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(54) METHODS AND SYSTEMS FOR MAPPING CARDIAC RESTITUTION

VERFAHREN UND SYSTEME ZUR ABBILDUNG DER HERZWIEDERHERSTELLUNG

PROCÉDÉS ET SYSTÈMES DE CARTOGRAPHIE DE LA RESTITUTION CARDIAQUE

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Description

BACKGROUND

[0001] US 2013/006131 A1 relates to the field of medicine and to a system and method for targeting rhythm irregularities and rhythm disorders of biological rhythms using shaped ablation.

[0002] US 2014/187989 A1 relates to cardiac mapping systems configured to estimate restitution curves based on recorded activation signals.

[0003] The instant disclosure relates to electrophysiological mapping, such as may be performed in cardiac diagnostic and therapeutic procedures. In particular, the instant disclosure relates to systems, apparatuses, and methods for mapping cardiac restitution.

[0004] "Restitution" refers to a functional relationship between the duration of a cardiac action potential and the length of the quiescent interval preceding it. In many cases, this relationship reflects limited change in action potential duration ("APD") over a broad range of long diastolic intervals ("DI") and shortening of the APD at shorter DIs. APD restitution can therefore be thought of as a form of adaptation to changes in heart rate.

[0005] An APD restitution curve can be constructed by varying the DI and plotting the resulting APD. To the first order, an APD restitution curve reflects the underlying dynamics of the system during steady-state conditions. For APD restitution curves with steep slopes (*i.e.*, greater than one), small changes in DI result in large changes in APD. On the other hand, for APD restitution curves with shallow slopes (*i.e.*, less than one), small changes in DI are damped out over subsequent beats. Research has shown that steep restitution slopes can lead to breakup of spiral waves in tissue.

[0006] "Cardiac electrogram restitution" is an analogous functional relationship between the length of a preceding interval (*e.g.*, cycle length or DI) and the successive duration (*e.g.*, APD, activation recovery interval ("ARI"), or EGM width). This relationship shows a form of adaptation to changes in heart rate and studies tissue properties that control the dynamic behavior of the heart.

[0007] It would be desirable to map cardiac restitution in real time during an electrophysiology ("EP") study.

BRIEF SUMMARY

[0008] A method in accordance with the invention is defined in claim 1.

[0009] A graphical representation of the at least one restitution metric can also be output on a three-dimensional model of the region of the cardiac surface.

[0010] The restitution data can include quiescent interval data (*e.g.*, DI data and cycle length data) and/or cardiac repolarization activity data (*e.g.*, APD data, ARI data, and EGM width data).

[0011] According to aspects of the disclosure, the step of identifying a subset of the plurality of EP data points forming an EP data point cluster about the anchor EP data point includes identifying a subset of the plurality of EP data points falling within a sphere centered at the anchor EP data point. The radius of the sphere can be user defined; one suitable radius is 9 mm.

[0012] In additional aspects of the disclosure, the step of fitting a restitution curve to the restitution data of the subset of the plurality of EP data points forming the EP data point cluster about the anchor EP data point includes fitting an exponential restitution curve to the restitution data of the subset of the plurality of EP data points forming the EP data point cluster about the anchor EP data point. The exponential restitution curve can be defined by the equation $y = f(x) = -a * e^{-\lambda x} + b$, wherein x is quiescent interval data, y is cardiac repolarization activity data, and a, b, and λ are restitution parameters that can, in turn, be determined by optimizing a cost function.

[0013] One cost function, particularly suitable for use in steady-state restitution analysis, is $\min_\theta \sum_{j=1}^{N} (f(x^{i,j}, \theta^i) - y^{i,j})^2$, wherein i designates the region of the cardiac surface; j designates the j^{th} EP data point, of a total of N EP data points, defining the region i of the cardiac surface; the restitution parameters a, b, and λ are collectively designated θ; and a is between 0.1 and 1, inclusive; b is between 0 and 1, inclusive; and λ is between 0.1 and 100, inclusive.

[0014] Another suitable cost function, particularly suitable for use in dynamic restitution analysis, is $\min_\theta \sum_{m=0}^{K} (f(x^{i,j,m}, \theta^j) - y^{i,j,m})^2$, wherein i designates the region of the cardiac surface; j designates the j^{th} EP data point defining the region i of the cardiac surface; m designates the m^{th} beat, of a total of K beats, measured at the j^{th} EP data point defining the region i of the cardiac surface; the restitution parameters a, b, and λ are collectively designated θ; and a is between 0.1 and 1, inclusive; b is between 0 and 1, inclusive; and λ is between 0.1 and 100, inclusive.

[0015] It is also contemplated, particularly in the case of a steady-state restitution analysis, that the step of identifying at least one restitution metric for the region of the cardiac surface from the restitution curve can include assigning an identical restitution metric for the region of the cardiac surface to the anchor EP data point and to each EP data point of the subset of the plurality of EP data points forming the EP data point cluster about the anchor EP data point.

[0016] Also disclosed herein is a method of mapping cardiac restitution, including the steps: acquiring a plurality of EP data points, each EP data point of the plurality of EP data points including location data, quiescent interval data, and cardiac repolarization activity data; inputting the plurality of EP data points to a signal processor, and, using the signal processor: identifying a subset of the plurality of EP data points forming an EP data point cluster; fitting a restitution curve to the quiescent interval data and the cardiac repolarization activity data of the subset of the plurality of EP data points forming the EP data point cluster; and identifying at least one restitution metric for the EP data point cluster using the restitution curve; and outputting a graphical representation of the identified at least one restitution metric for the EP data point cluster on a three-dimensional model of a region of a cardiac surface including the EP data point cluster.

[0017] The step of fitting a restitution curve to the quiescent interval data and the cardiac repolarization activity data of the subset of the plurality of EP data points forming the EP data point cluster can include fitting an exponential function using the quiescent interval data as the independent variable of the exponential function and the cardiac repolarization activity data as the dependent variable of the exponential function.

[0018] The step of outputting a graphical representation of the identified at least one restitution metric for the EP data point cluster on a three-dimensional model of a region of a cardiac surface including the EP data point cluster can include outputting a single graphical representation over an entirety of the region of the cardiac surface including the EP data point cluster. This is particularly suitable for steady-state restitution analysis.

[0019] The step of identifying at least one restitution metric for the EP data point cluster using the restitution curve can include identifying one or more of a maximum slope of the restitution curve and an asymptotic limit of the restitution curve.

[0020] A system in accordance with the invention is defined in claim 14. The system can also optionally include a mapping processor configured to generate and output a graphical representation of the at least one restitution metric for the EP data point cluster on a three-dimensional representation of a portion of a cardiac surface including the EP data point cluster.

[0021] The foregoing and other aspects, features, details, utilities, and advantages of the present invention will be apparent from reading the following description and claims, and from reviewing the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022]

Figure 1 is a representative restitution curve.

Figure 2 is a schematic of an electrophysiology system, such as may be used in an electrophysiology study.

Figure 3 depicts an exemplary multi-electrode catheter used in an electrophysiology study.

Figure 4 is a flowchart of representative steps that can be followed to map cardiac restitution according to an embodiment of the disclosure.

Figure 5 illustrates the identification of an EP data point cluster according to embodiments of the instant disclosure.

Figure 6A is a representative restitution map according to the teachings herein resulting from a steady-state restitution protocol.

Figure 6B is a representative restitution map according to the teachings herein resulting from a dynamic restitution protocol.

DETAILED DESCRIPTION

[0023] The present disclosure provides methods, apparatuses, and systems for the creation of electrophysiology ("EP") maps (*e.g.*, electrocardiographic maps) including cardiac restitution data. The ordinarily skilled artisan will be familiar with EP mapping generally, such that aspects thereof will only be described herein to the extent necessary to understand the cardiac restitution maps disclosed herein.

[0024] For purposes of illustration only, therefore, aspects of the cardiac restitution mapping techniques disclosed herein will be described with reference to cardiac restitution analysis and cardiac restitution maps based on APD as a function of DI. It should be understood, however, that these teachings can be extended by analogy to other metrics. For example, cycle length ("CL") can be used instead of DI as the independent variable, while ARI and/or EGM width can be used instead of APD as the dependent variable.

[0025] The term "quiescent interval data" is used herein to refer to the independent variable in a cardiac restitution analysis, such as DI and/or CL. The term "cardiac repolarization activity data" is used herein to refer to the dependent variable in a cardiac restitution analysis, such as APD, ARI, and/or EGM width. Representative methods, systems, and apparatus for measuring and mapping DI, APD, and/or ARI are described in United States provisional application no. 62/238,323, filed 7 October 2015. The term "restitution data" (or "cardiac restitution data") is used herein to refer collectively to quiescent interval data and cardiac repolarization activity data.

[0026] Various clinical protocols are known for measuring cardiac restitution. In a dynamic restitution protocol, for example, the heart is paced at a given CL until steady-state is reached, with APD and DI recorded for the duration. The process is then repeated with other CLs.

[0027] Another known clinical protocol is a steady-state (S1-S2) restitution protocol. In this protocol, the heart is paced at a fixed CL (S1) until steady-state is reached. Once steady-state is reached, the pacing is perturbed by a stimulus (S2) after waiting for a variable-length interval. The heart is then again paced at the fixed CL (S1) until steady-state is again reached, and pacing is perturbed by a different stimulus (S2). This allows the DIs and APDs resulting from the application of various stimuli (S2) to be recorded.

[0028] Via application of the foregoing protocols, or any other suitable protocol, a restitution curve can be constructed by varying DI and plotting the resulting APD. More particularly, a cardiac restitution curve can be constructed by varying the length of the preceding quiescent interval and plotting the duration of the successive cardiac repolarization activity. The restitution curve can then be constructed by fitting an exponential curve, or any other suitable curve, to the resultant data points.

[0029] A representative restitution curve 100 is shown in Figure 1. The form of restitution curve 100 reveals certain valuable information, including maximum slope 102 and asymptotic limit 104. These are referred to herein as "restitution metrics." The instant disclosure advantageously provides methods, systems, and apparatus for mapping restitution metrics in real time (that is, during the course of an EP study).

[0030] Figure 2 shows a schematic diagram of an electrophysiology system 8 for conducting cardiac electrophysiology studies by navigating a cardiac catheter and measuring electrical activity occurring in a heart 10 of a patient 11 and three-dimensionally mapping the electrical activity and/or information related to or representative of the electrical activity so measured. System 8 can be used, for example, to create an anatomical model of the patient's heart 10 using one or more electrodes. System 8 can also be used to measure electrophysiology data at a plurality of points along a cardiac surface and store the measured data in association with location information for each measurement point at which the electrophysiology data was measured, for example to create a diagnostic data map of the patient's heart 10.

[0031] As one of ordinary skill in the art will recognize, and as will be further described below, system 8 can determine the location, and in some aspects the orientation, of objects, typically within a three-dimensional space, and express those locations as position information determined relative to at least one reference.

[0032] For simplicity of illustration, the patient 11 is depicted schematically as an oval. In the embodiment shown in Figure 1, three sets of surface electrodes (*e.g.*, patch electrodes) are shown applied to a surface of the patient 11, defining three generally orthogonal axes, referred to herein as an x-axis, a y-axis, and a z-axis. In other embodiments the electrodes could be positioned in other arrangements, for example multiple electrodes on a particular body surface. As a further alternative, the electrodes do not need to be on the body surface, but could be positioned internally to the body or on an external frame.

[0033] In Figure 2, the x-axis surface electrodes 12, 14 are applied to the patient along a first axis, such as on the lateral sides of the thorax region of the patient (*e.g.*, applied to the patient's skin underneath each arm) and may be referred to as the Left and Right electrodes. The y-axis electrodes 18, 19 are applied to the patient along a second axis generally orthogonal to the x-axis, such as along the inner thigh and neck regions of the patient, and may be referred to as the Left Leg and Neck electrodes. The z-axis electrodes 16, 22 are applied along a third axis generally orthogonal to both the x-axis and the y-axis, such as along the sternum and spine of the patient in the thorax region, and may be referred to as the Chest and Back electrodes. The heart 10 lies between these pairs of surface electrodes 12/14, 18/19, and 16/22.

[0034] An additional surface reference electrode (*e.g.*, a "belly patch") 21 provides a reference and/or ground electrode for the system 8. The belly patch electrode 21 may be an alternative to a fixed intra-cardiac electrode 31, described in further detail below. It should also be appreciated that, in addition, the patient 11 may have most or all of the conventional electrocardiogram ("ECG" or "EKG") system leads in place. In certain embodiments, for example, a standard set of 12 ECG leads may be utilized for sensing electrocardiograms on the patient's heart 10. This ECG information is available to the system 8 (*e.g.*, it can be provided as input to computer system 20). Insofar as ECG leads are well understood, and for the sake of clarity in the figures, only one lead 6 and its connection to computer system 20 is illustrated in Figure 2.

[0035] A representative catheter 13 having at least one electrode 17 (*e.g.*, a distal electrode) is also depicted in schematic fashion in Figure 2. This representative catheter electrode 17 can be referred to as a "measurement electrode" or a "roving electrode." Typically, multiple electrodes on catheter 13, or on multiple such catheters, will be used. In one embodiment, for example, system 8 may utilize sixty-four electrodes on twelve catheters disposed within the heart and/or vasculature of the patient.

[0036] In other embodiments, system 8 may utilize a single catheter that includes multiple (*e.g.*, eight) splines, each of which in turn includes multiple (*e.g.*, eight) electrodes. Of course, these embodiments are merely exemplary, and any number of electrodes and catheters may be used. Indeed, in some embodiments, a high density mapping catheter, such as the EnSite™ Array™ non-contact mapping catheter of St. Jude Medical, Inc., can be utilized.

[0037] Likewise, it should be understood that catheter 13 (or multiple such catheters) are typically introduced into the heart and/or vasculature of the patient via one or more introducers and using familiar procedures. For purposes of this disclosure, a segment of an exemplary multi-electrode catheter 13 is shown in Figure 3. In Figure 3, catheter 13 extends into the left ventricle 50 of the patient's heart 10 through a transseptal sheath 35. The use of a transseptal approach to the left ventricle is well known and will be familiar to those of ordinary skill in the art, and need not be further described herein. Of course, catheter 13 can also be introduced into the heart 10 in any other suitable manner.

[0038] Catheter 13 includes electrode 17 on its distal tip, as well as a plurality of additional measurement electrodes 52, 54, 56 spaced along its length in the illustrated embodiment. Typically, the spacing between adjacent electrodes will be known, though it should be understood that the electrodes may not be evenly spaced along catheter 13 or of equal size to each other. Since each of these electrodes 17, 52, 54, 56 lies within the patient, location data may be collected simultaneously for each of the electrodes by system 8.

[0039] Similarly, each of electrodes 17, 52, 54, and 56 can be used to gather electrophysiological data from the cardiac surface. The ordinarily skilled artisan will be familiar with various modalities for the acquisition and processing of electrophysiology data points (including, for example, both contact and non-contact electrophysiological mapping), such that further discussion thereof is not necessary to the understanding of the conduction velocity mapping techniques disclosed herein. Likewise, various techniques familiar in the art can be used to generate a graphical representation from the plurality of electrophysiology data points. Insofar as the ordinarily skilled artisan will appreciate how to create electrophysiology maps from electrophysiology data points, the aspects thereof will only be described herein to the extent necessary to understand the maps disclosed herein.

[0040] Returning now to Figure 2, in some embodiments, a fixed reference electrode 31 (*e.g.*, attached to a wall of the heart 10) is shown on a second catheter 29. For calibration purposes, this electrode 31 may be stationary (*e.g.*, attached to or near the wall of the heart) or disposed in a fixed spatial relationship with the roving electrodes (*e.g.*, electrodes 17, 52, 54, 56), and thus may be referred to as a "navigational reference" or "local reference." The fixed reference electrode 31 may be used in addition or alternatively to the surface reference electrode 21 described above. In many instances, a coronary sinus electrode or other fixed electrode in the heart 10 can be used as a reference for measuring voltages and displacements; that is, as described below, fixed reference electrode 31 may define the origin of a coordinate system.

[0041] Each surface electrode is coupled to a multiplex switch 24, and the pairs of surface electrodes are selected by software running on a computer 20, which couples the surface electrodes to a signal generator 25. Alternately, switch 24 may be eliminated and multiple (*e.g.*, three) instances of signal generator 25 may be provided, one for each measurement axis (that is, each surface electrode pairing).

[0042] The computer 20, for example, may comprise a conventional general-purpose computer, a special-purpose computer, a distributed computer, or any other type of computer. The computer 20 may comprise one or more processors 28, such as a single central processing unit (CPU), or a plurality of processing units, commonly referred to as a parallel processing environment, which may execute instructions to practice the various aspects disclosed herein.

[0043] Generally, three nominally orthogonal electric fields are generated by a series of driven and sensed electric dipoles (*e.g.*, surface electrode pairs 12/14, 18/19, and 16/22) in order to realize catheter navigation in a biological conductor. Alternatively, these orthogonal fields can be decomposed and any pairs of surface electrodes can be driven as dipoles to provide effective electrode triangulation. Likewise, the electrodes 12, 14, 18, 19, 16, and 22 (or any other number of electrodes) could be positioned in any other effective arrangement for driving a current to or sensing a current from an electrode in the heart. For example, multiple electrodes could be placed on the back, sides, and/or belly of patient 11. For any desired axis, the potentials measured across the roving electrodes resulting from a predetermined set of drive (source-sink) configurations may be combined algebraically to yield the same effective potential as would be obtained by simply driving a uniform current along the orthogonal axes.

[0044] Thus, any two of the surface electrodes 12, 14, 16, 18, 19, 22 may be selected as a dipole source and drain with respect to a ground reference, such as belly patch 21, while the unexcited electrodes measure voltage with respect to the ground reference. The roving electrodes 17, 52, 54, 56 placed in the heart 10 are exposed to the field from a current pulse and are measured with respect to ground, such as belly patch 21. In practice the catheters within the heart 10 may contain more or fewer electrodes than the four shown, and each electrode potential may be measured. As previously noted, at least one electrode may be fixed to the interior surface of the heart to form a fixed reference electrode 31, which is also measured with respect to ground, such as belly patch 21, and which may be defined as the origin of the coordinate system relative to which localization system 8 measures positions. Data sets from each of the surface electrodes, the internal electrodes, and the virtual electrodes may all be used to determine the location of the roving electrodes 17, 52, 54, 56 within heart 10.

[0045] The measured voltages may be used by system 8 to determine the location in three-dimensional space of the electrodes inside the heart, such as roving electrodes 17, 52, 54, 56, relative to a reference location, such as reference electrode 31. That is, the voltages measured at reference electrode 31 may be used to define the origin of a coordinate system, while the voltages measured at roving electrodes 17, 52, 54, 56 may be used to express the location of roving electrodes 17, 52, 54, 56 relative to the origin. In some embodiments, the coordinate system is a three-dimensional (x, y, z) Cartesian coordinate system, although other coordinate systems, such as polar, spherical, and cylindrical coordinate systems, are contemplated.

[0046] As should be clear from the foregoing discussion, the data used to determine the location of the electrode(s) within the heart is measured while the surface electrode pairs impress an electric field on the heart. The electrode data may also be used to create a respiration compensation value used to improve the raw location data for the electrode locations as described in United States patent no. 7,263,397. The electrode data may also be used to compensate for changes in the impedance of the body of the patient as described, for example, in United States patent no. 7,885,707.

[0047] In one representative embodiment, the system

8 first selects a set of surface electrodes and then drives them with current pulses. While the current pulses are being delivered, electrical activity, such as the voltages measured with at least one of the remaining surface electrodes and *in vivo* electrodes, is measured and stored. Compensation for artifacts, such as respiration and/or impedance shifting, may be performed as indicated above.

[0048] In some embodiments, system 8 is the EnSite™ Velocity™ cardiac mapping and visualization system of St. Jude Medical, Inc., which generates electrical fields as described above, or another such system that relies upon electrical fields. Other systems, however, may be used in connection with the present teachings, including for example, the CARTO navigation and location system of Biosense Webster, Inc., the AURORA® system of Northern Digital Inc., or Sterotaxis' NIOBE® Magnetic Navigation System, all of which utilize magnetic fields rather than electrical fields. The localization and mapping systems described in the following patents can also be used with the present invention: United States Patent Nos. 6,990,370; 6,978,168; 6,947,785; 6,939,309; 6,728,562; 6,640,119; 5,983,126; and 5,697,377.

[0049] One methodology of mapping cardiac restitution will be explained herein with reference to the flowchart 400 of representative steps presented as Figure 4. In some embodiments, for example, flowchart 400 may represent several exemplary steps that can be carried out by the computer 20 of Figure 2 (*e.g.*, by one or more processors 28) to identify and map cardiac restitution as described herein. It should be understood that the representative steps described below can be either hardware- or software-implemented. For the sake of explanation, the term "signal processor" is used herein to describe both hardware- and software-based implementations of the teachings herein.

[0050] In step 402, a plurality of electrophysiology ("EP") data points are acquired, for example using a multi-electrode catheter as described above. As described above, each EP data point will include location information and EP information including, without limitation, information regarding APD (or other cardiac repolarization activity data) and DI (or other quiescent interval data) at the relevant location.

[0051] In block 404, a user selects one of the collected EP data points to serve as the basis for defining a region of a cardiac surface. This point is referred to herein as an "anchor EP data point" or "intrinsic EP data point." Although the user can select any of the collected EP data points as the anchor EP data point, it is advantageous to select a sinus rhythm point as the anchor EP data point. It is also desirable for the anchor EP data point to be selected when the measuring catheter (*e.g.*, catheter 13) is in stable contact with a point on the cardiac surface.

[0052] In block 406, a cluster of EP data points surrounding the anchor EP data point is identified. According to aspects of the instant disclosure, this EP data point cluster includes all EP data points that fall within a sphere surrounding the anchor EP data point, based, for example, upon their three dimensional Euclidean distance to the anchor EP data point. The radius of the sphere can be user-defined or preselected; in embodiments of the disclosure, the radius is 9 mm. In other embodiments, the radius of the sphere is greater or lesser than 9 mm.

[0053] The EP data point cluster defines a region *i* of the cardiac surface about the anchor EP data point. This is shown in two dimensions in Figure 5. As shown in Figure 5, the nomenclature $\mathrm{DxL}^{i,0}$ is used to denote the anchor EP data point for the i^{th} region of the cardiac surface and the nomenclature $\mathrm{DxL}^{i,j}$ is used to denote the j^{th} EP data point within the i^{th} region of the cardiac surface (that is, the j^{th} member of the EP data point cluster). It should also be understood that the EP data point cluster includes, and thus the i^{th} region of the cardiac surface is defined by, a total of N EP data points; in Figure 5, $N = 5$.

[0054] Of course, it is contemplated that more than one anchor EP data point can be selected, which will result in the definition of a corresponding number of EP data point clusters and regions of the cardiac surface. This can also result in detecting EP data points that fall within the sphere of multiple anchor EP data points; this conflict can be resolved in various ways. For example, in some embodiments, the overlapping EP data point can be added to the region as to which its distance to the anchor EP data point is smallest. In other embodiments, the overlapping EP data point can be counted in both regions. In still other embodiments, the user can choose which region will include the overlapping EP data point.

[0055] A restitution curve is fit to the restitution data of the EP data point cluster in block 408. As described above, the restitution curve is an exponential curve and can have the form $y = f(x) = -a * e^{-\lambda x} + b$. As further described above, quiescent interval data (*e.g.*, DI data) is used as the independent variable x, while cardiac repolarization activity data (*e.g.*, APD) is used as the dependent variable y. a, b, and λ are referred to as "restitution parameters" and can be determined by optimizing a cost function. In particular, the cost function to be optimized can depend upon the type of clinical protocol applied (*e.g.*, steady-state or dynamic).

[0056] For example, in the case of a steady-state protocol, the cost function can take the form $\min_\theta \sum_{j=1}^{N} (f(x^{i,j}, \theta^{i}) - y^{i,j})^2$.

[0057] As another example, in the case of a dynamic protocol, the cost function can take the form $\min_\theta \sum_{m=0}^{K} (f(x^{i,j,m}, \theta^{j}) - y^{i,j,m})^2$. In this instance, m denotes the m^{th} beat, of a total of K beats, measured at the j^{th} EP data point of the EP data point cluster.

[0058] In both cost functions described above, a, b, and λ are collectively denoted as parameter set θ. A bounded gradient-free optimization algorithm can be applied to optimize the parameter set θ, with bounds on a

of [0.1, 1], on *b* of [0,1], and on λ of [0.1, 100].

[0059] Once the restitution curve is fit, one or more restitution metrics (*e.g.*, maximum slope of restitution curve; asymptotic limit of restitution curve) can be identified. In the case of a steady-state protocol, the same restitution metric is applied to all EP data points within the region *i* (block 410). That is, for a steady-state restitution protocol, each and every EP data point within a given EP data point cluster will be assigned the same restitution metric for purposes of mapping cardiac restitution.

[0060] In the case of a dynamic protocol, on the other hand, the various EP data points in the EP data point cluster for a given region *i* can have different restitution metrics assigned thereto (block 412). In particular, a restitution curve can be fit to each EP data point individually over a series of beats.

[0061] In block 414, a graphical representation of the restitution metric can be displayed, for example on a three-dimensional model of the region of the cardiac surface.

[0062] Figure 6A illustrates a representative restitution map 602 for a steady-state protocol. As shown in Figure 6A, each EP data point 604 within a particular region (*e.g.*, region 606), is assigned the same restitution metric. Greyscale or false color can be used to depict various values for the restitution metric on a model 608 of the cardiac surface.

[0063] Figure 6B illustrates a representative restitution map 610 for a dynamic protocol. As shown in Figure 6B, the EP data points 604 can have individualized restitution metrics. As with Figure 6A, greyscale or false color can be used to depict various values for the restitution metric on model 608 of the cardiac surface.

[0064] Although several embodiments of this invention have been described above with a certain degree of particularity, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the spirit or scope of this invention.

[0065] For example, although methods of analyzing and mapping cardiac restitution are described primarily with reference to a single region of the cardiac surface, it should be understood that the steps described herein (*e.g.*, as depicted in Figure 4) can be repeated for multiple regions of the cardiac surface.

[0066] All directional references (*e.g.*, upper, lower, upward, downward, left, right, leftward, rightward, top, bottom, above, below, vertical, horizontal, clockwise, and counterclockwise) are only used for identification purposes to aid the reader's understanding of the present invention, and do not create limitations, particularly as to the position, orientation, or use of the invention. Joinder references (*e.g.*, attached, coupled, connected, and the like) are to be construed broadly and may include intermediate members between a connection of elements and relative movement between elements. As such, joinder references do not necessarily infer that two elements are directly connected and in fixed relation to each other.

[0067] It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative only and not limiting. Changes in detail or structure may be made without departing from the scope of the invention as defined in the appended claims.

Claims

1. A method of mapping cardiac restitution, comprising:

receiving a plurality of electrophysiology ("EP") data points at a signal processor, each EP data point of the plurality of EP data points comprising location data and restitution data,
wherein the location data of one EP data point is different to location data of another EP data point;
receiving user input defining an anchor EP data point of the plurality of EP data points;
identifying a subset of the plurality of EP data points forming an EP data point cluster about the anchor EP data point, wherein the EP data point cluster defines a region of a cardiac surface;
fitting a restitution curve to the restitution data of each of the EP data points having different location data of the subset of the plurality of EP data points forming the EP data point cluster about the anchor EP data point; and
identifying at least one restitution metric for the region of the cardiac surface from the restitution curve.

2. The method according to claim 1, further comprising outputting a graphical representation of the at least one restitution metric on a three-dimensional model of the region of the cardiac surface.

3. The method according to claim 1, wherein the restitution data comprises one of:

quiescent interval data, and wherein the quiescent interval data comprises one or more of DI data and cycle length data, and
cardiac repolarization activity data, and wherein the cardiac repolarization activity data comprises one or more of APD data, ARI data, and EGM width data.

4. The method according to claim 1, wherein identifying a subset of the plurality of EP data points forming an EP data point cluster about the anchor EP data point comprises identifying a subset of the plurality of EP data points falling within a sphere centered at the anchor EP data point.

5. The method according to claim 4, wherein a radius of the sphere is user defined.

6. The method according to claim 4, wherein the sphere comprises a sphere of radius 9 mm.

7. The method according to claim 1, wherein fitting a restitution curve to the restitution data of the subset of the plurality of EP data points forming the EP data point cluster about the anchor EP data point comprises fitting an exponential restitution curve to the restitution data of the subset of the plurality of EP data points forming the EP data point cluster about the anchor EP data point.

8. The method according to claim 7, wherein the exponential restitution curve is defined by an equation $y = f(x) = -a * e^{-\lambda x} + b$, wherein x comprises quiescent interval data, y comprises cardiac repolarization activity data, and a, b, and λ comprise a plurality of restitution parameters.

9. The method according to claim 8, wherein the plurality of restitution parameters a, b, and λ are determined by optimizing a cost function.

10. The method according to claim 9, wherein the cost function is defined as $\min_{\theta} \sum_{j=1}^{N} (f(x^{i,j}, \theta^{i}) - y^{i,j})^2$, wherein:

i designates the region of the cardiac surface;
j designates the j^{th} EP data point, of a total of *N* EP data points, defining the region *i* of the cardiac surface;
the restitution parameters *a*, *b*, and λ are collectively designated θ; and
a is between 0.1 and 1, inclusive;
b is between 0 and 1, inclusive; and
λ is between 0.1 and 100, inclusive.

11. The method according to claim 9, wherein the cost function is defined as $\min_{\theta} \sum_{m=0}^{K} (f(x^{i,j,m}, \theta^{j}) - y^{i,j,m})^2$, wherein:

i designates the region of the cardiac surface;
j designates the j^{th} EP data point defining the region *i* of the cardiac surface;
m designates the m^{th} beat, of a total of *K* beats, measured at the j^{th} EP data point defining the region *i* of the cardiac surface;
the restitution parameters *a*, *b*, and λ are collectively designated θ; and

a is between 0.1 and 1, inclusive;
b is between 0 and 1, inclusive; and
λ is between 0.1 and 100, inclusive.

12. The method according to claim 1, wherein the at least one restitution metric for the region of the cardiac surface comprises at least one of a maximum restitution curve slope and a restitution curve asymptotic limit.

13. The method according to claim 1, wherein identifying at least one restitution metric for the region of the cardiac surface from the restitution curve further comprises assigning an identical restitution metric for the region of the cardiac surface to the anchor EP data point and to each EP data point of the subset of the plurality of EP data points forming the EP data point cluster about the anchor EP data point.

14. A system for mapping cardiac restitution, comprising:
a cardiac restitution analysis processor (28) configured:

to receive a plurality of EP data points, each EP data point of the plurality of EP data points comprising location data and restitution data, the restitution data comprising quiescent interval data and cardiac repolarization activity data; wherein the location data of one EP data point is different to location data of another EP data point;
to identify a subset of the plurality of EP data points forming an EP data point cluster, wherein the EP data point cluster defines a region of a cardiac surface;
to fit a restitution curve to the restitution data of the subset of the plurality of EP data points having different location data forming the EP data point cluster; and
to identify at least one restitution metric for the EP data point cluster from the restitution curve.

15. The system according to claim 14, further comprising a mapping processor (28) configured to generate and output a graphical representation of the at least one restitution metric for the EP data point cluster on a three-dimensional representation of a portion of a cardiac surface including the EP data point cluster.

Patentansprüche

1. Verfahren zur Abbildung einer kardialen Restitution, mit:

Empfangen einer Mehrzahl von elektrophysiologischen ("EP") Datenpunkten an einem Signalprozessor, wobei jeder EP Datenpunkt von

der Mehrzahl von EP Datenpunkten Ortsdaten und Restitutionsdaten aufweist,
wobei die Ortsdaten von einem EP Datenpunkt verschieden sind zu Ortsdaten eines anderen EP Datenpunkts;
Empfangen einer Benutzereingabe, die einen EP Ankerdatenpunkt von der Mehrzahl von EP Datenpunkten definiert;
Identifizieren eines Nebensatzes von der Mehrzahl von EP Datenpunkten, die eine EP Datenpunktgruppe um den EP Ankerdatenpunkt bilden, wobei die EP Datenpunktgruppe eine Region einer Herzoberfläche definiert;
Anpassen einer Restitutionskurve an die Restitutionsdaten von jedem der EP Datenpunkte, die unterschiedliche Ortsdaten des Nebensatzes von der Mehrzahl von EP Datenpunkten aufweisen, die die EP Datenpunktgruppe um den EP Ankerdatenpunkt bilden; und
Identifizieren von mindestens einer Restitutionsmetrik für die Region der Herzoberfläche aus der Restitutionskurve.

2. Verfahren nach Anspruch 1, ferner mit einem Ausgeben einer grafischen Darstellung der mindestens einen Restitutionsmetrik auf einem dreidimensionalen Model der Region der Herzoberfläche.

3. Verfahren nach Anspruch 1, bei dem die Restitutionsdaten aufweisen:

Ruheintervalldaten, wobei die Ruheintervalldaten mindestens DI Daten und/oder Zykluslängendaten aufweisen, und/oder
Herzrepolarisierungsaktivitätsdaten, wobei die Herzrepolarisierungsaktivitätsdaten APD Daten, ARI Daten und/oder EGM Breitendaten aufweisen.

4. Verfahren nach Anspruch 1, bei dem das Identifizieren eines Nebensatzes von der Mehrzahl von EP Datenpunkten, die eine EP Datenpunktgruppe um den EP Ankerdatenpunkt bilden, ein Identifizieren eines Nebensatzes der Mehrzahl von EP Datenpunkten aufweist, die innerhalb einer Kugel liegen, die an den EP Ankerdatenpunkt zentriert ist.

5. Verfahren nach Anspruch 4, bei dem ein Radius der Kugel benutzerdefiniert ist.

6. Verfahren nach Anspruch 4, bei dem die Kugel eine Kugel mit einem Radius von 9 mm aufweist.

7. Verfahren nach Anspruch 1, bei dem das Anpassen einer Restitutionskurve an die Restitutionsdaten des Nebensatzes der Mehrzahl von EP Datenpunkten, die die EP Datenpunktgruppe um den EP Ankerdatenpunkt bilden, ein Anpassen einer exponentiellen Restitutionskurve an die Restitutionsdaten des Nebensatzes der Mehrzahl von EP Datenpunkten aufweist, die die EP Datenpunktgruppe um den EP Ankerdatenpunkt bilden.

8. Verfahren nach Anspruch 7, bei dem die exponentielle Restitutionskurve definiert ist durch eine Gleichung $y = f(x) = -a * e^{-\lambda x} + b$, wobei x die Ruheintervalldaten aufweist, y die Herzrepolarisierungsaktivitätsdaten aufweist, und a, b und λ eine Mehrzahl von Restitutionsparametern aufweisen.

9. Verfahren nach Anspruch 8, bei dem die Mehrzahl der Restitutionsparameter a, b und λ bestimmt sind durch Optimieren einer Kostenkurve.

10. Verfahren nach Anspruch 9, bei dem die Kostenkurve definiert ist durch $\min_{\theta} \sum_{j=1}^{N} \left(f\left(x^{i,j}, \theta^{i}\right) - y^{i,j}\right)^2$, wobei:

i die Region der Herzoberfläche angibt;
j den j-ten EP Datenpunkt von insgesamt N EP Datenpunkten angibt, die die Region i der Herzoberfläche definieren;
die Restitutionsparameter a, b und λ zusammen als θ bezeichnet sind; und
a zwischen 0,1 und 1, jeweils eingeschlossen, liegt;
b zwischen 0 und 1, jeweils eingeschlossen, liegt; und
λ zwischen 0,1 und 100, jeweils eingeschlossen, liegt.

11. Verfahren nach Anspruch 9, bei dem die Kostenkurve definiert ist durch $\min_{\theta} \sum_{m=0}^{K} \left(f\left(x^{i,j,m}, \theta^{j}\right) - y^{i,j,m}\right)^2$, wobei:

i die Region der Herzoberfläche angibt;
j den j-ten EP Datenpunkt angibt, der die Region i der Herzoberfläche definiert;
m den m-ten Schlag von insgesamt K Schlägen angibt, gemessen an dem j-ten EP Datenpunkt, der die Region i der Herzoberfläche definiert;
die Restitutionsparameter a, b und λ kollektiv als θ bezeichnet sind; und
a zwischen 0,1 und 1, jeweils eingeschlossen, liegt;
b zwischen 0 und 1, jeweils eingeschlossen, liegt; und
λ zwischen 0,1 und 100, jeweils eingeschlossen, liegt.

12. Verfahren nach Anspruch 1, bei dem die mindestens eine Restitutionsmetrik für die Region der Herzoberfläche mindestens eine maximale Restitutionskurvensteigung und/oder eine asymptotische Restitutionskurvengrenze aufweist.

13. Verfahren nach Anspruch 1, bei dem das Identifizieren von mindestens einer Restitutionsmetrik für die Region der Herzoberfläche aus der Restitutionskurve ferner ein Zuordnen einer identischen Restitutionsmetrik für die Region der Herzoberfläche zu dem EP Ankerdatenpunkt und zu jedem EP Datenpunkt des Nebensatzes der Mehrzahl von EP Datenpunkten aufweist, die die EP Datenpunktgruppe um den EP Ankerdatenpunkt bilden.

14. System zum Abbilden einer kardialen Restitution, mit:
einem Herzrestitutionsanalyseprozessor (28), der konfiguriert ist:

> zum Empfangen einer Mehrzahl von EP Datenpunkten, wobei jeder EP Datenpunkt der Mehrzahl von EP Datenpunkten Ortsdaten und Restitutionsdaten aufweist, wobei die Restitutionsdaten Ruheintervalldaten und Herzrepolarisierungsaktivitätsdaten aufweisen; wobei die Ortsdaten von einem EP Datenpunkt verschieden sind zu Ortsdaten von einem anderen EP Datenpunkt;
> zum Identifizieren eines Nebensatzes der Mehrzahl von EP Datenpunkten, die eine EP Datenpunktgruppe bilden, wobei die EP Datenpunktgruppe eine Region einer Herzoberfläche definiert;
> zum Anpassen einer Restitutionskurve an die Restitutionsdaten des Nebensatzes der Mehrzahl von EP Datenpunkten, die verschiedene Ortsdaten aufweisen, die die EP Datenpunktgruppe bilden; und
> zum Identifizieren von mindestens einer Restitutionsmetrik für die EP Datenpunktgruppe aus der Restitutionskurve.

15. System nach Anspruch 14, ferner mit einem Abbildungsprozessor (28), der konfiguriert ist zum Erzeugen und Ausgeben einer grafischen Darstellung von mindestens einer Restitutionsmetrik für die EP Datenpunktgruppe auf einer dreidimensionalen Darstellung eines Bereichs einer Herzoberfläche, der die EP Datenpunktgruppe enthält.

Revendications

1. Procédé de cartographie de restitution cardiaque, comprenant les étapes consistant à :

> recevoir une pluralité de points de données électrophysiologiques ("EP") à un processeur de signal, chaque point de données EP de la pluralité de points de données EP comprenant des données d'emplacement et de restitution,
> dans lequel les données d'emplacement d'un point de données EP sont différentes des données d'emplacement d'un autre point de données EP ;
> recevoir une entrée utilisateur définissant un point de données EP d'ancrage de la pluralité de points de données EP ;
> identifier un sous-ensemble de la pluralité de points de données EP formant un nuage de points de données EP autour du point de données EP d'ancrage, dans lequel le nuage de points de données EP définit une région d'une surface cardiaque ;
> ajuster une courbe de restitution à des données de restitution de chacun des points de données EP ayant des données d'emplacement différentes du sous-ensemble de la pluralité de points de données EP formant un nuage de points de données EP autour du point de données EP d'ancrage ; et
> identifier au moins une mesure de restitution pour la région de la surface cardiaque à partir de la courbe de restitution.

2. Procédé selon la revendication 1, comprenant en outre la sortie d'une représentation graphique d'au moins une mesure de restitution sur un modèle en trois dimensions de la région de la surface cardiaque.

3. Procédé selon la revendication 1, dans lequel les données de restitution comprennent l'un des éléments suivants :

> des données d'intervalle de repos, et dans lequel les données d'intervalle de repos comprennent une ou plusieurs données parmi des données DI et des données de longueur de cycle, et des données d'activité de repolarisation cardiaque, et dans lequel les données d'activité de repolarisation cardiaque comprennent une ou plusieurs données parmi des données APD, des données ARI et des données de largeur EGM.

4. Procédé selon la revendication 1, dans lequel l'identification d'un sous-ensemble de la pluralité de points de données EP formant un nuage de points de données EP autour du point de données EP d'ancrage comprend l'identification d'un sous-ensemble de la pluralité de points de données EP compris dans une sphère centrée au point de données EP d'ancrage.

5. Procédé selon la revendication 4, dans lequel un rayon de la sphère est défini par l'utilisateur.

6. Procédé selon la revendication 4, dans lequel la sphère comprend une sphère d'un rayon de 9 mm.

7. Procédé selon la revendication 1, dans lequel l'ajustement d'une courbe de restitution aux données de restitution du sous-ensemble de la pluralité de points de données EP formant le nuage de points de données EP autour du point de données EP d'ancrage comprend l'adaptation d'une courbe de restitution exponentielle aux données de restitution du sous-ensemble de la pluralité de points de données EP formant le nuage de points de données EP autour du point de données EP d'ancrage.

8. Procédé selon la revendication 7, dans lequel la courbe de restitution exponentielle est définie par une équation $y = f(x) = -a * e^{-\lambda x} + b$, dans lequel x comprend des données d'intervalle de repos, y comprend des données d'activité de repolarisation cardiaque, et a, b et λ comprennent une pluralité de paramètres de restitution.

9. Procédé selon la revendication 8, dans lequel la pluralité des paramètres de restitution a, b et λ sont déterminés en optimisant une fonction de coût.

10. Procédé selon la revendication 9, dans lequel la fonction de coût est définie comme $\min_{\theta} \sum_{j=1}^{N} (f(x^{i,j}, \theta^{i}) - y^{i,j})^2$ où :

i désigne la région de la surface cardiaque ;

j désigne le $j^{\text{ème}}$ point de données EP, d'un total de N points de données EP, définissant la région i de la surface cardiaque ;

les paramètres de restitution a, b et λ sont désignés collectivement par θ ; et

a est compris entre 0,1 et 1, inclusivement ;

b est compris entre 0 et 1, inclusivement ; et

λ est compris entre 0,1 et 100, inclusivement.

11. Procédé selon la revendication 9, dans lequel la fonction de coût est définie comme $\min_{\theta} \sum_{m=0}^{K} (f(x^{i,j,m}, \theta^{j}) - y^{i,j,m})^2$ où :

i désigne la région de la surface cardiaque ;

j désigne le $j^{\text{ème}}$ point de données EP définissant la région i de la surface cardiaque ;

m désigne le $m^{\text{ème}}$ rythme, d'un total de K rythme, mesuré au $j^{\text{ème}}$ point de données EP définissant la région i de la surface cardiaque ;

les paramètres de restitution a, b et λ sont désignés collectivement par θ ; et

a est compris entre 0,1 et 1, inclusivement ;

b est compris entre 0 et 1, inclusivement ; et

λ est compris entre 0,1 et 100, inclusivement.

12. Procédé selon la revendication 1, dans lequel ladite au moins une mesure de restitution pour la région de la surface cardiaque comprend au moins une pente parmi une pente de courbe de restitution maximale et une limite asymptotique de courbe de restitution.

13. Procédé selon la revendication 1, dans lequel l'identification d'au moins une mesure de restitution pour la région de la surface cardiaque à partir de la courbe de restitution comprend en outre l'affectation d'une mesure de restitution identique pour la région de la surface cardiaque au point de données EP d'ancrage et à chaque point de données EP du sous-ensemble de la pluralité des points de données EP formant le nuage de points de données EP autour du point de données EP d'ancrage.

14. Système de cartographie de restitution cardiaque, comprenant :
un processeur d'analyse de restitution cardiaque (28) configuré :

pour recevoir une pluralité de points de données EP, chaque point de données EP de la pluralité de points de données EP comprenant des données d'emplacement et des données de restitution, les données de restitution comprenant des données d'intervalle de repos et des données d'activité de repolarisation cardiaque ; dans lequel les données d'emplacement d'un point de données EP sont différentes des données d'emplacement d'un autre point de données EP ;

pour identifier un sous-ensemble de la pluralité de points de données EP formant un nuage de points de données EP, dans lequel le nuage de points de données EP définit une région d'une surface cardiaque ;

pour ajuster une courbe de restitution à des données de restitution du sous-ensemble de la pluralité de points de données EP ayant des données d'emplacement différentes formant le nuage de points de données EP ; et

pour identifier au moins une mesure de restitution pour le nuage de points de données EP à partir de la courbe de restitution.

15. Système selon la revendication 14, comprenant en outre un processeur de cartographie (28) configuré pour générer et délivrer une représentation graphique dudit au moins une mesure de restitution pour le nuage de points de données EP sur une représentation en trois dimensions d'une partie d'une surface cardiaque comprenant le nuage de points de données EP.

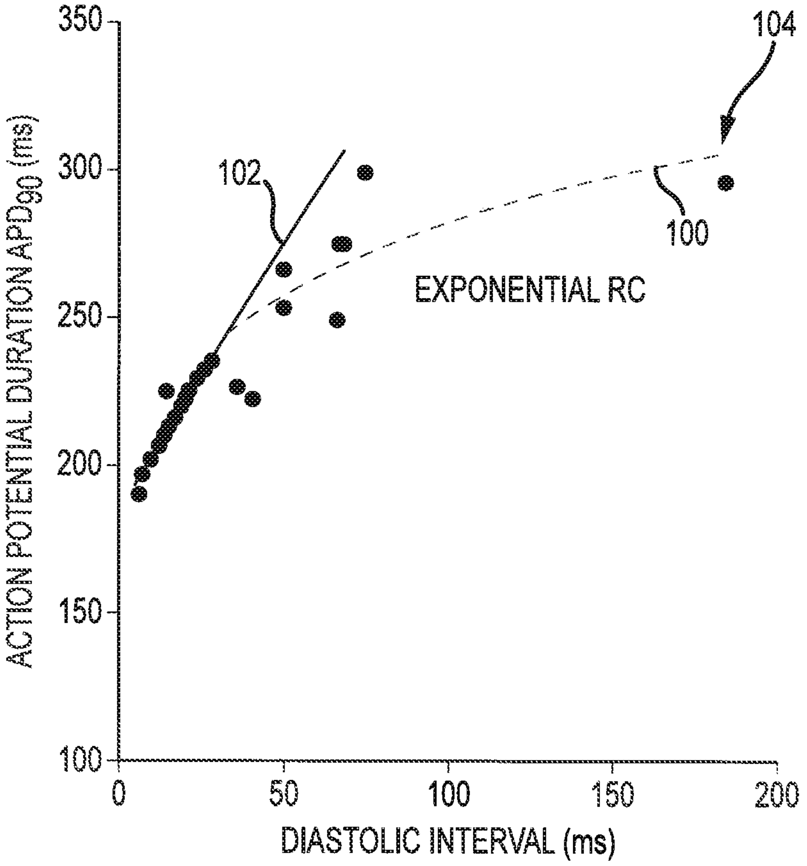
350
300
250
200
150
100
0
50
100
150
200
ACTION POTENTIAL DURATION APD90 (ms)
DIASTOLIC INTERVAL (ms)
102
104
100
EXPONENTIAL RC

FIG.1

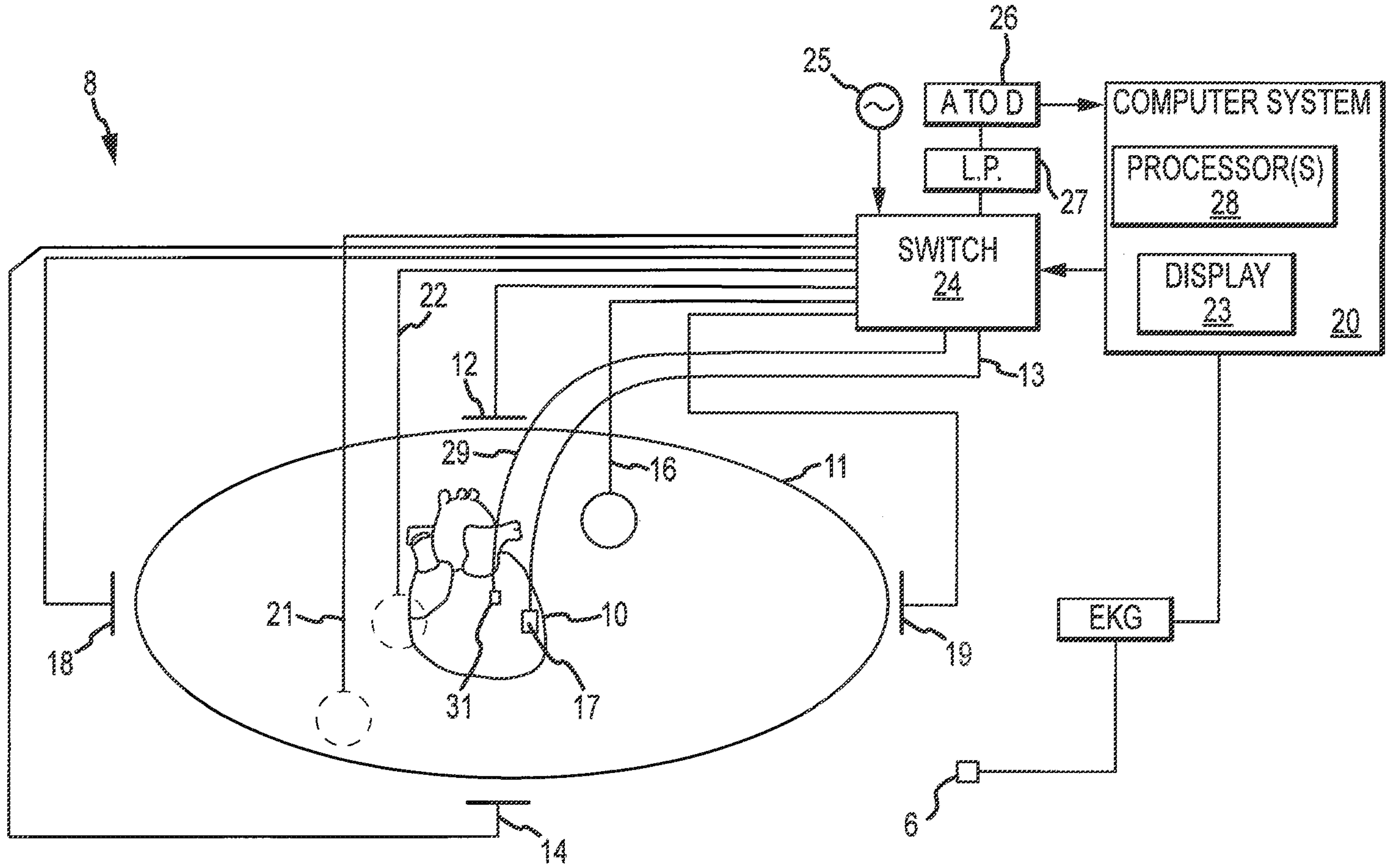
8
25
26
A TO D
COMPUTER SYSTEM
PROCESSOR(S)
28
L.P.
27
SWITCH
24
DISPLAY
23
20
22
12
13
29
16
11
21
10
18
19
EKG
31
17
6
14

FIG.2

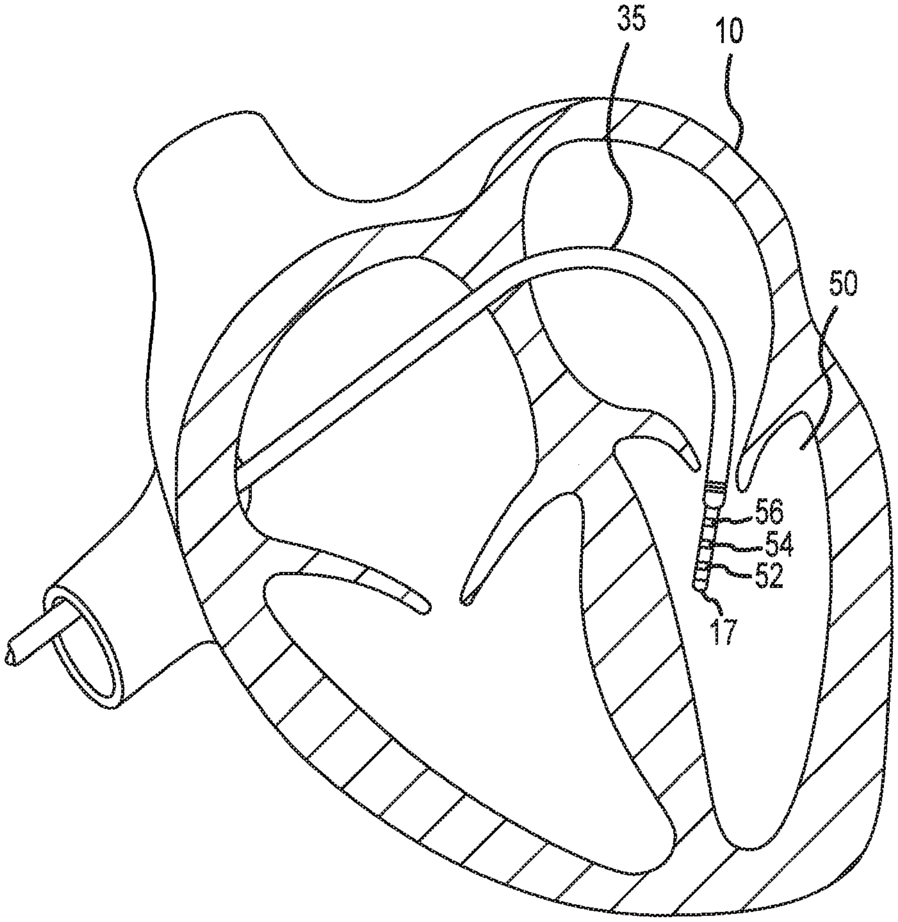

FIG.3

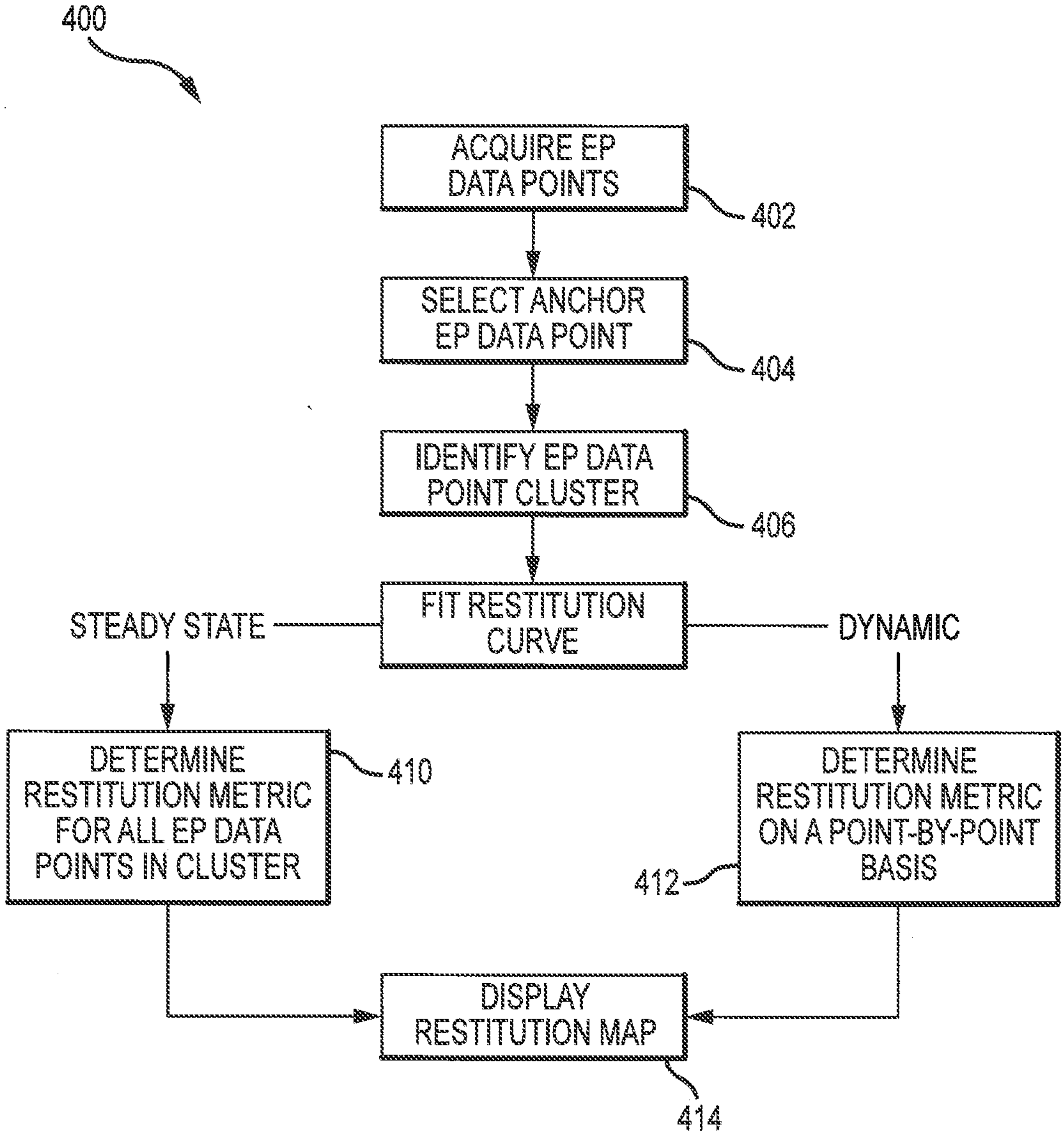
400
ACQUIRE EP DATA POINTS
402
SELECT ANCHOR EP DATA POINT
404
IDENTIFY EP DATA POINT CLUSTER
406
FIT RESTITUTION CURVE
STEADY STATE
DYNAMIC
DETERMINE RESTITUTION METRIC FOR ALL EP DATA POINTS IN CLUSTER
410
DETERMINE RESTITUTION METRIC ON A POINT-BY-POINT BASIS
412
DISPLAY RESTITUTION MAP
414

FIG.4

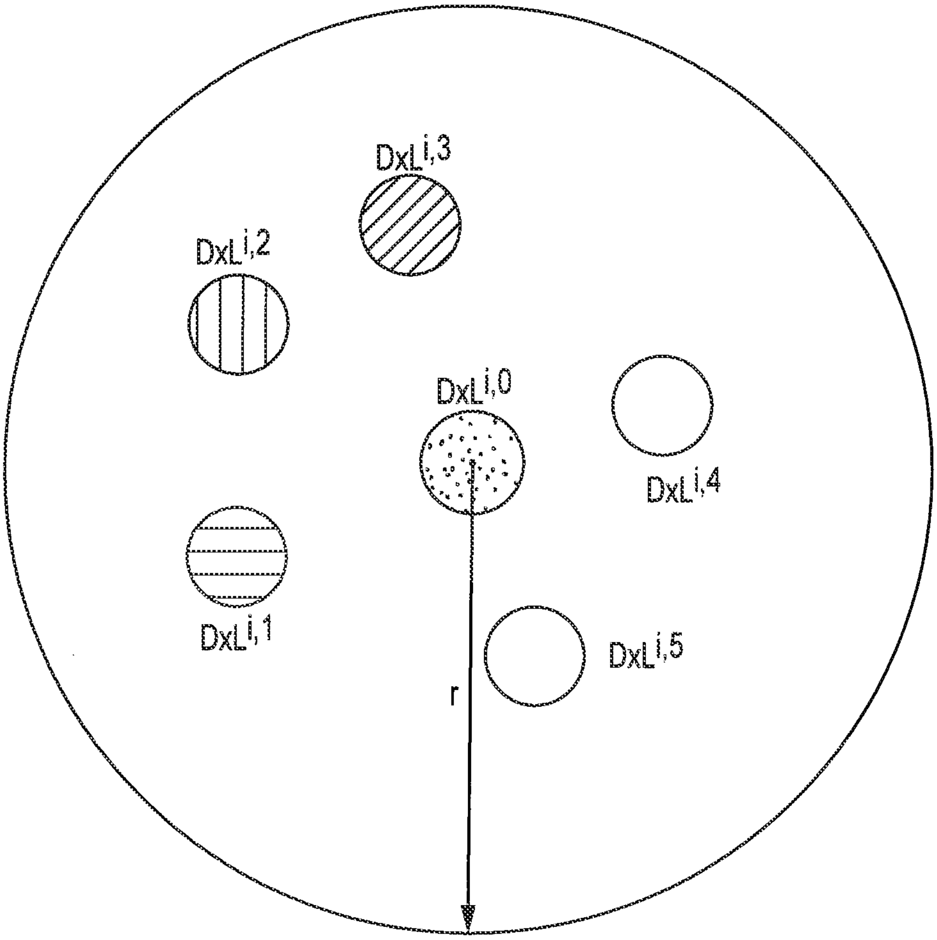

FIG.5

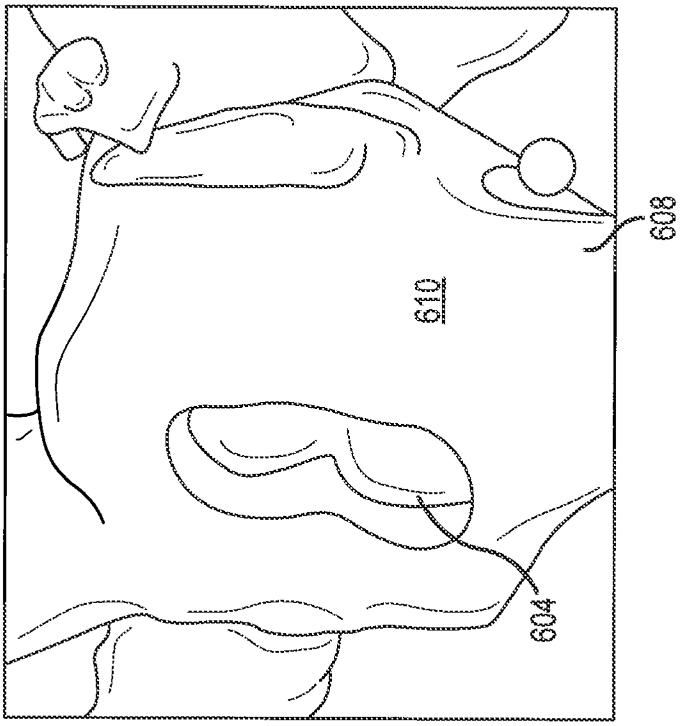

FIG.6B

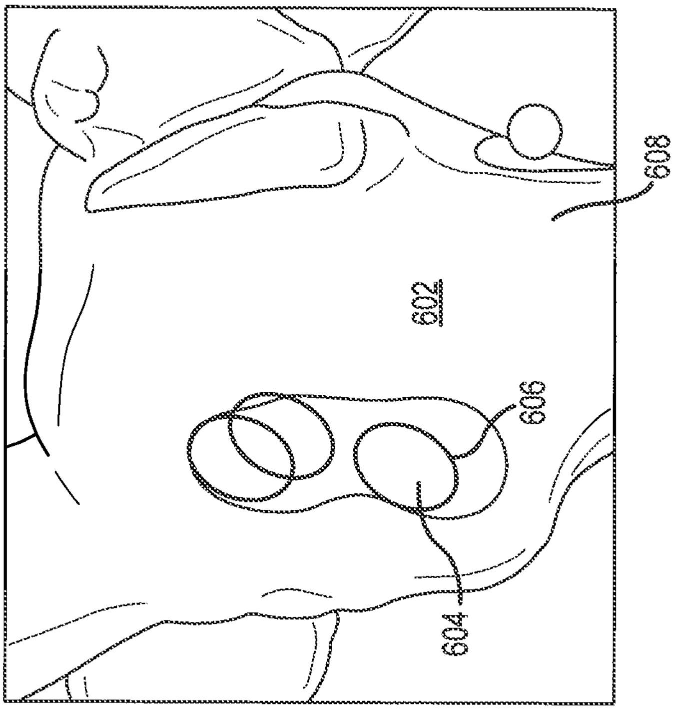

FIG.6A

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- US 6728562 B **[0048]**
- US 6640119 B **[0048]**
- US 5983126 A **[0048]**
- US 5697377 A **[0048]**

专利名称(译)	说明心律恢复的方法和系统		
公开(公告)号	EP3344135B1	公开(公告)日	2019-12-11
申请号	EP2016781254	申请日	2016-09-29
[标]申请(专利权)人(译)	圣犹达医疗用品心脏病学部门有限公司		
申请(专利权)人(译)	ST.犹达医疗用品，心脏病DIVISION，INC.		
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IPC分类号	A61B5/042 A61B5/00		
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优先权	62/238451 2015-10-07 US		
其他公开文献	EP3344135A1		
外部链接	Espacenet		

摘要(译)

一种映射心脏恢复的方法，包括：接收包括位置和恢复数据的多个EP数据点；以及 识别形成EP数据点簇的EP数据点的子集； 将恢复曲线拟合到形成集群的EP数据点的恢复数据； 从恢复曲线中识别出对应于该簇的心脏表面区域的至少一个恢复度量。 恢复曲线可以是使用静态间隔数据（例如，DI和/或CL）作为自变量和心脏复极化活动数据（例如，APD，ARI和/或EGM宽度）作为因变量的指数函数。 可以通过优化成本函数来确定指数函数的参数。 还可以在心脏表面的三维模型上输出恢复度量的图形表示。

$$\min_{\theta} \sum_{j=1}^{N} \left(f\left(x^{i,j}, \theta^{i}\right) - y^{i,j} \right)^{2},$$