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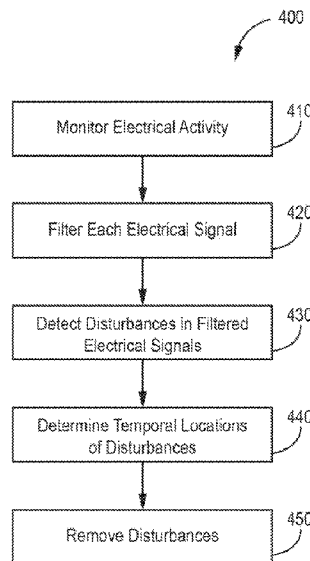


FIG. 4

(57) Abstract: Systems and methods are described herein for detecting disturbances in cardiac signals. An electrode apparatus includes a plurality of external electrodes to be disposed proximate a patients skin. A computing apparatus includes processing circuitry. The computing apparatus is operably coupled to the electrode apparatus. The computing apparatus is configured to monitor electrical activity from tissue of a patient using a plurality of external electrodes to generate a plurality of electrical signals. At least one of the electrical signals of the plurality of electrical signals is filtered. At least one disturbance in the at least one electrical signal is detected using the at least one filtered signal. A temporal location of the at least one disturbance in the at least one electrical signal is determined based on a time that the at least one filtered signal crosses a predetermined threshold.



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## DISTURBANCE DETECTION AND REMOVAL IN CARDIAC SIGNALS

[0001] The disclosure herein relates to systems and methods for use in the detection and removal of disturbances in cardiac signal using a plurality of external electrodes.

[0002] Implantable medical devices (IMDs), such as implantable pacemakers, cardioverters, defibrillators, or pacemaker-cardioverter-defibrillators, provide therapeutic electrical stimulation to the heart. IMDs may provide pacing to address bradycardia, or pacing or shocks in order to terminate tachyarrhythmia, such as tachycardia or fibrillation. In some cases, the medical device may sense intrinsic depolarizations of the heart, detect arrhythmia based on the intrinsic depolarizations (or absence thereof), and control delivery of electrical stimulation to the heart if arrhythmia is detected based on the intrinsic depolarizations.

[0003] IMDs may also provide cardiac resynchronization therapy (CRT), which is a form of pacing. CRT involves the delivery of pacing to the left ventricle, or both the left and right ventricles. The timing and location of the delivery of pacing pulses to the ventricle(s) may be selected to improve the coordination and efficiency of ventricular contraction.

[0004] Systems for implanting medical devices may include workstations or other equipment in addition to the implantable medical device itself. In some cases, these other pieces of equipment assist the physician or other technician with placing the intracardiac leads at particular locations on the heart. In some cases, the equipment provides information to the physician about the electrical activity of the heart and the location of the intracardiac lead. The equipment may perform similar functions as the medical device, including delivering electrical stimulation to the heart and sensing the depolarizations of the heart. In some cases, the equipment may include equipment for obtaining an electrocardiogram (ECG) via electrodes on the surface, or skin, of the patient. More specifically, the patient may have a plurality of electrodes on an ECG belt or vest that surrounds the torso of the patient. After the belt or vest has been secured to the torso, a physician can perform a series of tests to evaluate a patient's cardiac response. The evaluation process can include detection of a baseline rhythm in which no electrical

stimuli is delivered to cardiac tissue and another rhythm after electrical stimuli is delivered to the cardiac tissue.

[0005] The ECG electrodes placed on the body surface of the patient may be used for various therapeutic purposes (e.g., cardiac resynchronization therapy) including optimizing lead location, pacing parameters, etc. based on one or more metrics derived from the signals captured by the ECG electrodes. For example, electrical heterogeneity information may be derived from electrical activation times computed from multiple electrodes on the body surface.

[0006] Further, the signals from multiple electrodes on the body surface can be used to determine one or more specific ECG features such as, e.g., QRS onset, peak, QRS offset, etc. for a series of multiple heartbeats. Such ECG features may be used by themselves to evaluate cardiac health and/or therapy, or may be used to calculate, or compute, activation times. However, in one or more instances, signals upon which activation times are based, or computed from, may contain various disturbances that may, for example, result false detection of activation times. Detection and/or removal of these disturbances may lead to more accurate determination of activation times.

## SUMMARY

[0007] The exemplary systems and methods described herein may be configured to assist users (e.g., physicians) in configuring cardiac therapy (e.g., cardiac therapy being performed on a patient during and/or after implantation of cardiac therapy apparatus). The systems and methods may be described as being noninvasive. For example, the systems and methods may not need implantable devices such as leads, probes, sensors, catheters, etc. to evaluate and configure the cardiac therapy. Instead, the systems and methods may use electrical measurements taken noninvasively using, e.g., a plurality of external electrodes attached to the skin of a patient about the patient's torso.

[0008] One exemplary system for use in cardiac evaluation may include an electrode apparatus comprises a plurality of external electrodes to be disposed proximate a patient's skin. A computing apparatus comprises processing circuitry. The computing apparatus is operably coupled to the electrode apparatus. The computing apparatus is configured to

monitor electrical activity from tissue of a patient using a plurality of external electrodes to generate a plurality of electrical signals. At least one of the electrical signals of the plurality of electrical signals is filtered. At least one disturbance in the at least one electrical signal is detected using the at least one filtered signal. A temporal location of the at least one disturbance in the at least one electrical signal is determined based on a time that the at least one filtered signal crosses a predetermined threshold.

[0009] One exemplary system for use in cardiac evaluation may include an electrode apparatus comprising a plurality of external electrodes to be disposed proximate a patient's skin. A computing apparatus comprises processing circuitry. The computing apparatus is operably coupled to the electrode apparatus. The computing apparatus is configured to monitor electrical activity from tissue of a patient using a plurality of external electrodes to generate a plurality of electrical signals. At least one disturbance is detected in at least one of the plurality of electrical signals. Temporal locations of the at least one disturbance in the at least one electrical signal are determined. The at least one disturbance is removed based on the temporal locations of the at least one disturbance in the at least one electrical signal.

[0010] An exemplary method for use in cardiac evaluation includes monitoring electrical activity from tissue of a patient using a plurality of external electrodes to generate a plurality of electrical signals. At least one electrical signal of the plurality of electrical signals is filtered. At least one disturbance is detected in the at least one electrical signal using the at least one filtered signal. A temporal location of the at least one disturbance in the at least one electrical signal is determined based on a time that the at least one filtered signal crosses a predetermined threshold.

[0011] In one or more embodiments, the illustrative systems and methods may be described as utilizing a filtering algorithm that starts with a sampled signal. Next, the sampling frequency may be used to determine an appropriate threshold for a second derivative (or higher order) of a pacing spike for a known pulse width or range of pulse widths. The signal may be processed, or "run through," the second derivative filter and the resulting signal may be examined for threshold crossings. If threshold crossings are identified, the temporal location of the crossing is recorded. The original signal (or a

commonly filtered ECG signal) may then be examined at the recorded temporal location. The pacing spike may be removed from the original signal via a smoothing across a window (e.g., fixed and adjusted for pulse width, or auto calculated based on a baseline departure and return) that starts slightly before the temporal location and extends beyond the temporal location sufficiently to remove the pacing spike.

[0012] The above summary is not intended to describe each embodiment or every implementation of the present disclosure. A more complete understanding will become apparent and appreciated by referring to the following detailed description and claims taken in conjunction with the accompanying drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIG. 1 is a diagram of an exemplary system including electrode apparatus, display apparatus, and computing apparatus.

[0014] FIGS. 2-3 are diagrams of exemplary external electrode apparatus for measuring torso-surface potentials.

[0015] FIG. 4 is a block diagrams of an exemplary method for detecting and removing disturbances.

[0016] FIG. 5 is a detailed block diagram of a process of the exemplary method of FIG. 4.

[0017] FIGS. 6A and 6B show examples of a plurality of sampled electrical signals.

[0018] FIG. 7 illustrates an example of filtered electrical signals.

[0019] FIG. 8A illustrates example signals after removal of the disturbances in some of the signals within a window.

[0020] FIG. 8B shows the signals of FIG. 8A with additional filtering.

[0021] FIG. 9A illustrates an example where false activation times are detected due to a disturbance.

[0022] FIG. 9B shows the same signals shown in FIG. 9A with the disturbance removed.

[0023] FIG. 10 is a diagram of an illustrative system including an illustrative implantable medical device (IMD).

[0024] FIG. 11A is a diagram of the illustrative IMD of FIG. 10.

[0025] FIG. 11B is a diagram of an enlarged view of a distal end of the electrical lead disposed in the left ventricle of FIG. 11A.

[0026] FIG. 12A is a block diagram of an illustrative IMD, e.g., of the systems of FIGS. 10-11.

[0027] FIG. 12B is another block diagram of an illustrative IMD (e.g., an implantable pulse generator) circuitry and associated leads employed in the systems of FIGS. 10-11).

#### DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

[0028] In the following detailed description of illustrative embodiments, reference is made to the accompanying figures of the drawing which form a part hereof, and in which are shown, by way of illustration, specific embodiments which may be practiced. It is to be understood that other embodiments may be utilized and structural changes may be made without departing from (e.g., still falling within) the scope of the disclosure presented hereby.

[0029] Illustrative systems and methods shall be described with reference to FIGS. 1-12. It will be apparent to one skilled in the art that elements or processes from one embodiment may be used in combination with elements or processes of the other embodiments, and that the possible embodiments of such systems, methods, and devices using combinations of features set forth herein is not limited to the specific embodiments shown in the Figures and/or described herein. Further, it will be recognized that the embodiments described herein may include many elements that are not necessarily shown to scale. Still further, it will be recognized that timing of the processes and the size and shape of various elements herein may be modified but still fall within the scope of the present disclosure, although certain timings, one or more shapes and/or sizes, or types of elements, may be advantageous over others.

[0030] A plurality of electrocardiogram (ECG) signals (e.g., torso-surface potentials) may be measured, or monitored, using a plurality of external electrodes positioned about the surface, or skin, of a patient. The ECG signals may be used to evaluate and configure cardiac therapy such as, e.g., cardiac therapy provide by an implantable medical device performing cardiac resynchronization therapy (CRT). As described herein, the ECG signals may be gathered or obtained noninvasively since, e.g., implantable electrodes may not be used to measure the ECG signals. Further, the ECG signals may be used to determine cardiac electrical activation times, which may be used to generate various metrics (e.g., electrical heterogeneity information) that may be used by a user (e.g., physician) to optimize one or more settings, or parameters, of cardiac therapy (e.g., pacing therapy) such as CRT.

[0031] Various illustrative systems, methods, and graphical user interfaces may be configured to use electrode apparatus including external electrodes, display apparatus, and computing apparatus to noninvasively assist a user (e.g., a physician) in the evaluation of cardiac health and/or the configuration (e.g., optimization) of cardiac therapy. An illustrative system 100 including electrode apparatus 110, computing apparatus 140, and a remote computing device 160 is depicted in FIG. 1.

[0032] The electrode apparatus 110 as shown includes a plurality of electrodes incorporated, or included, within a band wrapped around the chest, or torso, of a patient 14. The electrode apparatus 110 is operatively coupled to the computing apparatus 140 (e.g., through one or wired electrical connections, wirelessly, etc.) to provide electrical signals from each of the electrodes to the computing apparatus 140 for analysis, evaluation, etc. Illustrative electrode apparatus may be described in U.S. Patent No. 9,320,446 entitled "Bioelectric Sensor Device and Methods" filed March 27, 2014 and issued on March 26, 2016. Further, illustrative electrode apparatus 110 will be described in more detail in reference to FIGS. 2-3.

[0033] Although not described herein, the illustrative system 100 may further include imaging apparatus. The imaging apparatus may be any type of imaging apparatus configured to image, or provide images of, at least a portion of the patient in a noninvasive manner. For example, the imaging apparatus may not use any components or parts that



may be located within the patient to provide images of the patient except noninvasive tools such as contrast solution. It is to be understood that the illustrative systems, methods, and interfaces described herein may further use imaging apparatus to provide noninvasive assistance to a user (e.g., a physician) to locate, or place, one or more pacing electrodes proximate the patient's heart in conjunction with the configuration of cardiac therapy.

[0034] For example, the illustrative systems and methods may provide image guided navigation that may be used to navigate leads including electrodes, leadless electrodes, wireless electrodes, catheters, etc., within the patient's body while also providing noninvasive cardiac therapy configuration including determining an effective, or optimal, pre-excitation intervals such as A-V and V-V intervals, etc. Illustrative systems and methods that use imaging apparatus and/or electrode apparatus may be described in U.S. Pat. App. Pub. No. 2014/0371832 to Ghosh published on December 18, 2014, U.S. Pat. App. Pub. No. 2014/0371833 to Ghosh et al. published on December 18, 2014, U.S. Pat. App. Pub. No. 2014/0323892 to Ghosh et al. published on October 30, 2014, U.S. Pat. App. Pub. No. 2014/0323882 to Ghosh et al. published on October 20, 2014.

[0035] Illustrative imaging apparatus may be configured to capture x-ray images and/or any other alternative imaging modality. For example, the imaging apparatus may be configured to capture images, or image data, using isocentric fluoroscopy, bi-plane fluoroscopy, ultrasound, computed tomography (CT), multi-slice computed tomography (MSCT), magnetic resonance imaging (MRI), high frequency ultrasound (HIFU), optical coherence tomography (OCT), intra-vascular ultrasound (IVUS), two dimensional (2D) ultrasound, three dimensional (3D) ultrasound, four dimensional (4D) ultrasound, intraoperative CT, intraoperative MRI, etc. Further, it is to be understood that the imaging apparatus may be configured to capture a plurality of consecutive images (e.g., continuously) to provide video frame data. In other words, a plurality of images taken over time using the imaging apparatus may provide video frame, or motion picture, data. An exemplary system that employs ultrasound can be found in U.S. Pat. App. Pub. No. 2017/0303840 entitled NONINVASIVE ASSESSMENT OF CARDIAC RESYNCHRONIZATION THERAPY to Stadler et al. Additionally, the images may also be obtained and displayed in two, three, or four dimensions. In more advanced forms, four-dimensional surface rendering of the heart or other regions of the body may also be

achieved by incorporating heart data or other soft tissue data from a map or from pre-operative image data captured by MRI, CT, or echocardiography modalities. Image datasets from hybrid modalities, such as positron emission tomography (PET) combined with CT, or single photon emission computer tomography (SPECT) combined with CT, could also provide functional image data superimposed onto anatomical data, e.g., to be used to navigate implantable apparatus to target locations within the heart or other areas of interest.

[0036] Systems and/or imaging apparatus that may be used in conjunction with the illustrative systems and method described herein are described in U.S. Pat. App. Pub. No. 2005/0008210 to Evron et al. published on January 13, 2005, U.S. Pat. App. Pub. No. 2006/0074285 to Zarkh et al. published on April 6, 2006, U.S. Pat. No. 8,731,642 to Zarkh et al. issued on May 20, 2014, U.S. Pat. No. 8,861,830 to Brada et al. issued on October 14, 2014, U.S. Pat. No. 6,980,675 to Evron et al. issued on December 27, 2005, U.S. Pat. No. 7,286,866 to Okerlund et al. issued on October 23, 2007, U.S. Pat. No. 7,308,297 to Reddy et al. issued on December 11, 2011, U.S. Pat. No. 7,308,299 to Burrell et al. issued on December 11, 2011, U.S. Pat. No. 7,321,677 to Evron et al. issued on January 22, 2008, U.S. Pat. No. 7,346,381 to Okerlund et al. issued on March 18, 2008, U.S. Pat. No. 7,454,248 to Burrell et al. issued on November 18, 2008, U.S. Pat. No. 7,499,743 to Vass et al. issued on March 3, 2009, U.S. Pat. No. 7,565,190 to Okerlund et al. issued on July 21, 2009, U.S. Pat. No. 7,587,074 to Zarkh et al. issued on September 8, 2009, U.S. Pat. No. 7,599,730 to Hunter et al. issued on October 6, 2009, U.S. Pat. No. 7,613,500 to Vass et al. issued on November 3, 2009, U.S. Pat. No. 7,742,629 to Zarkh et al. issued on June 22, 2010, U.S. Pat. No. 7,747,047 to Okerlund et al. issued on June 29, 2010, U.S. Pat. No. 7,778,685 to Evron et al. issued on August 17, 2010, U.S. Pat. No. 7,778,686 to Vass et al. issued on August 17, 2010, U.S. Pat. No. 7,813,785 to Okerlund et al. issued on October 12, 2010, U.S. Pat. No. 7,996,063 to Vass et al. issued on August 9, 2011, U.S. Pat. No. 8,060,185 to Hunter et al. issued on November 15, 2011, and U.S. Pat. No. 8,401,616 to Verard et al. issued on March 19, 2013.

[0037] The computing apparatus 140 and the remote computing device 160 may each include display apparatus 130, 170, respectively, that may be configured to display and analyze data such as, e.g., electrical signals (e.g., electrocardiogram data),

electrical activation times, electrical heterogeneity information, etc. For example, one cardiac cycle, or one heartbeat, of a plurality of cardiac cycles, or heartbeats, represented by the electrical signals collected or monitored by the electrode apparatus 110 may be analyzed and evaluated for one or more metrics including activation times and electrical heterogeneity information that may be pertinent to the therapeutic nature of one or more parameters related to cardiac therapy such as, e.g., pacing parameters, lead location, etc. More specifically, for example, the QRS complex of a single cardiac cycle may be evaluated for one or more metrics such as, e.g., QRS onset, QRS offset, QRS peak, electrical heterogeneity information (EHI), electrical activation times referenced to earliest activation time, left ventricular or thoracic standard deviation of electrical activation times (LVED), standard deviation of activation times (SDAT), average left ventricular or thoracic surrogate electrical activation times (LVAT), QRS duration (e.g., interval between QRS onset to QRS offset), difference between average left surrogate and average right surrogate activation times, relative or absolute QRS morphology, difference between a higher percentile and a lower percentile of activation times (higher percentile may be 90%, 80%, 75%, 70%, etc. and lower percentile may be 10%, 15%, 20%, 25% and 30%, etc.), other statistical measures of central tendency (e.g., median or mode), dispersion (e.g., mean deviation, standard deviation, variance, interquartile deviations, range), etc. Further, each of the one or more metrics may be location specific. For example, some metrics may be computed from signals recorded, or monitored, from electrodes positioned about a selected area of the patient such as, e.g., the left side of the patient, the right side of the patient, etc.

[0038] In at least one embodiment, one or both of the computing apparatus 140 and the remote computing device 160 may be a server, a personal computer, a tablet computer, a mobile device, and a cellular telephone. The computing apparatus 140 may be configured to receive input from input apparatus 142 (e.g., a keyboard) and transmit output to the display apparatus 130, and the remote computing device 160 may be configured to receive input from input apparatus 162 (e.g., a touchscreen) and transmit output to the display apparatus 170. One or both of the computing apparatus 140 and the remote computing device 160 may include data storage that may allow for access to processing programs or routines and/or one or more other types of data, e.g., for analyzing a plurality of electrical signals captured by the electrode apparatus 110, for determining

QRS onsets, QRS offsets, medians, modes, averages, peaks or maximum values, valleys or minimum values, for determining electrical activation times, for driving a graphical user interface configured to noninvasively assist a user in configuring one or more pacing parameters, or settings, such as, e.g., pacing rate, ventricular pacing rate, A-V interval, V-V interval, pacing pulse width, pacing vector, multipoint pacing vector (e.g., left ventricular vector quad lead), pacing voltage, pacing configuration (e.g., biventricular pacing, right ventricle only pacing, left ventricle only pacing, etc.), and arrhythmia detection and treatment, rate adaptive settings and performance, etc.

[0039] The computing apparatus 140 may be operatively coupled to the input apparatus 142 and the display apparatus 130 to, e.g., transmit data to and from each of the input apparatus 142 and the display apparatus 130, and the remote computing device 160 may be operatively coupled to the input apparatus 162 and the display apparatus 170 to, e.g., transmit data to and from each of the input apparatus 162 and the display apparatus 170. For example, the computing apparatus 140 and the remote computing device 160 may be electrically coupled to the input apparatus 142, 162 and the display apparatus 130, 170 using, e.g., analog electrical connections, digital electrical connections, wireless connections, bus-based connections, network-based connections, internet-based connections, etc. As described further herein, a user may provide input to the input apparatus 142, 162 to view and/or select one or more pieces of configuration information related to the cardiac therapy delivered by cardiac therapy apparatus such as, e.g., an implantable medical device.

[0040] Although as depicted the input apparatus 142 is a keyboard and the input apparatus 162 is a touchscreen, it is to be understood that the input apparatus 142, 162 may include any apparatus capable of providing input to the computing apparatus 140 and the computing device 160 to perform the functionality, methods, and/or logic described herein. For example, the input apparatus 142, 162 may include a keyboard, a mouse, a trackball, a touchscreen (e.g., capacitive touchscreen, a resistive touchscreen, a multi-touch touchscreen, etc.), etc. Likewise, the display apparatus 130, 170 may include any apparatus capable of displaying information to a user, such as a graphical user interface 132, 172 including electrode status information, graphical maps of electrical activation, a plurality of signals for the external electrodes over one or more heartbeats,

QRS complexes, various cardiac therapy scenario selection regions, various rankings of cardiac therapy scenarios, various pacing parameters, electrical heterogeneity information (EHI), textual instructions, graphical depictions of anatomy of a human heart, images or graphical depictions of the patient's heart, graphical depictions of locations of one or more electrodes, graphical depictions of a human torso, images or graphical depictions of the patient's torso, graphical depictions or actual images of implanted electrodes and/or leads, etc. Further, the display apparatus 130, 170 may include a liquid crystal display, an organic light-emitting diode screen, a touchscreen, a cathode ray tube display, etc.

[0041] The processing programs or routines stored and/or executed by the computing apparatus 140 and the remote computing device 160 may include programs or routines for computational mathematics, matrix mathematics, decomposition algorithms, compression algorithms (e.g., data compression algorithms), calibration algorithms, image construction algorithms, signal processing algorithms (e.g., various filtering algorithms, Fourier transforms, fast Fourier transforms, etc.), standardization algorithms, comparison algorithms, vector mathematics, or any other processing used to implement one or more illustrative methods and/or processes described herein. Data stored and/or used by the computing apparatus 140 and the remote computing device 160 may include, for example, electrical signal/waveform data from the electrode apparatus 110 (e.g., a plurality of QRS complexes), electrical activation times from the electrode apparatus 110, cardiac sound/signal/waveform data from acoustic sensors, graphics (e.g., graphical elements, icons, buttons, windows, dialogs, pull-down menus, graphic areas, graphic regions, 3D graphics, etc.), graphical user interfaces, results from one or more processing programs or routines employed according to the disclosure herein (e.g., electrical signals, electrical heterogeneity information, etc.), or any other data that may be used for carrying out the one and/or more processes or methods described herein.

[0042] In one or more embodiments, the illustrative systems, methods, and interfaces may be implemented using one or more computer programs executed on programmable computers, such as computers that include, for example, processing capabilities, data storage (e.g., volatile or non-volatile memory and/or storage elements), input devices, and output devices. Program code and/or logic described herein may be applied to input data to perform functionality described herein and generate desired output

information. The output information may be applied as input to one or more other devices and/or methods as described herein or as would be applied in a known fashion.

[0043] The one or more programs used to implement the systems, methods, and/or interfaces described herein may be provided using any programmable language, e.g., a high-level procedural and/or object orientated programming language that is suitable for communicating with a computer system. Any such programs may, for example, be stored on any suitable device, e.g., a storage media, that is readable by a general or special purpose program running on a computer system (e.g., including processing apparatus) for configuring and operating the computer system when the suitable device is read for performing the procedures described herein. In other words, at least in one embodiment, the illustrative systems, methods, and interfaces may be implemented using a computer readable storage medium, configured with a computer program, where the storage medium so configured causes the computer to operate in a specific and predefined manner to perform functions described herein. Further, in at least one embodiment, the illustrative systems, methods, and interfaces may be described as being implemented by logic (e.g., object code) encoded in one or more non-transitory media that includes code for execution and, when executed by a processor or processing circuitry, is operable to perform operations such as the methods, processes, and/or functionality described herein.

[0044] The computing apparatus 140 and the remote computing device 160 may be, for example, any fixed or mobile computer system (e.g., a controller, a microcontroller, a personal computer, minicomputer, tablet computer, etc.). The exact configurations of the computing apparatus 140 and the remote computing device 160 are not limiting, and essentially any device capable of providing suitable computing capabilities and control capabilities (e.g., signal analysis, mathematical functions such as medians, modes, averages, maximum value determination, minimum value determination, slope determination, minimum slope determination, maximum slope determination, graphics processing, etc.) may be used. As described herein, a digital file may be any medium (e.g., volatile or non-volatile memory, a CD-ROM, a punch card, magnetic recordable tape, etc.) containing digital bits (e.g., encoded in binary, trinary, etc.) that may be readable and/or writeable by the computing apparatus 140 and the remote computing device 160 described herein. Also, as described herein, a file in user-readable format may be any representation

of data (e.g., ASCII text, binary numbers, hexadecimal numbers, decimal numbers, graphically, etc.) presentable on any medium (e.g., paper, a display, etc.) readable and/or understandable by a user.

[0045] In view of the above, it will be readily apparent that the functionality as described in one or more embodiments according to the present disclosure may be implemented in any manner as would be known to one skilled in the art. As such, the computer language, the computer system, or any other software/hardware which is to be used to implement the processes described herein shall not be limiting on the scope of the systems, processes, or programs (e.g., the functionality provided by such systems, processes, or programs) described herein.

[0046] The illustrative electrode apparatus 110 may be configured to measure body-surface potentials of a patient 14 and, more particularly, torso-surface potentials of a patient 14. As shown in FIG. 2, the illustrative electrode apparatus 110 may include a set, or array, of external electrodes 112, a strap 113, and interface/amplifier circuitry 116. The electrodes 112 may be attached, or coupled, to the strap 113 and the strap 113 may be configured to be wrapped around the torso of a patient 14 such that the electrodes 112 surround the patient's heart. As further illustrated, the electrodes 112 may be positioned around the circumference of a patient 14, including the posterior, lateral, posterolateral, anterolateral, and anterior locations of the torso of a patient 14.

[0047] The illustrative electrode apparatus 110 may be further configured to measure, or monitor, sounds from at least one or both the patient 14. As shown in FIG. 2, the illustrative electrode apparatus 110 may include a set, or array, of acoustic sensors 120 attached, or coupled, to the strap 113. The strap 113 may be configured to be wrapped around the torso of a patient 14 such that the acoustic sensors 120 surround the patient's heart. As further illustrated, the acoustic sensors 120 may be positioned around the circumference of a patient 14, including the posterior, lateral, posterolateral, anterolateral, and anterior locations of the torso of a patient 14.

[0048] Further, the electrodes 112 and the acoustic sensors 120 may be electrically connected to interface/amplifier circuitry 116 via wired connection 118. The interface/amplifier circuitry 116 may be configured to amplify the signals from the

electrodes 112 and the acoustic sensors 120 and provide the signals to one or both of the computing apparatus 140 and the remote computing device 160. Other illustrative systems may use a wireless connection to transmit the signals sensed by electrodes 112 and the acoustic sensors 120 to the interface/amplifier circuitry 116 and, in turn, to one or both of the computing apparatus 140 and the remote computing device 160, e.g., as channels of data. In one or more embodiments, the interface/amplifier circuitry 116 may be electrically coupled to the computing apparatus 140 using, e.g., analog electrical connections, digital electrical connections, wireless connections, bus-based connections, network-based connections, internet-based connections, etc.

[0049] Although in the example of FIG. 2 the electrode apparatus 110 includes a strap 113, in other examples any of a variety of mechanisms, e.g., tape or adhesives, may be employed to aid in the spacing and placement of electrodes 112 and the acoustic sensors 120. In some examples, the strap 113 may include an elastic band, strip of tape, or cloth. Further, in some examples, the strap 113 may be part of, or integrated with, a piece of clothing such as, e.g., a t-shirt. In other examples, the electrodes 112 and the acoustic sensors 120 may be placed individually on the torso of a patient 14. Further, in other examples, one or both of the electrodes 112 (e.g., arranged in an array) and the acoustic sensors 120 (e.g., also arranged in an array) may be part of, or located within, patches, vests, and/or other manners of securing the electrodes 112 and the acoustic sensors 120 to the torso of the patient 14. Still further, in other examples, one or both of the electrodes 112 and the acoustic sensors 120 may be part of, or located within, two sections of material or two patches. One of the two patches may be located on the anterior side of the torso of the patient 14 (to, e.g., monitor electrical signals representative of the anterior side of the patient's heart, measure surrogate cardiac electrical activation times representative of the anterior side of the patient's heart, monitor or measure sounds of the anterior side of the patient, etc.) and the other patch may be located on the posterior side of the torso of the patient 14 (to, e.g., monitor electrical signals representative of the posterior side of the patient's heart, measure surrogate cardiac electrical activation times representative of the posterior side of the patient's heart, monitor or measure sounds of the posterior side of the patient, etc.). And still further, in other examples, one or both of the electrodes 112 and the acoustic sensors 120 may be arranged in a top row and bottom row that extend from the anterior side of the patient 14 across the left side of the patient 14 to



the posterior side of the patient 14. Yet still further, in other examples, one or both of the electrodes 112 and the acoustic sensors 120 may be arranged in a curve around the armpit area and may have an electrode/sensor-density that less dense on the right thorax than the other remaining areas.

[0050] The electrodes 112 may be configured to surround the heart of the patient 14 and record, or monitor, the electrical signals associated with the depolarization and repolarization of the heart after the signals have propagated through the torso of a patient 14. Each of the electrodes 112 may be used in a unipolar configuration to sense the torso-surface potentials that reflect the cardiac signals. The interface/amplifier circuitry 116 may also be coupled to a return or indifferent electrode (not shown) that may be used in combination with each electrode 112 for unipolar sensing.

[0051] In some examples, there may be about 12 to about 50 electrodes 112 and about 12 to about 50 acoustic sensors 120 spatially distributed around the torso of a patient. Other configurations may have more or fewer electrodes 112 and more or fewer acoustic sensors 120. It is to be understood that the electrodes 112 and acoustic sensors 120 may not be arranged or distributed in an array extending all the way around or completely around the patient 14. Instead, the electrodes 112 and acoustic sensors 120 may be arranged in an array that extends only part of the way or partially around the patient 14. For example, the electrodes 112 and acoustic sensors 120 may be distributed on the anterior, posterior, and left sides of the patient with less or no electrodes and acoustic sensors proximate the right side (including posterior and anterior regions of the right side of the patient).

[0052] The computing apparatus 140 may record and analyze the torso-surface potential signals sensed by electrodes 112 and the sound signals sensed by the acoustic sensors 120, which are amplified/conditioned by the interface/amplifier circuitry 116. The computing apparatus 140 may be configured to analyze the electrical signals from the electrodes 112 to provide electrocardiogram (ECG) signals, information, or data from the patient's heart as will be further described herein. The computing apparatus 140 may be configured to analyze the electrical signals from the acoustic sensors 120 to

provide sound signals, information, or data from the patient's body and/or devices implanted therein (such as a left ventricular assist device).

[0053] Additionally, the computing apparatus 140 and the remote computing device 160 may be configured to provide graphical user interfaces 132, 172 depicting various information related to the electrode apparatus 110 and the data gathered, or sensed, using the electrode apparatus 110. For example, the graphical user interfaces 132, 172 may depict ECGs including QRS complexes obtained using the electrode apparatus 110 and sound data including sound waves obtained using the acoustic sensors 120 as well as other information related thereto. Illustrative systems and methods may noninvasively use the electrical information collected using the electrode apparatus 110 and the sound information collected using the acoustic sensors 120 to evaluate a patient's cardiac health and to evaluate and configure cardiac therapy being delivered to the patient.

[0054] Further, the electrode apparatus 110 may further include reference electrodes and/or drive electrodes to be, e.g. positioned about the lower torso of the patient 14, that may be further used by the system 100. For example, the electrode apparatus 110 may include three reference electrodes, and the signals from the three reference electrodes may be combined to provide a reference signal. Further, the electrode apparatus 110 may use of three caudal reference electrodes (e.g., instead of standard references used in a Wilson Central Terminal) to get a "true" unipolar signal with less noise from averaging three caudally located reference signals.

[0055] FIG. 3 illustrates another illustrative electrode apparatus 110 that includes a plurality of electrodes 112 configured to surround the heart of the patient 14 and record, or monitor, the electrical signals associated with the depolarization and repolarization of the heart after the signals have propagated through the torso of the patient 14 and a plurality of acoustic sensors 120 configured to surround the heart of the patient 14 and record, or monitor, the sound signals associated with the heart after the signals have propagated through the torso of the patient 14. The electrode apparatus 110 may include a vest 114 upon which the plurality of electrodes 112 and the plurality of acoustic sensors 120 may be attached, or to which the electrodes 112 and the acoustic sensors 120 may be coupled. In at least one embodiment, the plurality, or array, of electrodes 112 may be used

to collect electrical information such as, e.g., surrogate electrical activation times. Similar to the electrode apparatus 110 of FIG. 2, the electrode apparatus 110 of FIG. 3 may include interface/amplifier circuitry 116 electrically coupled to each of the electrodes 112 and the acoustic sensors 120 through a wired connection 118 and be configured to transmit signals from the electrodes 112 and the acoustic sensors 120 to computing apparatus 140. As illustrated, the electrodes 112 and the acoustic sensors 120 may be distributed over the torso of a patient 14, including, for example, the posterior, lateral, posterolateral, anterolateral, and anterior locations of the torso of a patient 14.

[0056] The vest 114 may be formed of fabric with the electrodes 112 and the acoustic sensors 120 attached to the fabric. The vest 114 may be configured to maintain the position and spacing of electrodes 112 and the acoustic sensors 120 on the torso of the patient 14. Further, the vest 114 may be marked to assist in determining the location of the electrodes 112 and the acoustic sensors 120 on the surface of the torso of the patient 14. In some examples, there may be about 25 to about 256 electrodes 112 and about 25 to about 256 acoustic sensors 120 distributed around the torso of the patient 14, though other configurations may have more or fewer electrodes 112 and more or fewer acoustic sensors 120.

[0057] The illustrative systems and methods may be used to provide noninvasive assistance to a user in the evaluation of a patient's cardiac health and/or evaluation and configuration of cardiac therapy being presently delivered to the patient (e.g., by an implantable medical device delivering pacing therapy, by a LVAD, etc.). Further, it is to be understood that the computing apparatus 140 and the remote computing device 160 may be operatively coupled to each other in a plurality of different ways so as to perform, or execute, the functionality described herein. For example, in the embodiment depicted, the computing device 140 may be wireless operably coupled to the remote computing device 160 as depicted by the wireless signal lines emanating therebetween. Additionally, as opposed to wireless connections, one or more of the computing apparatus 140 and the remoting computing device 160 may be operably coupled through one or wired electrical connections.

[0058] According to embodiments described herein, the ECG belt is used with CRT systems to calculate the SDAT of cardiac cycles (or heart beats). According to various embodiments, the ECG belt is used to calculate the SDAT of cardiac cycles after CRT paces. For example, the ECG belt may be used to calculate the SDAT of cardiac cycles for biventricular and/or left ventricular paces. Embodiments described herein may be used in non-CRT pacing. If the SDAT is inaccurate, the output of the ECG belt could be misleading and could potentially impact lead placement (e.g. lead not being placed at the optimal spot) and/or optimal device programming. For example, if the SDAT is inaccurate, the SDAT may be artificially low, causing the lead to be left in its current position, rather than repositioned to get a better response. Disturbances in the signals detected by the ECG belt could cause false activation times to be detected leading to an inaccurate SDAT. Detecting and/or removing the disturbance could reduce the risk of an inaccurate SDAT.

[0059] An exemplary method 400 for detecting disturbances in electrical signals is depicted in FIG. 4. As shown, the method 400 includes monitoring 410 electrical activity to generate a plurality of electrical signals. According to various embodiments, the electrical activity is monitored using a plurality of electrodes. The plurality of electrodes may be external surface electrodes configured in a band or a vest similar to as described herein with respect to FIGS. 1-3. Each of the electrodes may be positioned or located about the torso of the patient so as to monitor electrical activity (e.g., acquire torso-potentials) from a plurality of different locations about the torso of the patient. Each of the different locations where the electrodes are located may correspond to the electrical activation of different portions or regions of cardiac tissue of the patient's heart.

[0060] The plurality of electrical signals are filtered 420. According to embodiments described herein, the electrical signals are filtered using a higher order filter such as a second order filter, for example. In some embodiments, the filter may be a second order difference filter. According to various implementations, the filter may be a second order derivative filter. More specifically, each of the plurality of electrical signals may be filtered individually resulting in a plurality of filtered signals. Further, in some embodiments, each of the plurality of electrical signals may be filtered by the same filter.

Therefore, the plurality of electrical signals may be processed to put them in a form so as to be able to detect disturbances.

[0061] At least one disturbance is detected 430 in the filtered electrical signals. The disturbance may be detected by determining that the filtered signal crosses a predetermined threshold, for example. The disturbance may include one or more of pacing spikes and/ muscle generated noise. Other types of disturbance may include artifacts due to movement, breathing, etc. The detection methods described herein may be used to detect a His potential for use in His bundle pacing or left bundle potential for targeted lead placement aiming to capture the left bundle in a patient with conduction system disease like left bundle branch block.

[0062] In one or more embodiments, a temporal location of the at least one disturbance in the at least one electrical signal is determined 440 based on a time that an absolute value the amplitude of the at least one filtered signal crosses a predetermined amplitude threshold. The predetermined threshold may be based on a sampling rate of the at least one electrical signal. In some cases, the threshold may be determined based on a predetermined number of samples of the electrical signals. According to various embodiments, the temporal location of the disturbance is determined by a predetermined threshold. The predetermined threshold may be based on amplitude measurements of the electrical signals. More specifically, the predetermined threshold may be determined by determining a time when the filtered signal reaches a predetermined amplitude.

[0063] According to one or more embodiments, the detected disturbance may be removed 450 from at least one of the plurality of electrical signals. The disturbance may be removed 450 using various methods. For example, the disturbance may be removed 450 by smoothing the electrical signals within a window using the determined temporal location of the disturbance. Smoothing the electrical signals within a window may be performed, or executed, using any known smoothing algorithm or technique. For instance, the electrical signals may be smoothed within a window by replacing one or more signals within the window with a line to connect the signals at their start and end points within the window. In some cases, a best fit line may replace the electrical signal in the window

and/or the window during the disturbance is blanked such that it is not used for activation time determinations.

[0064] The window, within which the disturbance may be removed, may begin, or have a start time, a predetermined period of time prior to the temporal location of the disturbance. Likewise, the window may end, or have an end time, a predetermined period of time following the temporal location of the disturbance. In other words, the window may start a predetermined period of time before the temporal location of the at least one disturbance and extend a predetermined amount of time after the temporal location. For example, a predetermined period of time prior to the temporal location of the disturbance (for determination of the window) may be between about 0.5 ms milliseconds (ms) to about 2 ms. In at least one embodiment, the predetermined period of time prior to the temporal location of the disturbance is about 1 ms. Further, for example, a predetermined period of time following the temporal location of the disturbance (for determination of the window) may be between about 5 ms to about 15 ms. In at least one embodiment, the predetermined period of time following the temporal location of the disturbance is about 10 ms.

[0065] Further, in at least one embodiment, the window may be a fixed length from a predetermined start point. For example, the window length may be in a range of about 5 ms to about 15 ms. In some cases, the window length is about 10 ms. The window start time and end time may be determined based on a baseline departure from the threshold amplitude and a return to the threshold amplitude. In other words, the window start time may be based on a first threshold crossing and the end time may be based on a second threshold crossing occurring after the first threshold crossing.

[0066] After the at least one disturbance has been removed, the electrical signals may be used to determine a plurality of activation times. Further, electrical heterogeneity information may be determined based on the plurality of cardiac activation times.

[0067] In some embodiments, more than one disturbance is detected and/or removed. For example, a first disturbance may be detected and a second disturbance occurring after the first disturbance may also be detected. The first disturbance and/or the second disturbance may be removed by smoothing the electrical signal within a window starting a predetermined amount of time before the temporal location of the first disturbance and

extending a predetermined amount of time after the second disturbance. While two disturbances are described here, it is to be understood that more disturbances may be detected and/or removed from the electrical signals. Additionally, in some embodiments, each of the first and second disturbances and any other additional disturbance may be removed individually, each within its own window.

[0068] According to one or more embodiments, the disturbances are detected in at least one of the electrical signals. In some cases, a detected disturbance is only removed if it is sensed in a predetermined number of electrical signals of the plurality of electrical signals. FIG. 5 shows a process 500 for removing disturbances in electrical signals based on a disturbance detected in a predetermined number of electrical signals in accordance with embodiments described herein. A plurality of electrical signals are sensed using a plurality of electrodes. At least one disturbance is detected 510. It is determined whether there is a disturbance in at least a predetermined number of the sensed electrical signals. The predetermined number of signals within which the disturbance needs to be detected may be in a range of about three to about ten. In some cases, the predetermined number of signals within which the disturbance needs to be detected is four. If it is determined 510 that a disturbance is not detected in at least the predetermined number of electrical signals, then the disturbance is not removed 520. If it is determined 510 that a disturbance is detected in at least the predetermined number of electrical signals, the disturbance is removed 530 from at least the predetermined number of electrical signals. In some cases, if it is determined 510 that a disturbance is detected in at least the predetermined number of electrical signals, the disturbance is removed 530 from all of the plurality of electrical signals. In some implementations, if a disturbance is detected in the predetermined number of electrical signals, the disturbance is removed from more than the predetermined number of signals, but less than all of the electrical signals.

[0069] According to various implementations, the disturbance may only be removed if it is sensed in predetermined number of electrical signals that are derived from a group predetermined electrodes. For example, the disturbance may only be removed if it is sensed in at least four electrical signals that are derived from four electrodes in a subset of the electrodes. For example, the subset of electrodes may be about 12 electrodes located in a top row and left of the sternum on the anterior and left of the spine on the posterior.

[0070] FIGS. 6A and 6B show examples of a plurality of sampled electrical signals in accordance with embodiments described herein. As shown, a portion of an electrical signal, or electrical activity, is plotted on along a time axis 605. As described herein, the sampled electrical signals may be filtered and activation times may be determined based on the filtered signals. According to various implementations, the activation times may be determined based on a slope of the filtered signal. FIG. 6B illustrates a close-up view in the vertical direction of the signals shown in FIG. 6A.

[0071] In this example, the sensed signals include cardiac activity 610 in response to a pace. A first disturbance 612 and smaller second disturbance 620 appear before the sensed cardiac response activity 610. The first disturbance 612 and/or the second disturbance 620 have a slope that may be indicative of an activation time of the signal. This can lead to a false detections of activation times which may result in inaccurate data. More specifically, the fiducial point used to determine the activation time for each signal may be the temporal location of the greatest slope within each signal, and the disturbances may cause, or create, the greatest slope within each signal resulting in inaccurate activation time data.

[0072] To detect the disturbances, a sampling frequency is used to determine a threshold for a second (or higher order) difference of the disturbance for a known pulse width or range of pulse widths. The signals are run through the second order filter and the resulting filtered signal is examined for threshold crossings. FIG. 7 illustrates an example of sampled signals after being filtered using a second order filter. Signals 710 whose amplitude exceed the threshold 720 are detected as disturbances. Once the disturbances 710 are identified, the temporal locations of the disturbances are determined. This may be done by determining a time that the disturbances cross the threshold 720, for example.

[0073] As described herein, the disturbances are removed from at least one signal within a window. FIG. 8A illustrates example signals after removal of the disturbances in some of the signals within window 825. Here it can be observed that the disturbances have been removed on the signals having straight sections within the window 825. FIG. 8B shows the signals of FIG. 8A with additional filtering as described herein. Here, it can be observed that the disturbances have been removed. The activation times can now be determined based on these filtered signals without interference from the disturbances.



[0074] As described herein, without removing the disturbances from the electrical signals, inaccurate activation times may be detected. FIG. 9A illustrates an example in which false activation times 930 are detected based on a location of the disturbance 925. Detection and/or removal of the one or more disturbances may be used to reduce the occurrence of false activation time detection. Detection of the disturbances may be accomplished using a controller, for example. In some cases, detection of the disturbances is carried out using a commercial chip. FIG. 9B shows the same signals shown in FIG. 9A, but with the disturbance 925 removed. As can be observed, the false activation time 930 is no longer detected. The SDAT generated based on the electrical activation times of the electrical signals of the FIG. 9A is 46.0 ms, and the SDAT generated based on the electrical activation times of the electrical signals of the FIG. 9B is 28.5 ms. Thus, disturbance removal according to the present disclosure may result in a measurable improvement in the accuracy of a measurement of electrical cardiac heterogeneity such as, e.g., SDAT.

[0075] Illustrative cardiac therapy systems and devices may be further described herein with reference to FIGS. 10-12 that may utilize the illustrative systems, interfaces, methods, and processes described herein with respect to FIGS. 1-9.

[0076] FIG. 10 is a conceptual diagram illustrating an illustrative therapy system 10 that may be used to deliver pacing therapy to a patient 14. Patient 14 may, but not necessarily, be a human. The therapy system 10 may include an implantable medical device 16 (IMD), which may be coupled to leads 18, 20, 22. The IMD 16 may be, e.g., an implantable pacemaker, cardioverter, and/or defibrillator, that delivers, or provides, electrical signals (e.g., paces, etc.) to and/or senses electrical signals from the heart 12 of the patient 14 via electrodes coupled to one or more of the leads 18, 20, 22.

[0077] The leads 18, 20, 22 extend into the heart 12 of the patient 14 to sense electrical activity of the heart 12 and/or to deliver electrical stimulation to the heart 12. In the example shown in FIG. 10, the right ventricular (RV) lead 18 extends through one or more veins (not shown), the superior vena cava (not shown), and the right atrium 26, and into the right ventricle 28. The left ventricular (LV) coronary sinus lead 20 extends through one or more veins, the vena cava, the right atrium 26, and into the coronary sinus 30 to a region adjacent to the free wall of the left ventricle 32 of the heart 12. The right atrial (RA)

lead 22 extends through one or more veins and the vena cava, and into the right atrium 26 of the heart 12.

[0078] The IMD 16 may sense, among other things, electrical signals attendant to the depolarization and repolarization of the heart 12 via electrodes coupled to at least one of the leads 18, 20, 22. In some examples, the IMD 16 provides pacing therapy (e.g., pacing pulses) to the heart 12 based on the electrical signals sensed within the heart 12. The IMD 16 may be operable to adjust one or more parameters associated with the pacing therapy such as, e.g., A-V delay and other various timings, pulse wide, amplitude, voltage, burst length, etc. Further, the IMD 16 may be operable to use various electrode configurations to deliver pacing therapy, which may be unipolar, bipolar, quadripolar, or further multipolar. For example, a multipolar lead may include several electrodes that can be used for delivering pacing therapy. Hence, a multipolar lead system may provide, or offer, multiple electrical vectors to pace from. A pacing vector may include at least one cathode, which may be at least one electrode located on at least one lead, and at least one anode, which may be at least one electrode located on at least one lead (e.g., the same lead, or a different lead) and/or on the casing, or can, of the IMD. While improvement in cardiac function as a result of the pacing therapy may primarily depend on the cathode, the electrical parameters like impedance, pacing threshold voltage, current drain, longevity, etc. may be more dependent on the pacing vector, which includes both the cathode and the anode. The IMD 16 may also provide defibrillation therapy and/or cardioversion therapy via electrodes located on at least one of the leads 18, 20, 22. Further, the IMD 16 may detect arrhythmia of the heart 12, such as fibrillation of the ventricles 28, 32, and deliver defibrillation therapy to the heart 12 in the form of electrical pulses. In some examples, IMD 16 may be programmed to deliver a progression of therapies, e.g., pulses with increasing energy levels, until a fibrillation of heart 12 is stopped.

[0079] FIGS. 11A-11B are conceptual diagrams illustrating the IMD 16 and the leads 18, 20, 22 of therapy system 10 of FIG. 13 in more detail. The leads 18, 20, 22 may be electrically coupled to a therapy delivery module (e.g., for delivery of pacing therapy), a sensing module (e.g., for sensing one or more signals from one or more electrodes), and/or any other modules of the IMD 16 via a connector block 34. In some examples, the proximal ends of the leads 18, 20, 22 may include electrical contacts that electrically

couple to respective electrical contacts within the connector block 34 of the IMD 16. In addition, in some examples, the leads 18, 20, 22 may be mechanically coupled to the connector block 34 with the aid of set screws, connection pins, or another suitable mechanical coupling mechanism.

[0080] Each of the leads 18, 20, 22 includes an elongated insulative lead body, which may carry a number of conductors (e.g., concentric coiled conductors, straight conductors, etc.) separated from one another by insulation (e.g., tubular insulative sheaths). In the illustrated example, bipolar electrodes 40, 42 are located proximate to a distal end of the lead 18. In addition, bipolar electrodes 44, 45, 46, 47 are located proximate to a distal end of the lead 20 and bipolar electrodes 48, 50 are located proximate to a distal end of the lead 22.

[0081] The electrodes 40, 44, 45, 46, 47, 48 may take the form of ring electrodes, and the electrodes 42, 50 may take the form of extendable helix tip electrodes mounted retractably within the insulative electrode heads 52, 54, 56, respectively. Each of the electrodes 40, 42, 44, 45, 46, 47, 48, 50 may be electrically coupled to a respective one of the conductors (e.g., coiled and/or straight) within the lead body of its associated lead 18, 20, 22, and thereby coupled to a respective one of the electrical contacts on the proximal end of the leads 18, 20, 22.

[0082] Additionally, electrodes 44, 45, 46 and 47 may have an electrode surface area of about 5.3 mm<sup>2</sup> to about 5.8 mm<sup>2</sup>. Electrodes 44, 45, 46, and 47 may also be referred to as LV1, LV2, LV3, and LV4, respectively. The LV electrodes (i.e., left ventricle electrode 1 (LV1) 44, left ventricle electrode 2 (LV2) 45, left ventricle electrode 3 (LV3) 46, and left ventricle 4 (LV4) 47 etc.) on the lead 20 can be spaced apart at variable distances. For example, electrode 44 may be a distance of, e.g., about 21 millimeters (mm), away from electrode 45, electrodes 45 and 46 may be spaced a distance of, e.g. about 1.3 mm to about 1.5 mm, away from each other, and electrodes 46 and 47 may be spaced a distance of, e.g. 20 mm to about 21 mm, away from each other.

[0083] The electrodes 40, 42, 44, 45, 46, 47, 48, 50 may further be used to sense electrical signals (e.g., morphological waveforms within electrograms (EGM)) attendant to the depolarization and repolarization of the heart 12. The electrical signals are conducted to the IMD 16 via the respective leads 18, 20, 22. In some examples, the IMD 16 may also

deliver pacing pulses via the electrodes 40, 42, 44, 45, 46, 47, 48, 50 to cause depolarization of cardiac tissue of the patient's heart 12. In some examples, as illustrated in FIG. 11A, the IMD 16 includes one or more housing electrodes, such as housing electrode 58, which may be formed integrally with an outer surface of a housing 60 (e.g., hermetically-sealed housing) of the IMD 16 or otherwise coupled to the housing 60. Any of the electrodes 40, 42, 44, 45, 46, 47, 48, 50 may be used for unipolar sensing or pacing in combination with the housing electrode 58. It is generally understood by those skilled in the art that other electrodes can also be selected to define, or be used for, pacing and sensing vectors. Further, any of electrodes 40, 42, 44, 45, 46, 47, 48, 50, 58, when not being used to deliver pacing therapy, may be used to sense electrical activity during pacing therapy.

[0084] As described in further detail with reference to FIG. 11A, the housing 60 may enclose a therapy delivery module that may include a stimulation generator for generating cardiac pacing pulses and defibrillation or cardioversion shocks, as well as a sensing module for monitoring the electrical signals of the patient's heart (e.g., the patient's heart rhythm). The leads 18, 20, 22 may also include elongated electrodes 62, 64, 66, respectively, which may take the form of a coil. The IMD 16 may deliver defibrillation shocks to the heart 12 via any combination of the elongated electrodes 62, 64, 66 and the housing electrode 58. The electrodes 58, 62, 64, 66 may also be used to deliver cardioversion pulses to the heart 12. Further, the electrodes 62, 64, 66 may be fabricated from any suitable electrically conductive material, such as, but not limited to, platinum, platinum alloy, and/or other materials known to be usable in implantable defibrillation electrodes. Since electrodes 62, 64, 66 are not generally configured to deliver pacing therapy, any of electrodes 62, 64, 66 may be used to sense electrical activity and may be used in combination with any of electrodes 40, 42, 44, 45, 46, 47, 48, 50, 58. In at least one embodiment, the RV elongated electrode 62 may be used to sense electrical activity of a patient's heart during the delivery of pacing therapy (e.g., in combination with the housing electrode 58, or defibrillation electrode-to-housing electrode vector).

[0085] The configuration of the illustrative therapy system 10 illustrated in FIGS. 10-12 is merely one example. In other examples, the therapy system may include epicardial leads and/or patch electrodes instead of or in addition to the transvenous leads 18, 20, 22

illustrated in FIG. 10. Additionally, in other examples, the therapy system 10 may be implanted in/around the cardiac space without transvenous leads (e.g., leadless/wireless pacing systems) or with leads implanted (e.g., implanted transvenously or using approaches) into the left chambers of the heart (in addition to or replacing the transvenous leads placed into the right chambers of the heart as illustrated in FIG. 10). Further, in one or more embodiments, the IMD 16 need not be implanted within the patient 14. For example, the IMD 16 may deliver various cardiac therapies to the heart 12 via percutaneous leads that extend through the skin of the patient 14 to a variety of positions within or outside of the heart 12. In one or more embodiments, the system 10 may utilize wireless pacing (e.g., using energy transmission to the intracardiac pacing component(s) via ultrasound, inductive coupling, RF, etc.) and sensing cardiac activation using electrodes on the can/housing and/or on subcutaneous leads.

[0086] In other examples of therapy systems that provide electrical stimulation therapy to the heart 12, such therapy systems may include any suitable number of leads coupled to the IMD 16, and each of the leads may extend to any location within or proximate to the heart 12. For example, other examples of therapy systems may include three transvenous leads located as illustrated in FIGS. 10-12. Still further, other therapy systems may include a single lead that extends from the IMD 16 into the right atrium 26 or the right ventricle 28, or two leads that extend into a respective one of the right atrium 26 and the right ventricle 28.

[0087] FIG. 12A is a functional block diagram of one illustrative configuration of the IMD 16. As shown, the IMD 16 may include a control module 81, a therapy delivery module 84 (e.g., which may include a stimulation generator), a sensing module 86, and a power source 90.

[0088] The control module, or apparatus, 81 may include a processor 80, memory 82, and a telemetry module, or apparatus, 88. The memory 82 may include computer-readable instructions that, when executed, e.g., by the processor 80, cause the IMD 16 and/or the control module 81 to perform various functions attributed to the IMD 16 and/or the control module 81 described herein. Further, the memory 82 may include any volatile, non-volatile, magnetic, optical, and/or electrical media, such as a random-access memory

(RAM), read-only memory (ROM), non-volatile RAM (NVRAM), electrically-erasable programmable ROM (EEPROM), flash memory, and/or any other digital media. An illustrative capture management module may be the left ventricular capture management (LVCM) module described in U.S. Pat. No. 7,684,863 entitled "LV THRESHOLD MEASUREMENT AND CAPTURE MANAGEMENT" and issued March 23, 2010.

[0089] The processor 80 of the control module 81 may include any one or more of a microprocessor, a controller, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field-programmable gate array (FPGA), and/or equivalent discrete or integrated logic circuitry. In some examples, the processor 80 may include multiple components, such as any combination of one or more microprocessors, one or more controllers, one or more DSPs, one or more ASICs, and/or one or more FPGAs, as well as other discrete or integrated logic circuitry. The functions attributed to the processor 80 herein may be embodied as software, firmware, hardware, or any combination thereof.

[0090] The control module 81 may control the therapy delivery module 84 to deliver therapy (e.g., electrical stimulation therapy such as pacing) to the heart 12 according to a selected one or more therapy programs, which may be stored in the memory 82. More, specifically, the control module 81 (e.g., the processor 80) may control various parameters of the electrical stimulus delivered by the therapy delivery module 84 such as, e.g., A-V delays, V-V delays, pacing pulses with the amplitudes, pulse widths, frequency, or electrode polarities, etc., which may be specified by one or more selected therapy programs (e.g., A-V and/or V-V delay adjustment programs, pacing therapy programs, pacing recovery programs, capture management programs, etc.). As shown, the therapy delivery module 84 is electrically coupled to electrodes 40, 42, 44, 45, 46, 47, 48, 50, 58, 62, 64, 66, e.g., via conductors of the respective lead 18, 20, 22, or, in the case of housing electrode 58, via an electrical conductor disposed within housing 60 of IMD 16. Therapy delivery module 84 may be configured to generate and deliver electrical stimulation therapy such as pacing therapy to the heart 12 using one or more of the electrodes 40, 42, 44, 45, 46, 47, 48, 50, 58, 62, 64, 66.

[0091] For example, therapy delivery module 84 may deliver pacing stimulus (e.g., pacing pulses) via ring electrodes 40, 44, 45, 46, 47, 48 coupled to leads 18, 20, 22 and/or helical

tip electrodes 42, 50 of leads 18, 22. Further, for example, therapy delivery module 84 may deliver defibrillation shocks to heart 12 via at least two of electrodes 58, 62, 64, 66. In some examples, therapy delivery module 84 may be configured to deliver pacing, cardioversion, or defibrillation stimulation in the form of electrical pulses. In other examples, therapy delivery module 84 may be configured deliver one or more of these types of stimulation in the form of other signals, such as sine waves, square waves, and/or other substantially continuous time signals.

[0092] The IMD 16 may further include a switch module 85 and the control module 81 (e.g., the processor 80) may use the switch module 85 to select, e.g., via a data/address bus, which of the available electrodes are used to deliver therapy such as pacing pulses for pacing therapy, or which of the available electrodes are used for sensing. The switch module 85 may include a switch array, switch matrix, multiplexer, or any other type of switching device suitable to selectively couple the sensing module 86 and/or the therapy delivery module 84 to one or more selected electrodes. More specifically, the therapy delivery module 84 may include a plurality of pacing output circuits. Each pacing output circuit of the plurality of pacing output circuits may be selectively coupled, e.g., using the switch module 85, to one or more of the electrodes 40, 42, 44, 45, 46, 47, 48, 50, 58, 62, 64, 66 (e.g., a pair of electrodes for delivery of therapy to a bipolar or multipolar pacing vector). In other words, each electrode can be selectively coupled to one of the pacing output circuits of the therapy delivery module using the switching module 85.

[0093] The sensing module 86 is coupled (e.g., electrically coupled) to sensing apparatus, which may include, among additional sensing apparatus, the electrodes 40, 42, 44, 45, 46, 47, 48, 50, 58, 62, 64, 66 to monitor electrical activity of the heart 12, e.g., electrocardiogram (ECG)/electrogram (EGM) signals, etc. The ECG/EGM signals may be used to measure or monitor activation times (e.g., ventricular activations times, etc.), heart rate (HR), heart rate variability (HRV), heart rate turbulence (HRT), deceleration/acceleration capacity, deceleration sequence incidence, T-wave alternans (TWA), P-wave to P-wave intervals (also referred to as the P-P intervals or A-A intervals), R-wave to R-wave intervals (also referred to as the R-R intervals or V-V intervals), P-wave to QRS complex intervals (also referred to as the P-R intervals, A-V intervals, or P-

Q intervals), QRS-complex morphology, ST segment (i.e., the segment that connects the QRS complex and the T-wave), T-wave changes, QT intervals, electrical vectors, etc.

[0094] The switch module 85 may also be used with the sensing module 86 to select which of the available electrodes are used, or enabled, to, e.g., sense electrical activity of the patient's heart (e.g., one or more electrical vectors of the patient's heart using any combination of the electrodes 40, 42, 44, 45, 46, 47, 48, 50, 58, 62, 64, 66). Likewise, the switch module 85 may also be used with the sensing module 86 to select which of the available electrodes are not to be used (e.g., disabled) to, e.g., sense electrical activity of the patient's heart (e.g., one or more electrical vectors of the patient's heart using any combination of the electrodes 40, 42, 44, 45, 46, 47, 48, 50, 58, 62, 64, 66), etc. In some examples, the control module 81 may select the electrodes that function as sensing electrodes via the switch module within the sensing module 86, e.g., by providing signals via a data/address bus.

[0095] In some examples, sensing module 86 includes a channel that includes an amplifier with a relatively wider pass band than the R-wave or P-wave amplifiers. Signals from the selected sensing electrodes may be provided to a multiplexer, and thereafter converted to multi-bit digital signals by an analog-to-digital converter for storage in memory 82, e.g., as an electrogram (EGM). In some examples, the storage of such EGMs in memory 82 may be under the control of a direct memory access circuit.

[0096] In some examples, the control module 81 may operate as an interrupt-driven device and may be responsive to interrupts from pacer timing and control module, where the interrupts may correspond to the occurrences of sensed P-waves and R-waves and the generation of cardiac pacing pulses. Any necessary mathematical calculations may be performed by the processor 80 and any updating of the values or intervals controlled by the pacer timing and control module may take place following such interrupts. A portion of memory 82 may be configured as a plurality of recirculating buffers, capable of holding one or more series of measured intervals, which may be analyzed by, e.g., the processor 80 in response to the occurrence of a pace or sense interrupt to determine whether the patient's heart 12 is presently exhibiting atrial or ventricular tachyarrhythmia.



[0097] The telemetry module 88 of the control module 81 may include any suitable hardware, firmware, software, or any combination thereof for communicating with another device, such as a programmer. For example, under the control of the processor 80, the telemetry module 88 may receive downlink telemetry from and send uplink telemetry to a programmer with the aid of an antenna, which may be internal and/or external. The processor 80 may provide the data to be uplinked to a programmer and the control signals for the telemetry circuit within the telemetry module 88, e.g., via an address/data bus. In some examples, the telemetry module 88 may provide received data to the processor 80 via a multiplexer.

[0098] The various components of the IMD 16 are further coupled to a power source 90, which may include a rechargeable or non-rechargeable battery. A non-rechargeable battery may be selected to last for several years, while a rechargeable battery may be inductively charged from an external device, e.g., on a daily or weekly basis.

[0099] FIG. 15B is another embodiment of a functional block diagram for IMD 16 that depicts bipolar RA lead 22, bipolar RV lead 18, and bipolar LV CS lead 20 without the LA CS pace/sense electrodes and coupled with an implantable pulse generator (IPG) circuit 31 having programmable modes and parameters of a bi-ventricular DDD/R type known in the pacing art. In turn, the sensor signal processing circuit 91 indirectly couples to the timing circuit 43 and via data and control bus to microcomputer circuitry 33. The IPG circuit 31 is illustrated in a functional block diagram divided generally into a microcomputer circuit 33 and a pacing circuit 21. The pacing circuit 21 includes the digital controller/timer circuit 43, the output amplifiers circuit 51, the sense amplifiers circuit 55, the RF telemetry transceiver 41, the activity sensor circuit 35 as well as a number of other circuits and components described below.

[0100] Crystal oscillator circuit 89 provides the basic timing clock for the pacing circuit 21 while battery 29 provides power. Power-on-reset circuit 87 responds to initial connection of the circuit to the battery for defining an initial operating condition and similarly, resets the operative state of the device in response to detection of a low battery condition. Reference mode circuit 37 generates stable voltage reference and currents for the analog circuits within the pacing circuit 21. Analog-to-digital converter (ADC) and

multiplexer circuit 39 digitize analog signals and voltage to provide, e.g., real time telemetry of cardiac signals from sense amplifiers 55 for uplink transmission via RF transmitter and receiver circuit 41. Voltage reference and bias circuit 37, ADC and multiplexer 39, power-on-reset circuit 87, and crystal oscillator circuit 89 may correspond to any of those used in illustrative implantable cardiac pacemakers.

[0101] If the IPG is programmed to a rate responsive mode, the signals output by one or more physiologic sensors are employed as a rate control parameter (RCP) to derive a physiologic escape interval. For example, the escape interval is adjusted proportionally to the patient's activity level developed in the patient activity sensor (PAS) circuit 35 in the depicted, illustrative IPG circuit 31. The patient activity sensor 27 is coupled to the IPG housing and may take the form of a piezoelectric crystal transducer. The output signal of the patient activity sensor 27 may be processed and used as an RCP. Sensor 27 generates electrical signals in response to sensed physical activity that are processed by activity circuit 35 and provided to digital controller/timer circuit 43. Activity circuit 35 and associated sensor 27 may correspond to the circuitry disclosed in U.S. Pat. No. 5,052,388 entitled "METHOD AND APPARATUS FOR IMPLEMENTING ACTIVITY SENSING IN A PULSE GENERATOR" and issued on October 1, 1991 and U.S. Pat. No. 4,428,378 entitled "RATE ADAPTIVE PACER" and issued on January 31, 1984. Similarly, the illustrative systems, apparatus, and methods described herein may be practiced in conjunction with alternate types of sensors such as oxygenation sensors, pressure sensors, pH sensors, and respiration sensors, for use in providing rate responsive pacing capabilities. Alternately, QT time may be used as a rate indicating parameter, in which case no extra sensor is required. Similarly, the illustrative embodiments described herein may also be practiced in non-rate responsive pacemakers.

[0102] Data transmission to and from the external programmer is accomplished by way of the telemetry antenna 57 and an associated RF transceiver 41, which serves both to demodulate received downlink telemetry and to transmit uplink telemetry. Uplink telemetry capabilities may include the ability to transmit stored digital information, e.g., operating modes and parameters, EGM histograms, and other events, as well as real time EGMs of atrial and/or ventricular electrical activity and marker channel pulses indicating the occurrence of sensed and paced depolarizations in the atrium and ventricle.

[0103] Microcomputer 33 contains a microprocessor 80 and associated system clock and on-processor RAM and ROM chips 82A and 82B, respectively. In addition, microcomputer circuit 33 includes a separate RAM/ROM chip 82C to provide additional memory capacity. Microprocessor 80 normally operates in a reduced power consumption mode and is interrupt driven. Microprocessor 80 is awakened in response to defined interrupt events, which may include A-TRIG, RV-TRIG, LV-TRIG signals generated by timers in digital timer/controller circuit 43 and A-EVENT, RV-EVENT, and LV-EVENT signals generated by sense amplifiers circuit 55, among others. The specific values of the intervals and delays timed out by digital controller/timer circuit 43 are controlled by the microcomputer circuit 33 by way of data and control bus from programmed-in parameter values and operating modes. In addition, if programmed to operate as a rate responsive pacemaker, a timed interrupt, e.g., every cycle or every two seconds, may be provided in order to allow the microprocessor to analyze the activity sensor data and update the basic A-A, V-A, or V-V escape interval, as applicable. In addition, the microprocessor 80 may also serve to define variable, operative A-V delay intervals, V-V delay intervals, and the energy delivered to each ventricle and/or atrium.

[0104] In one embodiment, microprocessor 80 is a custom microprocessor adapted to fetch and execute instructions stored in RAM/ROM unit 82 in a conventional manner. It is contemplated, however, that other implementations may be suitable to practice the present disclosure. For example, an off-the-shelf, commercially available microprocessor or microcontroller, or custom application-specific, hardwired logic, or state-machine type circuit may perform the functions of microprocessor 80.

[0105] Digital controller/timer circuit 43 operates under the general control of the microcomputer 33 to control timing and other functions within the pacing circuit 21 and includes a set of timing and associated logic circuits of which certain ones pertinent to the present disclosure are depicted. The depicted timing circuits include URI/LRI timers 83A, V-V delay timer 83B, intrinsic interval timers 83C for timing elapsed V-EVENT to V-EVENT intervals or V-EVENT to A-EVENT intervals or the V-V conduction interval, escape interval timers 83D for timing A-A, V-A, and/or V-V pacing escape intervals, an A-V delay interval timer 83E for timing the A-LVp delay (or A-RVp delay) from a

preceding A-EVENT or A-TRIG, a post-ventricular timer 83F for timing post-ventricular time periods, and a date/time clock 83G.

[0106] The A-V delay interval timer 83E is loaded with an appropriate delay interval for one ventricular chamber (e.g., either an A-RVp delay or an A-LVp) to time-out starting from a preceding A-PACE or A-EVENT. The interval timer 83E triggers pacing stimulus delivery and can be based on one or more prior cardiac cycles (or from a data set empirically derived for a given patient).

[0107] The post-event timer 83F times out the post-ventricular time period following an RV-EVENT or LV-EVENT or a RV-TRIG or LV-TRIG and post-atrial time periods following an A-EVENT or A-TRIG. The durations of the post-event time periods may also be selected as programmable parameters stored in the microcomputer 33. The post-ventricular time periods include the PVARP, a post-atrial ventricular blanking period (PAVBP), a ventricular blanking period (VBP), a post-ventricular atrial blanking period (PVARP) and a ventricular refractory period (VRP) although other periods can be suitably defined depending, at least in part, on the operative circuitry employed in the pacing engine. The post-atrial time periods include an atrial refractory period (ARP) during which an A-EVENT is ignored for the purpose of resetting any A-V delay, and an atrial blanking period (ABP) during which atrial sensing is disabled. It should be noted that the starting of the post-atrial time periods and the A-V delays can be commenced substantially simultaneously with the start or end of each A-EVENT or A-TRIG or, in the latter case, upon the end of the A-PACE which may follow the A-TRIG. Similarly, the starting of the post-ventricular time periods and the V-A escape interval can be commenced substantially simultaneously with the start or end of the V-EVENT or V-TRIG or, in the latter case, upon the end of the V-PACE which may follow the V-TRIG. The microprocessor 80 also optionally calculates A-V delays, V-V delays, post-ventricular time periods, and post-atrial time periods that vary with the sensor-based escape interval established in response to the RCP(s) and/or with the intrinsic atrial and/or ventricular rate.

[0108] The output amplifiers circuit 51 contains a RA pace pulse generator (and a LA pace pulse generator if LA pacing is provided), a RV pace pulse generator, a LV pace pulse generator, and/or any other pulse generator configured to provide atrial and ventricular

pacing. In order to trigger generation of an RV-PACE or LV-PACE pulse, digital controller/timer circuit 43 generates the RV-TRIG signal at the time-out of the A-RVp delay (in the case of RV pre-excitation) or the LV-TRIG at the time-out of the A-LVp delay (in the case of LV pre-excitation) provided by A-V delay interval timer 83E (or the V-V delay timer 83B). Similarly, digital controller/timer circuit 43 generates an RA-TRIG signal that triggers output of an RA-PACE pulse (or an LA-TRIG signal that triggers output of an LA-PACE pulse, if provided) at the end of the V-A escape interval timed by escape interval timers 83D.

[0109] The output amplifiers circuit 51 includes switching circuits for coupling selected pace electrode pairs from among the lead conductors and the IND-CAN electrode 20 to the RA pace pulse generator (and LA pace pulse generator if provided), RV pace pulse generator and LV pace pulse generator. Pace/sense electrode pair selection and control circuit 53 selects lead conductors and associated pace electrode pairs to be coupled with the atrial and ventricular output amplifiers within output amplifiers circuit 51 for accomplishing RA, LA, RV and LV pacing.

[0110] The sense amplifiers circuit 55 contains sense amplifiers for atrial and ventricular pacing and sensing. High impedance P-wave and R-wave sense amplifiers may be used to amplify a voltage difference signal that is generated across the sense electrode pairs by the passage of cardiac depolarization wavefronts. The high impedance sense amplifiers use high gain to amplify the low amplitude signals and rely on pass band filters, time domain filtering and amplitude threshold comparison to discriminate a P-wave or R-wave from background electrical noise. Digital controller/timer circuit 43 controls sensitivity settings of the atrial and ventricular sense amplifiers 55.

[0111] The sense amplifiers may be uncoupled from the sense electrodes during the blanking periods before, during, and after delivery of a pace pulse to any of the pace electrodes of the pacing system to avoid saturation of the sense amplifiers. The sense amplifiers circuit 55 includes blanking circuits for uncoupling the selected pairs of the lead conductors and the IND-CAN electrode 20 from the inputs of the RA sense amplifier (and LA sense amplifier if provided), RV sense amplifier and LV sense amplifier during the ABP, PVABP and VBP. The sense amplifiers circuit 55 also includes switching circuits

for coupling selected sense electrode lead conductors and the IND-CAN electrode 20 to the RA sense amplifier (and LA sense amplifier if provided), RV sense amplifier and LV sense amplifier. Again, sense electrode selection and control circuit 53 selects conductors and associated sense electrode pairs to be coupled with the atrial and ventricular sense amplifiers within the output amplifiers circuit 51 and sense amplifiers circuit 55 for accomplishing RA, LA, RV, and LV sensing along desired unipolar and bipolar sensing vectors.

[0112] Right atrial depolarizations or P-waves in the RA-SENSE signal that are sensed by the RA sense amplifier result in a RA-EVENT signal that is communicated to the digital controller/timer circuit 43. Similarly, left atrial depolarizations or P-waves in the LA-SENSE signal that are sensed by the LA sense amplifier, if provided, result in a LA-EVENT signal that is communicated to the digital controller/timer circuit 43. Ventricular depolarizations or R-waves in the RV-SENSE signal are sensed by a ventricular sense amplifier result in an RV-EVENT signal that is communicated to the digital controller/timer circuit 43. Similarly, ventricular depolarizations or R-waves in the LV-SENSE signal are sensed by a ventricular sense amplifier result in an LV-EVENT signal that is communicated to the digital controller/timer circuit 43. The RV-EVENT, LV-EVENT, and RA-EVENT, LA-SENSE signals may be refractory or non-refractory and can inadvertently be triggered by electrical noise signals or aberrantly conducted depolarization waves rather than true R-waves or P-waves.

[0113] The techniques described in this disclosure, including those attributed to the IMD 16, the computing apparatus 140, and/or various constituent components, may be implemented, at least in part, in hardware, software, firmware, or any combination thereof. For example, various aspects of the techniques may be implemented within one or more processors, including one or more microprocessors, DSPs, ASICs, FPGAs, or any other equivalent integrated or discrete logic circuitry, as well as any combinations of such components, embodied in programmers, such as physician or patient programmers, stimulators, image processing devices, or other devices. The term "module," "processor," or "processing circuitry" may generally refer to any of the foregoing logic circuitry, alone or in combination with other logic circuitry, or any other equivalent circuitry.

[0114] Such hardware, software, and/or firmware may be implemented within the same device or within separate devices to support the various operations and functions described in this disclosure. In addition, any of the described units, modules, or components may be implemented together or separately as discrete but interoperable logic devices. Depiction of different features as modules or units is intended to highlight different functional aspects and does not necessarily imply that such modules or units must be realized by separate hardware or software components. Rather, functionality associated with one or more modules or units may be performed by separate hardware or software components or integrated within common or separate hardware or software components.

[0115] When implemented in software, the functionality ascribed to the systems, devices and techniques described in this disclosure may be embodied as instructions on a computer-readable medium such as RAM, ROM, NVRAM, EEPROM, FLASH memory, magnetic data storage media, optical data storage media, or the like. The instructions may be executed by processing circuitry and/or one or more processors to support one or more aspects of the functionality described in this disclosure.

#### [0116] ILLUSTRATIVE EMBODIMENTS

[0117] Embodiment 1. A system for use in cardiac evaluation comprising:

- i. an electrode apparatus comprising a plurality of external electrodes to be disposed proximate a patient's skin; and
- ii. a computing apparatus comprising processing circuitry, the computing apparatus operably coupled to the electrode apparatus and configured to:
  - iii. monitor electrical activity from tissue of a patient using a plurality of external electrodes to generate a plurality of electrical signals;
    - i. filter at least one of the electrical signals of the plurality of electrical signals;
    - ii. detect at least one disturbance in the at least one electrical signal using the at least one filtered signal; and

- iii. determine a temporal location of the at least one disturbance in the at least one electrical signal based on a time that the at least one filtered signal crosses a predetermined threshold.

[0118] Embodiment 2. The system of embodiment 1, wherein the electrical activity comprises electrical activation times representative of depolarization of cardiac tissue that propagates through the torso of the patient.

[0119] Embodiment 3. The system as in any one of embodiments 1-2, wherein the plurality of external electrodes comprises a plurality of surface electrodes to be located proximate skin of the patient's torso.

[0120] Embodiment 4. The system as in any one of embodiments 1-3, wherein the predetermined threshold is based on a sampling rate of the at least one electrical signal.

[0121] Embodiment 5. The system as in any one of embodiments 1-4, further wherein the computing apparatus is configured to remove the at least one disturbance.

[0122] Embodiment 6. The system of embodiment 5, wherein after removing the at least one disturbance, the computing apparatus is configured to use the electrical signals to determine a plurality of cardiac activation times.

[0123] Embodiment 7. The system as in any one of embodiments 1-6, wherein the computing apparatus is configured to smooth the at least one electrical signal within a window starting at a predetermined time period before the temporal location of the at least one disturbance and extending a predetermined amount of time after the temporal location of the at least one disturbance.

[0124] Embodiment 8. The system as in any one of embodiments 1-7, wherein the computing apparatus is configured to:

- i. determine temporal locations of the at least one disturbance in at least two electrical signals; and



- ii. smooth the plurality of electrical signals at the temporal locations of the at least one disturbance in the at least two signals.

[0125] Embodiment 9. The system as in any one of embodiments 1-8, wherein the computing apparatus is configured to filter the at least one electrical signal using a second difference filter.

[0126] Embodiment 10. The system as in any one of embodiments 1-9, wherein the computing apparatus is configured to determine the predetermined threshold based on a predetermined pulse width range.

[0127] Embodiment 11. The system as in any one of embodiments 1-10, wherein the computing apparatus is configured to determine the temporal location of the at least one disturbance within a predetermined window, the predetermined window based on an amplitude of the at least one electrical signal.

[0128] Embodiment 12. The system as in any one of embodiments 1-11, wherein the at least one disturbance comprises one or more of a pacing spike and muscle generated noise.

[0129] Embodiment 13. A system for use in cardiac evaluation comprising:

- i. an electrode apparatus comprising a plurality of external electrodes to be disposed proximate a patient's skin; and
  - i. a computing apparatus comprising processing circuitry, the computing apparatus operably coupled to the electrode apparatus and configured to:
    - ii. monitor electrical activity from tissue of a patient using a plurality of external electrodes to generate a plurality of electrical signals;
    - iii. detect at least one disturbance in at least one of the plurality of electrical signals;
    - iv. determine temporal locations of the at least one disturbance in the at least one electrical signal; and

v. remove the at least one disturbance based on the temporal locations of the at least one disturbance in the at least one electrical signal.

[0130] Embodiment 14. The system of embodiment 13, wherein the computing apparatus is configured to remove the at least one disturbance based on the temporal location of the at least one disturbance in the at least one electrical signal if the at least one disturbance is detected in at least a selected number of the plurality of signals.

[0131] Embodiment 15. The system of embodiment 14, wherein the selected number comprises at least four of the electrical signals.

[0132] Embodiment 16. The system as in any one of embodiments 13-15, wherein the computing apparatus is configured to smooth the plurality of signals within a window starting at a predetermined time period before the temporal location of the at least one disturbance and extending a predetermined amount of time after the temporal location of the at least one disturbance.

[0133] Embodiment 17. The system as in any one of embodiments 13-16 wherein after removing the at least one disturbance, the computing apparatus is configured to use the electrical signals to determine a plurality of cardiac activation times.

[0134] Embodiment 18. A method for use in cardiac evaluation comprising:

- i. monitoring electrical activity from tissue of a patient using a plurality of external electrodes to generate a plurality of electrical signals;
- ii. filtering at least one electrical signal of the electrical signals of the plurality of electrical signals;
- iii. detecting at least one disturbance in the at least one electrical signal using the at least one filtered signal; and
- iv. determining a temporal location of the at least one disturbance in the at least one electrical signal based on a time that the at least one filtered signal crosses a predetermined threshold.

[0135] Embodiment 19. The method of embodiment 18, wherein the electrical activity comprises electrical activation times representative of depolarization of cardiac tissue that propagates through the torso of the patient.

[0136] Embodiment 20. The method as in any one of embodiments 18-19, wherein the plurality of external electrodes comprises a plurality of surface electrodes to be located proximate skin of the patient's torso.

[0137] Embodiment 21. The method as in any one of embodiments 18-20, wherein the predetermined threshold is based on a sampling rate of the at least one electrical signal.

[0138] Embodiment 22. The method as in any one of embodiments 18-21, further comprising removing the at least one disturbance from the at least one electrical signal.

[0139] Embodiment 23. The method of embodiment 22, wherein removing the at least one disturbance comprises smoothing the at least one electrical signal within a window starting at a predetermined time period before the temporal location of the at least one disturbance and extending a predetermined amount of time after the temporal location of the at least one disturbance.

[0140] Embodiment 24. The method as in any one of embodiments 22-23, wherein detecting at least one disturbance in the at least one electrical signal using the at least one filtered signal comprises detecting at least a first disturbance and a second disturbance in the at least one electrical signal, the second disturbance occurring after the first disturbance,

i. wherein determining a temporal location of the at least one disturbance in the at least one electrical signal comprises determining a temporal location of the first disturbance and the second disturbance,

ii. wherein the method further comprises removing the first disturbance and the second disturbance by smoothing the at least one electrical signal within a window starting at a predetermined amount of time before the temporal location of the first disturbance and extending a predetermined amount of time after the second disturbance.

[0141] Embodiment 25. The method as in any one of embodiments 22-24, further comprising, after removing the at least one disturbance, using the electrical signals to determine a plurality of cardiac activation times.

[0142] Embodiment 26. The method as in any one of embodiments 18-25, wherein determining the temporal location of the at least one disturbance comprises:

- i. determining temporal locations of the at least one disturbance in at least two electrical signals; and
- ii. smoothing the plurality of electrical signals at the temporal locations of the at least one disturbance in the at least two signals.

[0143] Embodiment 27. The method as in any one of embodiments 18-26, wherein filtering the at least one electrical signal comprises filtering the at least one signal using a second difference filter.

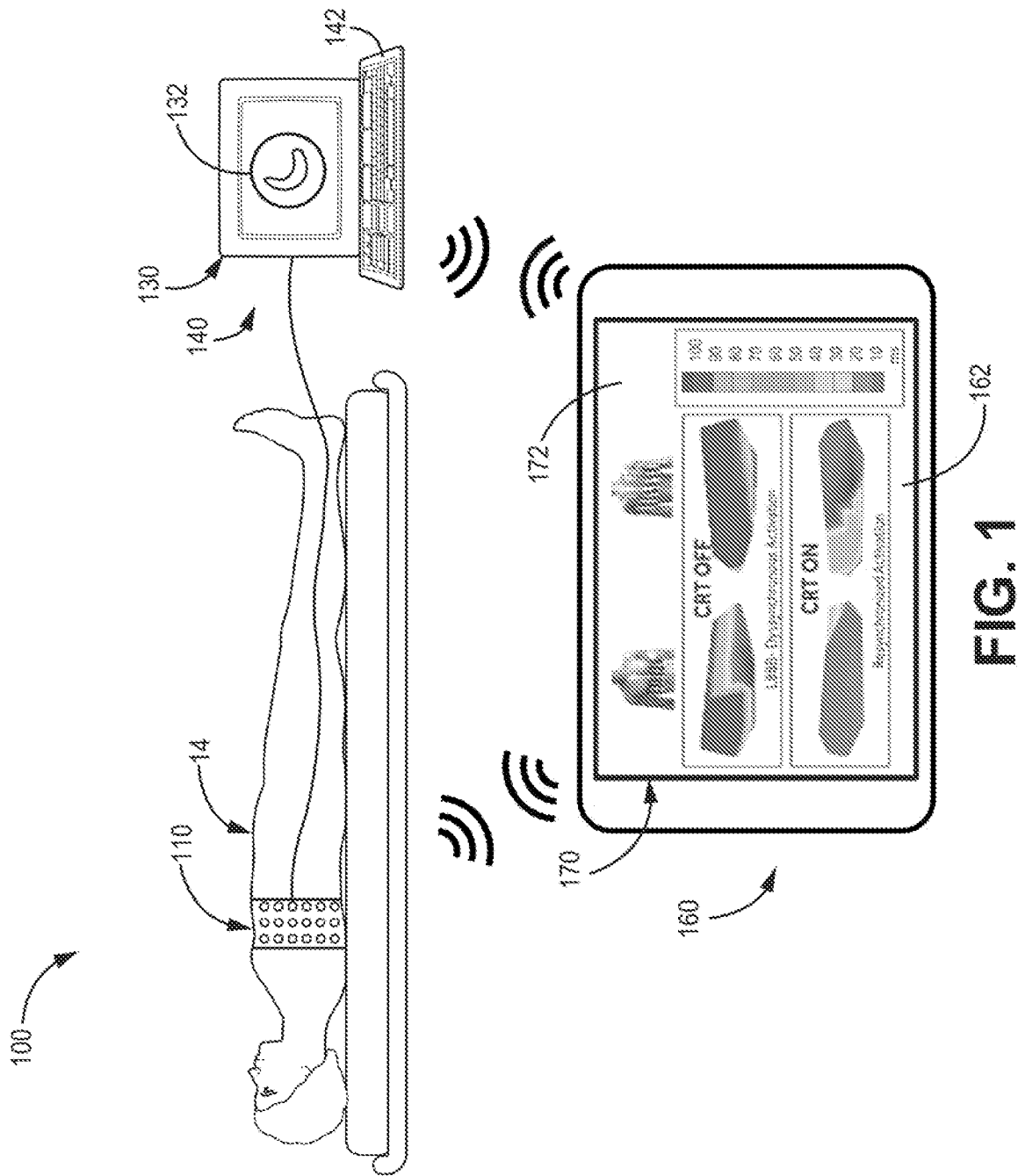
[0144] This disclosure has been provided with reference to illustrative embodiments and is not meant to be construed in a limiting sense. As described previously, one skilled in the art will recognize that other various illustrative applications may use the techniques as described herein to take advantage of the beneficial characteristics of the apparatus and methods described herein. Various modifications of the illustrative embodiments, as well as additional embodiments of the disclosure, will be apparent upon reference to this description.

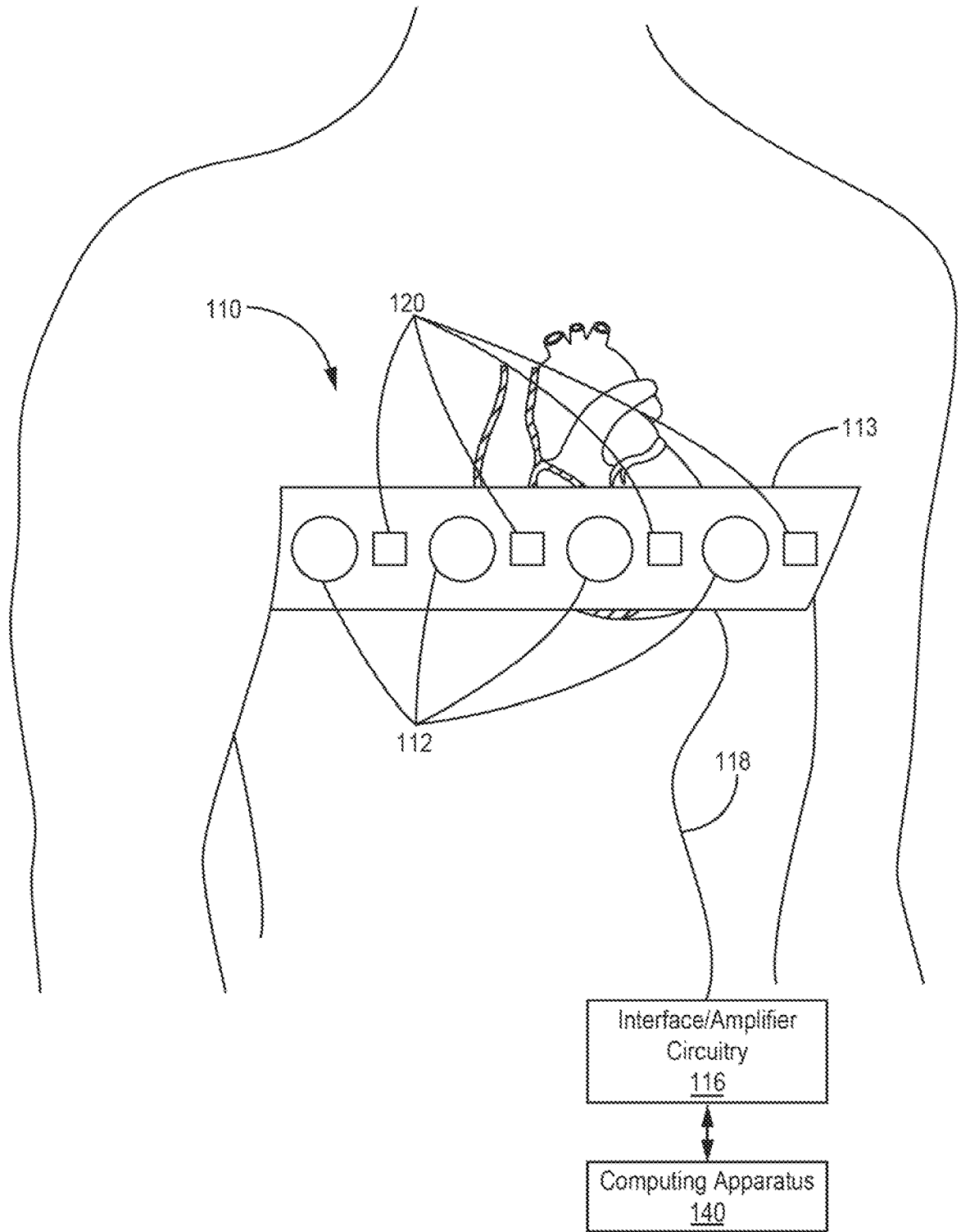
## CLAIMS

What is claimed:

1. A system for use in cardiac evaluation comprising:
  - an electrode apparatus comprising a plurality of external electrodes to be disposed proximate a patient's skin; and
  - a computing apparatus comprising processing circuitry, the computing apparatus operably coupled to the electrode apparatus and configured to:
    - monitor electrical activity from tissue of a patient using a plurality of external electrodes to generate a plurality of electrical signals;
    - filter at least one of the electrical signals of the plurality of electrical signals;
    - detect at least one disturbance in the at least one electrical signal using the at least one filtered signal; and
    - determine a temporal location of the at least one disturbance in the at least one electrical signal based on a time that the at least one filtered signal crosses a predetermined threshold.
2. The system of claim 1, wherein the electrical activity comprises electrical activation times representative of depolarization of cardiac tissue that propagates through the torso of the patient.
3. The system of any of claims 1-2, wherein the plurality of external electrodes comprises a plurality of surface electrodes to be located proximate skin of the patient's torso.
4. The system of any of claims 1-3, wherein the predetermined threshold is based on a sampling rate of the at least one electrical signal.
5. The system of any of claims 1-4, further wherein the computing apparatus is configured to remove the at least one disturbance.

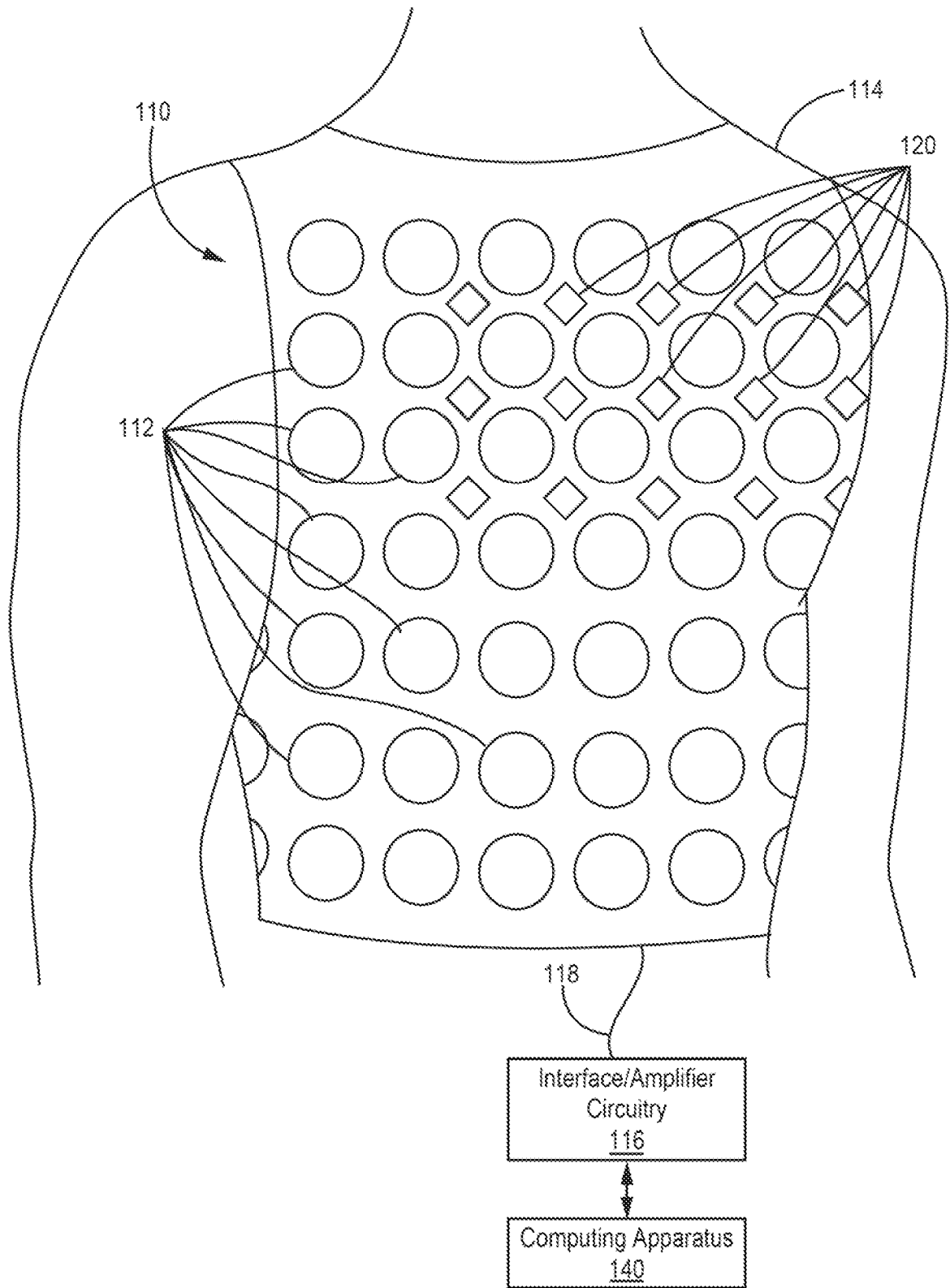
6. The system of claim 5, wherein after removing the at least one disturbance, the computing apparatus is configured to use the electrical signals to determine a plurality of cardiac activation times.
7. The system of any of claims 1-6, wherein the computing apparatus is configured to smooth the at least one electrical signal within a window starting at a predetermined time period before the temporal location of the at least one disturbance and extending a predetermined amount of time after the temporal location of the at least one disturbance.
8. The system of any of claims 1-7, wherein the computing apparatus is configured to:
  - determine temporal locations of the at least one disturbance in at least two electrical signals; and
  - smooth the plurality of electrical signals at the temporal locations of the at least one disturbance in the at least two signals.
9. The system of any of claims 1-8, wherein the computing apparatus is configured to filter the at least one electrical signal using a second difference filter.
10. The system of any of claims 1-9, wherein the computing apparatus is configured to determine the predetermined threshold based on a predetermined pulse width range.
11. The system of any of claims 1-10, wherein the computing apparatus is configured to determine the temporal location of the at least one disturbance within a predetermined window, the predetermined window based on an amplitude of the at least one electrical signal.
12. The system of any of claims 1-11, wherein the at least one disturbance comprises one or more of a pacing spike and muscle generated noise.



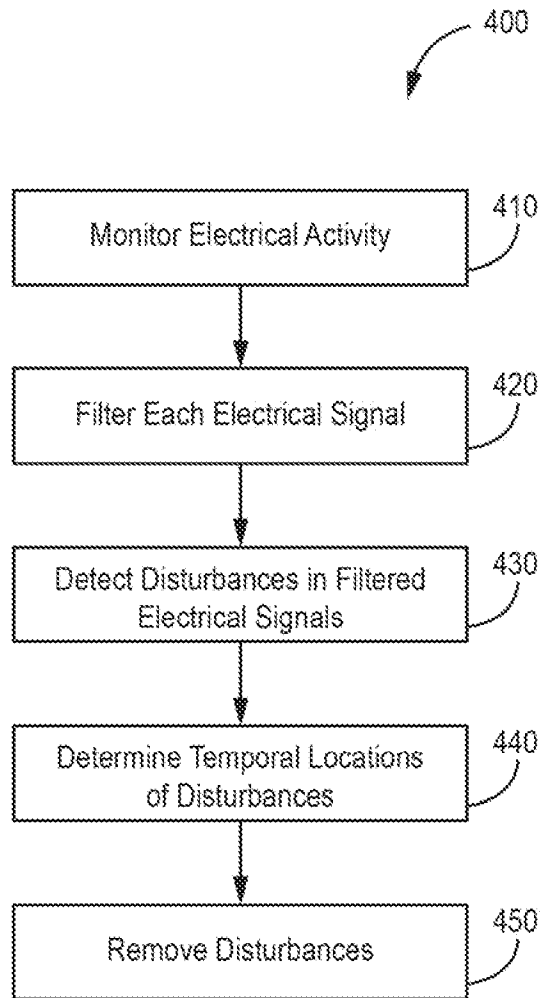


**FIG. 2**

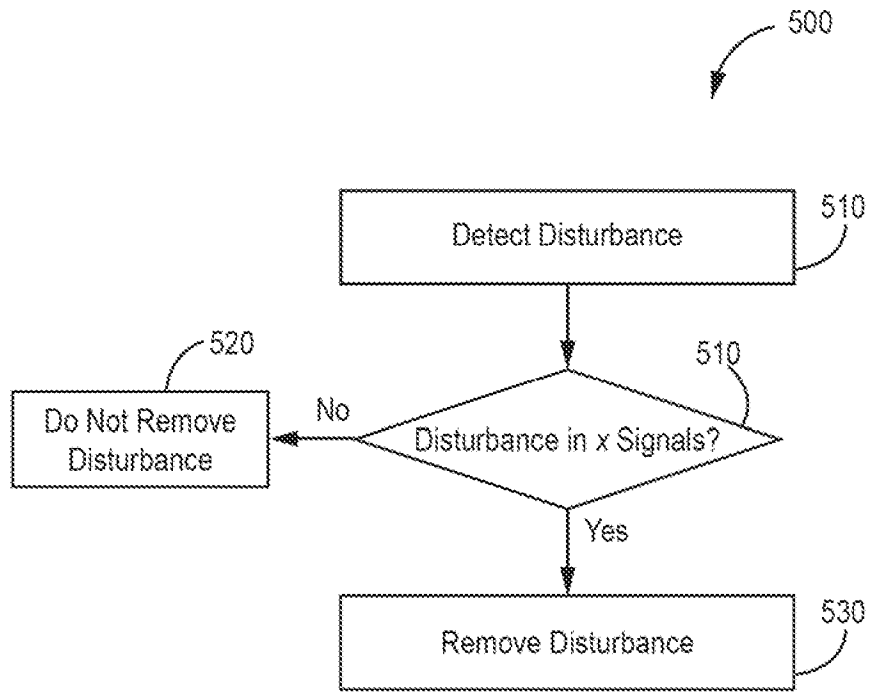




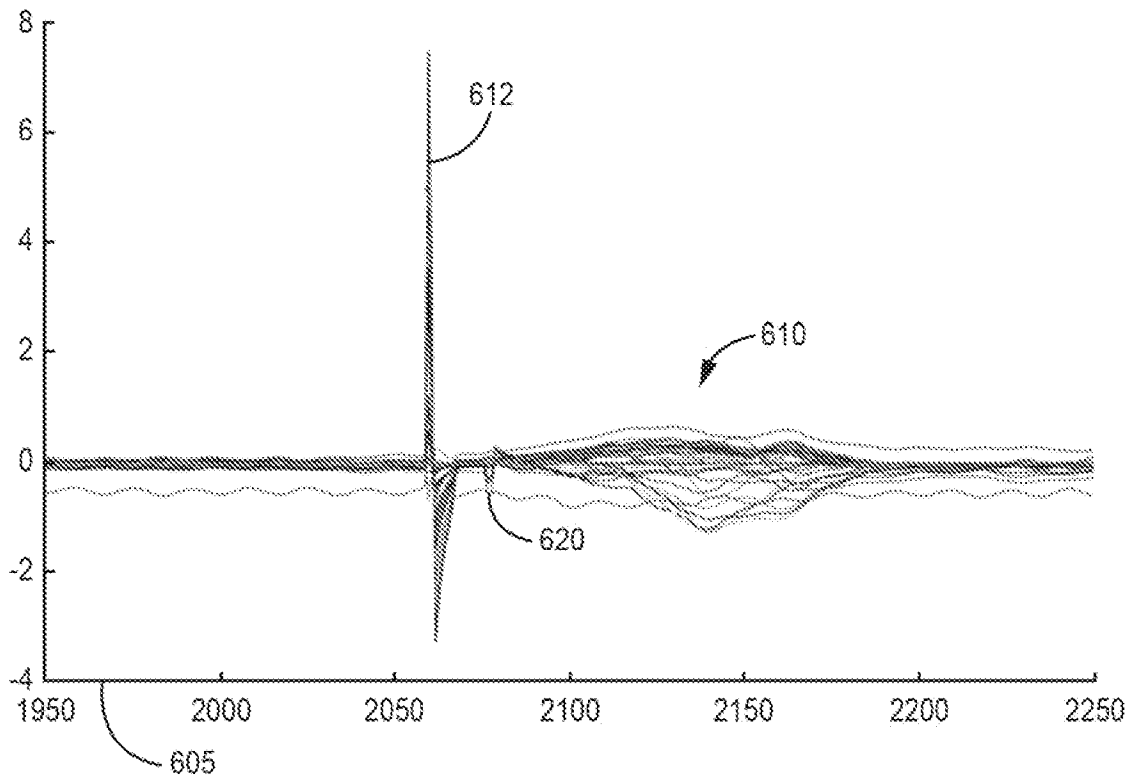
**FIG. 3**



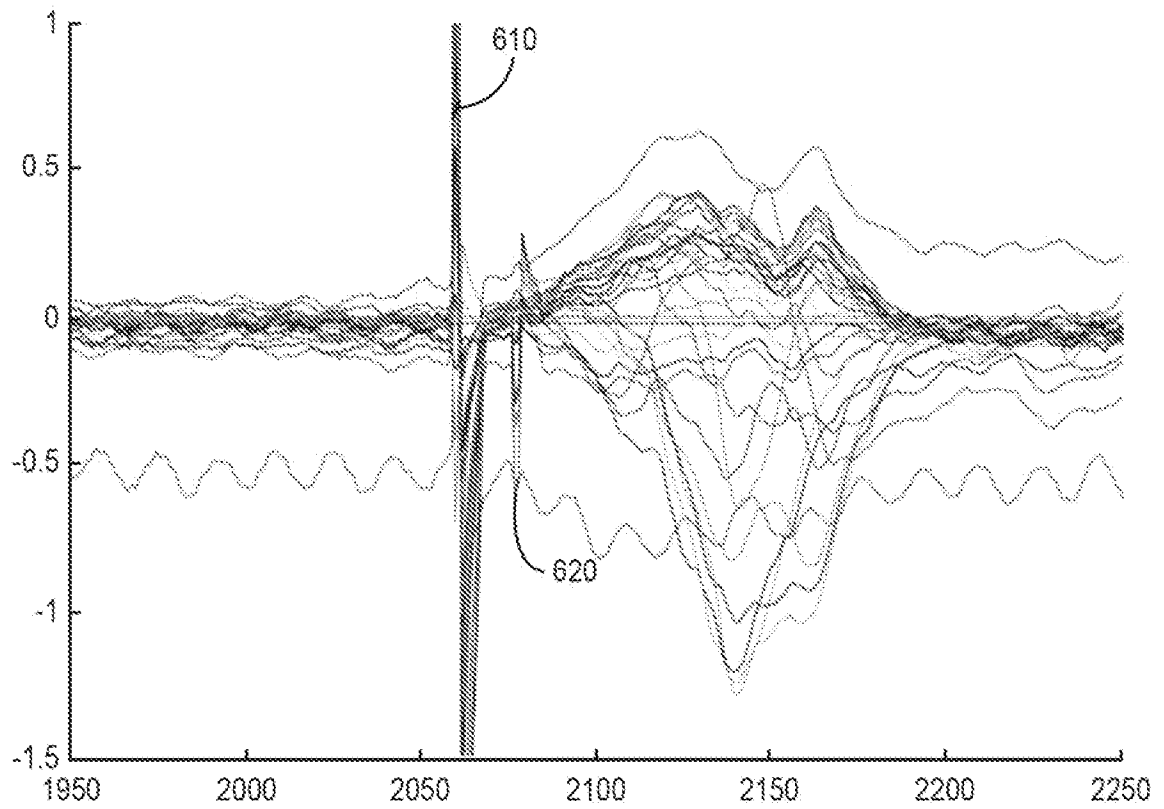
**FIG. 4**



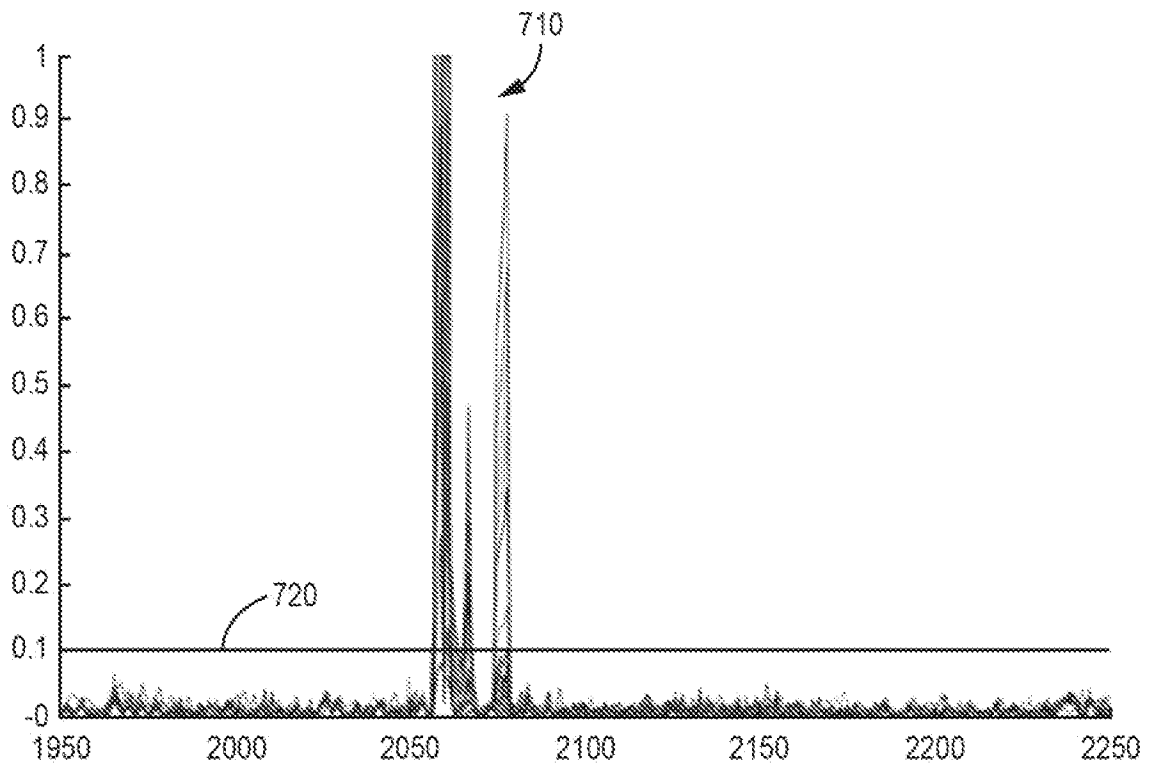
**FIG. 5**



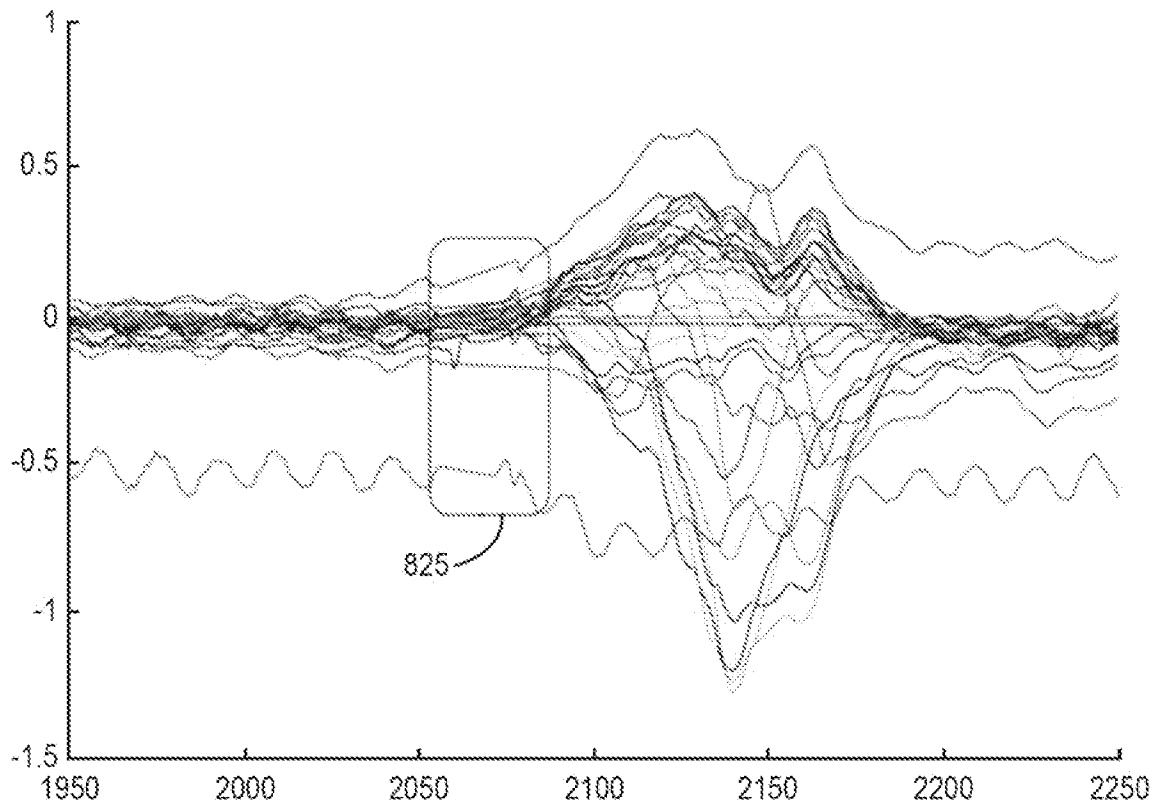
**FIG. 6A**



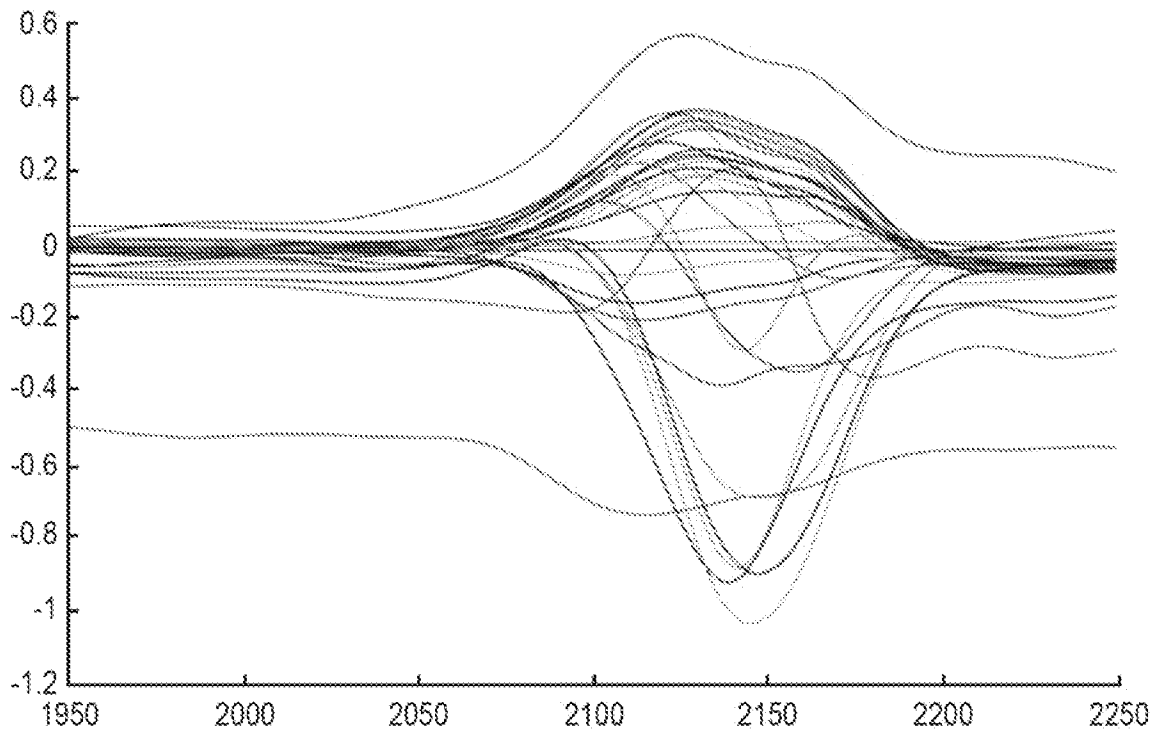
**FIG. 6B**



**FIG. 7**

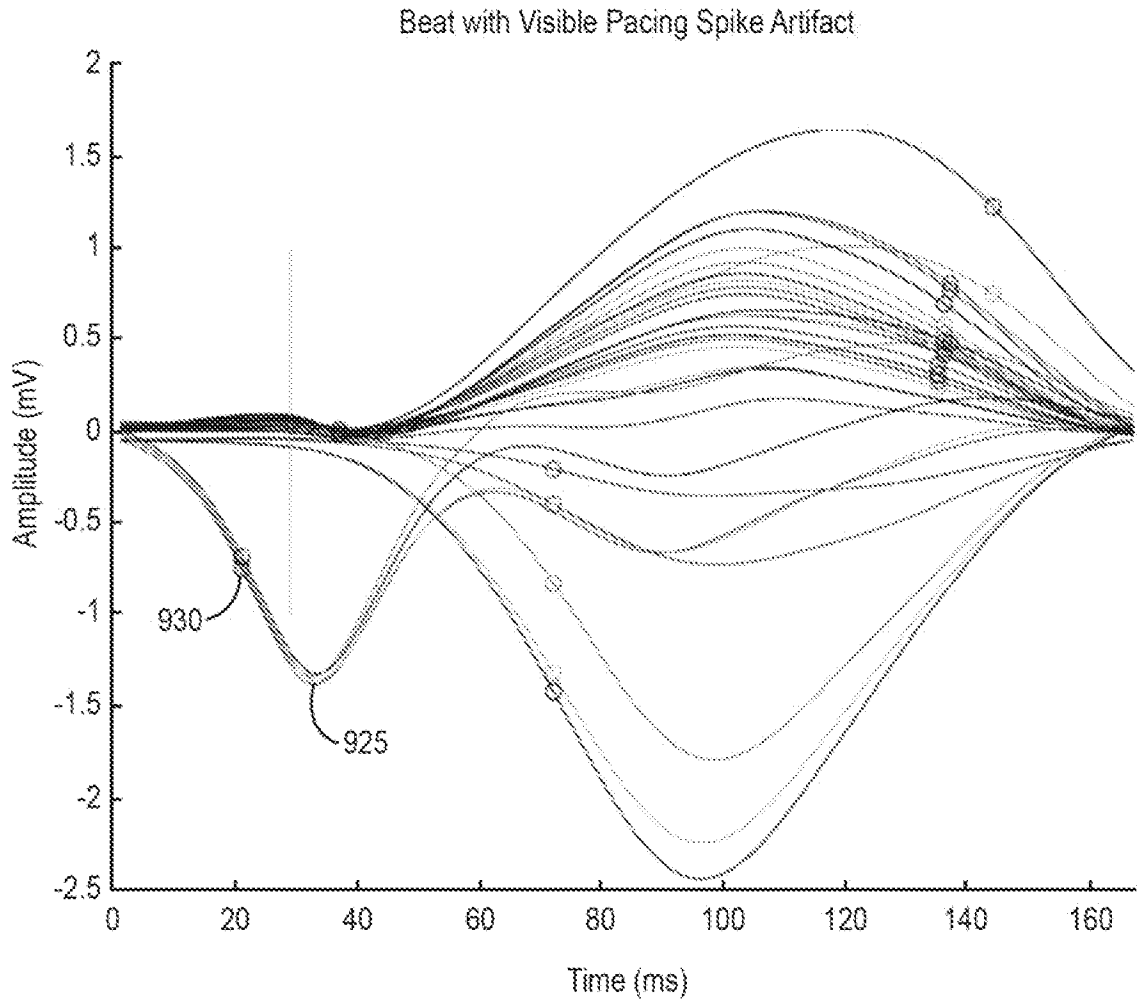


**FIG. 8A**

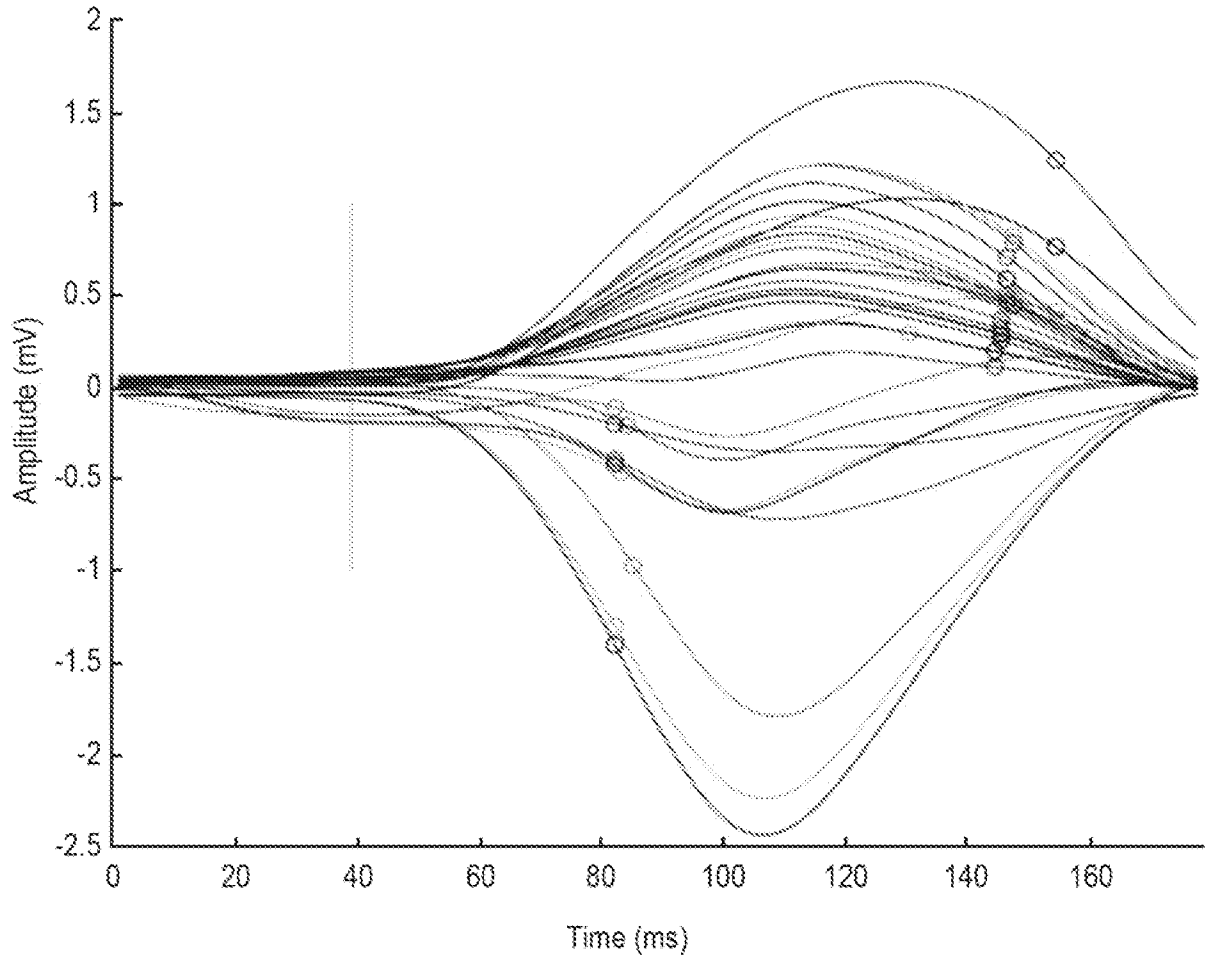


**FIG. 8B**

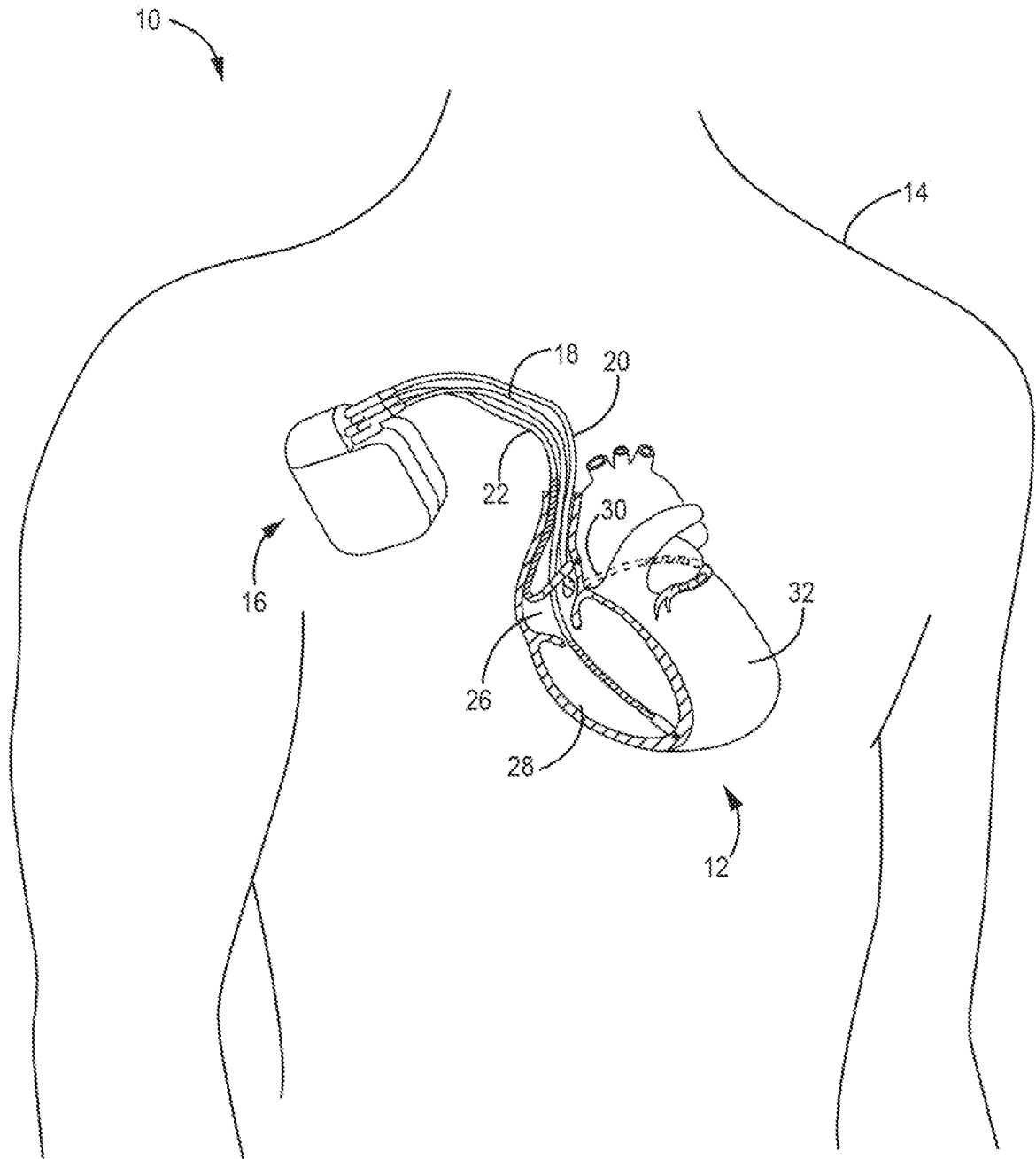




**FIG. 9A**



**FIG. 9B**



**FIG. 10**

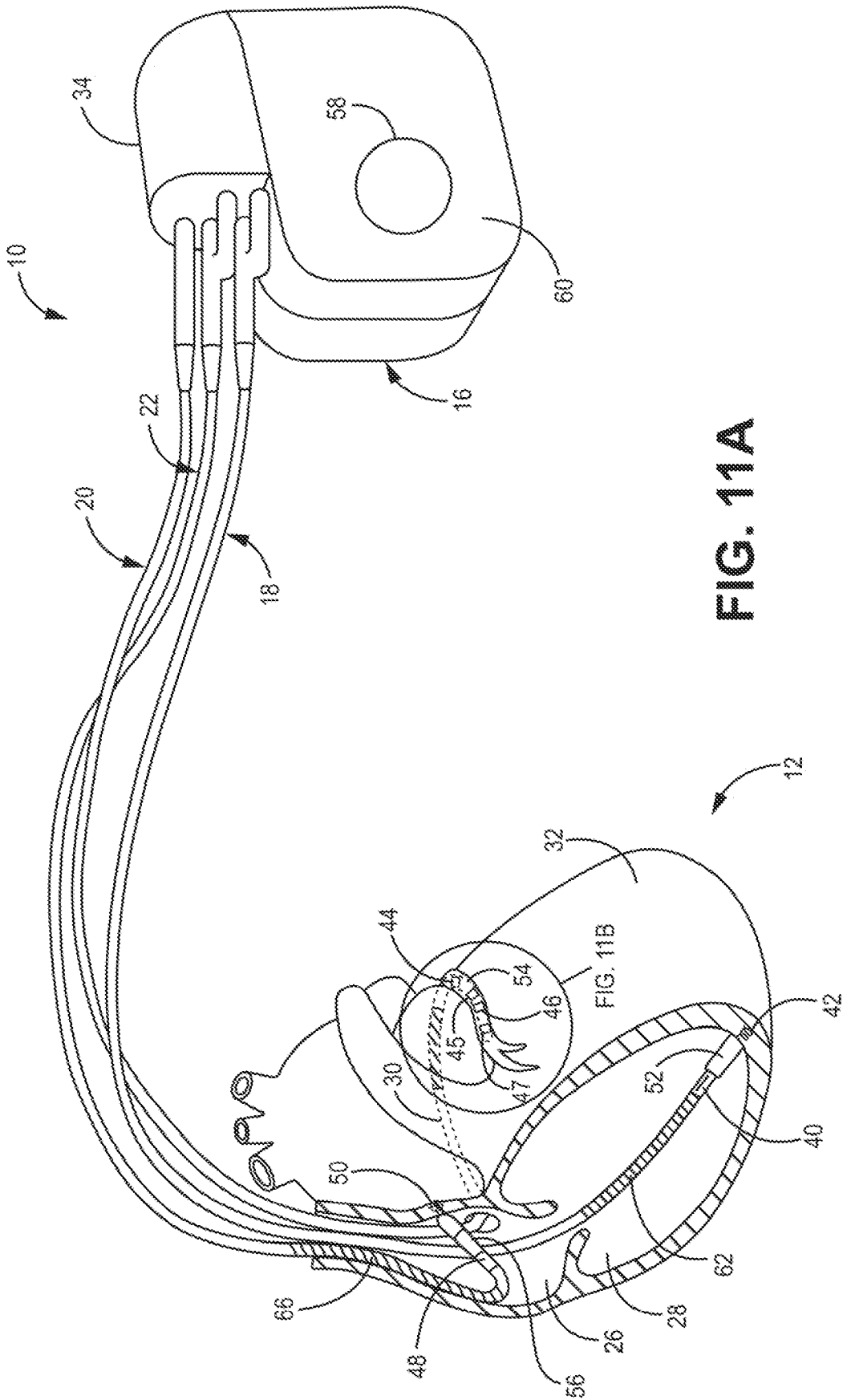
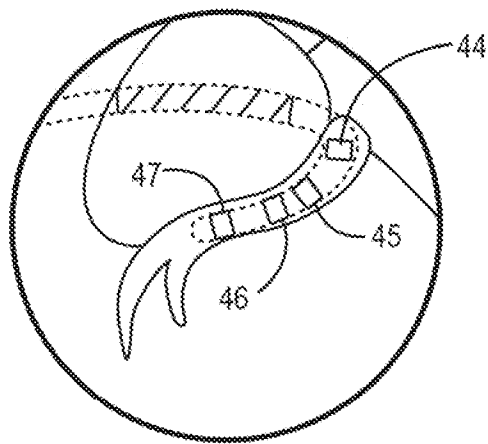
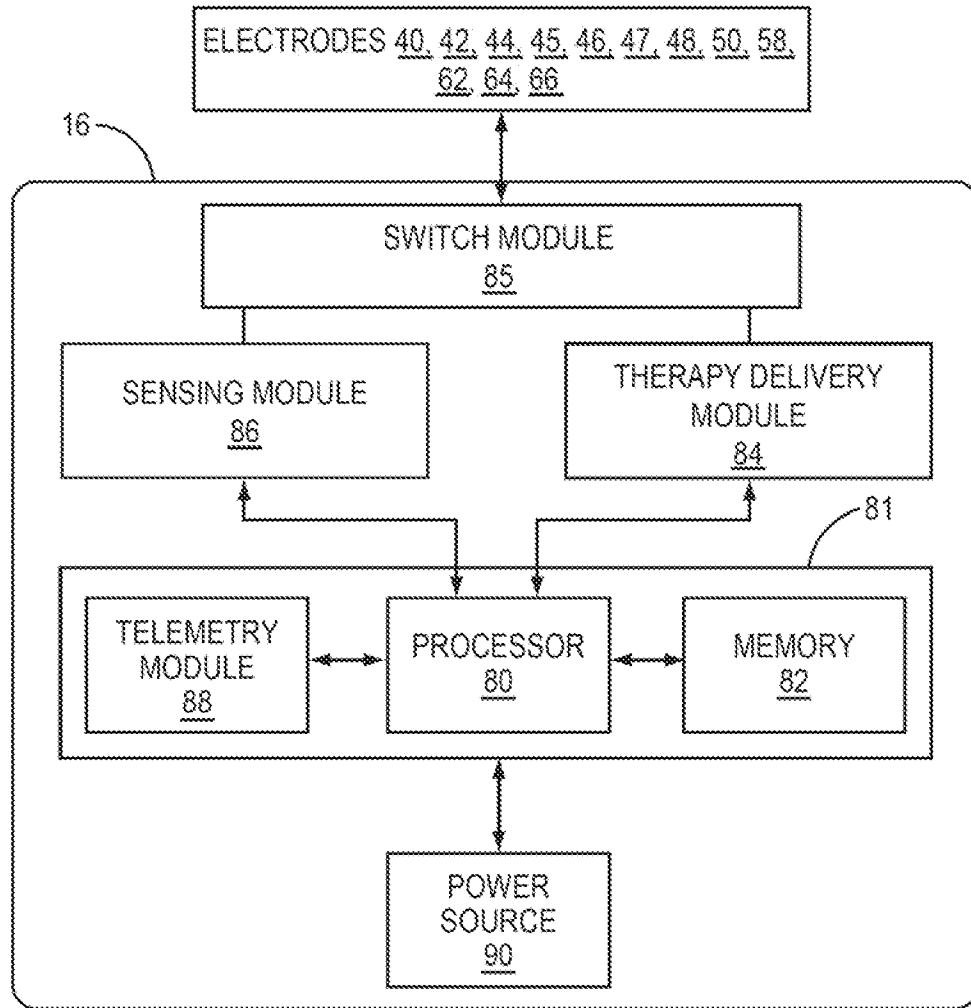


FIG. 11A



**FIG. 11B**



**FIG. 12A**

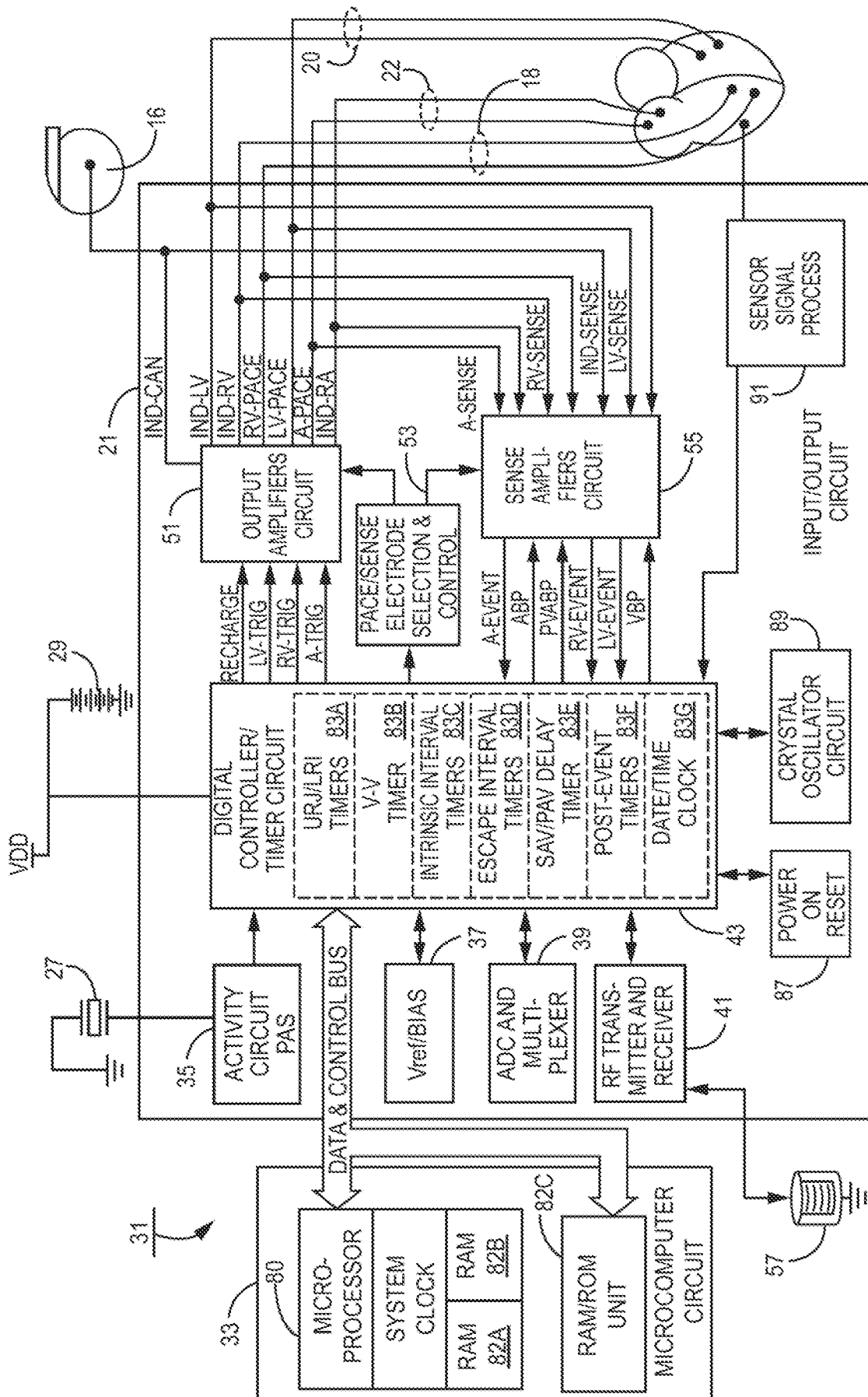


FIG. 12B

# INTERNATIONAL SEARCH REPORT

International application No <b>PCT/US2021/012876</b>
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**A. CLASSIFICATION OF SUBJECT MATTER**  
 INV. A61N1/04      A61B5/00      A61N1/37  
 ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
**A61N A61B**

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**EPO-Internal, WPI Data**

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A A A	US 2018/264258 A1 (CHENG YA-JIAN [US] ET AL) 20 September 2018 (2018-09-20) paragraphs [0147] - [0157]; claim 1; figures 1, 2, 3, 11B ----- US 6 115 628 A (STADLER ROBERT [US] ET AL) 5 September 2000 (2000-09-05) the whole document ----- US 10 123 745 B1 (KATRA RODOLPHE [US] ET AL) 13 November 2018 (2018-11-13) the whole document -----	1-3,5,6, 9,12 4,7,8, 10,11  1-12  1-12

Further documents are listed in the continuation of Box C.

See patent family annex.

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Date of the actual completion of the international search

**30 April 2021**

Date of mailing of the international search report

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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