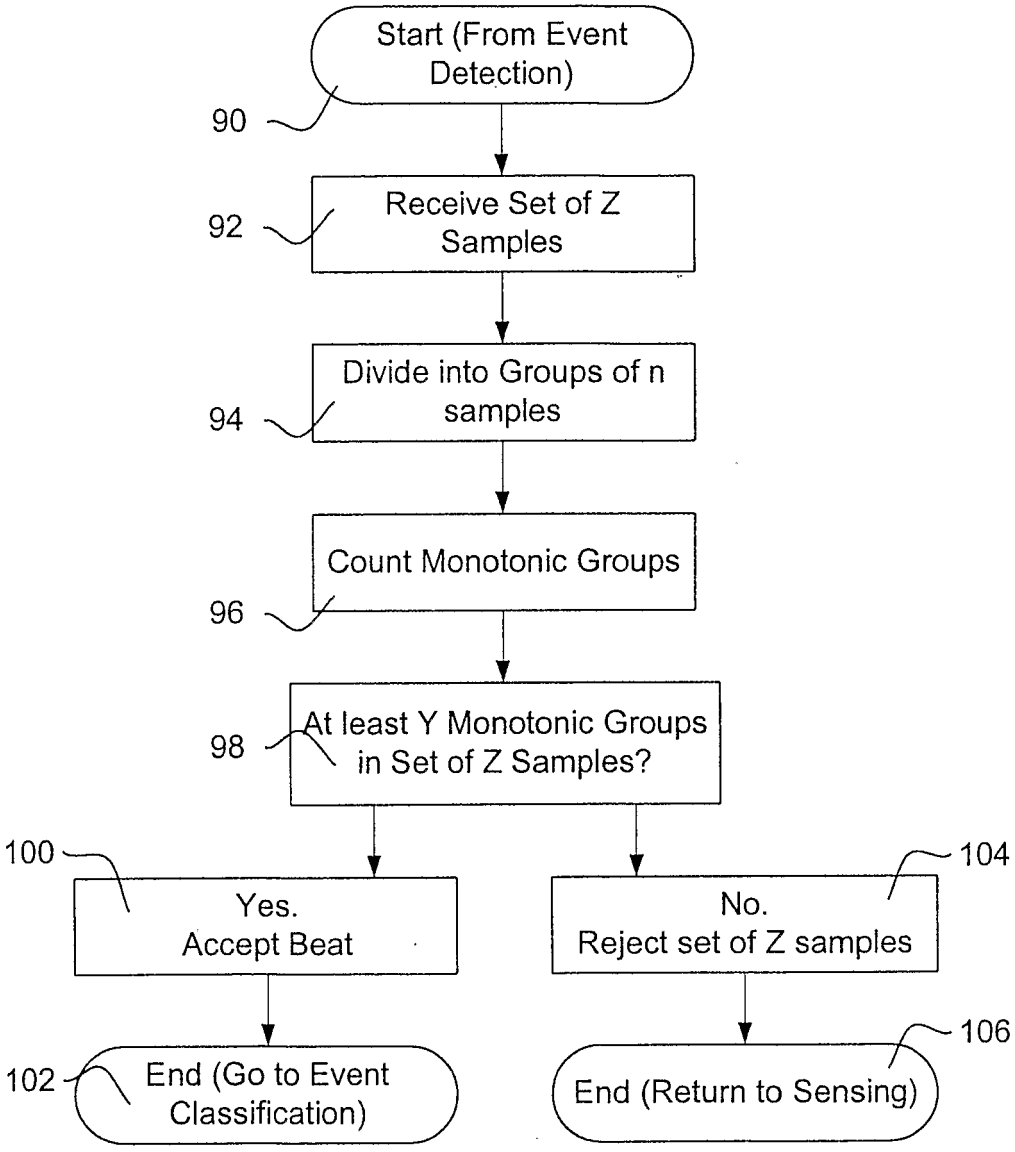

Start (From Event Detection)
90
Receive Set of Z Samples
92
Divide into Groups of n samples
94
Count Monotonic Groups
96
At least Y Monotonic Groups in Set of Z Samples?
98
100
Yes. Accept Beat
104
No. Reject set of Z samples
102
End (Go to Event Classification)
106
End (Return to Sensing)

*FIG. 8*

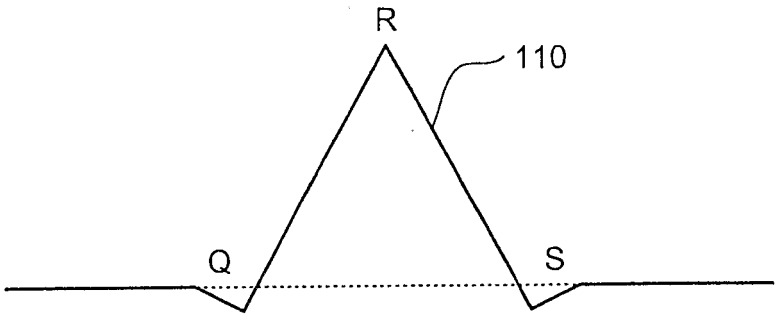



FIG. 9A

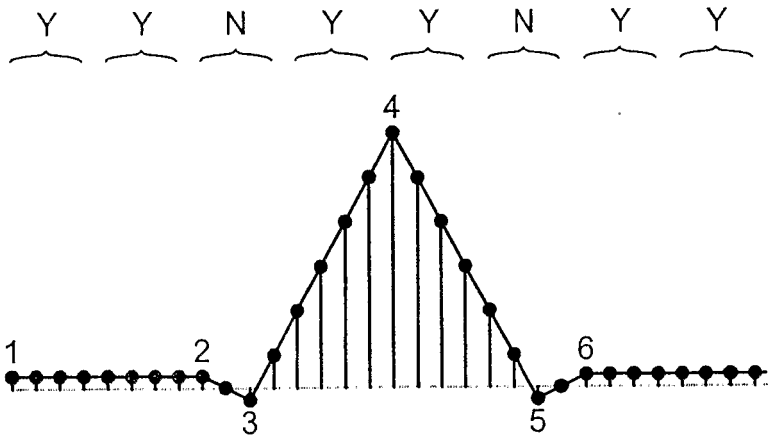



FIG. 9B

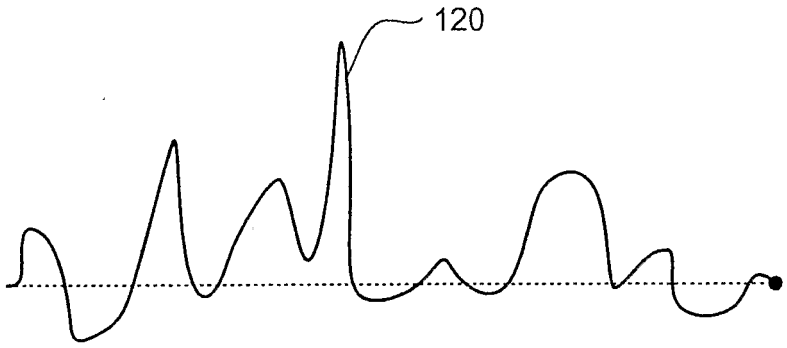



FIG. 10A

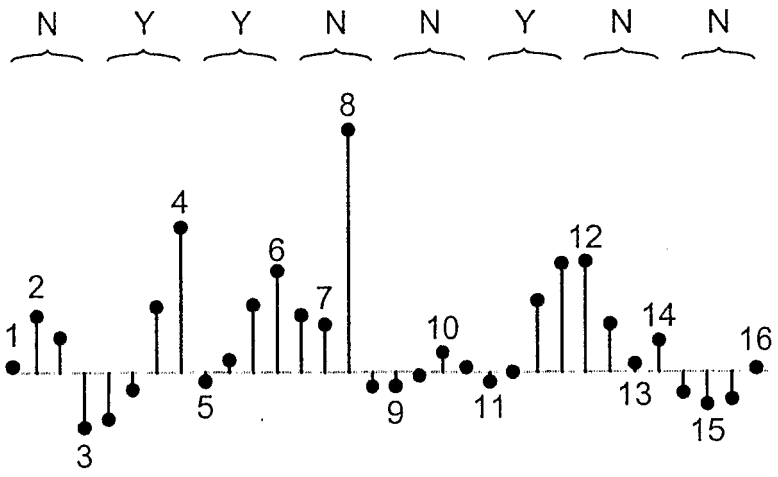



FIG. 10B

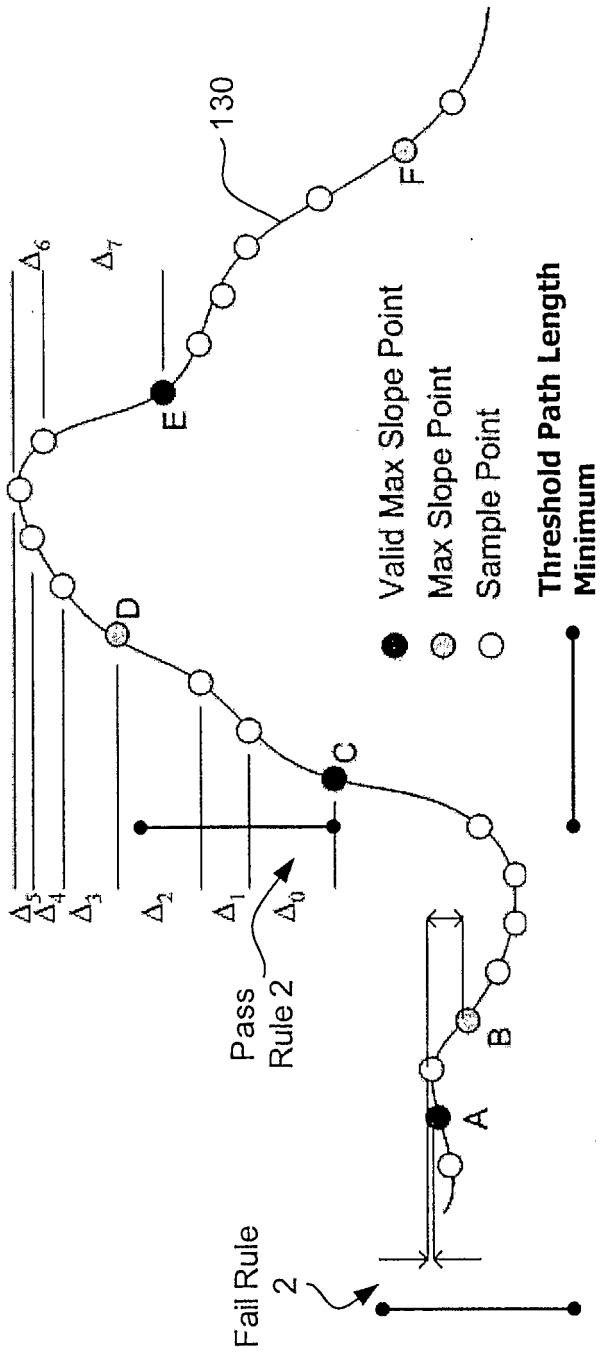

130
F
E
D
C
B
A
Δ6
Δ7
Δ5
Δ4
Δ3
Δ2
Δ1
Δ0
Pass
Rule 2
Fail Rule
2
Valid Max Slope Point
Max Slope Point
Sample Point
Threshold Path Length
Minimum

*FIG. 11*

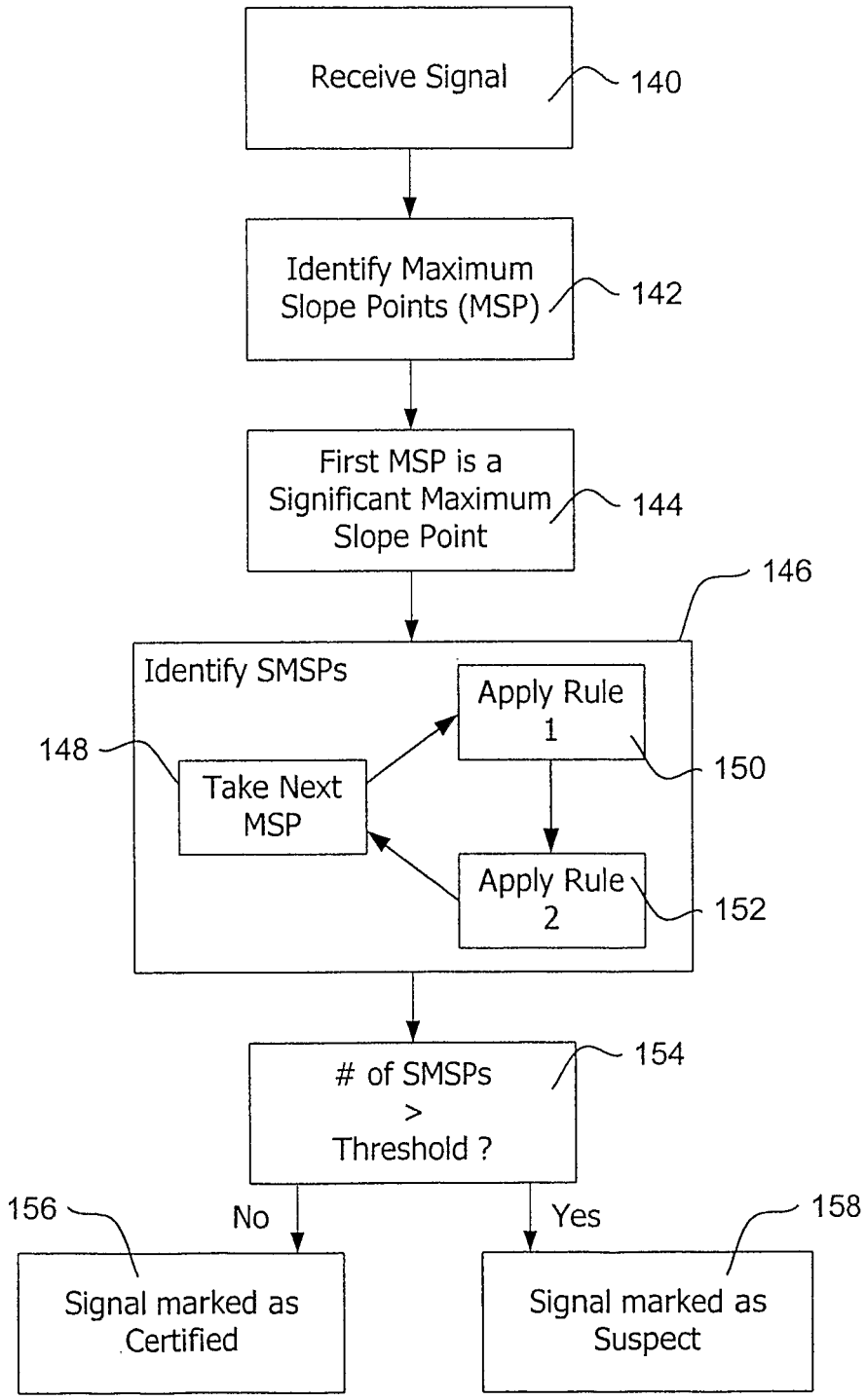

Receive Signal
140
Identify Maximum Slope Points (MSP)
142
First MSP is a Significant Maximum Slope Point
144
146
Identify SMSPs
Apply Rule 1
148
Take Next MSP
150
Apply Rule 2
152
# of SMSPs > Threshold ?
154
156
No
Yes
158
Signal marked as Certified
Signal marked as Suspect

*FIG. 12*

| | | | |
|---|---|---|---|
| 专利名称(译) | 用于执行心脏波形评估的方法和设备 | | |
| 公开(公告)号 | EP1631350A2 | 公开(公告)日 | 2006-03-08 |
| 申请号 | EP2004753836 | 申请日 | 2004-06-02 |
| [标]申请(专利权)人(译) | 卡梅伦保健公司 | | |
| 申请(专利权)人(译) | CAMERON HEALTH，INC. | | |
| 当前申请(专利权)人(译) | CAMERON HEALTH，INC. | | |
| [标]发明人 | PALREDDY SUREKHA<br>WARREN JAY A<br>PHILLIPS JAMES WILLIAM | | |
| 发明人 | PALREDDY, SUREKHA<br>WARREN, JAY, A.<br>PHILLIPS, JAMES, WILLIAM | | |
| IPC分类号 | A61N1/365 A61B5/00 A61B5/042 A61B5/0452 A61N1/362 A61N1/368 | | |
| CPC分类号 | A61N1/365 A61B5/0031 A61B5/0422 A61B5/04525 A61B5/7207 A61B5/7239 A61N1/3622 A61N1/368 | | |
| 代理机构(译) | 法思博事务所 | | |
| 优先权 | 60/475279 2003-06-02 US<br>10/858598 2004-06-01 US | | |
| 其他公开文献 | EP1631350B1 | | |
| 外部链接 | Espacenet | | |


摘要(译)

本发明涉及一种用于心律管理装置的传感结构。本发明的感测架构提供了用于通过心律管理设备认证检测到的事件的方法和装置。此外，通过利用增强的能力来仅精确地识别所需的那些感测事件，并防止使用标记为可疑的事件，本发明的感测架构可以更好地区分适合于设备治疗的节律和不适合于设备治疗的节奏。