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(54) **Title**: CARDIAC MAPPING USING LATENCY INTERPOLATION

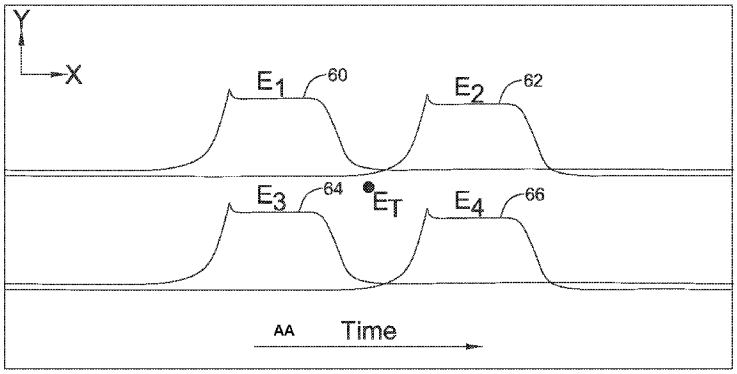

FIG. 10

(57) **Abstract**: Medical devices and methods for using medical devices are disclosed. An example mapping medical device may include a catheter shaft with a plurality of electrodes. The plurality of electrodes may include a first pair of electrodes, a second pair of electrodes, a third pair of electrodes and a fourth pair of electrodes. The mapping medical device may further include a processor, wherein the processor may be configured to determine a first latency between the first pair of electrodes, determine a second latency between the second pair of electrodes, determine a third latency between the third pair of electrodes, determine a fourth latency between the fourth pair of electrodes, and determine a target signal by interpolating the first latency, the second latency, the third latency and the fourth latency.

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CARDIAC MAPPING USING LATENCY INTERPOLATION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. §119 to U.S. Provisional Application Serial No. 61/899,033, filed November 1, 2013, the entirety of which is incorporated herein by reference.

TECHNICAL FIELD

The present disclosure pertains to medical devices, and methods for manufacturing medical devices. More particularly, the present disclosure pertains to elongated intracorporeal medical devices including a tubular member connected with other structures, and methods for manufacturing and using such devices.

BACKGROUND OF THE INVENTION

A wide variety of intracorporeal medical devices have been developed for medical use, for example, intravascular use. Some of these devices include guidewires, catheters, and the like. These devices are manufactured by any one of a variety of different manufacturing methods and may be used according to any one of a variety of methods. Of the known medical devices and methods, each has certain advantages and disadvantages. There is an ongoing need to provide alternative medical devices as well as alternative methods for manufacturing and using medical devices.

BRIEF SUMMARY

The invention provides design, material, manufacturing method, and use alternatives for medical devices. An example mapping medical device is disclosed. An example mapping medical device may comprise:

a catheter shaft with a plurality of electrodes coupled thereto, wherein the plurality of electrodes includes a first pair of electrodes, a second pair of electrodes, a third pair of electrodes and a fourth pair of electrodes;

a processor, wherein the processor is configured to:

determine a first latency between the first pair of electrodes;

determine a second latency between the second pair of electrodes;

determine a third latency between the third pair of electrodes;

determine a fourth latency between the fourth pair of electrodes; and

determine a target signal by interpolating the first latency, the second latency, the third latency and the fourth latency.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal further includes sensing a change in electrical potential at the first pair of electrodes over a time period.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal further includes sensing a change in electrical potential at the second pair of electrodes over the time period.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal includes calculating a first intermediate signal.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal includes collecting a first set of data corresponding to the change in electrical potential at the first pair of electrodes over the time period, collecting a second set of data corresponding to the change in electrical potential at the second pair of electrodes over the time period, and timeshifting the first set of data and timeshifting the second set of data.

Alternatively or additionally to any of the embodiments above, wherein calculating the first intermediate signal includes calculating a weighted average of the timeshifted first set of data and the timeshifted second set of data.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal further includes sensing a change in electrical potential at the third pair of electrodes over the time period.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal further includes sensing a change in electrical potential at the fourth pair of electrodes over the time period.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal includes calculating a second intermediate signal.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal includes collecting a third set of data corresponding to the change in electrical potential at the third pair of electrodes over the time period, collecting a fourth set of data corresponding to the change in electrical potential at the

fourth pair of electrodes over the time period, and timeshifting the third set of data and timeshifting the fourth set of data.

Alternatively or additionally to any of the embodiments above, wherein calculating a second intermediate signal includes calculating a weighted average of the timeshifted third set of data and the timeshifted fourth set of data.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal includes timeshifting the first intermediate signal, timeshifting the second intermediate signal and calculating a weighted average of the first and second intermediate signals.

Alternatively or additionally to any of the embodiments above, wherein the first pair of electrodes is positioned directly adjacent the second pair of electrodes.

Alternatively or additionally to any of the embodiments above, wherein one or more electrodes are positioned between the first and second pairs of electrodes.

Alternatively or additionally to any of the embodiments above, further comprising the step of ablating a location of the target signal.

Alternatively or additionally to any of the embodiments above, wherein the first pair of electrodes includes a first electrode and a second electrode.

Alternatively or additionally to any of the embodiments above, wherein the second pair of electrodes includes a third electrode and a fourth electrode.

Alternatively or additionally to any of the embodiments above, wherein the third pair of electrodes includes a first electrode and a third electrode.

Alternatively or additionally to any of the embodiments above, wherein the fourth pair of electrodes includes a second electrode and a fourth electrode.

An example method for delivering a medical mapping device comprises:

delivering the medical mapping device of any one of the disclosed embodiments into the heart of a patient.

An example method for mapping an anatomical structure may comprise:

determining a first latency between a first and a second electrode on a medical device;

determining a second latency between a third and a fourth electrode on the medical device;

determining a third latency between a first and a third electrode on the medical device;

determining a fourth latency between a second and a fourth electrode on the medical device; and

determining a target signal by interpolating the first latency, the second latency, the third latency and the fourth latency.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal further includes sensing a change in electrical potential at the first electrode over a time period.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal further includes sensing a change in electrical potential at the second electrode over the time period.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal includes calculating a first intermediate signal.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal includes collecting a first set of data corresponding to the change in electrical potential at the first electrode over the time period, collecting a second set of data corresponding to the change in electrical potential at the second electrode over the time period, and timeshifting the first set of data and timeshifting the second set of data.

Alternatively or additionally to any of the embodiments above, wherein calculating a first intermediate signal includes calculating a weighted average of the timeshifted first set of data and the timeshifted second set of data.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal further includes sensing a change in electrical potential at the third electrode over the time period.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal further includes sensing a change in electrical potential at the fourth electrode over the time period.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal includes calculating a second intermediate signal.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal includes collecting a third set of data corresponding to the change in electrical potential at the third electrode over the time period, collecting a fourth set of data corresponding to the change in electrical potential at the fourth

electrode over the time period, timeshifting the third set of data and timeshifting the fourth set of data.

Alternatively or additionally to any of the embodiments above, wherein calculating a second intermediate signal includes calculating a weighted average of the timeshifted third set of data and the timeshifted fourth set of data.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal includes timeshifting the first intermediate signal, timeshifting the second intermediate signal and calculating a weighted average of the first and second intermediate signals to determine the target signal

Alternatively or additionally to any of the embodiments above, wherein the first electrode is positioned directly adjacent the second electrode.

Alternatively or additionally to any of the embodiments above, wherein one or more electrodes are positioned between the first and second electrodes.

Alternatively or additionally to any of the embodiments above, further comprising the step of ablating a location of the target signal.

An example method for mapping an anatomical structure comprises:

providing a mapping medical device, the medical device including a catheter shaft with a plurality of electrodes coupled thereto, wherein the plurality of electrodes includes a first pair of electrodes, a second pair of electrodes, a third pair of electrodes and a fourth pair of electrodes;

determining a first latency between the first pair of electrodes;

determining a second latency between the second pair of electrodes;

determining a third latency between the third pair of electrodes;

determining a fourth latency between the fourth pair of electrodes; and

determining a target signal by interpolating the first latency, the second latency, the third latency and the fourth latency.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal further includes sensing a change in electrical potential at the first pair of electrodes over a time period.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal further includes sensing a change in electrical potential at the second pair of electrodes over the time period.

Alternatively or additionally to any of the embodiments above, wherein the medical device includes a processor and wherein determining the target signal includes using the processor to calculate a first intermediate signal.

Alternatively or additionally to any of the embodiments above, wherein the processor collects a first set of data corresponding to the change in electrical potential at the first pair of electrodes over the time period, wherein the processor collects a second set of data corresponding to the change in electrical potential at the second pair of electrodes over the time period, and wherein the processor timeshifts the first set of data and timeshifts the second set of data.

Alternatively or additionally to any of the embodiments above, wherein using the processor to calculate a first intermediate signal includes calculating a weighted average of the timeshifted first set of data and the timeshifted second set of data.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal further includes sensing a change in electrical potential at the third pair of electrodes over the time period.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal further includes sensing a change in electrical potential at the fourth pair of electrodes over the time period.

Alternatively or additionally to any of the embodiments above, wherein determining the target signal includes using the processor to calculate a second intermediate signal.

Alternatively or additionally to any of the embodiments above, wherein the processor collects a third set of data corresponding to the change in electrical potential at the third pair of electrodes over the time period, wherein the processor collects a fourth set of data corresponding to the change in electrical potential at the fourth pair of electrodes over the time period, and wherein the processor timeshifts the third set of data and timeshifts the fourth set of data.

Alternatively or additionally to any of the embodiments above, wherein using the processor to calculate a second intermediate signal includes calculating a weighted average of the timeshifted third set of data and the timeshifted fourth set of data.

Alternatively or additionally to any of the embodiments above, wherein the processor timeshifts the first intermediate signal, wherein the processor timeshifts the second intermediate signal and wherein the processor calculates a weighted average of the first and second intermediate signals to determine the target signal

Alternatively or additionally to any of the embodiments above, the first pair of electrodes is positioned directly adjacent the second pair of electrodes.

Alternatively or additionally to any of the embodiments above, wherein one or more electrodes are positioned between the first and second pairs of electrodes.

Alternatively or additionally to any of the embodiments above, further comprising the step of ablating a location of the target signal.

Alternatively or additionally to any of the embodiments above, wherein the first pair of electrodes includes a first electrode and a second electrode.

Alternatively or additionally to any of the embodiments above, wherein the second pair of electrodes includes a third electrode and a fourth electrode.

Alternatively or additionally to any of the embodiments above, wherein the third pair of electrodes includes a first electrode and a third electrode.

Alternatively or additionally to any of the embodiments above, wherein the fourth pair of electrodes includes a second electrode and a fourth electrode.

The above summary of some embodiments is not intended to describe each disclosed embodiment or every implementation of the present disclosure. The Figures, and Detailed Description, which follow, more particularly exemplify these embodiments.

BRIEF DECRIPTION OF THE DRAWINGS

The disclosure may be more completely understood in consideration of the following detailed description in connection with the accompanying drawings, in which:

FIG. 1 is a schematic view of an embodiment of a catheter system for accessing a targeted tissue region in the body for diagnostic and therapeutic purposes.

FIG. 2 is a schematic view of an embodiment of a mapping catheter having a basket functional element carrying structure for use in association with the system of FIG. 1.

FIG. 3 is a schematic view of an embodiment of the basket functional element including a plurality of mapping electrodes.

FIG. 4 is an illustration of an example excitation wavefront and four electrodes arranged in a 2x2 distribution.

FIG. 5 is an illustration of two example electrogram signals and an example electrogram of a targeted signal.

FIG. 6 is an illustration of an example electrogram signal over a time period positioned in a coordinate system.

FIG. 7 is an illustration of an example electrogram signal over a time period positioned in a coordinate system.

FIG. 8 is an illustration of an example electrogram signal over a time period positioned in a coordinate system.

FIG. 9 is an illustration of an example electrogram signal over a time period positioned in a coordinate system.

FIG. 10 is an illustration of the example electrogram signals of FIGS. 6-9 positioned in a coordinate system.

FIG. 11 is an illustration of two example electrogram curves and an example intermediate signal.

FIG. 12 is an illustration of two example electrogram curves and an example intermediate signal.

FIG. 13 is an illustration of two example intermediate signals and an example final interpolated electrogram signal.

While the disclosure is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure.

DETAILED DESCRIPTION

For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

All numeric values are herein assumed to be modified by the term "about," whether or not explicitly indicated. The term "about" generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In many instances, the terms "about" may include numbers that are rounded to the nearest significant figure.

The recitation of numerical ranges by endpoints includes all numbers within that range (e.g. 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

As used in this specification and the appended claims, the singular forms "a", "an", and "the" include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

It is noted that references in the specification to "an embodiment", "some embodiments", "other embodiments", etc., indicate that the embodiment described may include one or more particular features, structures, and/or characteristics. However, such recitations do not necessarily mean that all embodiments include the particular features, structures, and/or characteristics. Additionally, when particular features, structures, and/or characteristics are described in connection with one embodiment, it should be understood that such features, structures, and/or characteristics may also be used connection with other embodiments whether or not explicitly described unless clearly stated to the contrary.

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

Mapping the electrophysiology of heart rhythm disorders often involves the introduction of a constellation catheter or other mapping/sensing device having a plurality of sensors into a cardiac chamber. The sensors detect the electric activity of the heart at sensor locations. It may be desirable to have the electric activity processed into electrogram signals that accurately represent cellular excitation through cardiac tissue relative to the sensor locations. A processing system may then analyze and output the signal to a display device. The physician may use the displayed information to perform a diagnostic procedure. However, in some cases the sensing electrodes may fail to accurately detect electrical activity of heart. For example, the sensors may fail entirely to detect a signal or they may detect far-field electrical activity and/or electrical artifacts.

The processing system may be configured to detect a variety of activation signals generated by the electrical activity of the myocardial tissue and sensed by adjacent electrodes. However, a limited number of electrodes on the constellation catheter or other mapping/sensing device may limit the resolution of the activation pattern sensing. Therefore, it may be desirable to interpolate a weak or non-existent activation signal. Standard interpolation methods may have limitations due to the

transient nature of activation signals and the non-instantaneous nature of activation signal propagation across electrodes. The methods and systems disclosed herein are designed to overcome at least some of the limitations of standard interpolation methods to interpolate weak or non-existent activation signals. For example, some of the methods disclosed herein may include interpolating methods that account for latency effects inherent in the propagation of cellular excitation signals. Other methods and medical devices are also disclosed.

FIG. 1 is a schematic view of a system 10 for accessing a targeted tissue region in the body for diagnostic and/or therapeutic purposes. FIG. 1 generally shows the system 10 deployed in the left atrium of the heart. Alternatively, system 10 can be deployed in other regions of the heart, such as the left ventricle, right atrium, or right ventricle. While the illustrated embodiment shows the system 10 being used for ablating myocardial tissue, the system 10 (and the methods described herein) may alternatively be configured for use in other tissue ablation applications, such as procedures for ablating tissue in the prostrate, brain, gall bladder, uterus, nerves, blood vessels and other regions of the body, including in systems that are not necessarily catheter-based.

The system 10 includes a mapping probe 14 and an ablation probe 16. In FIG. 1, each is separately introduced into the selected heart region 12 through a vein or artery (e.g., the femoral vein or artery) through suitable percutaneous access.

Alternatively, the mapping probe 14 and ablation probe 16 can be assembled in an integrated structure for simultaneous introduction and deployment in the heart region 12.

The mapping probe 14 may have a flexible catheter body 18. The distal end of the catheter body 18 carries a three-dimensional multiple electrode structure 20. In the illustrated embodiment, the structure 20 takes the form of a basket defining an open interior space 22 (see FIG. 2), although other multiple electrode structures could be used wherein the geometry of the electrode structure and electrode locations may be known. The multiple electrode structure 20 carries a plurality of mapping electrodes 24 (not explicitly shown on FIG. 1, but shown on FIG. 2) each having an electrode location and channel. Each electrode 24 may be configured to sense intrinsic physiological activity in the anatomical region. In some embodiments, the electrodes 24 may be configured to detect activation signals of the intrinsic physiological activity within the anatomical structure, e.g., the activation times of cardiac activity.

The electrodes 24 are electrically coupled to a processing system 32. A signal wire (not shown) may be electrically coupled to each electrode 24 on the basket structure 20. The wires extend through the body 18 of the probe 14 and electrically couple each electrode 24 to an input of the processing system 32, as will be described later in greater detail. The electrodes 24 sense intrinsic electrical activity in the anatomical region, e.g., myocardial tissue. The sensed activity, e.g. activation signals, is processed by the processing system 32 to assist the physician by generating an anatomical map, e.g., a vector field map, to identify the site or sites within the heart appropriate for a diagnostic and/or treatment procedure, e.g. an ablation procedure. For example, the processing system 32 may identify a near-field signal component, i.e. activation signals originating from cellular tissue adjacent to the mapping electrode 24, or from an obstructive far-field signal component, i.e. activation signals originating from non-adjacent tissue. For example, the near-field signal component may include activation signals originating from atrial myocardial tissue whereas the far-field signal component may include activation signals originating from ventricular myocardial tissue. The near-field activation signal component may be further analyzed to find the presence of a pathology and to determine a location suitable for ablation for treatment of the pathology, e.g., ablation therapy.

The processing system 32 includes dedicated circuitry (e.g., discrete logic elements and one or more microcontrollers; application-specific integrated circuits (ASICs); or specially configured programmable devices, such as, for example, programmable logic devices (PLDs) or field programmable gate arrays (FPGAs)) for receiving and/or processing the acquired activation signals. In some embodiments, the processing system 32 includes a general purpose microprocessor and/or a specialized microprocessor (e.g., a digital signal processor, or DSP, which may be optimized for processing activation signals) that executes instructions to receive, analyze and display information associated with the received activation signals. In such implementations, the processing system 32 can include program instructions, which when executed, perform part of the signal processing. Program instructions can include, for example, firmware, microcode or application code that is executed by microprocessors or microcontrollers. The above-mentioned implementations are merely exemplary, and the reader will appreciate that the processing system 32 can take any suitable form.

In some embodiments, the processing system 32 may be configured to measure the intrinsic electrical activity in the myocardial tissue adjacent to the electrodes 24. For example, in some embodiments, the processing system 32 is configured to detect intrinsic electrical activity associated with a dominant rotor or divergent activation pattern in the anatomical feature being mapped. For example, dominant rotors and/or divergent activation patterns may have a role in the initiation and maintenance of atrial fibrillation, and ablation of the rotor path, rotor core, and/or divergent foci may be effective in terminating the atrial fibrillation. In either situation, the processing system 32 processes the sensed activation signals to generate a display of relevant characteristic, such as an APD map, a vector field map, a contour map, a reliability map, an electrogram, a cardiac action potential and the like. The relevant characteristics may be used by the physician to identify a site suitable for ablation therapy.

The ablation probe 16 includes a flexible catheter body 34 that carries one or more ablation electrodes 36. The one or more ablation electrodes 36 are electrically connected to a radio frequency generator (RF) 37 that is configured to deliver ablation energy to the one or more ablation electrodes 36. The ablation probe 16 may be movable with respect to the anatomical feature to be treated, as well as the structure 20. The ablation probe 16 may be positionable between or adjacent to electrodes 24 of the structure 20 as the one or more ablation electrodes 36 are positioned with respect to the tissue to be treated.

The processing system 32 outputs to a device 40 the display of relevant characteristics for viewing by a physician. In the illustrated embodiment, device 40 is a CRT, LED, or other type of display, or a printer). The device 40 presents the relevant characteristics in a format most useful to the physician. In addition, the processing system 32 may generate position-identifying output for display on the device 40 that aids the physician in guiding the ablation electrode(s) 36 into contact with tissue at the site identified for ablation.

FIG. 2 illustrates an embodiment of the mapping catheter 14 including electrodes 24 at the distal end suitable for use in the system 10 shown in FIG. 1. The mapping catheter 14 has a flexible catheter body 18, the distal end of which carries the three dimensional structure 20 configured to carry the mapping electrodes or sensors 24. The mapping electrodes 24 sense intrinsic electrical activity, e.g., activation signals, in the myocardial tissue, the sensed activity is then processed by

the processing system 32 to assist the physician in identifying the site or sites having a heart rhythm disorder or other myocardial pathology via a generated and displayed relevant characteristics. This information can then be used to determine an appropriate location for applying appropriate therapy, such as ablation, to the identified sites, and to navigate the one or more ablation electrodes 36 to the identified sites.

The illustrated three-dimensional structure 20 comprises a base member 41 and an end cap 42 between which flexible splines 44 generally extend in a circumferentially spaced relationship. As discussed above, the three dimensional structure 20 takes the form of a basket defining an open interior space 22. In some embodiments, the splines 44 are made of a resilient inert material, such as Nitinol metal or silicone rubber, and are connected between the base member 41 and the end cap 42 in a resilient, pretensed condition, to bend and conform to the tissue surface they contact. In the illustrated embodiment, eight splines 44 form the three dimensional structure 20. Additional or fewer splines 44 could be used in other embodiments. As illustrated, each spline 44 carries eight mapping electrodes 24. Additional or fewer mapping electrodes 24 could be disposed on each spline 44 in other embodiments of the three dimensional structure 20. In the illustrated embodiment, the three dimensional structure 20 is relatively small (e.g., 40 mm or less in diameter). In alternative embodiments, the three dimensional structure 20 is even smaller or larger (e.g., 40 mm in diameter or greater).

A slidable sheath 50 may be movable along the major axis of the catheter body 18. Moving the sheath 50 forward (i.e., toward the distal end) causes the sheath 50 to move over the three dimensional structure 20, thereby collapsing the structure 20 into a compact, low profile condition suitable for introduction into and/or removal from an interior space of an anatomical structure, such as, for example, the heart. In contrast, moving the sheath 50 rearward (i.e., toward the proximal end) exposes the three dimensional structure 20, allowing the structure 20 to elastically expand and assume the pretensed position illustrated in FIG. 2.

A signal wire (not shown) is electrically coupled to each mapping electrode 24. The wires extend through the body 18 of the mapping catheter 20 into a handle 54, in which they are coupled to an external connector 56, which may be a multiple pin connector. The connector 56 electrically couples the mapping electrodes 24 to the processing system 32. Further details on mapping systems and methods for processing signals generated by the mapping catheter are discussed in U.S. Patent No. 6,070,094,

entitled "Systems and Methods for Guiding Movable Electrode Elements within Multiple Electrode Structure," U.S. Patent No. 6,233,491, entitled "Cardiac Mapping and Ablation Systems," and U.S. Patent No. 6,735,465, entitled "Systems and Processes for Refining a Registered Map of a Body Cavity," the disclosures of which are hereby expressly incorporated herein by reference.

To illustrate the operation of the system 10, FIG. 3 is a schematic side view of an embodiment of the basket structure 20 including a plurality of mapping electrodes 24. In the illustrated embodiment, the basket structure includes 64 mapping electrodes 24. The mapping electrodes 24 are disposed in groups of eight electrodes (labeled 1, 2, 3, 4, 5, 6, 7, and 8) on each of eight splines (labeled A, B, C, D, E, F, G, and H). While an arrangement of sixty-four mapping electrodes 24 is shown disposed on a basket structure 20, the mapping electrodes 24 may alternatively be arranged in different numbers, on different structures, and/or in different positions. In addition, multiple basket structures can be deployed in the same or different anatomical structures to simultaneously obtain signals from different anatomical structures.

After the basket structure 20 is positioned adjacent to the anatomical structure to be treated (e.g. left atrium, left ventricle, right atrium, or right ventricle of the heart), the processing system 32 is configured to record the activation signals from each electrode 24 channel related to physiological activity of the anatomical structure, i.e. the electrodes 24 measure electrical activation signals intrinsic to the physiology of the anatomical structure. The activation signals of physiological activity can be sensed in response to intrinsic physiological activity or based on a predetermined pacing protocol instituted by at least one of the plurality of electrodes 24.

FIG. 4 illustrates an example cellular activation wavefront propagating in the direction of four electrodes (E1, E2, E3 and E4) arranged in a 2x2 electrode distribution. It is contemplated that this disclosure may also apply to any number of electrode distributions. In this embodiment, the electrode configuration may be representative of four electrodes arranged on a constellation catheter, basket structure or similar sensing device. FIG. 4 generally illustrates the direction of cellular firing by the wavefront vector arrow 43, traveling toward electrodes E1, E2, E3 and E4. In this example, the direction of the wavefront vector 43 shows that the wavefront would likely reach electrode E1 before E2, E3 or E4. As the cells underlying electrode E1 depolarize in response to a change in electrical membrane potential, electrode E1 may "sense" an "activation event," i.e. a change in electrical potential relative to the cells'

resting state potential. In response, E1 may collect and send the change in electrical potential data to a processing system 32 which may output an electrogram signal to a display 40. Similarly, if adjacent cells fire in response to a change in electrical potential of adjacent cells, the wavefront may propagate toward electrode E2. Electrode E2 may then sense the change in electrical potential in a similar manner as electrode E1. The time lapse between the sensing of a change in electrical potential of cellular firing of E1 to E2 can be characterized as a latency time interval between the sensing by E1 and E2.

The direction of cellular activation wavefront propagation in a normal heart may occur in preferential directions. However, in a disease state, the myocardial tissue (i.e. cardiac myocytes) may not behave "normally." Rather, cellular firing may occur in multiple directions relative to position of sensing electrodes along a constellation catheter or similar sensing device. For example, the example wavefront vector 43 illustrated in FIG. 4 may represent a path of cellular firing which is not directly aligned in either the X or Y direction relative to electrodes E1, E2, E3 and E4. However, the wavefront vector can be understood to be the summation of a wavefront vector component in the X direction and a wavefront vector component in the Y direction. Therefore, as the activation wavefront approaches electrodes E1-E4, electrode E1 will likely sense the example wavefront first, followed by electrodes E2, E3 and E4 in the order in which the wavefront reaches each of E2-E4, respectively.

It can be appreciated that if a second wavefront approached electrodes E1-E4 from a direction different from that of the first wavefront, electrodes E1-E4 may sense the second wavefront propagation in a different order than the first wavefront, depending on the precise path that the cellular firing occurs relative to the electrode distribution. For example, the wavefront may reach E3, followed by E4, E1 and then E2. Further, it can be appreciated that because each wavefront vector is a summation of vector components in the X and Y directions, latencies may be calculated between the sensing of any of E1, E2, E3 and E4 in any order.

As indicated above, it may be desirable to sense, map and display cellular activation propagation signals generated by the electrical activity of myocardial tissue. For example, it may be desirable to display activation signals correlating to the electrical discharge of myocardial cells. The shape of the signals may indicate abnormal wavefront excitation propagation.

The arrangement, size, spacing and location of electrodes along a constellation catheter or other mapping/sensing device, in combination with the specific geometry of the targeted anatomical structure, may dictate the accuracy with which sensing electrodes collect and transmit electrical activity of targeted cellular tissue. For example, a limited number of electrodes present on a constellation catheter or other sensing device may decrease the resolution of the data acquired from the target activation pattern sensing. Because it may not be practical or desirable to increase the number of electrodes or decrease the spacing between electrodes on the sensing device, it may be desirable to interpolate an electrical signal occurring between electrodes. For example, in addition to sensing cellular firing at electrode locations E1-E4, it may be desirable to approximate cellular firing at some location intermediate electrodes E1-E4.

FIG. 5 illustrates two example electrograms generated from a cellular excitation wavefront passing underneath two example electrodes E1 and E2. In this example, the wavefront passes under E1 at a time before it passes under E2. As shown in the figures, the example electrogram for each electrode sensor visually represents the depolarization of the cells underlying electrodes E1 and E2 at different times. The time delay between the firing of cells underneath E1 and cells underneath E2 may be referred to as the "latency" between E1 and E2. Further, Fig. 5 illustrates an "interpolated" electrogram of a theoretical electrode (labeled E_{12}) which would theoretically be located at a point between E1 and E2. Utilizing standard linear interpolation methods, without taking into account the latency present between the cellular firing of E1 and E2, may result in an electrogram represented by the dashed line 46 in FIG. 5. Using standard interpolation methods, therefore, results in an interpolated electrogram whose shape is unrepresentative of the electrograms (i.e. E1 & E2) from which the interpolated electrogram (E_{12}) is derived. Therefore, an interpolation method which accounts for latency effects may provide a more accurate interpolated electrogram.

FIG. 6 illustrates an example electrogram 60 generated from an example electrode E1 located at an example position in a Cartesian coordinate system. While the position of E1 in FIG. 6 is located within X & Y coordinates, it is contemplated that E1 could be located at any position in 3-dimensional space. Electrode E1 may represent an electrode positioned along a spline of a constellation catheter or similar sensing device such as those shown herein. As an example cellular activation

wavefront passes underneath E1 over a time period, an electrogram 60 is generated which graphically displays the voltage potential of depolarizing cell relative to their resting voltage.

Similarly, FIGS. 7-9 illustrate example electrograms 62, 64, 66 generated from example electrodes E2, E3 and E4 located at an example position in a Cartesian coordinate system. While the position of E2, E3 and E4 in FIGS. 7-9 are located within X & Y coordinates, it is contemplated that E2, E3 and E4 could be located at any position in 3-dimensional space. Electrodes E2, E3 and E4 may represent electrodes positioned along a spline of a constellation catheter or similar sensing device. As an example cellular activation wavefront passes underneath E2, E3 or E4 over a time period, electrograms 62, 64, 66 are generated which graphically displays the voltage potential of depolarizing cells relative to their resting voltage.

FIG. 10 is a schematic example of the collection of electograms 60, 62, 64, 66 of example electrodes E1-E4 described in FIGS. 6-9. As can be seen from FIG 10, each of electrodes E1-E4 are positioned apart from one another at example positions in a Cartesian coordinate system. Similarly to FIGS. 6-9, while the position of E2, E3 and E4 in FIGS. 7-9 are located within X & Y coordinates, it is contemplated that E2, E3 and E4 could be located at any position in 3-dimensional space. Electrodes E2, E3 and E4 may represent electrodes positioned along a spline of a constellation catheter or similar sensing device. As an example cellular activation wavefront passes underneath E2, E3 or E4 over a time period, the electrograms 60, 62, 64, 66 are generated which graphically display the voltage potential of depolarizing cells relative to their resting voltage. Further, FIG. 10 illustrates the location of an example target electrode (labeled E_T). It may be desirable to interpolate the electrogram of target electrode E_T based on the data sensed and collected by electrodes E1-E4.

Accordingly, an example embodiment may include a catheter body 18 including a plurality of electrodes 24 designed to be inserted into a cardiac chamber of a patient's heart. For example, the electrode structure 20 may be a constellation catheter or similar sensing device. As stated above, the plurality of electrodes 24 may be connected to a processor 32. The processor 32 may collect, analyze and output data related to example electrodes E1-E4 discussed above. Further, the processor 32 may analyze and generate an interpolated electrogram of an example targeted electrode E_T discussed above. The processor 32 may output the date relating to the electrogram to a display device 40.

FIG. 11 illustrates an example beginning step to determine a target signal by interpolating a first latency, a second latency, a third latency and a fourth latency. It is contemplated that processor 32 may also be able to determine a target signal by interpolating a first latency, a second latency, a third latency and a fourth latency. Similarly to that discussed above, example electrodes E1 and E2 may sense and collect the voltage potential of a cellular wavefront excitation occurring as a wavefront moves underneath E1 and E2, respectively. Electrode E2 may sense the wavefront at a later point in time as compared to E1. Therefore, a latency will exist between the sensing of the excitation wavefront by E1 and E2.

Cardiac action potentials may fire at predictable rates. Consequently, cardiac cellular excitation signals may propagate at predictable velocities. Additionally, the position of electrodes E1 and E2 relative to each other may be known if they are located on a constellation catheter or similar sensing device. Therefore, knowing the relative positions of E1 and E2 relative to one another and the velocity of the excitation wavefront as it propagates underneath E1 and E2, the latency between E1 and E2 may be calculated. This example illustrates electrodes E1 and E2 aligned along the X axis. However, as stated above, it can be appreciated that the latency between two electrodes can be calculated in any direction for any wavefront excitation based on the summation of the vector components of the wavefront vector. Further, the latency at any point intermediate E1 and E2 may be calculated utilizing similar methodology. For example, the latency corresponding to the position of targeted electrode E_T may be calculated. The following equation may be utilized in calculating the latency of targeted electrode E_T:

$$L_{X1} = x/dX * L_{12}$$

Once latency L_{X1} is calculated, the electrogram signals sensed and collected at example electrodes E1 and E2 may be time shifted by a processor 32. Time shifting the signals at electrodes E1 and E2 may reduce the error which may be introduced if the signals were interpolated according to a method which does not take account of any latency effects. Therefore, in order to account for the latency effects inherent in cellular wavefront propagation, the example electrogram collected at E1 may be time shifted forward by latency L_{X1} and electrode E2 may be time shifted backward by latency L_{X1}.

After time shifting the electogram signals at E1 and E2 by latency L_{X1}, the resultant signals may be averaged by processor 32 to calculate an intermediate signal I_{X1} 68. The contribution of electrogram signals (sensed and collected at electrodes E1 and E2, for example) to the intermediate signal I_{X1} 68 may be weighted according to their theoretical position relative to a final target signal. For example, it may be desired to interpolate an electrogram signal at a theoretical electrode E_T positioned closer to E1. In that case, the "contribution" of the signal collected at E1 may be directly proportionate to its distance from E_T. The following equation may be utilized in calculating the weighted-average signal of E1 and E2, identified as I_{X1} 68 and labeled as such in FIG. 11:

$$I_{X1}(t) = (1-x/dX)*E1(t-L_{X1}) + (x/dX)*(E2)*(t+L_{12}-L_{X1})$$

FIG. 12 illustrates the generation of an intermediate signal I_{X2} 70 from electrogram signals E3 and E4 according to the method disclosed with respect to intermediate signal I_{X1} 68. The following equation may be utilized in calculating the weighted-average signal of E3 and E4, identified as I_{X2} and labeled as such in FIG. 12:

$$L_{X2} = x/dX*L_{34}$$

$$I_{X2}(t) = (1-x/dX)*E3(t-L_{X2}) + (x/dX)*(E4)*(t+L_{34}-L_{X2})$$

FIG. 13 illustrates the generation of a final, interpolated signal 72 representing an electogram signal at targeted electrode E_T. Similarly to the above discussion regarding calculating latencies in the X direction, latencies representing the time duration for a cellular excitation wavefront propagation to travel in the Y direction may be calculated. For example, the following equations may be utilized to calculate latencies of the targeted electrode E_T in the Y direction between electrodes 1&3 and 2&4, respectfully:

$$L_{Y1} = y/dY*L_{13}$$

$$L_{Y2} = y/dY*L_{24}$$

In a method similar to that discussed relative to time shifting the signals along the X axis, to account for the latency effects in generating the interpolated signal for E_T, intermediate signals I_{X1} and I_{X2} may be time shifted in the Y direction. For

example, intermediate signal I_{X1} may be time shifted in the forward direction by latency L_Y. L_Y may be calculated by the following equation:

$$L_Y = (1-x/dX)*L_{Y1} + (x/dX)*L_{Y2}$$

Similarly, intermediate signal I_{X2} may be time shifted in the backward direction by latency L_{GL}. L_{GL} may be calculated by the following equation:

$$L_{GL} = (1-x/dX)*L_{13} + (x/dX)*L_{24}$$

To obtain the final, interpolated signal 72, the resultant time shifted intermediate signals I_{X1} 68 and I_{X2} 70 may be averaged by a processor 32. The intermediate signal I_{X1} 68 may further be weighted according to its theoretical position relative to I_{X1} 68 and I_{X2} 70. For example, it may be desired to interpolate an electrogram signal at a theoretical electrode E_T positioned closer to I_{X1} 68, and therefore, the "contribution" of I_{X1} 68 may be weighted as such. The following equation may be utilized in calculating the final interpolated signal 72 by taking the weighted-average of signals I_{X1} 68 and I_{X2} 70:

$$E_T(t) = (1-y/dY)*I_{X1}(t-L_Y) + (y/dY)*I_{X2}(t+L_{GL}-L_Y)$$

The above calculations are made in accordance with electrodes E1-E4 being positioned orthogonal to each other in an arbitrary coordinate system, indicated by X and Y directions. However, the positioning of electrodes E1-E4 within example X and Y coordinates is merely one example how they may be positioned relative to each other. This disclosure contemplates an interpolated signal may be generated from electrogram signals collected from numerous spatial relationships among multiple electrode pairs.

Further, in this disclosure, interpolation of target electrode E_T was initiated along the X direction. Initiating the interpolation calculations along the X direction is merely a matter of convention. The method disclosed herein may be initiated along the Y (or any other) direction. Consequently, steps described in the X and Y directions in the disclosed examples may be interchanged, i.e. they would occur in the Y and X directions, respectively.

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the disclosure. This may include, to the extent that it is appropriate, the use of any of the features of one example embodiment being used in other embodiments. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A mapping medical device, comprising:

a catheter shaft with a plurality of electrodes coupled thereto, wherein the plurality of electrodes includes a first pair of electrodes, a second pair of electrodes, a third pair of electrodes and a fourth pair of electrodes;

a processor, wherein the processor is configured to:

determine a first latency between the first pair of electrodes;

determine a second latency between the second pair of electrodes;

determine a third latency between the third pair of electrodes;

determine a fourth latency between the fourth pair of electrodes; and

determine a target signal by interpolating the first latency, the second latency, the third latency and the fourth latency.

2. The medical device of claim 1, wherein determining the target signal further includes sensing a change in electrical potential at the first pair of electrodes and/or the second pair of electrodes over a time period, and wherein determining the target signal includes calculating a first intermediate signal.

3. The medical device of any one of claims 1-2, wherein determining the target signal includes collecting a first set of data corresponding to the change in electrical potential at the first pair of electrodes over the time period, collecting a second set of data corresponding to the change in electrical potential at the second pair of electrodes over the time period, and timeshifting the first set of data and timeshifting the second set of data.

4. The medical device of any one of claims 2-4, wherein calculating the first intermediate signal includes calculating a weighted average of the timeshifted first set of data and the timeshifted second set of data.

5. The medical device of any one of claims 1-4, wherein determining the target signal further includes sensing a change in electrical potential at the third pair of electrodes and/or the fourth pair of electrodes over the time period, and wherein determining the target signal includes calculating a second intermediate signal.

6. The medical device of any one of claims 1-5, wherein determining the target signal includes collecting a third set of data corresponding to the change in electrical potential at the third pair of electrodes over the time period, collecting a fourth set of data corresponding to the change in electrical potential at the fourth pair of electrodes over the time period, and timeshifting the third set of data and timeshifting the fourth set of data.

7. The medical device of any one of claims 5-6, wherein calculating a second intermediate signal includes calculating a weighted average of the timeshifted third set of data and the timeshifted fourth set of data.

8. The medical device of any one of claims 5-7, wherein determining the target signal includes timeshifting the first intermediate signal, timeshifting the second intermediate signal and calculating a weighted average of the first and second intermediate signals.

9. The medical device of any one of claims 1-8, wherein the first pair of electrodes is positioned directly adjacent the second pair of electrodes.

10. The medical device of any one of claims 1-9, wherein one or more electrodes are positioned between the first and second pairs of electrodes.

11. The medical device of any one of claims 1-10, further comprising the step of ablating a location of the target signal.

12. The medical device of any one of claims 1-11, wherein the first pair of electrodes includes a first electrode and a second electrode.

13. The medical device of any one of claims 1-12, wherein the second pair of electrodes includes a third electrode and a fourth electrode.

14. The medical device of any one of claims 1-13, wherein the third pair of electrodes includes a first electrode and a third electrode.

15. The medical device of any one of claims 1-14, wherein the fourth pair of electrodes includes a second electrode and a fourth electrode.

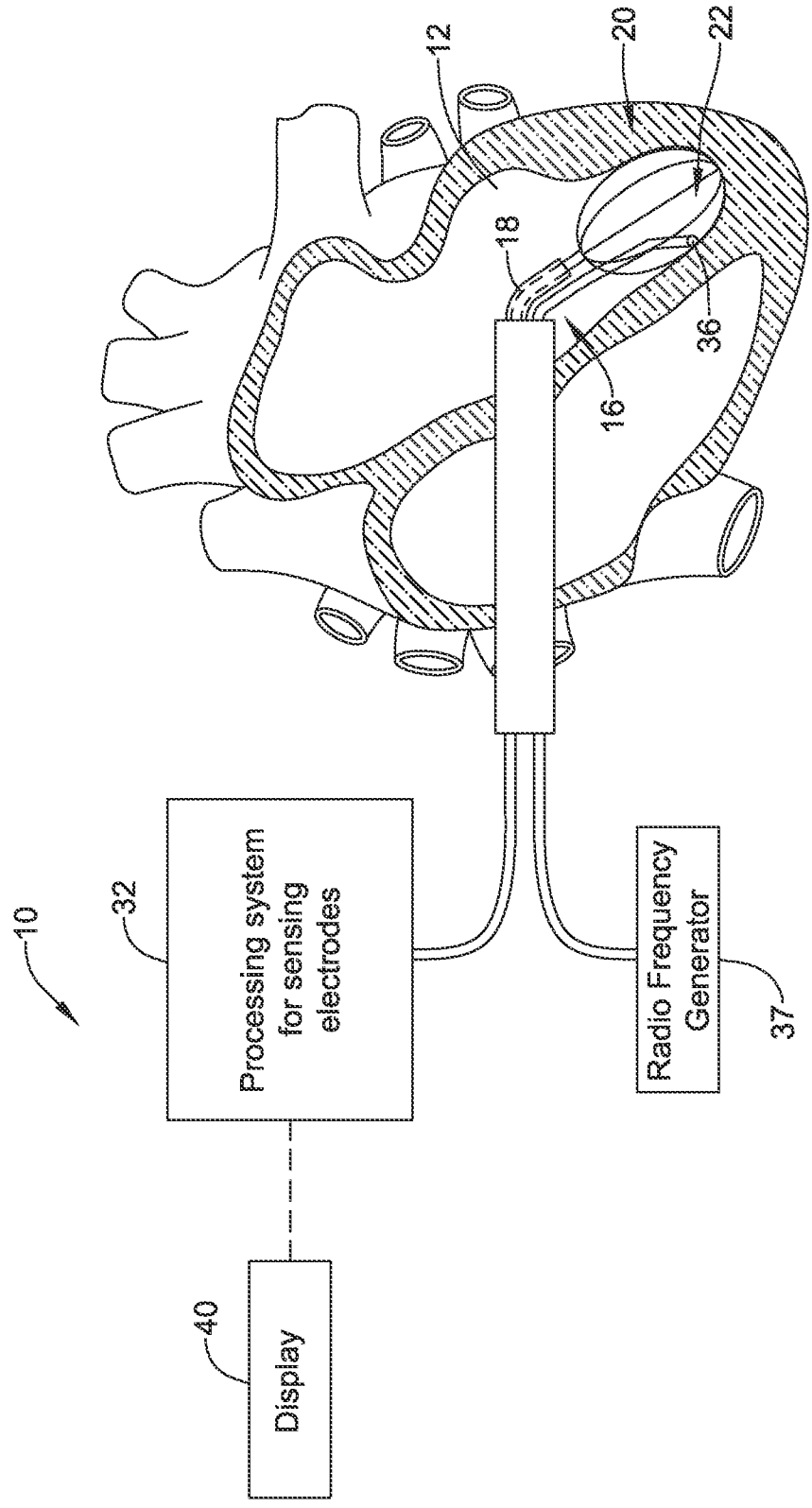
12
20
22
18
36
16
10
32
Processing system for sensing electrodes
Radio Frequency Generator
37
40
Display

FIG. 1

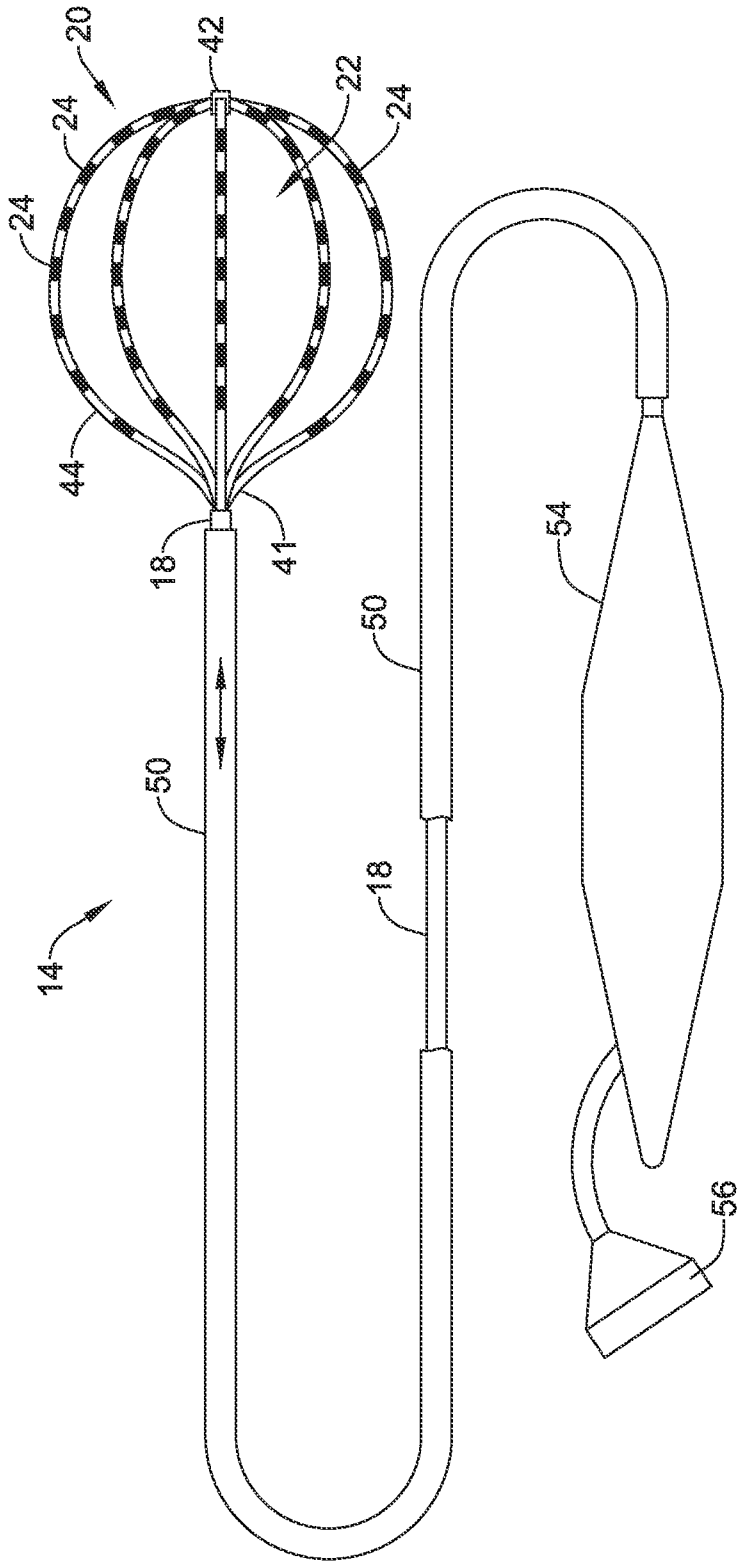

FIG. 2

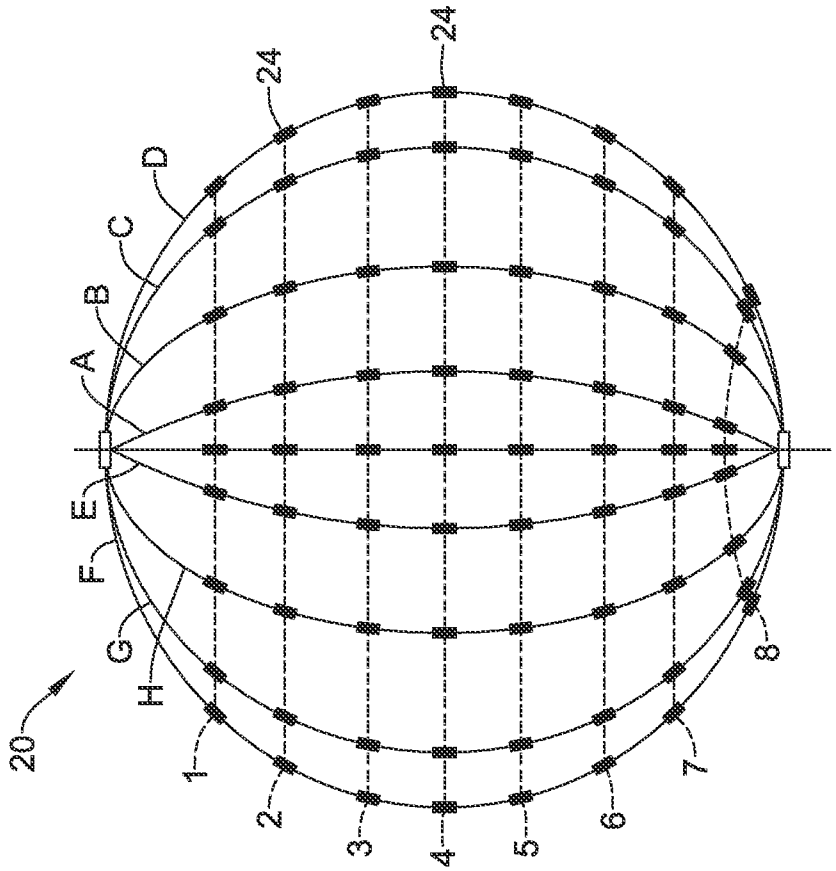

FIG. 3

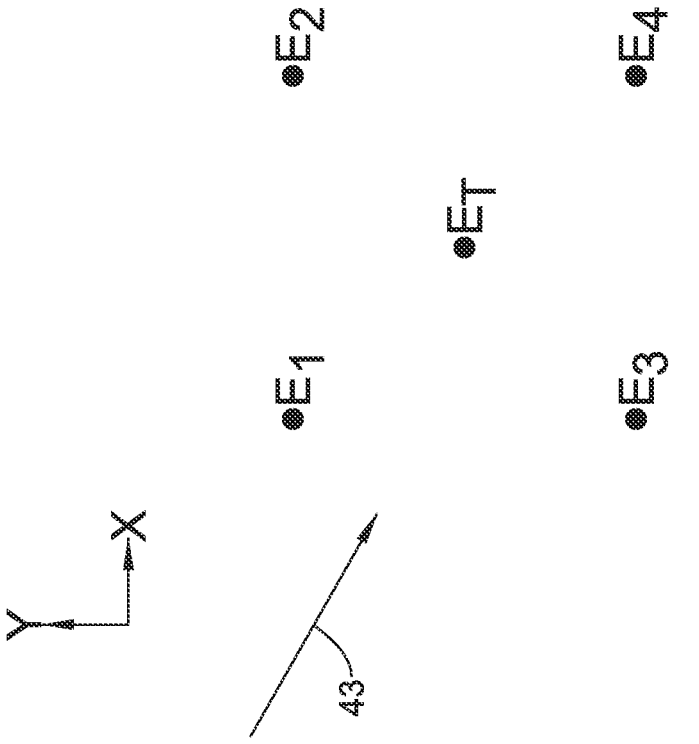

FIG. 4

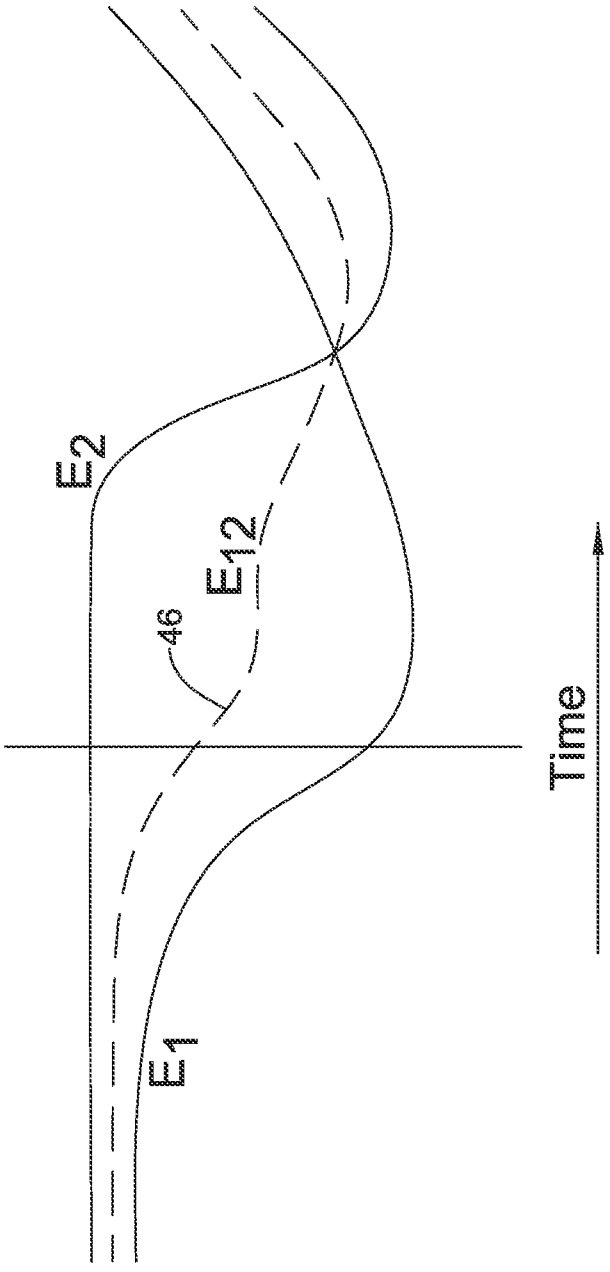

FIG. 5

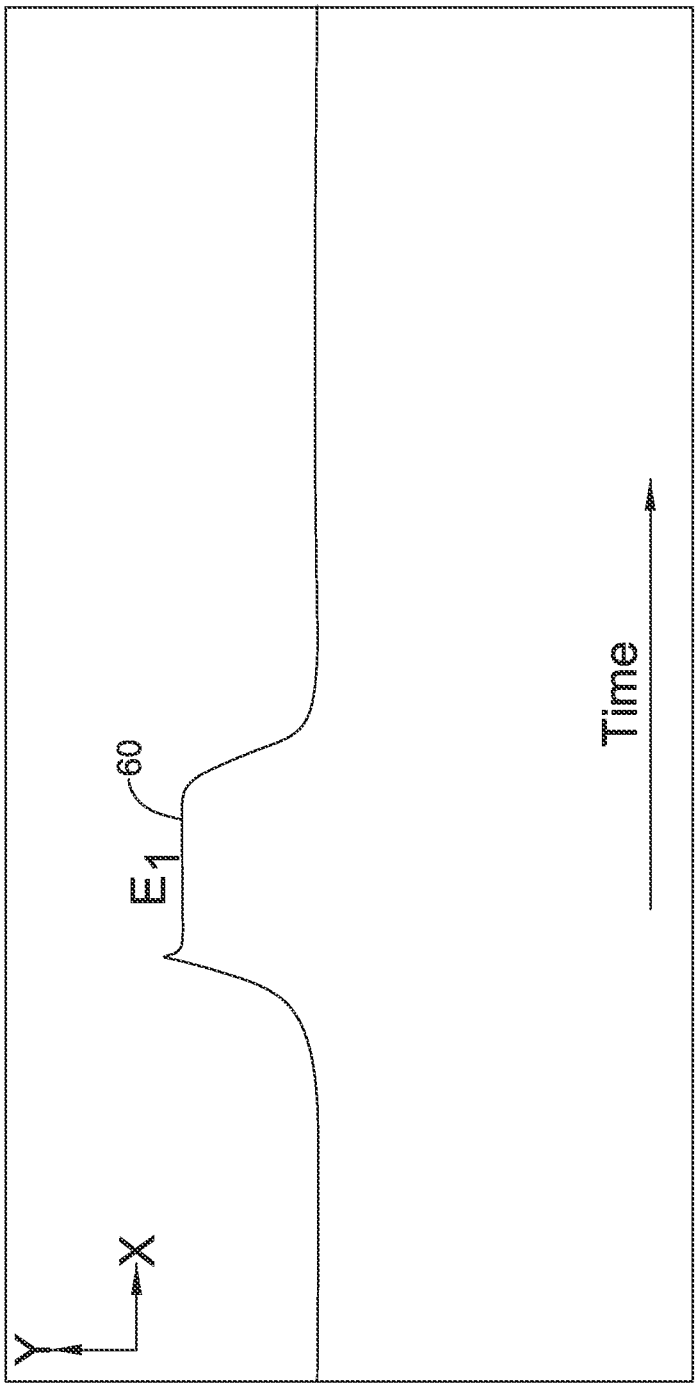

FIG. 6

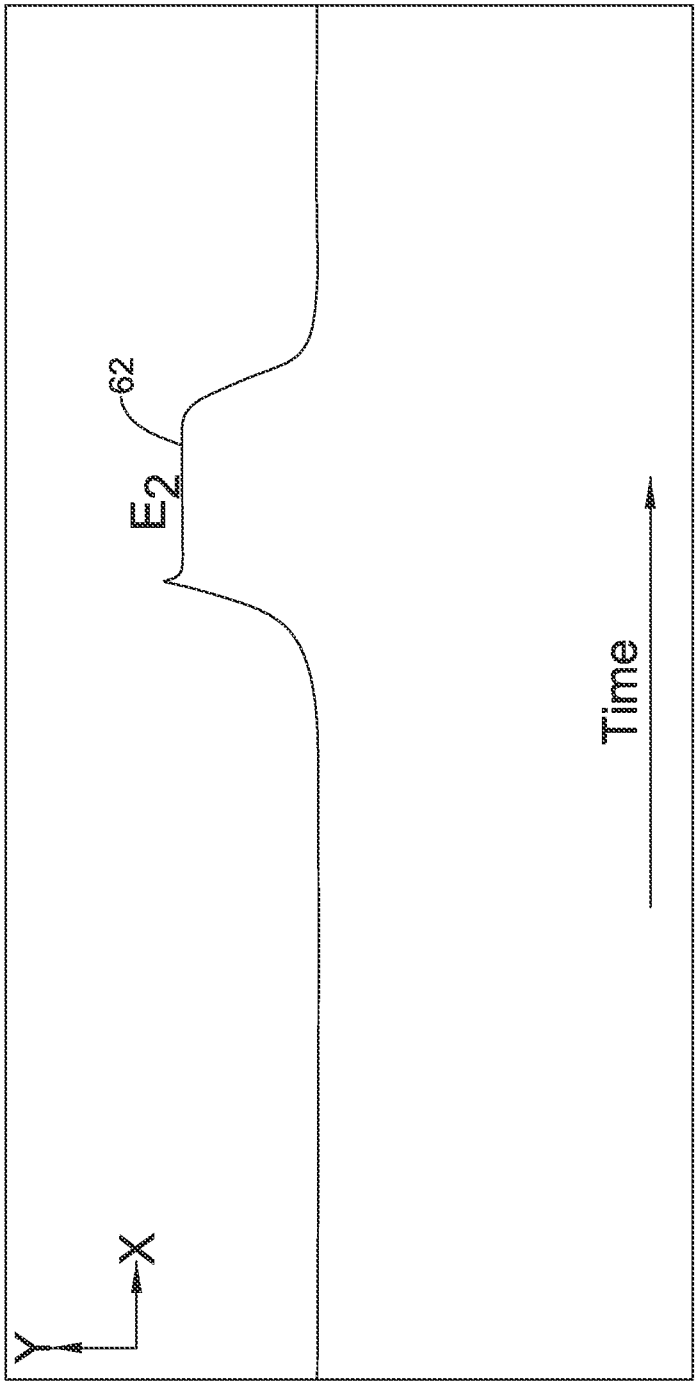

FIG. 7

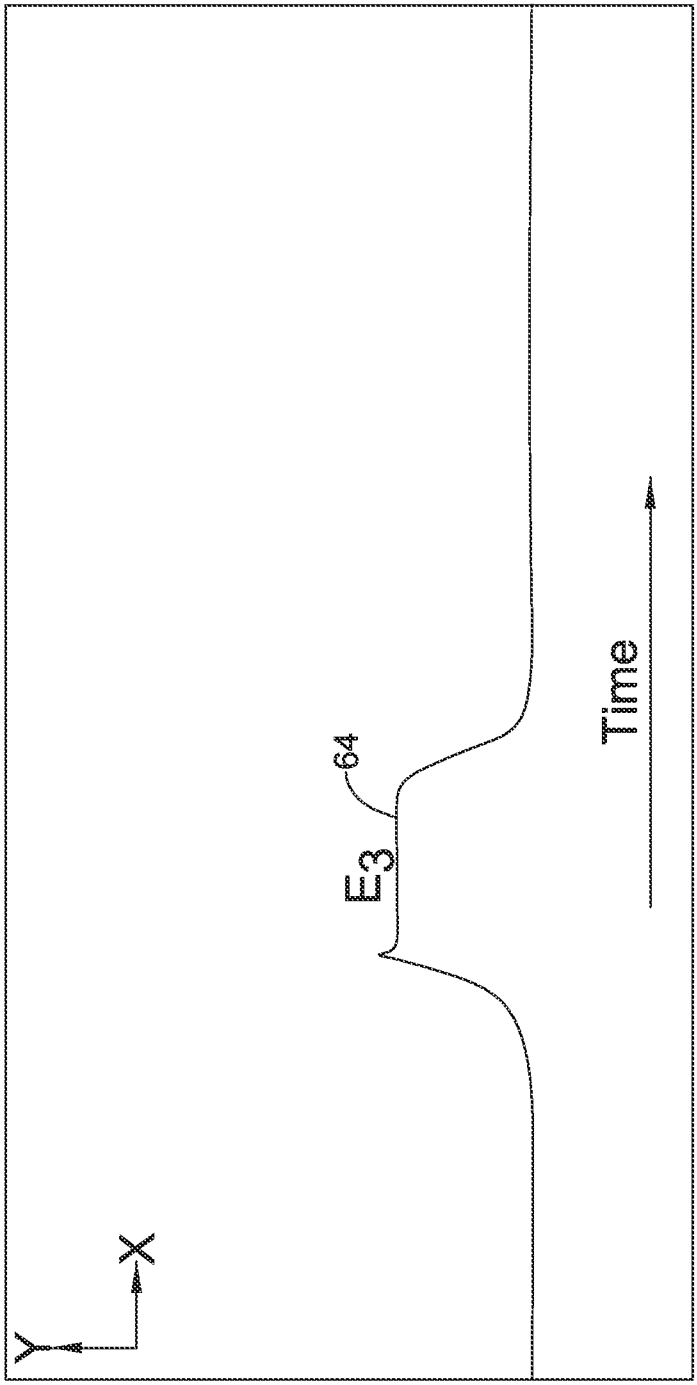

FIG. 8

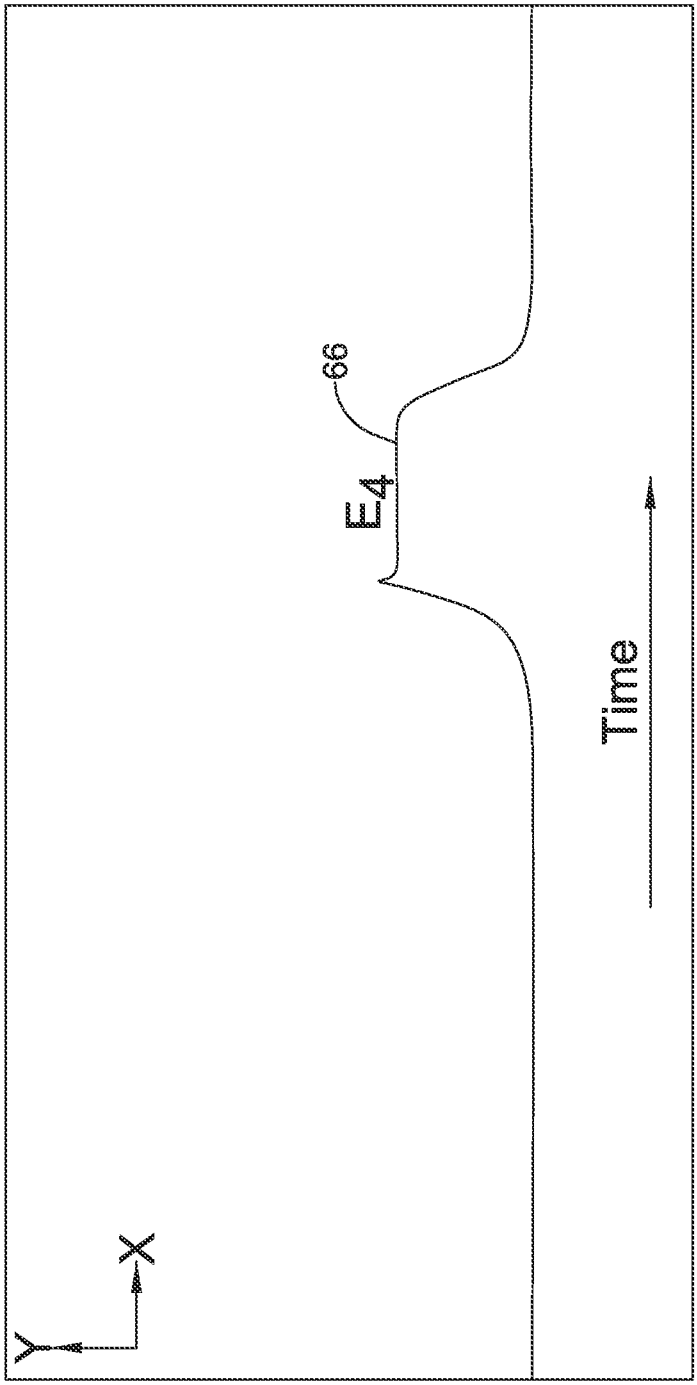

FIG. 9

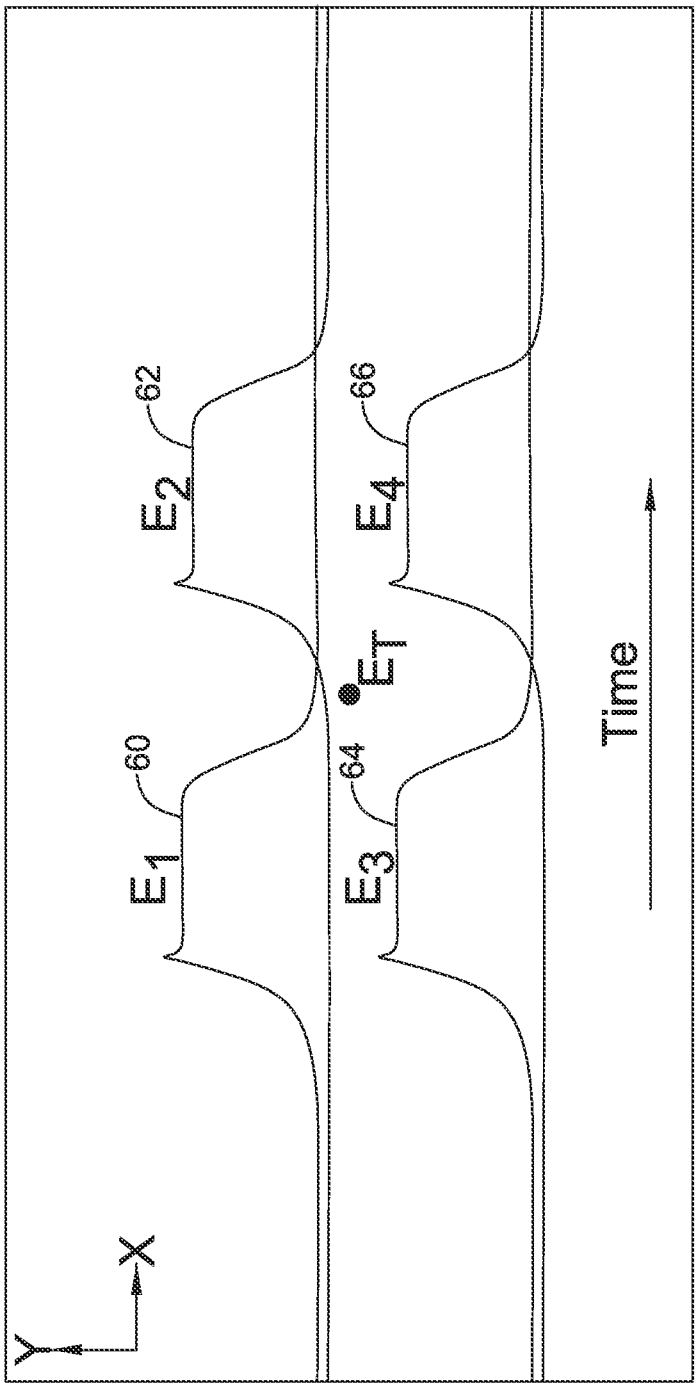

FIG. 10

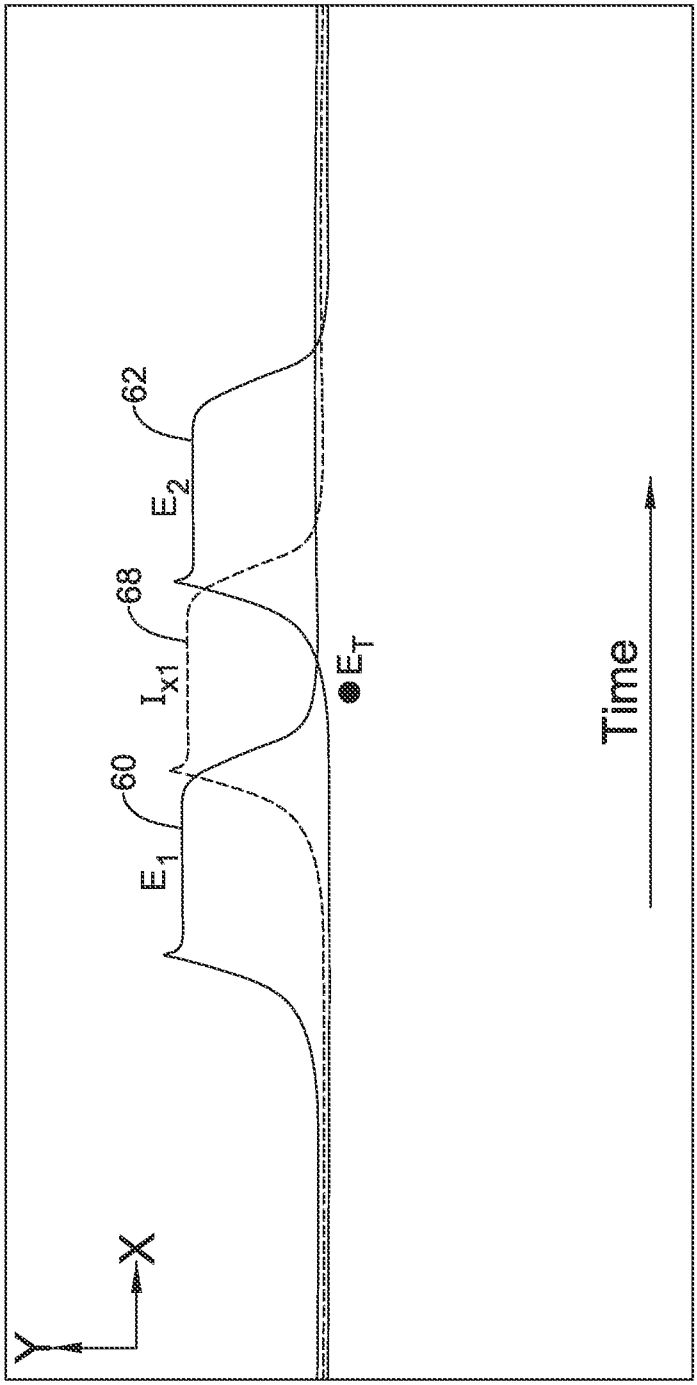

FIG. 11

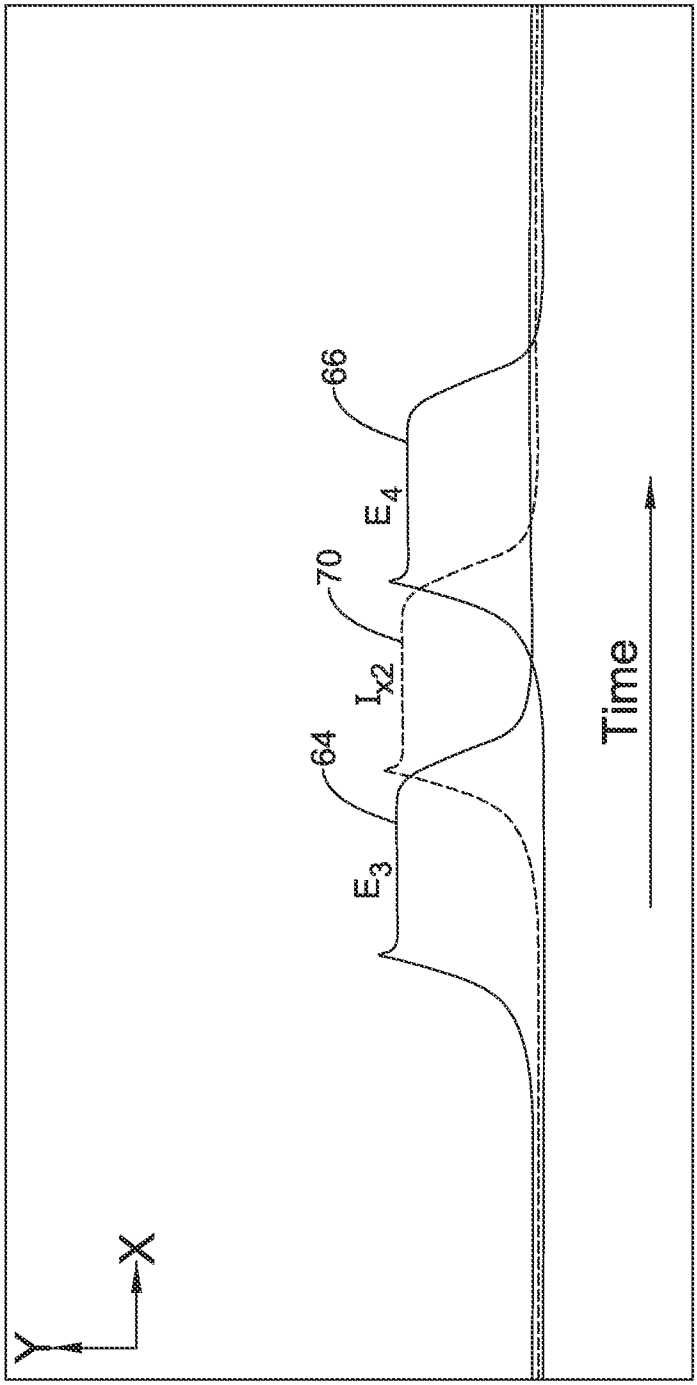

FIG. 12

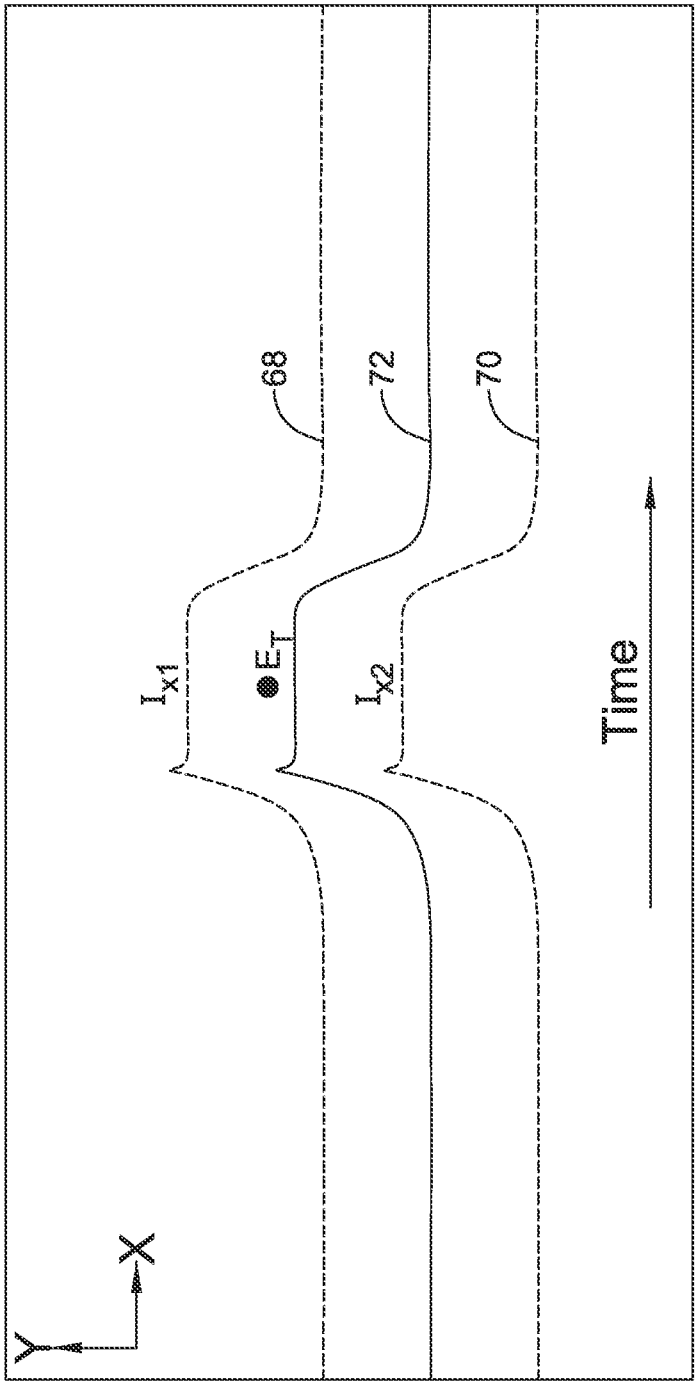

FIG. 13

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/063148

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/042 A61B5/0452 A61B5/0402 A61B5/0464
ADD. A61B5/00 A61N1/06 A61B18/14

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

B. FIELDS SEARCHED

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

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 687 737 A (BRANHAM BARRY H [US] ET AL) 18 November 1997 (1997-11-18) column 7, line 44 column 8, line 41 column 9, line 16 column 10, lines 56-57 column 25, line 59 column 26, lines 28-30 column 29, line 29 figures 1, 5, 7, 8	1-15
X	US 2013/173222 A1 (VOTH ERIC J [US]) 4 July 2013 (2013-07-04) paragraphs [0043], [0047], [0089], [0101] figures 1, 3	1-15

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 January 2015	04/02/2015

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Meyer, Wolfgang

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 657 755 A (DESAI JAWAHAR M [US]) 19 August 1997 (1997-08-19) column 6, line 26 column 7, lines 1-17 column 10, lines 1-65 figures 2, 3	1-15
A	QUAN NI ET AL: "A Novel Interpolation Method for Electric Potential Fields in the Heart during Excitation", ANNALS OF BIOMEDICAL ENGINEERING, vol. 26, no. 4, 1 July 1998 (1998-07-01), pages 597-607, XP055096022, ISSN: 0090-6964, DOI: 10.1114/1.41 chapter "Algorithm and implementation"; page 599, right-hand column equations (2),(3) figures 1-3	2-8
A	YE H HE ET AL: "An interactive graphical system for automated mapping and display of cardiac rhythms", JOURNAL OF ELECTROCARDIOLOGY, vol. 32, no. 3, 1 July 1999 (1999-07-01), pages 225-241, XP055128661, ISSN: 0022-0736, DOI: 10.1016/S0022-0736(99)90105-X the whole document	1-15
A	BLANCHARD S M ET AL: "Four digital algorithms for activation detection from unipolar epicardial electrograms", IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING, IEEE SERVICE CENTER, PISCATAWAY, NJ, USA, vol. 36, no. 2, 1 February 1989 (1989-02-01), pages 256-261, XP011476750, ISSN: 0018-9294, DOI: 10.1109/10.16473 the whole document	1-15
A	SUSAN M. BLANCHARD ET AL: "Interpolating Unipolar Epicardial Potentials from Electrodes Separated by Increasing Distances", PACING AND CLINICAL ELECTROPHYSIOLOGY, vol. 12, no. 12, 1 December 1989 (1989-12-01), pages 1938-1955, XP055164541, ISSN: 0147-8389, DOI: 10.1111/j.1540-8159.1989.tb01887.x the whole document	1-15

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2014/063148

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		EP 2797502 A1	05-11-2014
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		WO 2013101257 A1	04-07-2013
US 5657755 A	19-08-1997	NONE	

专利名称(译)	使用延迟插值的心脏映射		
公开(公告)号	EP3062694A1	公开(公告)日	2016-09-07
申请号	EP2014796981	申请日	2014-10-30
[标]申请(专利权)人(译)	波士顿科学西美德公司		
申请(专利权)人(译)	BOSTON SCIENTIFIC SCIMED，INC.		
当前申请(专利权)人(译)	BOSTON SCIENTIFIC SCIMED，INC.		
[标]发明人	THAKUR PRAMODSINGH HIRASINGH MASKARA BARUN SHOME SHIBAJI SHUROS ALLAN C ARCOT KRISHNAMURTHY SHANTHA SAHA SUNIPA		
发明人	THAKUR, PRAMODSINGH HIRASINGH MASKARA, BARUN SHOME, SHIBAJI SHUROS, ALLAN, C. ARCOT-KRISHNAMURTHY, SHANTHA SAHA, SUNIPA		
IPC分类号	A61B5/042 A61B5/0452 A61B5/0402 A61B5/0464 A61B5/00 A61N1/06 A61B18/14		
CPC分类号	A61B5/04028 A61B5/0422 A61B5/0452 A61B5/0464 A61B5/6858 A61B5/7278 A61B18/1492 A61B2018/0016 A61B2018/00267 A61B2018/00351 A61B2018/00577 A61B2018/1467 A61B2018/1475 A61N1/06 A61B5/6852		
优先权	61/899033 2013-11-01 US		
外部链接	Espacenet		

摘要(译)

公开了医疗装置和使用医疗装置的方法。示例性医疗装置的示例可包括具有多个电极的导管轴。多个电极可包括第一对电极，第二对电极，第三对电极和第四对电极。所述绘图医疗设备还可包括处理器，其中所述处理器可被配置为确定所述第一对电极之间的第一等待时间，确定所述第二对电极之间的第二等待时间，确定所述第三对电极之间的第三等待时间，确定第四对电极之间的第四等待时间，并通过内插第一等待时间，第二等待时间，第三等待时间和第四等待时间来确定目标信号。