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(54) **SYSTEMS AND METHODS FOR EVALUATING CARDIAC THERAPY**

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See application file for complete search history.

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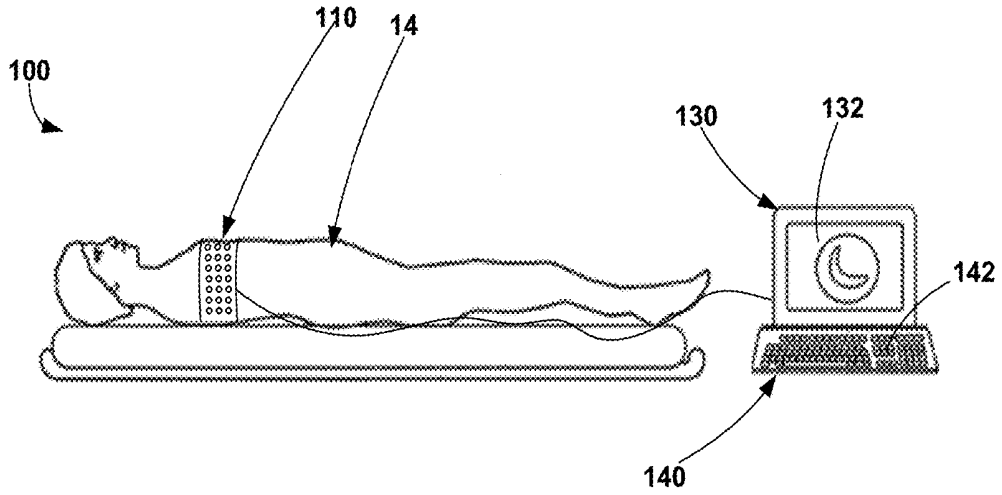
(57) **ABSTRACT**

Systems and methods are described herein for assisting a user in evaluation of cardiac therapy. The systems and methods may monitor electrical activity of a patient using external electrode apparatus to provide baseline cardiac information and therapy cardiac information and determine whether the cardiac pacing, or therapy, location is acceptable. If the cardiac pacing, or therapy, location is unacceptable, location information representative of a location that may more effective may be generated based on the therapy cardiac information.

24 Claims, 13 Drawing Sheets



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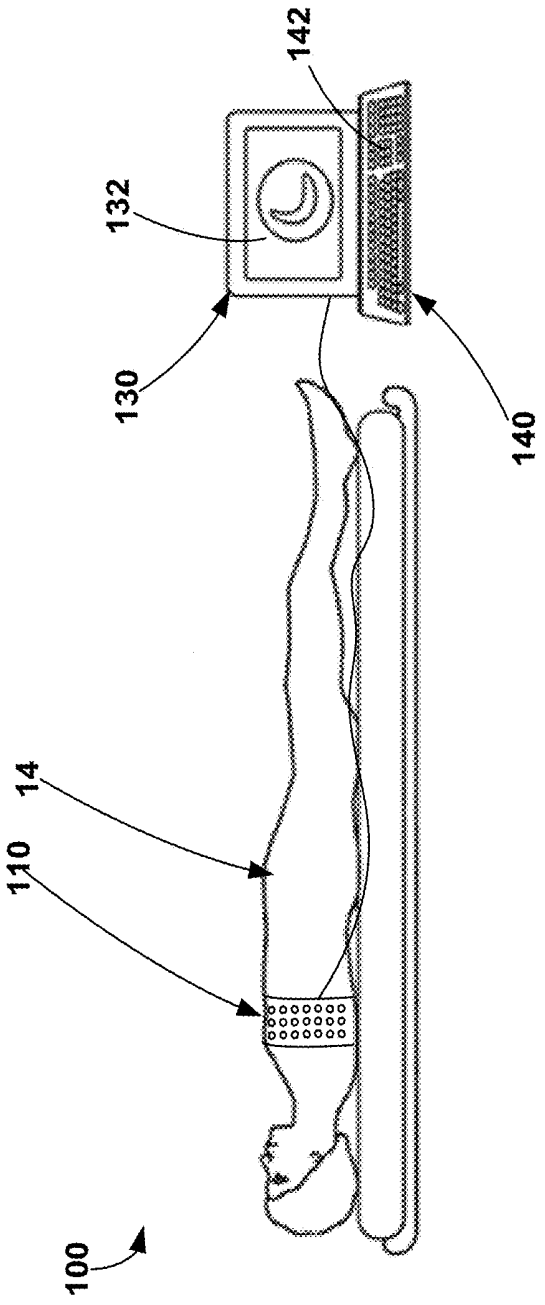


FIG. 1

FIG. 2

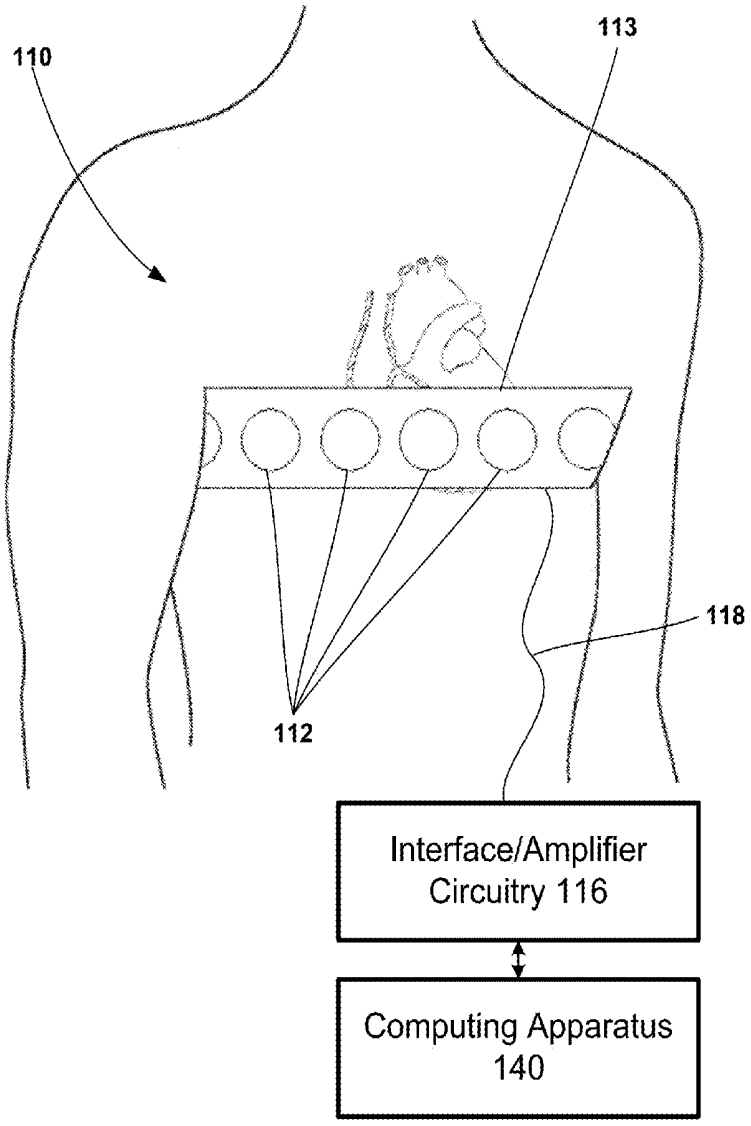

110
113
118
112
Interface/Amplifier Circuitry 116
Computing Apparatus 140

FIG. 3

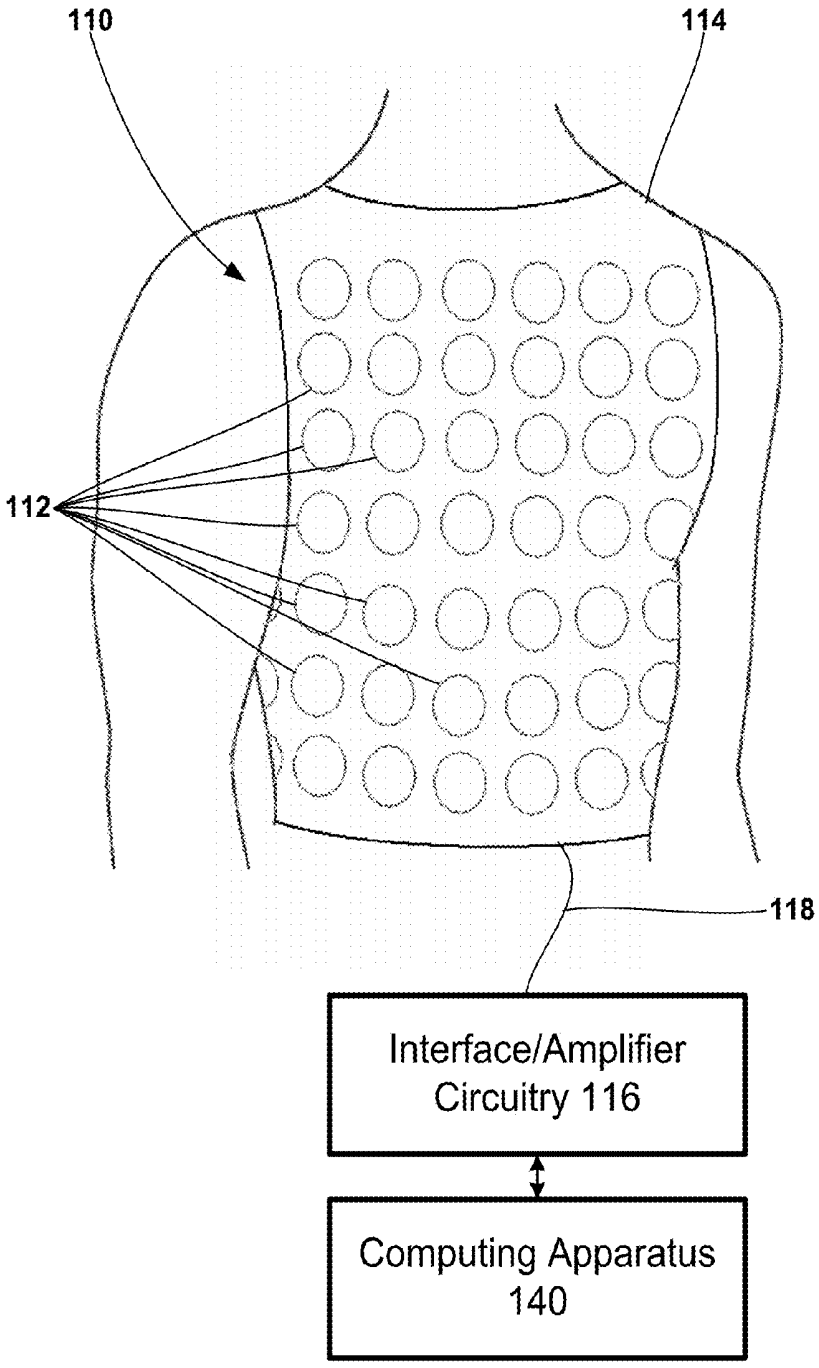
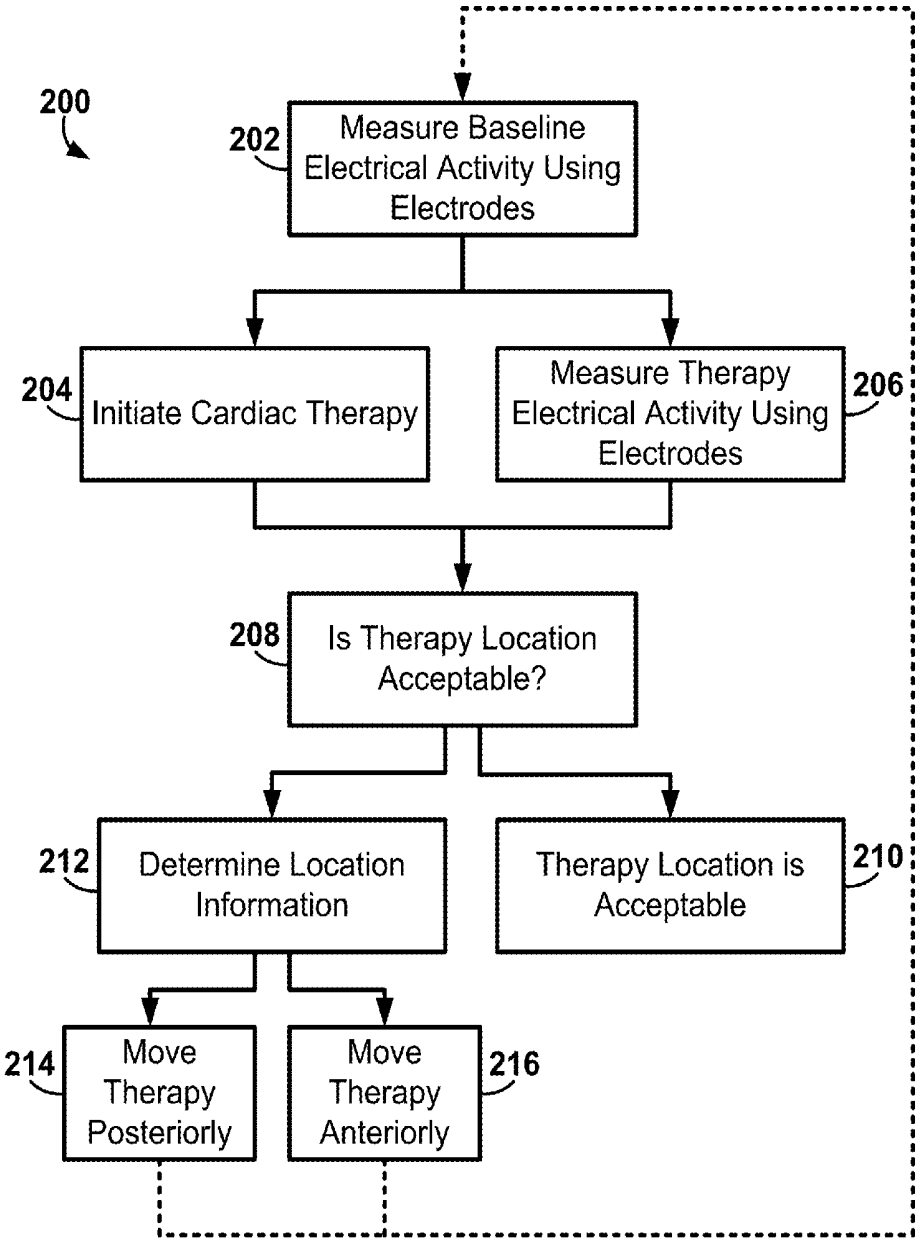

110
114
112
118
Interface/Amplifier Circuitry 116
Computing Apparatus 140

FIG. 4


200
202
Measure Baseline Electrical Activity Using Electrodes
204
Initiate Cardiac Therapy
206
Measure Therapy Electrical Activity Using Electrodes
208
Is Therapy Location Acceptable?
212
Determine Location Information
210
Therapy Location is Acceptable
214
Move Therapy Posteriorly
216
Move Therapy Anteriorly

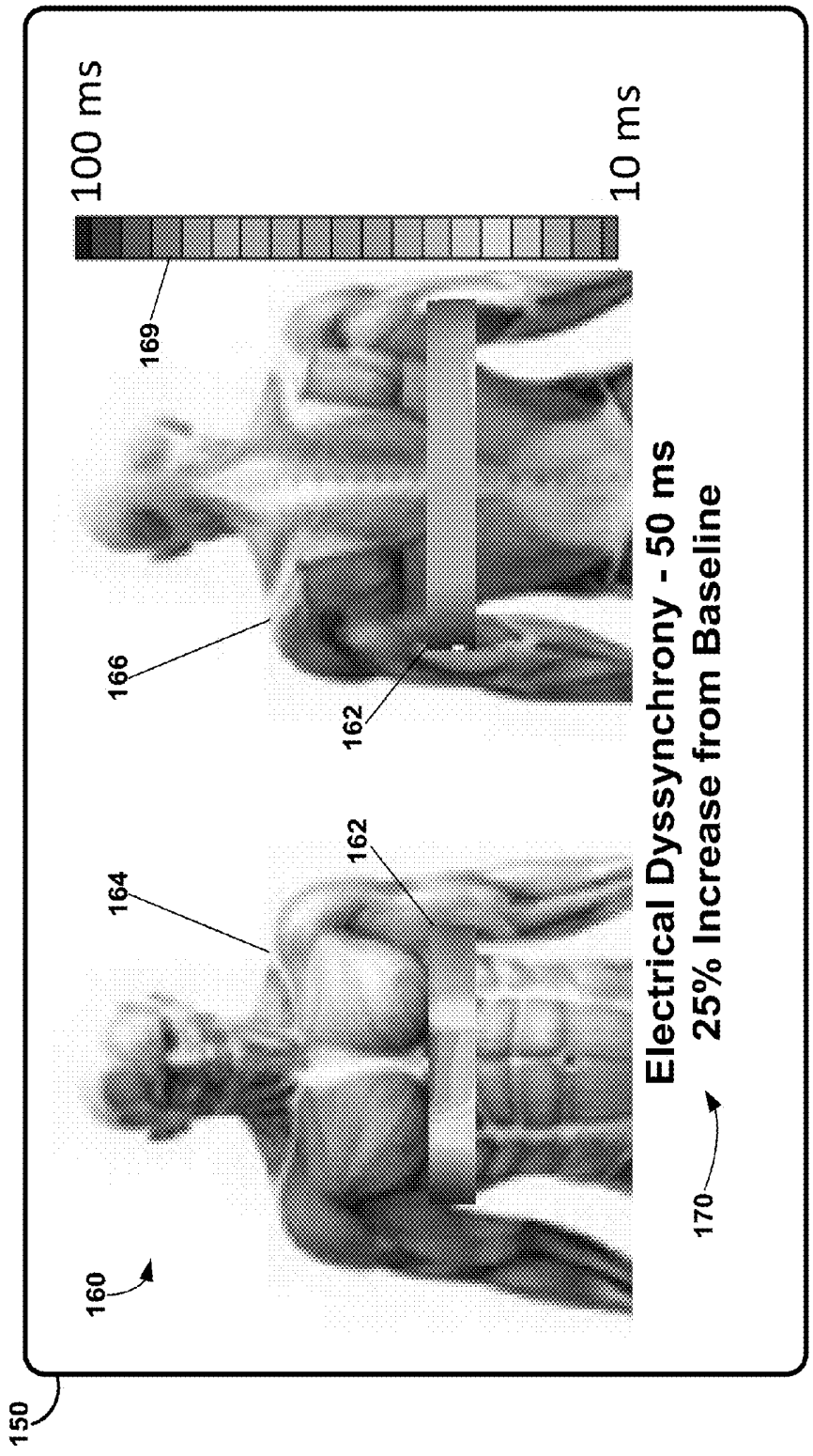
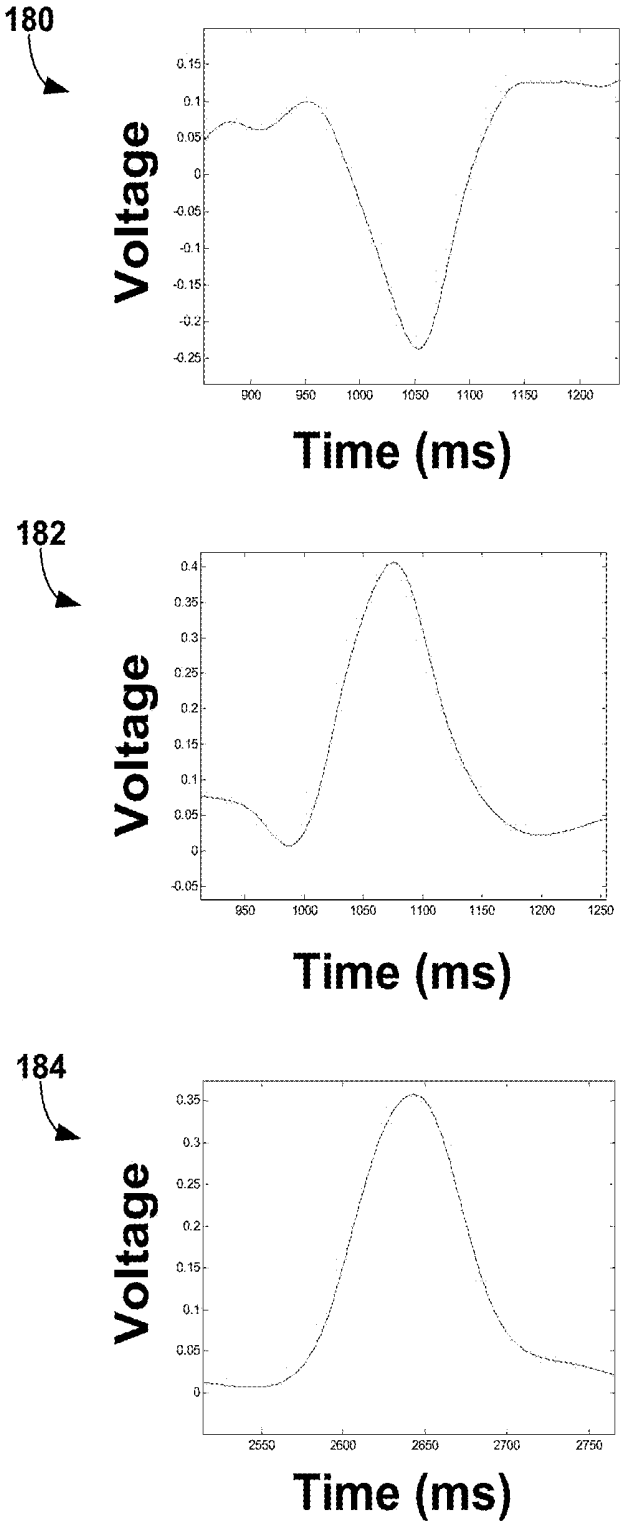

100 ms
10 ms
169
166
162
164
162
160
170
Electrical Dyssynchrony - 50 ms
25% Increase from Baseline
150

FIG. 5

FIG. 6


180
Voltage
0.15
0.1
0.05
0
-0.05
-0.1
-0.15
-0.2
-0.25
900
950
1000
1050
1100
1150
1200
Time (ms)
182
Voltage
0.4
0.35
0.3
0.25
0.2
0.15
0.1
0.05
0
-0.05
950
1000
1050
1100
1150
1200
1250
Time (ms)
184
Voltage
0.35
0.3
0.25
0.2
0.15
0.1
0.05
0
2550
2600
2650
2700
2750
Time (ms)

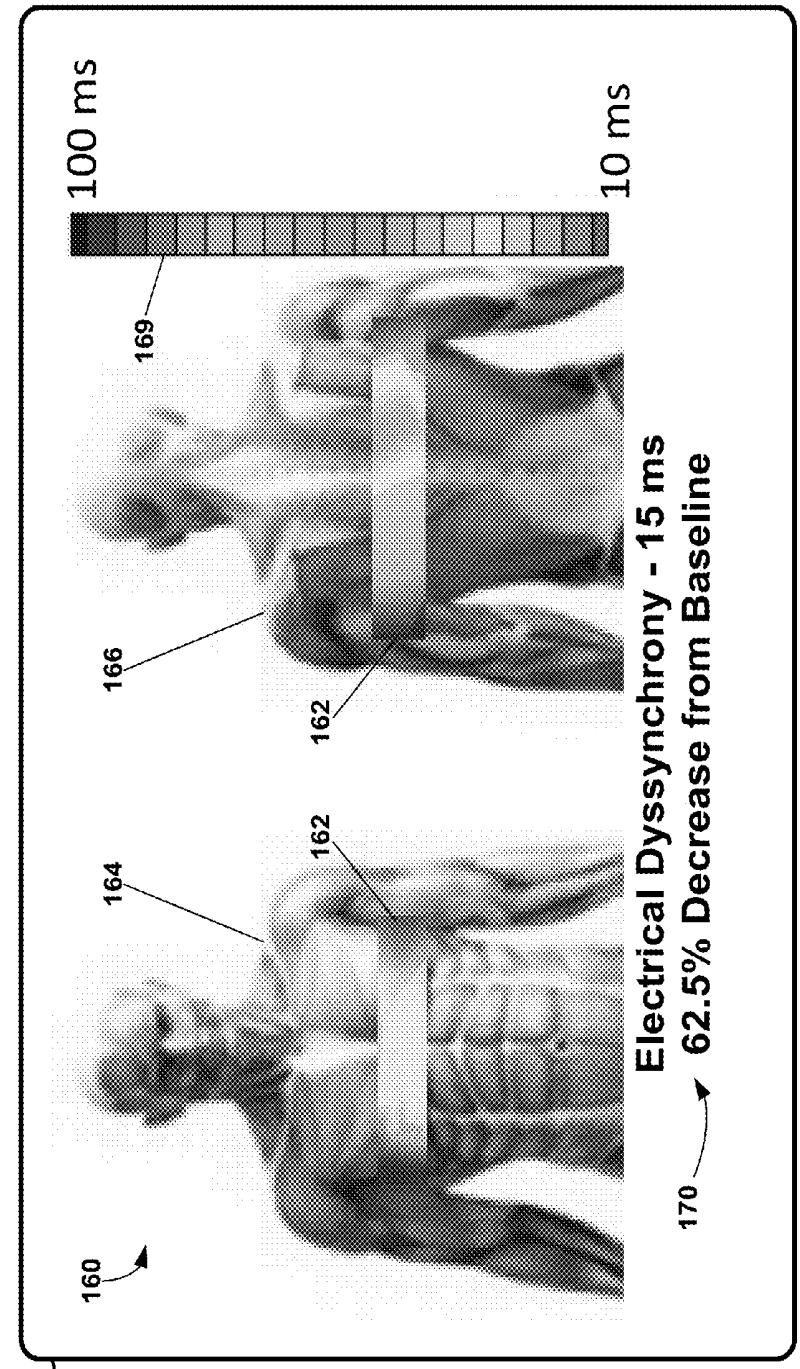

100 ms
10 ms
169
166
162
164
162
160
Electrical Dyssynchrony - 15 ms
62.5% Decrease from Baseline
170
151

FIG. 7

FIG. 8

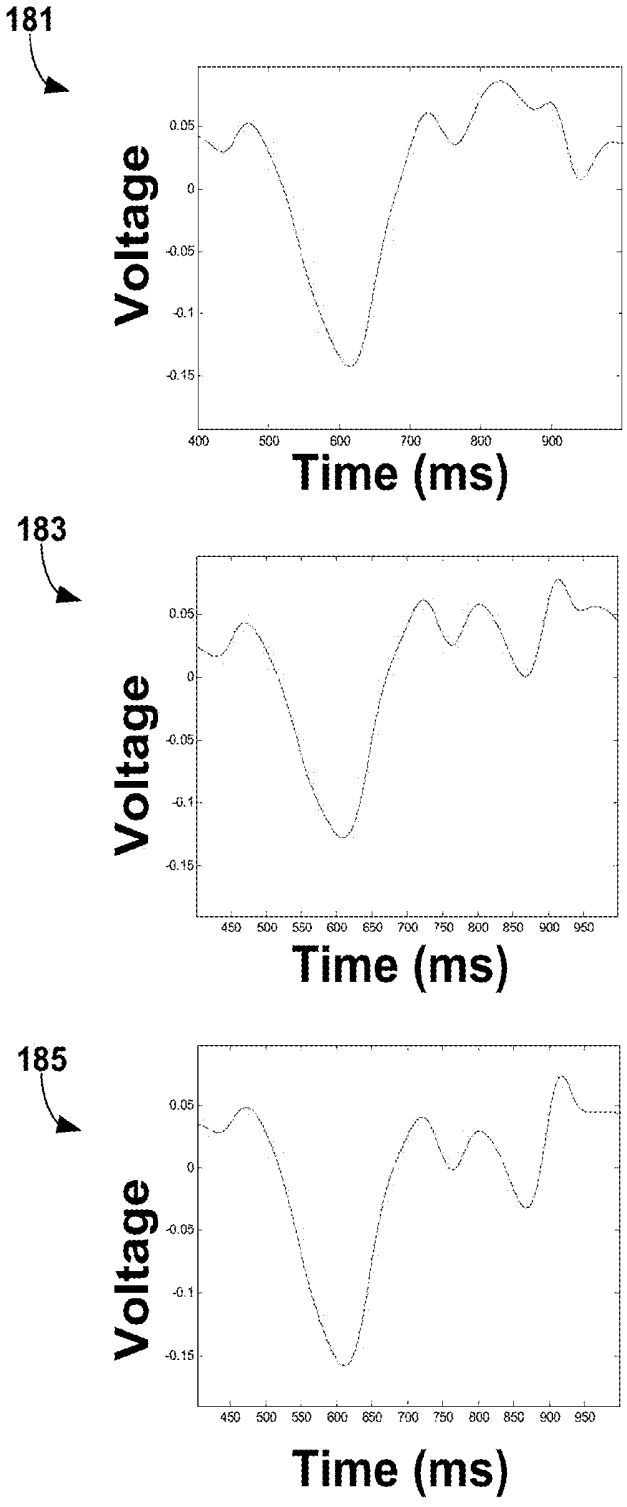
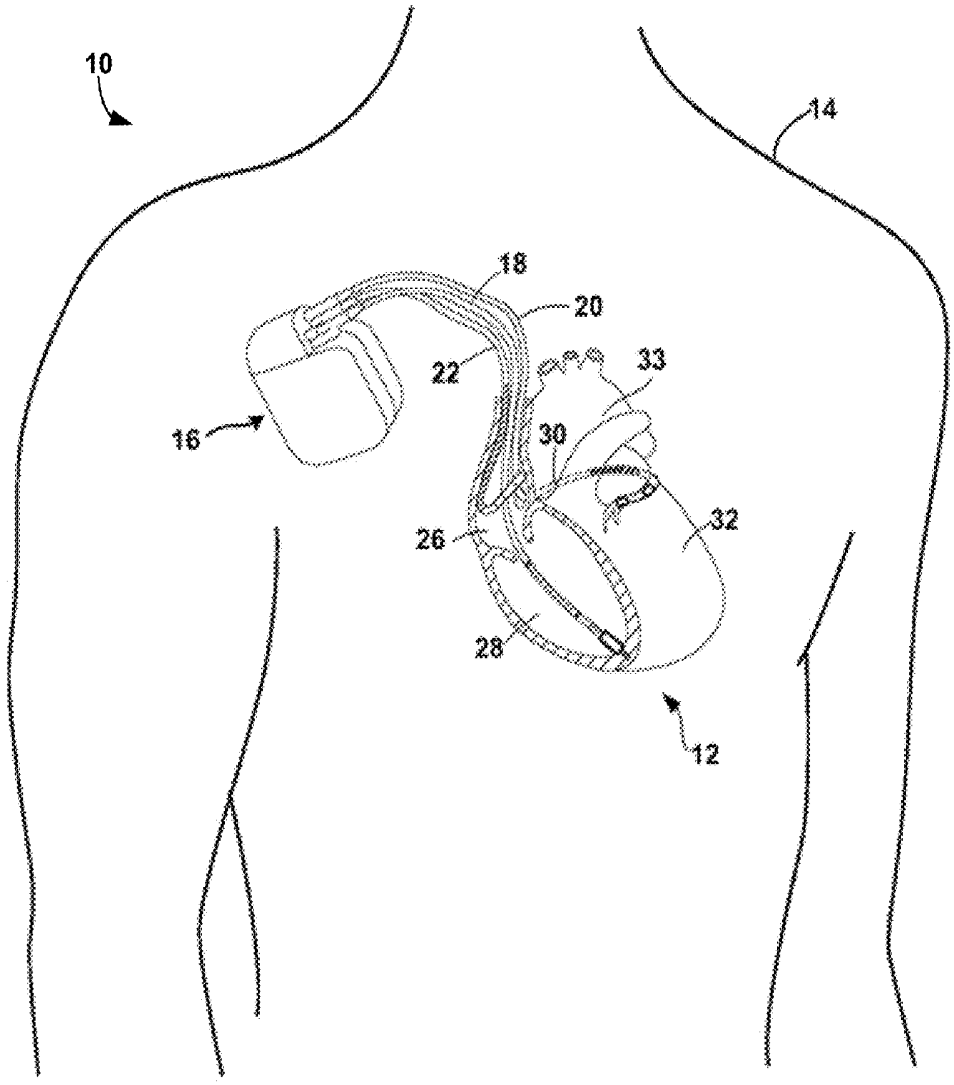

181
Voltage
0.05
0
-0.05
-0.1
-0.15
400 500 600 700 800 900
Time (ms)
183
Voltage
0.05
0
-0.05
-0.1
-0.15
450 500 550 600 650 700 750 800 850 900 950
Time (ms)
185
Voltage
0.05
0
-0.05
-0.1
-0.15
450 500 550 600 650 700 750 800 850 900 950
Time (ms)

FIG. 9



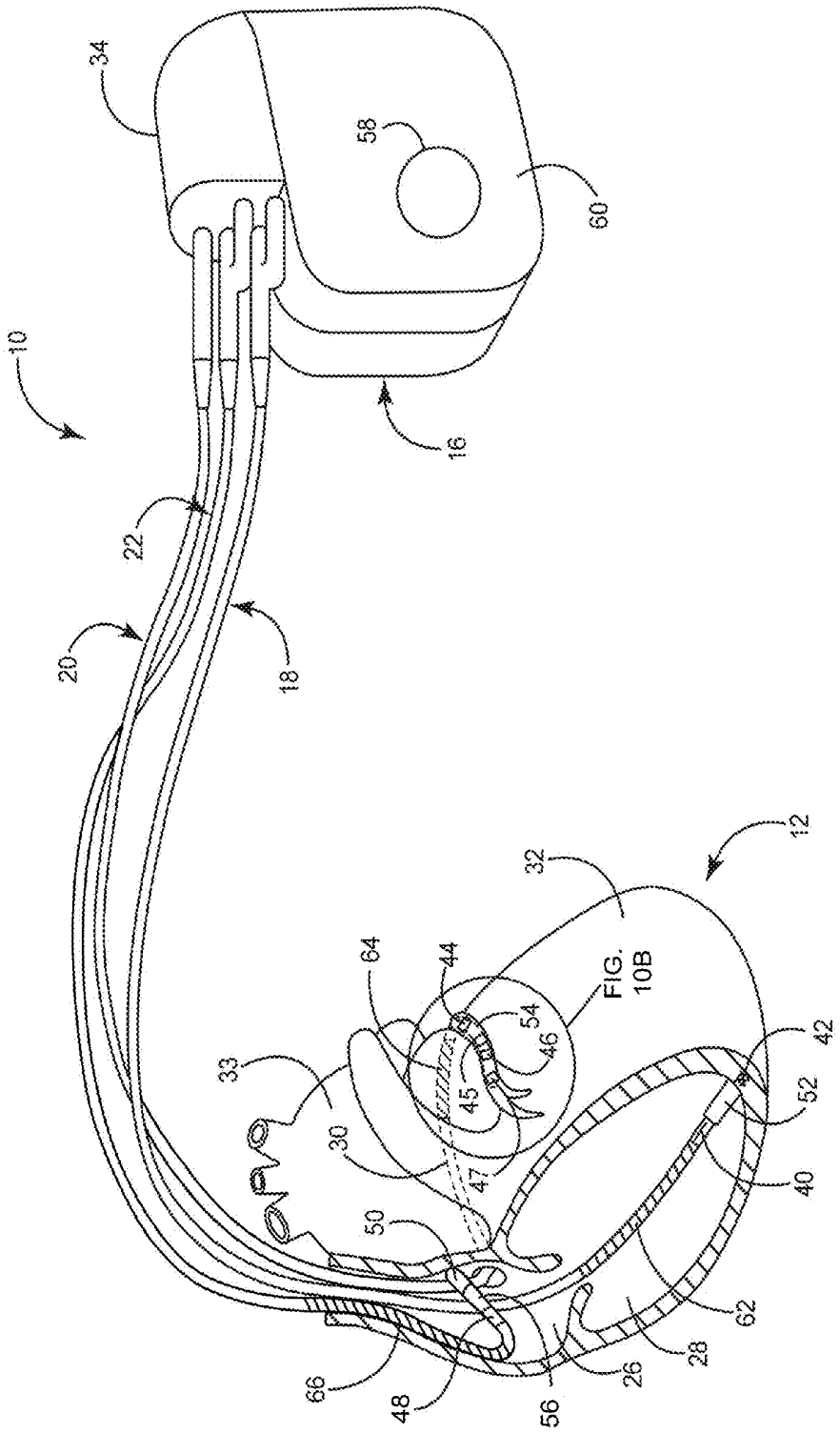

34
58
60
10
16
22
20
18
12
32
64
44
FIG. 10B
54
46
33
45
42
52
30
47
40
50
62
28
66
48
26
56

FIG. 10A

FIG. 10B

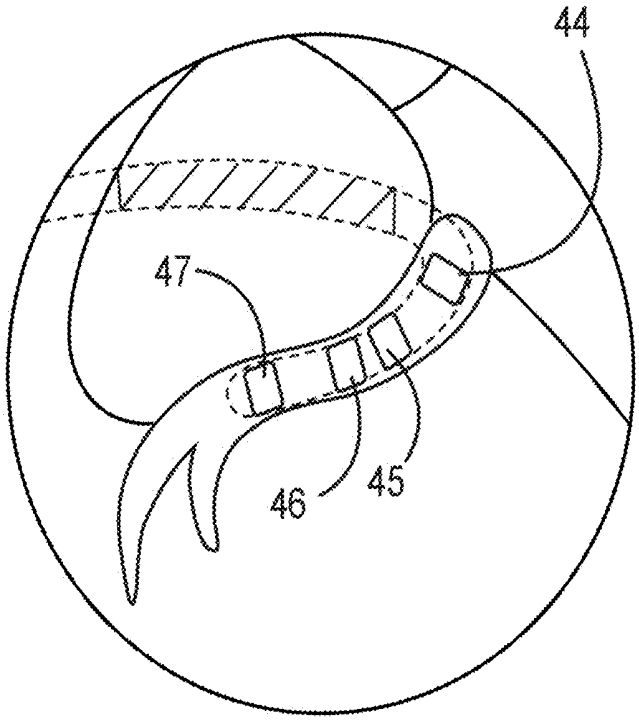
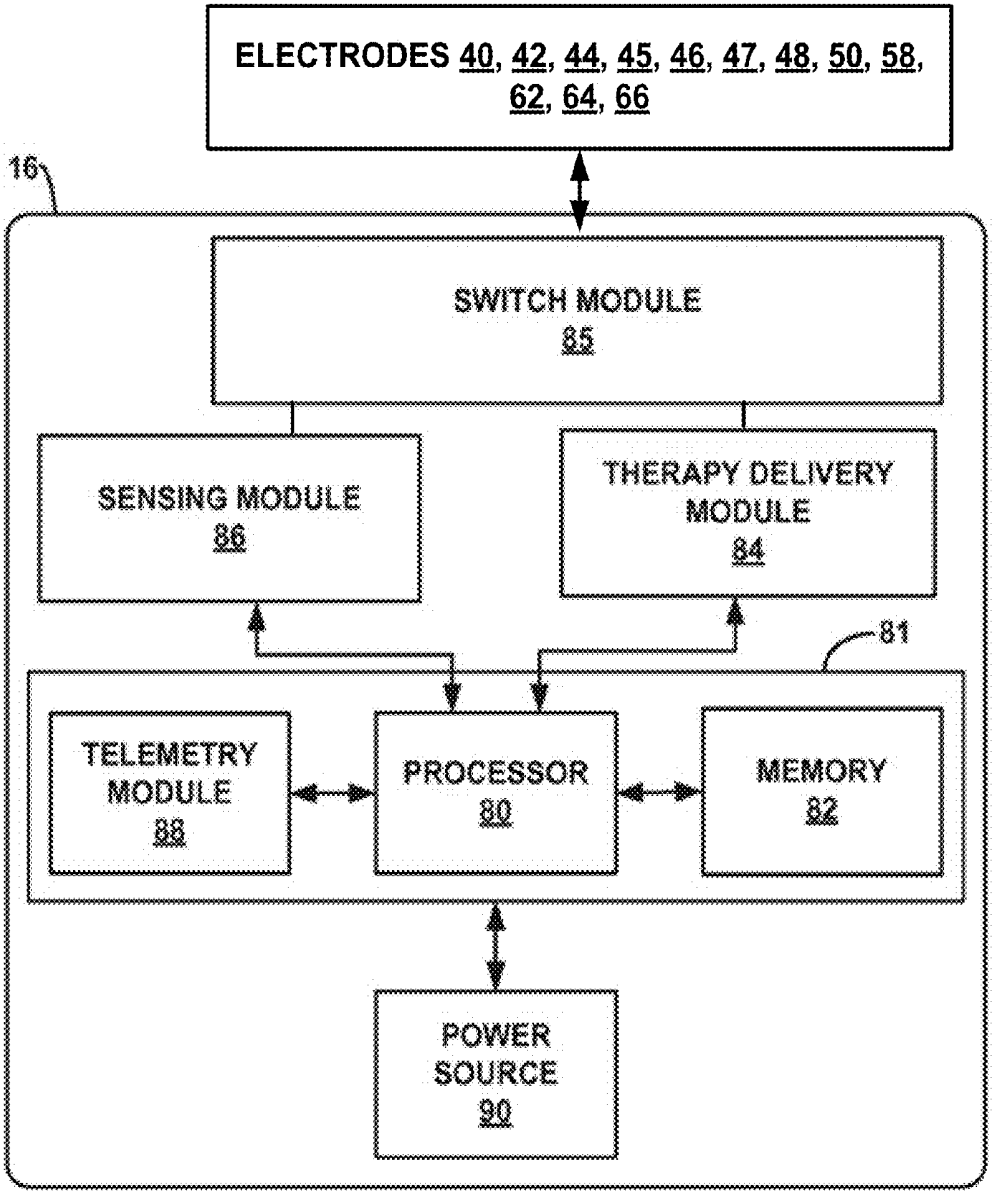


FIG. 11A


ELECTRODES 40, 42, 44, 45, 46, 47, 48, 50, 58, 62, 64, 66
16
SWITCH MODULE 85
SENSING MODULE 86
THERAPY DELIVERY MODULE 84
81
TELEMETRY MODULE 88
PROCESSOR 80
MEMORY 82
POWER SOURCE 90

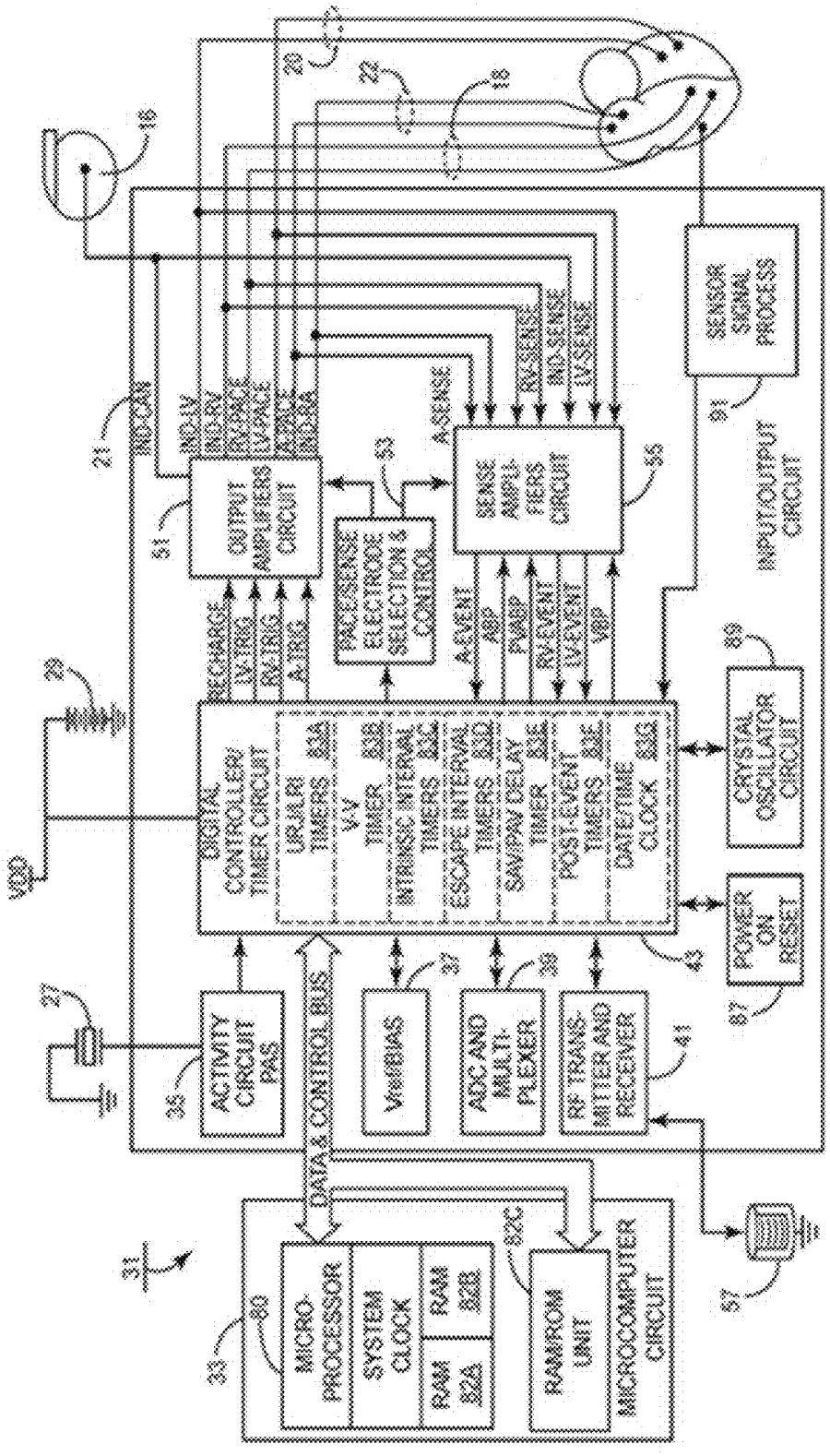

16
20
22
18
21
IND.CAN
IND.LV
RV.PACE
LV.PACE
A.PACE
RV.SENSE
IND.SENSE
LV.SENSE
A.SENSE
SENSOR SIGNAL PROCESS
91
INPUT/OUTPUT CIRCUIT
51
OUTPUT AMPLIFIERS CIRCUIT
53
PACE/SENSE ELECTRODE SELECTION & CONTROL
SENSE AMPLIFIERS CIRCUIT
55
RECHARGE
LV.TRIG.
RV.TRIG.
A.TRIG.
A.EVENT
ASP
PVAP
RV.EVENT
LV.EVENT
VSP
89
CRYSTAL OSCILLATOR CIRCUIT
29
VDD
DIGITAL CONTROLLER/ TIMER CIRCUIT
URI./LRI TIMERS 82A
V-V TIMER 82B
INTRINSIC INTERVAL TIMERS 82C
ESCAPE INTERVAL TIMERS 82D
SAV/PAV DELAY TIMER 82E
POST-EVENT TIMERS 82F
DATE/TIME CLOCK 82G
POWER ON RESET
87
43
27
35
ACTIVITY CIRCUIT/ PAS
DATA & CONTROL BUS
VrefBIAS
37
ADC AND MULTI-PLEXER
38
RF TRANS-MITTER AND RECEIVER
41
31
33
80
MICRO-PROCESSOR
SYSTEM CLOCK
RAM 82B
RAM 82A
I2C
RAM/ROM UNIT
MICROCOMPUTER CIRCUIT
67

FIG. 11B

SYSTEMS AND METHODS FOR EVALUATING CARDIAC THERAPY

This application claims the benefit of U.S. Provisional Patent Application 62/031,727 entitled "Systems and Methods for Evaluating Cardiac Therapy" and filed on Jul. 31, 2014, which is incorporated herein by reference in its entirety.

The disclosure herein relates to systems and methods for use in the evaluation of cardiac therapy to be performed or being performed on a patient.

Cardiac therapy, such as cardiac resynchronization therapy (CRT), may correct symptoms of electrical dyssynchrony of a patient's heart by providing pacing therapy to one or both ventricles or atria, e.g., by providing pacing to encourage earlier activation of the left or right ventricles. By pacing the ventricles, the ventricles may be controlled such that they contract in synchrony.

Providing cardiac therapy to a patient may involve determining effective and/or optimal pacing locations (e.g., locations for delivering pacing therapy) and determining effective programming of device parameters. During implantation, the location of one or more electrodes may be adjusted to be positioned in an effective and/or optimal location to deliver pacing therapy to the patient (e.g., for CRT). Further, after implantation, one or more different pacing vectors may be selected to deliver effective and/or optimal pacing therapy to the patient (e.g., for CRT). Additionally, the selection of the timing of the pacing pulses delivered to the electrodes, such as atrioventricular (AV) and interventricular (VV) delays, may also be adjusted to deliver effective and/or optimal pacing therapy.

SUMMARY

The exemplary systems, methods, and interfaces described herein may be configured to assist a user (e.g., a physician) in evaluating cardiac therapy (e.g., cardiac therapy being performed on a patient during and/or after implantation of cardiac therapy apparatus). The systems, methods, and interfaces may be described as being noninvasive. For example, the systems, methods, and interfaces may not need, or include, implantable devices such as leads, probes, sensors, catheters, etc. to evaluate cardiac therapy. Instead, the systems, methods, and interfaces 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.

The exemplary systems and methods may monitor baseline electrical activity (e.g., no cardiac therapy is delivered during baseline monitoring) and therapy electrical activity using a plurality of external electrodes during the delivery of cardiac therapy from the patient. The baseline electrical activity and the therapy electrical activity may be compared to determine whether the cardiac therapy could be improved (e.g., does the cardiac therapy meet or exceed an acceptable level or criterion). If the cardiac therapy may be improved, the exemplary systems and methods may determine location information representative of a pacing, or therapy, location that may be more effective (e.g., may improve upon the previous pacing location) based on the therapy cardiac information.

The pacing, or therapy, location may be changed in multiple ways such as, e.g., moving the pacing electrode, selecting a different pacing vector, etc. If a different pacing vector is to be selected, one or more different cathodes may be selected and/or one or more different anodes may be selected for use in cardiac pacing therapy. The location information generated, or determined, by the exemplary systems and methods may indicate which direction the pacing location may be moved to such as, e.g., a posterior direction, an anterior direction, a lateral direction, etc.

One exemplary system for use in evaluation of cardiac therapy may include electrode apparatus and computing apparatus. The electrode apparatus may include a plurality of external electrodes configured to be located proximate tissue of a patient (e.g., surface electrodes positioned in an array configured to be located proximate the skin of the torso of the patient). The computing apparatus may be coupled to the electrode apparatus and may be configured to monitor electrical activity using the plurality of external electrodes to generate baseline cardiac information (e.g., heterogeneity information) representative of at least one of mechanical cardiac functionality and electrical cardiac functionality and monitor electrical activity using the plurality of external electrodes to generate therapy cardiac information (e.g., heterogeneity information) representative of at least one of mechanical cardiac functionality and electrical cardiac functionality during delivery of pacing therapy at a pacing location. The computing apparatus may be further configured to determine whether the pacing location for the pacing therapy is acceptable based on the baseline cardiac information and the therapy cardiac information (e.g., determining whether a comparison of the baseline cardiac information to the therapy cardiac information satisfies a threshold value) and determine, if the pacing location is determined to be unacceptable, location information (e.g., an anterior direction, a posterior direction, etc.) representative of a location that would be more effective than the pacing location based on the therapy cardiac information.

One exemplary method for use in evaluation of cardiac therapy may include monitoring electrical activity using a plurality of external electrodes proximate tissue of a patient (e.g., surface electrodes positioned in an array configured to be located proximate the skin of the torso of the patient) to generate baseline cardiac information (e.g., heterogeneity information) representative of at least one of mechanical cardiac functionality and electrical cardiac functionality and monitoring electrical activity using the plurality of external electrodes proximate tissue of the patient to generate therapy cardiac information (e.g., heterogeneity information) representative of at least one of mechanical cardiac functionality and electrical cardiac functionality during delivery of pacing therapy at a pacing location. The exemplary method may further include determining whether the pacing location for the pacing therapy is acceptable based on the baseline cardiac information and the therapy cardiac information (e.g., determining whether a comparison of the baseline cardiac information to the therapy cardiac information satisfies a threshold value) and determining, if the pacing location is determined to be unacceptable, location information (e.g., an anterior direction, a posterior direction, etc.) representative of a location that would be more effective than the pacing location based on the therapy cardiac information.

One exemplary system for use in evaluation of cardiac therapy may include electrode means and computing means. The electrode means may include a plurality of external electrodes configured to be located proximate tissue of a patient (e.g., surface electrodes positioned in an array configured to be located proximate the skin of the torso of the patient). The computing means may be for monitoring electrical activity using the plurality of external electrodes to generate baseline cardiac information (e.g., heterogeneity

information) representative of at least one of mechanical cardiac functionality and electrical cardiac functionality and monitoring electrical activity using the plurality of external electrodes to generate therapy cardiac information (e.g., heterogeneity information) representative of at least one of mechanical cardiac functionality and electrical cardiac functionality during delivery of pacing therapy at a pacing location. The computing means may be further for determining whether the pacing location for the pacing therapy is acceptable based on the baseline cardiac information and the therapy cardiac information (e.g., determining whether a comparison of the baseline cardiac information to the therapy cardiac information satisfies a threshold value) and determining, if the pacing location is determined to be unacceptable, location information (e.g., an anterior direction, a posterior direction, etc.) representative of a location that would be more effective than the pacing location based on the therapy cardiac information.

In one or more embodiments, the pacing therapy may be delivered by at least one implantable electrode coupled to at least one lead, and the embodiments may be configured to assist a user in selecting one or more of an implant location for the at least one implantable electrode and a pacing vector to be used with the at least one implantable electrode.

In one or more embodiments, the plurality of external electrodes may include at least one anterior electrode located proximate an anterior side of the patient and at least one posterior electrode locate proximate a posterior side of the patient, and the location information may include an anterior direction if an anterior electrical activation delay monitored by the at least one anterior electrode is greater than a posterior electrical activation delay monitored by the at least one posterior electrode. Further, the location information may include a posterior direction if an anterior electrical activation delay monitored by the at least one anterior electrode is less than or equal to a posterior electrical activation delay monitored by the at least one posterior electrode.

In one or more embodiments, display apparatus may include a graphical user interface that is configured to assist a user in evaluating cardiac pacing location, and the location information may be displayed on the graphical user interface. In at least one embodiment, a graphical representation of surrogate cardiac electrical activation times from the electrical activity monitored during the delivery of pacing therapy at the pacing location about a portion of human anatomy may be displayed on the graphical user interface. In at least one embodiment, the portion of human anatomy on the graphical user interface may be color-scaled according to the surrogate cardiac electrical activation times.

In one or more embodiments, monitoring electrical activity using the plurality of external electrodes may include adjusting a parameter of the pacing therapy at least twice and monitoring the electrical activity using the plurality of external electrodes to generate therapy cardiac information for each adjustment. In at least on embodiment, the parameter includes at least one of a pacing timing interval, a pacing vector, and a pacing mode.

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

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

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

FIG. **4** is a block diagram of an exemplary method for cardiac therapy evaluation.

FIG. **5** is an exemplary graphical user interface depicting therapy cardiac information including graphical electrical activation information and electrical heterogeneity information.

FIG. **6** depicts three electrical signals corresponding to the therapy cardiac information of FIG. **5**.

FIG. **7** is another exemplary graphical user interface depicting therapy cardiac information including graphical electrical activation information and electrical heterogeneity information.

FIG. **8** depicts three electrical signals corresponding to the therapy cardiac information of FIG. **7**.

FIG. **9** is a diagram of an exemplary system including an exemplary implantable medical device (IMD).

FIG. **10**A is a diagram of the exemplary IMD of FIG. **9**.

FIG. **10**B is a diagram of an enlarged view of a distal end of the electrical lead disposed in the left ventricle of FIG. **10**A.

FIG. **11**A is a block diagram of an exemplary IMD, e.g., of the systems of FIGS. **9-10**.

FIG. **11**B is another block diagram of an exemplary IMD (e.g., an implantable pulse generator) circuitry and associated leads employed in the systems of FIGS. **9-10**.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

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.

Exemplary systems and methods shall be described with reference to FIGS. **1-11**. 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 methods and systems 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.

Cardiac electrical activation times can be detected or estimated in proximity of a reference location (e.g., which can be a chosen location for the left ventricle lead during implant) using unipolar electrocardiogram (ECG) recordings. Such electrical activation times may be measured and displayed, or conveyed, to an implanter by a system which acquires the ECG signals and generates the metric of electrical activation times (e.g., depolarization) measured from various ECG locations. As described herein, at least in one or more embodiments, electrical activation times displayed on a graphical user interface may be used in noninvasive evaluation of cardiac therapy.

Various exemplary systems, methods, and 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 therapy. An exemplary system **100** including electrode apparatus **110**, display apparatus **130**, and computing apparatus **140** is depicted in FIG. **1**.

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. Exemplary electrode apparatus may be described in U.S. patent application Ser. No. 14/227,719 entitled "Bioelectric Sensor Device and Methods" and filed Mar. 27, 2014, which is incorporated herein by reference in its entirety. Further, exemplary electrode apparatus **110** will be described in more detail in reference to FIGS. **2-3**.

Although not described herein, the exemplary 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 exemplary 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 select a pacing electrode or pacing vector proximate the patient's heart in conjunction with the evaluation of cardiac therapy.

For example, the exemplary systems, methods, and interfaces 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 evaluation including determining location information (e.g., location information for the electrodes). Exemplary systems and methods that use imaging apparatus and/or electrode apparatus may be described in U.S. patent application Ser. No. 13/916,353 filed on Jun. 12, 2013 and entitled "Implantable Electrode Location Selection," U.S. patent application Ser. No. 13/916,377 filed on Jun. 12, 2013 and entitled "Implantable Electrode Location Selection," U.S. patent application Ser. No. 14/227,955 filed on Mar. 27, 2014 and entitled "Systems, Methods, and Interfaces for Identifying Effective Electrodes," U.S. patent application Ser. No. 14/227,919 filed on Mar. 27, 2014 and entitled "Systems, Methods, and Interfaces for Identifying Optical Electrical Vectors," each of which is incorporated herein by reference in its entirety.

Exemplary 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. 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 treatment apparatus proximate target locations within the heart or other areas of interest.

Systems and/or imaging apparatus that may be used in conjunction with the exemplary systems and method described herein are described in U.S. Pat. App. Pub. No. 2005/0008210 to Evron et al. published on Jan. 13, 2005, U.S. Pat. App. Pub. No. 2006/0074285 to Zarkh et al. published on Apr. 6, 2006, U.S. Pat. App. Pub. No. 2011/0112398 to Zarkh et al. published on May 12, 2011, U.S. Pat. App. Pub. No. 2013/0116739 to Brada et al. published on May 9, 2013, U.S. Pat. No. 6,980,675 to Evron et al. issued on Dec. 27, 2005, U.S. Pat. No. 7,286,866 to Okerlund et al. issued on Oct. 23, 2007, U.S. Pat. No. 7,308,297 to Reddy et al. issued on Dec. 11, 2011, U.S. Pat. No. 7,308,299 to Burrell et al. issued on Dec. 11, 2011, U.S. Pat. No. 7,321,677 to Evron et al. issued on Jan. 22, 2008, U.S. Pat. No. 7,346,381 to Okerlund et al. issued on Mar. 18, 2008, U.S. Pat. No. 7,454,248 to Burrell et al. issued on Nov. 18, 2008, U.S. Pat. No. 7,499,743 to Vass et al. issued on Mar. 3, 2009, U.S. Pat. No. 7,565,190 to Okerlund et al. issued on Jul. 21, 2009, U.S. Pat. No. 7,587,074 to Zarkh et al. issued on Sep. 8, 2009, U.S. Pat. No. 7,599,730 to Hunter et al. issued on Oct. 6, 2009, U.S. Pat. No. 7,613,500 to Vass et al. issued on Nov. 3, 2009, U.S. Pat. No. 7,742,629 to Zarkh et al. issued on Jun. 22, 2010, U.S. Pat. No. 7,747,047 to Okerlund et al. issued on Jun. 29, 2010, U.S. Pat. No. 7,778,685 to Evron et al. issued on Aug. 17, 2010, U.S. Pat. No. 7,778,686 to Vass et al. issued on Aug. 17, 2010, U.S. Pat. No. 7,813,785 to Okerlund et al. issued on Oct. 12, 2010, U.S. Pat. No. 7,996,063 to Vass et al. issued on Aug. 9, 2011, U.S. Pat. No. 8,060,185 to Hunter et al. issued on Nov. 15, 2011, and U.S. Pat. No. 8,401,616 to Verard et al. issued on Mar. 19, 2013, each of which is incorporated herein by reference in its entirety.

The display apparatus **130** and the computing apparatus **140** may be configured to display and analyze data such as, e.g., electrical signals (e.g., electrocardiogram data), cardiac information representative of at least one of mechanical cardiac functionality and electrical cardiac functionality, etc. Cardiac information may include, e.g., electrical heterogeneity information or electrical dyssynchrony information, surrogate electrical activation information or data, etc. that is generated using electrical signals gathered, monitored, or collected, using the electrode apparatus **110**. In at least one embodiment, the computing apparatus **140** may be a server, a personal computer, or a tablet computer. The computing apparatus **140** may be configured to receive input from input apparatus **142** and transmit output to the display apparatus **130**. Further, the computing apparatus **140** 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

driving a graphical user interface configured to noninvasively assist a user in evaluating a pacing location (e.g., the location of an implantable electrode used for pacing, the location of pacing therapy delivered by a particular pacing vector, etc.).

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**. For example, the computing apparatus **140** may be electrically coupled to each of the input apparatus **142** and the display apparatus **130** 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** to manipulate, or modify, one or more graphical depictions displayed on the display apparatus **130** and to view and/or select one or more pieces of information related to the cardiac therapy.

Although as depicted the input apparatus **142** is a keyboard, it is to be understood that the input apparatus **142** may include any apparatus capable of providing input to the computing apparatus **140** to perform the functionality, methods, and/or logic described herein. For example, the input apparatus **142** may include a mouse, a trackball, a touchscreen (e.g., capacitive touchscreen, a resistive touchscreen, a multi-touch touchscreen, etc.), etc. Likewise, the display apparatus **130** may include any apparatus capable of displaying information to a user, such as a graphical user interface **132** including cardiac information, textual instructions, graphical depictions of electrical activation information, 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** may include a liquid crystal display, an organic light-emitting diode screen, a touchscreen, a cathode ray tube display, etc.

The processing programs or routines stored and/or executed by the computing apparatus **140** 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 required to implement one or more exemplary methods and/or processes described herein. Data stored and/or used by the computing apparatus **140** may include, for example, electrical signal/waveform data from the electrode apparatus **110**, electrical activation times from the electrode apparatus **110**, 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, cardiac information, etc.), or any other data that may be necessary for carrying out the one and/or more processes or methods described herein.

In one or more embodiments, the exemplary 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.

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 exemplary systems, methods, and/or 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 exemplary systems, methods, and/or 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, is operable to perform operations such as the methods, processes, and/or functionality described herein.

The computing apparatus **140** may be, for example, any fixed or mobile computer system (e.g., a controller, a microcontroller, a personal computer, mini computer, tablet computer, etc.). The exact configuration of the computing apparatus **140** is not limiting, and essentially any device capable of providing suitable computing capabilities and control capabilities (e.g., 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 computing apparatus **140** 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.

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.

Electrical activation times of the patient's heart may be useful to evaluate cardiac therapy being delivered to a patient. Surrogate electrical activation information or data of one or more regions of a patient's heart may be monitored, or determined, using electrode apparatus **110** as shown in FIG. **1** and in FIG. **2-3**. The exemplary 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 exemplary

electrode apparatus **110** may include a set, or array, of 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**.

Further, the electrodes **112** 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 provide the signals to the computing apparatus **140**. Other exemplary systems may use a wireless connection to transmit the signals sensed by electrodes **112** to the interface/amplifier circuitry **116** and, in turn, the computing apparatus **140**, e.g., as channels of data. For example, the interface/amplifier circuitry **116** may be electrically coupled to each of the computing apparatus **140** and the display apparatus **130** using, e.g., analog electrical connections, digital electrical connections, wireless connections, bus-based connections, network-based connections, internet-based connections, etc.

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**. In some examples, the strap **113** may include an elastic band, strip of tape, or cloth. In other examples, the electrodes **112** may be placed individually on the torso of a patient **14**. Further, in other examples, electrodes **112** (e.g., arranged in an array) may be part of, or located within, patches, vests, and/or other manners of securing the electrodes **112** to the torso of the patient **14**. Still further, in other examples, the electrodes **112** may be part of, or located within, two sections of material or two "patches." One of the two sections or 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) and the other section or 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).

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. In some examples, there may be about 12 to about 50 electrodes **112** spatially distributed around the torso of patient. Other configurations may have more or fewer electrodes **112**.

The computing apparatus **140** may record and analyze the torso-surface potential signals sensed by electrodes **112** and amplified/conditioned by the interface/amplifier circuitry **116**. The computing apparatus **140** may be configured to analyze the signals from the electrodes **112** to provide surrogate electrical activation information or data such as surrogate cardiac electrical activation times, e.g., representative of actual, or local, electrical activation times of one or more regions of the patient's heart as will be further described herein. For example, electrical signals measured at the left anterior surface location of a patient's torso may be representative, or surrogates, of electrical signals of the left anterior left ventricle region of the patient's heart, electrical signals measured at the left lateral surface location of a patient's torso may be representative, or surrogates, of electrical signals of the left lateral left ventricle region of the patient's heart, electrical signals measured at the left posterolateral surface location of a patient's torso may be representative, or surrogates, of electrical signals of the posterolateral left ventricle region of the patient's heart, and electrical signals measured at the posterior surface location of a patient's torso may be representative, or surrogates, of electrical signals of the posterior left ventricle region of the patient's heart. In one or more embodiments, measurement of activation times can be performed by measuring the period of time between an onset of cardiac depolarization (e.g., onset of QRS complex) and the next onset of cardiac depolarization. In one or more embodiments, measurement of activation times can be performed by picking an appropriate fiducial point (e.g., peak values, minimum values, minimum slopes, maximum slopes, zero crossings, threshold crossings, etc. of a near or far-field EGM) and measuring time between fiducial points (e.g., within the electrical activity).

Additionally, the computing apparatus **140** may be configured to provide graphical user interfaces depicting the surrogate electrical activation times obtained using the electrode apparatus **110**. Exemplary systems, methods, and/or interfaces may noninvasively use the electrical information collected using the electrode apparatus **110** to evaluate cardiac therapy being delivered to the patient.

FIG. **3** illustrates another exemplary 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**. The electrode apparatus **110** may include a vest **114** upon which the plurality of electrodes **112** may be attached, or to which the electrodes **112** 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** through a wired connection **118** and be configured to transmit signals from the electrodes **112** to computing apparatus **140**. As illustrated, the electrodes **112** may be distributed over the torso of a patient **14**, including, for example, the anterior, lateral, posterolateral, anterolateral, and posterior surfaces of the torso of the patient **14**.

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

As described herein, the electrode apparatus **110** may be configured to measure electrical information (e.g., electrical signals) representing different regions of a patient's heart. For example, activation times of different regions of a

patient's heart can be approximated from surface electrocardiogram (ECG) activation times measured using surface electrodes in proximity to surface areas corresponding to the different regions of the patient's heart.

The exemplary systems, methods, and interfaces may be used to provide noninvasive assistance to a user in the evaluation of cardiac therapy (e.g., cardiac therapy being presently-delivered to a patient during implantation or after implantation). Further, the exemplary systems, methods, and interfaces may be used to assist a user in the configuration of the cardiac therapy being delivered to a patient.

Exemplary method **200** depicted in FIG. **4** may be used to provide this functionality. The exemplary method **200** may be generally described to be used in the noninvasive evaluation of cardiac therapy. The exemplary method **200** may be described as being noninvasive because the method does not use invasive apparatus to perform the evaluation of the cardiac therapy. The cardiac therapy being delivered, however, may be described as being invasive such as, e.g., one or more pacing electrodes implanted proximate a patient's heart. The exemplary method **200** may be used to evaluate the invasive cardiac therapy.

The exemplary method **200** may include monitoring, or measuring, electrical activity using a plurality of external electrodes **202**. The electrical activity monitored during process **202** may be referred to as "baseline" electrical activity because no therapy is delivered to the patient such that the patient's heart is in its natural, or intrinsic, rhythm.

The plurality of external electrodes may be similar to the external electrodes provided by the electrode apparatus **110** as described herein with respect to FIGS. **1-3**. For example, the plurality of external electrodes may be part, or incorporated into, a vest or band that is located about a patient's torso. More specifically, the plurality of electrodes may be described as being surface electrodes positioned in an array configured to be located proximate the skin of the torso of a patient.

The monitored baseline electrical activity may be used to generate baseline cardiac information. The baseline cardiac information may be described as information, or data, representative of at least one of mechanical cardiac functionality and electrical cardiac functionality. The baseline cardiac information may include electrical heterogeneity information. Electrical heterogeneity information and other cardiac therapy information may be described in U.S. Provisional Patent Application No. 61/834,133 entitled "METRICS OF ELECTRICAL DYSSYNCHRONY AND ELECTRICAL ACTIVATION PATTERNS FROM SURFACE ECG ELECTRODES" and filed on Jun. 12, 2013, which is hereby incorporated by reference it its entirety.

Electrical heterogeneity information may be defined as information indicative of at least one of mechanical synchrony or dyssynchrony of the heart and/or electrical synchrony or dyssynchrony of the heart. In other words, electrical heterogeneity information may represent a surrogate of actual mechanical and/or electrical functionality. In at least one embodiment, electrical heterogeneity information may be used to determine a surrogate value representative of the maximum left ventricular pressure rate. The left ventricular pressure may be typically monitored invasively with a pressure sensor located in the left ventricular of a patient's heart. As such, the use of electrical heterogeneity information to determine a surrogate value representative of the maximum left ventricular pressure rate may avoid invasive monitoring using a left ventricular pressure sensor.

In at least one embodiment, the electrical heterogeneity information may include a standard deviation of ventricular activation times corresponding to some or all of the external electrodes, e.g., of the electrode apparatus **110**. Further, regional electrical heterogeneity information may be include standard deviations and/or averages of activation times corresponding to electrodes located in certain anatomic areas of the torso. For example, external electrodes on the left side of the torso of a patient may be used to compute regional left electrical heterogeneity information.

The electrical heterogeneity information may be generated using one or more various systems and/or methods. Electrical heterogeneity information may be generated using an array, or a plurality, of surface electrodes and/or imaging systems as described in U.S. Pat. App. Pub. No. 2012/0283587 A1 published Nov. 8, 2012 and entitled "ASSESSING INRA-CARDIAC ACTIVATION PATTERNS AND ELECTRICAL DYSSYNCHRONY," U.S. Pat. App. Pub. No. 2012/0284003 A1 published Nov. 8, 2012 and entitled "ASSESSING INTRA-CARDIAC ACTIVATION PATTERNS", and U.S. Pat. No. 8,180,428 B2 issued May 15, 2012 and entitled "METHODS AND SYSTEMS FOR USE IN SELECTING CARDIAC PACING SITES," each of which is incorporated herein by reference in its entirety.

Electrical heterogeneity information may include one or more metrics or indices. For example, one of the metrics, or indices, of electrical heterogeneity may be a standard deviation of activation-times (SDAT) measured by some or all of the electrodes on the surface of the torso of patient. In some examples, the SDAT may be calculated using the estimated cardiac activation times over the surface of a model heart.

Another metric, or index, of electrical heterogeneity may be a left standard deviation of surrogate electrical activation times (LVED) monitored by external electrodes located proximate the left side of patient. Further, another metric, or index, of electrical heterogeneity may include an average of surrogate electrical activation times (LVAT) monitored by external electrodes located proximate the left side of patient. The LVED and LVAT may be determined (e.g., calculated, computed, etc.) from electrical activity measured only by electrodes proximate the left side of the patient, which may be referred to as "left" electrodes. The left electrodes may be defined as any surface electrodes located proximate the left ventricle, which includes region to left of the patient's sternum and spine. In one embodiment, the left electrodes may include all anterior electrodes on the left of the sternum and all posterior electrodes to the left of the spine. In another embodiment, the left electrodes may include all anterior electrodes on the left of the sternum and all posterior electrodes. In yet another embodiment, the left electrodes may be designated based on the contour of the left and right sides of the heart as determined using imaging apparatus (e.g., x-ray, fluoroscopy, etc.).

Another exemplary metric, or index, of dyssynchrony may be a range of activation times (RAT) that may be computed as the difference between the maximum and the minimum torso-surface or cardiac activation times, e.g., overall, or for a region. The RAT reflects the span of activation times while the SDAT gives an estimate of the dispersion of the activation times from a mean. The SDAT also provides an estimate of the heterogeneity of the activation times, because if activation times are spatially heterogeneous, the individual activation times will be further away from the mean activation time, indicating that one or more regions of heart have been delayed in activation. In some examples, the RAT may be calculated using the estimated cardiac activation times over the surface of a model heart.

Another exemplary metric, or index, of electrical heterogeneity information may include estimates of a percentage of surface electrodes located within a particular region of interest for the torso or heart whose associated activation times are greater than a certain percentile, such as, for example the 70th percentile, of measured QRS complex duration or the determined activation times for surface electrodes. The region of interest may, e.g., be a posterior, left anterior, and/or left-ventricular region. The exemplary metric, or index, may be referred to as a percentage of late activation (PLAT). The PLAT may be described as providing an estimate of percentage of the region of interest, e.g., posterior and left-anterior area associated with the left ventricular area of heart, which activates late. A large value for PLAT may imply delayed activation of a substantial portion of the region, e.g., the left ventricle, and the potential benefit of electrical resynchronization through CRT by pre-exciting the late region, e.g., of left ventricle. In other examples, the PLAT may be determined for other subsets of electrodes in other regions, such as a right anterior region to evaluate delayed activation in the right ventricle. Furthermore, in some examples, the PLAT may be calculated using the estimated cardiac activation times over the surface of a model heart for either the whole heart or for a particular region, e.g., left or right ventricle, of the heart.

In one or more embodiments, the cardiac information may include indicators of favorable changes in global cardiac electrical activation such as, e.g., described in Sweeney et al., "Analysis of Ventricular Activation Using Surface Electrocardiography to Predict Left Ventricular Reverse Volumetric Remodeling During Cardiac Resynchronization Therapy," Circulation, 2010 Feb. 9, 121(5): 626-34 and/or Van Deursen, et al., "Vectorcardiography as a Tool for Easy Optimization of Cardiac Resynchronization Therapy in Canine LBBB Hearts," Circulation Arrhythmia and Electrophysiology, 2012 Jun. 1, 5(3): 544-52, each of which is incorporated herein by reference in its entirety. Cardiac information may also include measurements of improved cardiac mechanical function measured by imaging or other systems to track motion of implanted leads within the heart as, e.g., described in Ryu et al., "Simultaneous Electrical and Mechanical Mapping Using 3D Cardiac Mapping System: Novel Approach for Optimal Cardiac Resynchronization Therapy," Journal of Cardiovascular Electrophysiology, 2010 February, 21(2): 219-22, Sperzel et al., "Intraoperative Characterization of Interventricular Mechanical Dyssynchrony Using Electroanatomic Mapping System—A Feasibility Study," Journal of Interventional Cardiac Electrophysiology, 2012 November, 35(2): 189-96, and/or U.S. Pat. App. Pub. No. 2009/0099619 A1 entitled "METHOD FOR OPTIMIZAING CRT THERAPY" and published on Apr. 16, 2009, each of which is incorporated herein by reference in its entirety.

After the collection of electrical activity for the generation of baseline cardiac information **202**, the exemplary method **200** may initiate the delivery of cardiac therapy **204** such as, e.g., cardiac pacing therapy. The cardiac therapy **204** may be delivered by at least one implantable electrode coupled to at least one lead. In at least one embodiment, the cardiac therapy **204** may be delivered by a leadless electrode. Exemplary cardiac therapy may be further described herein with reference to FIGS. **9-11**. As described herein, although the cardiac therapy delivery may be described as being invasive, the exemplary method may be described as non-invasive because the exemplary method may only initiate the delivery of the cardiac therapy and further uses electrical signals that are monitored, or taken, from the patient non-invasively.

Similar to process **202**, the exemplary method **200** may include monitoring, or measuring, electrical activity using a plurality of external electrodes **206** during the delivery of the cardiac therapy **204**. The electrical activity may be referred to as "therapy" electrical activity because cardiac therapy is being delivered to the patient. The plurality of external electrodes may be the same electrodes used to monitor baseline electrical activity **202** and may be located in the same location, or position, as the same electrodes used to monitor baseline electrical activity **202** (e.g., the electrodes may not have been moved, removed, or repositioned after monitoring baseline electrical activity **202**). The electrodes may be similar to the external electrodes provided by the electrode apparatus **110** as described herein with respect to FIGS. **1-3**.

The monitored therapy electrical activity may be used to generate therapy cardiac information. The therapy cardiac information may be described as information, or data, representative of at least one of mechanical cardiac functionality and electrical cardiac functionality during the delivery of cardiac therapy. Further, therapy cardiac information may include the same, or similar, information as described herein with respect to the baseline cardiac information.

During the delivery of cardiac therapy **204** and the monitoring of electrical activity to generate therapy cardiac information **206**, the exemplary method may further modify, or adjust, one or more pacing parameters, each for a selected period of time, to, e.g., obtain therapy cardiac information for each of the one or more pacing parameters. The pacing parameters may include one or more of a pacing time interval (e.g., sensed atrioventricular (AV) delay, paced AV delay, sensed interventricular (VV) delay, paced interventricular (VV) delay, etc.), a pacing vector, and a pacing mode.

For example, pacing therapy may be delivered at a given, or selected, left ventricular location at a plurality of sensed AV delays such as, e.g., 90 milliseconds (ms), 60 ms, and 30 ms. The electrical activity used to generate the therapy cardiac information may be monitored for each of the plurality of sensed AV delays.

The exemplary method **200** may then determine whether the therapy, or pacing, location is acceptable **208** based on the baseline cardiac information and the therapy cardiac information. As used herein, therapy or pacing location may be defined as the one or more locations of the apparatus used to deliver the cardiac therapy to the patient. For example, a pacing location may be the location of the pacing electrode used as the cathode in a pacing vector. In other examples, the pacing location may be a plurality of locations of pacing electrodes (e.g. cathodes and/or anodes) used in pacing vectors (e.g., used in multipoint pacing, etc.).

The baseline cardiac information and the therapy cardiac information may be compared to determine whether the pacing, or therapy, location is acceptable (e.g., effective in delivering therapy). In at least one embodiment, the results from the comparison between the baseline cardiac information and the therapy cardiac information may be analyzed in view of one or more threshold values. If the cardiac therapy was adjusted, the therapy cardiac information for each of the cardiac therapy adjustments may be compared to the baseline cardiac information to determine if the pacing location is acceptable for any of the cardiac adjustments.

In at least one embodiment, the exemplary method **200** analyzes whether the delivery of cardiac therapy results in a

reduction in electrical dyssynchrony from the patient's intrinsic, or natural, rhythm. The reduction in electrical dyssynchrony may be based on one or more metrics, or indices, as described herein with respect to the electrical heterogeneity. Further, the metrics may be used in combination (e.g., some metrics of dyssynchrony may be valued more than others, etc.). In at least one embodiment, the reduction in electrical dyssynchrony may be based on SDAT.

Further, the reduction may be computed as a percentage, and a threshold value may be greater than or equal to about 10%. For example, if the reduction in electrical dyssynchrony of the therapy cardiac information relative to the baseline cardiac information is greater than or equal to 10%, then the pacing, or therapy, location may be determined to be acceptable. In some embodiments, the threshold value may be greater than or equal about 5%, greater than or equal about 15%, greater than or equal about 20%, greater than or equal about 25%, greater than or equal about 30%, greater than or equal about 40%, greater than or equal about 50%, etc. In some embodiments, the threshold value may be less than or equal to about 75%, less than or equal to about 60%, less than or equal to about 50%, less than or equal to about 40%, less than or equal to about 35%, less than or equal to about 30%, less than or equal to about 25%, etc.

If the exemplary method **200** determines that the pacing location is acceptable based on the baseline cardiac information and the therapy cardiac information **208**, the pacing, or therapy, location may be determined to be acceptable **210**. If the exemplary method **200** determines that the pacing location is unacceptable **208**, the method **200** may then determine location information (e.g., alternative location information) for the cardiac therapy **212**. As used herein, location information may include information representative of a location that may be more effective than the current, or present, pacing location.

The location information may be determined based on the therapy cardiac information. For example, electrical activation times from the therapy cardiac information may be evaluated and used to determine the location information. More specifically, averages, standard deviations, medians, modes, ranges, interquartile deviations, other statistical measures of central tendency and dispersion, etc. of electrical activation times for one or more regions or areas of the patient may be used to evaluate and/or determine the location information. Further, the metric of electrical activation times for one region may be compared to the metric of electrical activation times for another region. In some embodiments, if the metric of electrical activation for a first region is greater than the metric of electrical activation for a second region, then the location information may be determined to move the pacing location towards the first or second region depending on the metric used. Generally, the location information may indicate movement towards a region that indicates slower electrical activation such that, e.g., movement of pacing towards the slow electrically activated region will increase the activation times of the slow electrically activated region.

In at least one embodiment, one or more external electrodes located on the posterior side of the torso of the patient, or posterior electrodes, and one or more external electrodes located on the anterior side of the torso of the patient, or anterior electrodes, may be used to monitor, or capture, electrical activation times for the posterior and anterior, respectively, of the patient. If the posterior electrical activation delays monitored by the posterior electrodes (e.g., one posterior electrode, all the posterior electrodes, a selected portion of posterior electrodes, etc.) are greater than or equal to the anterior electrical activation delays monitored by anterior electrodes (e.g., one anterior electrode, all the anterior electrodes, a selected portion of anterior electrodes, etc.), then the exemplary method **200** may determine location information that indicates that the cardiac therapy should be moved in a posterior direction **214**. Conversely, if the anterior electrical activation delays monitored by the anterior electrodes are greater than the posterior electrical activation delays monitored by posterior electrodes, then the exemplary method **200** may determine location information that indicates that the cardiac therapy should be moved in an anterior direction **216**.

Although the anterior and posterior directions are described more specifically, it is to be understood that the location information may include more than the anterior direction and posterior direction such as anterior-lateral (e.g., anterior-lateral may be more posterior than anterior), lateral (e.g., lateral is more posterior than anterior-lateral), posterior-lateral (e.g., posterior-lateral is more posterior to lateral), etc.

After the location information is determined **212**, **214**, **216**, the location information may be provided (e.g., displayed on a graphical user interface, etc.) to a user. The user may then re-position the cardiac therapy based on the location information. For example, the user may move a lead upon which a pacing electrode is attached to different location based on the location information. If the location information included a posterior direction, the user may move the pacing electrode posteriorly, or in a posterior direction, to a new pacing location. Conversely, if the location information included an anterior direction, the user may move the pacing electrode anteriorly, or in an anterior direction, to a new pacing location.

Instead of physically moving the pacing electrode, a user may select a different pacing vector (e.g., using one or more different pacing electrodes) to move the therapy in the direction as indicated by the location information. For example, if the location information included a posterior direction, the user may select a pacing vector that delivers pacing therapy in a new location that is closer to the posterior of the patient than the previous pacing location. Conversely, if the location information included an anterior direction, the user may select a pacing vector that delivers pacing therapy in a new location that is closer to the anterior of the patient than the previous pacing location.

Further, as indicated by the dotted line extending from processes **214**, **216** to process **202**, the exemplary method **200** may be performed again with the baseline electrical activity being monitor during cardiac therapy being delivered using the new pacing location. In other embodiments, the method **200** may be iterative and a user may continue using the method **200** until the user is satisfied with the pacing location.

As described herein with reference to FIG. **1**, the exemplary systems and methods described herein may use display apparatus **130** including a graphical user interface **132**. The graphical user interface **132** may be configured to, among other things, present information for use in assisting a user in evaluating a cardiac pacing, or therapy, location, in assisting a user in assessing a patient's cardiac health, in assisting a user in navigating at least one implantable electrode to a region of the patient's heart, etc. For example, the graphical user interface **132** may be configured to display the location information determined by method **200**.

Further, the graphical user interface **132** may be configured to depict, or display, a graphical representation of surrogate cardiac electrical activation times from the moni-

tored electrical activity about a portion of human anatomy monitored during intrinsic rhythm and/or during the delivery of cardiac therapy. In at least one embodiment, the surrogate cardiac electrical activation times may be represented about a portion of human anatomy by color scaling a portion of human anatomy on the graphical user interface **132** according to the surrogate cardiac electrical activation times.

An exemplary graphical user interface (GUI) **150** for use in evaluating cardiac therapy is depicted in FIG. **5**. As shown, the GUI **150** may include, among other things, a graphical representation **160** of measured surrogate electrical activation times and cardiac information **170** for cardiac resynchronization therapy pacing using a left ventricular lead located in an anterolateral branch of the coronary sinus.

The graphical representation **160** of measured surrogate cardiac electrical activation times may be depicted in a variety of fashions. As shown, the surrogate electrical activation times are shown as a color-coded, or color-scaled, segment **162** (although shown in grayscale) extending over, or wrapped around, a graphical representation of a human torso **164**, **166**. More specifically, an anterior side of a human torso **164** and a posterior side of a human torso **166** are depicted, each including a color-coded segment **162** graphically depicting surrogate electrical activation times measured, e.g., using the electrical apparatus described herein with reference to FIGS. **1-3**. Further, the graphical representation **160** of measured surrogate cardiac electrical activation times shown on the anterior side of a human torso **164** may be measured using electrodes located on, or proximate to, the anterior side of the patient's torso, and likewise, the graphical representation **160** of measured surrogate cardiac electrical activation times shown on the posterior side of the human torso **166** may be measured using electrodes located on, or proximate to, the posterior side of the patient's torso. In other words, the graphical representation **160** of measured surrogate cardiac electrical activation times shown on the anterior side of the human torso **164** correlates to actual electrical signals measured using electrodes configured to measure electrical signals on the anterior side of the patient's torso, and the graphical representation **160** of measured surrogate cardiac electrical activation times shown on the posterior side of the human torso **166** correlates to actual electrical signals measured using electrodes configured to measure electrical signals on the posterior side of the patient's torso. The graphical representation **160** further includes a color-coded scale **169** (although shown in grayscale) corresponding to the color-coded segments **162**, to, e.g., provide basis for the coloring of the color-coded segments **162**.

Additional exemplary graphical representations of surrogate electrical activation times may be described in U.S. Patent Application Publication No. 2012/0284003 A1 published on Nov. 8, 2012 and entitled "Assessing Intra-Cardiac Activation Patterns" and U.S. Patent Application Publication No. 2012/0283587 A1 published on Nov. 8, 2012 and entitled "Assessing Intra-Cardiac Activation Patterns and Electrical Dyssynchrony," each of which is hereby incorporated by reference in its entirety.

In other embodiments, the surrogate electrical activation times may be color-coded across the entire graphical depiction of a human torso and/or any smaller or larger part of human anatomy. Further, in at least one embodiment, the graphical depictions of a human torso **164**, **166** may be actual images of the patient being evaluated. The surrogate cardiac electrical activation times may be further depicted alphanumerically over a graphical depiction of human anatomy. For example, a plurality of surrogate cardiac electrical activation times in milliseconds may be graphically overlaid over the torsos **164**, **166**. In one or more embodiments, the graphical depiction of a portion of human anatomy displayed on the exemplary graphical user interfaces may include a graphical representation of a human heart.

The exemplary GUI **150** of FIG. **5** further includes cardiac information **170** representative of at least one of mechanical cardiac functionality and electrical cardiac functionality. As shown, the cardiac information **170** includes electrical dyssynchrony (e.g., a global dyssynchrony metric, or index, such as SDAT) generated by the cardiac therapy being delivered, which is 50 ms, and the percentage increase from the baseline electrical dyssynchrony, which is 25%. The cardiac information **170** was generated by cardiac therapy being delivered from a lateral location of the LV lead.

Since the electrical dyssynchrony has increased, the exemplary systems and methods may determine that the pacing location is unacceptable, and thus, may determine location information based on the therapy cardiac information. As shown by the color-coded segments **162** about the anterior and posterior torsos **164**, **166** of the patient, the delayed electrical activation appears to be primarily in the posterior areas, and thus, the determined location information may include a posterior direction (e.g., move the therapy in a posterior direction).

Additionally, an electrical signal **180** monitored by one or more right lateral external electrodes, an electrical signal **182** monitored by one or more left posterior external electrodes, and an electrical signal **184** monitored by one or more left lateral external electrodes electrical signals is depicted in FIG. **6** that correspond to the therapy cardiac information shown in FIG. **5**. As can be seen by these signals, the signals in FIG. **6** are out of phase indicating presence of electrical heterogeneity and a lack of synchrony. Also, from the cardiac map **162** in FIG. **5**, it may be apparent that most of the delay (e.g., blue color-coded area) is in the posterior area, which indicates that cardiac therapy (LV pacing lead) may be moved more posteriorly to correct the electrical delay seen on the posterior side during pacing therapy from the current location. Further, such signals **180**, **182**, **184** may be displayed on the graphical user interface **150**, e.g., if a user would like to view them.

Another exemplary GUI **151** for use in evaluating cardiac therapy is depicted in FIG. **7**. Similar to the GUI **150**, the GUI **151** may include, among other things, a graphical representation **160** of measured surrogate electrical activation times and cardiac information **170**. In this example, the graphical representation **160** of measured surrogate electrical activation times and the cardiac information **170** are monitored, or generated, from cardiac resynchronization therapy pacing using a left ventricular lead located in a posterolateral branch of the coronary sinus. The posterolateral branch of the coronary is more posterior than the previous lateral location that generated the cardiac information of FIGS. **5-6**.

As shown, the cardiac information **170** includes electrical dyssynchrony generated by the cardiac therapy being delivered, which is 15 ms, and the percentage decrease, or reduction, from the baseline electrical dyssynchrony, which is 62.5%. Since the electrical dyssynchrony has decreased, the exemplary systems and methods may determine that the pacing location is acceptable.

Additionally, an electrical signal **181** monitored by one or more right lateral external electrodes, an electrical signal **183** monitored by one or more left posterior external electrodes, and an electrical signal **185** monitored by one or

more left lateral external electrodes electrical signals is depicted in FIG. **8** that correspond to the therapy cardiac information shown in FIG. **7**. As can be seen in FIG. **8**, these signals are in-phase and are indicative of successful electrical resynchronization. Further, such signals **181**, **183**, **185** may be displayed on the graphical user interface **151**, e.g., if a user would like to view them.

The exemplary systems, methods, and graphical user interfaces described herein may be used with respect to the implantation and configuration of an implantable medical device (IMD) and/or one or more leads configured to be located proximate one or more portions of a patient's heart. For example, the exemplary systems, methods, and interfaces may be used in conjunction with an exemplary therapy system **10** described herein with reference to FIGS. **9-11**.

FIG. **9** is a conceptual diagram illustrating an exemplary 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**.

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. **9**, 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**.

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., AV 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, quadripoloar, 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.

FIGS. **10A-10B** are conceptual diagrams illustrating the IMD **16** and the leads **18**, **20**, **22** of therapy system **10** of FIG. **9** 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.

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**.

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**.

Additionally, electrodes **44**, **45**, **46** and **47** may have an electrode surface area of about 5.3 mm^2 to about 5.8 mm^2. Electrodes **44**, **45**, **46**, and **47** may also be referred to as LV**1**, LV**2**, LV**3**, and LV**4**, respectively. The LV electrodes (i.e., left ventricle electrode **1** (LV**1**) **44**, left ventricle electrode **2** (LV**2**) **45**, left ventricle electrode **3** (LV**3**) **46**, and left ventricle **4** (LV**4**) **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.

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. **10A**, 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.

As described in further detail with reference to FIG. **10**A, 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 patients 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).

The configuration of the exemplary therapy system **10** illustrated in FIGS. **9**-**11** 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. **9**. 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. **9**). 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.

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. **9**-**11**. 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**.

FIG. **11**A is a functional block diagram of one exemplary 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**.

The control module **81** may include a processor **80**, memory **82**, and a telemetry module **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 exemplary 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 Mar. 23, 2010, which is incorporated herein by reference in its entirety.

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.

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., AV delays, VV 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., AV and/or VV 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**.

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.

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**.

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.

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.

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.

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.

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.

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.

FIG. **11**B is another embodiment of a functional block diagram for IMD **16**. FIG. **11**B 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.

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 exemplary implantable cardiac pacemakers.

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, exemplary 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 a 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 Oct. 1, 1991 and U.S. Pat. No. 4,428,378 entitled "RATE ADAPTIVE PACER" and issued on Jan. 31, 1984, each of which is incorporated herein by reference in its entirety. Similarly, the exemplary 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 exemplary embodiments described herein may also be practiced in non-rate responsive pacemakers.

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.

Microcomputer **33** contains a microprocessor **80** and associated system clock and on-processor RAM and ROM chips **82**A and **82**B, respectively. In addition, microcomputer circuit **33** includes a separate RAM/ROM chip **82**C 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 AV delay intervals, V-V delay intervals, and the energy delivered to each ventricle and/or atrium.

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 invention. 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**.

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 invention are depicted. The depicted timing circuits include URI/LRI timers **83**A, V-V delay timer **83**B, intrinsic interval timers **83**C 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 **83**D for timing A-A, V-A, and/or V-V pacing escape intervals, an AV delay interval timer **83**E for timing the A-LVp delay (or A-RVp delay) from a preceding A-EVENT or A-TRIG, a post-ventricular timer **83**F for timing post-ventricular time periods, and a date/time clock **83**G.

The AV delay interval timer **83**E 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 **83**E 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).

The post-event timer **83**F 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 AV 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 AV 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 AV delays, VV 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.

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 AV delay interval timer **83**E (or the V-V delay timer **83**B). 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 **83**D.

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.

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**.

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.

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.

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.

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.

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 one or more processors to support one or more aspects of the functionality described in this disclosure.

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.

What is claimed:

1. A system for use in evaluation of cardiac therapy comprising:

electrode apparatus comprising a plurality of external electrodes configured to be located proximate tissue of a patient; and

computing apparatus coupled to the electrode apparatus and configured to:

monitor electrical activity using the plurality of external electrodes to generate baseline cardiac information representative of at least one of mechanical cardiac functionality and electrical cardiac functionality,

monitor electrical activity using the plurality of external electrodes to generate therapy cardiac information representative of at least one of mechanical cardiac functionality and electrical cardiac functionality during delivery of pacing therapy at a pacing location,

determine whether the pacing location for the pacing therapy is acceptable based on the baseline cardiac information and the therapy cardiac information, and

determine, if the pacing location is determined to be unacceptable, location information representative of a direction from the pacing location where delivery of pacing therapy would be more effective than the pacing location based on the therapy cardiac information.

2. The system of claim **1**, wherein the pacing therapy is delivered by at least one implantable electrode coupled to at least one lead, wherein the system is configured to assist a user in selecting one or more of an implant location for the at least one implantable electrode and a pacing vector to be used with the at least one implantable electrode.

3. The system of claim **1**, wherein the location information comprises one of an anterior direction and a posterior direction.

4. The system of claim **1**, wherein the plurality of external electrodes comprises at least one anterior electrode located proximate an anterior side of the patient and at least one posterior electrode locate proximate a posterior side of the patient, wherein the location information comprises an anterior direction if an anterior electrical activation delay monitored by the at least one anterior electrode is greater than a posterior electrical activation delay monitored by the at least one posterior electrode, and wherein the location information comprises a posterior direction if an anterior electrical activation delay monitored by the at least one anterior electrode is less than or equal to a posterior electrical activation delay monitored by the at least one posterior electrode.

5. The system of claim **1**, wherein the baseline cardiac information comprises baseline electrical heterogeneity information and the therapy cardiac information comprises therapy electrical heterogeneity information.

6. The system of claim **1**, wherein determining whether the pacing location for the pacing therapy is acceptable based on the baseline cardiac information and the therapy cardiac information comprises determining whether a comparison of the baseline cardiac information to the therapy cardiac information satisfies a threshold value.

7. The system of claim **1**, wherein the plurality of external electrodes comprises surface electrodes positioned in an array configured to be located proximate the skin of the torso of the patient.

8. The system of claim **1**, wherein the system further comprises display apparatus, wherein the display apparatus comprises a graphical user interface are configured to assist a user in evaluating cardiac pacing location, wherein the computing apparatus is further configured to display the location information on the graphical user interface.

9. The system of claim **1**, wherein the system further comprises display apparatus, wherein the display apparatus comprises a graphical user interface are configured to assist a user in evaluating cardiac pacing location, wherein the computing apparatus is further configured to display a graphical representation of surrogate cardiac electrical activation times from the electrical activity monitored during the delivery of pacing therapy at the pacing location about a portion of human anatomy.

10. The system of claim **9**, wherein displaying the graphical representation of the surrogate cardiac electrical activation times about a portion of human anatomy comprises color scaling the portion of human anatomy on the graphical user interface according to the surrogate cardiac electrical activation times.

11. The system of claim **1**, wherein monitoring electrical activity using the plurality of external electrodes to generate therapy cardiac information representative of at least one of mechanical cardiac functionality and electrical cardiac functionality during delivery of pacing therapy at the pacing location comprises:

adjusting a parameter of the pacing therapy at least twice; and

monitoring the electrical activity using the plurality of external electrodes to generate therapy cardiac information for each adjustment.

12. The system of claim **11**, wherein the parameter comprises at least one of a pacing timing interval, a pacing vector, and a pacing mode.

13. A method for use in evaluation of cardiac therapy comprising:

monitoring electrical activity using a plurality of external electrodes proximate tissue of a patient to generate baseline cardiac information representative of at least one of mechanical cardiac functionality and electrical cardiac functionality;

monitoring electrical activity using the plurality of external electrodes proximate tissue of the patient to generate therapy cardiac information representative of at least one of mechanical cardiac functionality and electrical cardiac functionality during delivery of pacing therapy at a pacing location;

determining whether the pacing location for the pacing therapy is acceptable based on the baseline cardiac information and the therapy cardiac information; and

determining, when the pacing location is determined to be unacceptable, location information representative of a direction from the pacing location where delivery of pacing therapy would be more effective than the pacing location based on the therapy cardiac information.

14. The method of claim **13**, wherein the pacing therapy is delivered by at least one implantable electrode coupled to at least one lead, wherein the method is configured to assist a user in selecting one or more of an implant location for the at least one implantable electrode and a pacing vector to be used with the at least one implantable electrode.

15. The method of claim **13**, wherein the location information comprises one of an anterior direction and a posterior direction.

16. The method of claim **13**, wherein the plurality of external electrodes comprises at least one anterior electrode located proximate an anterior side of the patient and at least one posterior electrode locate proximate a posterior side of the patient, wherein the location information comprises an anterior direction if an anterior electrical activation delay monitored by the at least one anterior electrode is greater than a posterior electrical activation delay monitored by the at least one posterior electrode, and wherein the location information comprises a posterior direction if an anterior electrical activation delay monitored by the at least one anterior electrode is less than or equal to a posterior electrical activation delay monitored by the at least one posterior electrode.

17. The method of claim **13**, wherein the baseline cardiac information comprises baseline electrical heterogeneity information and the therapy cardiac information comprises therapy electrical heterogeneity information.

18. The method of claim **13**, wherein determining whether the pacing location for the pacing therapy is acceptable based on the baseline cardiac information and the therapy cardiac information comprises determining whether a com-

parison of the baseline cardiac information to the therapy cardiac information satisfies a threshold value.

19. The method of claim **13**, wherein the plurality of external electrodes comprises surface electrodes positioned in an array configured to be located proximate the skin of the torso of the patient.

20. The method of claim **13**, wherein the method further comprises displaying the location information on a graphical user interface configured to assist a user in evaluating cardiac pacing location.

21. The method of claim **13**, wherein the method further comprises displaying a graphical representation of surrogate cardiac electrical activation times from the electrical activity monitored during the delivery of pacing therapy at the pacing location about a portion of human anatomy.

22. The method of claim **21**, wherein displaying the graphical representation of the surrogate cardiac electrical activation times about a portion of human anatomy comprises color scaling the portion of human anatomy on the graphical user interface according to the surrogate cardiac electrical activation times.

23. The method of claim **13**, wherein monitoring electrical activity using the plurality of external electrodes to generate therapy cardiac information representative of at least one of mechanical cardiac functionality and electrical cardiac functionality during delivery of pacing therapy at the pacing location comprises:

adjusting a parameter of the pacing therapy at least twice; and

monitoring the electrical activity using the plurality of external electrodes to generate therapy cardiac information for each adjustment.

24. The method of claim **23**, wherein the parameter comprises at least one of a pacing timing interval, a pacing vector, and a pacing mode.

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摘要(译)

本文描述了用于帮助用户评估心脏治疗的系统和方法。该系统和方法可以使用外部电极设备监测患者的电活动，以提供基线心脏信息和治疗心脏信息，并确定心脏起搏或治疗位置是否可接受。如果心脏起搏或治疗位置是不可接受的，则可以基于治疗心脏信息生成表示可能更有效的位置的位置信息。