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# (54) CARDIAC RESYNCHRONIZATION THERAPY FOR IMPROVED HEMODYNAMICS BASED ON DISORDERED BREATHING DETECTION

(76) Inventors: **Quan Ni**, Shoreview, MN (US); **Douglas Daum**, Lino Lakes, MN (US); **Jeffrey E. Stahmann**, Ramsey, MN (US); **Kent Lee**, Fridley, MN (US); **Jesse Hartley**, Lino Lakes, MN (US)

Correspondence Address:
**HOLLINGSWORTH & FUNK, LLC**
**Suite 125**
**8009 34th Avenue South**
**Minneapolis, MN 55425 (US)**

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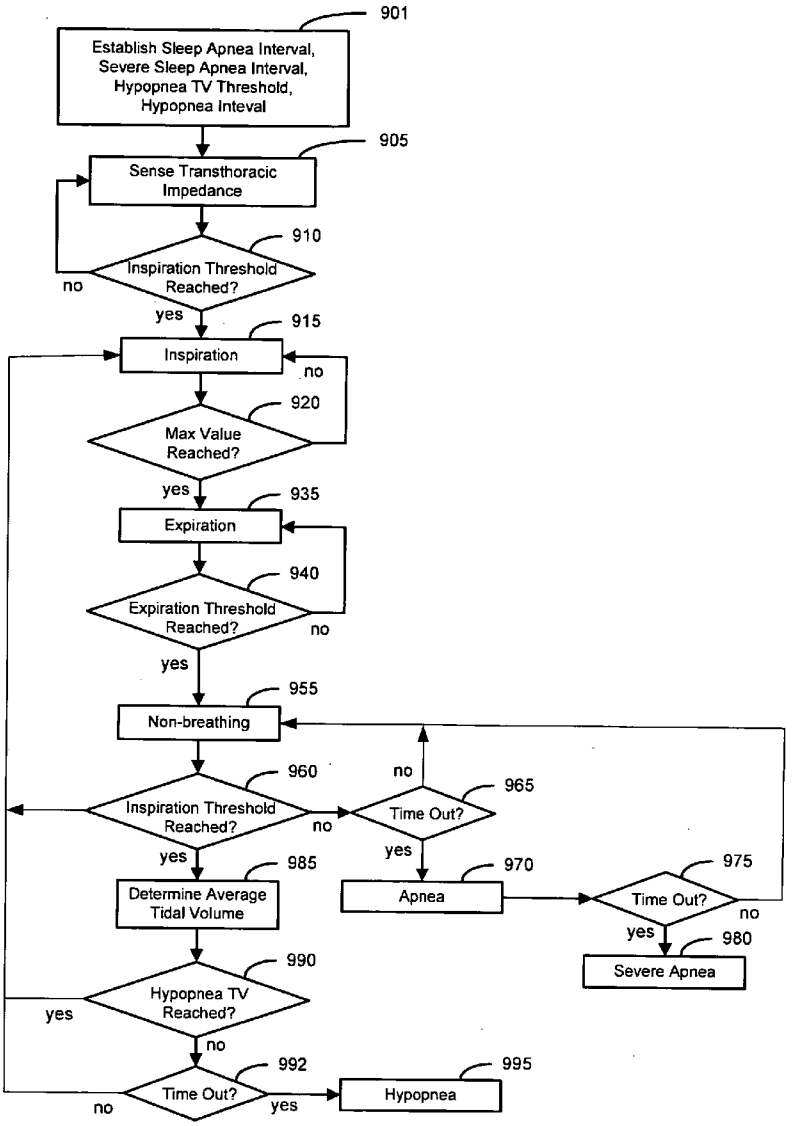
(57) **ABSTRACT**

The presence of disordered breathing is detected using an implantable medical device. A cardiac condition is detected that is indicative of the patient's cardiac status. Based on the presence of disordered breathing and the cardiac condition, the patient is identified as suitable for a cardiac resynchronization therapy.



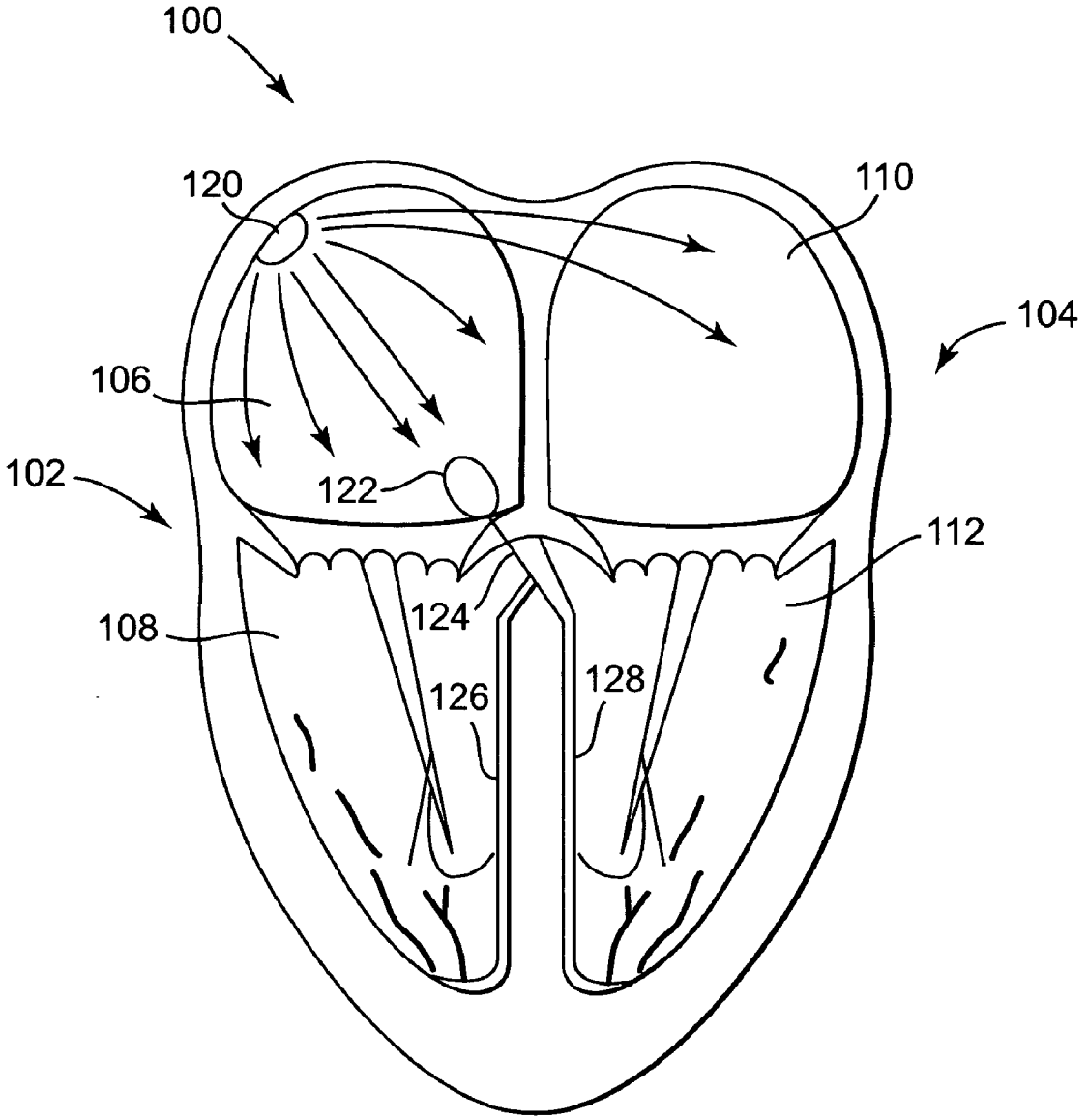



Fig. 1

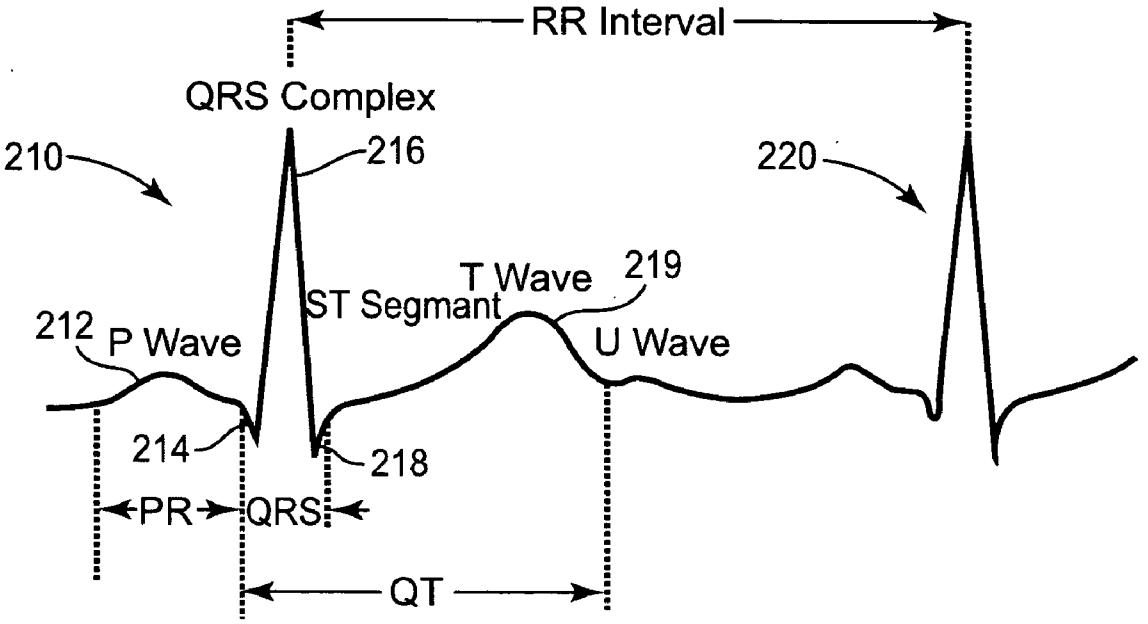

RR Interval
QRS Complex
210
216
220
T Wave
219
ST Segmant
212
P Wave
U Wave
214
218
PR
QRS
QT

Fig. 2

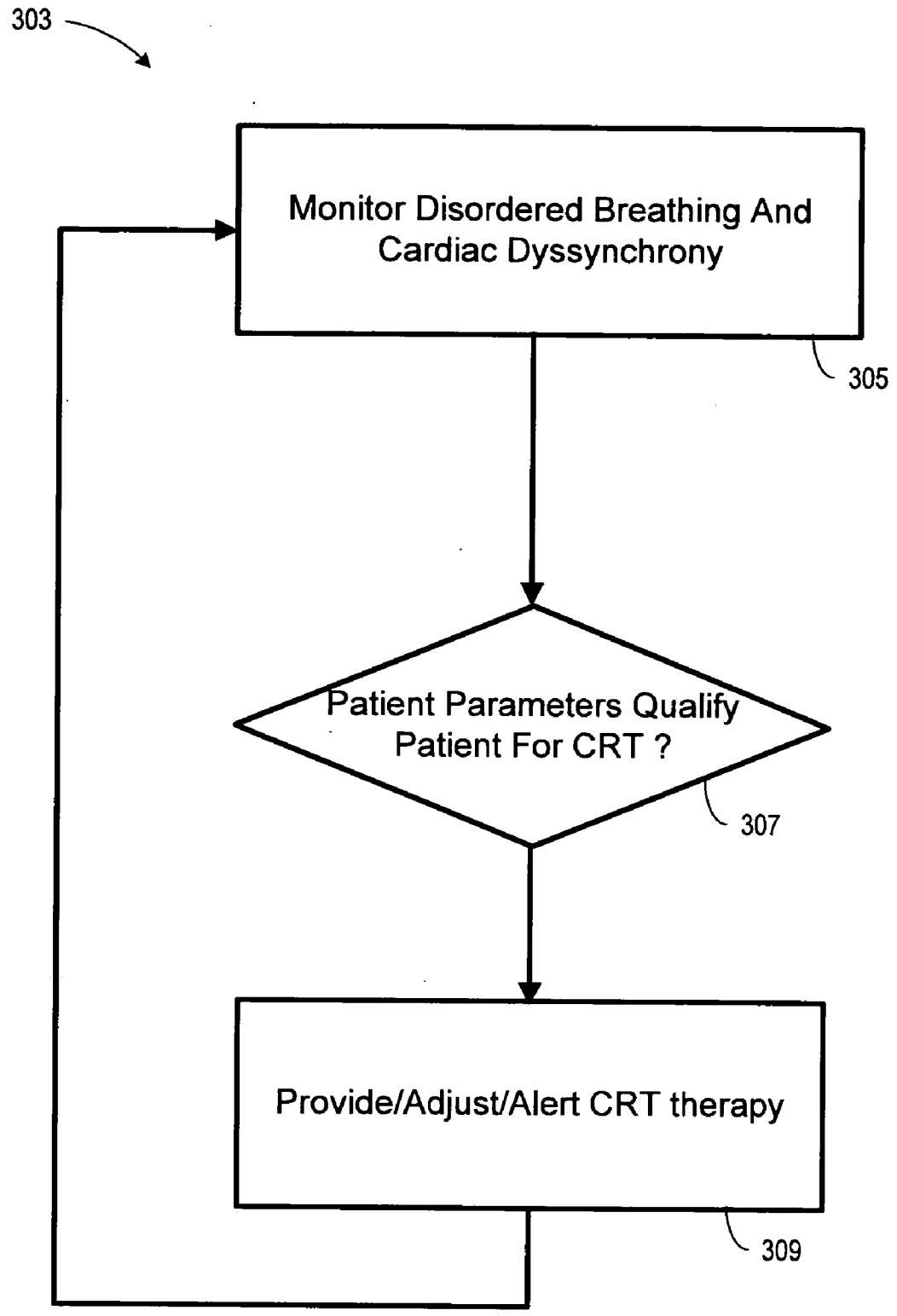

303
Monitor Disordered Breathing And Cardiac Dyssynchrony
305
Patient Parameters Qualify Patient For CRT ?
307
Provide/Adjust/Alert CRT therapy
309

*FIG. 3A*

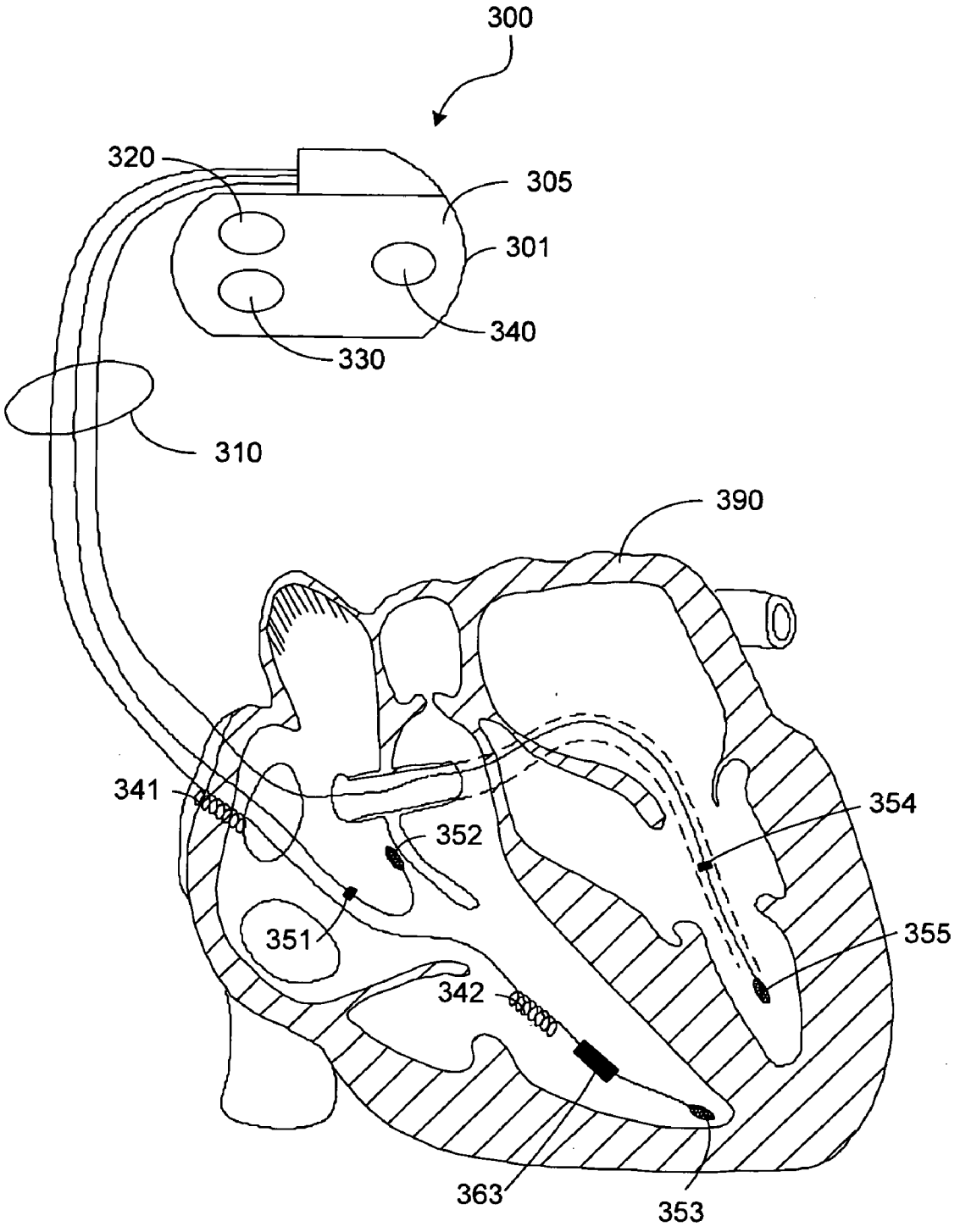



Fig. 3B

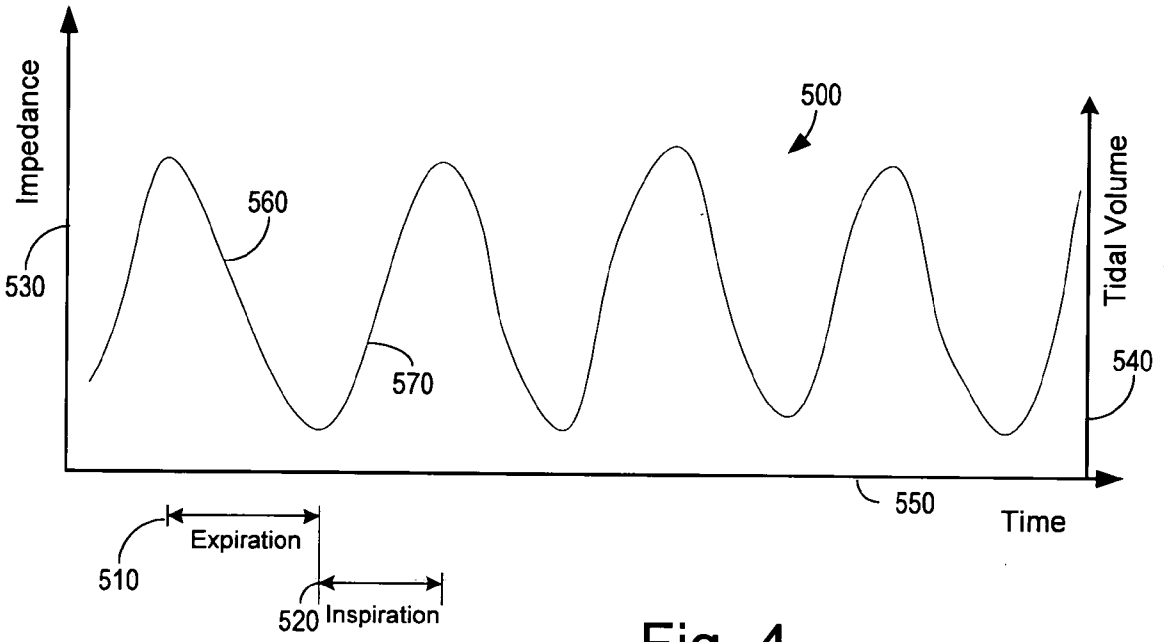

Impedance
500
560
530
570
Tidal Volume
540
550
Time
Expiration
510
520
Inspiration

Fig. 4

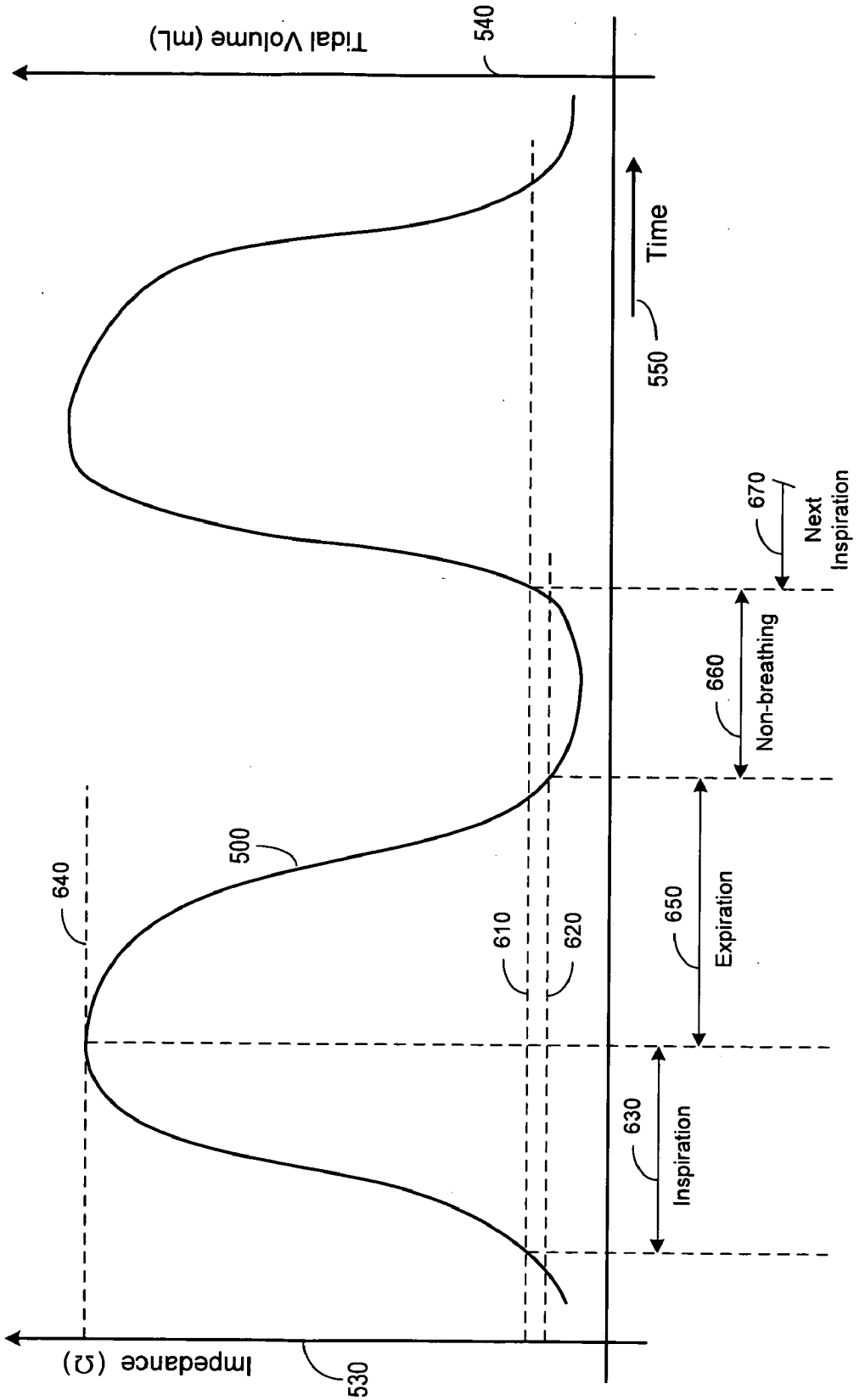

Tidal Volume (mL)
540
Time
550
670
Next Inspiration
660
Non-breathing
650
Expiration
630
Inspiration
500
640
610
620
Impedance (Ω)
530

Fig. 5

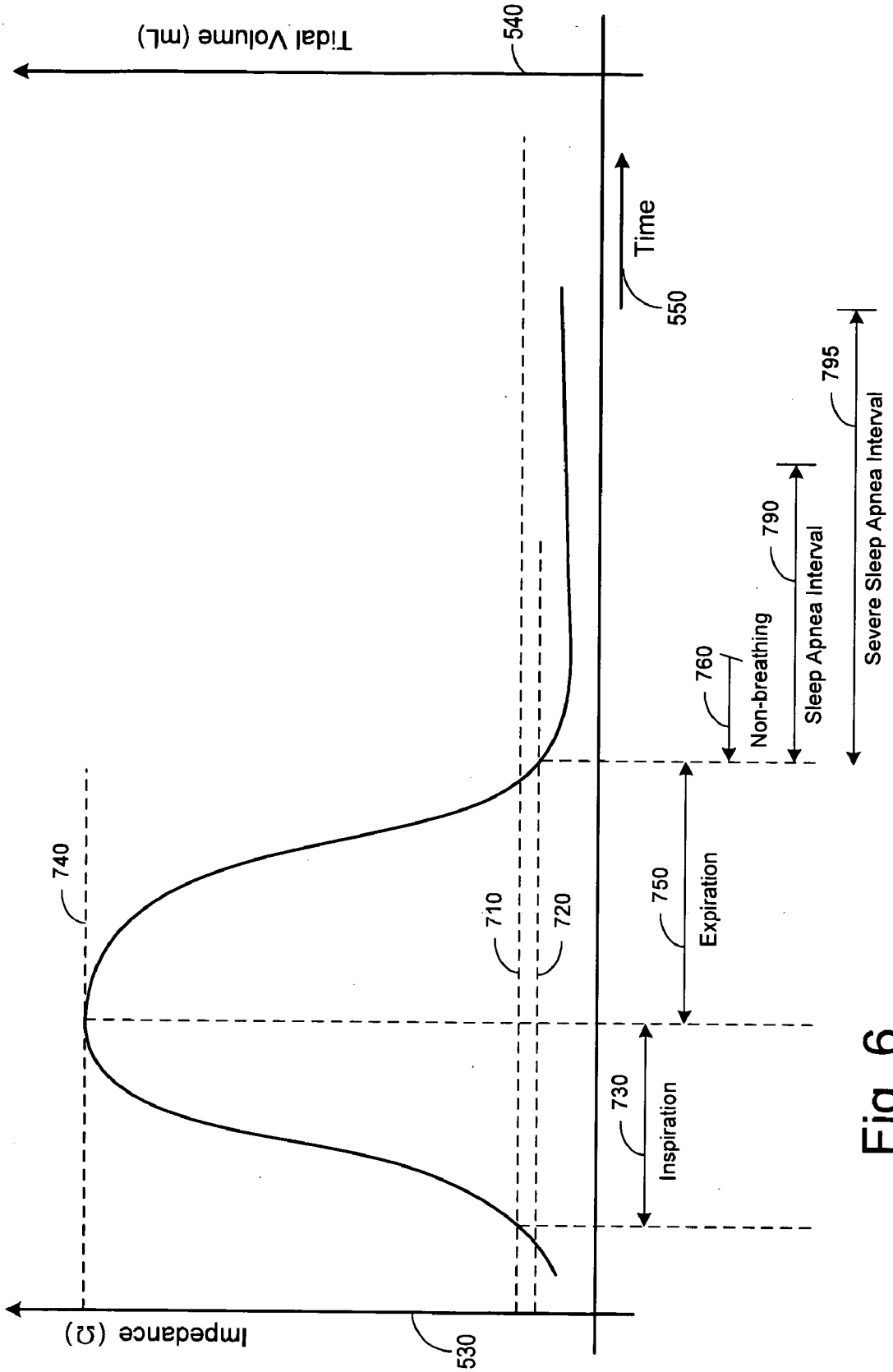

Tidal Volume (mL)
540
Time
550
795
Severe Sleep Apnea Interval
790
Sleep Apnea Interval
760
Non-breathing
740
710
720
750
Expiration
730
Inspiration
Impedance (Ω)
530

Fig. 6

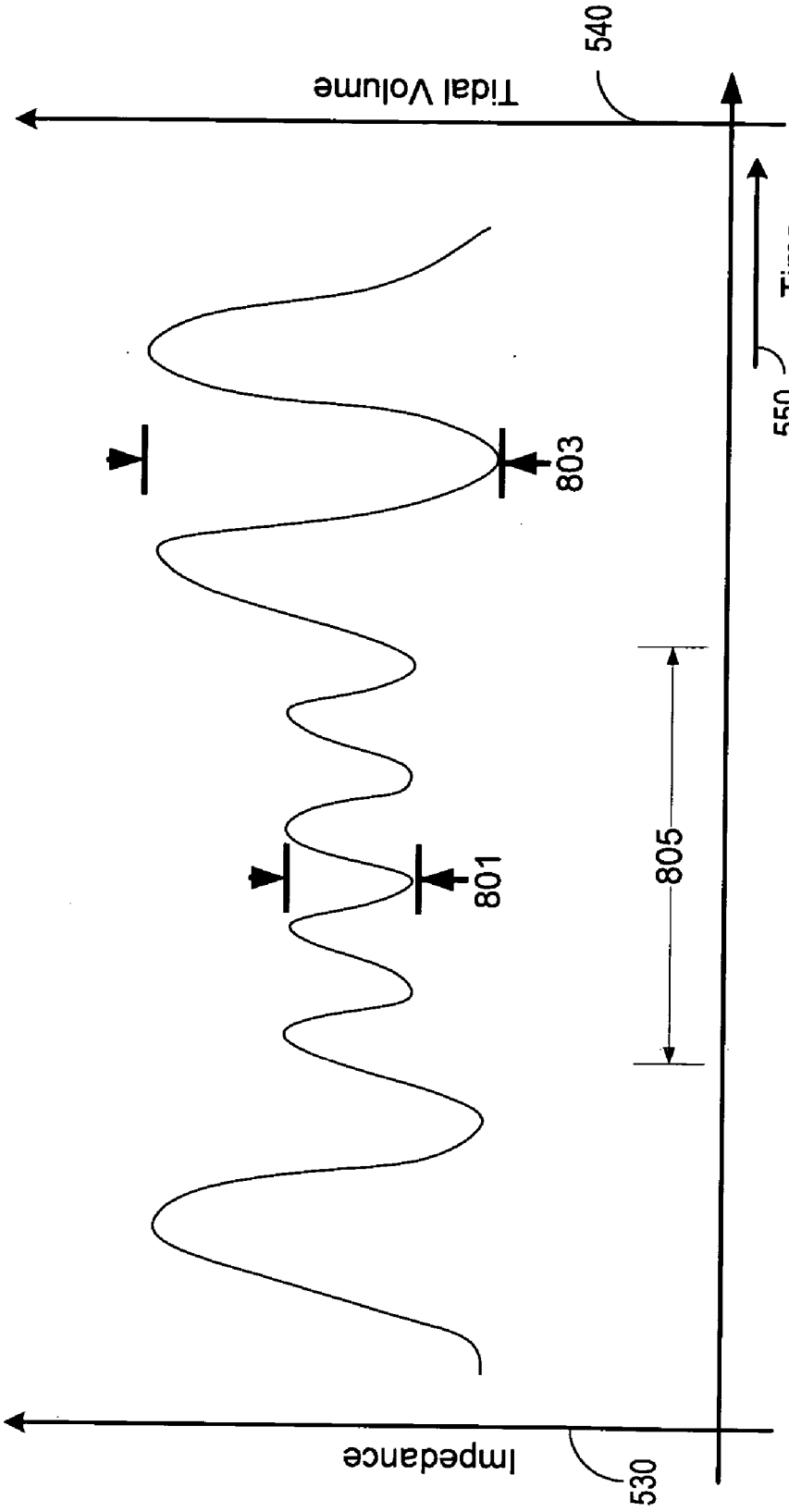



Fig. 7

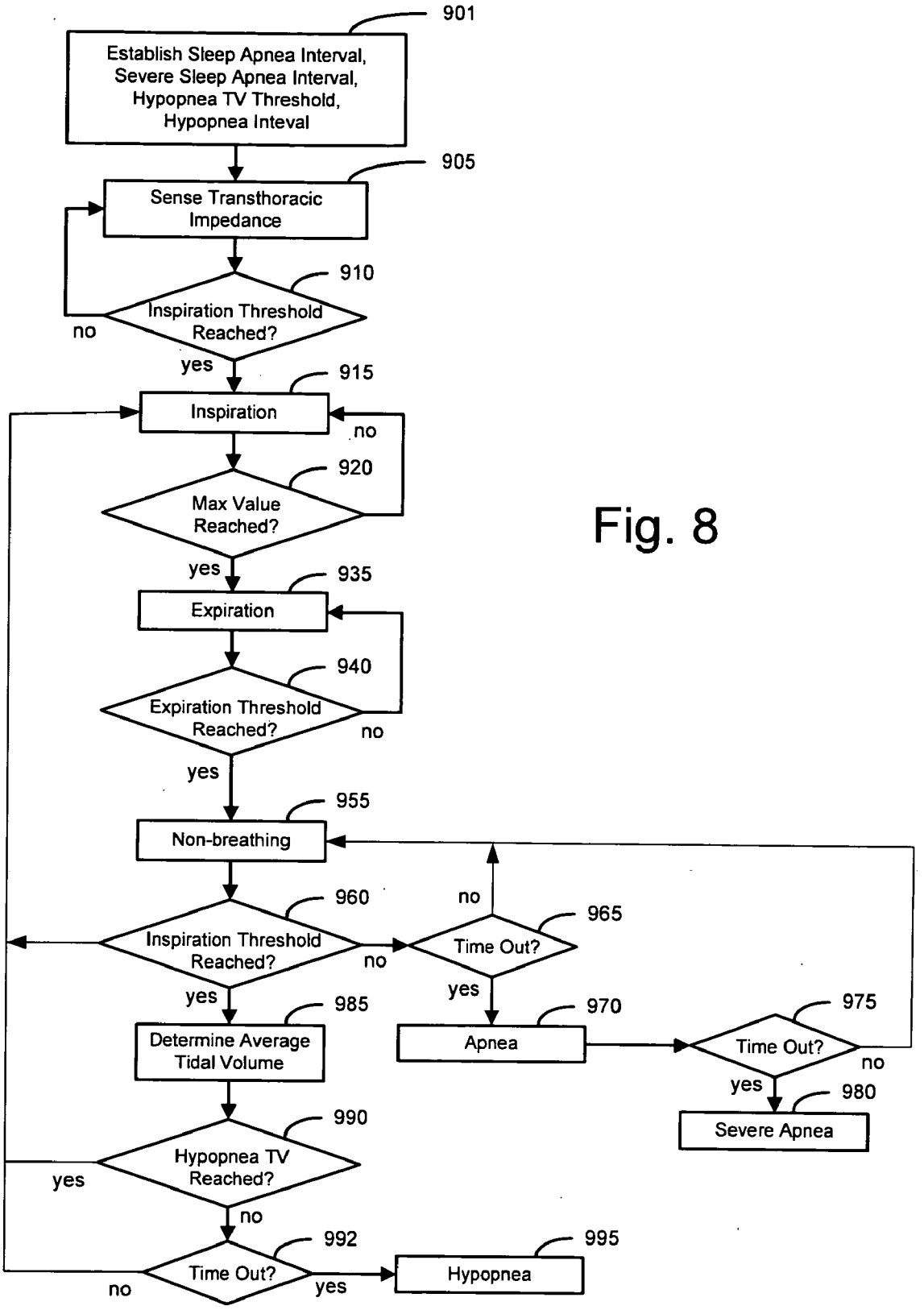
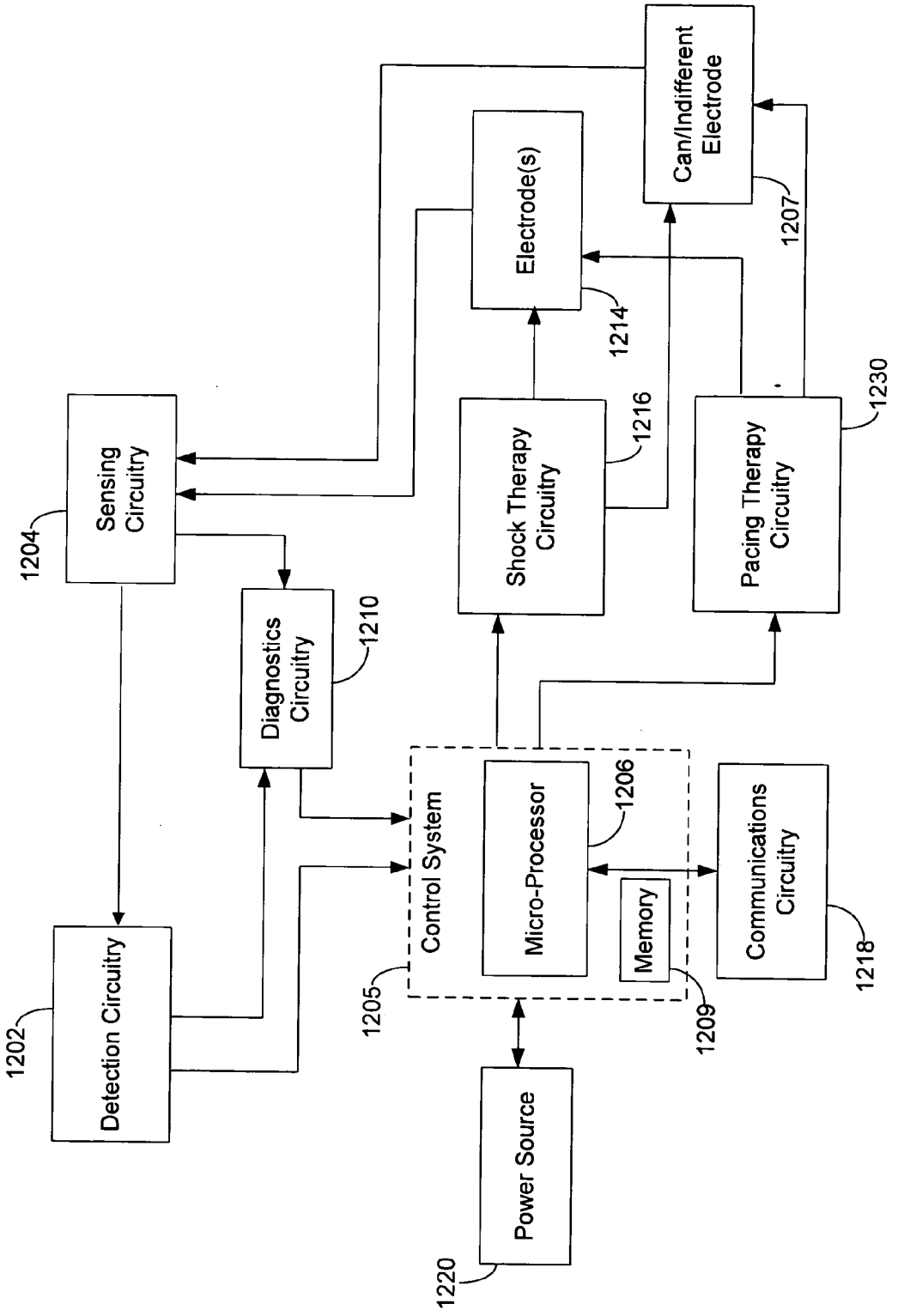

901
Establish Sleep Apnea Interval, Severe Sleep Apnea Interval, Hypopnea TV Threshold, Hypopnea Inteval
905
Sense Transthoracic Impedance
910
Inspiration Threshold Reached?
no
yes
915
Inspiration
no
920
Max Value Reached?
yes
935
Expiration
940
Expiration Threshold Reached?
no
yes
955
Non-breathing
960
Inspiration Threshold Reached?
no
965
Time Out?
no
yes
985
Determine Average Tidal Volume
970
Apnea
975
Time Out?
no
yes
980
Severe Apnea
990
Hypopnea TV Reached?
yes
no
992
Time Out?
no
yes
995
Hypopnea

Fig. 8

Fig. 9


Can/Indifferent Electrode
1207
Electrode(s)
1214
Sensing Circuitry
1204
Shock Therapy Circuitry
1216
Pacing Therapy Circuitry
1230
Diagnostics Circuitry
1210
Control System
1205
Micro-Processor
1206
Memory
1209
Communications Circuitry
1218
Detection Circuitry
1202
Power Source
1220

# CARDIAC RESYNCHRONIZATION THERAPY FOR IMPROVED HEMODYNAMICS BASED ON DISORDERED BREATHING DETECTION

## FIELD OF THE INVENTION

[0001] The present invention relates generally to implantable medical devices and, more particularly, to cardiac sensing and/or stimulation devices with disordered breathing detection.

## BACKGROUND OF THE INVENTION

[0002] The healthy heart produces regular, synchronized contractions. Rhythmic contractions of the heart are normally initiated by the sinoatrial (SA) node, which is a group of specialized cells located in the upper right atrium. The SA node is the normal pacemaker of the heart, typically initiating 60-100 heartbeats per minute. When the SA node is pacing the heart normally, the heart is said to be in normal sinus rhythm.

[0003] If the heart's electrical activity becomes uncoordinated or irregular, the heart is denoted to be arrhythmic. Cardiac arrhythmia impairs cardiac efficiency and may be a potential life-threatening event. Cardiac arrhythmias have a number of etiological sources, including tissue damage due to myocardial infarction, infection, or degradation of the heart's ability to generate or synchronize the electrical impulses that coordinate contractions.

[0004] Bradycardia occurs when the heart rhythm is too slow. This condition may be caused, for example, by impaired function of the SA node, denoted sick sinus syndrome, or by delayed propagation or blockage of the electrical impulse between the atria and ventricles. Bradycardia produces a heart rate that is too slow to maintain adequate circulation.

[0005] When the heart rate is too rapid, the condition is denoted tachycardia. Tachycardia may have its origin in either the atria or the ventricles. Tachycardias occurring in the atria of the heart, for example, include atrial fibrillation and atrial flutter. Both conditions are characterized by rapid contractions of the atria. Besides being hemodynamically inefficient, the rapid contractions of the atria may also adversely affect the ventricular rate.

[0006] Ventricular tachycardia occurs, for example, when electrical activity arises in the ventricular myocardium at a rate more rapid than the normal sinus rhythm. Ventricular tachycardia may quickly degenerate into ventricular fibrillation. Ventricular fibrillation is a condition denoted by extremely rapid, uncoordinated electrical activity within the ventricular tissue. The rapid and erratic excitation of the ventricular tissue prevents synchronized contractions and impairs the heart's ability to effectively pump blood to the body, which is a fatal condition unless the heart is returned to sinus rhythm within a few minutes.

[0007] Implantable cardiac rhythm management systems have been used as an effective treatment for patients with serious arrhythmias, as well as for patients with conditions such as heart failure. These systems typically include one or more leads and circuitry to sense signals from one or more interior and/or exterior surfaces of the heart. Such systems also include circuitry for generating electrical pulses that are applied to cardiac tissue at one or more interior and/or exterior surfaces of the heart. For example, leads extending into the patient's heart are connected to electrodes that contact the myocardium for sensing the heart's electrical signals and for delivering pulses to the heart in accordance with various therapies for treating arrhythmias.

[0008] People with severe cardiopulmonary deficiencies, such as those associated with chronic heart failure and other cardiopulmonary maladies, are particularly susceptible to morbidities associated with disordered breathing conditions such as sleep apnea. Disordered breathing may be caused by a wide spectrum of respiratory conditions involving the disruption of the normal respiratory cycle. Although disordered breathing often occurs during sleep, the condition may also occur while the patient is awake. Respiratory disruption can be particularly serious for patients concurrently suffering from cardiovascular deficiencies, such as congestive heart failure. Unfortunately, disordered breathing is often undiagnosed. If left untreated, the effects of disordered breathing may result in serious health consequences for the patient.

[0009] Various types of disordered respiration have been identified, including, for example, apnea, hypopnea, dyspnea, hyperpnea, tachypnea, orthopnea, paroxysmal nocturnal dyspnea, and periodic breathing, including Cheyne-Stokes respiration (CSR). Apnea is a fairly common disorder characterized by periods of interrupted breathing. Apnea is typically classified based on its etiology. One type of apnea, denoted obstructive apnea, occurs when the patient's airway is obstructed by the collapse of soft tissue in the rear of the throat. Central apnea is caused by a derangement of the central nervous system control of respiration. The patient ceases to breathe when control signals from the brain to the respiratory muscles are absent or interrupted. Mixed apnea is a combination of the central and obstructive apnea types. Regardless of the type of apnea, people experiencing an apnea event stop breathing for a period of time. The cessation of breathing may occur repeatedly during sleep, sometimes hundreds of times a night and sometimes for a minute or longer.

## SUMMARY OF THE INVENTION

[0010] The present invention is directed to methods and devices that detect the presence of disordered breathing and a cardiac condition indicative of a patient's cardiac status. Methods and devices of the present invention are further directed to identifying a patient as suitable for a cardiac resynchronization therapy based on the presence of disordered breathing and a cardiac condition indicative of a patient's cardiac status.

[0011] According to embodiments of the present invention, the presence of disordered breathing is detected using an implantable medical device. A cardiac condition is detected that is indicative of the patient's cardiac status. Based on the presence of disordered breathing and the cardiac condition, the patient is identified as suitable for a cardiac resynchronization therapy.

[0012] Such methods may further involve delivering at least one of a cardiac pacing therapy other than a cardiac resynchronization therapy, a cardiac shock therapy, and a cardiac neurostimulation therapy. Detecting the presence of disordered breathing may involve detecting at least one of

obstructive sleep apnea, central sleep apnea, hypopnea, orthopnea, paroxysmal nocturnal dyspnea, and Cheyne-Stokes respiration.

[0013] The implantable medical device may be enabled to perform the cardiac resynchronization therapy based on identifying the patient as suitable for the cardiac resynchronization therapy. For example, a pulse generator may be provided in the implantable medical device and coupled to electrodes, and the pulse generator and electrodes may be configured for cardiac resynchronization therapy delivery. One or more of initiating, terminating, adjusting, or optimizing the cardiac resynchronization therapy may be effected in response to detecting the presence of disordered breathing and the cardiac condition.

[0014] Detecting the cardiac condition may involve detecting a ventricular dysynchrony in the patient's heart via an implantable or patient-external sensing arrangement. Detecting the cardiac condition may also involve detecting left ventricular systolic dysfunction via an implantable or patient-external sensing arrangement. Detecting the cardiac condition may further involve detecting a left ventricular systolic dysfunction comprising a left ventricular ejection fraction value less than a predetermined limit. Detecting the cardiac condition may involve determining that a QRS complex pulse width of a cardiac cycle exceeds a predetermined limit. Detecting the cardiac condition may also involve detecting a ventricular wall motion asynchrony that exceeds a predetermined limit.

[0015] Detecting the presence of disordered breathing may be used to trigger an alert using a patient-external device or a transfer of data from the implantable medical device to the patient-external device. Detecting the presence of disordered breathing may involve detecting an apnea/hypopnea index greater than a predetermined limit. According to one approach, the implantable medical device may be enabled to perform a first cardiac resynchronization therapy in response to detecting obstructive sleep apnea, and enabled to perform a second cardiac resynchronization therapy after detecting central sleep apnea.

[0016] In embodiments that incorporate a pulse generator, methods of the present invention provide for adjusting an atrioventricular delay based on the detected disordered breathing. The cardiac resynchronization therapy, in such embodiments, may involve selecting a cardiac stimulation vector based on the detected disordered breathing.

[0017] In accordance with other embodiments, an implantable medical device included a housing configured for implantation in a patient. A lead system comprises an electrode arrangement and is coupled to the housing. A processor is provided in the housing and coupled to the lead system. The processor is configured to detect presence of disordered breathing, detect a cardiac condition indicative of the patient's cardiac status, and identify the patient as suitable for a cardiac resynchronization therapy based on the presence of disordered breathing and the cardiac condition.

[0018] The implantable medical device may include a pulse generator coupled to the processor and configured to deliver at least one of a cardiac pacing therapy other than a cardiac resynchronization therapy, a cardiac shock therapy, and a cardiac neurostimulation therapy. The processor may be configured to enable the pulse generator to perform the cardiac resynchronization therapy based on identifying the patient as suitable for the cardiac resynchronization therapy. The processor may be configured to adjust an atrioventricular delay based on the detected disordered breathing. The processor may be configured to detect at least one of obstructive sleep apnea, central sleep apnea, hypopnea, orthopnea, paroxysmal nocturnal dyspnea, and Cheyne-Stokes respiration.

[0019] In other embodiments, one or both of an implantable sensor arrangement and a patient-external sensor arrangement may be coupled to the implantable medical device. The processor may be configured to detect a ventricular dysynchrony in the patient's heart via one or both of the implantable or patient-external sensing arrangement. The processor may be coupled to communication circuitry configured to facilitate wireless communication between the processor and a patient-external device or system. The patient-external device or system may be configured to generate a clinician alert to initiate, terminate, adjust, or optimize the cardiac resynchronization therapy. The implantable medical device may include a transthoracic impedance measuring circuitry coupled to the processor and configured to detect patient breathing.

[0020] The above summary of the present invention is not intended to describe each embodiment or every implementation of the present invention. Advantages and attainments, together with a more complete understanding of the invention, will become apparent and appreciated by referring to the following detailed description and claims taken in conjunction with the accompanying drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0021] FIG. **1** is a sectional view of a heart illustrating the chambers and electrical conduction pathways;

[0022] FIG. **2** is a pictorial diagram of an electrocardiogram (ECG) waveform for two consecutive heartbeats;

[0023] FIG. **3**A illustrates an embodiment of a method in accordance with the present invention that qualifies a patient for cardiac resynchronization therapy (CRT) using a cardiac dyssynchrony measurement, and a detection and measurement of an AHI index value;

[0024] FIG. **3**B is an illustration of an implantable cardiac device including a lead assembly shown implanted in a sectional view of a heart, in accordance with embodiments of the invention;

[0025] FIG. **4** is a graph of a normal respiration signal measured by a transthoracic impedance sensor that may be utilized for monitoring, diagnosis and/or therapy in accordance with embodiments of the invention;

[0026] FIG. **5** is a respiration signal graph illustrating respiration intervals used for disordered breathing detection according to embodiments of the invention;

[0027] FIG. **6** is a graph of a respiration signal illustrating various intervals that may be used for detection of apnea in accordance with embodiments of the invention;

[0028] FIG. **7** is a respiration graph illustrating abnormally shallow respiration utilized in detection of disordered breathing in accordance with embodiments of the invention;

[0029] FIG. **8** is a flow chart illustrating a method of apnea and/or hypopnea detection according to embodiments of the invention; and

[0030] FIG. **9** is a block diagram illustrating various components of a cardiac monitoring and/or stimulation device in accordance with an embodiment of the present invention.

[0031] While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail below. It is to be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the invention is intended to cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

## DETAILED DESCRIPTION OF VARIOUS EMBODIMENTS

[0032] In the following description of the illustrated embodiments, references are made to the accompanying drawings, which form a part hereof, and in which is shown by way of illustration, various embodiments in which the invention may be practiced. It is to be understood that other embodiments may be utilized, and structural and functional changes may be made without departing from the scope of the present invention.

[0033] An implanted device according to the present invention may include one or more of the features, structures, methods, or combinations thereof described hereinbelow. For example, a monitoring device, diagnostic device, or a stimulation device (e.g., cardiac stimulator or cardiac neurostimulation device) may be implemented to include one or more of the advantageous features and/or processes described below. It is intended that such a monitor, diagnostic device, stimulator, or other implanted or partially implanted device need not include all of the features described herein, but may be implemented to include selected features that provide for unique structures and/or functionality. Such a device may be implemented to provide a variety of therapeutic or diagnostic functions.

[0034] A wide variety of implantable monitoring and/or stimulation devices may be configured to implement methodologies of the present invention, including cardiac monitoring or pacing devices, cardiac defibrillation devices, cardiac neurostimulation devices, cardio-respiratory detection of therapy devices, and other implantable devices that provide for monitoring of physiological signals of a patient. Such devices may include, for example, cardiac resynchronization therapy for improved hemodynamics based on disordered breathing detection in accordance with the present invention. Other non-limiting, representative examples of cardiac devices includes cardiac monitors, pacemakers, cardiovertors, defibrillators, resynchronizers, and other cardiac monitoring and therapy delivery devices. These devices may be configured with a variety of electrode arrangements, including transvenous, endocardial, and epicardial electrodes (i.e., intrathoracic electrodes), and/or subcutaneous, non-intrathoracic electrodes, including can, header, and indifferent electrodes, and subcutaneous array or lead electrodes (i.e., non-intrathoracic electrodes).

[0035] Embodiments of the present invention may be implemented in the context of a wide variety of medical devices, such as those listed above, and are referred to herein generally as patient-internal medical devices (PIMD) for convenience. A PIMD implemented in accordance with the present invention may incorporate one or more of the electrode types identified above and/or combinations thereof.

[0036] The following description is directed generally to aspects of the invention embodied in various types of implantable cardiac devices. It is understood that aspects of the invention may be implemented in other types of implantable medical devices, such as cardio-respiratory monitoring devices, cardiac neurostimulation devices, and other monitoring, diagnostic, or stimulation devices, as for example.

[0037] The heart is a muscular organ comprising multiple chambers that operate in concert to circulate blood throughout the body's circulatory system. As shown in FIG. **1**, a heart **100** includes a right-side portion or pump **102** and a left-side portion or pump **104**. The right-side portion **102** includes a right atrium **106** and a right ventricle **108**. Similarly, the left-side portion **104** includes a left atrium **110** and a left ventricle **112**. Oxygen-depleted blood returning to the heart **100** from the body collects in the right atrium **106**. When the right atrium **106** fills, the oxygen-depleted blood passes into the right ventricle **108** where it can be pumped to the lungs (not shown) via the pulmonary arteries (not shown). Within the lungs, waste products (e.g., carbon dioxide) are removed from the blood and expelled from the body and oxygen is transferred to the blood. Oxygen-rich blood returning to the heart **100** from the lungs via the pulmonary veins (not shown) collects in the left atrium **110**. The circuit between the right-side portion **102**, the lungs, and the left atrium **110** is generally referred to as the pulmonary circulation. When the left atrium **110** fills, the oxygen-rich blood passes into the left ventricle **112** where it can be pumped throughout the entire body. In so doing, the heart **100** is able to supply oxygen to the body and facilitate the removal of waste products from the body.

[0038] To circulate blood throughout the body's circulatory system as described above, a beating heart performs a cardiac cycle that includes a systolic phase and a diastolic phase. During the systolic phase (e.g., systole), the ventricular muscle cells of the right and left ventricles **108**, **112** contract to pump blood through the pulmonary circulation and throughout the body, respectively. Conversely, during the diastolic phase (e.g., diastole), the ventricular muscle cells of the right and left ventricles **108**, **112** relax, during which the right and left atriums **106**, **110** contract to force blood into the right and left ventricles **108**, **112**, respectively. Typically, the cardiac cycle occurs at a frequency between 60 and 100 cycles per minute and can vary depending on physical exertion and/or emotional stimuli, such as, pain or anger. The volume of blood pumped from the left ventricle (expressed as a percentage), relative to the total volume of blood in the left ventricle before contraction, is known as the left ventricular ejection fraction (LVEF).

[0039] The contractions of the muscular walls of each chamber of the heart **100** are controlled by a complex conduction system that propagates electrical signals to the heart muscle tissue to effectuate the atrial and ventricular contractions necessary to circulate the blood. As shown in

FIG. **1**, the complex conduction system includes an atrial node **120** (e.g., the sinoatrial node) and a ventricular node **122** (e.g., the atrioventricular node). The sinoatrial node **120** initiates an electrical impulse that spreads through the muscle tissues of the right and left atriums **106**, **110** and the atrioventricular node **122**. As a result, the right and left atriums **106**, **110** contract to pump blood into the right and left ventricles **108**, **112** as discussed above. At the atrioventricular node **122**, the electrical signal is momentarily delayed before propagating through the right and left ventricles **108**, **112**. Within the right and left ventricles **108**, **112**, the ventricular conduction system includes right and left bundles branches **126**, **128** that extend from the atrioventricular node **122** via a Bundle of His **124**. The electrical impulse spreads through the muscle tissues of the right and left ventricles **108**, **112** via the right and left bundle branches **126**, **128**, respectively. As a result, the right and left ventricles **108**, **112** contract to pump blood throughout the body as discussed above.

[**0040**] Normally, the muscular walls of each chamber of the heart **100** contract synchronously in a precise sequence to efficiently circulate the blood as described above. In particular, both the right and left atriums **106**, **110** contract (e.g., atrial contractions) and relax synchronously. Shortly after the atrial contractions, both the right and left ventricles **108**, **112** contract (e.g., ventricular contractions) and relax synchronously. Several disorders or arrhythmias of the heart can prevent the heart from operating normally, such as, blockage of the conduction system, heart disease (e.g., coronary artery disease), abnormal heart valve function, or heart failure.

[**0041**] Blockage in the conduction system can cause a slight or severe delay in the electrical impulses propagating through the atrioventricular node **122**, causing inadequate ventricular relations and filling. In situations where the blockage is in the ventricles (e.g., the right and left bundle branches **126**, **128**), the right and/or left ventricles **108**, **112** can only be excited through slow muscle tissue conduction. As a result, the muscular walls of the affected ventricle (**108** and/or **112**) do not contract synchronously (e.g., asynchronous contraction), thereby, reducing the overall effectiveness of the heart **100** to pump oxygen-rich blood throughout the body. For example, asynchronous contraction of the left ventricular muscles can degrade the global contractility (e.g., the pumping power) of the left ventricle **112** which can be measured by the peak ventricular pressure change during systole (denoted as "LV+dp/dt"). A decrease in LV+dp/dt corresponds to a worsened pumping efficiency.

[**0042**] Similarly, heart valve disorders (e.g., valve regurgitation or valve stenosis) can interfere with the heart's **100** ability to pump blood, thereby, reducing stroke volume (i.e., aortic pulse pressure) and/or cardiac output.

[**0043**] Various medical procedures have been developed to address these and other heart disorders. In particular, cardiac resynchronization therapy can be used to improve the conduction pattern and sequence of the heart. CRT involves the use of an artificial electrical stimulator that is surgically implanted within the patient's body. Leads from the stimulator can be affixed at a desired location within the heart to effectuate synchronous atrial and/or ventricular contractions. Typically, the location of the leads (e.g., stimulation site) is selected based upon the severity and/or location of the blockage. Electrical stimulation signals can be delivered to resynchronize the heart, thereby, improving cardiac performance.

[**0044**] Results from clinical studies have shown that hemodynamic response to CRT typically varies from patient to patient, ranging from very positive (e.g., improvement) to substantially negative (e.g., deterioration). Additionally, hemodynamic response can also vary based upon the stimulation site used to apply CRT. CRT therapy is currently not indicated for patients with mild symptoms of heart failure, due to the potential for a negative hemodynamic response as seen in the above mentioned clinical study results.

[**0045**] Sleep disordered breathing (SDB), including obstructive and central sleep apneas and hypopneas, can cause patho-physiological changes that directly relate to progression of heart failure. Mechanical therapy for obstructive sleep apnea (OSA) has shown benefits in reduced daytime systolic hypertension, mean heart rate, left-ventricular end-systolic dimensions, and improved LVEF. This suggests a cause-effect relationship between OSA and CHF. Patients with early stage CHF and OSA are likely to have a worse clinical trajectory than patients without SDB. CSA, unlike OSA, can arise as a consequence of heart failure. CSA associated with CSR may be considered as a reflection of severely compromised cardiac function with elevated left-ventricular filling pressure. CSA may also reflect acute changes of left-ventricular function. Overnight deterioration of cardiac function related to OSA in the early part of sleep may cause a shift to CSA in the later part of sleep. Thus, CSA during sleep may provide an early indication of impaired left-ventricular function before the impairment is reflected in general functional status, such as assessed by New York Heart Association (NYHA) functional class.

[**0046**] Methods and devices in accordance with the present invention identify a subset of patients who are likely positive responders to CRT. In patients qualified according to embodiments of the present invention, the presence of sleep disordered breathing is used to invoke and/or perform one or more of the following actions: 1) Identify cardiac rhythm management (CRM) patients likely to benefit from CRT; 2) Enable CRT using a CRM system already implanted in a patient; 3) Improve a CRT therapy using an SDB index; 4) Display and/or provide information of a patient's SDB presence and/or severity to a clinician; 5) Adjust a CRM device's parameters based on a measured severity of SDB; and 6) Adjust a CRM device's parameters based on a detected presence and/or a measured severity of one or more of OSA, Central sleep apnea (CSA), orthopnea, paroxysmal nocturnal dyspnea, and Cheyne-Stokes respiration (CSR). Providing and/or adjusting CRT therapy in qualified patients may reduce cardiac dyssynchrony, improve cardiac function, reduce SDB, and/or improve the prognosis of heart failure patients.

[**0047**] The subset of CHF patients that may benefit from CRT may be qualified by one or more of the following measurements in combination with sleep disordered breathing detection of CSA, CSR and/or an apnea/hypopnea index (AHI) value or other useful disordered breathing index value greater than a predetermined limit, such as about 15 episodes per hour. Qualifying measurements include: an LVEF less than a predetermined limit (e.g., about 0.4), ventricular dysynchrony (which may be detected via implantable or

patient-external sensors) beyond a predetermined threshold or limit, such as a QRS complex width greater than a predetermined threshold, such as about 120 milliseconds, left ventricular dysfunction detected via implantable or patient-external sensors, ventricular wall motion asynchrony that exceeds a predetermined limit (such as is described in commonly owned US Patent Publication 2004/0015081, which is hereby incorporated herein by reference), and an NYHA functional classification of III or IV.

[0048] As an example, a device or method in accordance with the present invention may qualify a patient for CRT using a cardiac dyssynchrony measurement as obtained by the QRS complex width, and a detection and measurement of an AHI index value. Referring to FIG. **2**, an ECG waveform **200** describes the activation sequence of a patient's heart as recorded, for example, by a bi-polar cardiac sensing electrode of such a device. FIG. **2** is a magnified view of a first heartbeat **210** and a second heartbeat **220** of a patient's ECG waveform.

[0049] Referring to the first heartbeat **210**, the portion of the ECG waveform representing depolarization of the atrial muscle fibers is referred to as a P-wave **212**. Depolarization of the ventricular muscle fibers is collectively represented by a Q **214**, R **216**, and S **218** waves of the ECG waveform **200**, typically referred to as the QRS complex, which is a well-known morphologic feature of electrocardiograms. Finally, the portion of the waveform representing repolarization of the ventricular muscle fibers is known as a T wave **219**. Between contractions, the ECG waveform returns to an isopotential level.

[0050] The sensed ECG waveform **200** illustrated in FIG. **2** is typical of a far-field ECG signal, effectively a superposition of all the depolarizations occurring within the heart that result in contraction. The ECG waveform **200** may also be obtained indirectly, such as by using a signal separation methodology. Signal separation methodologies, such as blind source separation (BSS), are able to separate signals from individual sources that are mixed together into a composite signal. Signal separation techniques may be used to determine ventricular dyssynchrony, such as is further described in commonly owned U.S. patent application Ser. No. 10/955,397 filed on Sep. 30, 2004, which is hereby incorporated herein by reference.

[0051] For purposes of illustration, and not of limitation, various embodiments of devices that may be used to identify a patient as suitable for cardiac resynchronization therapy based on disordered breathing detection in accordance with the present invention are described herein in the context of PIMDs that may be implanted under the skin in the chest region of a patient. A PIMD may, for example, be implanted subcutaneously such that all or selected elements of the device are positioned on the patient's front, back, side, or other body locations suitable for monitoring physiological signals and, if so configured, delivering a therapy to the patient. For example, the PIMD may be configured to provide for monitoring of cardiac activity and/or delivering cardiac stimulation therapy. It is understood that elements of the PIMD may be located at several different body locations, such as in the chest, abdominal, or subclavian region with electrode elements respectively positioned at different regions near, around, in, or on the heart.

[0052] The primary housing (e.g., the active or non-active can) of the PIMD, for example, may be configured for positioning outside of the rib cage at an intercostal or subcostal location, within the abdomen, or in the upper chest region (e.g., subclavian location, such as above the third rib). In one implementation, one or more leads incorporating electrodes may be located in direct contact with the heart, great vessel or coronary vasculature, such as via one or more leads implanted by use of conventional transvenous delivery approaches. In another implementation, one or more electrodes may be located on the primary housing and/or at other locations about, but not in direct contact with the heart, great vessel or coronary vasculature.

[0053] In a further implementation, for example, one or more electrode subsystems or electrode arrays may be used to sense cardiac activity and/or deliver cardiac stimulation energy in a PIMD configuration employing an active can or a configuration employing a non-active can. Electrodes may be situated at anterior and/or posterior locations relative to the heart. Examples of useful electrode locations and features that may be incorporated in various embodiments of the present invention are described in commonly owned, co-pending U.S. patent application Ser. No. 10/465,520 filed Jun. 19, 2003, entitled "Methods and Systems Involving Subcutaneous Electrode Positioning Relative to a Heart"; Ser. No. 10/795,126 filed Mar. 5, 2004, entitled "Wireless ECG In Implantable Devices"; and Ser. No. 10/738,608 filed Dec. 17, 2003, entitled "Noise Canceling Cardiac Electrodes," which are hereby incorporated herein by reference.

[0054] In particular configurations, systems and methods may perform functions traditionally performed by pacemakers, such as providing various pacing therapies as are known in the art, in addition to cardioversion/defibrillation therapies. Examples of pacemaker circuitry, structures and functionality, aspects of which may be incorporated in a PIMD of the present invention are disclosed in commonly owned U.S. Pat. Nos. 4,562,841; 5,284,136; 5,376,106; 5,036,849; 5,540,727; 5,836,987; 6,044,298; and 6,055,454, which are hereby incorporated herein by reference. It is understood that PIMD configurations may provide for non-physiologic pacing support in addition to, or to the exclusion of, bradycardia and/or anti-tachycardia pacing therapies.

[0055] Various embodiments described herein may be used in connection with congestive heart failure (CHF) monitoring, diagnosis, and/or therapy. A PIMD of the present invention may incorporate CHF features involving dual-chamber or bi-ventricular pacing therapy, cardiac resynchronization therapy, cardiac function optimization, or other CHF related methodologies. For example, any PIMD of the present invention may incorporate features of one or more of the following references: commonly owned U.S. patent application Ser. No. 10/270,035, filed Oct. 11, 2002, entitled "Timing Cycles for Synchronized Multisite Cardiac Pacing;" and U.S. Pat. Nos. 6,411,848; 6,285,907; 4,928,688; 6,459,929; 5,334,222; 6,026,320; 6,371,922; 6,597,951; 6,424,865; and 6,542,775, each of which is hereby incorporated herein by reference.

[0056] FIG. **3**A illustrates an embodiment of a method **303** in accordance with the present invention that qualifies a patient for CRT using a cardiac dyssynchrony and SDB detection/measurement **305**. The cardiac dyssynchrony and SDB detection/measurement **305** may be performed by a single device, such as a PIMD, or may be performed by a

PIMD in combination with an external device, such as by using an advanced patient management system, as will be further described below.

[0057] The cardiac dyssynchrony and SDB detection/measurement **305** involves a measure of cardiac function, such as LVEF, QRS complex width, or other measure of cardiac function, as well as a measure of SDB, such as an AHI or other measure/detection of OSA, CSA, CSR, or the like. A decision **307** qualifies the patient for CRT, such as by detecting/measuring a combination of a QRS complex width greater than about 120 milliseconds and an apnea/hypopnea index (AHI) value greater than about 15 episodes per hour, for example.

[0058] If the patient is qualified by decision **307**, then a CRT therapy **309** involves one or more of providing a CRT therapy, adjusting a CRT therapy, and/or alerting a clinician to the qualification of the patient for the CRT therapy. For example, the following actions may be implemented: 1) Identify the cardiac rhythm management (CRM) patient as likely to benefit from CRT; 2) Enable CRT using a CRM system already implanted in the patient; 3) Modify an existing CRT therapy using the AHI value; 4) Display and/or provide information of the patient's SDB presence and/or severity to a clinician; 5) Adjust a CRM device's parameters based on a measured severity of SDB; and 6) Adjust a CRM device's parameters based on a detected presence and/or a measured severity of one or more of OSA, Central sleep apnea (CSA), orthopnea, paroxysmal nocturnal dyspnea, and Cheyne-Stokes respiration (CSR). Providing and/or Adjusting CRT therapy **309** in qualified patients may reduce cardiac dyssynchrony, improve cardiac function, reduce SDB, and improve the prognosis of heart failure patients.

[0059] Referring now to FIG. **3**B, the implantable device illustrated in FIG. **3**B is an embodiment of a PIMD that may incorporate cardiac resynchronization therapy for improved hemodynamics based on disordered breathing detection and ventricular dyssynchrony measurement in accordance with the present invention. In this example, the implantable device includes a cardiac rhythm management device (CRM) **300** including an implantable pulse generator **305** electrically and physically coupled to an intracardiac lead system **310**.

[0060] Portions of the intracardiac lead system **310** are inserted into the patient's heart **390**. The intracardiac lead system **310** includes one or more electrodes configured to sense electrical cardiac activity of the heart, deliver electrical stimulation to the heart, sense the patient's transthoracic impedance, and/or sense other physiological parameters, e,g, cardiac chamber pressure or temperature. Portions of the housing **301** of the pulse generator **305** may optionally serve as a can electrode.

[0061] Communications circuitry is disposed within the housing **301** for facilitating communication between the pulse generator **305** and an external communication device, such as a portable or bed-side communication station, patient-carried/worn communication station, or external programmer, for example. The communications circuitry may also facilitate unidirectional or bidirectional communication with one or more implanted, external, cutaneous, or subcutaneous physiologic or non-physiologic sensors, patient-input devices and/or information systems.

[0062] The pulse generator **305** may optionally incorporate a motion detector **320** that may be used to sense patient activity as well as various respiratory and cardiac related conditions. For example, the motion detector **320** may be optionally configured to sense snoring, activity level, and/or chest wall movements associated with respiratory effort, for example. The motion detector **320** may be implemented as an accelerometer positioned in or on the housing **301** of the pulse generator **305**. If the motion sensor is implemented as an accelerometer, the motion sensor may also provide respiratory, e.g. rales, coughing, and cardiac, e.g. S1-S4 heart sounds, murmurs, and other acoustic information.

[0063] The pulse generator **305** may optionally incorporate a posture detector **340** that may be used to sense patient posture. Posture detection is beneficial in the evaluation of sleep and sleep disordered breathing.

[0064] The lead system **310** and pulse generator **305** of the CRM **300** may incorporate one or more transthoracic impedance sensors that may be used to acquire the patient's respiratory waveform, or other respiratory-related information. The transthoracic impedance sensor may include, for example, one or more intracardiac electrodes **341**, **342**, **351-355**, **363** positioned in one or more chambers of the heart **390**. The intracardiac electrodes **341**, **342**, **351-355**, **363** may be coupled to impedance drive/sense circuitry **330** positioned within the housing of the pulse generator **305**.

[0065] In one implementation, impedance drive/sense circuitry **330** generates a current that flows through the tissue between an impedance drive electrode **351** and a can electrode on the housing **301** of the pulse generator **305**. The voltage at an impedance sense electrode **352** relative to the can electrode changes as the patient's transthoracic impedance changes. The voltage signal developed between the impedance sense electrode **352** and the can electrode is detected by the impedance sense circuitry **330**. Other locations and/or combinations of impedance sense and drive electrodes are also possible.

[0066] The lead system **310** may include one or more cardiac pace/sense electrodes **351-355** positioned in, on, or about one or more heart chambers for sensing electrical signals from the patient's heart **390** and/or delivering pacing pulses to the heart **390**. The intracardiac sense/pace electrodes **351-355**, such as those illustrated in FIG. **3**B, may be used to sense and/or pace one or more chambers of the heart, including the left ventricle, the right ventricle, the left atrium and/or the right atrium. The lead system **310** may include one or more defibrillation electrodes **341**, **342** for delivering defibrillation/cardioversion shocks to the heart.

[0067] The pulse generator **305** may include circuitry for detecting cardiac arrhythmias and/or for controlling pacing or defibrillation therapy in the form of electrical stimulation pulses or shocks delivered to the heart through the lead system **310**. The pulse generator **305** may also incorporate circuitry, structures and functionality of the implantable medical devices disclosed in commonly owned U.S. Pat. Nos. 5,203,348; 5,230,337; 5,360,442; 5,366,496; 5,397,342; 5,391,200; 5,545,202; 5,603,732; and 5,916,243; 6,360,127; 6,597,951; and U.S. Pat. Publication No. 2002/0143264, which are hereby incorporated herein by reference.

[0068] Referring now to FIG. **4**, an impedance signal **500** is illustrated. Transthoracic impedance may be useful for detecting sleep-state and other indirect measurements of

brain activity, such as seizures, as well as breathing disorders. The impedance signal **500** may be developed, for example, from an impedance sense electrode in combination with a PIMD device. The impedance signal **500** is proportional to the transthoracic impedance, illustrated as an Impedance **530** on the abscissa of the left side of the graph in FIG. **4**.

[**0069**] The impedance **530** increases during any respiratory inspiration **520** and decreases during any respiratory expiration **510**. The impedance signal **500** is also proportional to the amount of air inhaled, denoted by a tidal volume **540**, illustrated on the abscissa of the right side of the graph in FIG. **4**. The variations in impedance during respiration, identifiable as the peak-to-peak variation of the impedance signal **500**, may be used to determine the respiration tidal volume **540**. Tidal volume **540** corresponds to the volume of air moved in a breath, one cycle of expiration **510** and inspiration **520**. A minute ventilation may also be determined, corresponding to the amount of air moved per a minute of time **550** illustrated on the ordinate of the graph in FIG. **4**.

[**0070**] The onset of breathing disorders may be determined using the impedance signal **530**, and detected breathing disorder information may be used to activate therapy in accordance with the present invention. During non-REM sleep, a normal respiration pattern includes regular, rhythmic inspiration—expiration cycles without substantial interruptions. When the tidal volume of the patient's respiration, as indicated by the transthoracic impedance signal, falls below a hypopnea threshold, then a hypopnea event is declared. For example, a hypopnea event may be declared if the patient's tidal volume falls below about 50% of a recent average tidal volume or other baseline tidal volume value for a predetermined time, e.g., equal to or greater than about 10 seconds. If the patient's tidal volume falls further to an apnea threshold, e.g., about 10% of the recent average tidal volume or other baseline value for a predetermined time, e.g., equal to or greater than about 10 seconds, an apnea event is declared.

[**0071**] An adequate quality and quantity of sleep is required to maintain physiological homeostasis. Prolonged sleep deprivation or periods of highly fragmented sleep ultimately has serious health consequences. Chronic lack of sleep may be associated with various cardiac or respiratory disorders affecting a patient's health and quality of life. Methods and systems for collecting and assessing sleep quality data are described in commonly owned U.S. patent application Ser. No. 10/642,998, entitled "Sleep Quality Data Collection and Evaluation," filed on Aug. 18, 2003, and hereby incorporated herein by reference. Evaluation of the patient's sleep patterns and sleep quality may be an important aspect of providing coordinated therapy to the patient, including respiratory and cardiac therapy.

[**0072**] FIGS. **5**, **6**, and **7** are graphs of transthoracic impedance and tidal volume, similar to FIG. **4** previously described. As stated earlier, using transthoracic impedance is one indirect method of determining brain state, such as by detecting sleep state, arousal, and disordered breathing, for example. As in FIG. **4**, FIGS. **5**, **6**, and **7**, illustrate the impedance signal **500** proportional to the transthoracic impedance, again illustrated as Impedance **530** on the abscissa of the left side of the graphs in FIGS. **5**, **6**, and **7**. The impedance **530** increases during any respiratory inspiration **520** and decreases during any respiratory expiration **510**. As before, the impedance signal **500** is also proportional to the amount of air inhaled, denoted the tidal volume **540**, illustrated on the abscissa of the right side of the graph in FIGS. **5**, **6**, and **7**. The magnitude of variations in impedance and tidal volume during respiration are identifiable as the peak-to-peak variation of the impedance signal **500**.

[**0073**] FIG. **5** illustrates respiration intervals used for disordered breathing detection useful in accordance with embodiments of the invention. Respiration intervals are used to detect apnea and hypopnea, as well as provide other sleep-state information for activating therapy in accordance with embodiments of the present invention. Detection of disordered breathing may involve defining and examining a number of respiratory cycle intervals. A respiration cycle is divided into an inspiration period corresponding to the patient inhaling, an expiration period, corresponding to the patient exhaling, and a non-breathing period occurring between inhaling and exhaling.

[**0074**] Respiration intervals are established using an inspiration threshold **610** and an expiration threshold **620**. The inspiration threshold **610** marks the beginning of an inspiration period **630** and is determined by the transthoracic impedance signal **500** rising above the inspiration threshold **610**. The inspiration period **630** ends when the transthoracic impedance signal **500** is a maximum **640**. The maximum transthoracic impedance signal **640** corresponds to both the end of the inspiration interval **630** and the beginning of an expiration interval **650**. The expiration interval **650** continues until the transthoracic impedance **500** falls below an expiration threshold **620**. A non-breathing interval **660** starts from the end of the expiration period **650** and continues until the beginning of a next inspiration period **670**.

[**0075**] Detection of sleep apnea and severe sleep apnea is illustrated in FIG. **6**. The patient's respiration signals are monitored and the respiration cycles are defined according to an inspiration **730**, an expiration **750**, and a non-breathing **760** interval as described in connection with FIG. **5**. A condition of sleep apnea is detected when a non-breathing period **760** exceeds a first predetermined interval **790**, denoted the sleep apnea interval. A condition of severe sleep apnea is detected when the non-breathing period **760** exceeds a second predetermined interval **795**, denoted the severe sleep apnea interval. For example, sleep apnea may be detected when the non-breathing interval exceeds about 10 seconds, and severe sleep apnea may be detected when the non-breathing interval exceeds about 20 seconds.

[**0076**] Hypopnea is a condition of disordered breathing characterized by abnormally shallow breathing. Hypopnea reduces oxygen to the brain, and is linked with altered brain activity and brain states. The altered brain activity and brain states indicative of hypopnea may be used by a PIMD device to activate therapy in accordance with embodiments of the present invention. FIG. **7** is a graph of tidal volume derived from transthoracic impedance measurements. The graph of FIG. **7** illustrates the tidal volume of a hypopnea episode compared to the tidal volume of a normal breathing cycle illustrated previously in FIG. **4**, which illustrated normal respiration tidal volume and rate. As shown in FIG. **7**, hypopnea involves a period of abnormally shallow respiration, possible at an increased respiration rate.

[0077] Hypopnea is detected by comparing a patient's respiratory tidal volume **803** to a hypopnea tidal volume **801**. The tidal volume for each respiration cycle may be derived from transthoracic impedance measurements acquired in the manner described previously. The hypopnea tidal volume threshold may be established by, for example, using clinical results providing a representative tidal volume and duration of hypopnea events. In one configuration, hypopnea is detected when an average of the patient's respiratory tidal volume taken over a selected time interval falls below the hypopnea tidal volume threshold. Furthermore, various combinations of hypopnea cycles, breath intervals, and non-breathing intervals may be used to detect hypopnea, where the non-breathing intervals are determined as described above.

[0078] In FIG. **7**, a hypopnea episode **805** is identified when the average tidal volume is significantly below the normal tidal volume. In the example illustrated in FIG. **7**, the normal tidal volume during the breathing process is identified as the peak-to peak value identified as the respiratory tidal volume **803**. The hypopnea tidal volume during the hypopnea episode **805** is identified as hypopnea tidal volume **801**. For example, the hypopnea tidal volume **801** may be about 50% of the respiratory tidal volume **803**. The value 50% is used by way of example only, and determination of thresholds for hypopnea events may be determined as any value appropriate for a given patient.

[0079] In the example above, if the tidal volume falls below 50% of the respiratory tidal volume **803**, the breathing episode may be identified as a hypopnea event, originating the measurement of the hypopnea episode **805**.

[0080] FIG. **8** is a flow chart illustrating a method of apnea and/or hypopnea detection useful for cardiac resynchronization therapy for improved hemodynamics based on disordered breathing detection in accordance with the present invention. Various parameters are established **901** before analyzing the patient's respiration for disordered breathing episodes, including, for example, inspiration and expiration thresholds, sleep apnea interval, severe sleep apnea interval, and hypopnea tidal volume (TV) threshold.

[0081] The patient's transthoracic impedance is measured **905** as described in more detail above. If the transthoracic impedance exceeds **910** the inspiration threshold, the beginning of an inspiration interval is detected **915**. If the transthoracic impedance remains below **910** the inspiration threshold, then the impedance signal is checked **905** periodically until inspiration **915** occurs.

[0082] During the inspiration interval, the patient's transthoracic impedance is monitored until a maximum value of the transthoracic impedance is detected **920**. Detection of the maximum value signals an end of the inspiration period and a beginning of an expiration period **935**.

[0083] The expiration interval is characterized by decreasing transthoracic impedance. When, at determination **940**, the transthoracic impedance falls below the expiration threshold, a non-breathing interval is detected **955**.

[0084] If the transthoracic impedance determination **960** does not exceed the inspiration threshold within a first predetermined interval, denoted the sleep apnea interval **965**, then a condition of sleep apnea is detected **970**. Severe sleep apnea **980** is detected if the non-breathing period extends beyond a second predetermined interval, denoted the severe sleep apnea interval **975**.

[0085] When the transthoracic impedance determination **960** exceeds the inspiration threshold, the tidal volume from the peak-to-peak transthoracic impedance is calculated, along with a moving average of past tidal volumes **985**. The peak-to-peak transthoracic impedance provides a value proportional to the tidal volume of the respiration cycle. This value is compared at determination **990** to a hypopnea tidal volume threshold. If, at determination **990**, the peak-to-peak transthoracic impedance is consistent with the hypopnea tidal volume threshold for a predetermined time **992**, then a hypopnea cycle **995** is detected.

[0086] FIG. **9** is a block diagram depicting various componentry of different arrangements of a PIMD in accordance with embodiments of the present invention. The components, functionality, and configurations depicted in FIG. **9** are intended to provide an understanding of various features and combinations of features that may be incorporated in a PIMD. It is understood that a wide variety of device configurations are contemplated, ranging from relatively sophisticated to relatively simple designs. As such, particular PIMD configurations may include some componentry illustrated in FIG. **9**, while excluding other componentry illustrated in FIG. **9**.

[0087] Illustrated in FIG. **9** is a processor-based control system **1205** which includes a micro-processor **1206** coupled to appropriate memory (volatile and/or non-volatile) **1209**, it being understood that any logic-based control architecture may be used. The control system **1205** is coupled to circuitry and components to sense, detect, and analyze electrical signals produced by the heart and deliver electrical stimulation energy to the heart under predetermined conditions to treat cardiac arrhythmias and/or other cardiac conditions. The control system **1205** and associated components also provide pacing therapy to the heart. The electrical energy delivered by the PIMD may be in the form of low energy pacing pulses or high-energy pulses for cardioversion or defibrillation.

[0088] Cardiac signals are sensed using the electrode(s) **1214** and the can or indifferent electrode **1207** provided on the PIMD housing. Cardiac signals may also be sensed using only the electrode(s) **1214**, such as in a non-active can configuration. As such, unipolar, bipolar, or combined unipolar/bipolar electrode configurations as well as multi-element electrodes and combinations of noise canceling and standard electrodes may be employed. The sensed cardiac signals are received by sensing circuitry **1204**, which includes sense amplification circuitry and may also include filtering circuitry and an analog-to-digital (A/D) converter. The sensed cardiac signals processed by the sensing circuitry **1204** may be received by noise reduction circuitry (not shown), which may further reduce noise before signals are sent to the detection circuitry **1202**.

[0089] Detection circuitry **1202** may include a signal processor that coordinates analysis of the sensed cardiac signals and/or other sensor inputs to detect cardiac arrhythmias, such as, in particular, tachyarrhythmia. Rate based and/or morphological discrimination algorithms may be implemented by the signal processor of the detection circuitry **1202** to detect and verify the presence and severity of an arrhythmic episode. Examples of arrhythmia detection

and discrimination circuitry, structures, and techniques, aspects of which may be implemented by a PIMD in accordance with the present invention are disclosed in commonly owned U.S. Pat. Nos. 5,301,677, 6,438,410, and 6,708,058, which are hereby incorporated herein by reference. Arrhythmia detection methodologies particularly well suited for implementation in cardiac monitoring and/or stimulation systems are described hereinbelow.

[0090] The detection circuitry **1202** communicates cardiac signal information to the control system **1205**. Memory circuitry **1209** of the control system **1205** contains parameters for operating in various monitoring, defibrillation, and, if applicable, pacing modes, and stores data indicative of cardiac signals received by the detection circuitry **1202**. The memory circuitry **1209** may also be configured to store historical ECG and therapy data, which may be used for various purposes and transmitted to an external receiving device as needed or desired.

[0091] In certain configurations, the PIMD may include diagnostics circuitry **1210**. The diagnostics circuitry **1210** typically receives input signals from the detection circuitry **1202** and the sensing circuitry **1204**. The diagnostics circuitry **1210** provides diagnostics data to the control system **1205**, it being understood that the control system **1205** may incorporate all or part of the diagnostics circuitry **1210** or its functionality. The control system **1205** may store and use information provided by the diagnostics circuitry **1210** for a variety of diagnostics purposes. This diagnostic information may be stored, for example, subsequent to a triggering event or at predetermined intervals, and may include system diagnostics, such as power source status, therapy delivery history, and/or patient diagnostics. The diagnostic information may take the form of electrical signals or other sensor data acquired immediately prior to therapy delivery.

[0092] According to a configuration that provides cardioversion and defibrillation therapies, the control system **1205** processes cardiac signal data received from the detection circuitry **1202** and initiates appropriate tachyarrhythmia therapies to terminate cardiac arrhythmic episodes and return the heart to normal sinus rhythm. The control system **1205** is coupled to shock therapy circuitry **1216**. The shock therapy circuitry **1216** is coupled to the electrode(s) **1214** and the can or indifferent electrode **1207** of the PIMD housing.

[0093] Upon command, the shock therapy circuitry **1216** delivers cardioversion and defibrillation stimulation energy to the heart in accordance with a selected cardioversion or defibrillation therapy. In a less sophisticated configuration, the shock therapy circuitry **1216** is controlled to deliver defibrillation therapies, in contrast to a configuration that provides for delivery of both cardioversion and defibrillation therapies. Examples of PIMD high energy delivery circuitry, structures and functionality, aspects of which may be incorporated in a PIMD of a type that may benefit from aspects of the present invention are disclosed in commonly owned U.S. Pat. Nos. 5,372,606; 5,411,525; 5,468,254; and 5,634,938, which are hereby incorporated herein by reference.

[0094] Arrhythmic episodes may also be detected and verified by morphology-based analysis of sensed cardiac signals as is known in the art. Tiered or parallel arrhythmia discrimination algorithms may also be implemented using both rate-based and morphologic-based approaches. Further, a rate and pattern-based arrhythmia detection and discrimination approach may be employed to detect and/or verify arrhythmic episodes, such as the approach disclosed in U.S. Pat. Nos. 6,487,443; 6,259,947; 6,141,581; 5,855,593; and 5,545,186, which are hereby incorporated herein by reference.

[0095] As is shown in FIG. **9**, the PIMD includes pacing therapy circuitry **1230** that is coupled to the control system **1205** and the electrode(s) **1214** and can/indifferent electrodes **1207**. Upon command, the pacing therapy circuitry **1230** delivers pacing pulses to the heart in accordance with a selected pacing therapy.

[0096] Control signals, developed in accordance with a pacing regimen by pacemaker circuitry within the control system **1205**, are initiated and transmitted to the pacing therapy circuitry **1230** where pacing pulses are generated. A pacing regimen may be modified by the control system **1205**. In one particular application, a sense vector optimization may be implemented to enhance capture detection and/or capture threshold determinations, such as by selecting an optimal vector for sensing an evoked response resulting from application of a capture pacing stimulus.

[0097] The PIMD shown in FIG. **9** may be configured to receive signals from one or more physiologic and/or non-physiologic sensors. Depending on the type of sensor employed, signals generated by the sensors may be communicated to transducer circuitry coupled directly to the detection circuitry **1202** or indirectly via the sensing circuitry **1204**. It is noted that certain sensors may transmit sense data to the control system **1205** without processing by the detection circuitry **1202**.

[0098] Communications circuitry **1218** is coupled to the microprocessor **1206** of the control system **1205**. The communications circuitry **1218** allows the PIMD to communicate with one or more receiving devices or systems situated external to the PIMD. By way of example, the PIMD may communicate with a patient-worn, portable or bedside communication system via the communications circuitry **1218**. In one configuration, one or more physiologic or non-physiologic sensors (subcutaneous, cutaneous, or external of patient) may be equipped with a short-range wireless communication interface, such as an interface conforming to a known communications standard, such as Bluetooth or IEEE 802 standards. Data acquired by such sensors may be communicated to the PIMD via the communications circuitry **1218**. It is noted that physiologic or non-physiologic sensors equipped with wireless transmitters or transceivers may communicate with a receiving system external of the patient.

[0099] The communications circuitry **1218** allows the PIMD to communicate with an external programmer. In one configuration, the communications circuitry **1218** and the programmer unit (not shown) use a wire loop antenna and a radio frequency telemetric link, as is known in the art, to receive and transmit signals and data between the programmer unit and communications circuitry **1218**. In this manner, programming commands and data are transferred between the PIMD and the programmer unit during and after implant. Using a programmer, a physician is able to set or modify various parameters used by the PIMD. For example, a physician may set or modify parameters affecting monitoring, detection, pacing, and defibrillation functions of the

PIMD, including pacing, resynchronization, and cardioversion/defibrillation therapy modes. The physician may, for example, modify pacing parameters or enable pacing therapies (e.g., CRT therapies) appropriate for a patient who has been identified as suitable for CRT therapy in a manner described herein. Enabling CRT therapies may, for example, involve downloading such therapies to the PIMD via a programmer, advanced patient management system, or other patient-external systems, or activating such therapies that may be stored (but previously unused) in PIMD memory.

[0100] Typically, the PIMD is encased and hermetically sealed in a housing suitable for implanting in a human body as is known in the art. Power to the PIMD is supplied by an electrochemical power source **1220** housed within the PIMD. In one configuration, the power source **1220** includes a rechargeable battery. According to this configuration, charging circuitry is coupled to the power source **1220** to facilitate repeated non-invasive charging of the power source **1220**. The communications circuitry **1218**, or separate receiver circuitry, is configured to receive RF energy transmitted by an external RF energy transmitter. The PIMD may, in addition to a rechargeable power source, include a non-rechargeable battery. It is understood that a rechargeable power source need not be used, in which case a long-life non-rechargeable battery is employed.

[0101] The detection circuitry **1202**, which is coupled to a microprocessor **1206**, may be configured to incorporate, or communicate with, specialized circuitry for processing sensed cardiac signals in manners particularly useful in a cardiac sensing and/or stimulation device. As is shown by way of example in FIG. **9**, the detection circuitry **1202** may receive information from multiple physiologic and non-physiologic sensors.

[0102] The detection circuitry **1202** may also receive information from one or more sensors that monitor skeletal muscle activity. In addition to cardiac activity signals, electrodes readily detect skeletal muscle signals. Such skeletal muscle signals may be used to determine the activity level of the patient. In the context of cardiac signal detection, such skeletal muscle signals are considered artifacts of the cardiac activity signal, which may be viewed as noise.

[0103] The components, functionality, and structural configurations depicted herein are intended to provide an understanding of various features and combination of features that may be incorporated in a PIMD. It is understood that a wide variety of PIMDs and other implantable cardiac monitoring and/or stimulation device configurations are contemplated, ranging from relatively sophisticated to relatively simple designs. As such, particular PIMD or cardiac monitoring and/or stimulation device configurations may include particular features as described herein, while other such device configurations may exclude particular features described herein.

[0104] The PIMD may detect a variety of physiological signals that may be used in connection with various diagnostic, therapeutic or monitoring implementations. For example, the PIMD may include sensors or circuitry for detecting respiratory system signals, cardiac system signals, and signals related to patient activity. In one embodiment, the PIMD senses intrathoracic impedance, from which various respiratory parameters may be derived, including, for example, respiratory tidal volume and minute ventilation. Sensors and associated circuitry may be incorporated in connection with a PIMD for detecting one or more body movement or body posture or position related signals. For example, accelerometers and GPS devices may be employed to detect patient activity, patient location, body orientation, or torso position.

[0105] A PIMD in accordance with the present invention may be used within the structure of an advanced patient management (APM) system. The advanced patient management system allows physicians to remotely and automatically monitor cardiac and respiratory functions, as well as other patient conditions. In one example, a PIMD implemented as a cardiac pacemaker, defibrillator, resynchronization device, cardiac neurostimulation device, or other implantable medical monitoring, diagnostic, or therapy device may be equipped with various telecommunications and information technologies that enable real-time data collection, diagnosis, and/or treatment of the patient. Various PIMD embodiments described herein may be used in connection with advanced patient management. Methods, structures, and/or techniques described herein, which may be adapted to provide for remote patient/device monitoring, diagnosis, therapy, or other APM related methodologies, may incorporate features of one or more of the following references: U.S. Pat. Nos. 6,221,011; 6,270,457; 6,277,072; 6,280,380; 6,312,378; 6,336,903; 6,358,203; 6,368,284; 6,398,728; and 6,440,066, which are hereby incorporated herein by reference.

[0106] Various modifications and additions can be made to the preferred embodiments discussed hereinabove without departing from the scope of the present invention. Accordingly, the scope of the present invention should not be limited by the particular embodiments described above, but should be defined only by the claims set forth below and equivalents thereof.

What is claimed is:

**1**. A method, comprising:

detecting presence of disordered breathing using an implantable medical device;

detecting a cardiac condition indicative of the patient's cardiac status; and

identifying the patient as suitable for a cardiac resynchronization therapy based on the presence of disordered breathing and the cardiac condition.

**2**. The method of claim 1, further comprising delivering at least one of a cardiac pacing therapy other than a cardiac resynchronization therapy, a cardiac shock therapy, and a cardiac neurostimulation therapy.

**3**. The method of claim 1, wherein detecting the presence of disordered breathing comprises detecting at least one of obstructive sleep apnea, central sleep apnea, hypopnea, orthopnea, paroxysmal nocturnal dyspnea, and Cheyne-Stokes respiration.

**4**. The method of claim 1, comprising enabling the implantable medical device to perform the cardiac resynchronization therapy based on identifying the patient as suitable for the cardiac resynchronization therapy.

**5**. The method of claim 1, wherein the implantable medical device comprises a pulse generator and electrodes that are configured for cardiac resynchronization therapy delivery.

6. The method of claim 1, wherein detecting the cardiac condition comprises detecting a ventricular dysynchrony in the patient's heart via an implantable or patient-external sensing arrangement.

7. The method of claim 1, wherein detecting the cardiac condition comprises detecting left ventricular systolic dysfunction via an implantable or patient-external sensing arrangement.

8. The method of claim 1, wherein detecting the cardiac condition comprises detecting a left ventricular systolic dysfunction comprising a left ventricular ejection fraction value less than a predetermined limit.

9. The method of claim 1, wherein detecting the cardiac condition comprises determining that a QRS complex pulse width of a cardiac cycle exceeds a predetermined limit.

10. The method of claim 1, wherein detecting the cardiac condition comprises detecting a ventricular wall motion asynchrony that exceeds a predetermined limit.

11. The method of claim 1, comprising one or more of initiating, terminating, adjusting, or optimizing the cardiac resynchronization therapy in response to detecting the presence of disordered breathing and the cardiac condition.

12. The method of claim 1, wherein detecting the presence of disordered breathing is used to trigger an alert using a patient-external device.

13. The method of claim 1, wherein detecting the presence of disordered breathing comprises detecting an apnea/hypopnea index greater than a predetermined limit.

14. The method of claim 1, comprising enabling the implantable medical device to perform a first cardiac resynchronization therapy in response to detecting obstructive sleep apnea, and enabling the implantable medical device to perform a second cardiac resynchronization therapy after detecting central sleep apnea.

15. The method of claim 2, comprising adjusting an atrioventricular delay based on the detected disordered breathing.

16. The method of claim 1, wherein the cardiac resynchronization therapy comprises selecting a cardiac stimulation vector based on the detected disordered breathing.

17. An implantable medical device, comprising:

a housing configured for implantation in a patient;

a lead system comprising an electrode arrangement and coupled to the housing; and

a processor provided in the housing and coupled to the lead system, the processor configured to detect presence of disordered breathing, detect a cardiac condition indicative of the patient's cardiac status, and identify the patient as suitable for a cardiac resynchronization therapy based on the presence of disordered breathing and the cardiac condition.

18. The device of claim 17, wherein implantable medical device comprises a pulse generator coupled to the processor and configured to deliver at least one of a cardiac pacing therapy other than a cardiac resynchronization therapy, a cardiac shock therapy, and a cardiac neurostimulation therapy.

19. The device of claim 18, wherein the processor is configured to enable the pulse generator to perform the cardiac resynchronization therapy based on identifying the patient as suitable for the cardiac resynchronization therapy.

20. The device of claim 18, wherein the processor is configured to adjust an atrioventricular delay based on the detected disordered breathing.

21. The device of claim 17, wherein the processor is configured to detect at least one of obstructive sleep apnea, central sleep apnea, hypopnea, orthopnea, paroxysmal nocturnal dyspnea, and Cheyne-Stokes respiration.

22. The device of claim 17, further comprising one or both of an implantable sensor arrangement and a patient-external sensor arrangement coupled to the implantable medical device, the processor configured to detect a ventricular dysynchrony in the patient's heart via the one or both of the implantable or patient-external sensing arrangement.

23. The device of claim 17, wherein the processor is coupled to communication circuitry configured to facilitate wireless communication between the processor and a patient-external device or system.

24. The device of claim 23, wherein patient-external device or system is configured to generate a clinician alert to initiate, terminate, adjust, or optimize the cardiac resynchronization therapy.

25. The device of claim 17, wherein the implantable medical device comprises transthoracic impedance measuring circuitry coupled to the processor and configured to detect patient breathing.

26. An implantable medical device, comprising:

means for detecting presence of disordered breathing from within a patient;

means for detecting a cardiac condition indicative of the patient's cardiac status; and

means for identifying the patient as suitable for a cardiac resynchronization therapy based on the presence of disordered breathing and the cardiac condition.

27. The device of claim 26, comprising means for alerting a clinician that the patient is suitable for the cardiac resynchronization therapy.

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