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(56) References cited:
US-A- 5 817 135
US-A1- 2012 203 123
US-A1- 2013 226 263
US-A1- 2015 157 273

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Description

TECHNICAL FIELD

[0001] This document relates generally to medical devices, and more particularly, to systems, devices and methods for detecting and managing cardiac arrhythmias.

BACKGROUND

[0002] Implantable medical devices (IMDs) have been used for monitoring patient health condition or disease states and delivering therapies. For example, implantable cardioverter-defibrillators (ICDs) may be used to monitor for certain abnormal heart rhythms and to deliver electrical energy to the heart to correct the abnormal rhythms. Some IMDs may be used to monitor for chronic worsening of cardiac hemodynamic performance, such as due to congestive heart failure (CHF), and to provide cardiac stimulation therapies, including cardiac resynchronization therapy (CRT) to correct cardiac dyssynchrony within a ventricle or between ventricles.

[0003] The IMDs may be programmed to store physiological data in a memory. The physiological data may be retrieved and presented to a system user such as a clinician in a display device. The system user may review the stored physiological data to determine the presence or causes of a physiological event, or to determine whether a device therapy results in desired therapeutic outcome.

[0004] Some IMDs are able to detect cardiac arrhythmias, such as atrial fibrillation (AF). AF is the most common clinical arrhythmia affecting millions of people. During AF, disorganized electrical pulses originated from regions in or near an atrium may lead to irregular conductions to ventricles, thereby causing inappropriately fast and irregular heart rate. AF may be paroxysmal that may last from minutes to days before it stops by itself, persistent that may last for over a week and typically requires medication or other treatment to revert to normal sinus rhythm, or permanent where a normal heart rhythm cannot be restored with treatment. Timely detection of AF, and storing electrograms and other physiological information associated with the AF, may be clinically important for assessing progression of AF. US2012203123 discloses a control circuit which can specify a lower number of turns for the turn count threshold to increase sensitivity for the pacemaker dependent patient.

OVERVIEW

[0005] Implantable medical devices are capable of detecting physiological events, such as cardiac arrhythmias or progression of chronic heart diseases, and obtaining sampled values of cardiac electrical activity signals such as electrograms. Some IMDs may further be communicated with multiple physiological sensors that may measure various physiological signals. The IMD may be programmed to monitor and store data sensed from some or all of the physiological sensors.

[0006] Capturing accurate electrogram or other physiological sensor information obtained over a longer period of time, such as chronically between regularly-scheduled outpatient office visits, may help the physician re-program the device, if needed, or to diagnose and assess the patient's condition. Recording of electrograms or other physiological sensor data may be limited by the restricted data storage space available within the IMD. In an IMD programmed to detect cardiac arrhythmias such as atrial fibrillation (AF) events, noise, motion artifacts, or cardiac rhythms other than the AF event may be inappropriately detected as AF events. Inappropriate arrhythmia detection may reduce detection specificity and result in inappropriate treatment to patients. Additionally, storing the inappropriately detected arrhythmic events may waste and quickly exhaust device memory. Alerts to clinicians of inappropriately detected arrhythmic events, or presenting to clinicians a large volume of inappropriately detected arrhythmic events for review or adjudication, may adversely affect the device efficacy and unwarrantedly increase the cost associated with patient management. For at least these reasons, the present inventors have recognized, among other things, substantial challenges and a demand for a more efficient arrhythmic detection and reporting system, while storing the most relevant arrhythmic events or presenting these events to a clinician.

[0007] This document discusses, among other things, systems, devices, and methods for detecting an arrhythmic event and storing physiological information associated with the detected arrhythmic event. A system may include a first detector to detect an arrhythmic event from a physiological signal sensed from a subject, and generate a confidence indicator indicating a confidence level of the detection of the arrhythmic event. If the confidence indicator indicates a relatively high confidence of arrhythmia detection, the system may provide the detected arrhythmic event to a first process for storing the detected arrhythmic event or generating an alert. If the confidence indicator indicates a relatively low confidence of arrhythmia detection, the system may provide the detected arrhythmic event to at least a second process including confirming the detected arrhythmic event.

In Example 1, a system may include a physiological sensor circuit to sense a physiological signal from a subject, a first arrhythmia detector circuit configured to detect an arrhythmic event from the sensed physiological signal, a confidence indicator generator circuit configured to generate a confidence indicator for the detected arrhythmic event, the confidence indicator indicating a confidence level of the detection of the arrhythmic event, and a controller circuit coupled to the arrhythmia detector circuit and configured to provide the detected arrhythmic event to a first

process in response to the confidence indicator indicating a first confidence level, and provide the detected arrhythmic event to at least a second process different from the first process in response to the confidence indicator indicating a different second confidence level.

Example 2 may include, or may optionally be combined with the subject matter of Example 1 to optionally include, the first arrhythmia detector circuit that may detect the arrhythmic event including an atrial or ventricular arrhythmia.

Example 3 may include, or may optionally be combined with the subject matter of one or any combination of Examples 1 or 2 to include, the controller circuit that may be configured to provide the detected arrhythmic event to the first process in response to the confidence indicator exceeding a confidence threshold indicative of a high confidence of the detection of the arrhythmic event. The first process may include storing the detected arrhythmic event in a memory circuit, or producing an alert signal.

Example 4 may include, or may optionally be combined with the subject matter of one or any combination of Examples 1 through 3 to include, the controller circuit that may, provide the detected arrhythmic event to the at least second process in response to the confidence indicator falling below a confidence threshold indicative of a low confidence of the detection of the arrhythmic event. The second process may include detecting the arrhythmic event using at least a second arrhythmia detector circuit to confirm the detected arrhythmic event. The second arrhythmia detector circuit may have more computational power or execute a more computationally intensive algorithm than the first arrhythmia detector.

Example 5 may include, or may optionally be combined with the subject matter of one or any combination of Examples 1 through 4 to include, the physiological sensor circuit that may receive the physiological signal including a cardiac signal, and the first arrhythmia detector circuit that may include a filter circuit to generate a signal metric from the cardiac signal, the first arrhythmia detector circuit configured to detect the arrhythmic event in response to the signal metric satisfying a specified condition.

Example 6 may include, or may optionally be combined with the subject matter of Example 5 to optionally include, the signal metric that may include a first number of stable beats from the cardiac signal within a specified time period, a second number of unstable beats from the cardiac signal within the specified time period, or a third number of a relative number between the first and second numbers.

Example 7 may include, or may optionally be combined with the subject matter of Example 5 to optionally include, the signal metric that may include a heart rate distribution of a plurality of heart rate measurements from the cardiac signal. The rate distribution may include a central tendency of the heart rate measurements, or a relative number of the heart beats falling within a specified margin of the central tendency of the heart rate measurements.

Example 8 may include, or may optionally be combined with the subject matter of Example 5 to optionally include, the signal metric that may include morphology measurements of a plurality of heart beats from the cardiac signal. The first arrhythmia detector circuit may detect the arrhythmic event using the morphology measurements of the plurality of heart beats.

Example 9 may include, or may optionally be combined with the subject matter of one or any combination of Examples 5 through 8 to include, the confidence indicator generator circuit that may determine for the detected arrhythmic event the confidence indicator including a confidence score proportional to a deviation of the signal metric from a reference value.

Example 10 may include, or may optionally be combined with the subject matter of Example 9 to optionally include, the confidence indicator generator circuit that may determine the confidence score using a combination of deviations of two or more signal metrics from respective reference values.

Example 11 may include, or may optionally be combined with the subject matter of one or any combination of Examples 5 through 10 to include, the confidence indicator generator circuit that may determine the confidence indicator based on a signal quality of the signal metric. The signal quality may include one of a signal-to-noise ratio, a detection of motion artifact, or a detection of ectopic beats.

Example 12 may include, or may optionally be combined with the subject matter of one or any combination of Examples 5 through 11 to include, the confidence indicator generator circuit that may determine the confidence indicator based on a medical history of the subject including one of a history of syncope, an arrhythmia history, an ablation procedure, or a duration of a prior arrhythmic event.

Example 13 may include, or may optionally be combined with the subject matter of one or any combination of Examples I through 12 to include, an output circuit that may be configured to generate a human-perceptible presentation of the detected arrhythmic events.

Example 14 may include, or may optionally be combined with the subject matter of Example 13 to optionally include, a prioritizer circuit that may include a comparator circuit to prioritize two or more detected arrhythmic events based on the respective confidence indicators. The output circuit may generate the presentation including at least a portion of the prioritized two or more detected arrhythmic events.

Example 15 may include, or may optionally be combined with the subject matter of Example 4 to option-

ally include, a first implantable device that may include the first arrhythmia detector circuit and a different second device including the second arrhythmia detector circuit.

In Example 16, a method for detecting an arrhythmic event via a medical system is disclosed. The method may include steps of: sensing a physiological signal from a subject; detecting, via a first arrhythmia detector, an arrhythmic event from the sensed physiological signal; generating a confidence indicator for the detected arrhythmic event, the confidence indicator indicating a confidence level of the detection of the arrhythmic event; and providing the detected arrhythmic event to a first process in response to the confidence indicator indicating a first confidence level, or providing the detected arrhythmic event to at least a second process different from the first process in response to the confidence indicator indicating a different second confidence level.

Example 17 may include, or may optionally be combined with the subject matter of Example 16 to optionally include, a method of generating one or more signal metrics from a cardiac signal. The detection of the arrhythmic event may include detecting an atrial or ventricular arrhythmia using the one or more signal metrics.

Example 18 may include, or may optionally be combined with the subject matter of Example 17 to optionally include, the one or more signal metrics that may include morphology measurements of a plurality of heart beats from the cardiac signal, and the detection of the arrhythmic event may be based on the morphology measurements of the plurality of heart beats.

Example 19 may include, or may optionally be combined with the subject matter of Example 16 to optionally include, a step of providing the detected arrhythmic event to the first process that may include, in response to the confidence indicator exceeding a confidence threshold indicative of a high confidence of the detection of the arrhythmic event, storing the detected arrhythmic event in a memory circuit or producing an alert signal.

Example 20 may include, or may optionally be combined with the subject matter of Example 16 to optionally include, the method of providing the detected arrhythmic event to the at least second process that may include, in response to the confidence indicator falling below a confidence threshold indicative of a low confidence of the detection of the arrhythmic event, confirming the detected arrhythmic event via at least a second arrhythmia detector having more computational power or executing computationally intensive algorithm than the first arrhythmia detector.

Example 21 may include, or may optionally be combined with the subject matter of Example 16 to optionally include, the confidence indicator that may include a confidence score proportional to deviations of the one or more signal metrics from respective reference values.

Example 22 may include, or may optionally be combined with the subject matter of Example 16 to optionally include, the confidence indicator that may be generated based on one of a signal quality of the signal metric or a medical history of the subject. The signal quality may include one of a signal-to-noise ratio, a detection of motion artifact, or a detection of ectopic beats, and the medical history may include one of a history of syncope, an arrhythmia history, an ablation procedure, or a duration of a prior arrhythmic event.

Example 23 may include, or may optionally be combined with the subject matter of Example 16 to optionally include, steps of prioritizing two or more detected arrhythmic events based on the respective confidence indicators, generating a presentation of at least a portion of the prioritized two or more detected arrhythmic events, and receiving from a user, via the user interface, adjudication of at least a portion of the prioritized two or more detected arrhythmic events.

[0008] This Overview is an overview of some of the teachings of the present application and not intended to be an exclusive or exhaustive treatment of the present subject matter. Further details about the present subject matter are found in the detailed description and appended claims. Other aspects of the disclosure will be apparent to persons skilled in the art upon reading and understanding the following detailed description and viewing the drawings that form a part thereof, each of which are not to be taken in a limiting sense. The scope of the present disclosure is defined by the appended claims and their legal equivalents.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Various embodiments are illustrated by way of example in the figures of the accompanying drawings. Such embodiments are demonstrative and not intended to be exhaustive or exclusive embodiments of the present subject matter.

FIG. 1 illustrates an example of a Cardiac Rhythm Management (CRM) system and portions of an environment in which the CRM system may operate.

FIG. 2 illustrates generally an example of an arrhythmia detection system configured to detect a target cardiac arrhythmia from a patient.

FIG. 3 illustrates generally an example of a circuit for generating a confidence score associated with a detection of cardiac arrhythmic event.

FIG. 4 illustrates generally an example of a portion of an arrhythmia detection and prioritization system.

FIG. 5 illustrates generally an example of a method for detecting a target cardiac arrhythmia from a pa-

tient.

FIG. 6 illustrates generally an example of a method for providing the detected arrhythmic events for further processing based on the confidence indicator associated with the detected arrhythmic events.

DETAILED DESCRIPTION

[0010] Disclosed herein are systems, devices, and methods for detecting a target physiologic event and storing physiologic information associated with the target physiologic event. The target physiologic event, such as an atrial fibrillation (AF) episode, can be detected from a physiological signal using a first detector. A confidence indicator indicating a confidence level of the detection of the arrhythmic event may be generated. The system may provide the detected arrhythmic event to a first process if the confidence indicator indicating a first confidence level, and to provide the detected arrhythmic event to at least a second process if the confidence indicator indicating a different second confidence level.

[0011] FIG. 1 illustrates generally an example of a Cardiac Rhythm Management (CRM) system 100 and portions of an environment in which the CRM system 100 may operate. The CRM system 100 may include an ambulatory medical device, such as an implantable medical device (IMD) 110 that may be electrically coupled to a heart 105 such as through one or more leads 108A-C, and an external system 120 that may communicate with the IMD 110 such as via a communication link 103. The IMD 110 may include an implantable cardiac device such as a pacemaker, an implantable cardioverter-defibrillator (ICD), or a cardiac resynchronization therapy defibrillator (CRT-D). In some examples, the CRM system may include one or more monitoring or therapeutic devices such as a subcutaneously implanted device, a wearable external device, a neural stimulator, a drug delivery device, a biological therapy device, or one or more other ambulatory medical devices. The IMD 110 may be coupled to, or may be substituted by a monitoring medical device such as a bedside or other external monitor.

[0012] The IMD 110 may include a hermetically sealed can housing 112 that may house an electronic circuit that may sense a physiological signal in the heart 105 and may deliver one or more therapeutic electrical pulses to a target region, such as in the heart, such as through one or more leads 108A-C. The CRM system 100 may include only one lead such as 108B, or may include two leads such as 108A and 108B.

[0013] The lead 108A may include a proximal end that may be configured to be connected to IMD 110 and a distal end that may be configured to be placed at a target location such as in the right atrium (RA) 131 of the heart 105. The lead 108A may have a first pacing-sensing electrode 141 that may be located at or near its distal end, and a second pacing-sensing electrode 142 that may be located at or near the electrode 141. The electrodes 141 and 142 may be electrically connected to the IMD 110 such as via separate conductors in the lead 108A, such as to allow for sensing of the right atrial activity and optional delivery of atrial pacing pulses. The lead 108B may be a defibrillation lead that may include a proximal end that may be connected to IMD 110 and a distal end that may be placed at a target location such as in the right ventricle (RV) 132 of heart 105. The lead 108B may have a first pacing-sensing electrode 152 that may be located at distal end, a second pacing-sensing electrode 153 that may be located near the electrode 152, a first defibrillation coil electrode 154 that may be located near the electrode 153, and a second defibrillation coil electrode 155 that may be located at a distance from the distal end such as for superior vena cava (SVC) placement. The electrodes 152 through 155 may be electrically connected to the IMD 110 such as via separate conductors in the lead 108B. The electrodes 152 and 153 may allow for sensing of a ventricular electrogram and may allow delivery of one or more ventricular pacing pulses, and electrodes 154 and 155 may allow for delivery of one or more ventricular cardioversion/defibrillation pulses. In an example, the lead 108B may include only three electrodes 152, 154 and 155. The electrodes 152 and 154 may be used for sensing or delivery of one or more ventricular pacing pulses, and the electrodes 154 and 155 may be used for delivery of one or more ventricular cardioversion or defibrillation pulses. The lead 108C may include a proximal end that may be connected to the IMD 110 and a distal end that may be configured to be placed at a target location such as in a left ventricle (LV) 134 of the heart 105. The lead 108C may be implanted through the coronary sinus 133 and may be placed in a coronary vein over the LV such as to allow for delivery of one or more pacing pulses to the LV. The lead 108C may include an electrode 161 that may be located at a distal end of the lead 108C and another electrode 162 that may be located near the electrode 161. The electrodes 161 and 162 may be electrically connected to the IMD 110 such as via separate conductors in the lead 108C such as to allow for sensing of the LV electrogram and allow delivery of one or more resynchronization pacing pulses from the LV. Additional electrodes may be included in or along the lead 108C. In an example, as illustrated in FIG. 1, a third electrode 163 and a fourth electrode 164 may be included in the lead 108. In some examples (not shown in FIG. 1), at least one of the leads 108A-C, or an additional lead other than the leads 108A-C, may be implanted under the skin surface without being within at least one heart chamber, or at or close to heart tissue.

[0014] The IMD 110 may include an electronic circuit that may sense a physiological signal. The physiological signal may include an electrogram or a signal representing mechanical function of the heart 105. The hermetically sealed can housing 112 may function as an electrode such as for sensing or pulse delivery. For example, an electrode from one or more of the leads 108A-C may be used together with the can housing 112 such as for unipolar sensing of an electrogram or for delivering one

or more pacing pulses. A defibrillation electrode from the lead 108B may be used together with the can housing 112 such as for delivering one or more cardioversion/defibrillation pulses. In an example, the IMD 110 may sense impedance such as between electrodes located on one or more of the leads 108A-C or the can housing 112. The IMD 110 may be configured to inject current between a pair of electrodes, sense the resultant voltage between the same or different pair of electrodes, and determine impedance using Ohm's Law. The impedance may be sensed in a bipolar configuration in which the same pair of electrodes may be used for injecting current and sensing voltage, a tripolar configuration in which the pair of electrodes for current injection and the pair of electrodes for voltage sensing may share a common electrode, or tetrapolar configuration in which the electrodes used for current injection may be distinct from the electrodes used for voltage sensing. In an example, the IMD 110 may be configured to inject current between an electrode on the RV lead 108B and the can housing 112, and to sense the resultant voltage between the same electrodes or between a different electrode on the RV lead 108B and the can housing 112. A physiological signal may be sensed from one or more physiological sensors that may be integrated within the IMD 110. The IMD 110 may also be configured to sense a physiological signal from one or more external physiological sensors or one or more external electrodes that may be coupled to the IMD 110. Examples of the physiological signal may include one or more of thoracic impedance, intracardiac impedance, arterial pressure, pulmonary artery pressure, RV pressure, LV coronary pressure, coronary blood temperature, blood oxygen saturation, one or more heart sounds, physical activity or exertion level, posture, respiration, body weight, or body temperature.

[0015] The arrangement and functions of these leads and electrodes are described above by way of non-limiting example and not by way of limitation. Depending on the need of the patient and the capability of the implantable device, other arrangements and uses of these leads and electrodes are contemplated.

[0016] As illustrated, the CRM system 100 may include a confidence-based arrhythmia detector 113 for detecting an arrhythmia, such as an atrial fibrillation (AF) event. The confidence-based arrhythmia detector 113 may generate a confidence indicator that indicates a confidence level of the detected arrhythmia. The detection of the arrhythmia and determination of the confidence score may be based on one or more signal metrics derived from a physiological signal. If the confidence indicator indicates a high confidence of arrhythmia being detected, the detected arrhythmic event may be provided to a first process, such as for storing the detected arrhythmia to a memory or generating an alert to a healthcare professional. If the confidence indicator indicates a low confidence associated with the detected arrhythmia, the detected arrhythmic event may be provided to at least a second process different from the first process, such as configuring a secondary arrhythmia detector with more computational power or resources to confirm the detected arrhythmic event, or configuring an arrhythmia adjudicator to receive arrhythmia adjudication from a clinician. Examples of the confidence-based arrhythmia detector 113 are described below, such as with reference to FIGS. 2-4.

[0017] The external system 120 may allow for programming of the IMD 110 and may receive information about one or more signals acquired by IMD 110, such as may be received via a communication link 103. The external system 120 may include a local external IMD programmer. The external system 120 may include a remote patient management system that may monitor patient status or adjust one or more therapies such as from a remote location.

[0018] The communication link 103 may include one or more of an inductive telemetry link, a radio-frequency telemetry link, or a telecommunication link, such as an internet connection. The communication link 103 may provide for data transmission between the IMD 110 and the external system 120. The transmitted data may include, for example, real-time physiological data acquired by the IMD 110, physiological data acquired by and stored in the IMD 110, therapy history data or data indicating IMD operational status stored in the IMD 110, one or more programming instructions to the IMD 110 such as to configure the IMD 110 to perform one or more actions that may include physiological data acquisition such as using programmably specifiable sensing electrodes and configuration, device self-diagnostic test, or delivery of one or more therapies.

[0019] The confidence-based arrhythmia detector 113, although illustrated in FIG. 1 as being implemented in the IMD 110, may alternatively be implemented in a subcutaneously implanted device, a wearable external device, a neural stimulator, a drug delivery device, a biological therapy device, or one or more diagnostic devices. In some examples, the confidence-based arrhythmia detector 113 may be implemented in the external system 120. The external system 120 may be configured to perform worsening heart failure (WHF) event detection such as using data extracted from the IMD 110 or data stored in a memory within the external system 120. The external system 120 may include a user interface that may display information about detection of the target physiological events, including onset and resets thresholds. In an example, portions of the confidence-based arrhythmia detector 113 may be distributed between the IMD 110 and the external system 120.

[0020] Portions of the IMD 110 or the external system 120 may be implemented using hardware, software, or any combination of hardware and software. Portions of the IMD 110 or the external system 120 may be implemented using an application-specific circuit that may be constructed or configured to perform one or more particular functions, or may be implemented using a general-purpose circuit that may be programmed or otherwise

configured to perform one or more particular functions. Such a general-purpose circuit may include a microprocessor or a portion thereof, a microcontroller or a portion thereof, or a programmable logic circuit, or a portion thereof. For example, a "comparator" may include, among other things, an electronic circuit comparator that may be constructed to perform the specific function of a comparison between two signals or the comparator may be implemented as a portion of a general-purpose circuit that may be driven by a code instructing a portion of the general-purpose circuit to perform a comparison between the two signals. While described with reference to the IMD 110, the CRM system 100 could include a subcutaneous medical device (e.g., subcutaneous ICD, subcutaneous diagnostic device), wearable medical devices (e.g., patch based sensing device), or other external medical devices.

[0021] FIG. 2 illustrates generally an example of an arrhythmia detection system 200 that may be configured to detect a target cardiac arrhythmia from a patient, such as an atrial fibrillation (AF) event. The arrhythmia detection system 200 may be an embodiment of the confidence-based arrhythmia detector 113. The arrhythmia detection system 200 may include one or more of a physiological sensor circuit 210, a signal processor circuit 220, an arrhythmia detector circuit 230, a controller circuit 240, and a user interface unit 250.

[0022] The physiological sensor circuit 210 may include a sense amplifier circuit to sense a physiological signal sensed from a patient. The physiological signals may be indicative or correlative of a disease state or a physical or physiological condition. The physiological signals may be sensed using one or more implantable, wearable, or otherwise ambulatory sensors associated with the patient. Examples of the physiological signals may include surface electrocardiography (ECG) such as sensed from electrodes on the body surface, subcutaneous ECG such as sensed from electrodes placed under the skin, intracardiac electrogram (EGM) sensed from the one or more electrodes of the leads 108A-C or the can housing 112, heart rate signal, heart rate variability signal, thoracic or cardiac impedance signal, arterial pressure signal, pulmonary artery pressure signal, left atrial pressure signal, RV pressure signal, LV coronary pressure signal, coronary blood temperature signal, blood oxygen saturation signal, heart sound signal such as sensed by an ambulatory accelerometer or acoustic sensors, physiological response to activity, apnea hypopnea index, one or more respiration signals such as a respiration rate signal or a tidal volume signal, brain natriuretic peptide (BNP), blood panel, sodium and potassium levels, glucose level and other biomarkers and bio-chemical markers, among others. The physiological sensor circuit 210 may include one or more other sub-circuits to digitize, filter, or perform other signal conditioning operations on the received physiological signal.

[0023] In an example, the signal physiological sensor circuit 210 may retrieve from an electronic medical record (EMR) system one or more patient historical physiological signals in response to a command signal. The command signal may be issued by a system user (e.g., a health-care professional) such as via an input device coupled to the instruction receiver 250, or generated automatically by the system in response to a specified event. The signal physiological sensor circuit 210 may include one or more sub-circuits that may perform signal conditioning or pre-processing, including signal amplification, digitization, or filtering, on the one or more physiological signals.

[0024] The signal processor circuit 220, coupled to the physiological sensor circuit 210, may include a filter circuit to filter the sensed physiological signal to generate one or more signal metrics 222. In an example, the signal processor circuit 220 includes a beats detector for detecting pulsatile activity of the heart, hereinafter referred to as "beats", from the sensed physiological signal. The beats may be detected from a cardiac electrical signal such as a surface electrocardiograph (ECG), a subcutaneous ECG, or an intracardiac electrogram (EGM). The beats may additionally or alternatively be detected from a cardiac mechanical signal indicative of pulsatile contraction of the heart, including a cardiac impedance signal, a heart sounds signal, or a blood pressure signal, among others. The cardiac mechanical signals may vary within a cardiac cycle, and exhibit a pulsatile pattern consistent with the periodic cardiac electrical activities. Beat detection may include detection of a EGC signal component such as a P wave, an R wave, a T wave, or a QRS complex, localized myocardial depolarization or repolarization sensed from a EGM signal, or peak or trough amplitude, peak value of an envelope or an integral, or other intensity measures of a cardiac impedance signal, a heart sound signal, or a blood pressure signal.

[0025] The signal metrics 222 may include timing parameters associated with the beats detected from the sensed physiological signal. Examples of the timing parameters may include cardiac intervals (CI) or heart rates (HR) signal, electro-mechanical delay such as a systolic timing interval (STI) such as measured between the onset of the QRS complex on the ECG or the atrial activation event in an intracardiac EGM and the S2 heart sound, a pre-ejection period (PEP) such as measured between the onset of the QRS and the S1 heart sound, a diastolic timing interval (DTI) such as measured between the S2 heart sound and the onset of the QRS complex on the ECG or the atrial activation event in an intracardiac EGM of the next cardiac cycle. Additionally or alternatively, the signal metrics 222 may include statistical or morphological parameters associated with the detected beats from the sensed physiological signal. Examples of the statistical or morphological parameters may include signal maximum or minimum within a specified time period such as a cardiac cycle, positive or negative slope or higher order statistics, or a signal power spectral density at a specified frequency range, among others. Depending on the types of the sensed physiological signal, examples

of the signal metrics may include thoracic impedance magnitude, S3 heart sound intensity, a ratio of S3 heart sound intensity to a reference heart sound intensity (such as S1 heart sound intensity, heart sound signal energy between R-wave and S2, or heart sound signal energy within a cardiac cycle), a respiration rate, a tidal volume, a ratio a respiration rate to a tidal volume, an activity intensity, or a time duration when the activity intensity is within a specified range or above a specified threshold, among others.

[0026] The arrhythmia detector circuit 230 may be configured to use at least the signal metrics 222 to detect a target cardiac arrhythmic event and to determine a confidence indicator for the detected arrhythmic event. Examples of cardiac arrhythmias may include atrial fibrillation (AF), atrial flutter (AFL), atrial tachycardia, paroxysmal supraventricular tachycardia (PSVT), Wolff-Parkinson-White (WPW) syndrome, ventricular tachycardia, ventricular fibrillation, bradycardia, or sinus pauses, among others.

[0027] The arrhythmia detector circuit 230 may be implemented as a part of a microprocessor circuit. The microprocessor circuit may be a dedicated processor such as a digital signal processor, application specific integrated circuit (ASIC), microprocessor, or other type of processor for processing information including the physiological signals received from the physiological sensor circuit 210. Alternatively, the microprocessor circuit may be a general purpose processor that may receive and execute a set of instructions of performing the functions, methods, or techniques described herein.

[0028] The arrhythmia detector circuit 230 may include circuit sets comprising one or more other circuits or sub-circuits, such as one or more of a first arrhythmia detector 232, a confidence indicator generator 234, at least a second arrhythmia detector 236, an alert generator circuit 238, and a memory circuit 239. The circuits or sub-circuits may, alone or in combination, perform the functions, methods, or techniques described herein. In an example, hardware of the circuit set may be immutably designed to carry out a specific operation (e.g., hardwired). In an example, the hardware of the circuit set may include variably connected physical components (e.g., execution units, transistors, simple circuits, etc.) including a computer readable medium physically modified (e.g., magnetically, electrically, moveable placement of invariant massed particles, etc.) to encode instructions of the specific operation. In connecting the physical components, the underlying electrical properties of a hardware constituent are changed, for example, from an insulator to a conductor or vice versa. The instructions enable embedded hardware (e.g., the execution units or a loading mechanism) to create members of the circuit set in hardware via the variable connections to carry out portions of the specific operation when in operation. Accordingly, the computer readable medium is communicatively coupled to the other components of the circuit set member when the device is operating. In an example, any of the physical components may be used in more than one member of more than one circuit set. For example, under operation, execution units may be used in a first circuit of a first circuit set at one point in time and reused by a second circuit in the first circuit set, or by a third circuit in a second circuit set at a different time.

[0029] The first arrhythmia detector circuit 232 may be configured to generate an initial detection of an arrhythmic event using the signal metrics 222 of the sensed physiological signal. In an example, based on the variability of the CI or HR associated with the detected beats, the detected heart beats may be classified into one of a plurality of beat classes including a stable beat class, an unstable beat class, and a random beat class. The first arrhythmia detector 232 may determine beat counts (i.e., number of beats within a specified time period) of the stable beats, unstable beats, or random beats, and generate a relative quantity, such as a difference, a ratio, a proportion, or a percentage, using the beat counts of the beat classes. Examples of the relative quantity may include a ratio of the number of unstable beats to a sum of the numbers of the stable and unstable beats, or a ratio of the number of random beats to a sum of the numbers of the stable and unstable beats. The first arrhythmia detector 232 may detect the target cardiac arrhythmic event, such as an AF event, in response to the relative quantity satisfying a specified condition, such as those disclosed in the commonly assigned Mahajan et al. U.S. Provisional Patent Application Serial No. 62/109,963, entitled "PHYSIOLOGIC EVENT DETECTION AND DATA STORAGE," filed on January 30, 2015, including its disclosure of beats classes and AF detection using at least the beat classes.

[0030] A heart rate distribution may be generated from a plurality of heart beats from the cardiac signal within a specified time period, and the signal metric may include a parameter extracted from the heart rate distribution. In an example, the distribution parameter may include a central tendency of heart rates within the specified time period. Examples of the central tendency may include a mean, a median, or a mode, among others. In another example, the distribution parameter may include a relative number of the heart beats falling within a specified margin of the central tendency of the heart rates.

[0031] The heart rate distribution may be represented by a heart rate histogram that includes percentages of the heart beats during a specified time period that fall within each of a plurality of heart rate bins. Each heart rate bin defines a range of heart rates. The indicator may include a mode of the heart rates, such as a histogram bin (or a representative heart rate value of that histogram bin) that includes the most heart beats with corresponding heart rates falling within that histogram bin. The indicator may alternatively or additionally include a heart rate density index (HRDI), which may be calculated as a percentage of the heart beats falling within the histogram bin including the mode of the heart rates. The first arrhythmia detector 232 may detect the target cardiac ar-

rhythmia such as an AF event in response to the mode of the heart rate or the HRDI each satisfies a specified condition, such as those disclosed in the commonly assigned Mahajan et al. U.S. Provisional Patent Application Serial No. 62/142,184, entitled "ATRIAL FIBRILLATION DETECTION," filed April 2, 2015, including its disclosure of the HRDI and the AF detection using at least the HRDI.

[0032] In various examples, the signal metric may include morphology measurements of a plurality of heart beats from a cardiac electrical or mechanical signal. The morphology measurements may include a plurality of morphological features such as samples selected from a portion of a waveform of the signal metric within a beat (or a cardiac cycle). In an example, the morphological features may include characteristic points of the waveform such as a peak, a trough, an inflection point, or one or more intermediate points between the characteristic points. The first arrhythmia detector 232 may receive from a user such as via the user interface unit 250, or retrieve from a memory device, a template that represents the morphology of the same signal metric that is obtained during a known rhythm such as a sinus rhythm or a specified arrhythmia such as AF. The first arrhythmia detector 232 may compare the morphology measurements of the plurality of beats to the template, and compute a similarity score between the morphology measurements and template. Examples of the similarity score may include a correlation, a sum of differences between the morphology measurements and scaled template, or a distance measure in a multi-dimensional signal feature space. In an example, the arrhythmia detector 232 may dynamically update the template using the morphology measurements of previous one or more beats that are morphologically similar to the received or retrieved template (such as the similarity score falling within a specified range). The first arrhythmia detector 232 may detect the cardiac arrhythmia in response to the similarity score satisfying a specified condition, such as when the difference falls below a specified detection threshold.

[0033] The confidence indicator generator 234 may generate for the detected arrhythmic event a confidence indicator indicating a confidence level of the detection of the arrhythmic event. The confidence indicator may include a categorical descriptor such as a "high", "medium", or "low" confidence, or a numerical confidence score within a specified range, where a higher score indicates a higher confidence about the presence of the cardiac arrhythmic event. In an example as illustrated in FIG. 2, the confidence indicator generator 234 may be coupled to the signal processor circuit 220, and to generate the confidence indicator based on a comparison of the signal metrics 222 and one or more thresholds. In an example, the same signal metrics used by the first arrhythmia detector 232 for detecting the cardiac arrhythmic event may be used for generating the confidence indicator. In an example, at least one signal metric for generating the confidence indicator may be different from the signal metrics for detecting the cardiac arrhythmic event by the first arrhythmia detector 232. Examples of the confidence indicator generator 234 are discussed below, such as with reference to FIG. 3.

[0034] The second arrhythmia detector 236 may be coupled to the first arrhythmia detector 232 and the confidence indicator generator 234, and configured to further detect the cardiac arrhythmic event when the confidence indicator associated with the first detection satisfies a specified condition, such as when a "low" confidence level is indicated or the numerical confidence score falls below a confidence threshold. In an example, the second arrhythmia detector 236 is to confirm the presence of arrhythmic event detected by the first arrhythmia detector 232. The second arrhythmia detector 236 may have more computational power than the first arrhythmia detector. In an example, the second arrhythmia detector 236 may detects cardiac arrhythmia using a computationally intensive algorithm, which may have a higher sensitivity or specificity or be configured to process larger amount of data for detecting the arrhythmic event than the first arrhythmia detector 232. Examples of the computationally intensive algorithm may include decision trees, neural networks, or support vector machine, among other linear or nonlinear pattern recognition methods. The computationally intensive algorithm may be implemented using circuits or sub-circuits, or a microprocessor that stores and executes a set of instructions such as for data processing. In an example, the second arrhythmia detector 236 may wait longer or use information in addition to the signal metrics 222 for detecting or confirming the cardiac arrhythmic event, such as additional data acquired by various physiological sensors. In an example, the second arrhythmia detector 236 may perform retrospective analysis of historical physiological data collected from the patient, as opposed to a real-time analysis such as used by the first arrhythmia detector. In some examples, additional arrhythmia detectors in addition to the second arrhythmia detector 236 may be included to further confirm or reject the presence of arrhythmic event.

[0035] Although the second arrhythmia detector 236 is shown as an example in FIG. 2 to be within the arrhythmia detector circuit 230, in some examples the second arrhythmia detector 236 may be implemented in a separate device than the first arrhythmia detector 232, such as in a programmer, a handheld, wearable, or other portable device, or a server. In an example, portions of the sub-circuits in the arrhythmia detector circuit 230, such as the first arrhythmia detector 232 and the second arrhythmia detector 236, may be distributed between the IMD 110 and the external system 120.

[0036] The alert generator 238 may be coupled to the first arrhythmia detector 232 and the confidence indicator generator 234, and configured to generate an alert for presenting to a clinician when the confidence indicator associated with the first detection satisfies a specified condition, such as when a "high" confidence level is indicated or the numerical confidence score exceeds a detection threshold. Additionally or alternatively, the detect-

ed arrhythmic event may be stored in a memory circuit 239 if a high confidence level of the first detection of arrhythmic event is indicated. In an example, the amount of data stored may be based on the confidence level of the first detection to achieve more efficient memory usage. For example, if the confidence is indicated to be "very high", such as when the confidence score exceeds a confidence threshold higher than the detection threshold, a shorter episode of a detected AF event may be stored. If the confidence is indicated to be "marginally high", a longer duration of a detected AF event that covers at least a portion of physiological data prior to the detected onset of the AF event or following the detected AF event, or additionally together with other patient physiological information during the detected AF event, may be stored. By providing more relevant information to the clinician to assist arrhythmia adjudication in case of a marginal confidence about the automated arrhythmia detection, the confidence-based information storage described herein may provide more efficient use of the computing resources and storage space, or to allow the clinician to more efficiently identify and review or skip reviewing arrhythmias of marginal confidence.

[0037] The confidence indicator generator 234 may be coupled to the second arrhythmia detector 236, and to generate a confidence indicator associated with the second detection when the second arrhythmia detector 236 confirms the cardiac arrhythmic events. If the confidence level satisfies a specified condition, such as when a "high" confidence level is indicated or the numerical confidence score exceeds a confidence threshold, the alert generator 238 may generate an alert for presenting to a clinician. In an example, the alert may be accompanied by a report presenting to the clinician including the first and second arrhythmia detections. Also in response to the high confidence level of the second detection of arrhythmic event, the detected arrhythmic event as confirmed by the second arrhythmia detector 236 may be stored in a memory circuit 239.

[0038] The controller circuit 240 may control the operations of the physiological sensor circuit 210, the signal processor circuit 220, the arrhythmia detector circuit 230, the user interface unit 250, and the data and instruction flow between these components. The controller circuit 240 may control the first and second arrhythmia detectors and the operations based on the detection and at confidence associated with the detection. For example, the controller circuit 240 may provide the first arrhythmia detection by the first arrhythmia detector 232 to a first process in response to the confidence score indicating a first confidence level, such as storing the detected arrhythmia to a memory circuit or generating an alert to a clinician if the confidence indicator indicates a high confidence of arrhythmia being detected. The controller circuit 240 may provide the detected arrhythmic event, as detected by first arrhythmia detector 232, to at least a second process different from the first process in response to the confidence score indicating a different second confidence level, such as configuring a secondary arrhythmia detector to confirm the detected arrhythmic event, or configuring an arrhythmia adjudicator to receive arrhythmia adjudication from a clinician, if the confidence indicator indicates a low confidence associated with the detected arrhythmia.

[0039] The user interface unit 250 may include a user input module 251 and an output module 252. In an example, at least a portion of the user interface unit 250 may be implemented in the external system 120. The user input module 251 may receive a user's programming input, such as respective parameters for arrhythmia detection used by the first arrhythmia detector 232 and the second arrhythmia detector 236, or the thresholds for categorizing the confidence level into a high or low confidence levels, among others. The user input module 251 may include an input device such as a keyboard, on-screen keyboard, mouse, trackball, touchpad, touch-screen, or other pointing or navigating devices. The input device may enable a system user to program the parameters used for sensing the physiological signals, detecting the arrhythmias, and generating alerts, among others. The output module 252 may generate a human-perceptible presentation of information including one or more of the detection of the target cardiac arrhythmia, confidence indicators associated with the detected arrhythmic events, alerts generated for the detected arrhythmias, or other system information. The output module 252 may include a display for displaying the information. The information may be presented in a table, a chart, a diagram, or any other types of textual, tabular, or graphical presentation formats, for displaying to a system user. The presentation of the output information may include audio or other media format to alert the system user of the detected physiological events.

[0040] In some examples, the arrhythmia detection system 200 may additionally include a therapy circuit 260 that is configured to deliver a therapy to the patient in response to the detection of the arrhythmia. Examples of the therapy may include electrostimulation therapy delivered to the heart, a nerve tissue, other target tissues, a cardioversion therapy, a defibrillation therapy, or drug therapy including delivering drug to a tissue or organ. In some examples, the therapy circuit 260 may modify an existing therapy, such as adjust a stimulation parameter or drug dosage.

[0041] Although the example as illustrated in FIG. 2 may be used for detecting cardiac arrhythmias, in some examples, at least a portion of the arrhythmia detector circuit 230 may be modified and configured to detect various physiologic events other than cardiac arrhythmias, including progression of a chronic disease, such as a worsening heart failure, heart failure decompensation, pulmonary edema, pulmonary condition exacerbation, asthma and pneumonia, myocardial infarction, dilated cardiomyopathy, ischemic cardiomyopathy, valvular disease, renal disease, chronic obstructive pulmonary disease, peripheral vascular disease, cerebrovascular dis-

ease, hepatic disease, diabetes, anemia, or depression, among others.

[0042] FIG. 3 illustrates generally an example of a confidence score generator circuit 300 for generating a confidence score associated with a detection of cardiac arrhythmic event. The confidence score generator circuit 300 may be an embodiment of the confidence indicator generator 234 of FIG. 2, and may be implemented in an IMD 110, or as a part of the external system 120. The confidence score generator circuit 300 may include one or more of a signal metric comparator 310, a signal quality analyzer 320, a patient indication receiver 330, and a blending circuit 350.

[0043] The signal metric comparator 310 may compare the signal metric 222 to one or more thresholds, and generate a confidence score associated with the arrhythmia detection. The confidence score may be proportional to a deviation of the signal metric 222 from a reference value such as the detection threshold used for detecting the cardia arrhythmic event. In an example, the first arrhythmia detector 232 may generate a beat ratio (R) of the number of unstable beats (N_U) to the sum of numbers of stable and unstable beats, that is, $R = N_U/(N_S+N_U)$. If the beat ratio exceeds a beat ratio threshold R_{TH} (that is $R > R_{TH}$), then an AF event is deemed detected. The first arrhythmia detector 232 may determine a confidence score (C_1) associated with the arrhythmia detection as $C_1 = f_1(R-R_{TH})$. In an example, the first arrhythmia detector 232 computes a morphological similarity score S between a template and morphology measurements of the signal metric, and detects the arrhythmic event if S exceeds the similarity threshold S_{TH}. The first arrhythmia detector 232 may determine a confidence score (C_2) associated with the arrhythmia detection as $C_2 = f_2(S-S_{TH})$. The functions f_1 and f_2 may each be a growth function, such as a linear growth, exponential growth, or other types of growth function. In an example, the first arrhythmia detector 232 may detect an AF event using both beat ratio R and morphological similarity S. The blending circuit 350 may combine the confidence scores associated with the detected arrhythmic event, such as using a linear function $C = k_1C_1+k_2C_2$ where k_1 and k_2 are scaling factors. Alternatively, the blending circuit 350 may include a multivariate function (g) of at least both the beat counts deviation ($R-R_{TH}$) and the similarity score deviation ($S-S_{TH}$), that is, $C = g(R-R_{TH}, S-S_{TH})$. The confidence score C may also be proportional to statistical or morpliological differences between a non-arrhythmic event and a sinus rhythm. In some examples, two or more signal metrics extracted from one or more physiological signals may be used for detecting cardia arrhythmias and for generating respective confidence scores. The blending circuit 350 may generate a composite confidence score using a linear or nonlinear combination of deviations of two or more signal metrics from respective detection thresholds.

[0044] The signal quality analyzer 320 may determine a signal quality indicator from the signal metrics 222, or the physiological signal from which the signal metrics 222 are generated, and generate a confidence score proportional to the signal quality. Examples of the signal quality indictor may include a signal-to-noise ratio (SNR), a detection of motion artifact, or a detection of ectopic beats such as premature atrial contractions (PACs) or premature ventricular contractions (PVCs). An indicator of low signal quality may be generated if the ectopic beat count within a specified time period exceeds a threshold, or the degree of motion artifact exceeds a specified noise floor, or the SNR falls below a threshold value. The signal quality analyzer 310 may generate a confidence score proportional to the deviation of the SNR, motion artifact level, or the ectopic beat counts from their respective reference values such as respective thresholds. In an example, the blending circuit 350 may generate a composite confidence score using a linear or nonlinear combination of deviations of various signal quality indicators from respective thresholds.

[0045] The patient indication receiver 330 may receive from the user input module 151 a user input, or from the memory circuit 239 stored information, of patient medical history. The patient medical history includes information relevant to patient risk of developing an arrhythmic event, or the responsiveness of a physiological sensor to an arrhythmic event. Examples of the medical history may include a history of syncope, an arrhythmia history, a medical procedure such as an ablation procedure, or a duration of a prior arrhythmic event, among others. For example, in determining the confidence score associated with a detected AF event, the confidence score may be decreased if the patient had a previous syncope episode, while the confidence score may be increased if the patient had a previous AF ablation procedure. If AF episodes with short durations have been frequently detected within a specified timeframe, the presently detected AF even is more likely a continuation of the underlying sustained AF rhythm and a higher confidence score may be assigned accordingly.

[0046] The blending circuit 350, in addition to combining confidences generated from different signal metrics or with different information sources within each of 310-330, may also combine factors affecting confidence of the arrhythmia detection from two or more of 310-330, and generate a composite confidence score for use in determining whether to confirm the detected arrhythmia at the second arrhythmia detector 236, or to generate the alert at the alert generator 238, or to store the detected arrhythmic events at the memory circuit 239.

[0047] FIG. 4 illustrates generally an example of a portion of an arrhythmia detection and prioritization system 400. The system 400 may be an embodiment of the arrhythmia detection system 200. The system 400 may include the arrhythmia detector circuit 230 to detect and confirm two or more arrhythmic events. The two or more confirmed arrhythmic events and their respective confidence scores may be stored in the memory circuit 239. The system 400 may include a prioritizer circuit 410 coupled to the arrhythmia detector circuit 230. The prioritizer

circuit 410 may include a comparator circuit to prioritize the two or more detected arrhythmic events in an order based on the respective confidence scores, such as an ascending order or a descending order of the confidence scores. The prioritized arrhythmic events, optionally along with their respective confidence scores, may be presented to the clinician at the output module 252. The prioritizer circuit 410 and the arrhythmia adjudicator module 420 may include hardware, software, or firmware communicatively coupled to one or more processors in order to carry out the operations described herein. In an example, the prioritizer circuit 410 or the arrhythmia adjudicator module 420 may be implemented as a part of a microprocessor circuit. Portions of the prioritizer circuit 410 or the arrhythmia adjudicator module 420 may be implemented in the IMD 110, in the external system 120, or distributed between the IMD 110 and the external system 120.

[0048] In an example, the prioritized arrhythmic events may be transmitted to an arrhythmia adjudicator module 420 that enables a clinician to provide adjudication input about the detected arrhythmic events. The adjudication input may include affirming, overriding, revising, or otherwise editing the detected arrhythmic events. In an example, the prioritizer circuit 410 may be configured, such as by the controller circuit 240, to present a portion of the detected arrhythmic events to the arrhythmia adjudicator module 420 for adjudication. For example, only those detected arrhythmic events having confidence scores below a specified confidence threshold or within a specified range thus indicative of a relative low confidence of detection are presented to the arrhythmia adjudicator module 420. In an example, the arrhythmia adjudicator module 420 may be implemented as a part of the user interface unit 450, and coupled to the user input module 251 and the output module 252 to enable a user such as a clinician to interactively adjudicate the detected arrhythmic events as presented on the output module 420.

[0049] FIG. 5 illustrates generally an example of a method 500 for detecting a target cardiac arrhythmia from a patient. Examples of cardiac arrhythmias may include atrial fibrillation (AF), atrial flutter (AFL), atrial tachycardia, paroxysmal supraventricular tachycardia (PSVT), Wolff-Parkinson-White (WPW) syndrome, ventricular tachycardia, ventricular fibrillation, bradycardia, or sinus pauses, among others. The method 500 may be implemented and operate in an ambulatory medical device such as an implantable or wearable medical device, or in a remote patient management system. In an example, the method 500 may be performed by the confidence-based arrhythmia detector 113 or any embodiment thereof, or by the external system 120.

[0050] The method 500 begins at 510 by sensing a physiological signal from a patient. Examples of the physiological signals may include surface electrocardiography (ECG) such as sensed from electrodes on the body surface, subcutaneous ECG such as sensed from electrodes placed under the skin, intracardiac electrogram (EGM) sensed from the one or more electrodes of the leads 108A-C or the can housing 112, heart rate signal, heart rate variability signal, thoracic or cardiac impedance signal, arterial pressure signal, pulmonary artery pressure signal, left atrial pressure signal, RV pressure signal, LV coronary pressure signal, coronary blood temperature signal, blood oxygen saturation signal, heart sound signal such as sensed by an ambulatory accelerometer or acoustic sensors, physiological response to activity, apnea hypopnea index, one or more respiration signals such as a respiration rate signal or a tidal volume signal, brain natriuretic peptide (BNP), blood panel, sodium and potassium levels, glucose level and other biomarkers and bio-chemical markers, among others.

[0051] The sensed physiological signal may be pre-processed, including one or more of signal amplification, digitization, filtering, or other signal conditioning operations. In an example, a plurality of heart beats may be detected from a cardiac electrical signal or a cardiac mechanical signal. One or more statistical or morphological signal metrics may be extracted from the pre-processed signal. The signal metrics may include timing parameters, or statistical or morphological parameters associated with the beats detected from the sensed physiological signal.

[0052] At 520, an arrhythmic event may be detected from the signal metrics, such as by using the arrhythmia detector circuit 230 as illustrated in FIG. 2. The arrhythmia detection may be based on timing information or morphology measurements from the signal metrics. In an example, based on the variability of the CI or the HR associated with the detected beats, the detected heart beats may be classified into one of a plurality of beat classes including a stable beat class, an unstable beat class, and a random beat class. The beat counts of each beat class within a specified time period may be determined, and a relative quantity such as a ratio of the number of unstable beats to a sum of the numbers of the stable and unstable beats, or a ratio of the number of random beats to a sum of the numbers of the stable and unstable beats, may be computed. An arrhythmic event, such as an AF event, may be detected if the relative quantity exceeds a detection threshold. In another example, a heart rate distribution may be generated using a plurality of heart rates within a specified time period, and a parameter extracted from the heart rate distribution may be used for detecting the arrhythmic event such an AF event. Examples of the distribution parameter may include a central tendency (e.g., a mode) of heart rates within the specified time period, or a relative number (e.g., a percentage) of the heart beats falling within a specified margin of the central tendency of the heart rates. An arrhythmic event, such as an AF event, may be detected if the central tendency of the heart rates, or the relative number of the heart beats within the margin of the central tendency satisfies a specified condition. In yet another example, morphology measurements may be extracted from a plurality of heart beats and compared to a mor-

phology template of a known cardia rhythm such as normal sinus rhythm or AF. An arrhythmic event, such as an AF event, may be detected if a similarity score between the template and the morphology measurements of the signal metrics satisfies a specified condition, such as when the difference falls below a specified detection threshold.

[0053] At 530, a confidence indicator may be generated for the detected arrhythmic event. The confidence indicator may have a categorical value or a numerical value. A numerical confidence score may be computed based on a comparison of the signal metrics and one or more thresholds. In an example, the confidence score may be proportional to deviations of the one or more signal metrics from respective reference values such as respective detection thresholds. As previously discussed with reference to FIG. 3, the confidence score associated with the detected AF event may be a linear or non-linear growth function of the beat ratio (R) (such as a ratio of the number of unstable beats to the sum of numbers of stable and unstable beats) and a beat ratio threshold R_{TH}, or a morphology similarity (S) (such as a correlation or a distance between a template and morphology measurements of the signal metric) and a threshold S_{TH}. In an example, the confidence indicator may be a composite confidence score computed as a linear or nonlinear combination of deviations of two or more signal metrics from respective thresholds. In some examples, the confidence indicator may be adjusted based on additional information including a signal quality of the signal metric or a medical history of the patient. Examples of the signal quality may include one of a signal-to-noise ratio, a detection of motion artifact, or a detection of ectopic beats such as premature atrial contractions (PACs) or premature ventricular contractions (PVCs). In an example, the confidence score may be proportional to the deviation of the SNR, motion artifact level, or the ectopic beat counts from their respective thresholds. Examples of the medical history may include one of a history of syncope, an arrhythmia history, an ablation procedure, or a duration of a prior arrhythmic event. In an example, the confidence score may be decreased if the patient had a previous syncope episode, while the confidence score may be increased if the patient had a previous AF ablation procedure.

[0054] At 540, the detected arrhythmias may be provided to different processes based on confidence indicator. If the confidence indicator indicates a high confidence of arrhythmia being detected, the detected arrhythmic event may be provided to a first process, such as for generating an alert to a healthcare professional of the detected arrhythmic event. If the confidence indicator indicates a low confidence associated with the detected arrhythmia, the detected arrhythmic event may be provided to at least at least a second process different from the first process, such as a reconfirmation of the detected arrhythmic event using a different detection process. A human-perceptible presentation of information, including one or more of the detection of the target cardiac arrhythmia, confidence indicators associated with the detected arrhythmic events, or alerts about the detected arrhythmias may be generated and presented to a clinician such as via the user interface 250 as illustrated in FIG. 2.

[0055] In some examples, as illustrated in FIG. 5, the method 500 may additionally include a step 550 of delivering a therapy to the patient in response to the detection of the arrhythmia. Examples of the therapy may include electrostimulation therapy delivered to the heart, a nerve tissue, other target tissues, a cardioversion therapy, a defibrillation therapy, or drug therapy including delivering drug to a tissue or organ. In some examples, at 550, an existing therapy may be modified to treat the detected arrhythmia, such as adjust a stimulation parameter or drug dosage.

[0056] FIG. 6 illustrates generally an example of a method 600 for providing the detected arrhythmic events for further processing based on the confidence indicator associated with the detected arrhythmic events. The method 600 may be an embodiment of the step 540 of the method 500. In an example, the method 600 may be implemented in and executed by the arrhythmia detection system 200 in FIG. 2, or the arrhythmia detection and prioritization system 400 in FIG. 4.

[0057] At 602, the confidence score such as generated at 530 in FIG. 5 may be compared to a confidence threshold which may be pre-determined or editable by a user. If the confidence score exceeds the confidence threshold, a high confidence of the detected arrhythmic event is indicated. The detected arrhythmic event, and optionally the corresponding confidence score, may be provided to a first process 610. The first process 610 may include storing the detected arrhythmic event (such as the physiological data during the detected arrhythmia) in a memory at 612. In an example, as previously discussed with reference to FIG. 2, the amount of date stored may be based on the confidence score, such that a shorter duration of the physiological data is stored for the detected arrhythmic event with higher confidence, and longer duration of the physiological data is stored for the detected arrhythmic event with lower confidence. The first process 610 may alternatively or additionally include producing an alert to a clinician of the detected arrhythmic event at 614. The alert may be accompanied by a report presenting to the clinician, which may include information such as arrhythmic event detection, confidence indicators associated with the detected arrhythmic events, or other system information.

[0058] If at 602 the confidence score does not exceed the confidence threshold, a low confidence of the detected arrhythmic event is indicated. The detected arrhythmic event, and optionally the corresponding confidence score, may be provided to a second process 620. The second process 620 may include confirming the detected arrhythmic event at 622, such as by using the second arrhythmia detector 236 or additional arrhythmia detectors. The confirmation of the detected arrhythmic event

may include retrospective analysis of historical physiological data collected from the patient, such as using a more computationally intensive arrhythmia detection algorithm or data from additional physiological sensors. If the arrhythmic event is confirmed, then at 624 a confidence score may be determined for the reconfirmed arrhythmic event. In an example, the confidence score used at 624 may be the confidence score associated with the initial detection, as determined at 530. In another example, the confidence score used at 624 may be generated using at least the arrhythmia confirmation result at 622, such that the confidence score is proportional to a deviation of a signal metric used by the second arrhythmia detector 236 from a corresponding threshold. The resulting confidence score thus computed may be different from the confidence score associated with the initial detection as determined at 530.

[0059] If the confidence score exceeds the confidence threshold at 624, a high confidence of the confirmed arrhythmic event is indicated. The confirmed arrhythmic event, and optionally the corresponding confidence score, may be provided to the first process 610, where the confirmed arrhythmic event may be stored, or an alert and optionally a report may be generated and presented to a clinician. However, if at 624 the arrhythmic event is not confirmed (such as the second arrhythmia detector 236 does not detect the same arrhythmic event that has been detected by the first arrhythmic detector 232, or if the confidence score falls below the confidence threshold), then at 626 the detected arrhythmic events may be prioritized in an order based on the respective confidence scores, such as an ascending order or a descending order of the confidence scores. At 628, the prioritized arrhythmic events, or a selected portion of the prioritized arrhythmic events such as those with confidence scores below a specified threshold, may be presented to a clinician for arrhythmia review or adjudication. The adjudication process may be performed via the arrhythmia adjudicator module 420 which enables a clinician to provide classification input about the detected arrhythmic events, including affirming, overriding, revising, or otherwise editing the detected arrhythmic events.

[0060] The above detailed description includes references to the accompanying drawings, which form a part of the detailed description. The drawings show, by way of illustration, specific embodiments in which the disclosure may be practiced. These embodiments are also referred to herein as "examples." Such examples may include elements in addition to those shown or described. However, the present inventors also contemplate examples in which only those elements shown or described are provided. Moreover, the present inventors also contemplate examples using any combination or permutation of those elements shown or described (or one or more aspects thereof), either with respect to a particular example (or one or more aspects thereof), or with respect to other examples (or one or more aspects thereof) shown or described herein.

[0061] In this document, the terms "a" or "an" are used, as is common in patent documents, to include one or more than one, independent of any other instances or usages of "at least one" or "one or more." In this document, the term "or" is used to refer to a nonexclusive or, such that "A or B" includes "A but not B," "B but not A," and "A and B," unless otherwise indicated. In this document, the terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein." Also, in the following claims, the terms "including" and "comprising" are open-ended, that is, a system, device, article, composition, formulation, or process that includes elements in addition to those listed after such a term in a claim are still deemed to fall within the scope of that claim. 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.

[0062] Method examples described herein may be machine or computer-implemented at least in part. Some examples may include a computer-readable medium or machine-readable medium encoded with instructions operable to configure an electronic device to perform methods as described in the above examples. An implementation of such methods may include code, such as microcode, assembly language code, a higher-level language code, or the like. Such code may include computer readable instructions for performing various methods. The code may form portions of computer program products. Further, in an example, the code may be tangibly stored on one or more volatile, non-transitory, or non-volatile tangible computer-readable media, such as during execution or at other times. Examples of these tangible computer-readable media may include, but are not limited to, hard disks, removable magnetic disks, removable optical disks (e.g., compact disks and digital video disks), magnetic cassettes, memory cards or sticks, random access memories (RAMs), read only memories (ROMs), and the like.

[0063] The invention is set out in the appended claims.

Claims

1. A system (400), comprising:

a physiological sensor circuit (210) including a sense amplifier to sense a physiological signal from a subject;

a first arrhythmia detector (232) circuit configured to detect an arrhythmic event from the sensed physiological signal;

a confidence indicator generator (234) circuit configured to generate a confidence indicator indicating a confidence level of the detection of the arrhythmic event; and

a controller circuit (240) coupled to the arrhythmia detector circuit (230), the controller circuit

(240) configured to:

provide the detected arrhythmic event to a first process (610) in response to the confidence indicator indicating a first confidence level; and
provide the detected arrhythmic event to at least a second process (620) different from the first process (610) to confirm the detected arrhythmic event in response to the confidence indicator indicating a second confidence level lower than the first confidence level.

2. The system (400) of claim 1, wherein the first arrhythmia detector (232) circuit is configured to detect the arrhythmic event including an atrial or ventricular arrhythmia.

3. The system (400) of any one of claims 1 or 2, wherein the controller circuit (240) is configured to, in response to the confidence indicator exceeding a confidence threshold indicative of a high confidence of the detection of the arrhythmic event, provide the detected arrhythmic event to the first process (610) including:

store the detected arrhythmic event in a memory circuit (239); or
produce an alert signal.

4. The system (400) of any one of claims 1 through 3 comprising a second arrhythmia detector (236) circuit configured to confirm the detected arrhythmic event,
wherein the second arrhythmia detector (236) circuit has more computational power or executes a more computationally intensive algorithm than the first arrhythmia detector (232).

5. The system (400) of any one of claims 1 through 4, wherein:

the physiological sensor circuit (210) is configured to receive the physiological signal including a cardiac signal; and
the first arrhythmia detector (232) circuit includes a filter circuit to generate a signal metric from the cardiac signal, the first arrhythmia detector (232) circuit configured to detect the arrhythmic event in response to the signal metric satisfying a specified condition.

6. The system (400) of claim 5, wherein the signal metric includes:

a first number of stable beats from the cardiac signal within a specified time period;
a second number of unstable beats from the cardiac signal within the specified time period; or
a third number of a relative number between the first and second numbers.

7. The system (400) of claim 5, wherein the signal metric includes a heart (105) rate distribution of a plurality of heart (105) rate measurements from the cardiac signal, the heart (105) rate distribution including:

a central tendency of the heart (105) rate measurements; or
a relative number of the heart (105) beats falling within a specified margin of the central tendency of the heart (105) rate measurements.

8. The system (400) of claim 5, wherein the signal metric includes morphology measurements of a plurality of heart (105) beats from the cardiac signal, and wherein the first arrhythmia detector (232) circuit is to detect the arrhythmic event using the morphology measurements of the plurality of heart (105) beats.

9. The system (400) of any one of claims 5 through 8, wherein the confidence indicator generator (234) circuit is to determine for the detected arrhythmic event the confidence indicator including a confidence score proportional to a deviation of the signal metric from a reference value.

10. The system (400) of claim 9, wherein the confidence indicator generator (234) circuit is to determine the confidence score using a combination of deviations of two or more signal metrics (222) from respective reference values.

11. The system (400) of claim any one of claims 5 through 10, wherein the confidence indicator generator (234) circuit is to determine the confidence indicator based on a signal quality of the signal metric, the signal quality including one of:

a signal-to-noise ratio;
a detection of motion artifact; or
a detection of ectopic beats.

12. The system (400) of claim any one of claims 5 through 11, wherein the confidence indicator generator (234) circuit is to determine the confidence indicator based on a medical history of the subject including one of:

a history of syncope;
an arrhythmia history;
an ablation procedure; or
a duration of a prior arrhythmic event.

13. The system (400) of any one of claims 1 through 12,

comprising an output circuit configured to generate a human-perceptible presentation of the detected arrhythmic events.

14. The system (400) of claim 13, further comprising a prioritizer circuit (410) including a comparator circuit to prioritize two or more detected arrhythmic events based on the respective confidence indicators, wherein the output circuit is configured to generate the presentation including at least a portion of the prioritized two or more detected arrhythmic events.

15. The system (400) of claim 4, further comprising a first implantable device including the first arrhythmia detector (232) circuit and a different second device including the second arrhythmia detector (236) circuit.

Patentansprüche

1. System (400), umfassend:

eine physiologische Sensorschaltung (210), die einen Messverstärker zum Erfassen eines physiologischen Signals von einem Subjekt aufweist;
eine erste Arrhythmie-Detektorschaltung (232), die dazu eingerichtet ist, ein Arrhythmie-Ereignis aus dem erfassten physiologischen Signal zu erkennen;
eine Konfidenzindikator-Erzeugungsschaltung (234), die dazu eingerichtet ist, einen Konfidenzindikator zu erzeugen, der ein Konfidenzniveau für die Erkennung des Arrhythmie-Ereignisses angibt; und
eine Steuerschaltung (240), die mit der Arrhythmie-Detektorschaltung (230) verbunden ist, wobei die Steuerschaltung (240) dazu eingerichtet ist:

als Reaktion darauf, dass der Konfidenzindikator ein erstes Konfidenzniveau angibt, das erkannte Arrhythmie-Ereignis einem ersten Prozess (610) zuzuführen; und
als Reaktion darauf, dass der Konfidenzindikator ein zweites Konfidenzniveau angibt, das niedriger ist als das erste Konfidenzniveau, das erkannte Arrhythmie-Ereignis mindestens einem zweiten Prozess (620) zuzuführen, der von dem ersten Prozess (610) verschieden ist, um so das erkannte Arrhythmie-Ereignis zu bestätigen.

2. System (400) nach Anspruch 1, wobei die erste Arrhythmie-Detektorschaltung (232) dazu eingerichtet ist, das Arrhythmie-Ereignis einschließlich einer atrialen oder ventrikulären Arrhythmie zu erkennen.

3. System (400) nach Anspruch 1 oder 2, wobei die Steuerschaltung (240) dazu eingerichtet ist, als Reaktion darauf, dass der Konfidenzindikator oberhalb einer Konfidenzschwelle liegt, die eine hohe Konfidenz des Erkennens des Arrhythmie-Ereignisses angibt, das erkannte Arrhythmie-Ereignis dem ersten Prozess (610) zuzuführen, der umfasst:
Speichern des erkannten Arrhythmie-Ereignisses in einer Speicherschaltung (239) oder Erzeugen eines Alarmsignals.

4. System (400) nach einem der Ansprüche 1 bis 3, das eine zweite Arrhythmie-Detektorschaltung (236) umfasst, die dazu eingerichtet ist, das erkannte Arrhythmie-Ereignis zu bestätigen,
wobei die zweite Arrhythmie-Detektorschaltung (236) über mehr Rechenleistung verfügt oder einen rechenintensiveren Algorithmus ausführt als der erste Arrhythmie-Detektor (232).

5. System (400) nach einem der Ansprüche 1 bis 4, wobei:

die physiologische Sensorschaltung (210) dazu eingerichtet ist, das physiologische Signal einschließlich eines Herzsignals zu empfangen; und
die erste Arrhythmie-Detektorschaltung (232) eine Filterschaltung zum Erzeugen einer Signalmetrik aus dem Herzsignal aufweist, wobei die erste Arrhythmie-Detektorschaltung (232) dazu eingerichtet ist, das Arrhythmie-Ereignis als Reaktion darauf zu erkennen, dass die Signalmetrik eine vorgegebene Bedingung erfüllt.

6. System (400) nach Anspruch 5, wobei die Signalmetrik umfasst:

eine erste Anzahl stabiler Herzschläge aus dem Herzsignal innerhalb eines vorgegebenen Zeitraums;
eine zweite Anzahl instabiler Herzschläge aus dem Herzsignal innerhalb des vorgegebenen Zeitraums; oder
eine dritte Anzahl als relative Anzahl zwischen der ersten und zweiten Zahl.

7. System (400) nach Anspruch 5, wobei die Signalmetrik eine Verteilung der Frequenz eines Herzens (105) aus einer Vielzahl von Messwerten der Frequenz des Herzens (105) aus dem Herzsignal umfasst, wobei die Verteilung der Frequenz des Herzens (105) umfasst:

eine zentrale Tendenz der Messwerte der Frequenz des Herzens (105); oder
eine relative Anzahl der Schläge des Herzens (105), die in einen vorgegebenen Bereich der

zentralen Tendenz der Messwerte der Frequenz des Herzens (105) fallen.

8. System (400) nach Anspruch 5, wobei die Signalmetrik Morphologiemesswerte aus einer Vielzahl von Schlägen des Herzens (105) aus dem Herzsignal umfasst und wobei die erste Arrhythmie-Detektorschaltung (232) das Arrhythmie-Ereignis unter Verwendung der Morphologiemesswerte aus der Vielzahl von Schlägen des Herzens (105) erkennt.

9. System (400) nach einem der Ansprüche 5 bis 8, wobei die Konfidenzindikator-Erzeugungsschaltung (234) für das erkannte Arrhythmie-Ereignis den Konfidenzindikator einschließlich einer Konfidenzpunktzahl ermittelt, die proportional zu einer Abweichung der Signalmetrik von einem Bezugswert ist.

10. System (400) nach Anspruch 9, wobei die Konfidenzindikator-Erzeugungsschaltung (234) die Konfidenzpunktzahl unter Verwendung einer Kombination von Abweichungen von zwei oder mehr Signalmetriken (222) von jeweiligen Bezugswerten ermittelt.

11. System (400) nach einem der Ansprüche 5 bis 10, wobei die Konfidenzindikator-Erzeugungsschaltung (234) den Konfidenzindikator auf Grundlage einer Signalqualität der Signalmetrik ermittelt, wobei die Signalqualität eins von Folgendem umfasst:

ein Signal-Rausch-Verhältnis;
ein Erfassen eines Bewegungsartefakts oder
ein Erfassen von Extrasystolen.

12. System (400) nach einem der Ansprüche 5 bis 11, wobei die Konfidenzindikator-Erzeugungsschaltung (234) den Konfidenzindikator auf Grundlage einer medizinischen Vorgeschichte des Subjekts ermitteln soll, die eins von Folgendem umfasst:

Synkopen in der Vorgeschichte;
Arrhythmien in der Vorgeschichte;
einen Eingriff zur Ablation oder
eine Dauer eines früheren Arrhythmie-Ereignisses.

13. System (400) nach einem der Ansprüche 1 bis 12, das eine Ausgabeschaltung umfasst, die dazu eingerichtet ist, eine für den Menschen wahrnehmbare Darstellung der erkannten Arrhythmie-Ereignisse zu erzeugen.

14. System (400) nach Anspruch 13, ferner umfassend eine Priorisierungsschaltung (410), die eine Vergleichsschaltung zur Priorisierung von zwei oder mehr erkannten Arrhythmie-Ereignissen auf Grundlage der jeweiligen Konfidenzindikatoren aufweist, wobei die Ausgabeschaltung dazu eingerichtet ist, die Darstellung zu erzeugen, die zumindest einen Teil der priorisierten zwei oder mehr erkannten Arrhythmie-Ereignisse umfasst.

15. System (400) nach Anspruch 4, ferner umfassend eine erste implantierbare Vorrichtung, die die erste Arrhythmie-Detektorschaltung (232) aufweist, und eine andere zweite Vorrichtung, die die zweite Arrhythmie-Detektorschaltung (236) aufweist.

Revendications

1. Système (400), comprenant :

un circuit de capteur physiologique (210) qui inclut un amplificateur de détection dont l'objet consiste à détecter un signal physiologique à partir d'un sujet ;
un premier circuit de détecteur d'arythmie (232) qui est configuré de manière à ce qu'il détecte un événement arythmique à partir du signal physiologique détecté ;
un circuit de générateur d'indicateur de confiance (234) qui est configuré de manière à ce qu'il génère un indicateur de confiance qui indique un niveau de confiance quant à la détection de l'événement arythmique ; et
un circuit de contrôleur (240) qui est couplé au circuit de détecteur d'arythmie (230), le circuit de contrôleur (240) étant configuré de manière à ce qu'il réalise les actions qui suivent :

la fourniture de l'événement arythmique détecté à un premier processus (610) en réponse au fait que l'indicateur de confiance indique un premier niveau de confiance ; et
la fourniture de l'événement arythmique détecté à au moins un second processus (620) qui est différent du premier processus (610) de manière à ce qu'il confirme l'événement arythmique détecté en réponse au fait que l'indicateur de confiance indique un second niveau de confiance qui est inférieur au premier niveau de confiance.

2. Système (400) selon la revendication 1, dans lequel le premier circuit de détecteur d'arythmie (232) est configuré de manière à ce qu'il détecte l'événement arythmique qui inclut une arythmie auriculaire ou ventriculaire.

3. Système (400) selon l'une quelconque des revendications 1 ou 2, dans lequel le circuit de contrôleur (240) est configuré de manière à ce que, en réponse au fait que l'indicateur de confiance excède un seuil de confiance qui est indicatif d'une confiance élevée

quant à la détection de l'événement arythmique, il fournisse l'événement arythmique détecté au premier processus (610), incluant :
le stockage de l'événement arythmique détecté dans un circuit de mémoire (239) ; ou la production d'un signal d'alerte.

4. Système (400) selon l'une quelconque des revendications 1 à 3, comprenant un second circuit de détecteur d'arythmie (236) qui est configuré de manière à ce qu'il confirme l'événement arythmique détecté ; dans lequel le second circuit de détecteur d'arythmie (236) dispose de plus de puissance de calcul ou exécute un algorithme davantage demandeur en termes de calcul que le premier circuit de détecteur d'arythmie (232).

5. Système (400) selon l'une quelconque des revendications 1 à 4, dans lequel :

le circuit de capteur physiologique (210) est configuré de manière à ce qu'il reçoive le signal physiologique qui inclut un signal cardiaque ; et
le premier circuit de détecteur d'arythmie (232) inclut un circuit de filtre dont l'objet consiste à générer une mesure de signal à partir du signal cardiaque, le premier circuit de détecteur d'arythmie (232) étant configuré de manière à ce qu'il détecte l'événement arythmique en réponse au fait que la mesure de signal satisfait une condition spécifiée.

6. Système (400) selon la revendication 5, dans lequel la mesure de signal inclut :

un premier nombre de battements stables qui sont issus du signal cardiaque à l'intérieur d'une période temporelle spécifiée ;
un deuxième nombre de battements non stables qui sont issus du signal cardiaque à l'intérieur de la période temporelle spécifiée ; ou
un troisième nombre qui est un nombre relatif entre les premier et deuxième nombres.

7. Système (400) selon la revendication 5, dans lequel la mesure de signal inclut une distribution de rythme cardiaque (105) d'une pluralité de mesures de rythme cardiaque (105) qui sont issues du signal cardiaque, la distribution de rythme cardiaque (105) incluant :

une tendance centrale des mesures de rythme cardiaque (105) ; ou
un nombre relatif des battements cardiaques (105) qui tombent à l'intérieur d'une marge spécifiée de la tendance centrale des mesures de rythme cardiaque (105).

8. Système (400) selon la revendication 5, dans lequel la mesure de signal inclut des mesures de morphologie d'une pluralité de battements cardiaques (105) qui sont issus du signal cardiaque, et dans lequel le premier circuit de détecteur d'arythmie (232) a pour objet de détecter l'événement arythmique en utilisant les mesures de morphologie de la pluralité de battements cardiaques (105).

9. Système (400) selon l'une quelconque des revendications 5 à 8, dans lequel le circuit de générateur d'indicateur de confiance (234) a pour objet de déterminer, pour l'événement arythmique détecté, l'indicateur de confiance qui inclut un score de confiance qui est proportionnel à une déviation de la mesure de signal par rapport à une valeur de référence.

10. Système (400) selon la revendication 9, dans lequel le circuit de générateur d'indicateur de confiance (234) a pour objet de déterminer le score de confiance en utilisant une combinaison de déviations de deux mesures de signal ou plus (222) par rapport à des valeurs de référence respectives.

11. Système (400) selon l'une quelconque des revendications 5 à 10, dans lequel le circuit de générateur d'indicateur de confiance (234) a pour objet de déterminer l'indicateur de confiance sur la base d'une qualité de signal de la mesure de signal, la qualité de signal incluant l'un des éléments informationnels qui suivent :

un rapport signal sur bruit ;
une détection d'artefact de mouvement ; ou
une détection de battements ectopiques.

12. Système (400) selon l'une quelconque des revendications 5 à 11, dans lequel le circuit de générateur d'indicateur de confiance (234) a pour objet de déterminer l'indicateur de confiance sur la base d'un historique médical du sujet incluant l'un des éléments informationnels qui suivent :

un historique de syncope ;
un historique d'arythmie ;
une procédure d'ablation ; ou
une durée d'un événement arythmique antérieur.

13. Système (400) selon l'une quelconque des revendications 1 à 12, comprenant un circuit de sortie qui est configuré de manière à ce qu'il génère une présentation pouvant être perçue par l'être humain des événements arythmiques détectés.

14. Système (400) selon la revendication 13, comprenant en outre un circuit de priorisation (410) qui inclut un circuit de comparateur dont l'objet consiste à prio-

riser deux événements arythmiques détectés ou plus sur la base des indicateurs de confiance respectifs ; dans lequel :
le circuit de sortie est configuré de manière à ce qu'il génère la présentation qui inclut au moins une partie des deux événements arythmiques détectés ou plus priorisés.

15. Système (400) selon la revendication 4, comprenant en outre un premier dispositif implantable qui inclut le premier circuit de détecteur d'arythmie (232) et un second dispositif différent qui inclut le second circuit de détecteur d'arythmie (236).

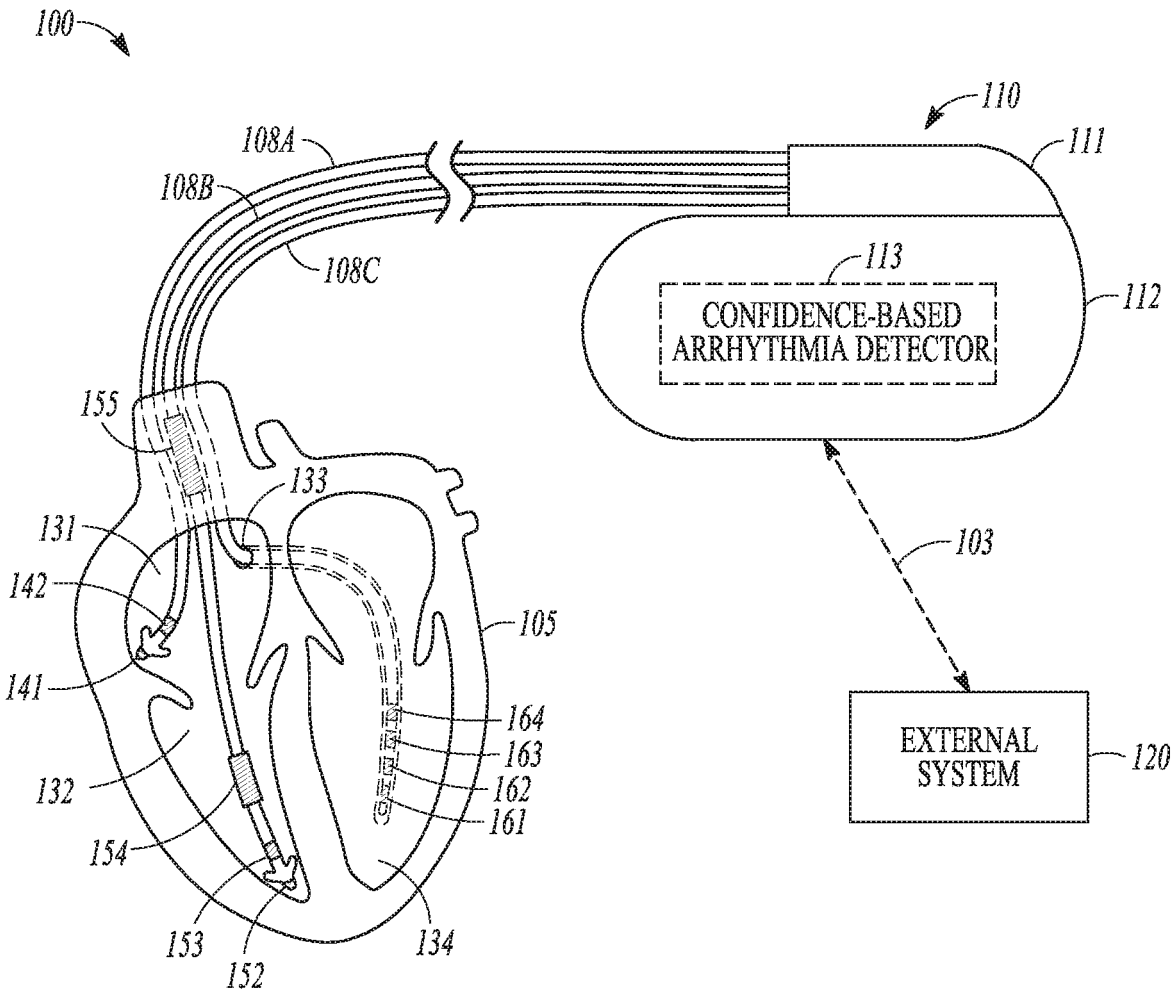
100
110
111
108A
108B
108C
113
CONFIDENCE-BASED ARRHYTHMIA DETECTOR
112
155
133
131
142
105
141
164
163
162
161
132
154
153
152
134
103
EXTERNAL SYSTEM
120

FIG. 1

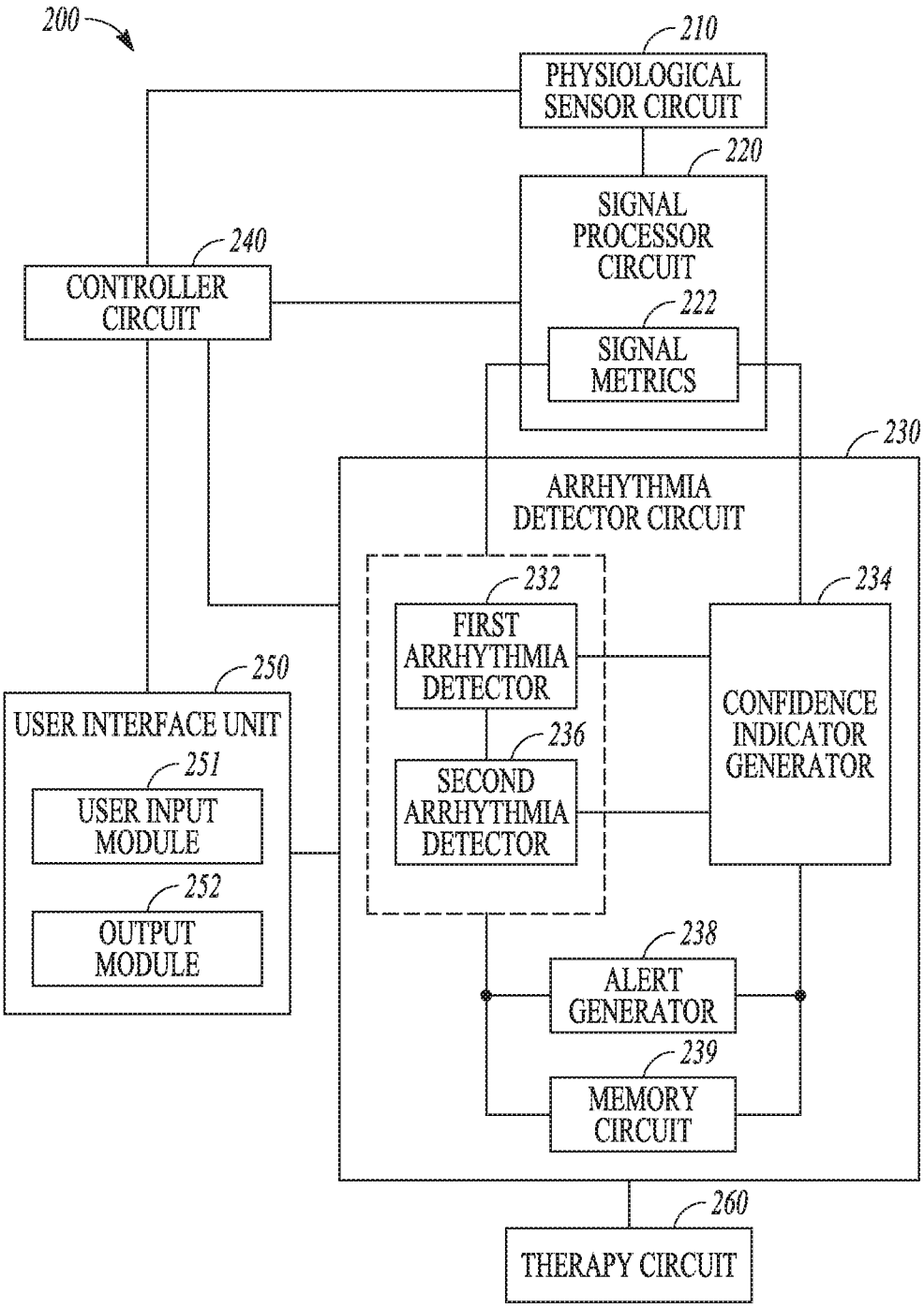
200
210
PHYSIOLOGICAL SENSOR CIRCUIT
220
SIGNAL PROCESSOR CIRCUIT
222
SIGNAL METRICS
240
CONTROLLER CIRCUIT
230
ARRHYTHMIA DETECTOR CIRCUIT
232
FIRST ARRHYTHMIA DETECTOR
234
CONFIDENCE INDICATOR GENERATOR
236
SECOND ARRHYTHMIA DETECTOR
250
USER INTERFACE UNIT
251
USER INPUT MODULE
252
OUTPUT MODULE
238
ALERT GENERATOR
239
MEMORY CIRCUIT
260
THERAPY CIRCUIT

FIG. 2

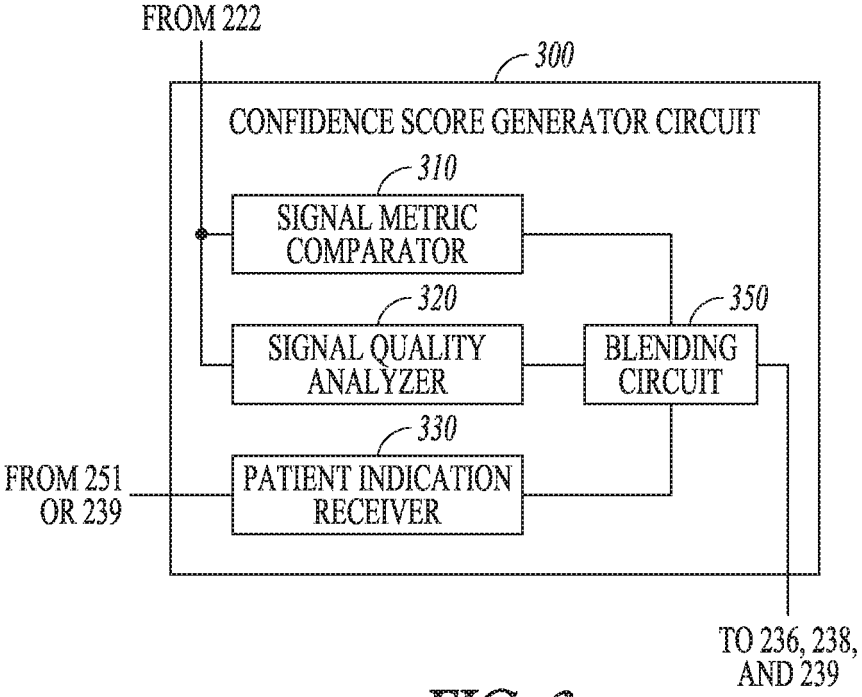
FROM 222
300
CONFIDENCE SCORE GENERATOR CIRCUIT
310
SIGNAL METRIC COMPARATOR
320
SIGNAL QUALITY ANALYZER
350
BLENDING CIRCUIT
330
FROM 251 OR 239
PATIENT INDICATION RECEIVER
TO 236, 238, AND 239

FIG. 3

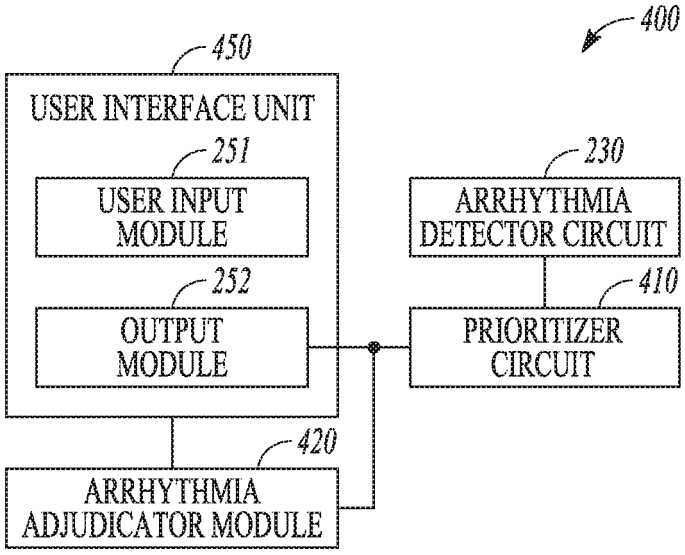
400
450
USER INTERFACE UNIT
251
USER INPUT MODULE
252
OUTPUT MODULE
230
ARRHYTHMIA DETECTOR CIRCUIT
410
PRIORITIZER CIRCUIT
420
ARRHYTHMIA ADJUDICATOR MODULE

FIG. 4

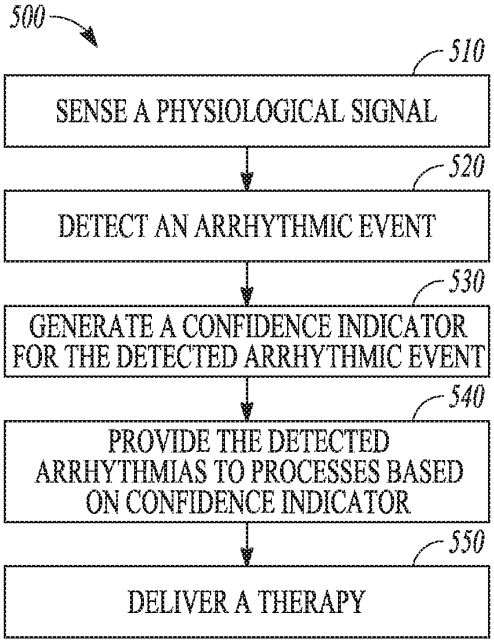
500
510
SENSE A PHYSIOLOGICAL SIGNAL
520
DETECT AN ARRHYTHMIC EVENT
530
GENERATE A CONFIDENCE INDICATOR FOR THE DETECTED ARRHYTHMIC EVENT
540
PROVIDE THE DETECTED ARRHYTHMIAS TO PROCESSES BASED ON CONFIDENCE INDICATOR
550
DELIVER A THERAPY

FIG. 5

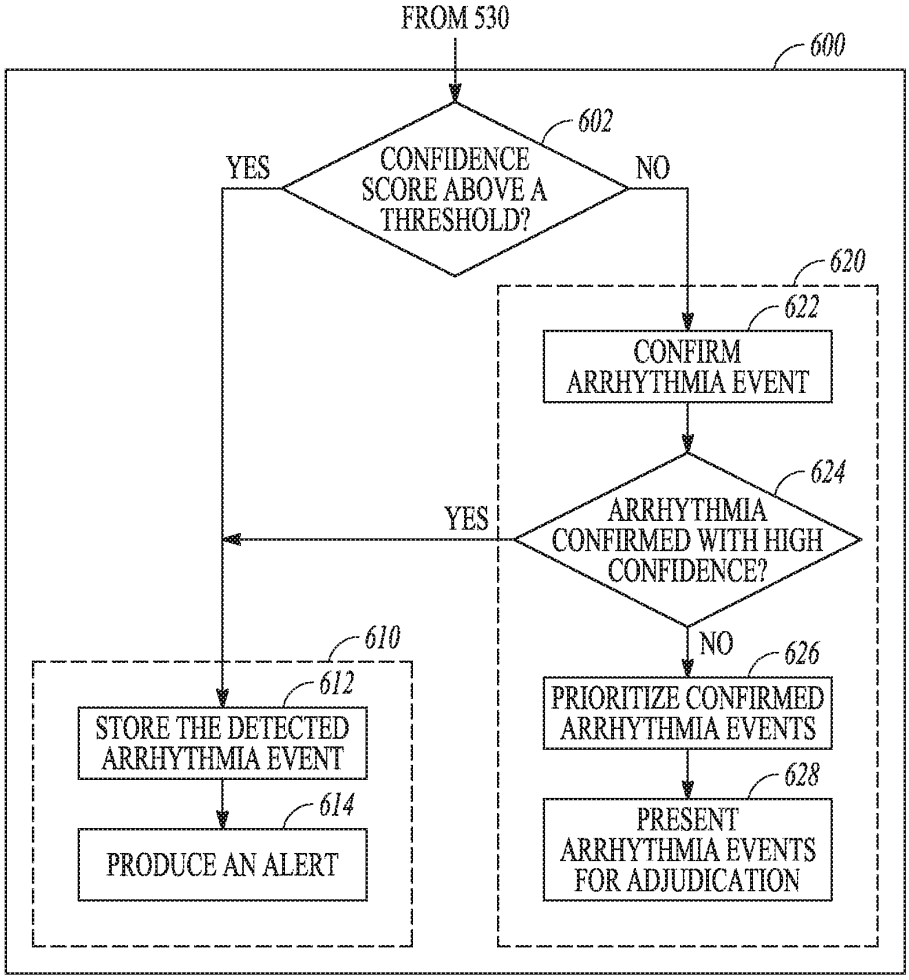
FROM 530
600
602
CONFIDENCE SCORE ABOVE A THRESHOLD?
YES
NO
620
622
CONFIRM ARRHYTHMIA EVENT
624
ARRHYTHMIA CONFIRMED WITH HIGH CONFIDENCE?
YES
NO
610
612
STORE THE DETECTED ARRHYTHMIA EVENT
614
PRODUCE AN ALERT
626
PRIORITIZE CONFIRMED ARRHYTHMIA EVENTS
628
PRESENT ARRHYTHMIA EVENTS FOR ADJUDICATION

FIG. 6

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 2012203123 A **[0004]**
- US 62109963, Mahajan **[0029]**
- US 62142184, Mahajan **[0031]**

专利名称(译)	基于信心的心律失常检测		
公开(公告)号	EP3439737B1	公开(公告)日	2020-01-22
申请号	EP2017718661	申请日	2017-04-04
[标]申请(专利权)人(译)	心脏起搏器股份公司		
申请(专利权)人(译)	心脏起搏器，INC.		
当前申请(专利权)人(译)	心脏起搏器，INC.		
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CPC分类号	A61B5/02405 A61B5/046 A61B5/0468 A61B5/076 A61B5/4836 A61B5/686 A61B5/7203 A61B5/7221 A61B5/746 A61N1/3621 A61N1/3627 A61N1/3704		
优先权	62/319055 2016-04-06 US		
其他公开文献	EP3439737A1		
外部链接	Espacenet		

摘要(译)

描述了用于检测心律不齐事件并存储与检测到的心律不齐事件相关联的生理信息的系统和方法。 系统可以包括第一检测器，该第一检测器从从受试者感测到的生理信号中检测心律不齐事件，并生成指示该心律不齐事件的检测的置信度的置信度指示符。 如果置信度指示符指示心律失常检测的相对高置信度，则系统可以将检测到的心律不齐事件提供给第一过程，以用于存储检测到的心律不齐事件或生成警报。 如果置信度指示符指示心律失常检测的相对低置信度，则系统可以将检测到的心律不齐事件提供给至少第二过程，包括确认或拒绝检测到的心律不齐事件。

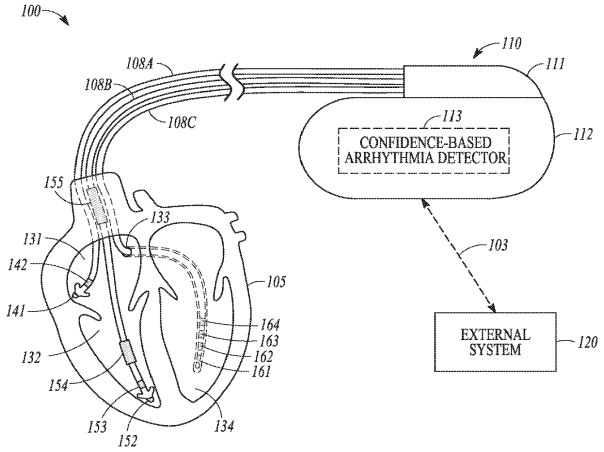

FIG. 1