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(54) PRESSURE AND IMPEDANCE BASED DISCRIMINATION OF HEMODYNAMIC STABILITY

DRUCK- UND IMPEDANZBASIERTE DISKRIMINIERUNG DER HÄMODYNAMISCHEN STABILITÄT

DISCRIMINATION À BASE DE PRESSION ET D'IMPÉDANCE DE STABILITÉ HÉMODYNAMIQUE

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Description

Field

[0001] This present disclosure generally relates to implantable medical devices and more specifically to implantable medical devices that sense cardiac impedance and pressure.

Background

[0002] Implantable medical devices (IMDs) provide a variety of monitoring, diagnostic, and therapy functions. For example, implantable pulse generators (IPGs) provide low power cardiac pacing and implantable cardioverter defibrillators (ICDs) provide high power defibrillation therapies (often in addition to pacing). These devices often monitor cardiac performance and provide targeted therapies based upon the data collected.

[0003] The performance of any given IMD is limited by the type of data collected. For example, most IMDs readily and accurately monitor heart rate. This parameter, while basic, provides invaluable information for cardiac devices. In many instances, this parameter alone provides sufficient information for the complete and proper operation of the device. IPGs may be set so as to deliver pacing whenever a patient's heart rate falls below a predetermined value (bradycardia). Often, the desired minimum value will be based on a secondary parameter, such as an activity level as sensed by an accelerometer. Thus, a desired target heart rate is set for a patient based upon a sensed activity level. If the patient's heart rate falls below this level, then the IPG provides a pacing therapy. As these values change and the patient's heart responds differently, the IPG preferably delivers therapy only when needed.

[0004] In the high power context, heart rate is also a core parameter. Ventricular tachycardia (VT) and ventricular fibrillation (VF) are potentially dangerous arrhythmias that generally correlate to heart rate. For example, VT would generally be classified for a rate of 150 to 250 beats per minute (bpm), while VF would be classified for rhythms greater than 250 bpm. Of course, during exercise, a patient's heart rate may fall within this prespecified VT range despite that rate being normal for the level of activity. Conversely, VF may occur at a lower rate and still be problematic. Thus, there is a desire to provide additional discrimination when detecting and categorizing VT/VF.

[0005] As VT/VF may be life threatening, discrimination protocols are set to err on the side of caution and provide therapy. False positives are problematic in that the high energy therapy may be physically uncomfortable and even painful to the patient. Furthermore, the therapy is often delivered without warning to the patient thereby taking them by surprise, even though the therapy is appropriately applied to a genuine arrhythmia. Therefore it is desirable to lower the frequency of both necessary and unnecessary shocks.

[0006] Many actual ventricular (or atrial) tachyarrhythmias spontaneously terminate after a very short duration. Since the hemodynamic status of the patient is unknown to the device at the time of therapy, most devices are programmed to deliver therapy as quickly as possible following detection. The time to therapy is generally limited by the time required to detect and confirm the arrhythmia as well as the time for the main defibrillation capacitors to charge. If hemodynamic parameters describing the stability of the arrhythmia were provided to the device, then an option would be available to delay therapy so that the arrhythmia might terminate spontaneously thereby avoiding the need to shock.

[0007] US 7,286,875 and US 2007/0149890 which are examples of medical devices according to the first part of claim 1, teach the use of hemodynamic parameters in treating arrhythmias.

Brief Summary

[0008] The present invention is defined in claim 1 with preferred embodiments as in the dependent claims.

[0009] In one embodiment, an implantable medical device (IMD) is provided that includes a microprocessor configured to control operation of the IMD; a pressure sensor coupled with the microprocessor and configured to provide ventricular pressure data to the microprocessor; and an impedance sensor coupled with the microprocessor and configured to provide ventricular impedance data to the microprocessor, wherein the microprocessor is configured to determine hemodynamic stability based upon a phase relationship between the ventricular pressure data and the ventricular impedance data.

[0010] In another embodiment, the IMD further includes a therapy delivery module operably coupled with the microprocessor, wherein the microprocessor causes the therapy delivery module to deliver a therapy based upon the determination of hemodynamic stability.

[0011] In another embodiment, the microprocessor precludes the therapy deliver module from delivering a high power therapy if an arrhythmia is determined to be hemodynamically stable.

[0012] In another embodiment, an implantable medical device is provided that includes

a microprocessor; a therapy delivery module operably coupled with the module and configured to selectively deliver a defibrillation waveform or a pacing therapy in response to a cardiac arrhythmia; a cardiac lead operably coupled with the microprocessor and the therapy delivery module and including one or more electrodes to provide the defibrillation waveform and the pacing therapy; an impedance sensor communicatively coupled with the microprocessor to deliver ventricular impedance data, wherein at least a portion of the impedance sensor includes at least one of the one or more electrodes to sense impedance; and a pressure sensor communicatively coupled with the microprocessor and configured to pro-

vide ventricular pressure data to the microprocessor, wherein the microprocessor is further configured to determine a phase relationship between the pressure data and the impedance data and to determine hemodynamic stability of a cardiac rhythm based upon the determined phase relationship.

[0013] In another embodiment, the microprocessor precludes the therapy delivery module from delivering the defibrillation waveform unless the cardiac rhythm is hemodynamically unstable.

[0014] In another embodiment, the microprocessor precludes the therapy delivery module from delivering the defibrillation waveform unless the cardiac rhythm is hemodynamically unstable or until a less aggressive therapy has proven unsuccessful if the cardiac rhythm is hemodynamically stable.

[0015] In yet another embodiment, an IMD is provided that includes means for sensing cardiac pressure; means for sensing cardiac impedance; and means for determining hemodynamic stability based upon a phase relationship between the sensed cardiac pressure and the sensed cardiac impedance.

[0016] Under normal hemodynamic conditions the left ventricular pressure is approximately ninety (90) degrees out of phase from the ventricular volume wave form in the time domain. However, under conditions of hemodynamic instability, this phase relationship is lost and the phase relationship between the signals becomes random. Under such conditions, it is unlikely that the ventricle can function adequately to maintain circulation and adequate cardiovascular function. Therefore, monitoring the phase relationship between pressure and impedance provides a method to monitor hemodynamic instability during an arrhythmia.

Brief description of the drawings

[0017]

FIG. 1 is an isovolumetric illustration of an IMD having a plurality of leads extending into a partially section view of a human heart.

FIG. 2 illustrates an alternative embodiment of an IMD.

FIG. 3 is a block diagram illustrating functional components of an IMD.

FIG. 4 is a collection of graphs illustrating various sensor data obtained during normal sinus rhythm (NSR), ventricular tachycardia (VT), and ventricular fibrillation (VF)

FIGS. 5A and 5B are phase loop plots of pressure and impedance data for NSR, VT, and VF events.

FIGS. 6A and 6B are graphs illustrating area calculations for the phase loop plots of FIGS.

5A and 5B.

FIG. 7 is a cross correlation plot of impedance and pressure measurements.

FIG. 8 is a flowchart describing an algorithm used in one embodiment of an IMD to determine hemodynamic stability based upon a phase relationship between pressure and impedance.

DETAILED DESCRIPTION

[0018] The present disclosure provides embodiments of IMDs that increase the sensitivity and specificity of ventricular tachyarrhythmia event (VT/VF) detection by utilizing a combination of sensed ventricular pressure data and sensed impedance data to determine the hemodynamic stability of a rhythm. The hemodynamic stability in turn is utilized to determine which rhythms require aggressive therapy (i.e., high energy defibrillation) and which rhythms require less aggressive therapies (e.g., anti-tachy pacing (ATP)) or do not require therapy at all.

[0019] The IMD determines a phase relationship between ventricular pressure and cardiac impedance. The phase relationship provides an accurate and readily discernable indication of hemodynamic stability. During a normal cardiac contraction, the left ventricle (LV) fills with blood and expands in volume. During this time, LV pressure increases until reaching a maximum. Conversely, as the volume of blood in the LV increases, the measured impedance across this heart chamber decreases duc to the conductivity of the blood. When the LV contracts it ejects a substantial portion of the blood volume thereby reducing the volume of blood in the chamber and lowering the LV pressure. With the lower blood volume, the measured impedance is higher. Thus, in a normal hemodynamically stable cardiac event cycle, measured pressure and measured impedance will be out of phase with one another. While described with respect to LV values, it should be appreciated that other cardiac pressure and impedance values will vary in a similar fashion and may be utilized accordingly, as will be described herein.

[0020] FIG. 1 illustrates an IMD 10 coupled with a heart 22 via a plurality of leads 14, 16, 18. The IMD 10 includes a housing or "can" 12 and a header portion 20. A right atrial (RA) lead 14 is coupled with the header 20 and includes one or more RA electrodes 25 disposed near a distal end and located within the right atrium of the heart 22. A right ventricular (RV) lead 16 is also coupled with the header 20. The RV lead 16 includes a tip electrode 26, a ring electrode 28, a pressure sensor 30 and a coil electrode 32. A left ventricular (LV) lead 18 includes a tip electrode 34. The LV lead 18 is coupled with the header 20 at its proximal end and is passed through the coronary sinus (CS) 24 and through a cardiac vein so that the electrode 34 is located proximate the left ventricle of the heart 22. The can 12 further includes a can electrode 30. It will be appreciated that the IMD 10 may be configured with different leads and/or with leads having different electrode configurations.

[0021] As an example, IMD 10 is illustrated in FIG. 2 having a single RV lead 52. Lead 52 has numerous electrodes and sensors disposed along its length and coupled with the can 12 via separate conductors. As illustrated,

RV lead 52 includes a SVC coil 54, atrial electrodes 56, 58, RV coil electrode 60, RV pressure sensor 30, and RV tip electrode 26. The components and operation of the IMD 10, configured as an ICD are generally conventional and will not be described in detail. FIG. 3 is a block diagram illustrating some of these components. As illustrated, the IMD 10 includes a microprocessor 100 coupled with a battery or power supply 110. A memory 105 is provided and includes a portion dedicated to storing the operational algorithms and parameters for device function as used in combination with the microprocessor. In addition, and typically separate, a portion of writeable memory is provided to store data collected by the IMD 10. The microprocessor 100 controls operation of the therapy delivery module 115 based upon the stored algorithms, parameters and protocols, to deliver, for example, defibrillation waveforms when required. Alternative therapies, such as pacing, cardioversion, anti-tachy pacing, and the like may also be provided and delivered via therapy control module 115.

[0022] Numerous sensors may be included to provide data to the IMD 10. Three are illustrated herein. Namely, the IMD 10 includes an impedance sensor 120, a pressure sensor 125 and an EGM sensor 130. Any pairing of the electrodes illustrates in FIGS. 1 and 2 (as well as other known electrode types/positions) may be utilized to gather EGM data as well as impedance measurements. The pressure sensor 125 utilizes a pressure sensor disposed on, within or proximate the heart 22. As illustrated, the pressure sensor 125 utilizes a RV pressure sensor 30 disposed within the right ventricle. It should be appreciated the direct measurement of left ventricular (or arterial) pressure may be ideal, however placing such a sensor in the left ventricle is challenging. As will be described below, RV pressure data is sufficiently similar to LV pressure data to facilitate implementation. The impedance sensor 120 operates by driving current between a pair of electrodes and measuring the resulting signal, either with the same receiving electrode or by utilizing one or more electrodes other than the driving pair.

[0023] Impedance may be measured between one or more electrode pairs within a single heart chamber (e.g., the right ventricle). A constant current stimulation field is established between electrode pairs disposed within the ventricle. Impedance (or its inverse, conductance) is measured between adjacent electrode pairs and the value from each electrode pair is summed to derive an impedance/conductance signal that is proportional to the volume of the heart chamber measured. Specifically,

$$V(t) = \frac{G(t)\rho l^2}{\alpha} + V_p$$

wherein, V is equal to the total heart chamber volume, G is equal to conductivity, p is equal to the resistivity of blood, 1 is the interelectrode distance, and V_p and α are correction factors accounting for current leakage out of the electrical field and non-homogeneity of the electrical field.

[0024] Alternatively, direct impedance measurements from an RV electrode (e.g., RV tip electrode 26) across the LV to e.g., the LV tip electrode 34 or the can electrode 36 will approximate LV impedance.

[0025] FIG. 4 is a graph 400 illustrating sampled data of various types and for various cardiac rhythms correlated together. As illustrated, for each type of data collected, the results for a sinus rhythm 405, VT 410, and VF 415 are illustrated. ECG (or EGM) data 420 illustrate a stable sinus rhythm 405 with discernable R waves. For VT 410, the ECG signal 410 illustrates signals of similar amplitude; however, due to the greatly increased rate the frequency is greater than that of the sinus rhythm 405. With VF 415, the signal 420 becomes irregular but still has a high frequency.

[0026] For the impedance values 425, the amplitudes of the waveforms tend to decrease, measured values decrease, and of course, frequency increases as the rhythms progress from sinus 405, to VT 410 and VF 415. For LV pressure 430 and RV pressure 435, there is also a notable decrease in amplitudes and an increase in frequency.

[0027] It will be appreciated that *ex post facto* analysis of these rhythms is deceptive. That is, to take idealized data during known rhythms for purposes of correlation and discussion tends to diminish the difficulty in processing these signals in real time. For example, on an analysis of ECG data 420 the distinction between sinus rhythm 405 and VT 410 may simply be rate, which as discussed above may be generally categorized but is often overlapping. The impedance values 425 illustrated tend to show a distinction between the rhythms; however, in a real world environment noise and other normal variation may obscure these differences; rendering both false positives and false negatives. Further, the amplitude changes may not be sufficiently discernable and the differences in actual measured values may be so patient specific as to make rhythm classification quite difficult. Similarly, with the pressure data 430, 435 there may be difficulty in establishing thresholds that reliably discriminate rhythms across patient populations. What this data set does illustrate is that the nature of the rhythm does have an effect on each of these parameters.

[0028] As previously stated, when in a normal sinus rhythm (NSR), cardiac pressure (more specifically ventricular pressure) is out of phase with (ventricular) impedance. This relationship is illustrated in the phase plots of FIGS. 5A and 5B. FIG. 5A is a phase plot based upon LV pressure data and FIG. 5B is a phase plot based upon RV pressure data. In both graphs, conductance (inverse of impedance) is plotted on the X axis while pressure is plotted on the Y axis. As illustrated, the out of phase relationship during NSR leads to a phase loop plot 500a, 500b that defines a substantial internal area. This indicates hemodynamic stability. That is, in efficient cardiac

cycles changes in pressure inversely correlate to changes in the volume of the heart chamber (which correlated to impedance/conductance).

[0029] Conversely, in hemodynamically unstable rhythms blood flow (i.e., output) is reduced. For example, in VF the ventricle may be rapidly quivering which produces fluctuations in pressure. Without substantial cardiac output, the blood volume is not changing substantially despite these pressure variations; hence impedance changes will fail to correspond. In the phase plots of FIGS. 5A and 5B a hemodynamically unstable VT 505a, 505b and VF 510a, 510b are illustrated. As pressure and impedance are no longer out of phase, the resulting phase plot is chaotic and fails to define a substantive area.

[0030] This result is further illustrated in the bar graphs of FIGS. 6A and 6B, which show the area defined by the phase plots of FIG. 5A and 5B respectively. Area may be calculated using any of a variety of mathematical techniques, such as integrating an equation representing the phase plot. These graphs also define a parameter of stroke work, which corresponds to the integral of pressure with respect to volume (approximated as conductance). Stroke work approximates the work done by the ventricle to eject the stroke volume. Thus, higher stroke work corresponds with hemodynamic stability. As illustrated, the hemodynamically stable sinus rhythm has a significantly larger area as compared to the hemodynamically unstable VT and VF rhythms.

[0031] In practice, this classification would be utilized to determine whether particular therapy options were necessary or appropriate. In the illustrated examples, both the VT and VF episodes are hemodynamically unstable and a high power therapy (defibrillation) would be appropriate. In most instances, VF would be hemodynamically unstable and require such therapy. VT, on the other hand, while an arrhythmia may in fact be hemodynamically stable. That is, despite the high rate, cardiac output may be sufficient. Though not illustrated, if a VT were present and hemodynamically stable the proper phase relationship between pressure and impedance would be maintained and the phase loop diagram for this VT rhythm would more closely approximate that of NSR. In such a case, alternative therapy options become available and may be attempted for a longer period of time. For example, anti-tachy pacing (ATP) is a viable option. Further, because the current data monitors hemodynamic stability, ATP may be given a longer period of time before resorting to a more aggressive therapy. Spontaneous termination of the arrhythmia may also occur before the rhythm becomes unstable, thus eliminating the need for therapy.

[0032] FIG. 7 is another mechanism to illustrate the relationship between pressure and impedance. Specifically, FIG. 7 is a cross-correlation plot between right ventricular pressure and intrathoracic impedance during sinus rhythm (solid line) and VT/VT (solid/dashed line) derived from the same data used to produce the previous figures. As illustrated, VT/VF results in a dramatic shift in both the amplitude and time lag of the maximum correlation. These changes indicate a hemodynamically unstable arrhythmia.

[0033] FIG. 8 is a flowchart describing a method of utilizing the phase relationship between pressure and impedance to determine hemodynamic stability in the selection and application of therapy. In this embodiment, a patient specific baseline is determined (800). A patient with an IMD 10 is monitored during a period of confirmed normal sinus rhythm (NSR). Pressure and impedance values are collected and correlated. It should be appreciated that in other embodiments, baseline data may be estimated from relevant patient populations.

[0034] The IMD 10 operates normally in accordance with known processing algorithms until VT/VF is suspected (810). This would most likely be based upon rate. At this point, pressure and impedance values are again measured (820), the phase relationship calculated, and the results are compared (830) with the previously established baseline to determine (840) if there is a difference. This may be done algorithmically by calculating an area defined by a phase plot between impedance/conductance measures verses pressure or plotting a cross-correlation between pressure and impedance. It should be appreciated that other mathematical or algorithmic techniques may be utilized to denote and quantify the phase relationship between pressure and impedance will remaining within the scope of the present disclosure.

If there is no difference or the difference is less than a threshold, the IMD 10 determines (850) that the rhythm is hemodynamically stable (850). In this instance, the IMD 10 may (depending upon the other parameters of the rhythm) leave the rhythm untreated or deliver therapies that are less aggressive than defibrillation (such as ATP).

[0035] If the comparison between the current pressure/impedance data indicates a large difference (840), then the IMD 10 determines (870) that the rhythm is hemodynamically unstable and that high power therapy (defibrillation) is warranted (880).

[0036] The particular thresholds set may be based upon on patient population data or set to patient specific parameters. Referring to FIGS. 5A, 5B, 6A, and 6B there is a clear distinction between hemodynamically stable and unstable rhythms. In one embodiment, the threshold is set to a particular percentage of the baseline NSR area taken from the phase plots. Thus, if the measured values fall below X percent of baseline, the rhythm is declared unstable. For example, in one embodiment if the measured data is less than 50% of the baseline, the rhythm is declared unstable. In another embodiment, if the measured data is less than 10% of the baseline, the rhythm is declared unstable.

[0037] As described, the IMD 10 relies upon other parameters (e.g., rate) to trigger a suspected VT/VF (810), at which point, impedance and pressure are measured (820) and compared (830) with a baseline. It should be

appreciated that in an alternative embodiment, impedance and pressure are measured continuously or at a high frequency and either continuously (or frequently) compared with the baseline. In this manner, the phase relationship between pressure and impedance would be useful to initially indicate a hemodynamically unstable rhythm, rather than to just confirm the same. Further, when used in this manner, the phase relationship may identify a declining cardiac rhythm and permit less aggressive therapy prior to reaching hemodynamic instability.

[0038] As described, various embodiments utilize a phase relationship between sensed pressure and impedance data to determine the hemodynamic stability of a given cardiac rhythm. This determination is then utilized to select an appropriate therapy.

[0039] Techniques and technologies described herein in terms of functional and/or logical block components and various processing steps. It should be appreciated that such block components may be realized by any number of hardware, software, and/or firmware components configured to perform the specified functions. For example, an embodiment of a system or a component may employ various integrated circuit components, e.g., memory elements, digital signal processing elements, logic elements, look-up tables, or the like, which may carry out a variety of functions under the control of one or more microprocessors or other control devices. In addition, those skilled in the art will appreciate that embodiments may be practiced in conjunction with any number of IMD configurations, medical device therapies, and monitoring/diagnostic equipment, and that the system described herein is merely one suitable example.

For the sake of brevity, conventional techniques related to signal sensing and signal processing, and other functional aspects of the systems (and the individual operating components of the systems) may not have been described in detail herein. Furthermore, the connecting lines shown in the various figures contained herein are intended to represent example functional relationships and/or physical couplings between the various elements. It should be noted that many alternative or additional functional relationships or physical connections may be present in an embodiment of the subject matter. The system embodiments may be described herein with reference to symbolic representations of operations, processing tasks, and functions that may be performed by various computing components or devices. Such operations, tasks, and functions are sometimes referred to as being computer-executed, computerized, software-implemented, or computer-implemented. In practice, one or more processor devices can carry out the described operations, tasks, and functions by manipulating electrical signals representing data bits at memory locations in the system memory, as well as other processing of signals. The memory locations where data bits are maintained are physical locations that have particular electrical, magnetic, optical, or organic properties corresponding to the data bits.

When implemented in software or firmware, various elements of the systems described herein (which may reside at an IMD, an external monitor device, or elsewhere in the system environment) are essentially the code segments or instructions that perform the various tasks. The program or code segments can be stored in a processor-readable medium or transmitted by a computer data signal embodied in a carrier wave over a transmission medium or communication path. The "processor-readable medium" or "machine-readable medium" may include any medium that can store or transfer information. Examples of the processor-readable medium include an electronic circuit, a semiconductor memory device, a ROM, a flash memory, an erasable ROM (EROM), a floppy diskette, a CD-ROM, an optical disk, a hard disk, a fiber optic medium, a radio frequency (RF) link, or the like. The computer data signal may include any signal that can propagate over a transmission medium such as electronic network channels, optical fibers, air, electromagnetic paths, or RF links.

While the system and method have been described in terms of what are presently considered to be specific embodiments, the disclosure need not be limited to the disclosed embodiments. It is intended to cover various modifications and similar arrangements included within the scope of the claims.

Claims

1. An implantable medical device (IMD) comprising:

a microprocessor (100) configured to control operation of the IMD;
a pressure sensor (135) coupled with the microprocessor and configured to provide ventricular pressure data to the microprocessor; and
an impedance sensor (120) coupled with the microprocessor and configured to provide ventricular impedance data to the microprocessor,
characterized in that the microprocessor is configured to calculate a phase relationship between the ventricular pressure data and the ventricular impedance data and determine hemodynamic stability based upon a comparison of the calculated phase relationship to a predetermined out of phase relationship between the ventricular pressure data and the ventricular impedance data corresponding to a sinus rhythm.

2. The IMD of claim 1, further comprising a therapy delivery module (115) operably coupled with the microprocessor, wherein the microprocessor causes the therapy delivery module to deliver a therapy based upon the determination of hemodynamic stability.

3. The IMD of claim 2, wherein the microprocessor pre-

cludes the therapy delivery module from delivering a high power therapy if an arrhythmia is determined to be hemodynamically stable.

4. The IMD of claim 1, wherein the pressure sensor is disposed on a right ventricular lead (16).

5. The IMD of claim 1, wherein the pressure sensor is disposed on a left ventricular lead (18).

6. The IMD of claim 1, wherein the pressure sensor is a left ventricular pressure sensor.

7. The IMD of claim 1, wherein the impedance sensor includes a plurality of electrodes disposed along a single lead and configured to generate a constant current stimulation field.

8. The IMD of claim 1, wherein the impedance sensor includes a right ventricular electrode and a left ventricular electrode.

9. The IMD of claim 1, wherein the impedance sensor includes a right ventricular electrode and a can electrode.

10. The implantable medical device of claim 1, further comprising:

a therapy delivery module (115) operably coupled with the module and configured to selectively deliver a defibrillation waveform or a pacing therapy in response to a cardiac arrhythmia; and
a cardiac lead (14, 16, 18) operably coupled with the microprocessor and the therapy delivery module and including one or more electrodes to provide the defibrillation waveform and the pacing therapy; and
wherein at least a portion of the impedance sensor includes at least one of the one or more electrodes to sense impedance.

11. The IMD of claim 10, wherein the microprocessor precludes the therapy delivery module from delivering the defibrillation waveform unless the cardiac rhythm is hemodynamically unstable.

12. The IMD of claim 10, wherein the microprocessor precludes the therapy delivery module from delivering the defibrillation waveform unless the cardiac rhythm is hemodynamically unstable or until a less aggressive therapy has proven unsuccessful if the cardiac rhythm is hemodynamically stable.

13. The IMD of claim 11, wherein the pressure sensor is coupled with the cardiac lead.

14. The IMD of claim 11, wherein the one or more electrodes includes a plurality of electrodes (25) disposed along the cardiac lead and are configured to generate a constant current stimulation field.

Patentansprüche

1. Implantierbare medizinische Vorrichtung (IMD), die Folgendes enthält:

einen Mikroprozessor (100), der konfiguriert ist, den Betrieb der IMD zu steuern;
einen Drucksensor (135), der an den Mikroprozessor gekoppelt ist und konfiguriert ist, ventrikuläre Druckdaten für den Mikroprozessor bereitzustellen; und
einen Impedanzsensor (120), der an den Mikroprozessor gekoppelt ist und konfiguriert ist, ventrikuläre Impedanzdaten für den Mikroprozessor bereitzustellen, **dadurch gekennzeichnet, dass** der Mikroprozessor konfiguriert ist, eine Phasenbeziehung zwischen den ventrikulären Druckdaten und den ventrikulären Impedanzdaten zu berechnen und die hämodynamische Stabilität anhand eines Vergleichs der berechneten Phasenbeziehung mit einer vorgegebenen phasenverschobenen Beziehung zwischen den ventrikulären Druckdaten und den ventrikulären Impedanzdaten in Übereinstimmung mit einem Sinusrhythmus zu bestimmen.

2. IMD nach Anspruch 1, die ferner ein Therapieverabreichungsmodul (115) enthält, das betriebstechnisch an den Mikroprozessor gekoppelt ist, wobei der Mikroprozessor das Therapieverabreichungsmodul dazu veranlasst, eine Therapie anhand der Bestimmung der hämodynamischen Stabilität zu verabreichen.

3. IMD nach Anspruch 2, wobei der Mikroprozessor das Therapieverabreichungsmodul daran hindert, eine leistungsstarke Therapie zu verabreichen, wenn eine Arrhythmie als hämodynamisch stabil bestimmt wird.

4. IMD nach Anspruch 1, wobei der Drucksensor an einer rechtsventrikulären Leitung (16) angeordnet ist.

5. IMD nach Anspruch 1, wobei der Drucksensor an einer linksventrikulären Leitung (18) angeordnet ist.

6. IMD nach Anspruch 1, wobei der Drucksensor ein linksventrikulärer Drucksensor ist.

7. IMD nach Anspruch 1, wobei der Impedanzsensor mehrere Elektroden beinhaltet, die entlang einer ein-

zelnen Leitung angeordnet sind und konfiguriert sind, ein Konstantstromstimulationsfeld zu erzeugen.

8. IMD nach Anspruch 1, wobei der Impedanzsensor eine rechtsventrikuläre Elektrode und eine linksventrikuläre Elektrode enthält.

9. IMD nach Anspruch 1, wobei der Impedanzsensor eine rechtsventrikuläre Elektrode und eine Kapselelektrode enthält.

10. Implantierbare medizinische Vorrichtung nach Anspruch 1, die ferner enthält:

ein Therapieverabreichungsmodul (115), das betriebstechnisch an das Modul gekoppelt ist und konfiguriert ist, selektiv eine Defibrillationswellenform oder eine Schrittmachertherapie als Reaktion auf eine kardiale Arrhythmie zu verabreichen; und
eine kardiale Leitung (14, 16, 18), die betriebstechnisch an den Mikroprozessor und das Therapieverabreichungsmodul gekoppelt ist und eine oder mehrere Elektroden enthält, um die Defibrillationswellenform und die Schrittmachertherapie bereitzustellen; und
wobei mindestens ein Abschnitt des Impedanzsensors mindestens eine der einen oder der mehreren Elektroden beinhaltet, um eine Impedanz zu erfassen.

11. IMD nach Anspruch 10, wobei der Mikroprozessor das Therapieverabreichungsmodul daran hindert, die Defibrillationswellenform zu verabreichen, außer wenn der kardiale Rhythmus hämodynamisch instabil ist.

12. IMD nach Anspruch 10, wobei der Mikroprozessor das Therapieverabreichungsmodul daran hindert, die Defibrillationswellenform zu verabreichen, außer wenn der kardiale Rhythmus hämodynamisch instabil ist oder bis sich eine weniger aggressive Therapie als erfolglos erwiesen hat, wenn der kardiale Rhythmus hämodynamisch stabil ist.

13. IMD nach Anspruch 11, wobei der Drucksensor an die kardiale Leitung gekoppelt ist.

14. IMD nach Anspruch 11, wobei die eine oder die mehreren Elektroden mehrere Elektroden (25) enthalten, die entlang der kardialen Leitung angeordnet sind und konfiguriert sind, ein Konstantstromstimulationsfeld zu erzeugen.

Revendications

1. Dispositif médical implantable (IMD) comportant :

un microprocesseur (100) configuré pour commander le fonctionnement du dispositif médical implantable ;
un capteur de pression (135) couplé au processeur et configuré pour fournir des données de pression ventriculaire au microprocesseur ; et
un capteur d'impédance (120) couplé au processeur et configuré pour fournir des données d'impédance ventriculaire au microprocesseur, **caractérisé en ce que** le microprocesseur est configuré pour calculer une relation de phase entre les données de pression ventriculaire et les données d'impédance ventriculaire et déterminer une stabilité hémodynamique sur la base d'une comparaison de la relation de phase calculée à une relation déphasée prédéterminée entre les données de pression ventriculaire et les données d'impédance ventriculaire correspondant à un rythme sinusal.

2. Dispositif médical implantable selon la revendication 1, comportant en outre un module d'administration de thérapie (115) couplé de manière opérationnelle au microprocesseur, dans lequel le microprocesseur amène le module d'administration de thérapie à administrer une thérapie sur la base de la détermination de la stabilité hémodynamique.

3. Dispositif médical implantable selon la revendication 2, dans lequel le processeur empêche le module d'administration de thérapie d'administrer une thérapie à haute puissance si une arythmie est déterminée comme étant hémodynamiquement stable.

4. Dispositif médical implantable selon la revendication 1, dans lequel le capteur de pression est disposé sur une dérivation ventriculaire droite (16).

5. Dispositif médical implantable selon la revendication 1, dans lequel le capteur de pression est disposé sur une dérivation ventriculaire gauche (18).

6. Dispositif médical implantable selon la revendication 1, dans lequel le capteur de pression est un capteur de pression ventriculaire gauche.

7. Dispositif médical implantable selon la revendication 1, dans lequel le capteur d'impédance comprend une pluralité d'électrodes disposées le long d'une dérivation unique et configurées pour générer un champ de stimulation à courant constant.

8. Dispositif médical implantable selon la revendication 1, dans lequel le capteur d'impédance comprend une

électrode ventriculaire droite et une électrode ventriculaire gauche.

9. Dispositif médical implantable selon la revendication 1, dans lequel le capteur d'impédance comprend une électrode ventriculaire droite et une électrode à gaine.

10. Dispositif médical implantable selon la revendication 1, comportant en outre :

un module d'administration de thérapie (115) couplé de manière opérationnelle au module et configuré pour administrer de manière sélective une forme d'onde de défibrillation ou une thérapie de stimulation en réponse à une arythmie cardiaque ; et
une dérivation cardiaque (14, 16, 18) couplée de manière rationnelle au processeur et au module d'administration de thérapie et comprenant une ou plusieurs électrodes pour délivrer la forme d'onde de défibrillation et la thérapie de stimulation ; et
dans lequel au moins une partie du capteur d'impédance comprend au moins l'une parmi l'électrode ou les électrodes pour détecter une impédance.

11. Dispositif médical implantable selon la revendication 10, dans lequel le microprocesseur empêche le module d'administration de thérapie de délivrer la forme d'onde de défibrillation sauf si le rythme cardiaque est hémodynamiquement instable.

12. Dispositif médical implantable selon la revendication 10, dans lequel le processeur empêche le module d'administration de thérapie d'administrer la forme d'onde de défibrillation sauf si le rythme cardiaque est hémodynamiquement instable ou jusqu'à ce que une thérapie moins agressive se soit avérée inefficace si le rythme cardiaque est hémodynamiquement stable.

13. Dispositif médical implantable selon la revendication 11, dans lequel le capteur de pression est couplé à la dérivation cardiaque.

14. Dispositif médical implantable selon la revendication 11, dans lequel l'électrode ou les électrodes comprennent une pluralité d'électrodes (25) disposées le long de la dérivation cardiaque et sont configurées pour générer un champ de stimulation à courant constant.

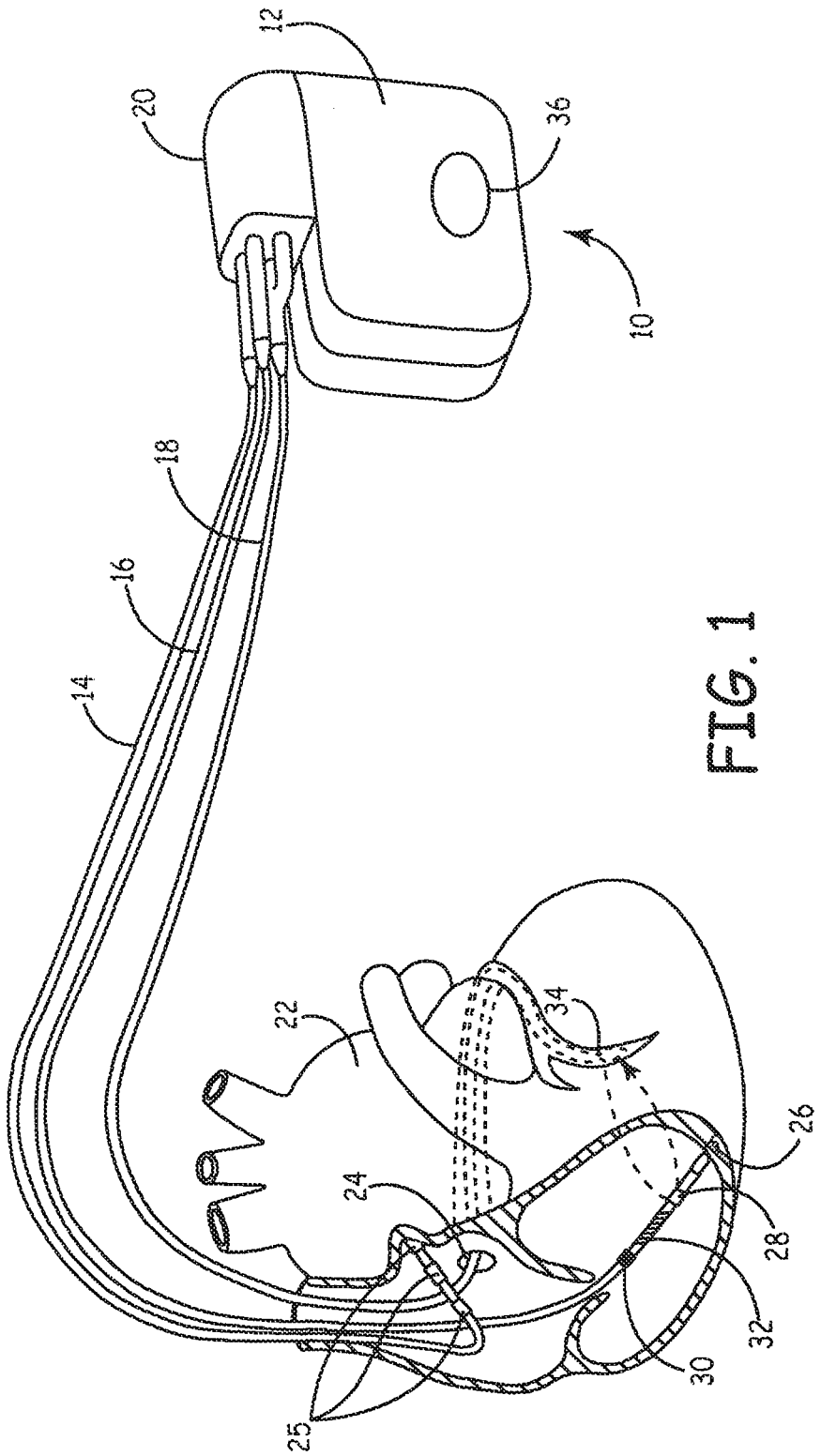

FIG. 1

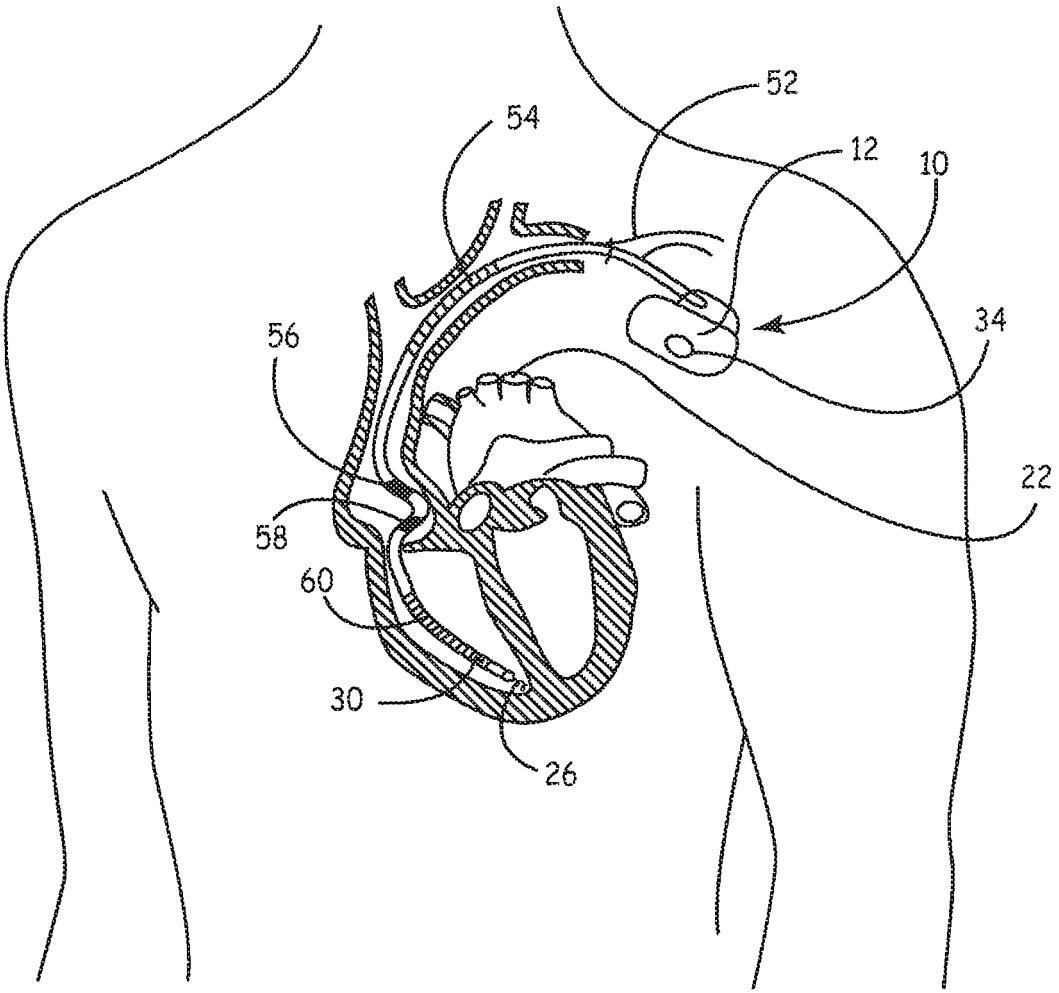

FIG. 2

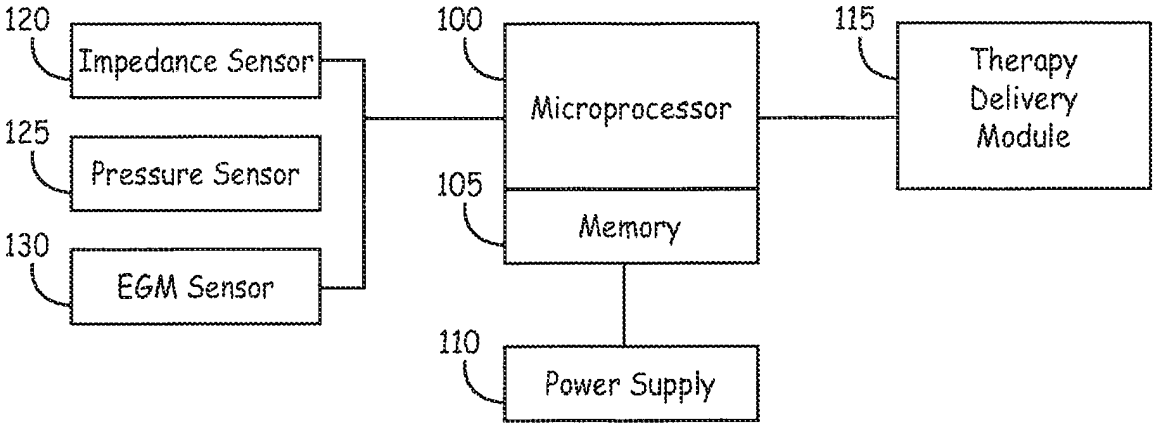
120
Impedance Sensor
125
Pressure Sensor
130
EGM Sensor
100
Microprocessor
105
Memory
110
Power Supply
115
Therapy Delivery Module

FIG. 3

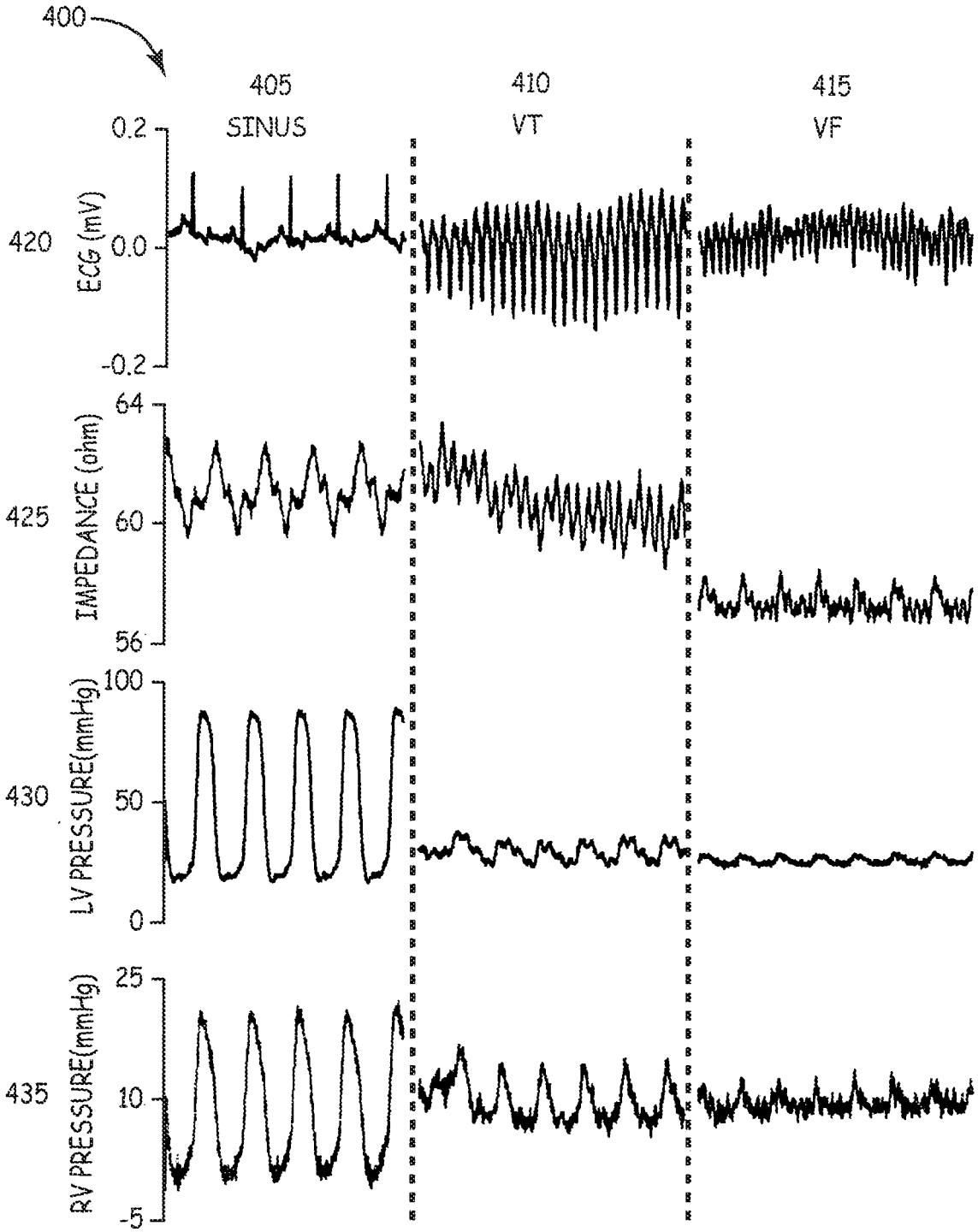
400
405
SINUS
410
VT
415
VF
420
ECG (mV)
0.2
0.0
-0.2
425
IMPEDANCE (ohm)
64
60
56
430
LV PRESSURE(mmHg)
100
50
0
435
RV PRESSURE(mmHg)
25
10
-5

FIG. 4

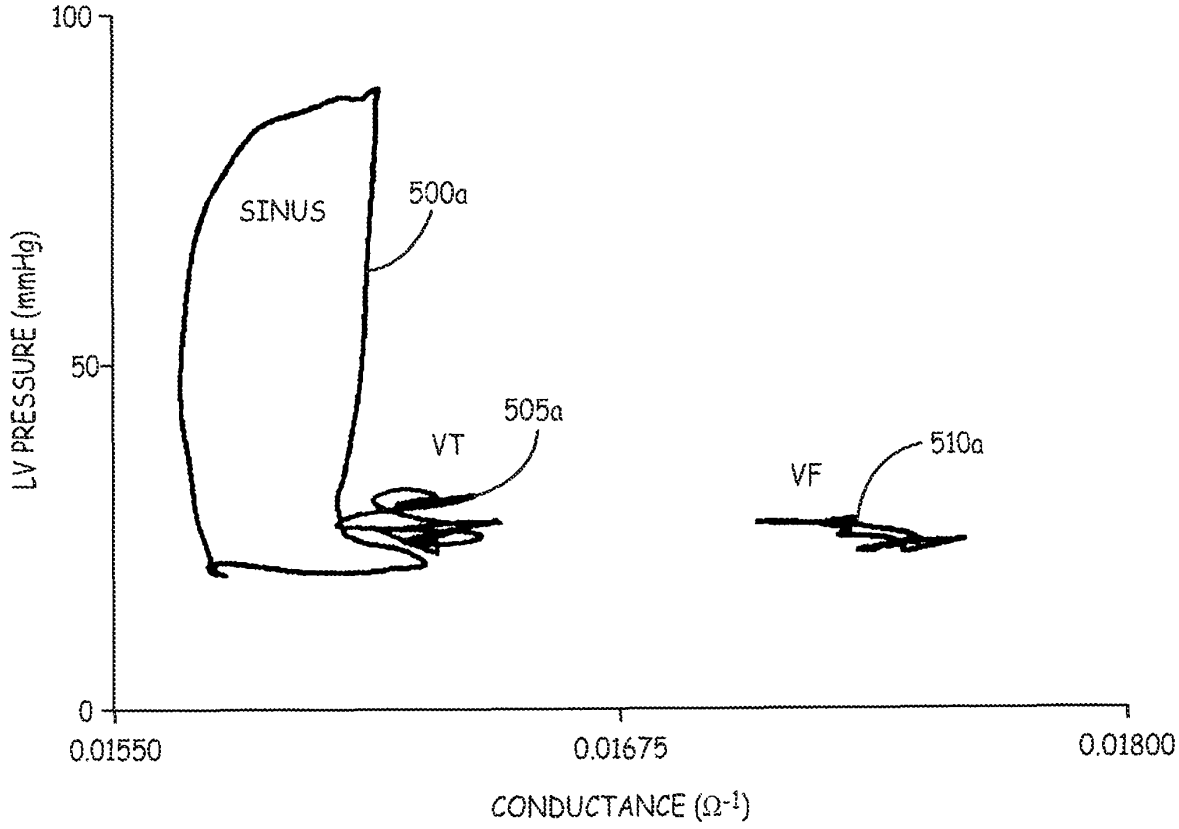
100
50
0
LV PRESSURE (mmHg)
SINUS
500a
VT
505a
VF
510a
0.01550
0.01675
0.01800
CONDUCTANCE (Ω-1)

FIG. 5A

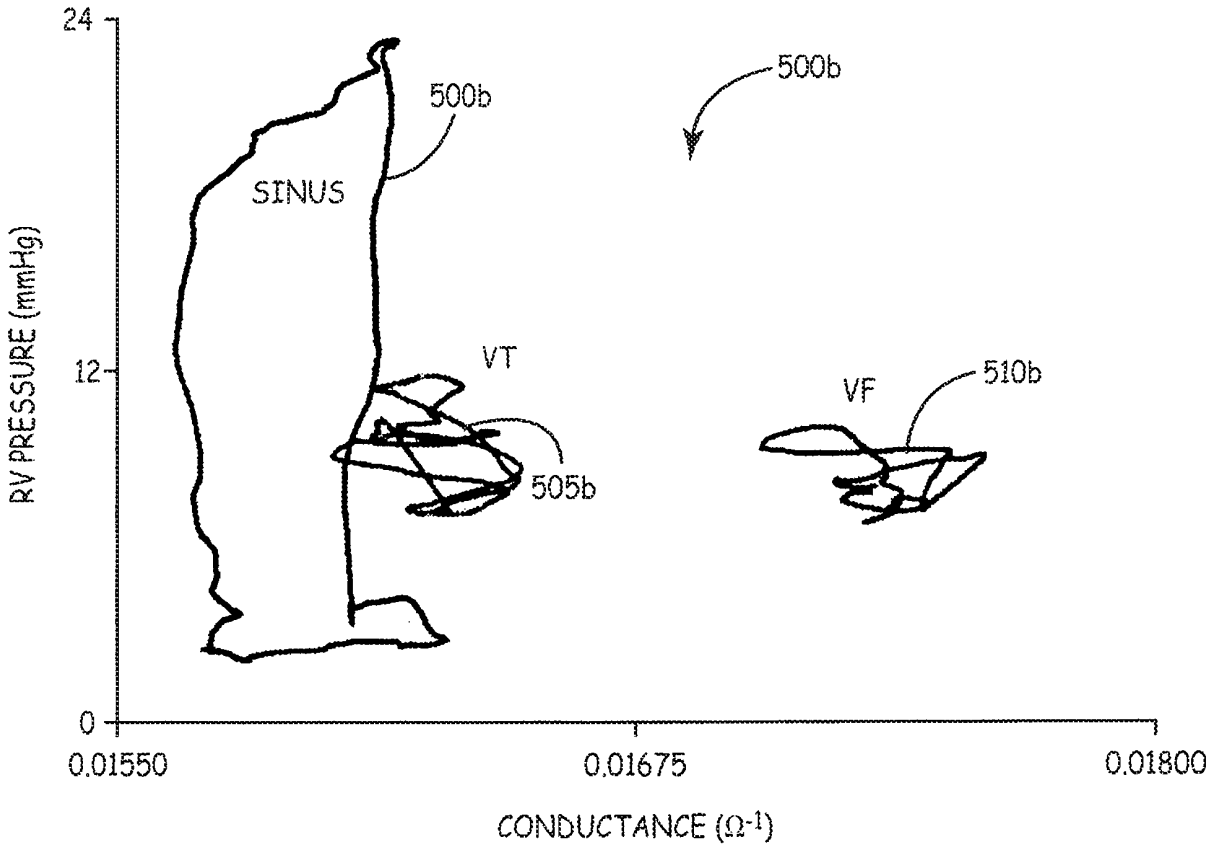
24
12
0
RV PRESSURE (mmHg)
500b
SINUS
500b
VT
505b
VF
510b
0.01550
0.01675
0.01800
CONDUCTANCE (Ω-1)

FIG. 5B

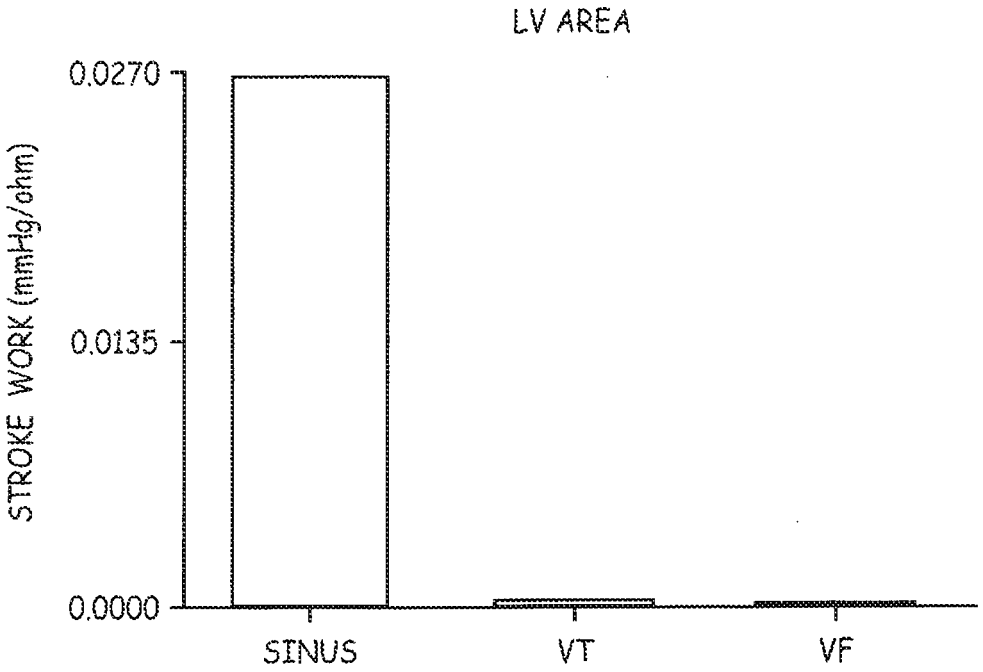
LV AREA
STROKE WORK (mmHg/ohm)
0.0270
0.0135
0.0000
SINUS
VT
VF

FIG. 6A

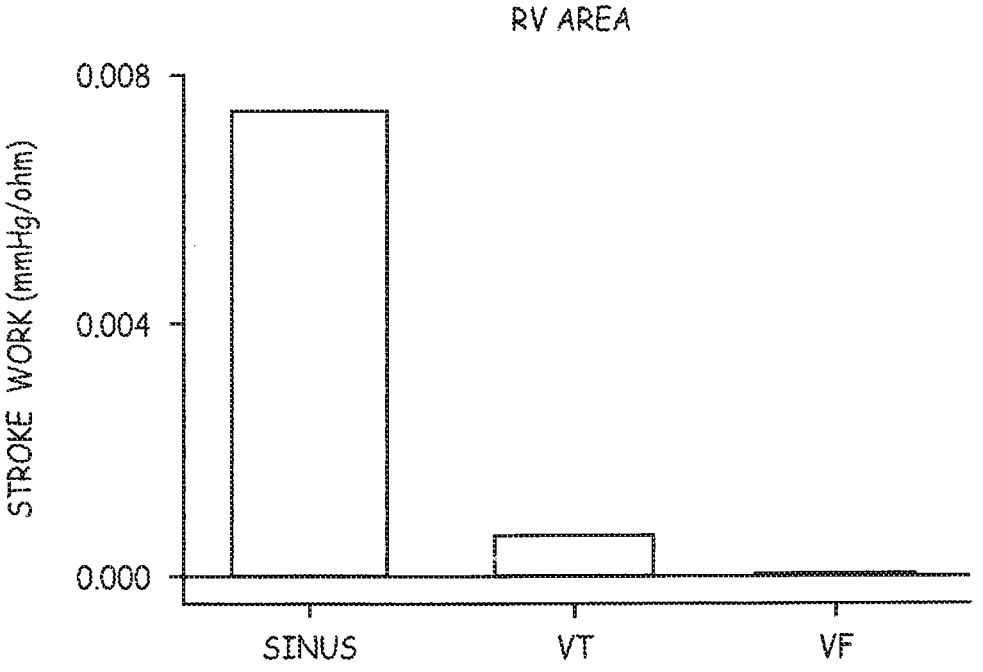
RV AREA
STROKE WORK (mmHg/ohm)
0.008
0.004
0.000
SINUS
VT
VF

FIG. 6B

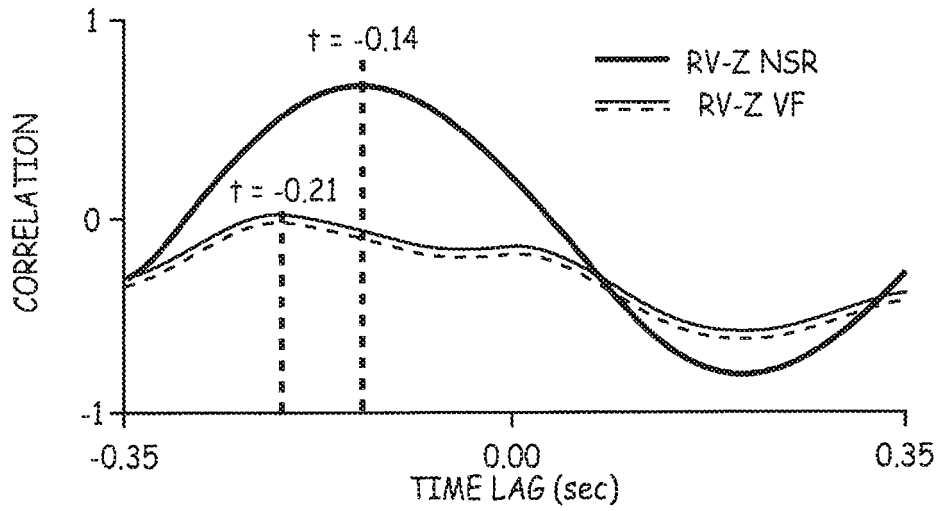
1
0
-1
CORRELATION
τ = -0.14
τ = -0.21
RV-Z NSR
RV-Z VF
-0.35
0.00
0.35
TIME LAG (sec)

FIG. 7

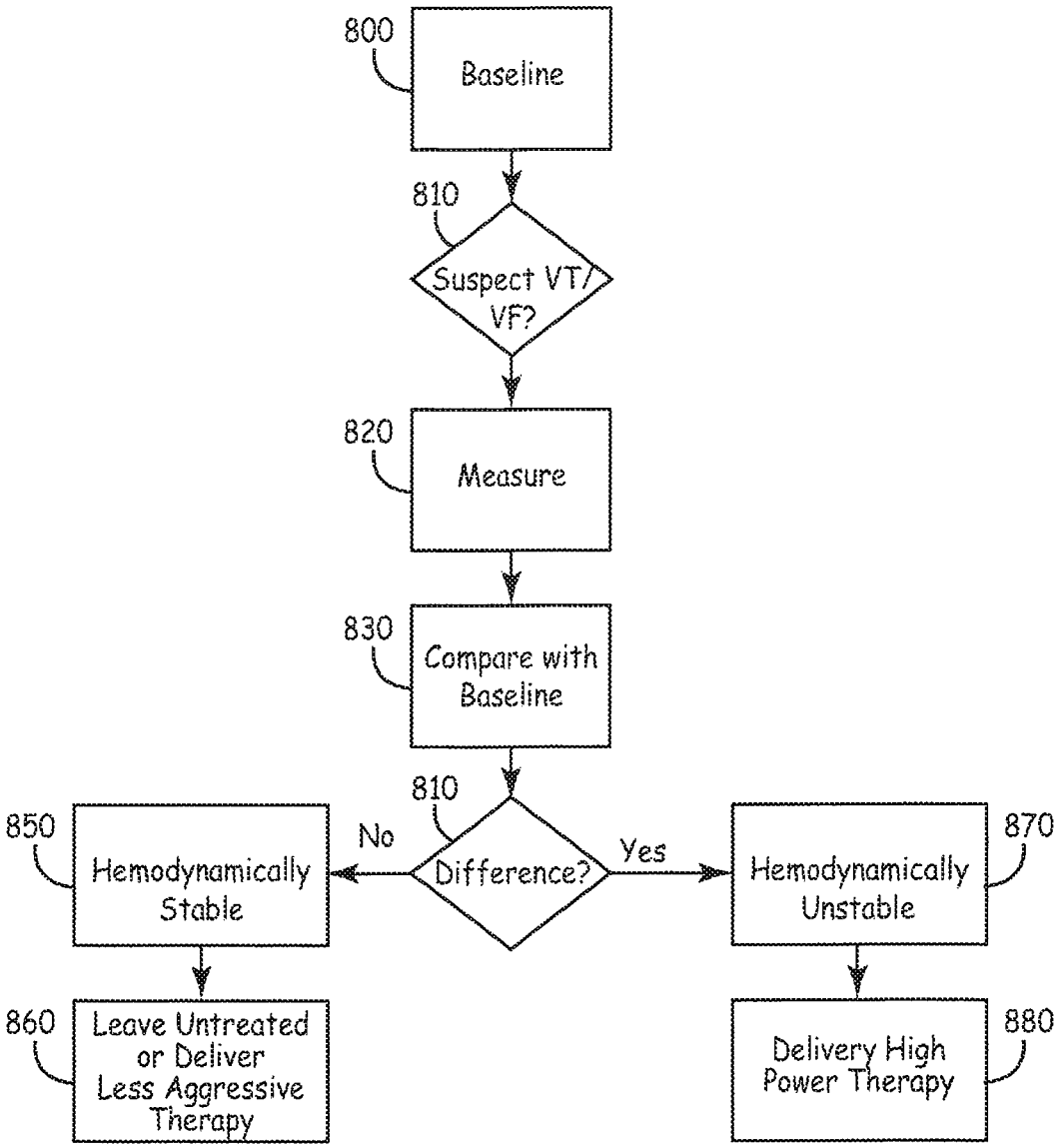
800
Baseline
810
Suspect VT/ VF?
820
Measure
830
Compare with Baseline
810
Difference?
No
Yes
850
Hemodynamically Stable
870
Hemodynamically Unstable
860
Leave Untreated or Deliver Less Aggressive Therapy
880
Delivery High Power Therapy

FIG. 8

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 7286875 B **[0007]**
- US 20070149890 A **[0007]**

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当前申请(专利权)人(译)	美敦力公司，INC.		
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发明人	HETTRICK, DOUGLAS, A. VINCENT, KEVIN, P. SARKAR, SHANTANU CHO, YONG, K. ZIELINSKI, TODD, M.		
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摘要(译)

植入式心律转复除颤器评估心律失常的血液动力学稳定性以确定是否进行除颤。该装置获得心脏压力和心脏阻抗数据并评估这些参数之间的相位关系。血流动力学稳定的节律将导致异相关系。