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Ghosh

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(54) **IDENTIFICATION OF HEALTHY VERSUS UNHEALTHY SUBSTRATE FOR PACING FROM A MULTIPOLAR LEAD**

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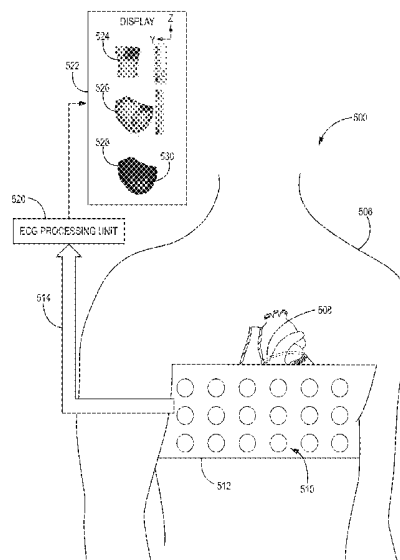
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(57) **ABSTRACT**

A medical device system performs a method determining presence of scar tissue. Torso-surface potential signals are received by a processor from multiple electrodes distributed on a torso of a patient. The processor extracts features of the potential signal from each electrode and stores values of the features in a non-transitory storage medium. The processor determines a scar indicator index for each of the electrodes from the stored features and identifies which ones of the electrodes have an affirmative scar indicator index. An overall scar burden index is determined as a proportion of the electrodes with an affirmative scar indicator index.

22 Claims, 7 Drawing Sheets



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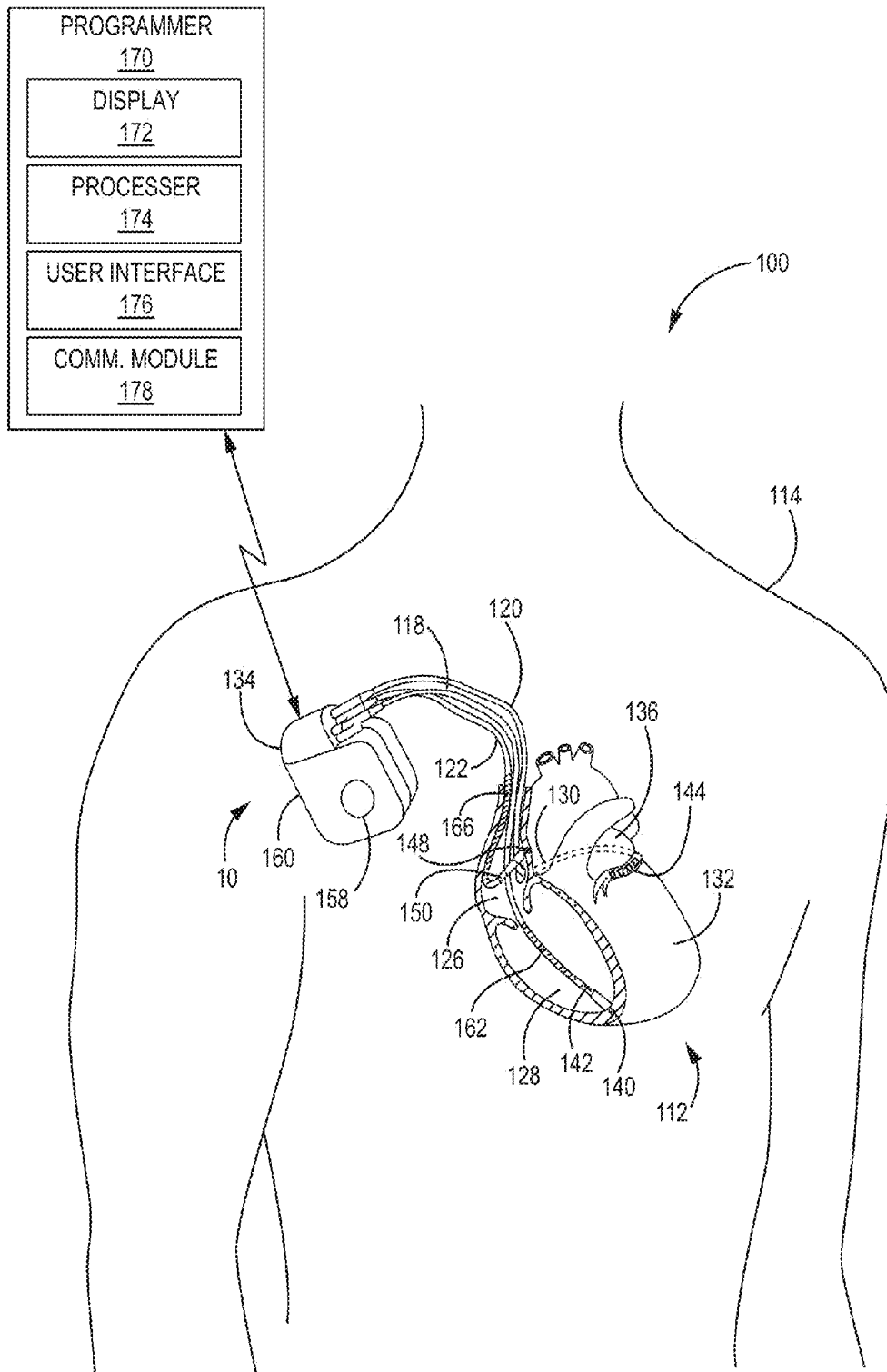
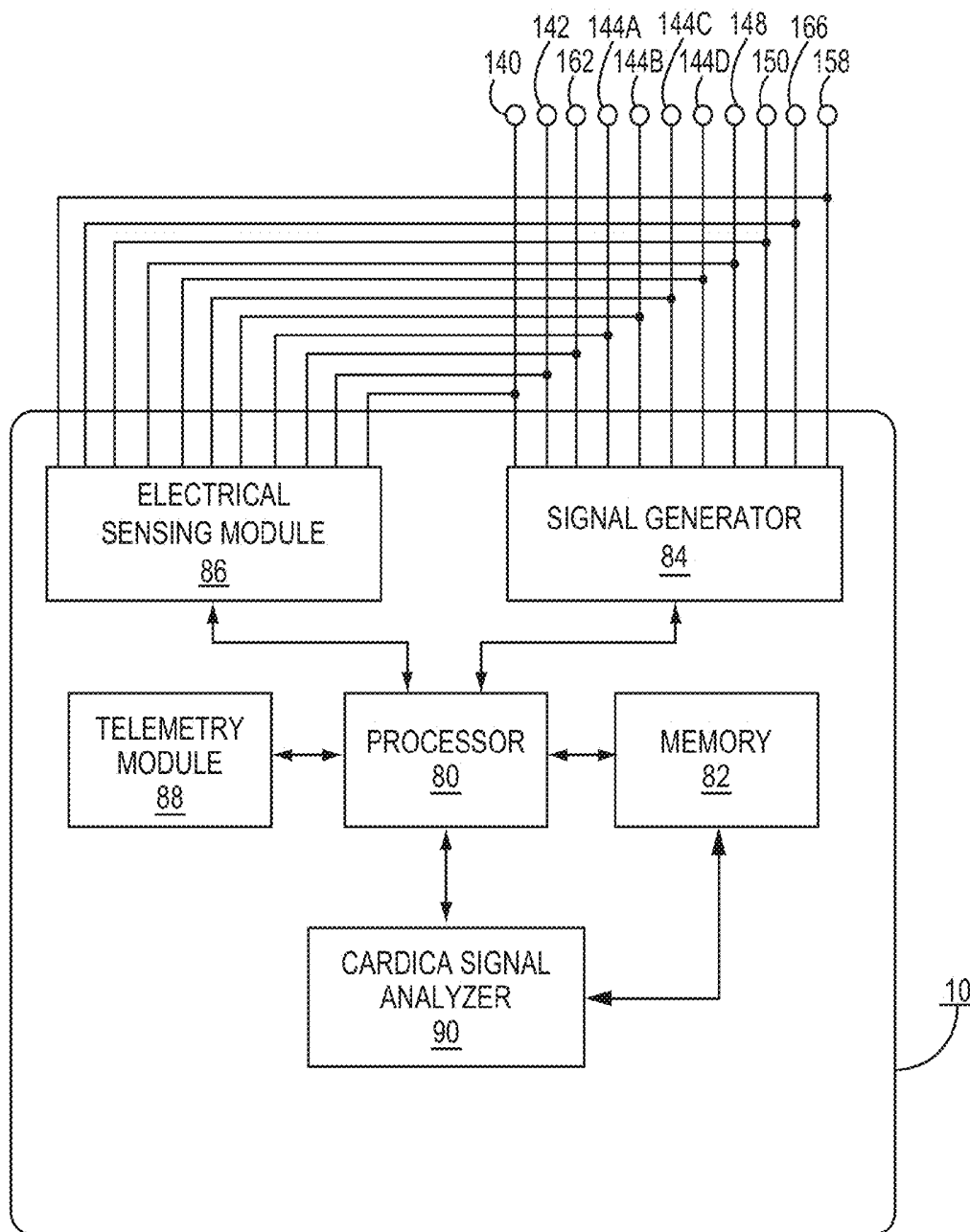
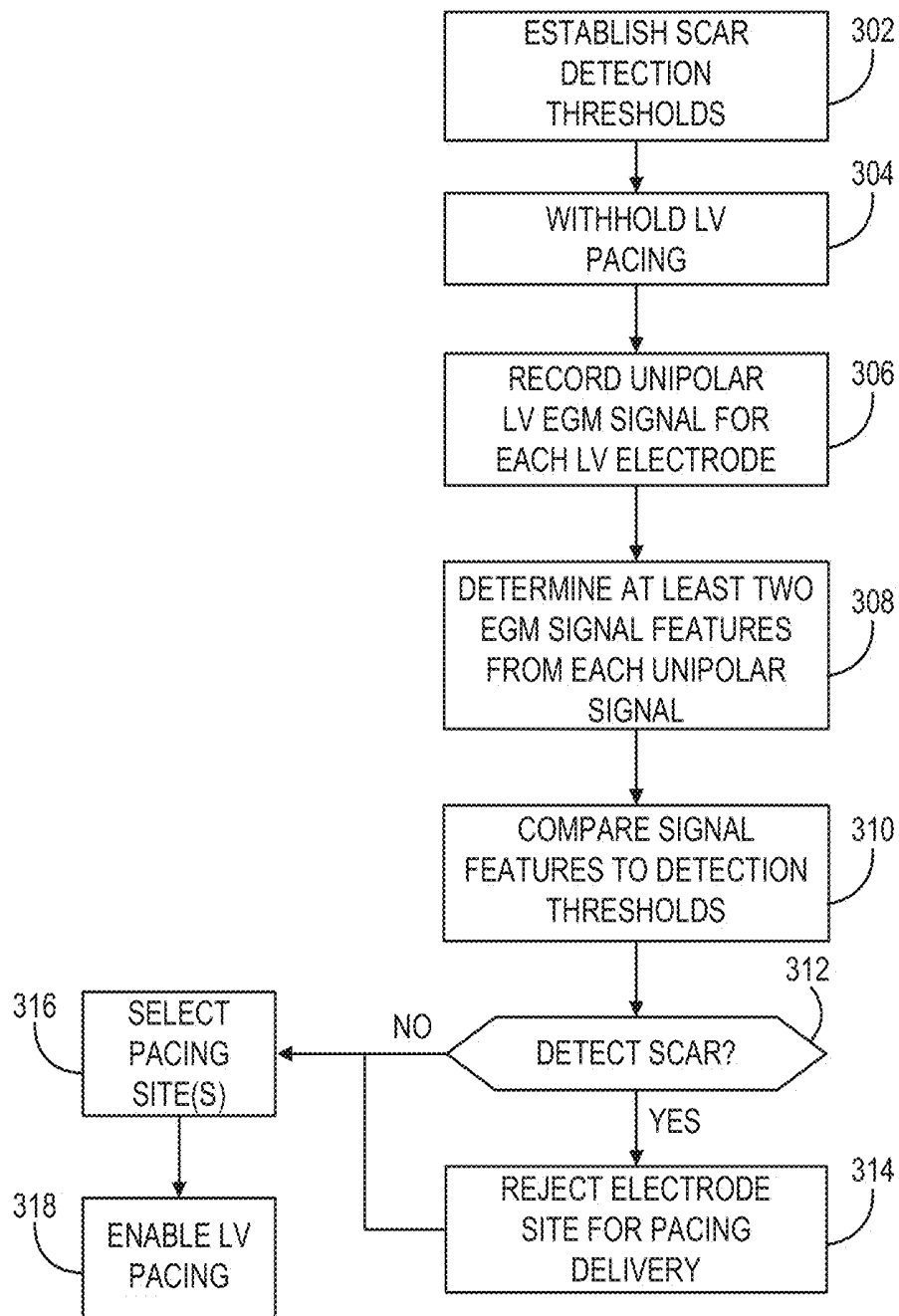
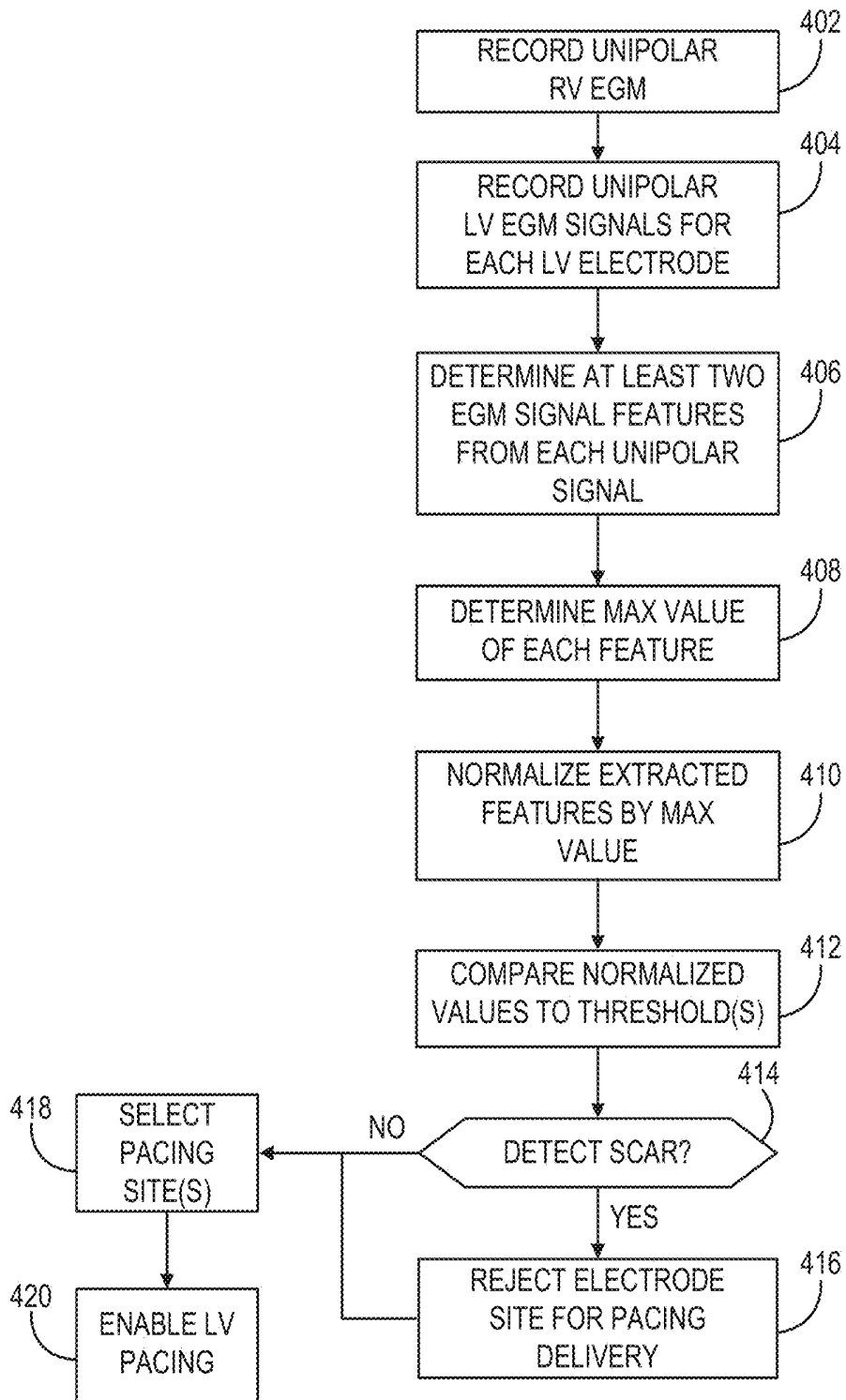


FIG. 1

**FIG. 2**

300**FIG. 3**

400**FIG. 4**

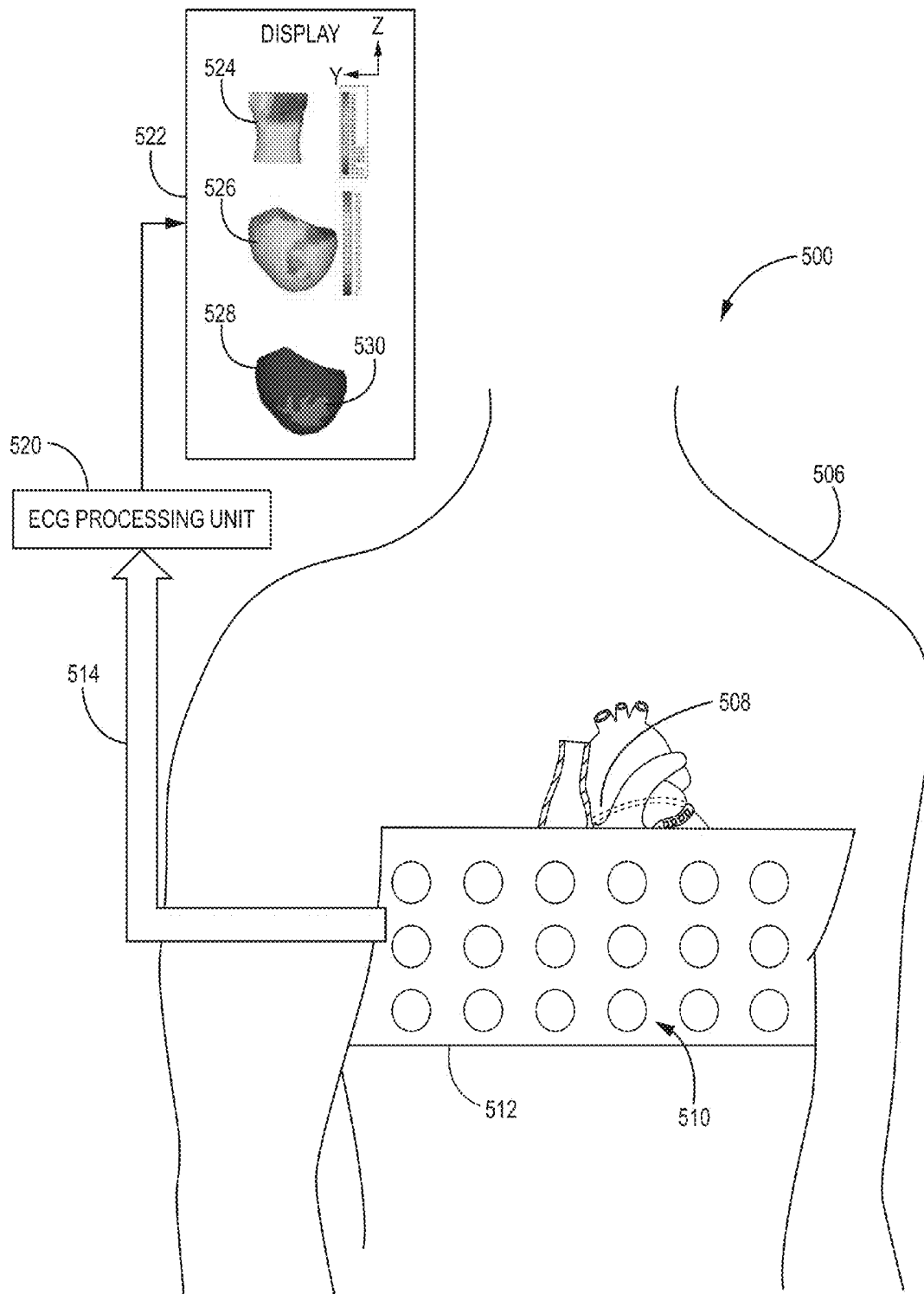
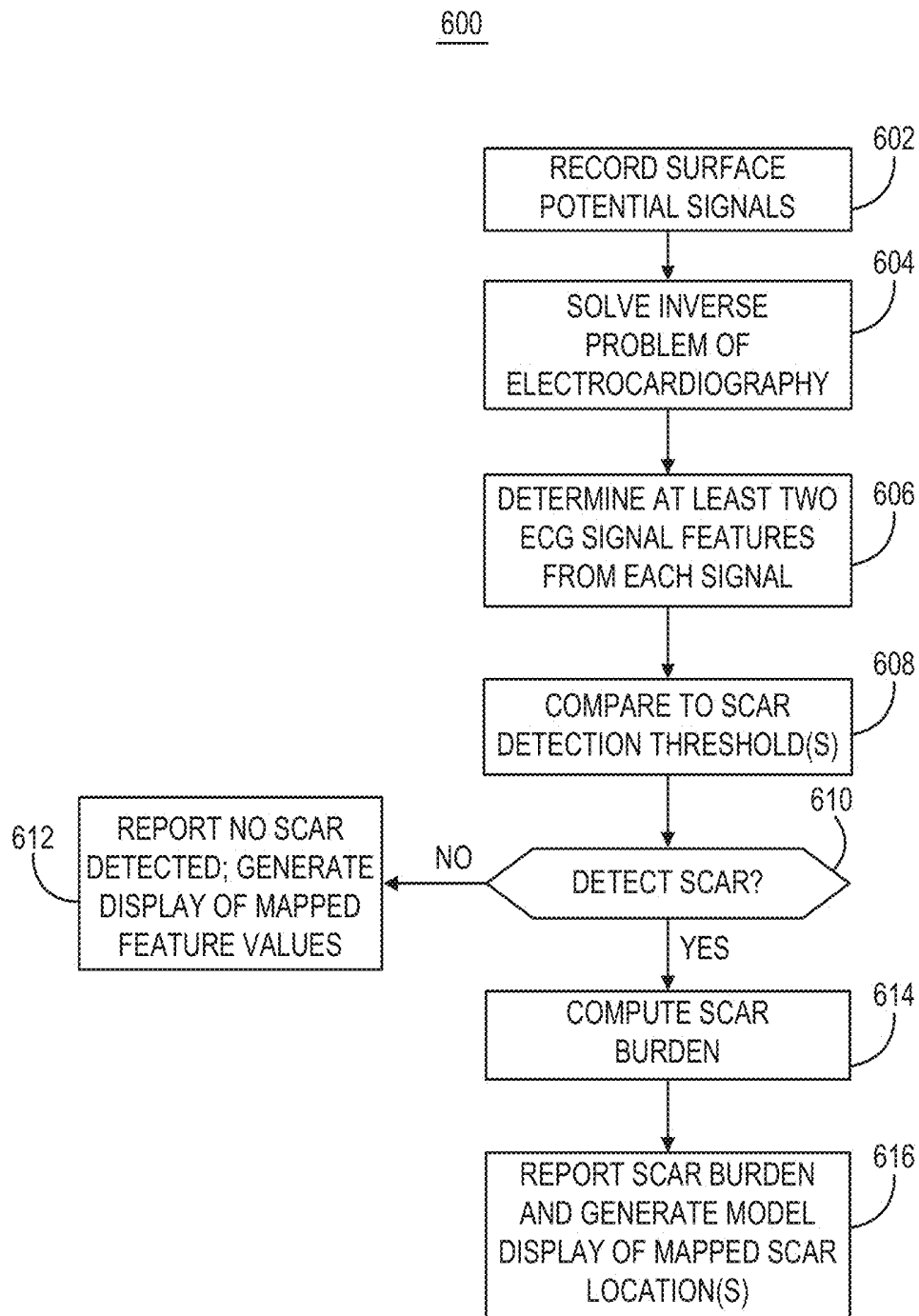
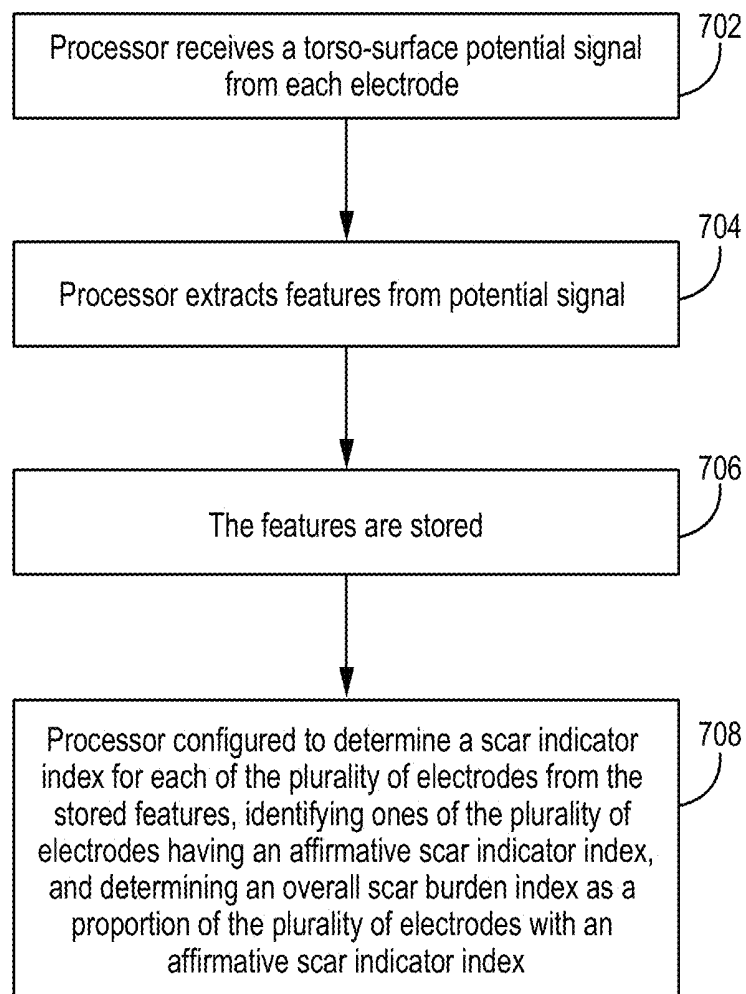


FIG. 5

**FIG. 6**

**FIG. 7**

1

IDENTIFICATION OF HEALTHY VERSUS UNHEALTHY SUBSTRATE FOR PACING FROM A MULTIPOLAR LEAD

TECHNICAL FIELD

The disclosure relates generally to identifying the presence of healthy versus unhealthy cardiac substrate and particularly a system and method for identifying substrate for receiving cardiac pacing.

BACKGROUND

Myocardial ischemia or myocardial infarction can produce areas of scar tissue in the myocardial substrate that will be unresponsive to cardiac pacing. If a patient having myocardial scar tissue requires cardiac pacing, the location of the scar tissue is preferably avoided in positioning pacing electrodes. However, the location of the scar tissue may be unknown without performing imaging procedures, such as magnetic resonance imaging (MRI), which may be costly, require catheterization or contrast agents, and may not be readily available in some geographic areas.

Cardiac resynchronization therapy (CRT) is one type of cardiac pacing therapy that is used as a treatment for heart failure patients in which one or more heart chambers are electrically stimulated (paced) to restore or improve heart chamber synchrony. Achieving a positive clinical benefit from CRT is dependent on several therapy control parameters including selection of pacing site(s) and the relative timing of pacing pulses delivered in the right and/or left ventricles. For example, selection of a CRT pacing site that avoids myocardial scar tissue is important in achieving clinical benefit. Systems and methods are needed for identifying myocardial scar tissue versus healthy myocardial substrate at a potential pacing site in a patient receiving CRT or other pacing therapy without requiring costly imaging technology.

SUMMARY

In general, the disclosure is directed towards techniques for determining presence of scar tissue. In one embodiment, a method determines the presence of scar tissue by a processing device receiving a torso-surface potential signal from multiple electrodes distributed on a torso of a patient. Features of the potential signal from each of the plurality of electrodes are extracted and stored in a non-transitory storage medium. A scar indicator index is determined for each of the electrodes from the stored features. The electrodes having an affirmative scar indicator index are identified, and an overall scar burden index is determined as a proportion of the electrodes with an affirmative scar indicator index.

In another embodiment, a medical device system for determining presence of scar tissue includes a processor receiving means for receiving a torso-surface potential signal from each of multiple electrodes distributed on a torso of a patient and processor means for extracting features of the potential signal from each of the plurality of electrodes. The features are stored, and a processor determines a scar indicator index for each of the electrodes from the stored features, identifies electrodes having an affirmative scar indicator index, and determines an overall scar burden index as a proportion of the electrodes with an affirmative scar indicator index.

In another embodiment, a non-transitory, computer readable storage medium stores instructions for causing a processor of a medical device system to perform a method for determining presence of myocardial scar tissue. The method

2

includes receiving a torso-surface potential signal from electrodes distributed on a torso of a patient, extracting features of the potential signal from each of the electrodes, storing values of the features in a non-transitory storage medium, determining a scar indicator index for each of the electrodes from the stored features, identifying electrodes having an affirmative scar indicator index, and determining an overall scar burden index as a proportion of the electrodes with an affirmative scar indicator index.

Other embodiments and aspects of a system and method for determining presence of scar tissue are described herein. The details of one or more aspects of the disclosure are set forth in the accompanying drawings and the description below.

Other features, objects, and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 is a schematic diagram of one embodiment of an implantable medical device (IMD) system in which techniques disclosed herein may be implemented to provide therapy to a heart of a patient.

FIG. 2 is a functional block diagram illustrating one example configuration of an IMD.

FIG. 3 is a flow chart of a method for detecting myocardial scar tissue according to one embodiment.

FIG. 4 is a flow chart of a method for extracting unipolar EGM signal features for detecting scar tissue according to one embodiment.

FIG. 5 is a schematic diagram of an external system for determining presence of scar tissue in a patient's heart.

FIG. 6 is a flow chart of a method for determining a scar burden index according to one embodiment.

FIG. 7 is a flow chart of a method for determining a scar burden index according to one embodiment.

DETAILED DESCRIPTION

FIG. 1 is a schematic diagram of one embodiment of an implantable medical device (IMD) system 100 in which techniques disclosed herein may be implemented to provide therapy to heart 112 of patient 114. System 100 includes IMD 10 coupled to leads 118, 120, and 122 which carry multiple electrodes. IMD 10 is configured for bidirectional communication with programmer 170. IMD 10 may be, for example, an implantable pacemaker or implantable cardioverter defibrillator (ICD) that provides electrical signals to heart 112 via electrodes coupled to one or more of leads 118, 120, and 122 for pacing, cardioverting and defibrillating the heart 112. IMD 10 is capable of delivering pacing in one or more heart chambers, and in the embodiment shown, is configured for multi-chamber pacing and sensing in the right atrium (RA) 126, the right ventricle (RV) 128, and the left ventricle (LV) 132 using leads 118, 120 and 122.

IMD 10 delivers RV pacing pulses and senses RV intracardiac electrogram (EGM) signals using RV tip electrode 140 and RV ring electrode 142. RV lead 118 is shown to carry a coil electrode 162 which may be used for delivering high voltage cardioversion or defibrillation shock pulses. IMD 10 senses LV EGM signals and delivers LV pacing pulses using the electrodes 144 carried by a multipolar coronary sinus lead 120, extending through the RA 126 and into a cardiac vein 130 via the coronary sinus. In some embodiments, coronary sinus lead 120 may include electrodes positioned along the left atrium (LA) 136 for sensing left atrial (LA) EGM signals and delivering LA pacing pulses.

IMD 10 senses RA EGM signals and delivers RA pacing pulses using RA lead 122, carrying tip electrode 148 and ring electrode 150. RA lead 122 is shown to be carrying coil electrode 166 which may be positioned along the superior vena cava (SVC) for use in delivering cardioversion/defibrillation shocks. In other embodiments, RV lead 118 carries both the RV coil electrode 162 and the SVC coil electrode 166. IMD 10 may detect tachyarrhythmias of heart 112, such as fibrillation of ventricles 128 and 132, and deliver high voltage cardioversion or defibrillation therapy to heart 112 in the form of electrical shock pulses. Pacing and sensing of the cardiac chambers is typically achieved using the pace/sense electrodes 140, 142, 144, 148 and 150, however in some embodiments coil electrodes 162 and/or 166 may be used in sensing and/or pacing electrode vectors.

While IMD 10 is shown in a right pectoral implant position in FIG. 1, a more typical implant position, particularly when IMD 10 is embodied as an ICD, is a left pectoral implant position. In other embodiments, IMD 10 may be implanted in an abdominal location.

IMD 10 includes internal circuitry for performing the functions attributed to IMD 10. Housing 160 encloses the internal circuitry. It is recognized that the housing 160 or portions thereof may be configured as an active electrode 158 for use in cardioversion/defibrillation shock delivery or used as an indifferent electrode for unipolar pacing or sensing configurations with any electrodes carried by leads 118, 120 and 122. IMD 10 includes a connector block 134 having connector bores for receiving proximal lead connectors of leads 118, 120 and 122. Electrical connection of electrodes carried by leads 118, 120 and 122 and IMD internal circuitry is achieved via various connectors and electrical feedthroughs included in connector block 134.

IMD 10 is configured for delivering CRT by delivering pacing pulses in one or both ventricles 128 and 132 for controlling and improving ventricular synchrony. LV pacing may be delivered using a selected pacing vector that utilizes at least one electrode 144 on multipolar LV lead 120. RV pacing is delivered using RV tip electrode 140 and ring electrode 142. CRT may be delivered by pacing in a single ventricular chamber (LV or RV) or both chambers (biventricular pacing) depending on patient need. The methods described herein are implemented in a dual or multi-chamber pacemaker or ICD delivering pacing pulses to the right and/or left ventricles using programmable pacing pulse timing parameters and selected pacing sites and pacing vectors.

While a multi-chamber ICD is shown in FIG. 1, it is recognized that techniques disclosed herein may be implemented in a single chamber, dual chamber or multi-chamber pacemaker, with or without anti-arrhythmia therapies such as cardioversion and defibrillation shock capabilities. For example, techniques disclosed herein for identifying pacing site(s) for CRT may be used for guiding selection of a pacing site for any pacing therapy by identifying myocardial scar tissue at a potential pacing site.

Programmer 170 includes a display 172, a processor 174, a user interface 176, and a communication module 178 including wireless telemetry circuitry for communication with IMD 10. In some examples, programmer 170 may be a handheld device or a microprocessor-based home monitor or bedside programming device. A user, such as a physician, technician, nurse or other clinician, may interact with programmer 170 to communicate with IMD 10. For example, the user may interact with programmer 170 via user interface 176 to retrieve currently programmed operating parameters, physiological data collected by IMD 10, or device-related diagnostic information from IMD 10. A user may also interact with programmer

170 to program IMD 10, e.g., select values for operating parameters of the IMD. A user interacting with programmer 170 can initiate a test to identify scar tissue at a potential pacing site according to the techniques disclosed herein. As will be described, in a test to identify scar tissue, a multi-polar lead is used to record multiple unipolar EGM signals, determine a combination of EGM signal features from each of the EGM signals, and analyze the combination of EGM signal features to detect scar tissue at an electrode site.

Programmer 170 includes a communication module 178 to enable wireless communication with IMD 10. Examples of communication techniques used by system 100 include low frequency or radiofrequency (RF) telemetry, which may be an RF link established via Bluetooth, WiFi, or MICS for example. In some examples, programmer 170 may include a programming head that is placed proximate to the patient's body near the IMD 10 implant site, and in other examples programmer 170 and IMD 10 may be configured to communicate using a distance telemetry algorithm and circuitry that does not require the use of a programming head and does not require user intervention to maintain a communication link.

It is contemplated that programmer 170 may be coupled to a communications network via communications module 178 for transferring data to a remote database or computer to allow remote monitoring and management of patient 114 using the techniques described herein. Remote patient management systems may be configured to utilize the presently disclosed techniques to enable a clinician to review test data, programmed therapy parameters and authorize programming of IMD 10. Reference is made to commonly-assigned U.S. Pat. Nos. 6,599,250 (Webb et al.), 6,442,433 (Linberg et al.), 6,418,346 (Nelson et al.), and 6,480,745 (Nelson et al.) for general descriptions and examples of network communication systems for use with implantable medical devices for remote patient monitoring and device programming, all of which patents are hereby incorporated herein by reference in their entirety.

FIG. 2 is a functional block diagram illustrating one example configuration of IMD 10. In the example illustrated by FIG. 2, IMD 10 includes a processor and control unit 80, also referred to herein as "processor" 80, memory 82, signal generator 84, electrical sensing module 86, and telemetry module 88. IMD 10 further includes cardiac signal analyzer 90.

Memory 82 may include computer-readable instructions that, when executed by processor 80, cause IMD 10 and processor 80 to perform various functions attributed throughout this disclosure to IMD 10, processor 80, and cardiac signal analyzer 90. The computer-readable instructions may be encoded within memory 82. Memory 82 may comprise non-transitory, computer-readable storage media including any volatile, non-volatile, magnetic, optical, 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, or any other digital media with the sole exception being a transitory propagating signal.

Processor and control unit 80 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), or equivalent discrete or integrated logic circuitry. In some examples, 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, or one or more FPGAs, as well as other discrete or integrated logic circuitry. The functions attributed to processor 80 herein may

be embodied as software, firmware, hardware or any combination thereof. In one example, cardiac signal analyzer 90 may, at least in part, be stored or encoded as instructions in memory 82 that are executed by processor and control unit 80.

Processor and control unit 80 includes a therapy control unit that controls signal generator 84 to deliver electrical stimulation therapy, e.g., cardiac pacing or CRT, to heart 112 according to a selected one or more therapy programs, which may be stored in memory 82. Signal generator 84 is electrically coupled to electrodes 140, 142, 144A-144D (collectively 144), 148, 150, 158, 162, and 166 (all of which are shown in FIG. 1), e.g., via conductors of the respective leads 118, 120, 122, or, in the case of housing electrode 158, via an electrical conductor disposed within housing 160 of IMD 10. Signal generator 84 is configured to generate and deliver electrical stimulation therapy to heart 112 via selected combinations of electrodes 140, 142, 144, 148, 150, 158, 162, and 166. Signal generator 84 delivers cardiac pacing pulses according to therapy control parameters during CRT. CRT is delivered to a pacing site identified as not being over scar tissue as will be described herein.

Signal generator 84 may include a switch module (not shown) and processor and control 80 may use the switch module to select, e.g., via a data/address bus, which of the available electrodes are used to deliver pacing pulses. Processor 80 controls which of electrodes 140, 142, 144A-144D, 148, 150, 158, 162, and 166 is coupled to signal generator 84 for delivering stimulus pulses, e.g., via the switch module. The switch module may include a switch array, switch matrix, multiplexer, or any other type of switching device suitable to selectively couple a signal to selected electrodes.

Sensing module 86 monitors cardiac electrical signals for sensing cardiac electrical events, e.g. P-waves and R-waves, from selected ones of electrodes 140, 142, 144A-144D, 148, 150, 158, 162, or 166 in order to monitor electrical activity of heart 112. Sensing module 86 may also include a switch module to select which of the available electrodes are used to sense the cardiac electrical activity. In some examples, processor 80 selects the electrodes to function as sense electrodes, or the sensing vector, via the switch module within sensing module 86.

Sensing module 86 includes multiple sensing channels, each of which may be selectively coupled to respective combinations of electrodes 140, 142, 144A-144D, 148, 150, 158, 162, or 166 to detect electrical activity of a particular chamber of heart 112. Each sensing channel may comprise an amplifier that outputs an indication to processor 80 in response to sensing of a cardiac depolarization, in the respective chamber of heart 112. In this manner, processor 80 may receive sense event signals corresponding to the occurrence of R-waves and P-waves in the various chambers of heart 112, e.g. ventricular sense events and atrial sense events corresponding to intrinsic depolarization of the respective heart chamber. Sensing module 86 may further include digital signal processing circuitry for providing processor 80 or cardiac signal analyzer 90 with digitized EGM signals.

In various embodiments, one or more sensing channels may be selectively coupled to electrodes 144 included on multipolar lead 120 for sensing unipolar EGM signals for detecting scar tissue. In one embodiment, sensing module 86 includes an LV sensing channel and electrodes 144a, 144b, 144c and 144d are selectively coupled one at a time in a unipolar sensing configuration in combination with a common anode, such as housing electrode 158, coil electrode 162, or coil electrode 166, to acquire a unipolar EGM signal for each of the respective locations of electrodes 144a-144d along LV tissue.

A digitized EGM signal obtained using each of the electrodes 144a-144d is analyzed by cardiac signal analyzer 90 to extract a combination of EGM signal features, e.g. at least two features, from each of the unipolar sensed signals. The extracted features are analyzed to detect scar tissue as will be described in greater detail below. In response to detecting scar tissue, processor 80 may generate a notification for transmission via telemetry module 88 and/or establish or alter a pacing electrode selection for delivering CRT therapy. Processor 80 and cardiac signal analyzer 90 may collectively represent processor means for determining the presence of scar tissue as described herein.

Memory 82 stores intervals, counters, or other data used by processor 80 to control the delivery of pacing pulses by signal generator 84. Such data may include intervals and counters used by processor 80 to control the delivery of pacing pulses to one or both of the left and right ventricles for CRT. The intervals and/or counters are, in some examples, used by processor 80 to control the timing of delivery of pacing pulses relative to an intrinsic or paced event in another chamber.

Other examples of functional block diagrams of IMD 10 may be seen with respect to U.S. patent application Ser. No. 13/916,353 (e.g., FIGS. 17A-17B) filed Jun. 12, 2013, and assigned to the assignee of the present invention, the disclosure of which is incorporated by reference in its entirety herein.

FIG. 3 is a flow chart 300 of one method for detecting myocardial scar tissue according to one embodiment. The method described in conjunction with FIG. 3 is directed to the illustrative embodiment shown in FIG. 1 of an IMD 10 coupled to a quadripolar lead having four electrodes 144A-144D positioned along the LV for delivering LV pacing pulses during CRT. It is recognized, however, that the techniques disclosed herein may be utilized in a variety of embodiments that include multiple electrodes positioned along a heart chamber carried by one or more medical electrical leads.

When multiple electrodes are available, conventional "short" bipolar pairs that enable recording of a true, near-field bipolar signal can be used to detect myocardial scar tissue by detecting changes in the bipolar EGM signal due to changes in the local, near-field EGM signal. However, as the distance between the sensing pair of electrodes increases, the volume of tissue contributing to the recorded EGM signal will increase. More far-field electrical activity will be contributing to the recorded signal reducing the sensitivity of the signal to detecting scar tissue at the sensing electrode site. A multipolar lead may provide multiple sensing/pacing sites, however the spacing between electrodes along the multipolar lead may be greater than that required to record a bipolar signal with great enough sensitivity to reliably detect EGM signal changes caused by scar tissue. The process shown by flow chart 300 provides a technique for detecting the presence of scar tissue at an electrode site independent of inter-electrode spacing when multiple electrodes are positioned at various sites along a heart chamber.

The process shown by flow chart 300 may be performed at the time an IMD and associated leads are being initially implanted, at a time of repositioning or replacing a cardiac lead, on a periodic basis after implanting the IMD and associated leads. In some embodiments, the process shown by flow chart 300 may be performed in response to a change in a monitored parameter, such as a change in a hemodynamic parameter or a change in a pacing capture threshold.

At block 302, scar tissue detection thresholds are established. Thresholds for detecting scar may be based on previous EGM baseline recordings obtained from the patient, EGM recordings obtained from the patient at the time the test

for detecting scar is being performed, or based on empirical data from a population of patients. Thresholds are applied to at least two EGM signal features determined from each unipolar EGM signal. Separate thresholds may be applied to each of the two or more EGM signal features individually or to a single metric or index computed from the two or more EGM signal features and a single threshold applied to the metric.

At block 304, LV pacing is withheld. EGM signals for the purposes of detecting myocardial scar tissue in the LV are recorded during a baseline rhythm which typically does not involve pacing from the LV lead or electrodes. The heart rhythm may be an intrinsic heart rhythm with no pacing delivered in any heart chamber, an atrial paced rhythm, an RV paced rhythm, or during pacing in an atrial chamber and the RV. It is contemplated that in some cases another LV lead or electrode may be present different than the pacing electrodes and associated sites being tested for scar tissue that could be used for pacing during recording of unipolar EGM signals at the LV pacing sites under test.

At block 306, unipolar LV EGM signals are recorded by sensing module 86 for each LV electrode 144a-d available when no LV pacing is being delivered. The LV EGM signals are recorded using a common anode paired with each LV electrode for sensing n different unipolar EGM signals when n electrodes are positioned along the LV. The different unipolar EGM signals may be recorded one at a time in a sequential manner or simultaneously depending on the number of sensing channels available in the sensing module 86 IMD 10. Each unipolar signal may be recorded for at least one cardiac cycle and generally will be recorded for multiple cycles, e.g. 3 to 12 cycles, for obtaining representative EGM signal features from for a given sensing electrode site.

At block 308, at least two different EGM signal features are extracted from each recorded unipolar signal. At least two different signal features are extracted in case a single feature of the unipolar EGM does not provide a great enough sensitivity to reliably detect EGM signal changes due to scar tissue. The signal features extracted from each unipolar EGM signal may include, but are not limited to, metrics of the QRS amplitude, negativity of the Q-wave, and fractionation of the EGM signal. It is recognized that numerous techniques can be conceived for determining a metric of QRS signal amplitude, a metric of Q-wave negativity, and a metric of QRS fractionation.

For the sake of illustration, a metric of QRS amplitude may be determined as the peak-to-peak amplitude difference during a QRS sensing window. The QRS amplitude is expected to be reduced when scar tissue is present at the sensing electrode as compared to healthy tissue at the sensing electrode.

A broad negative Q-wave is also evidence of scar tissue. A metric of Q-wave negativity can be extracted from the EGM signal by counting the number of digitized EGM sample points that are negative during a QRS sensing window, by determining a summation of EGM sample point values over a QRS sensing window, or by determining an integral or area defined by the EGM signal sample points over a sensing window.

Scar tissue may also cause fractionation of the EGM signal, i.e. multiple peaks rather than a single R-wave peak. A metric of fractionation of the EGM signal may be extracted from the EGM signal by counting a number of slope sign changes, counting a number of peaks, or counting a number of inflection points during a QRS sensing window.

In one embodiment, at least two metrics of QRS amplitude, Q-wave negativity, and/or EGM fractionation are determined from each unipolar EGM signal at block 308. These metrics

are compared to the established detection thresholds at block 310, individually and/or in a combined metric. Criteria may be defined for detecting scar tissue. For example, at least two out of three EGM signal features must meet a respective scar detection threshold to detect scar tissue at a sensing electrode site. If scar detection threshold(s)/criteria are satisfied at block 312, the electrode used to record the associated EGM signal is rejected as a pacing site at block 314.

At block 316, pacing site(s) for delivering pacing therapy are selected. Any electrodes available after rejecting those electrodes associated with scar detection may be selected for therapy delivery and additional pacing site selection criteria may be applied to select a pacing site according to the particular pacing application. Pacing site selection may be performed automatically at block 316 by rejecting any electrodes identified as being located along scar tissue and applying any other therapy pacing site selection criteria, e.g. low capture threshold, low impedance etc. Pacing site selection may alternatively be performed by a clinician after transmitting a notification to an external programmer or other device that scar has been detected and indicating the associated electrode(s). At block 318, LV pacing is enabled such that a desired therapy can be delivered according to programmed therapy control parameters at the selected pacing site(s).

FIG. 4 is a flow chart 400 of a method for extracting unipolar EGM signal features for detecting scar tissue according to one embodiment. At block 402, heart activity is sensed at an electrode positioned along the RV to produce a unipolar EGM waveform of RV heart activity. The RV unipolar EGM signal is recorded during an intrinsic rhythm or during atrial pacing, while no RV pacing is being delivered.

At block 404, heart activity is sensed at each electrode positioned along the LV to produce unipolar EGM waveforms corresponding to each LV electrode site. At least two features are extracted from each of the RV and LV unipolar EGM waveforms at block 406. The extracted EGM features are representative of the heart activity at the associated electrode site and may include a metric of QRS waveform amplitude, a metric of Q-wave negativity, and a metric of QRS waveform fractionation. In an illustrative embodiment, one feature extracted from the unipolar EGM waveform is a peak-to-peak amplitude difference as a metric of QRS amplitude. In another embodiment, one extracted feature is a percentage of the EGM waveform sample points having a negative polarity out of all of the EGM waveform sample points during the QRS sensing window as a metric of Q-wave negativity. In yet another embodiment, one extracted feature is a number of times the slope of the EGM waveform changes between a positive slope and a negative slope (in either direction) as a metric of fractionation of the QRS signal. Any combination of at least two features of the EGM waveform may be extracted.

The features may be extracted by first setting a QRS window. The QRS window is centered at an R-wave sensed by a sense amplifier included in the IMD sensing module in one embodiment and extends a predetermined time interval earlier and later than the R-wave sense marker generated by the sense amplifier. The EGM features may then be extracted from the waveform sample points during the window. A given feature may be extracted on a beat-by-beat basis for a predetermined number of beats and then averaged to determine an average feature representative of heart activity at the electrode site or a median or mode of the extracted features may be determined. Alternatively, the EGM waveform may be ensemble averaged over the QRS window for multiple beats then a feature can be extracted from the averaged QRS waveform.

The features are determined for each unipolar EGM signal recorded, and at block 408 a maximum of an EGM feature determined from all recorded signals is identified. The maximum value, which may be an absolute value, of a given EGM feature is used to normalize the given EGM feature values extracted from each unipolar EGM waveform at block 410. In this way, a percentage difference in a feature value is determined relative to a maximum feature value. For example, if a unipolar EGM signal has a normal peak-to-peak amplitude difference and another unipolar EGM signal has a normalized peak-to-peak amplitude that is 50% of the normal peak-to-peak amplitude, the 50% lower peak-to-peak amplitude is a signal feature indicating scar tissue at the associated electrode site. One or more extracted features may be normalized by a maximum and compared to a threshold percentage for identifying scar tissue at block 412. It is recognized that in some cases, feature values may be normalized by a minimum feature value, a mean feature value or other reference value. In some examples, a value used to normalize extracted features values is extracted from the RV EGM.

A normalized or non-normalized value may indicate scar when the value exceeds a threshold percentage or level or is less than a threshold percentage or level depending on the particular feature. For example, a peak-to-peak amplitude difference may be normalized by a maximum and required to be less than a threshold percentage, e.g. 50%, while the percentage of negative sample points may be required to be greater than a threshold percentage. A number of slope changes may be left un-normalized and compared to a threshold number. In some embodiments, a threshold applied to the feature values extracted from the LV unipolar EGM signals is derived from the RV unipolar EGM signal.

If at least two extracted features of a unipolar EGM signal indicate scar tissue based on the detection threshold comparison, as determined at decision block 414, scar is detected at the associated electrode site. The electrode is rejected for use in delivering a pacing therapy at block 416 and/or a notification indicating detection of scar tissue and recommended rejection of the pacing site may be generated. Pacing site(s) may be selected at block 418 from electrodes that were not determined to be located along scar tissue and the pacing therapy may be enabled at block 420 using the selected pacing site(s). In this example, the selected pacing site is along the LV for delivering CRT.

FIG. 5 is a schematic diagram of an external system 500 for determining presence of scar tissue in a patient's heart. In some cases, an implanted lead may not be available for detecting EGM evidence of scar tissue or an implanted electrode may not be located to produce an EGM signal sensitive enough to reliably detect scar tissue. In these situations, a system and method for determining the presence of scar tissue without requiring costly or complex imaging systems may be needed to determine if scar is present and provide some assessment relating to the relative size of the scar in a metric referred to herein as the "scar burden." By approximating a location of scar tissue and the scar burden, a clinician can make informed treatment decisions. For example, if a patient is a candidate for CRT, knowledge of the presence of scar and an estimate of the scar burden is useful to a clinician in prescribing CRT and in planning lead and electrode placement for delivering CRT.

System 500 includes external surface electrodes 510, shown carried by a wearable band or strap 512 for positioning the electrodes 510 in skin contact along the torso of a patient 506. Electrodes 510 may alternatively be adhesive skin electrodes. Electrodes 510 are positioned at multiple points along the patient's torso to record surface potential signals. The

electrodes 510 may be equally distributed circumferentially around the patient's torso in one example.

In one embodiment, electrodes 510 are used to acquire surface potential signals from heart 508 by strap 512 wrapped around the torso of patient 506 such that the electrodes 510 surround heart 508. Electrodes 510 may be positioned around the circumference of patient 506, including the posterior, lateral, and anterior surfaces of the torso of patient 506. In other examples, electrodes 512 may be positioned on any one or more of the posterior, lateral, and anterior surfaces of the torso. Electrodes 510 may be electrically connected to an ECG processing unit 520 via a wired connection 514. Some configurations may use a wireless connection to transmit the signals sensed by electrodes 510 to ECG processing unit 520, e.g., as channels of data.

Although in the example of FIG. 5, strap 512 is shown carrying surface electrodes 510, 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 510 in a distributed manner along a patient's torso to surround heart 508. In some examples, strap 512 may include an elastic band, strip of tape, or cloth. In other examples, electrodes 510 may be placed individually on the torso of patient 506.

Electrodes 510 record the electrical signals associated with the depolarization and repolarization of heart 508. Each of electrodes 510 may be used in a unipolar configuration to sense the surface potentials that reflect cardiac electrical activity. ECG processing unit 520 may also be coupled to a return or indifferent electrode (not shown) which may be used in combination with each of electrodes 510 for unipolar sensing.

ECG processing unit 520 may record and analyze the surface potential signals, referred to generally herein as "ECG" signals, sensed by electrodes 510. Processing unit 520 may be configured to provide an output to a user indicating presence of scar tissue in heart 112. The user may make a diagnosis, prescribe CRT, position therapy devices, e.g., leads, or adjust or select treatment parameters based on the indicated scar tissue.

The strap 512 carrying electrodes 510 is one illustrative embodiment of an apparatus that is useful in recording surface ECG signals from which presence of scar tissue can be determined. Other surface cardiac signal recording apparatus may be used for acquiring cardiac signal data from which presence scar tissue can be determined. Other signal recording apparatus and techniques may include 12-lead ECG electrodes, a vest carrying an array of electrodes, and vectorcardiography.

The electrodes 510 are coupled to an ECG processing unit 520 via electrical conductors 514. ECG signals are received by ECG processing unit 520 which extracts ECG features from each received signal for producing an ECG feature map. ECG features may be extracted from each ECG signal recorded from electrodes 510 in a manner similar to the techniques described above for extracting unipolar EGM features. For example, a QRS amplitude metric, a Q-wave negativity metric, an ECG fractionation metric or any combination thereof may be determined from the surface ECG signals as scar indicator indices.

The ECG features are thereby used for determining scar indicator indices, individually or in a combined form, and are compared to a scar detection threshold by ECG processing unit 520 to determine if scar tissue is present at a myocardial tissue site. The ECG processing unit 520 reports if scar tissue is detected and reports a scar burden, e.g. via display screen/monitor 522 coupled to ECG processing unit. The ECG processing unit 520 may produce a graphical display 524 of a

2-dimensional or 3-dimensional model of the patient's torso superimposed with a color-coded mapping of the extracted ECG feature values projected onto the torso model based upon the electrode locations along the patient's torso.

In some embodiments, ECG processing unit **520** and display screen/monitor **522** may be implemented in an external programmer, such as programmer **170** shown in FIG. 1. A programmer, such as the CARELINK ENCORE® Programmer Model 29901, configured to receive signals from surface ECG electrodes is available from Medtronic, Inc., Minneapolis, Minn. The Medtronic CARELINK ENCORE® Programmer Model 29901 Reference Manual, 2013, is incorporated herein by reference in their entirety.

The ECG processing unit **520** may be configured to solve the inverse problem of electrocardiography to project ECG data onto a 2-dimensional or 3-dimensional heart model. A graphical display **526** may be produced from the data projected on a computer heart model to create a visual mapping of the surface potential data mapped to the heart model. ECG feature values may be represented as normalized values or percentages of a reference value of the respective feature.

Additionally or alternatively, a mapped location of scar tissue based on the ECG feature values may be presented in a graphical display **528**. The ECG processing unit **520** may be configured to identify boundaries of detected scar tissue on a model heart in response to determining an overall cardiac scar burden index and torso surface locations of the electrodes identified having an affirmative scar indicator index. The display **528** presents the boundaries **530** of scar tissue along the model heart and reports the overall cardiac scar burden index. As described below, a scar burden index may be computed as a percentage of the electrodes **510** having an affirmative scar indicator index.

No imaging of the actual patient anatomy is required to produce the graphical displays **524**, **526** and/or **528**. Rather the ECG data is mapped to a generic, graphical computer model of a patient's torso and/or heart and a graphical display is produced without taking an actual image, such as an MRI or CT image, from the patient.

The resolution of the ECG data mapped to a graphical anatomical model will depend on the number and spacing of surface electrodes **510** used. In some examples, there may be 12 to 16 electrodes spatially distributed around the torso of patient **506**. Other configurations may have more or fewer electrodes. In one embodiment, a minimum number of electrodes includes twelve electrodes arranged in two rows extending along the posterior torso and twelve electrodes arranged in two rows extending along the anterior torso for a total of twenty-four electrodes, which may be equally distributed circumferentially around the torso.

FIG. 6 is a flow chart **600** of a method for determining a scar burden index according to one embodiment. At block **602**, surface potential signals are recorded from skin electrodes distributed on a torso of a patient, for example as shown in FIG. 5. An ECG processing unit receives the potential signals from each surface electrode via the necessary electrical conductors or in some systems potential signals may be transmitted wirelessly from a body worn device to an ECG processing unit.

A processor included in the ECG processing unit solves the inverse problem of electrocardiography using a computer model of a heart anatomy and the received potential signals at block **604**. The potential signals resulting from the inverse problem solution are used to characterize heart activity on the surface of the heart model. Features are extracted from the potential signals corresponding to each of the torso-surface electrodes at block **606**. In one embodiment, at least two

features are determined from each signal, which may include a metric of the QRS signal amplitude, a metric of Q-wave negativity and/or a metric of QRS signal fractionation, or any combination thereof, as described previously. The potential signals and/or the determined features can be stored in a non-transitory storage medium, e.g. digital memory associated with the ECG processing unit.

A scar indicator index is determined by the processor from the potential signal features, which may be normalized or non-normalized and combined in a single index or used individually as scar indicator indices. Feature values may be normalized by determining a maximum, minimum, mean, median, mode or other reference value from all of the feature values determined from the distributed electrodes. The scar indicator indices determined for each electrode, from the potential signal produced at each surface electrode, are compared to a scar detection threshold at block **608** to identify which, if any, electrodes result in an affirmative scar indicator index. In this way, myocardial scar tissue is detected as being present at a cardiac location that corresponds to the torso-surface electrode that produced a potential signal resulting in a scar indicator index meeting a detection threshold requirement.

If scar tissue is detected at block **610** based upon one or more electrodes having an affirmative scar indicator index, a scar burden index is computed at block **614**. In one embodiment, the scar burden index is computed as a proportion of the torso-surface electrodes having an affirmative scar indicator index. Additionally or alternatively, a scar burden index may be determined as an estimated myocardial surface area based on the number and location of electrodes having an affirmative scar indicator index.

The scar burden index is reported at block **616**. The scar burden index may be reported with a graphical display of data derived from the surface potential signals mapped to an anatomical heart model. Data obtained from the surface potential signals can be mapped to a heart using a computer model of a heart and the potential signals. For example, this process may involve solving inverse problem of electrocardiography based on a model heart and a model torso onto which the measured surface signals are mapped. The solution of inverse problem would provide reconstructed unipolar EGM signals at points or sites on the surface of the model heart. The reconstructed unipolar EGM features may be extracted and criteria for scar detection may be applied as described above. Feature values or an indication of the presence of scar tissue can be mapped and displayed to a clinician. The boundaries of detected scar tissue may be estimated and presented on the display of a heart model based upon sites associated with affirmative scar indicator indices. If no scar is detected at block **610**, this result may be reported, and a display of a heart model mapped with signal feature values or scar indicator indices may optionally be generated at block **612**.

The scar burden index and estimated scar boundaries may be used by a clinician in making treatment decisions. For example, a patient being evaluated for CRT may be contraindicated for therapy if the scar burden exceeds a threshold value. Patients with a relatively high scar burden may not respond to CRT. Therefore, the scar burden index may be used as a predictor of patients that are expected to receive therapeutic benefit from CRT and those that are not. The reported scar burden at block **616** may include a recommendation for CRT therapy based on the determined scar burden exceeding a threshold scar burden (CRT not recommended) or not exceeding a threshold scar burden (CRT recommended).

FIG. 7 is a flow chart of a system and/or method is disclosed for determining a scar burden index. A system and/or

a method is disclosed that comprises a processor receiving means for receiving a torso-surface potential signal from each of a plurality of electrodes distributed on a torso of a patient at block 702. At block 704, a processor means extracts features of the potential signal from each of the plurality of electrodes. At block 706, the features are stored. At block 708, a processor means is configured to determine a scar indicator index for each of the plurality of electrodes from the stored features, identifying ones of the plurality of electrodes having an affirmative scar indicator index, and determining an overall scar burden index as a proportion of the plurality of electrodes with an affirmative scar indicator index.

Thus, various embodiments of a system and method for determining the presence of myocardial scar have been described. However, one of ordinary skill in the art will appreciate that various modifications may be made to the described embodiments without departing from the scope of the claims. For example, although specific examples of scar indicator indices or ECG signal features have been described, it is recognized that other indicators may be conceived and substituted in the scar detection techniques presented herein. Both an implantable system and an external system useful for determining presence of myocardial scar have been described separately, however, the techniques disclosed herein may be combined in any manner to include scar detection using one or both internal and external electrodes at the same or different time points in managing a patient and determining a patient's scar burden. These and other examples are within the scope of the following claims.

The invention claimed is:

1. A system comprising:
 - a processor receiving means for receiving a torso-surface potential signal from each of a plurality of electrodes distributed on a torso of a patient;
 - a processor means for extracting features of the potential signal from each of the plurality of electrodes;
 - a storing means for storing the features;
 - a processor means for determining a scar indicator index for each of the plurality of electrodes from the stored features, identifying ones of the plurality of electrodes having an affirmative scar indicator index, and determining an overall scar burden index as a proportion of the plurality of electrodes with an affirmative scar indicator index.
2. The system of claim 1, further comprising a processor generating means for generating a map containing anatomic locations of electrodes with an affirmative scar indicator index.
3. The system of claim 2, further comprising a display means for displaying values of the features mapped to a computer model of a patient's anatomy.
4. The system of claim 1, further comprising a processor means for determining an inverse problem of electrocardiography based on the torso-surface potential signals and an anatomical computer model of a human heart and torso.
5. The system of claim 1, further comprising a processor means for computing potentials on a surface of a computer model of a heart anatomy based on the torso-surface potential signals.
6. The system of claim 1, further comprising a processor means for identifying boundaries of scar tissue on a computer model heart in response to determining the overall cardiac scar burden index and torso surface locations of the ones of the plurality of electrodes identified with an affirmative scar indicator index.

7. The system of claim 6, further comprising a display means for displaying the boundaries of scar tissue along the model heart and the overall cardiac scar burden index.

8. The system of claim 1, wherein the features extracted from the potential signals for each of the plurality of electrodes comprise at least two of a QRS amplitude metric, a Q-wave negativity metric, and a QRS fractionation metric.

9. The system of claim 1, further comprising a processor means for estimating a scar burden surface area in response to the determined overall cardiac scar burden index and the ones of the plurality of electrodes identified with an affirmative scar indicator index.

10. The system of claim 1, further comprising reporting means for reporting the scar burden index and a therapy recommendation in response to the scar burden index.

11. A method comprising:

receiving by a processor a torso-surface potential signal from each of a plurality of electrodes distributed on a torso of a patient;

extracting by the processor features of the potential signal from each of the plurality of electrodes;

storing values of the features in a non-transitory storage medium;

determining by the processor a scar indicator index for each of the plurality of electrodes from the stored features;

identifying ones of the plurality of electrodes having an affirmative scar indicator index; and

determining an overall scar burden index as a proportion of the plurality of electrodes with an affirmative scar indicator index.

12. The method of claim 11, further comprising generating a map containing anatomic locations of electrodes with an affirmative scar indicator index.

13. The method of claim 12, further comprising displaying values of the features mapped to a computer model of a patient's anatomy.

14. The method of claim 11, further comprising determining an inverse problem of electrocardiography based on the torso-surface potential signals and an anatomical computer model of a human heart and torso.

15. The method of claim 11, further comprising computing potentials on a surface of a computer model of a heart anatomy based on the torso-surface potential signals.

16. The method of claim 11, further comprising identifying boundaries of scar tissue on a computer model of a heart in response to determining the overall cardiac scar burden index and torso surface locations of the ones of the plurality of electrodes identified with an affirmative scar indicator index.

17. The method of claim 16, further comprising displaying the boundaries of scar tissue along the computer model of the heart and the overall cardiac scar burden index.

18. The method of claim 11, wherein extracting the features from the potential signals for each of the plurality of electrodes comprises determining at least two of a QRS amplitude metric, a Q-wave negativity metric, and a QRS fractionation metric.

19. The method of claim 11, further comprising estimating a scar burden surface area in response to the determined overall cardiac scar burden index and the ones of the plurality of electrodes identified with an affirmative scar indicator index.

20. The method of claim 11, further comprising reporting the scar burden index and a therapy recommendation in response to the scar burden index.

15

21. A non-transitory, computer readable storage medium comprising instructions for causing a processor of a medical device system to perform a method, the method comprising:

- receiving a torso-surface potential signal from each of a plurality of electrodes distributed on a torso of a patient; 5
- extracting features of the potential signal from each of the plurality of electrodes;
- storing values of the features in a non-transitory storage medium;
- determining a scar indicator index for each of the plurality 10 of electrodes from the stored features;
- identifying ones of the plurality of electrodes having an affirmative scar indicator index; and
- determining an overall scar burden index as a proportion of the plurality of electrodes with an affirmative scar indi- 15 cator index.

22. An apparatus for determining presence of myocardial scar tissue, comprising:

16

- sensing means for receiving a torso-surface potential signal from each of a plurality of electrodes distributed on a torso of a patient;
- processing means for extracting features of the potential signal from each of the plurality of electrodes;
- storing means for storing values of the features in a non-transitory storage medium;
- processing means for determining a scar indicator index for each of the plurality of electrodes from the stored features;
- processing means for identifying ones of the plurality of electrodes having an affirmative scar indicator index; and
- processing means for determining an overall scar burden index as a proportion of the plurality of electrodes with an affirmative scar indicator index.

* * * * *

专利名称(译)	鉴定健康与不健康的基质，用于从多极导联起搏		
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[标]申请(专利权)人(译)	美敦力公司		
申请(专利权)人(译)	美敦力公司，INC.		
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摘要(译)

医疗设备系统执行确定瘢痕组织的存在的方法。处理器从分布在患者躯干上的多个电极接收躯干表面电位信号。处理器从每个电极提取电位信号的特征，并将特征值存储在非暂时性存储介质中。处理器根据存储的特征确定每个电极的瘢痕指示符指数，并识别哪些电极具有肯定的瘢痕指示符指数。总体瘢痕负荷指数被确定为具有肯定瘢痕指标指数的电极的比例。

