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(54) **METHODS AND DEVICES FOR DETECTING HEART SOUNDS TO MONITOR CARDIAC FUNCTION**

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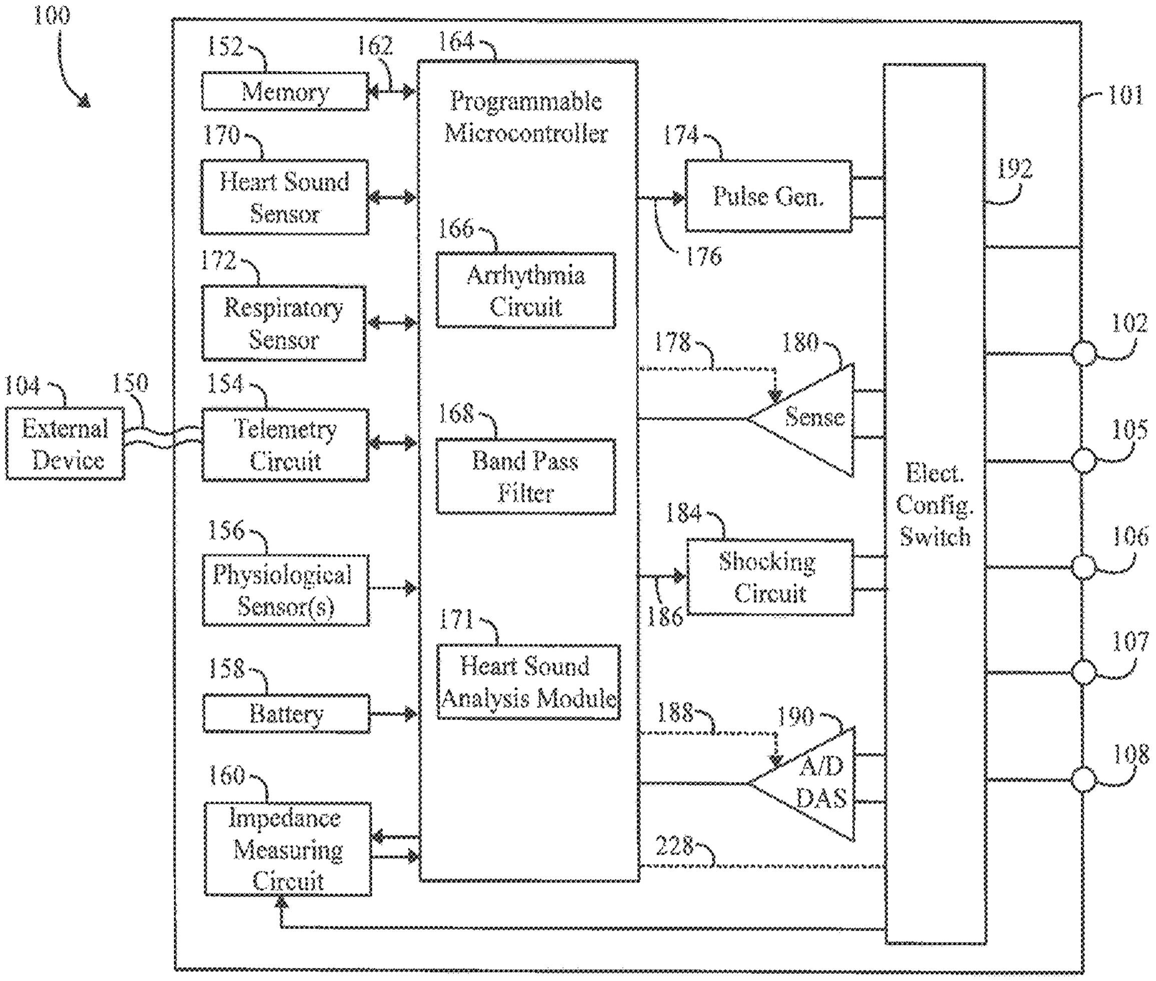
(57) **ABSTRACT**

Methods and implantable medical devices (IMDs) are provided for monitoring a cardiac function of a heart. A heart sound sensor is configured to sense heart sound signals of the subject. The IMD includes a memory to store program instructions. The IMD includes a processor that, when executing the program instructions, is configured to identify S2 signal segment from the heart sound signals, analyze the S2 signal segment to identify a pulmonary valve signal (P2 signal) and an aortic valve signal (A2 signal) within an S2 signal segment of the heart sound signals. The processor is configured to determine a time interval between the A2 and P2 signals, characterize the S2 signal segment to exhibit a first type of S2 split based on the time interval, and identify a cardiac condition based on a comparison of the first type of S2 split and a cardiac condition matrix.



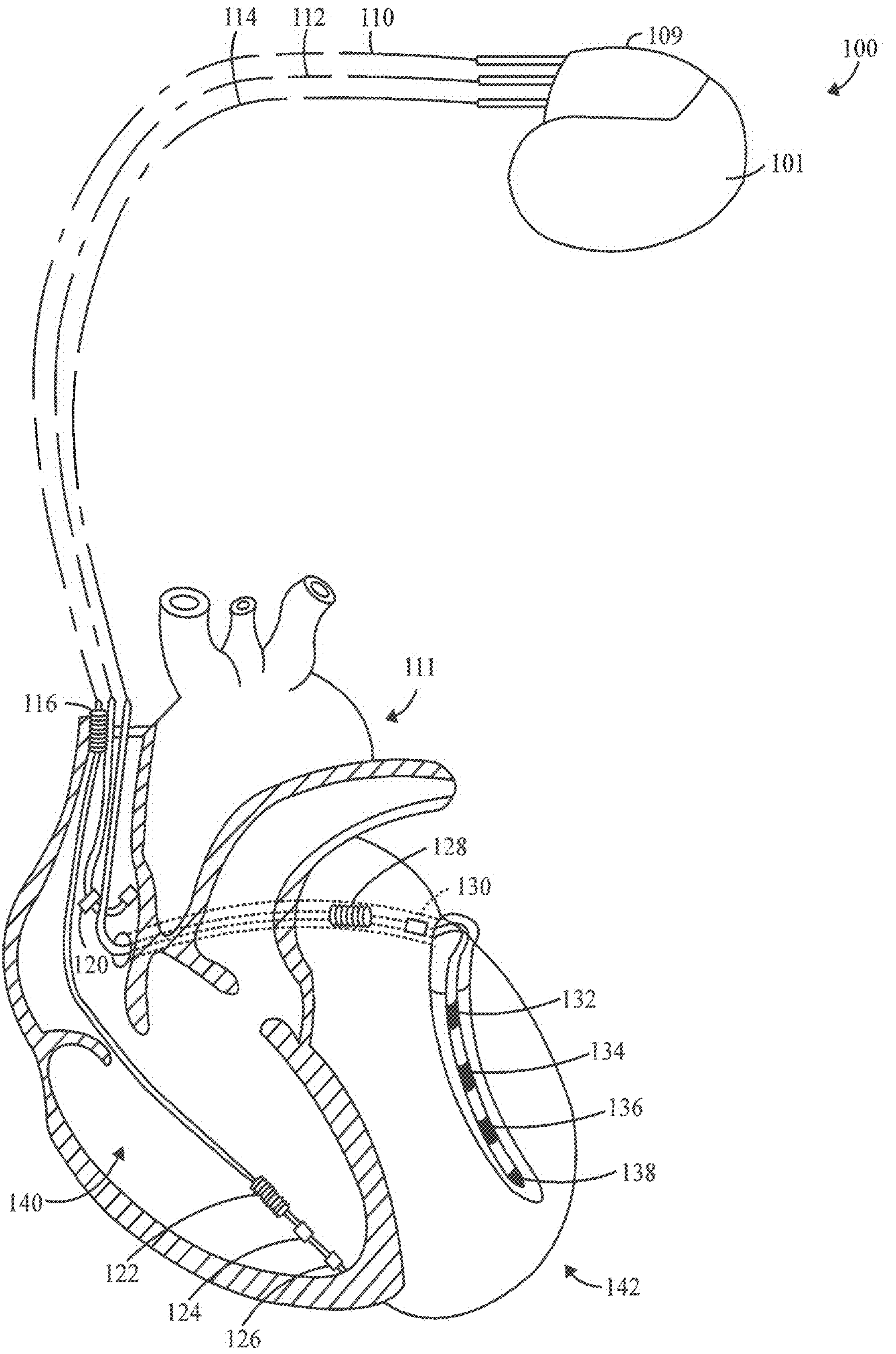

114
112
110
109
100
101
111
116
128
130
120
132
134
136
138
140
122
124
126
142

Figure 1

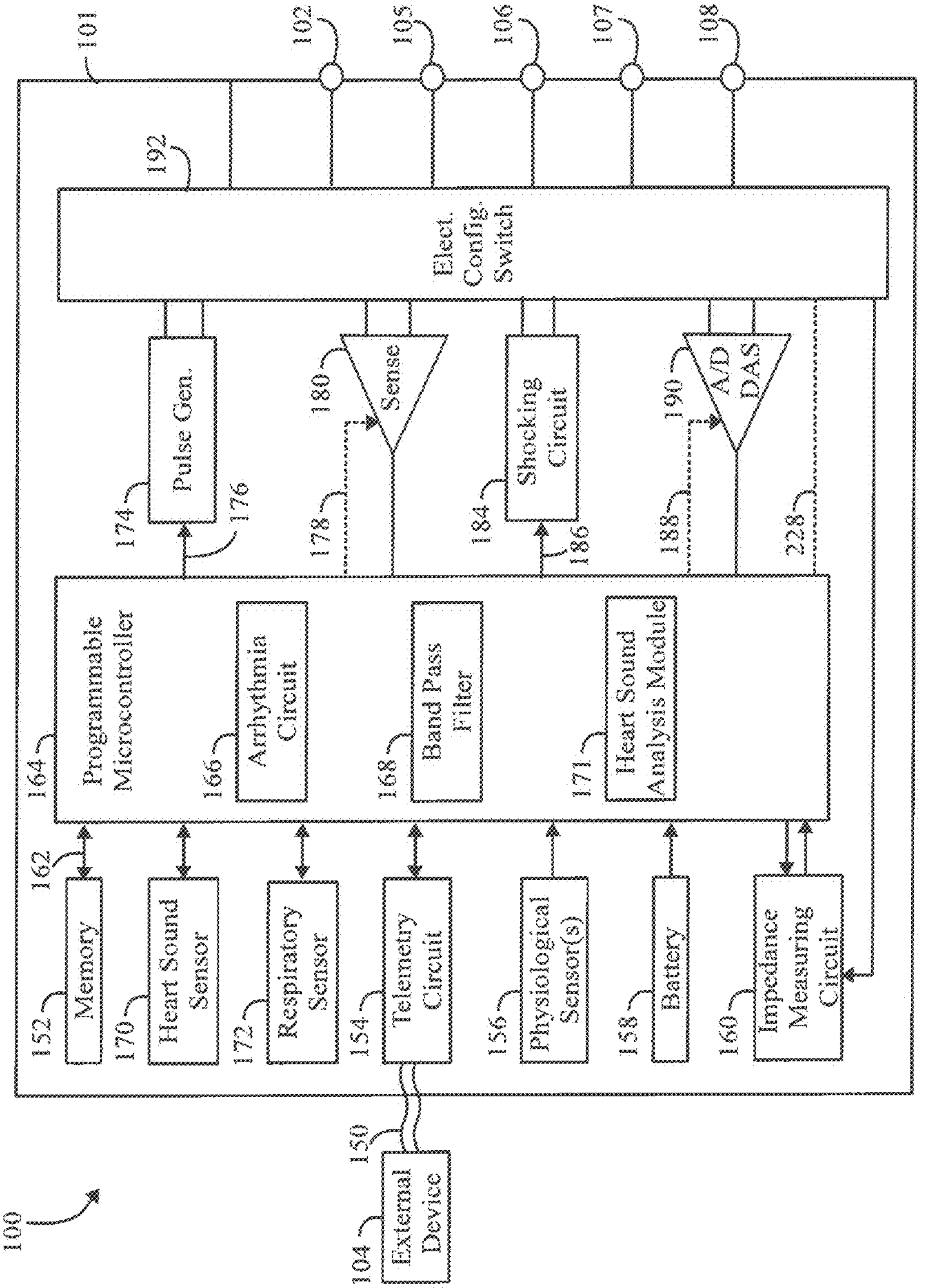

100
101
102
105
106
107
108
192
Elect. Config. Switch
174
Pulse Gen.
176
180
Sense
178
184
Shocking Circuit
186
190
A/D DAS
188
228
164
Programmable Microcontroller
166
Arrhythmia Circuit
168
Band Pass Filter
171
Heart Sound Analysis Module
162
152
Memory
170
Heart Sound Sensor
172
Respiratory Sensor
154
Telemetry Circuit
156
Physiological Sensor(s)
158
Battery
160
Impedance Measuring Circuit
150
104
External Device

Figure 2

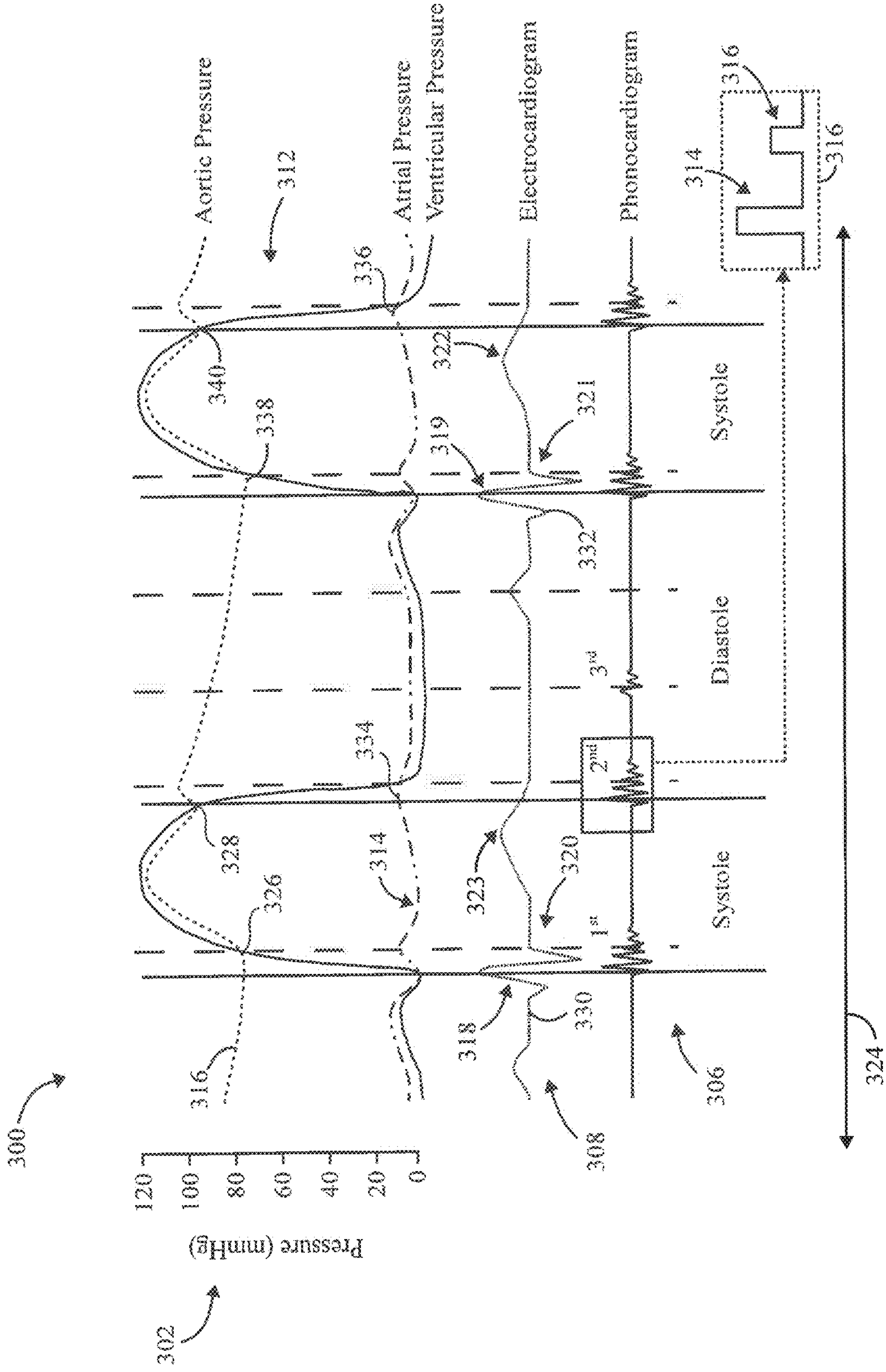

300
302
Pressure (mmHg)
120
100
80
60
40
20
0
316
Aortic Pressure
312
Atrial Pressure
Ventricular Pressure
Electrocardiogram
Phonocardiogram
326
328
338
340
314
334
336
318
319
320
321
322
323
330
332
308
306
1st
2nd
3rd
Systole
Diastole
Systole
314
316
316
316
324

Figure 3

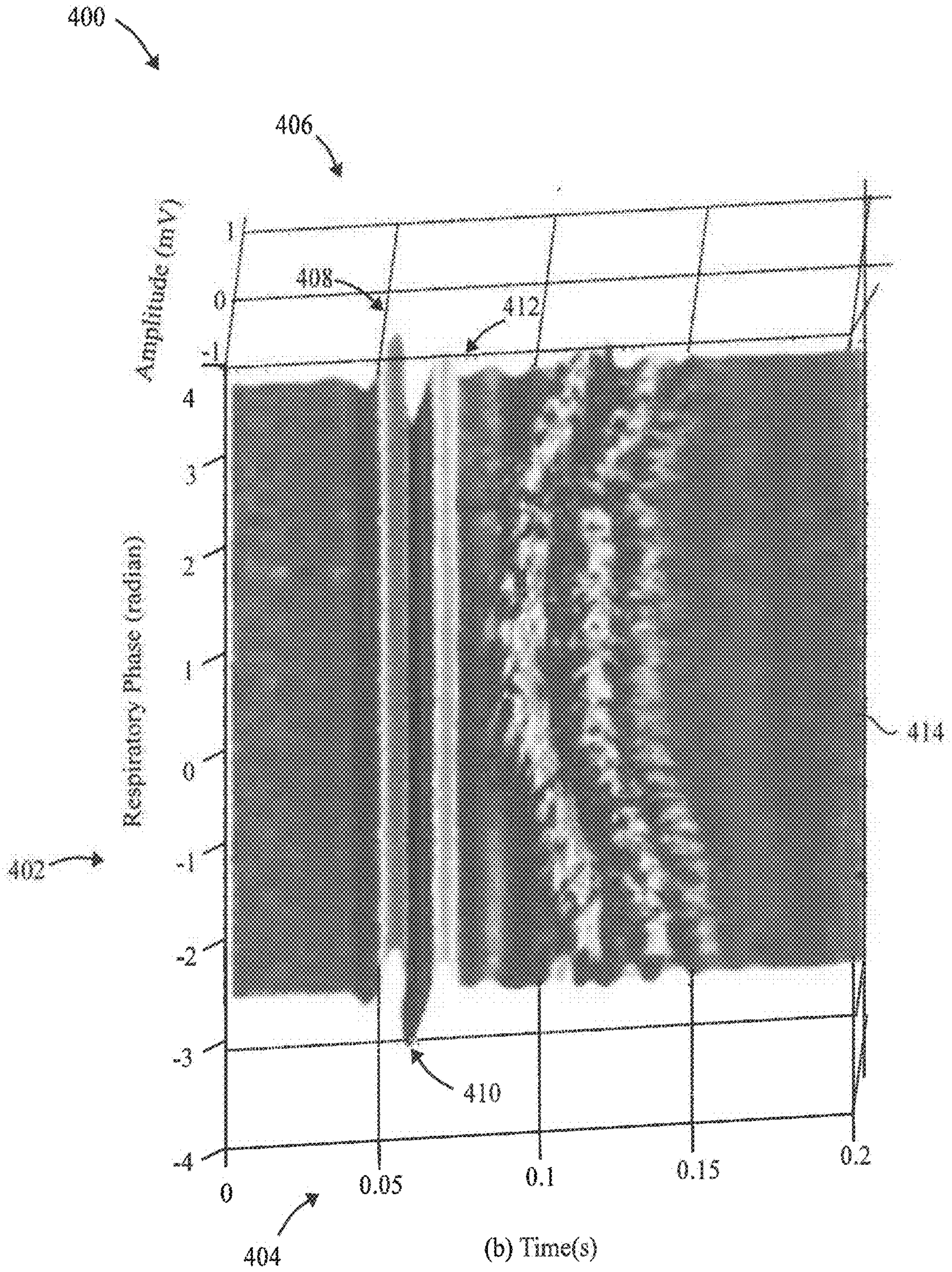

400
406
Amplitude (mV)
1
0
-1
408
412
414
Respiratory Phase (radian)
4
3
2
1
0
-1
-2
-3
-4
402
410
0
0.05
0.1
0.15
0.2
404
(b) Time(s)

Figure 4

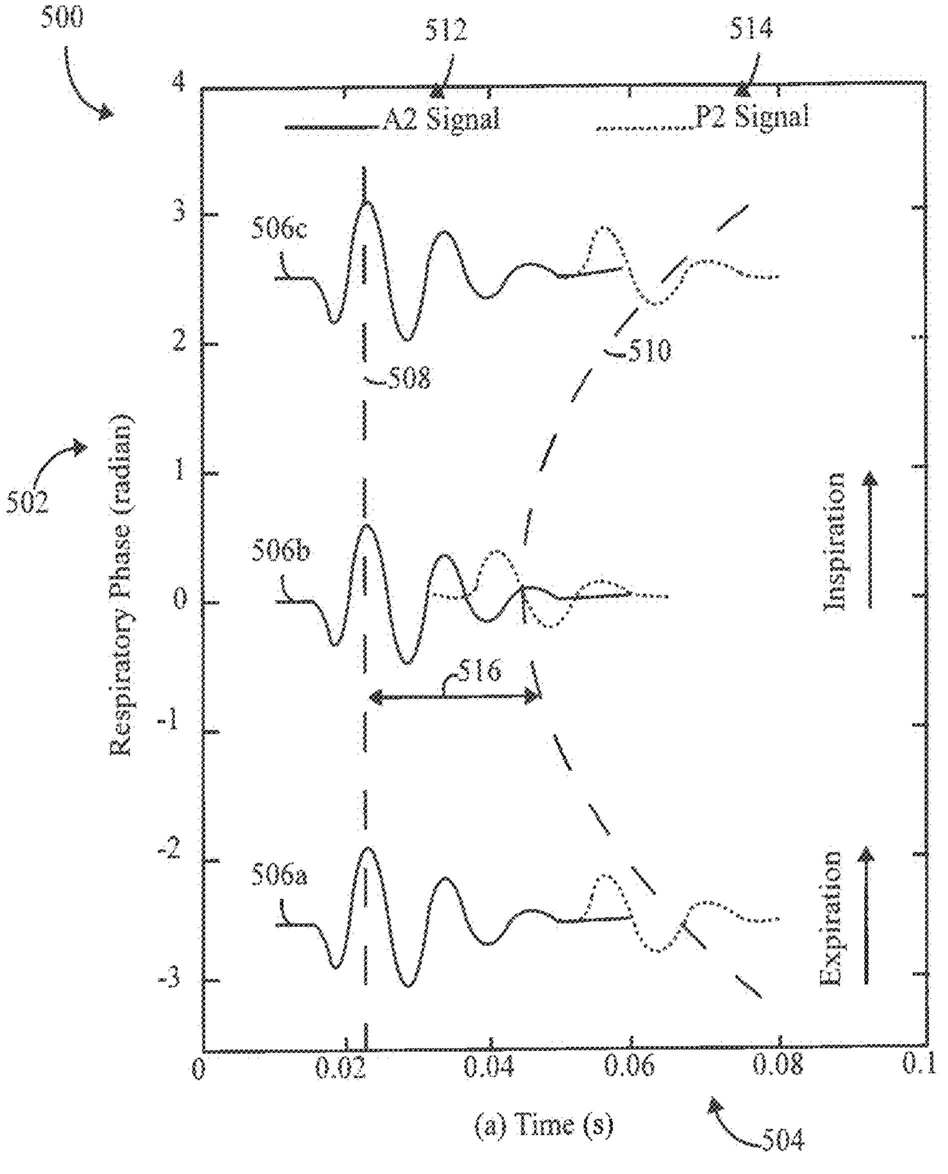

500
512
514
A2 Signal
P2 Signal
4
3
2
1
0
-1
-2
-3
506c
506b
506a
508
510
516
502
Respiratory Phase (radian)
Inspiration
Expiration
0
0.02
0.04
0.06
0.08
0.1
(a) Time (s)
504

Figure 5

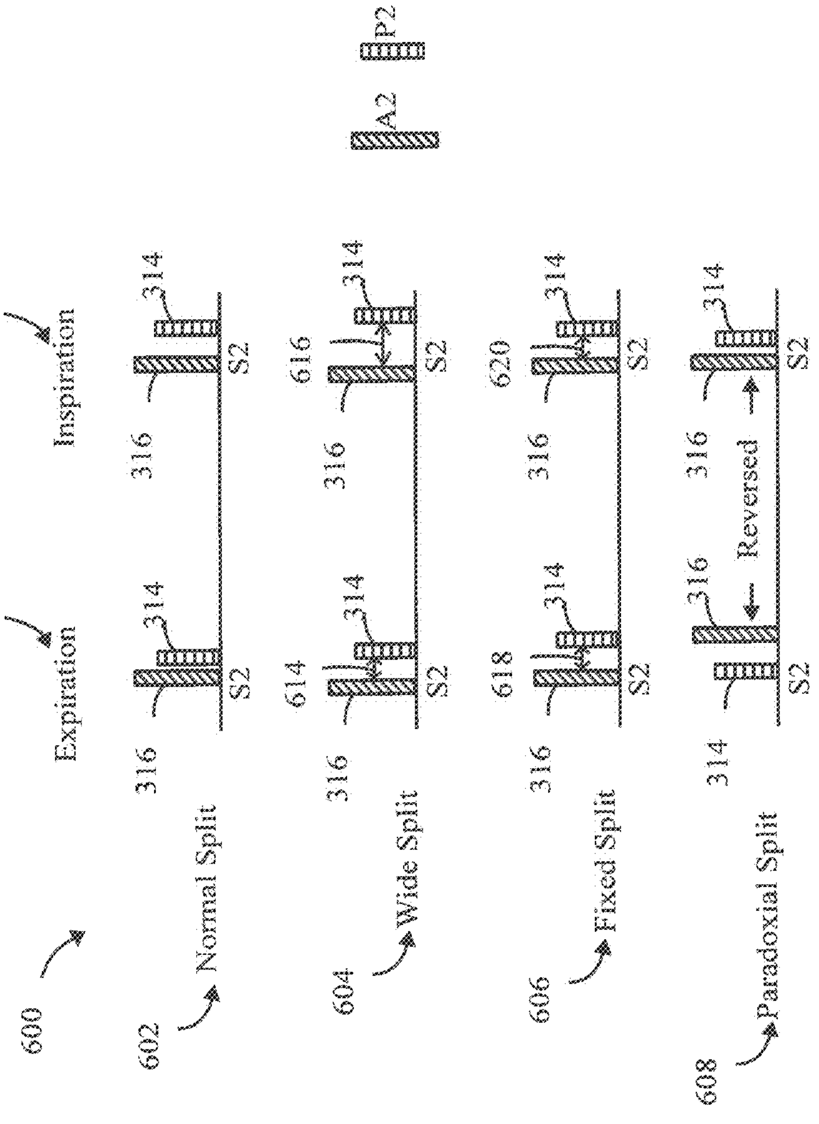

600
A2
P2
610
Expiration
612
Inspiration
602
Normal Split
316
314
S2
604
Wide Split
614
616
606
Fixed Split
618
620
608
Paradoxial Split
Reversed

Figure 6

700

		Right Heart 702	Left Heart 704	Great Vessels 706	Septum 708
710	Normal Split				
712	Wide Split	RBBB	Pre-Excitation of LV, LV Pacing, Premature LV Beats	Pulmonary Stenosis, Pulmonary Arterial Hypertension	
714	Split During Expiration	RV Pacing	Hypertrophic Cardiomyopathy LBBB	Aortic Stenosis	
716	Split During both Inspiration and Expiration: Fixed Split	Right Heart Failure		Pulmonary Hypertension	Atrial Septal Defect
718	Split during both Inspiration and Expiration		LBBB Pre-Excitation Of RV, RC Pacing, Premature RV Beats	Aortic Stenosis	
720	Single S2: Either from Loss of A2 or Loss of P2			Severe Aortic Stenosis, Severe Aortic Regurgitation, Congenital Absence of Pulmonary Valve	

Figure 7

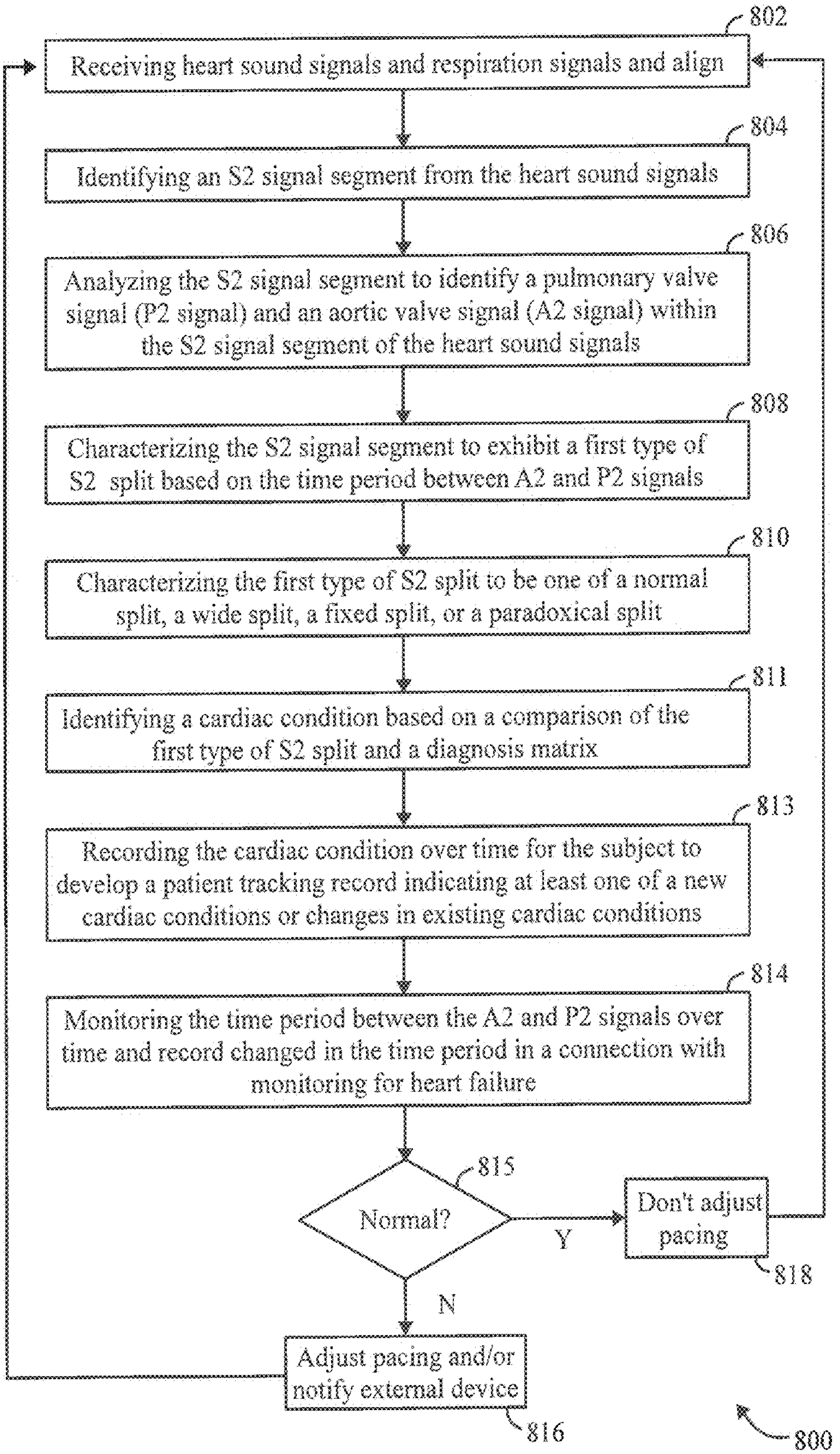

802
Receiving heart sound signals and respiration signals and align
804
Identifying an S2 signal segment from the heart sound signals
806
Analyzing the S2 signal segment to identify a pulmonary valve signal (P2 signal) and an aortic valve signal (A2 signal) within the S2 signal segment of the heart sound signals
808
Characterizing the S2 signal segment to exhibit a first type of S2 split based on the time period between A2 and P2 signals
810
Characterizing the first type of S2 split to be one of a normal split, a wide split, a fixed split, or a paradoxical split
811
Identifying a cardiac condition based on a comparison of the first type of S2 split and a diagnosis matrix
813
Recording the cardiac condition over time for the subject to develop a patient tracking record indicating at least one of a new cardiac conditions or changes in existing cardiac conditions
814
Monitoring the time period between the A2 and P2 signals over time and record changed in the time period in a connection with monitoring for heart failure
815
Normal?
Y
Don't adjust pacing
818
N
Adjust pacing and/or notify external device
816
800

Figure 8

METHODS AND DEVICES FOR DETECTING HEART SOUNDS TO MONITOR CARDIAC FUNCTION

BACKGROUND

[0001] Embodiments of the present disclosure generally relate to methods and implantable medical devices (IMDs) for detecting a cardiac function of a heart.

[0002] It has been proposed to utilize heart sounds in connection with monitoring certain cardiac functions. Heart sounds are the noises generated by the beating heart and the resultant flow of blood, and are typically referred to as S1, S2, S3 and S4. An S1 heart sound is caused by the sudden block of reverse blood flow due to closure of the atrioventricular valves (mitral and tricuspid) at the beginning of ventricular contraction. When the ventricles begin to contract, so do the papillary muscles in each ventricle. The papillary muscles are attached to the tricuspid and mitral valves via chorda tendinae, which bring the cusps of the valve closed (chorda tendinae also prevent the valves from blowing into the atria as ventricular pressure rises due to contraction). The closing of the inlet valves prevents regurgitation of blood from the ventricles back into the atria. The S1 sound results from reverberation within the blood associated with the sudden block of flow reversal by the valves.

[0003] An S2 heart sound is caused by the sudden block of reversing blood flow due to closure of the aortic valve and pulmonary valve at the end of ventricular systole, i.e beginning of ventricular diastole. As the left ventricle empties, the left ventricular pressure falls below the pressure in the aorta and aortic blood flow quickly reverses back toward the left ventricle, catching the aortic valve leaflets and is stopped by aortic (outlet) valve closure. Similarly, as the pressure in the right ventricle falls below the pressure in the pulmonary artery, the pulmonary (outlet) valve closes. The S2 sound results from reverberation within the blood associated with the sudden block of flow reversal.

[0004] However, opportunity remains for methods and devices to utilize heart sounds to monitor cardiac functions.

SUMMARY

[0005] In accordance with embodiments herein, an implantable medical device (IMD) is provided. The IMD includes a heart sound sensor configured to sense heart sound signals of the subject. The IMD includes a memory to store program instructions. The IMD includes a processor that, when executing the program instructions, is configured to identify and S2 signal segment from the heart sound signals, analyze the S2 signal segment to identify a pulmonary valve signal (P2 signal) and an aortic valve signal (A2 signal) within the S2 signal segment of the heart sound signals. The processor is configured to determine a time interval between the A2 and P2 signals, characterize the S2 signal segment to exhibit a first type of S2 split based on the time interval between the A2 and P2 signals, and identify a cardiac condition based on a comparison of the first type of S2 split and a cardiac condition matrix.

[0006] Optionally, the processor is configured to characterize the first type of S2 split to be one of a normal split, a wide split, a fixed split, or a paradoxical split. Additionally or alternatively, the processor is configured to identify the cardiac condition based on the cardiac condition matrix that is divided based on multiple types of S2 split and multiple local heart regions. The cardiac condition matrix further includes different cardiac conditions associated with each combination of the S2 split type and local heart region. Optionally, the local heart regions include a right heart region, a left heart region, a greater vessel region and a septum. The processor is configured to identify, for the first type of the S2 split corresponding right heart-related conditions, left heart-related conditions, and greater vessel-related conditions.

[0007] Optionally, the IMD includes a respiration sensor configured to sense a respiration signal of the subject. The processor is configured to apply a bandpass filter to the respiration signal to identify the P2 signal and the A2 signal from the S2 signal segment. Additionally or alternatively, the respiration sensor comprises at least one of an accelerometer, a pressure sensor, and an impedance sensor that are configured to indicate a respiratory phase of the subject.

[0008] The respiration signal includes an expiration phase and an inspiration phase that form at least part of a respiratory cycle of the subject. The processor is configured to identify expiration and inspiration time intervals between the P2 signal and the A2 signal in connection with the expiration and inspiration phases. Additionally or alternatively, the processor is configured to extract the P2 signal and the A2 signal based on a peak of the A2 signal and the slope of the P2 signal. Optionally, the IMD includes an electromyography (EMG) sensor configured to detect a cardiac signal of the subject. The processors configured to use the cardiac signal to apply a bandpass filter to the heart sound signal to identify the P2 signal and the A2 signal.

[0009] Optionally, the processor is configured to record the cardiac condition over time for the subject to develop a patient tracking record indicating at least one of a new cardiac conditions or changes in existing cardiac conditions. Additionally or alternatively, the processor is configured to monitor the time interval between the A2 and P2 signals over time and record changes in the time interval in connection with monitoring for heart failure. Optionally, the IMD includes a pulse generator to deliver pacing therapy based in part on programmed AV and VV delays. The processor is configured to monitor the time interval between the A2 and P2 signals over time and record changes in the time interval in connection with adjustments and at least one of the programmed AV or VV delay is for the IMD.

[0010] In accordance with embodiments herein, a method to manage an implantable medical device (IMD) is provided. The method includes receiving heart sound signals of the subject. The method includes identifying and S2 signal segment from the heart sound signals, analyzing the S2 signal segment to identify a pulmonary valve signal (P2 signal) and an aortic valve signal (A2 signal) within the S2 signal segment of the heart sound signals. The method includes characterizing the S2 signal segment to exhibit a first type of S2 split based on the time interval between the A2 and P2 signals, and identifying a cardiac condition based on a comparison of the first type of S2 split and a cardiac condition matrix.

[0011] Optionally, the method may include characterizing the first type of S2 split to be one of a normal split, a wide split, a fixed split, or paradoxical split. Additionally or alternatively, the identifying operation includes comparing the first type of S2 split to the cardiac condition matrix that is divided into multiple types of S2 split and multiple local heart regions. The cardiac condition matrix further including different cardiac conditions associated with each combination of the S2 split type and local heart region. Additionally or alternatively, the local heart regions include a right heart region, a left heart region, and a greater vessel region. Optionally, the method includes identifying the first type of S2 split, corresponding to right heart-related conditions, left heart rate-related conditions, and greater vessel-related conditions.

[0012] Optionally, the method includes receiving a respiration signal of the subject and applying a bandpass filter to the respiration signal to identify the P2 signal and the A2 signal from the S2 signal segment. Additionally or alternatively, the respiration sensor comprises at least one of an accelerometer, a pressure sensor, an impedance sensor that are configured to indicate a respiratory phase of the subject. Additionally or alternatively, the method includes extracting the P2 signal and the A2 signal based on the peak of the A2 signal and a slope of the P2 signal relative to the respiratory phase.

[0013] Optionally, the method includes receiving a respiration signal of the subject. The respiration signal including an expiration phase and an inspiration phase that form a respiratory cycle of the subject. Additionally or alternatively, the method includes identifying the P2 signal and the A2 signal based on expiration and inspiration phases. Optionally, the method includes receiving a cardiac signal of the subject, and applying a bandpass filter to the heart sound signal to identify the P2 signal and the A2 signal. Additionally or alternatively, the method includes recording the cardiac condition over time for the subject to develop a patient tracking record indicating at least one of a new cardiac conditions or changes in existing cardiac conditions. Additionally or alternatively, the method includes monitoring the time interval between the A2 and P2 signals over time and record changes in the time interval in connection with monitoring heart failure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] FIG. **1** illustrates an implantable medical device (IMD), in accordance with an embodiment.

[0015] FIG. **2** illustrates a schematic view of the IMD, in accordance with an embodiment.

[0016] FIG. **3** illustrates a graphical representation of signals that are representative of various characteristics of the heart, in accordance with an embodiment.

[0017] FIG. **4** illustrates a graphical representation of a respiration signal measured, in accordance with an embodiment.

[0018] FIG. **5** illustrates a graphical representation of shifts in the A2 signal and P2 signal components relative to one another in connection with different respiratory phases at which the S2 signal segment occurs, in accordance with an embodiment.

[0019] FIG. **6** illustrates a graphical representation of different types of S2 splits, in accordance with an embodiment.

[0020] FIG. **7** illustrates a cardiac condition matrix, in accordance with an embodiment.

[0021] FIG. **8** illustrates a flowchart of a method implemented to identify cardiac conditions, in accordance with an embodiment.

DETAILED DESCRIPTION

[0022] It will be readily understood that the components of the embodiments as generally described and illustrated in the Figures herein, may be arranged and designed in a wide variety of different configurations in addition to the described example embodiments. Thus, the following more detailed description of the example embodiments, as represented in the Figures, is not intended to limit the scope of the embodiments, as claimed, but is merely representative of example embodiments.

[0023] Reference throughout this specification to "one embodiment" or "an embodiment" (or the like) means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment. Thus, appearances of the phrases "in one embodiment" or "in an embodiment" or the like in various places throughout this specification are not necessarily all referring to the same embodiment.

[0024] Furthermore, the described features, structures, or characteristics may be combined in any suitable manner in one or more embodiments. In the following description, numerous specific details are provided to give a thorough understanding of embodiments. One skilled in the relevant art will recognize, however, that the various embodiments can be practiced without one or more of the specific details, or with other methods, components, materials, etc. In other instances, well-known structures, materials, or operations are not shown or described in detail to avoid obfuscation. The following description is intended only by way of example and simply illustrates certain example embodiments.

[0025] The systems and methods described herein may employ structures or aspects of various embodiments discussed herein. In various embodiments, certain operations may be omitted or added, certain operations may be combined, certain operations may be performed simultaneously, certain operations may be performed concurrently, certain operations may be split into multiple operations, certain operations may be performed in a different order, or certain operations or series of operations may be re-performed in an iterative fashion. It should be noted that other methods may be used, in accordance with an embodiment herein. Further, wherein indicated, the methods may be fully or partially implemented by one or more processors of one or more devices or systems. While the operations of some methods may be described as performed by the processor(s) of one device, additionally, some or all of such operations may be performed by the processor(s) of another device described herein.

[0026] Embodiments may be implemented in connection with one or more implantable medical devices (IMDs). Non-limiting examples of IMDs include one or more of neurostimulator devices, implantable leadless monitoring and/or therapy devices, and/or alternative implantable medical devices. For example, the IMD may represent a cardiac monitoring device, pacemaker, cardioverter, cardiac rhythm management device, defibrillator, neurostimulator, leadless monitoring device, leadless pacemaker, and/or the like. The IMD may include one or more structural and/or functional aspects of the device(s) described in U.S. Pat. No. 9,216,285 "Leadless Implantable Medical Device Having Removable And Fixed Components" and U.S. Pat. No. 8,831,747 "Leadless Neurostimulation Device And Method Including The Same", which are hereby incorporated by reference.

Additionally or alternatively, the IMD may include one or more structural and/or functional aspects of the device(s) described in U.S. Pat. No. 8,391,980 "Method And System For Identifying A Potential Lead Failure In An Implantable Medical Device" and U.S. Pat. No. 9,232,485 "System And Method For Selectively Communicating With An Implantable Medical Device", which are hereby incorporated by reference.

[0027] In accordance with an embodiment, methods and devices are provided that extract, from an S2 signal segment, a pulmonary valve component (P2 component of S2) and an aortic valve component (A2 component of S2). Responsive to inspiration, the chest wall expands and causes the intrathoracic pressure to become negative. An inspiration phase further induces an increase in venous blood return from the body into the right atrium via the superior and inferior venae cava. Additionally, during inspiration, a reduction is experienced in blood volume returning from the lungs into the left atrium, and an increase is experienced in blood volume in the right ventricle. The pulmonary valve stays open longer during ventricular systole due to an increase in ventricular emptying time. Alternatively, the aortic valve closes slightly earlier due to a reduction in left ventricular volume and ventricular emptying time. The P2 component of S2 is delayed relative to that of the A2 component of S2. The delay is represented as a slight broadening or even "split" of the second heart sound.

[0028] Responsive to an expiration phase, the chest wall collapses and decreases the negative intrathoracic pressure. There is an increase in blood return to the right ventricle versus the left ventricle, and the right ventricle volume pressure is reduced. The pulmonary valve closes earlier such that an overlap of the closing of the aortic valve, and the split may not be heard. The pressure in the right ventricle tries to open the pulmonary valve, during inspiration. The pressure in the pulmonary artery tries to close the pulmonary valve, during expiration. The closure of the pulmonary valve may be delayed due to the pressure in the right ventricle increased during inspiration, opposing the pressure in the pulmonary artery and keeping it open longer than in expiration.

[0029] Conventional methods do not provide feedback regarding a timing relationship between a pulmonary valve (P2 signal) and an aortic valve (A2 signal) of an S2 signal segment.

[0030] Embodiments herein utilize the timing relationship between P2 and A2 to obtain information regarding the cardiac condition of the subject (e.g., the patient). In accordance with embodiments herein, a processor identifies the S2 signal segment from the heart sound signals. Optionally, the processor may identify the S2 signal segment based on the heart sound signals alone or in combination with the cardiac signal and/or respiratory signals. The processor analyzes the S2 signal segment to identify the P2 signal and the A2 signal within the S2 signal segment from the heart sound signals. The processor determines a time interval between the A2 and P2 signals. The time interval represents a temporal difference between the A2 and P2 signals for a particular point in a respiratory cycle. The time interval may vary between inspiration and expiration phases and is referred to as inspiration time interval and expiration time interval. The processor characterizes the S2 signal segment to exhibit a first type of S2 split based on the time intervals between the A2 and P2 signals during different respiration cycles. The processor identifies a cardiac condition based on a comparison of the first type of the S2 split and a cardiac condition matrix. The cardiac condition matrix includes a collection of cardiac conditions associated with select combinations of local heart regions, activation of the local heart regions and WS2 split types. For example, the local heart region may have right ventricle (RV) pacing or left ventricle (LV) pacing of cardiac conditions. Additionally or alternatively, the cardiac condition matrix includes historical cardiac conditions associated with great vessels and septum. For example, the processors may compare an individual patient history and/or a patient database to determine if the great vessels and/or the septum includes cardiac conditions.

[0031] FIG. **1** illustrates an implantable medical device (IMD) **100** in electrical communication with multiple leads implanted into a patient's heart **111**. The IMD **100** may be a dual-chamber stimulation device, capable of treating both fast and slow arrhythmias with stimulation therapy, including cardioversion, pacing stimulation, an implantable cardioverter defibrillator, suspend tachycardia detection, tachyarrhythmia therapy, and/or the like. The IMD **100** includes a housing **101** to hold the electronic/computing components. The housing **101** (which is often referred to as the "can", "case", "encasing", or "case electrode") may be programmably selected to act as the return electrode for certain stimulus modes. The housing **101** further includes a connector **109** with a plurality of terminals **102**, **105**, **106**, **107**, **108** (shown in FIG. **2**).

[0032] The IMD **100** is shown in electrical connection with a heart **111** by way of a left atrial (LA) lead **120** having a right lead **112** and a left atrial (LA) ring electrode **128**. The IMD **100** is also in electrical connection with the heart **111** by way of a right ventricular (RV) lead **110** having, in this embodiment, a left ventricle (LV) electrode **132**, an LV electrode **134**, an LV electrode **136**, and an LV electrode **138**. The RV lead **110** is transvenously inserted into the heart **111** to place the RV coil **122** in the RV apex, and the SVC coil electrode **116**. Accordingly, the RV lead **110** is capable of receiving cardiac signals and delivering stimulation in the form of pacing and shock therapy to the right ventricle **140** (also referred to as the RV chamber).

[0033] The IMD **100** includes a left ventricle **142** (e.g., left chamber) pacing therapy, and is coupled to a multi-pole LV lead **114** designed for placement in various locations such as a "CS region" (e.g., venous vasculature of the left ventricle, including any portion of the coronary sinus (CS), great cardiac vein, left marginal vein, left posterior ventricular vein, middle cardiac vein, and/or small cardiac vein or any other cardiac vein accessible by the coronary sinus), the epicardial space, and/or the like. In an embodiment, the LV lead **114** is designed to receive atrial and ventricular cardiac signals and to deliver left ventricular pacing therapy using a set of multiple LV electrodes **132**, **134**, **136**, **138**. The LV lead **114** also may deliver left atrial pacing therapy using at least an LA ring electrode **128** and shocking therapy using at least the LA ring electrode **128**. In alternate embodiments, the LV lead **114** includes the LV electrodes **138**, **136**, **134**, and **132**, but does not include the LA electrode **130**. The LV lead **114** may be, for example, the Quartet™ LV pacing lead developed by St. Jude Medical Inc. (headquartered in St. Paul, Minn.), which includes four pacing electrodes on the LV lead. Although three leads **110**, **112**, and **114** are shown in FIG. **1**, fewer or additional leads with various configurations of pacing, sensing, and/or shocking electrodes may optionally be used. For example, the LV lead **114** may have more or less than four LV electrodes **132-138**.

[0034] When selecting a target venous branch for the LV lead **114**, several factors may be taken into account. For example, it may be desirable to maximize the LV mass that may be captured by the LV lead **114**. Accordingly, to maximize LV mass exposure, certain venous branches may be preferred for positioning the LV lead **114**. Further, a diameter and trajectory of the venous branch are also considered to ensure that the venous branch will support the chronic stability of the LV lead **114**. Passive fixation of the LV lead **114** may be established through the anatomy of the host venous branch which causes the LV lead **114** to extend the distal portion thereof in a manner that differs from the LV lead's preformed shape. Optionally, additional factors to be considered when placing the LV lead **114** may include reducing myocardial capture thresholds, avoiding atrial and phrenic nerve stimulation and the like. After the LV lead **114** is positioned, the LV pacing vectors may be selected.

[0035] The LV electrode **138** (also referred to as P4) is shown as being the most "distal" LV electrode with reference to how far the electrode is from the right ventricle **140**. The LV electrode **132** (also referred to as D1) is shown as being the most "proximal" LV electrode **132-138** to the left ventricle **142**. The LV electrodes **136** and **134** are shown as being "middle" LV electrodes (also referred to as M3 and M2), between the distal and proximal LV electrodes **138** and **132**, respectively. Accordingly, so as to more aptly describe their relative locations, the LV electrodes **138**, **136**, **134**, and **132** may be referred to respectively as electrodes D1, M2, M3, and P4 (where "D" stands for "distal", "M" stands for "middle", and "P" stands from "proximal", and the s are arranged from most distal to most proximal, as shown in FIG. **1**). Optionally, more or fewer LV electrodes may be provided on the lead **114** than the four LV electrodes D1, M2. M3, and P4.

[0036] The LV electrodes **132-138** are configured such that each electrode may be utilized to deliver pacing pulses and/or sense pacing pulses (e.g., monitor the response of the LV tissue to a pacing pulse). In a pacing vector or a sensing vector, each LV electrode **132-138** may be controlled to function as a cathode (negative electrode). Pacing pulses may be directionally provided between electrodes to define a pacing vector. In a pacing vector, a generated pulse is applied to the surrounding myocardial tissue through the cathode. The electrodes that define the pacing vectors may be electrodes in the heart **111** or located externally to the heart **111** (e.g., on a housing/case device **101**). For example, the housing/case **101** may be referred to as the housing **101** and function as an anode in unipolar pacing and/or sensing vectors. The RV coil **122** may also function as an anode in unipolar pacing and/or sensing vectors. The LV electrodes **132-138** may be used to provide various different vectors. Some of the vectors are intraventricular LV vectors (e.g., vectors between two of the LV electrodes **132-138**), while other vectors are interventricular vectors (e.g., vectors between an LV electrode **132-138** and the RV coil **122** or another electrode remote from the left ventricle **142**). Below is a list of exemplary bipolar sensing vectors with LV cathodes that may be used for sensing using the LV electrodes D1, M2, M3, and P4 and the RV coil **122**. It may be noted, that various other types of leads and IMDs may be used with various other types of electrodes and combinations of electrodes. The foregoing electrode types/combinations are provided as non-limiting examples. Further, it is recognized that utilizing an RV coil electrode as an anode is merely one example. Various other electrodes may be configured as the anode electrode.

Implantable Medical Device

[0037] FIG. **2** illustrates a schematic view of the IMD **100**. The IMD **100** has a housing **101** to hold the electronic/computing components. The housing **101** (which is often referred to as the "can," "case," "encasing," or new to me makes "case electrode") may be programmably selected to act as the return electrode for certain stimulus modes. The housing **101** further includes a connector (not shown) with a plurality of terminals **102**, **105**, **106**, **107** and **108**. The terminals may be connected to electrodes that are located in various locations within and about the heart. For example, the terminals may include: an electrode **102** to be coupled to a first electrode (e.g., a tip electrode) located in a first chamber; an electrode **105** to be coupled to a second electrode (e.g., tip electrode) located in a second chamber; an electrode **106** to be coupled to an electrode (e.g., ring) located in the first chamber; an electrode **107** to be coupled to an electrode located (e.g., ring electrode) in the second chamber; and an electrode **108** to be coupled to an electrode (e.g., coil) located in the SVC **116**. The type and location of each electrode may vary. For example, the electrodes may include various combinations of a ring, a tip, a coil and shocking electrodes and the like.

[0038] The IMD **100** includes a programmable microcontroller **164** that controls various operations of the IMD **100**, including cardiac monitoring and stimulation therapy. The microcontroller **164** includes a microprocessor (or equivalent control circuitry), one or more processors, RAM and/or ROM memory, logic and timing circuitry, state machine circuitry, and I/O circuitry. The IMD **100** further includes an atrial and/or ventricular pulse generator **174** that generates stimulation pulses for connecting the desired electrodes to the appropriate I/O circuits, thereby facilitating electrode programmability. The switch **192** is controlled by a control signal **186** from the microcontroller **164**.

[0039] A single pulse generator **174** is illustrated. Optionally, the IMD **100** may include multiple pulse generators, similar to the pulse generator **174**, where each pulse generator is coupled to one or more electrodes and controlled by the microcontroller **164** to deliver select stimulus pulse(s) to the corresponding one or more electrodes. The IMD **100** includes sensing circuitry **180** selectively coupled to one or more electrodes that perform sensing operations, through the switch **192** to detect the presence of cardiac activity in any chamber of the heart **111**. The output of the sensing circuitry **180** is connected to the microcontroller **164** which, in turn, triggers, or inhibits the pulse generator **174** in response to the absence or presence of cardiac activity. The sensing circuitry **180** receives a control signal **178** from the microcontroller **164** for purposes of controlling the gain, threshold, polarization charge removal circuitry (not shown), and the timing of any blocking circuitry (not shown) coupled to the inputs of the sensing circuitry.

[0040] In the example of FIG. **2**, a single sensing circuit **180** is illustrated. Optionally, the IMD **100** may include multiple sensing circuits **180**, similar to the sensing circuit **180**, where each sensing circuit is coupled to one or more electrodes and controlled by the microcontroller **164** to sense electrical activity detected at the corresponding one or more electrodes. The sensing circuit **180** may operate in a unipolar sensing configuration or a bipolar sensing configuration.

[0041] The IMD **100** further includes an analog-to-digital (A/D) data acquisition system (DAS) **190** coupled to one or more electrodes via the switch **192** to sample cardiac signals across any pair of desired electrodes. The A/D converter **190** is configured to acquire intracardiac electrogram signals, convert the raw analog data into digital data and store the digital data for later processing and/or telemetric transmission to an external device **104** (e.g., a programmer, local transceiver, or a diagnostic system analyzer). The A/D converter **190** is controlled by a control signal **188** from the microcontroller **164**.

[0042] The microcontroller **164** includes an arrhythmia circuit **166** for analyzing cardiac activity signals sensed by the sensing circuit **180** and/or the A/D converter **190**. The arrhythmia circuit **166** is configured to analyze cardiac signals sensed by the electrode and to deliver a therapy based on the cardiac signals. The arrhythmia detection circuit **166** declaring arrhythmias, in response to which, the microcontroller **164** determines an appropriate therapy. For example, responsive to the arrhythmia detection circuit **166** identifying a tachyarrhythmia, the microcontroller **164** directs the shocking circuit **184** to deliver a shock and/or directs the ATP pulse generator **174** to deliver an ATP therapy. The microcontroller **164** controls the timing of the stimulation pulses, the timing of refractory periods, blanking intervals, noise detection windows, evoked response windows, alert intervals, marker channel timing, and/or the like.

[0043] The microcontroller **164** is operably coupled to a memory **152** by a suitable data/address bus **162**. The programmable operating parameters used by the microcontroller **164** are stored in the memory **152** and used to customize the operation of the IMD **100** to suit the needs of a particular patient. The operating parameters of the IMD **100** may be non-invasively programmed into the memory **152** through a telemetry circuit **154** in telemetric communication via communication link **150** (e.g., MICS, Bluetooth low energy, and/or the like) with the external device **104**. The telemetry circuit **154** allows intracardiac electrograms, A2-P2 time interval, S2 Split types, cardiac conditions and status information relating to the operation of the IMD **100** (as contained in the microcontroller **164** and/or memory **152**) to be sent to the external device **104** through the established communication link **150**. The memory **152** also stores a cardiac condition matrix, as described herein that is utilized in connection with identifying cardiac conditions. As explained hereafter, the cardiac condition is determined by comparing the cardiac condition matrix to a type of S2 split that is exhibited during one or more cardiac cycles. The cardiac condition matrix is divided into multiple types of the S2 split and multiple local heart regions. The cardiac condition matrix includes different cardiac conditions associated with each combination of the S2 split type and local heart region. The local heart regions include a right heart region, a left heart region, and a greater vessel region. The microcontroller **164** is configured to identify, for a given type of the S2 split, one or more corresponding right heart-related conditions, left heart-related conditions, and greater vessel-related conditions.

[0044] The IMD **100** can further include one or more physiological sensors **156**. Such sensors are commonly referred to as "rate-responsive" sensors because they are typically used to adjust pacing stimulation rates according to the exercise state of the patient. However, the physiological sensor **156** may further be used to detect changes in cardiac output, changes in the physiological condition of the heart, or diurnal changes in activity (e.g., detecting sleep and wake states). Signals generated by the physiological sensors **156** are passed to the microcontroller **164** for analysis. While shown as being included within the unit **100**, the physiological sensor(s) **156** may be external to the IMD **100**, yet still, be implanted within or carried by the patient. Examples of physiological sensors might include sensors that, for example, sense respiration rate, pH of blood, ventricular gradient, activity, position/posture, minute ventilation (MV), and/or the like.

[0045] A battery **158** provides operating power to all of the components in the IMD **100**. The battery **158** is capable of operating at low current drains for long periods of time, and is capable of providing a high-current pulses (for capacitor charging) when the patient requires a shock pulse (e.g., in excess of 2 A, at voltages above 2 V, for periods of 10 seconds or more). The battery **158** also desirably has a predictable discharge characteristic so that elective replacement time can be detected. As one example, the IMD **100** employs lithium/silver vanadium oxide batteries.

[0046] The IMD **100** further includes an impedance measuring circuit **160**, which can be used for many things, including sensing respiration phase. The impedance measuring circuit **160** is coupled to the switch **192** so that any desired electrode and/or terminal may be used to measure impedance in connection with monitoring respiration phase.

[0047] The microcontroller **164** further controls a shocking circuit **184** by way of a control signal **186**. The shocking circuit **184** generates shocking pulses of low (e.g., up to 0.5 joules), moderate (e.g., 0.5-10 joules), or high energy (e.g., 11 to 40 joules), as controlled by the microcontroller **164**. Such shocking pulses are applied to the patient's heart through shocking electrodes. It is noted that the shock therapy circuitry is optional and may not be implemented in the IMD **100**.

[0048] In accordance with embodiments herein, the microcontroller **164** is electrically coupled to a heart sound sensor **170**. The heart sound sensor **170** is configured to sense heart sound signals of the subject. The heart sound signal can include any signal indicative of at least a portion of a lease one heart sound of the subject. A heart sound of the subject can include an audible or mechanical noise or vibration indicative of blood flow through the heart or valve closures of the heart. Optionally, the heart sound signals may include an electrical or optical signal. The heart sound signals may represent a measurement, feature, characteristic, computation, or interval of at least a portion of at least one heart sound. For example, the heart sound signals may include at least one of an amplitude of a heart sound, a magnitude of the heart sound, a total energy of the heart sound, and interval between one heart sound feature and another heart sound feature, at least one heart sound characteristic normalized by at least one other heart sound characteristic, and/or the like.

[0049] The microcontroller **164** is electrically coupled to a respiratory sensor **172**. The respiratory sensor **172** is configured to sense a respiration signal of the subject. The respiration signal can include any signal indicative of at least a portion of a lease one respiration signal of the subject. The respiration signal of the subject can include an audible or mechanical noise or vibration indicative of blood flow through the heart or valve closures of the heart. Optionally, the respiration signal may include an electrical or optical signal.

[0050] The respiration signal is indicating of respiratory phases (e.g, an expiration phase, an inspiration phase). For example, the respiratory signal may include at least one of an amplitude of a respiration, a magnitude of the respiration, a total energy of the respiration, and/or interval between one respiration feature and another respiration feature, at least one respiration characteristic normalized by at least one other respiration characteristic, and/or the like. The respiratory sensor **172** measures the analog signal indicative of the respiratory signal.

[0051] Optionally, the respiratory sensor **172** may include at least one of an accelerometer, a pressure sensor, and/or an impedance sensor that is configured to indicate a respiratory phase of the subject. The respiratory sensor **172** may include a pressure sensor configured to sense differences in pressure of the lungs corresponding to the respiratory phase of the subject. For example, the pressure sensor identifies changes in a movement by the lungs (e.g., inspiration phase, expiration phase) representing the respiratory phases of the subject. Optionally, the pressure sensor may include at least one of inspiration, and expiration, a transition between inspiration and expiration, a transition between expiration and inspiration, and/or the like. The respiratory sensor **172** may include an impedance sensor configured to sense differences in pressure of the lungs corresponding to the respiratory phases of the subject. For example, the impedance sensor may include a transthoracic impedance sensor configured to measure the respiratory phases of the lungs.

[0052] The microcontroller **164** includes a heart sound analysis (HSA) module **171** that implements the methods described herein. Among other things, the HSA model **171** analyzes the heart sound signals to identify the S2 signal segment and to identify, within the S2 signal segment, the P2 signal and the A2 signal. The HSA module **171** may identify the A2 and P2 signals in various manners. For example, one technique for identifying the A2 and P2 signals from the S2 signal segment is described in Tang, Hong, et al., "Discrimination of Aortic and Pulmonary Components from the Second Heart Sound Using Respiratory Modulation and Measurement of Respiratory Split," Jul. 4, 2017, which is hereby incorporated by reference. The HSA module **171** further determines the expiration and inspiration time intervals between the A2 and P2 signals and characterizes the A2 signal segment to exhibit a select type of S2 split based on the expiration and inspiration time intervals. The HSA module **171** also identifies a cardiac condition based on a comparison of the select type of the S2 split and a cardiac condition matrix.

[0053] FIG. **3** illustrates a graphical representation **300** of signals that are representative of various characteristics of the heart. A cardiac signal **308** is acquired at one or more electrodes and the sensing circuit **180** and/or the A/D DAS **190**. For example, the cardiac signal **308** is shown over time for at least two cardiac cycles. A heart sound signal **306** is sensed by the heart sound sensor **170** and analyzed by the HSA module **171**. FIG. **3** also illustrates aortic, atrial and ventricular pressures in connection with various cardiac events.

[0054] The heart sound signals **306** include an S2 signal segment. For example, the S2 signal segment is shown over time along the horizontal axis **324**. The HSA module **171** is configured to identify the S2 signal segment of the heart sound signals **306**. The HSA module **171** analyzes the S2 signal segment to identify a pulmonary valve signal (a P2 signal **316**) and an aortic valve signal (an A2 signal **314**) within the S2 signal segment of the heart sound signals **306**. In FIG. **3**, detail **326** is provided to illustrate the A2 and P2 signal components within the S2 signal segment. The A2 signal **314** and/or the P2 signal **316** are identified from the heart sound signals **306** by passing the frequencies between 5-200 Hz from the bandpass filter **168**.

[0055] Optionally, the microcontroller **164** and/or HSA module **171** may use the cardiac signal **308** to identify timing markers that are used to align a search window to identify the A2 and P2 signals **314**, **316**. For example, the microcontroller **164** and/or HSA module **171** may identify the QRS complex **320-321** and one or more markers from the QRS complex **320-321** to determine an RR interval or more generally a cardiac cycle length. The microcontroller **164** and/or HSA module **171** may identify T waves 322, 323 separate from or based on the QRS markers. The microcontroller **164** and/or HSA module **171** overlay an A2 search window upon the S2 signal segment, where the heart sound signal segment within the A2 search window is analyzed to identify the A2 signal **314**. The A2 search window may be positioned over the S2 signal segment at a point in time following a peak of the T wave by a predetermined time duration. For example, the predetermined time duration may be defined as a fixed value programmed by a clinician. Alternatively, the predetermined time duration may be automatically determined based on the length of the cardiac cycle (e.g., a percentage of the cycle length).

[0056] Once the A2 signal **314** is identified, a P2 search window is overlaid upon the S2 signal segment and the HSA module **171** analyzes the S2 signal segment to identify the P2 signal **316**. Optionally, the A2 signal **314** and the P2 signal **316** may be identified in other manners.

Respiration Signal

[0057] FIG. **4** illustrates a graphical representation **400** of a respiration signal **414** measured in accordance with embodiments herein. The respiration signal **414** is shown along three different axes **402**, **404**, **406**. A horizontal axis **404** represents time, a vertical axis **402** represents the respiratory phase, and a height axis **406** represents an amplitude of the respiration signal **414**. The amplitudes are shown as millivolts that are identified by the respiratory sensor **172**. For example, the height axis **406** includes three peaks **408**, **410**, **412** that represent the different respiratory phases of the respiration signal **414**. The peaks **408** and **410** represent the expiration phase of the respiration signal **414**. The peak **410** represents the inspiration phase of the respiration signal **414**. For example, the inspiration phase and the expiration phase are example points along the respiratory phase of the respiration signal **414**. The amplitudes of the peaks **408**, **410**, **412** are shown along the height axis **406**.

[0058] FIG. **5** illustrates a graphical representation **500** of shifts in the A2 signal and P2 signal components relative to one another in connection with different respiratory phases at which the S2 signal segment occurs. FIG. **5** illustrates S2 signal segments **506**A-C extends along a horizontal axis **504** representing time. For example, the S2 signal segments **506**A-C corresponds to three points along the inspiration phase and the expiration phase. In accordance with embodiments herein, the microcontroller **164** collects first heart sound signals during an inspiration phase and second heart sound signals during an expiration phase. For example, from the first and second heart sound signals, the microcontroller **164** may determine the S2 signal segments **506**A and **506**C during an expiration phase and determine S2 signal segment **506**B during an inspiration phase.

[0059] For example, the S2 signal segments **506**A and **506**C exhibit a first relation between the A2 signal **512** and P2 signal **514** in connection with the expiration phase (e.g, as monitored by the respiratory sensor **172**). The S2 signal segments **506**B exhibits a second relation between the A2 signal **512** and P2 signal **514** in connection with the inspiration phase. For example, the microcontroller **164** utilizes the respiration signals to determine which respiratory phase a particular combination of the A2 signal **512** and the P2 signal **514** are collected in connection with.

[0060] The P2 signal **514** may be identified based on morphology (e.g., amplitude and/or slope). For example, the microcontroller **164** analyzes a slope and/or derivative of the respiratory signals and/or S2 signal segment. The microcontroller **164** may compare the slope and/or the derivative relative to one or more the respiratory signals stored in the memory **152**. The microcontroller **164** identifies the time interval **516** between the A2 and P2 signals **512**, **514**. For example, the microcontroller **164** calculates the time interval **516** between a characteristic of interest in the A2 and P2 signals **512**, **514**. The characteristic of interest may represent a maximum peak and/or slope in the A2 and P2 signals **512**, **514**.

[0061] The time intervals **516**, determined in connection with a combination of S2 signal segments for inspiration and expiration phases of a respiratory cycle are utilized to characterize a type of the S2 split. For example, the S2 split may exhibit various types. Once the type is characterized for the S2 split, the microcontroller **164** identifies a cardiac condition based on a comparison of the type of the S2 split and a cardiac condition matrix.

S2 Split Types

[0062] FIG. **6** illustrates a graphical representation **600** of different types of S2 splits that may be exhibited, including a normal split **602**, a wide split **604**, a fixed split **606**, and a paradoxical split **608**. The A2 signal **314** and the P2 signal **316** are shown divided into the expiration phase **610** and the inspiration phase **612**. The different types of split for the normal split **602**, wide split **604**, a fixed split **606**, and the paradoxical split **608** may be determined in connection with one or more cardiac cycles and respiratory cycles for which heart sound signals and respiration signals are collected over a period of time by the IMD **100** and/or the microcontroller **164**. For example, the period of time may represent years, months, days, and/or the like over a period of time.

[0063] The normal split **602** corresponds to a relation in which the A2 signal **314** and the P2 signal **316** are separated by a first/expiration time interval during the expiration phase and a second/inspiration longer time interval during the inspiration phase, where the first and/or second time intervals are less than corresponding predetermined normal split limits. For example, a normal split limit may be defined (e.g., manually programmed and/or automatically calculated). In order to be classified as a normal split, one or both of the expiration and inspiration time intervals should fall below the normal split limit. In addition, to be classified as a normal split, the first/expiration time interval is equal to or longer than the second/inspiration time interval by up to a predetermined limit. The inspiration and expiration time intervals may generally be referred to as split time intervals. The expiration-inspiration difference, between the first/expiration and second/inspiration time intervals corresponding to the separation between the A2 and P2 signals, may vary within a predetermined limit. Additionally or alternatively, a limit for the difference, between the first/expiration and second/inspiration time intervals, may be programmed to have a maximum upper difference. Additionally or alternatively, limits for the difference may be defined based on previous data collected in connection with the present patient and/or based on data collected in connection with a larger patient population.

[0064] The wide split **604** corresponds to a relation in which the A2 signal **314** and the P2 signal **316** are separated by a first/expiration time interval **614** during the expiration phase and a second/inspiration longer time interval **616** during the inspiration phase where the expiration and/or inspiration intervals **614**, **616** are greater than corresponding predetermined limits. When one or both of the expiration and inspiration time intervals **614**, **616** exceed the normal split limit, the combination is classified as a wide split **604**. Additionally or alternatively, the combination may be classified as a wide split **604** when the inspiration time interval **616** exceeds the expiration time interval **614** by more than a predetermined expiration-inspiration difference. In accordance with embodiments herein, when a wide split **604** is identified, the IMD **100** may vary the RV and/or the LV delays to correct for the wide split **604**. For example, the adjustment in the pacing delays of the RV and/or the LV may adjust the wide split **604**, which may change the splits **614**, **616** (e.g., the expiration and/or inspiration intervals **614**, **616**) to be within the normal split **602** range.

[0065] The fixed split **606** corresponds to a relation in which the A2 signal **314** and the P2 signal **316** are separated by a first/expiration time interval **618** during the expiration phase and a second/inspiration time interval **620** during the inspiration phase, where the expiration and inspiration time intervals **618**, **620** are substantially similar or with when a relatively close interval of one another. For example, the microcontroller **164** may determine the splits **618**, **620** (e.g., the expiration and inspiration time intervals **618**, **620**) may be similar to and/or the same relative to each other.

[0066] The paradoxical split **608** corresponds to a change in order of the A2 signal **314** and the P2 signal **316** relative to the order in the normal split **602**. For example, during the expiration phase **610**, the P2 signal **316** occurs prior to and/or before the A2 signal **314**. Additionally or alternatively, the A2 signal **314** occurs prior to and/or before the P2 signal **316** during the inspiration phase **612**. Based on the change of order of the A2 signal **314** and the P2 signal **316** between the expiration and/or inspiration phase is **610**, **612**, the microcontroller **164** may determine that paradoxical split **608** is present.

Cardiac Condition Matrix

[0067] FIG. **7** illustrates a cardiac condition matrix **700** formed in accordance with embodiments herein. The cardiac condition matrix **700** may be organized in various manners, such as in columns **702-708** related to different local heart regions, such as a right heart region, a left heart region, and a greater vessel region. The column **702** represents activation of the RV only pacing of the right ventricle. The column **704** represents activation of the LV only pacing of the left ventricle. The columns **706**, **708** do not correspond to activation of the RV and/or LV pacing. Instead, column **706** corresponds to conditions related to the greater vessels, while column **708** corresponds to conditions related to the septum. The conditions recorded in the matrix **700** may be determined based on history and/or recording of the cardiac condition over time of the subject. The history and/or recording of the cardiac condition of the subject may be based on a period of years, days, months and/or the like of the subject stored in the memory **152**.

[0068] The cardiac condition matrix **700** is also organized in rows **710-720** that correspond to different types of S2 splits. The cardiac condition matrix **700** further includes different cardiac conditions (CC) associated with each combination of the S2 split type and/or local heart region. By way of example, CC cell **722** in the matrix **700** indicates that, when an IMD provides RV only pacing and an S2 split type is identified to correspond to a wide split, the microcontroller **164** will identify a cardiac condition to represent right bundle branch block (RBBB) of the subject. As another example, CC cell **724** in the matrix **700** indicates that, when an IMD provides LV only pacing and an S2 split type is identified to correspond to a wide split, the microcontroller **164** will identify a cardiac condition to represent preexcitation of left ventricle, left ventricle pacing, and/or premature LV beats.

[0069] As indicated at CC cell **726**, when no pacing is provided, and a wide split is identified, the microcontroller **164** will identify the cardiac condition to represent pulmonic stenosis, pulmonary arterial hypertension. For example, one or more of the pulmonic stenosis and/or pulmonary arterial hypertension may be identified based on a history and/or recording the cardiac condition over time for the subject stored in the memory **152**. The microcontroller **164** may determine the pulmonic stenosis and/or pulmonary arterial hypertension based on the history and/or recording the cardiac condition over time of the subject stored in the memory **152**.

[0070] The matrix **700** further indicates that, when the S2 split type exhibits excessive split during expiration **714** and normal split during inspiration, during RV only pacing, the heart condition could be associated with the RV pacing. Alternatively, during LV only pacing, the heart condition corresponds to one or more of hypertrophic cardiomyopathy and/or left bundle branch block (LBBB). Alternatively, when no LV pacing and no RV pacing is applied, when excessive split occurs only during expiration, the cardiac condition is that the greater vessels are experiencing an aortic stenosis. For example, the aortic stenosis may be based on historical context and/or recording the cardiac condition over time for the subject stored in the memory **152**.

[0071] The matrix **700** further indicates certain cardiac conditions that may be present when the S2 split type exhibits a fixed split during both inspiration and expiration **716**. When the S2 split type is declared to exhibit a fixed split, when RV only pacing is present, the cardiac condition may indicate right heart failure. When the S2 split type is declared to exhibit a fixed split during LV only pacing, the cardiac condition may be unknown or indeterminate. When the S2 split type is declared to exhibit a fixed split during no LV pacing and no RV pacing, cardiac condition may indicate pulmonary hypertension.

[0072] The matrix **700** further indicates certain cardiac conditions that may be present when the S2 split type exhibits split during both inspiration and expiration **718**, but not a fixed split. In connection with the condition at **718**, when RV only pacing is applied, the cardiac condition may be unknown or indeterminate. When LV only pacing is applied, the cardiac condition may indicate LBBB, preexcitation of the RV, RV pacing related condition and/or premature RV beats.

[0073] The matrix **700** further indicates certain cardiac conditions that may be present when there is a loss of either the A2 signal or the P2 signal **720**. The loss of A2 and/or P2 signals may occur in obese patients, patients with emphysema, or excess pericardial fluid. For example, the A2 and/or the P2 signals **314**, **316** may be missing and/or lost by the heart sound sensor **170**, the respiratory sensor **172**, and/or the arrhythmia circuit **166**. When the foregoing conditions are present, the P2 signal may not be properly sensed. When the condition at **720** is identified, the cardiac condition may be determined to represent severe aortic stenosis, severe aortic regurgitation, and/or congenital absence of pulmonary valve.

[0074] Optionally, a cardiac condition may transition between different types of S2 split. For example, a wide split **712** may occur after and/or subsequent to a normal split **710** of the subject. For example, the IMD **100** may determine that the subject has had the normal split **710** for a period of time stored in the memory **152**. Responsive to the wide split **712**, the microcontroller **164** may determine and/or identify the cardiac condition based on a comparison of the time interval of the S2 split in the cardiac condition matrix **700**.

[0075] FIG. **8** illustrates a method implemented in accordance with embodiments for herein for utilizing A2 and P2 signals to identify cardiac conditions. The method **800**, for example, may employ or be performed by structures or assets of various embodiments (e.g., systems and/or methods and/or process flows) discussed herein. In various embodiments, certain steps may be omitted or added, certain steps may be combined, you certain steps may be performed concurrently, certain steps may be split into multiple steps, or certain steps may be performed in a different order.

[0076] Beginning at **802**, the microcontroller **164** receives the heart sound signals **306**. The heart sound sensor **170** measures an analog signal indicative of the heart sound signals **306**. Optionally at **802**, the microcontroller **164** receives respiration signals from the respiratory sensor **172**. For example, the respiratory sensor **172** measures an analog signal indicative of the respiratory sound. For example, an amplitude, a frequency, and/or the like of the analog signal may increase relative to the increase in pressure of the lungs, representing an inspiration phase. Additionally or alternatively, the amplitude, the frequency, and/or the like of the analog signal may decrease relative to the loss in pressure of the lungs, representing an expiration phase. Based on the inspiration and expiration phases, the respiratory sensor **172** determines the respiratory phase of the subject. At **802**, the microcontroller **164** aligns the heart sound signals and the respiration signals. Additionally or alternatively, the microcontroller **164** receives cardiac signal **308** from the arrhythmia circuit **166**. For example, the arrhythmia circuit **166** is configured to monitor cardiac activity signals of the subject.

Optionally, the arrhythmia circuit **166** may be utilized as an electromyography (EMG) sensor configured to detect a cardiac signal of the subject.

[0077] At **804**, the microcontroller **164** identifies an S2 signal segment from the heart sound signals. Optionally, the microcontroller **164** may identify a respiratory phase from the respiratory signals, analyze the cardiac signals **308** and the like.

[0078] At **806**, the microcontroller **164** analyzes the S2 signal segment to identify an A2 signal and a P2 signal within the S2 signal segment of the heart sound signals. For example, the microcontroller **164** may apply a bandpass filter **168** to the heart sound signals **306**. For example, the bandpass filter **168** is configured to allow frequencies between 5-200 Hz of the heart sound signals **306** acquired by the heart sound sensor **170** to form the revised heart sound signals **316**. Additionally or alternatively, the bandpass filter **168** is configured to allow frequencies between 0.05-1 Hz for the cardiac signal **308** and/or the respiratory signals **506**A-C acquired by the respiratory sensor **172**.

[0079] Optionally, the microcontroller **164** may align the revised heart sound signals **316** and the respiratory signals with each other. For example, the microcontroller **164** may align the revised heart sound signals **316** and the respiratory signals with the respiratory phases (e.g., the inspiration phase, the expiration phase). The microcontroller **164** may identify the A2 and P2 signals **314**, **316** in connection with respiratory phases of interest based on the respiratory signals. The microcontroller **164** may identify combinations of the A2 signal **512** and the P2 signal **514** in conjunction with the expiration phase and inspiration phase. The microcontroller **164** identifies and saves combinations of inspiration and expiration time intervals. The inspiration time interval is between the A2 and P2 signals of the inspiration phase and the expiration time interval is between the A2 and P2 signals of the expiration phase.

[0080] At **808**, the microcontroller **164** analyzes the inspiration and expiration time intervals and characterizes one or more S2 signal segments to exhibit a first type of S2 split based on the time intervals between the A2 and P2 signals during the corresponding phases of the respiratory cycle. Optionally, the microcontroller **164** compares the inspiration and expiration time intervals to a template. Additionally or alternatively, the microcontroller **164** may compare a difference between the inspiration and expiration time intervals with one or more templates stored in the memory **152**. The templates may represent one or more different time intervals.

[0081] At **810**, the microcontroller **164** characterizing the first type of S2 split to be one of a normal split **602**, a wide split **604**, a fixed split **606**, or a paradoxical split **608**. FIG. **6** illustrates examples of different types of splits and criteria to distinguish each type of split. At **811**, the microcontroller **164** identifies the cardiac condition based on a comparison of the first type of the S2 split and the cardiac condition matrix **700**. FIG. **7** illustrates examples of cardiac conditions that may be identified from the matrix **700**.

[0082] At **813**, the microcontroller **164** records the cardiac condition over time for the subject to develop a patient tracking record indicating at least one of a new cardiac conditions or changes in existing cardiac conditions. For example, the microcontroller **164** records the cardiac conditions received from the cardiac signal **308**. The microcontroller **164** may identify the patient tracking record indicating at least one of the new cardiac conditions. For example, the microcontroller **164** may identify adjustments to the QRS complex **318**, **319**, and/or the like that may indicate changes in the heart **111** of the subject. Optionally, the microcontroller **164** may identify changes in the A2 signal **314** and/or the P2 signal **316** that may indicate a change in the normal split **602**, the wide split **604**, the fixed split **606**, and/or the paradoxical split **608**.

[0083] At **814**, the microcontroller **164** monitors the split time intervals between the A2 and P2 signals over a period of time. The microcontroller **164** records changes in the split time intervals (e.g., inspiration and/or expiration time intervals) in connection with monitoring for heart failure. For example, the microcontroller **164** may identify changes in the split time interval that may represent adjustments from normal split **602** to at least one of the wide split **604**, fixed split **606**, and/or paradoxical split **608**.

[0084] At **815**, the microcontroller **164** determines whether the split time intervals are normal. For example, the microcontroller **164** may compare changes in the split time intervals relative to split time intervals associated with a normal split. When split time intervals are identified to change from a normal split to an abnormal split type, flow moves to **816**. When the split time intervals remain normal, flow moves to **818**. At **818**, responsive to the determination by the microcontroller **164** that the heart sound includes a normal split **710**, the microcontroller **164** may not adjust the pacing delays of the LV and/or the RV. The microcontroller **164** may not adjust the pacing delays of the RV and/or the LV pacing. Optionally, the microcontroller **164** may return to the operation **802** to receive heart sound signals of the subject.

[0085] At **816**, the microcontroller **164** identifies adjustments to be automatically applied in connection with identifying at least one of the wide split **604**, fixed split **606**, and/or paradoxical split **608**. For example, at **816**, responsive to the determination of a cardiac condition (e.g., wide split **712**, split duration expiration **714**, split during both inspiration and expiration (e.g., fix split) **716**, split during both inspiration and expiration **718**, loss of A2 signal **314** and/or loss of P2 signal **316**, the microcontroller **164** adjusts the pacing delays of the RV and/or the LV pacings, notify great vessels and/or septum. For example, the microcontroller **164** may adjust the pacing delays of the RV and/or the LV pacings to adjust the time interval between the A2 and the P2 signals **314**, **316**. The adjustment of the pacing delays may adjust the time interval, which may affect the wide split **604**, the fixed split **606**, and/or the paradoxical split **608**. Additionally or alternatively, the microcontroller **164** may notify the external device **104** of the cardiac conditions of the great vessels and/or septum.

[0086] The foregoing operations at **816**, **818** are described in connection with pacing features. Additionally or alternatively, adjustments may be made in connection with cardiac resynchronization therapy (CRT) timing delays. For example, based on the S2 split characterized and monitored, as described herein, a VV delay and/or an AV delay for a CRT device may be adjusted until the timing split approaches a normal split. In this alternative embodiment, at **816**, the VV delay and/or AV delay of a CRT device would be adjusted and the operations of FIG. **8** repeated until the timing split was deemed normal at **815**.

Closing Statements

[0087] It should be clearly understood that the various arrangements and processes broadly described and illustrated with respect to the Figures, and/or one or more individual components or elements of such arrangements and/or one or more process operations associated of such processes, can be employed independently from or together with one or more other components, elements and/or process operations described and illustrated herein. Accordingly, while various arrangements and processes are broadly contemplated, described and illustrated herein, it should be understood that they are provided merely in illustrative and non-restrictive fashion, and furthermore can be regarded as but mere examples of possible working environments in which one or more arrangements or processes may function or operate.

[0088] As will be appreciated by one skilled in the art, various aspects may be embodied as a system, method or computer (device) program product. Accordingly, aspects may take the form of an entirely hardware embodiment or an embodiment including hardware and software that may all generally be referred to herein as a "circuit," "module" or "system." Furthermore, aspects may take the form of a computer (device) program product embodied in one or more computer (device) readable storage medium(s) having computer (device) readable program code embodied thereon.

[0089] Any combination of one or more non-signal computer (device) readable medium(s) may be utilized. The non-signal medium may be a storage medium. A storage medium may be, for example, an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system, apparatus, or device, or any suitable combination of the foregoing. More specific examples of a storage medium would include the following: a portable computer diskette, a hard disk, a random access memory (RAM), a dynamic random access memory (DRAM), a read-only memory (ROM), an erasable programmable read-only memory (EPROM or Flash memory), a portable compact disc read-only memory (CD-ROM), an optical storage device, a magnetic storage device, or any suitable combination of the foregoing.

[0090] Program code for carrying out operations may be written in any combination of one or more programming languages. The program code may execute entirely on a single device, partly on a single device, as a stand-alone software package, partly on single device and partly on another device, or entirely on the other device. In some cases, the devices may be connected through any type of network, including a local area network (LAN) or a wide area network (WAN), or the connection may be made through other devices (for example, through the Internet using an Internet Service Provider) or through a hard wire connection, such as over a USB connection. For example, a server having a first processor, a network interface, and a storage device for storing code may store the program code for carrying out the operations and provide this code through its network interface via a network to a second device having a second processor for execution of the code on the second device.

[0091] Aspects are described herein with reference to the Figures, which illustrate example methods, devices and program products according to various example embodiments. These program instructions may be provided to a processor of a general purpose computer, special purpose computer, or other programmable data processing device or information handling device to produce a machine, such that the instructions, which execute via a processor of the device implement the functions/acts specified. The program instructions may also be stored in a device readable medium that can direct a device to function in a particular manner, such that the instructions stored in the device readable medium produce an article of manufacture including instructions which implement the function/act specified. The program instructions may also be loaded onto a device to cause a series of operational steps to be performed on the device to produce a device implemented process such that the instructions which execute on the device provide processes for implementing the functions/acts specified.

[0092] The units/modules/applications herein may include any processor-based or microprocessor-based system including systems using microcontrollers, reduced instruction set computers (RISC), application specific integrated circuits (ASICs), field-programmable gate arrays (FPGAs), logic circuits, and any other circuit or processor capable of executing the functions described herein. Additionally or alternatively, the modules/controllers herein may represent circuit modules that may be implemented as hardware with associated instructions (for example, software stored on a tangible and non-transitory computer readable storage medium, such as a computer hard drive, ROM, RAM, or the like) that perform the operations described herein. The above examples are exemplary only, and are thus not intended to limit in any way the definition and/or meaning of the term "controller." The units/modules/applications herein may execute a set of instructions that are stored in one or more storage elements, in order to process data. The storage elements may also store data or other information as desired or needed. The storage element may be in the form of an information source or a physical memory element within the modules/controllers herein. The set of instructions may include various commands that instruct the modules/applications herein to perform specific operations such as the methods and processes of the various embodiments of the subject matter described herein. The set of instructions may be in the form of a software program. The software may be in various forms such as system software or application software. Further, the software may be in the form of a collection of separate programs or modules, a program module within a larger program or a portion of a program module. The software also may include modular programming in the form of object-oriented programming. The processing of input data by the processing machine may be in response to user commands, or in response to results of previous processing, or in response to a request made by another processing machine.

[0093] It is to be understood that the subject matter described herein is not limited in its application to the details of construction and the arrangement of components set forth in the description herein or illustrated in the drawings hereof. The subject matter described herein is capable of other embodiments and of being practiced or of being carried out in various ways. Also, it is to be understood that the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The use of "including," "comprising," or "having" and variations thereof herein is meant to encompass the items listed thereafter and equivalents thereof as well as additional items.

[0094] It is to be understood that the above description is intended to be illustrative, and not restrictive. For example, the above-described embodiments (and/or aspects thereof) may be used in combination with each other. In addition, many modifications may be made to adapt a particular situation or material to the teachings herein without departing from its scope. While the dimensions, types of materials and coatings described herein are intended to define various parameters, they are by no means limiting and are illustrative in nature. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the embodiments should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. In the appended claims, the terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein." Moreover, in the following claims, the terms "first," "second," and "third," etc. are used merely as labels, and are not intended to impose numerical requirements on their objects or order of execution on their acts.

What is claimed is:

1. An implantable medical device, comprising:

a heart sound sensor configured to sense heart sound signals of a subject;

a memory to store program instructions; and

a processor that, when executing the program instructions, is configured to:

identify an S2 signal segment from the heart sound signals;

analyze the S2 signal segment to identify a pulmonary valve signal (P2 signal) and an aortic valve signal (A2 signal) within the S2 signal segment of the heart sound signals;

determine a time interval between the A2 and P2 signals;

characterize the S2 signal segment to exhibit a first type of S2 split based on the time interval between the A2 and P2 signals; and

identify a cardiac condition based on a comparison of the first type of the S2 split and a cardiac condition matrix.

2. The device of claim **1**, wherein the processor is configured to characterize the first type of S2 signal segment to be one of a normal split, a wide split, a fixed split, or a paradoxical split.

3. The device of claim **1**, wherein the processor is configured to identify the cardiac condition based on the cardiac condition matrix that is divided based multiple types of the S2 split and multiple local heart regions, the cardiac condition matrix further including different cardiac conditions associated with each combination of the S2 split type and local heart region.

4. The device of claim **3**, wherein the local heart regions include a right heart region, a left heart region, and a greater vessel region, the processor configured to identify, for the first type of the S2 split, corresponding right heart-related conditions, left heart-related conditions, and greater vessel-related conditions.

5. The device of claim **1**, further comprising a respiration sensor configured to sense a respiration signal of the subject, wherein the processor is configured to apply a bandpass filter to the respiration signal to identify the P2 signal and the A2 signal from the S2 signal segment.

6. The device of claim **5**, wherein the respiration sensor comprises at least one of an accelerometer, a pressure sensor, or an impedance sensor that is configured to indicate a respiratory phase of the subject.

7. The device of claim **1**, further comprising a respiration sensor configured to sense a respiration signal of the subject, the respiration signal including an expiration phase and an inspiration phase that form at least part of a respiratory cycle of the subject, wherein the processor is configured to identify expiration and inspiration time intervals between the P2 signal and the A2 signal in connection with the expiration and inspiration phases.

8. The device of claim **7**, wherein the processor is configured to extract the P2 signal and the A2 signal based on a peak of the A2 signal and a slope of the P2 signal.

9. The device of claim **1**, further comprising an electromyography (EMG) sensor configured to detect a cardiac signal of the subject, wherein the processor is configured to use the cardiac signal to apply a bandpass filter to the cardiac signal to identify the P2 signal and the A2 signal.

10. The device of claim **1**, wherein the processor is configured to record the cardiac condition over time for the subject.

11. The device of claim **1**, wherein the subject to develop a patient tracking record indicating at least one of new cardiac conditions or changes in existing cardiac conditions.

12. The device of claim **1**, wherein the processor is configured to monitor the time interval between the A2 and P2 signals over time and record changes in the time interval in connection with monitoring for heart failure.

13. The device of claim **1**, further comprising a pulse generator to deliver pacing therapy based in part on programmed AV and VV delays, wherein the processor is configured to monitor the time interval between the A2 and P2 signals over time and record changes in the time interval in connection with adjustments in at least one of the programmed AV or VV delays for the IMD.

14. A method to manage an implantable medical device (IMD) comprising:

receiving heart sound signals of a subject;

identifying an S2 signal segment from the heart sound signals;

analyzing the S2 signal segment to identify a pulmonary valve signal (P2 signal) and an aortic valve signal (A2 signal) within the S2 signal segment of the heart sound signals;

characterizing the S2 signal segment to exhibit a first type of S2 split based on the time interval between the A2 and P2 signals; and

identifying a cardiac condition based on a comparison of the first type of S2 split and a cardiac condition matrix.

15. The method of claim **13**, further comprising characterizing the first type of S2 split to be one of a normal split, a wide split, a fixed split, or a paradoxical split.

16. The method of claim **15**, wherein the local heart regions include a right heart region, a left heart region, and a greater vessel region; and

further comprising identifying the first type of the S2 split, corresponding a right heart-related conditions, a left heart-related conditions, we try to do and a greater vessel-related conditions.

17. The method of claim **17**, wherein the respiration sensor comprises at least one of an accelerometer, a pressure sensor, an impedance sensor that are configured to indicate a respiratory phase of the subject.

18. The method of claim **18**, further comprising extracting the P2 signal and the A2 signal based on a peak of the A2 signal and a slope of the P2 signal relative to the respiratory phase.

19. The method of claim **13**, further comprising receiving a respiration signal of the subject, the respiration signal including an expiration phase and an inspiration phase that form a respiratory cycle of the subject, and identifying the P2 signal and the A2 signal based on the expiration and inspiration phases.

20. The method of claim **13**, further comprising recording the cardiac condition over time for the subject to develop a patient tracking record indicating at least one of a new cardiac conditions or changes in existing cardiac conditions.

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专利名称(译)	检测心音以监测心脏功能的方法和设备		
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申请(专利权)人(译)	PACESETTER , INC.		
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IPC分类号	A61B7/04 A61B5/0205 A61B5/00 A61N1/365 A61B7/02		
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摘要(译)

提供了用于监视心脏的心脏功能的方法和可植入医疗设备（IMD）。 心音传感器被配置为感测对象的心音信号。 IMD包含用于存储程序指令的存储器。 IMD包括处理器，该处理器在执行程序指令时被配置为从心音信号中识别S2信号段，分析该S2信号段以识别肺动脉瓣信号（P2信号）和主动脉瓣信号（A2信号） 在心音信号的S2信号段内。 处理器被配置为确定A2和P2信号之间的时间间隔，基于该时间间隔表征S2信号段以表现出第一类型的S2分裂，并基于第一类型的S2的比较来识别心脏状况 拆分和心脏疾病矩阵。