(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
28 December 2017 (28.12.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/222634 A2

(51) International Patent Classification:
A61B 5/042 (2006.01) *A61B 5/06* (2006.01)
A61B 5/00 (2006.01)

(21) International Application Number:
PCT/US2017/029428

(22) International Filing Date:
25 April 2017 (25.04.2017)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/353,252 22 June 2016 (22.06.2016) US

(71) Applicant: **ST. JUDE MEDICAL, CARDIOLOGY DIVISION, INC.** [US/US]; 177 East County Road B, St. Paul, Minnesota 55117 (US).

(72) Inventors: **MARKOVITZ, Craig**; Jahnallee 7, 04109 Leipzig (DE). **QU, Fujian**; 1535 Touraine Dr, San Jose, California 95118 (US). **LI, Wenwen**; 1679 River Birch Ct, San Jose, California 95131 (US). **MCSPADDEN, Luke**; 1833 Edgecliffe Dr, Apt 2, Los Angeles, California 90026 (US).

(74) Agent: **RODGERS, James G.** et al.; St. Jude Medical, Cardiology Division, Inc., 177 East County Road B, St. Paul, Minnesota 55117 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:
— *with declaration under Article 17(2)(a); without abstract; title not checked by the International Searching Authority*

(54) Title: SYSTEM AND METHOD FOR ELECTROPHYSIOLOGY PROCEDURES

(57) Abstract:

WO 2017/222634 A2

SYSTEM AND METHOD FOR ELECTROPHYSIOLOGY PROCEDURES

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001[This application claims the benefit of United States provisional application no. 62/353,252, filed 22 June 2016, which is hereby incorporated by reference as though fully set forth herein.

BACKGROUND

[0002[The instant disclosure relates to electrophysiology procedures, such as cardiac diagnostic (*e.g.*, mapping) and therapeutic (*e.g.*, ablation) procedures. In particular, the instant disclosure relates to systems, apparatuses, and methods for the creation of anatomical models and for conducting electrophysiology studies.

[0003[It is desirable to create anatomical models in connection with various medical procedures. For example, cardiac models are often created in connection with cardiac electrophysiology studies. Those of ordinary skill in the art will be familiar with numerous ways to acquire and display cardiac models for use in cardiac electrophysiology studies (*e.g.*, using a roving catheter to gather a cloud of geometry points to which a surface is fit).

[0004[Once a cardiac model is created, that model can be used, for example, to display one or more electrophysiology maps. In general, electrophysiology maps are created from a plurality of electrophysiology data points, each of which includes both measured electrophysiology data and location data, allowing the measured electrophysiology information to be associated with a particular location in space (that is, allowing the measured electrophysiology information to be interpreted as indicative of electrical activity at a point on the patient's heart), and therefore displayed at the proper location on the cardiac model.

[0005[In certain extant approaches to non-contact electrophysiological mapping, a non-contact, multi-electrode mapping catheter is first introduced into the heart. Once the mapping catheter is placed, a roving catheter is introduced in order to create the cardiac model. The presence of the mapping catheter, however, can complicate the creation of the cardiac model, for example by impeding access by the roving catheter to portions of the heart. Moreover, the cardiac model can be invalidated if the mapping catheter moves during creation of the cardiac model.

BRIEF SUMMARY

[0006[Disclosed herein is a method of performing a cardiac electrophysiology procedure, including the steps of: inserting a catheter including at least one magnetic localization sensor into a patient's heart; generating a cardiac model using the catheter, wherein the cardiac model includes magnetic localization data measured using the at least one magnetic localization sensor; removing the catheter from the patient's heart; and, after removing the catheter from the patient's heart: inserting an electrophysiology catheter including at least one magnetic localization sensor into the patient's heart; placing the electrophysiology catheter in an initial location within the patient's heart; localizing the electrophysiology catheter within a coordinate system common to the cardiac model using the at least one magnetic localization sensor of the electrophysiology catheter; and performing the electrophysiology procedure using the electrophysiology catheter. The at least one magnetic localization sensor of the electrophysiology catheter can be positioned on a shaft of the electrophysiology catheter.

[0007[The electrophysiology procedure can be a diagnostic procedure, such as an electrophysiology mapping procedure, a therapeutic procedure, such as an ablation procedure, or a combination of both.

[0008[The electrophysiology device can be a multi-electrode electrophysiology mapping catheter, such as a non-contact electrophysiology mapping catheter.

[0009[In embodiments, the method can also include: monitoring for movement of the electrophysiology catheter from the initial location to a subsequent location; and re-localizing the electrophysiology catheter within the coordinate system common to the cardiac model using the at least one magnetic localization sensor of the electrophysiology catheter.

[0010[It is also contemplated that localizing the electrophysiology catheter within the coordinate system common to the cardiac model using the at least one magnetic localization sensor of the electrophysiology catheter can include determining a rotation angle of the at least one magnetic localization sensor of the electrophysiology catheter. For example, the electrophysiology catheter can include at least one radiopaque marker that is used to determine the rotation angle of the at least one magnetic localization sensor of the electrophysiology catheter. As another example, the rotation angle of the at least one magnetic localization sensor of the electrophysiology catheter can be determined using multiple electrodes on an electrophysiology mapping catheter.

[0011[According to another embodiment of the disclosure, a method of performing an electrophysiology procedure includes: generating a model of an anatomical region using a probe, wherein the probe includes at least one magnetic localization sensor, and wherein the model includes magnetic localization data measured using the at least one magnetic localization sensor; placing an electrophysiology device within the anatomical region, wherein the electrophysiology device includes at least one magnetic localization sensor; localizing the electrophysiology device within a coordinate system common to the model using the at least one magnetic localization sensor of the electrophysiology device; and performing the electrophysiology procedure using the electrophysiology device.

[0012[The method can include compensating for movement of the electrophysiology device during the electrophysiology procedure using the at least one magnetic localization sensor of the electrophysiology device. For example, the localizing step can be repeated if and when the electrophysiology device moves.

[0013[The electrophysiology procedure can include a diagnostic procedure and/or a therapeutic procedure.

[0014[The electrophysiology device can include a plurality of electrodes, and localizing the electrophysiology device within the coordinate system common to the model using the at least one magnetic localization sensor of the electrophysiology device can include using the plurality of electrodes to determine a rotation angle of the electrophysiology device.

[0015[Alternatively, the electrophysiology device can include a radiopaque marker, and localizing the electrophysiology device within the coordinate system common to the model using the at least one magnetic localization sensor of the electrophysiology device can include using the radiopaque marker to determine a rotation angle of the electrophysiology device.

[0016[In still other embodiments of the instant disclosure, a method of performing an electrophysiology procedure includes: inserting a probe carrying at least one magnetic localization sensor into an anatomical region; generating a model of the anatomical region by measuring a plurality of positions of the at least one magnetic localization sensor as it moves through the anatomical region; removing the probe from the anatomical region; and, after removing the probe from the anatomical region: positioning an electrophysiology device including at least one magnetic localization sensor at an initial position within the anatomical region; localizing the initial position of the electrophysiology device within a coordinate system common to the model of the anatomical region using the at least one magnetic localization sensor of the electrophysiology device; and performing the electrophysiology procedure using the electrophysiology device.

[0017[The method can include: monitoring for movement of the electrophysiology device from the initial position to a subsequent position; and localizing the subsequent position of the electrophysiology device within the coordinate system common to the model of the anatomical region using the at least one magnetic localization sensor of the electrophysiology device.

[0018[It is also contemplated that localizing the initial position of the electrophysiology device within the coordinate system common to the model of the anatomical region using the at least one magnetic localization sensor of the electrophysiology device can include determining a rotation angle of the electrophysiology device.

[0019[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

[0020[Figure 1 is a schematic diagram of a localization system, such as may be used in an electrophysiology procedure.

[0021[Figure 2 depicts an exemplary catheter, such as may be used to create a cardiac geometry as described herein.

[0022[Figure 3 depicts an exemplary electrophysiology catheter, such as may be used to carry out an electrophysiology procedure as disclosed herein.

[0023[Figure 4 is a flowchart of representative steps that can be carried out in the performance of an electrophysiology procedure as disclosed herein.

DETAILED DESCRIPTION

[0024[The present disclosure provides methods, apparatuses, and systems for the creation of anatomical models in connection with electrophysiology studies. For purposes of illustration, exemplary embodiments will be described in detail herein in the context of a cardiac electrophysiology mapping procedure. It is contemplated, however, that the methods, apparatuses, and systems described herein can be utilized in other contexts including, without limitation, cardiac ablation.

[0025[Figure 1 shows a schematic diagram of a system 8 for conducting cardiac electrophysiology studies by navigating and localizing one or more medical devices (*e.g.*, one or more catheters 13), creating one or more cardiac models, measuring electrical activity occurring in a heart 10 of a patient 11 (depicted schematically as an oval), and/or mapping and displaying the measured electrical activity and/or information related to or representative of the measured electrical activity on the cardiac model(s). System 8 can also be used to deliver therapy (*e.g.*, ablation) to heart 10.

[0026[Thus, 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 (*e.g.*, belly patch 21 and/or fixed reference 31). This data can, in turn, be used to create a model of the patient's heart 10 using one or more roving localization elements, as will be familiar to those of ordinary skill in the art.

[0027[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. These electrophysiology data points can be used to create one or more electrophysiology maps of the patient's heart 10 according to known techniques.

[0028[As depicted in Figure 1 and described herein, system 8 is a hybrid system that incorporates both impedance-based and magnetic-based localization capabilities. In some embodiments, system 8 includes the EnSite™ Velocity™ cardiac mapping and visualization system of St. Jude Medical, Inc., which generates electrical fields, or another localization system that relies upon electrical localization fields. Other localization systems, may be used in connection with the present teachings, including, without limitation, the CARTO navigation and location system of Biosense Webster, Inc., the AURORA® system of Northern Digital Inc., Sterotaxis' NIOBE® Magnetic Navigation System, as well as MediGuide™ Technology and the EnSite Precision™ system, both from St. Jude Medical, Inc. Insofar as the ordinarily skilled artisan will appreciate the basic operation of such localization systems, they are only described herein to the extent necessary to understand the instant disclosure.

[0029[Computer 20 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.

[0030[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 12, 14, 16, 18, 19, and 22) are shown coupled to a current source 25.

[0031[Figure 1 also depicts a magnetic source 30, which is coupled to magnetic field generators. In the interest of clarity, only two magnetic field generators 32 and 33 are depicted in Figure 1, but it should be understood that additional magnetic field generators (*e.g.*, a total of six magnetic field generators, defining three generally orthogonal axes analogous to those defined by patch electrodes 12, 14, 16, 18, 19, and 22) can be used without departing from the scope of the present teachings.

[0032[As mentioned above, system 8 can be used to create cardiac models, for example using a representative catheter 13 having at least one localization sensor. 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 catheter 13 is shown in Figure 2. In Figure 2, 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 need not be further described herein. Catheter 13 can also be introduced into the heart 10 in any other suitable manner.

[0033[Figure 2 also depicts multiple elements 17, 52, 54, 56 carried by catheter 13. According to aspects of the instant disclosure, at least one of elements 17, 52, 54, and 56 is a magnetic sensor that allows localization of catheter 13 within a magnetic localization field, such as may be generated by magnetic source 30 operating in conjunction with magnetic field generators 32, 33. Similarly, at least one of elements 17, 52, 54, 56 is an electrode that allows localization of catheter 13 within an impedance-based localization field, such as may be generated by current source 25 operating in conjunction with patch electrodes 12, 14, 16, 18, 19, 22.

[0034[In any event, those of ordinary skill in the art will be familiar with the use of such a catheter to create a cardiac model from a plurality of geometry points collected as catheter 13 moves through a heart chamber. As described in detail below, in embodiments of the disclosure, magnetic localizations of catheter 13 are used to generate the plurality of geometry points and the resultant cardiac model.

[0035[System 8 can also be used to create one or more electrophysiology maps. In general, electrophysiology maps are created from a plurality of electrophysiology data points, each of which includes both measured electrophysiology data and location data, allowing the measured electrophysiology information to be associated with a particular location in space (that is, allowing the measured electrophysiology information to be interpreted as indicative of electrical activity at a point on the patient's heart 10).

[0036[Figure 3 depicts a representative electrophysiology catheter 60, such as the EnSite™ Array™ non-contact mapping catheter of St. Jude Medical, Inc., placed into left ventricle 50 to carry out an electrophysiology procedure (*e.g.*, an electrophysiology mapping procedure) according to the teachings herein. Electrophysiology catheter 60 includes an electrode array 62 and an inflatable balloon 63 that can be expanded, such as through the use of a stylet 64 or via inflation of balloon 63 interior to array 62, to place electrode array 62 into a stable and reproducible geometric shape.

[0037[Electrode array 62 includes a braid of insulated wires 66. The insulation can be removed from wires 66 at predetermined locations to form a plurality of electrodes 68. Additional details of representative electrophysiology catheter 60 are described in United States patent no. 6,240,307, which is hereby incorporated by reference as though fully set forth herein.

[0038[According to aspects of the disclosure, electrophysiology catheter 60 also includes a magnetic localization sensor 70, which allows electrophysiology catheter 60 to be magnetically localized by magnetic source 30 operating in conjunction with magnetic field generators 32, 33. In embodiments, magnetic localization sensor 70 is positioned on shaft 72 of electrophysiology catheter 60 near electrode array 62. In the embodiment shown in Figure 3, magnetic localization sensor 70 is embedded within shaft 72 at a location proximal of electrode array 62. In other embodiments, magnetic localization sensor 70 can be positioned at other locations along the length of shaft 72. For example, magnetic localization sensor 70 can be embedded within a portion of shaft 72 that is co-radial with balloon 63 such that sensor 70 is centrally located relative to array 62.

[0039[Various aspects of the instant disclosure will now be described with reference to Figure 4, which is a flowchart depicting representative steps of an exemplary method 400 for carrying out a cardiac electrophysiology procedure according to aspects of the instant disclosure. In some embodiments, for example, Figure 4 may represent several exemplary steps that can be carried out by the computer 20 of Figure 1 (*e.g.*, by one or more processors 28 executing one or more specialized modules as further described below).

[0040[It should be understood that the teachings herein can be software- and/or hardware-implemented, and that they may be executed on a single CPU, which may have one or more threads, or distributed across multiple CPUs, each of which may have one or more threads, in a parallel processing environment.

[0041[In block 402 of Figure 4, a magnetically-localizable catheter (that is, a catheter including at least one magnetic localization sensor) is inserted into a patient’s heart. For example, as described above, catheter 13, carrying one or more magnetic localization sensors as shown in Figure 2 (*e.g.*, one or more of 17, 52, 54, 56), can be navigated into the patient’s ventricle 50 via a transseptal introducer 35.

[0042[In block 404, the magnetically-localizable catheter is used to generate a cardiac model. For example, as described above, catheter 13 can be moved through ventricle 50 in order to collect a cloud of geometry points by periodically detecting the position of the magnetic localization sensor(s) within a magnetic localization field generated by magnetic source 30 in conjunction with magnetic field generators 32, 33. Various approaches are known for creating a three-dimensional model of the cardiac geometry from such a cloud of geometry points. The resultant model includes magnetic localization data measured using the magnetic sensor(s) on catheter 13.

[0043[In block 406, the magnetically-localizable catheter is removed from the patient's heart. For example, catheter 13 can be withdrawn back through transseptal introducer 35. Introducer 35, on the other hand, can be left in place for further steps in the electrophysiology procedure as described below.

[0044[In block 408, electrophysiology catheter 60 is inserted into the patient's heart, for example as shown in Figure 3. As described above, electrophysiology catheter 60 includes at least one magnetic localization sensor 70 such that it is magnetically localizable. This enables electrophysiology catheter 60 to be localized within the cardiac model created in block 404, as described in further detail below.

[0045[Electrophysiology catheter 60 is placed in an initial location and prepared to collect electrophysiology data points in block 410. The precise sequence of events encompassed by block 410 may differ from one electrophysiology catheter to another. In the case of the EnSite™ Array™ catheter, for example, once electrophysiology catheter 60 is positioned, electrode array 62 can be expanded, which positions electrodes 68 to record electrical activity on the surface of the heart.

[0046[In block 412, electrophysiology catheter 60 is localized within the cardiac model created in block 404 using at least the localization of the at least one magnetic localization sensor 70 on electrophysiology catheter 60 and the magnetic localization data in the cardiac model. For example, one or more fiducial points (*e.g.*, the left ventricle apex) can be identified, and the localization thereof using both the at least one magnetic sensor 70 of electrophysiology catheter 60 and the localization data in the cardiac model can be used to confirm the initial localization of electrophysiology catheter 60 within the cardiac model.

[0047[The initial localization of electrophysiology catheter 60 in block 412 can also include determining a rotation angle of electrophysiology catheter 60. More particularly, block 412 can include determining a rotation angle of the at least one magnetic localization sensor 70 carried by electrophysiology catheter 60. In embodiments of the disclosure, electrophysiology catheter 60 includes a radiopaque marker 74, and the position of radiopaque marker 74, as determined using fluoroscopy, is used to determine the rotation angle of electrophysiology catheter 60.

[0048[In other embodiments of the disclosure, such as embodiments that utilize a multi-electrode electrophysiology catheter 60, an electric field created by the electrodes can be used to determine the rotation angle of electrophysiology catheter 60.

[0049[In still other embodiments, magnetic sensor 70 can be a six-degree-of-freedom magnetic sensor that can be used independently to determine the rotation angle of electrophysiology catheter 60.

[0050[In further embodiments, two magnetic sensors 70 can be used in conjunction to determine the rotation angle of electrophysiology catheter 60.

[0051[Once electrophysiology catheter 60 has been localized within the cardiac model, including any determination of the rotation angle of electrophysiology catheter 60, the electrophysiology procedure can be carried out in block 414. For example, electrophysiology catheter 60 can be used to perform a diagnostic procedure, such as electrophysiological mapping (*e.g.*, calculating electrical signals from raw signals sensed by electrophysiology catheter 60 and, in embodiments, displaying the calculated electrical signals over the cardiac model) and/or to perform a therapeutic procedure, such as an ablation procedure.

[0052[In contrast to many extant electrophysiology procedures, which are carried out with multiple catheters in the heart, the electrophysiology procedure described above is carried out with only a single catheter (namely, electrophysiology catheter 60) within the heart chamber. This minimizes the risk that electrophysiology catheter 60 will move from its initial location during the electrophysiology procedure.

[0053[Nonetheless, it should be understood that electrophysiology catheter 60 may be moved, either deliberately or accidentally, during the electrophysiology procedure. According to aspects of the disclosure, therefore, block 416 monitors for movement of electrophysiology catheter 60, for example from the initial location (block 410) to a subsequent location.

[0054[If movement is detected, block 418 can adjust (*e.g.*, compensate) for the new localization of electrophysiology catheter 60, thereby minimizing or eliminating the invalidation of previously collected data and ensuring that the electrophysiology procedure can continue substantially uninterrupted.

[0055[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.

[0056[For example, in the embodiments described above a first magnetically-localizable catheter (*e.g.*, catheter 13) is used to generate the geometry, and a second magnetically-localizable catheter (*e.g.*, catheter 60) is used to carry out the electrophysiology procedure. In other embodiments, however, a single magnetically-localizable catheter (*e.g.*, catheter 60) can be used both to generate the geometry and to carry out the electrophysiology procedure.

[0057[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.

[0058[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 spirit of the invention as defined in the appended claims.

CLAIMS

What is claimed is:

1. A method of performing a cardiac electrophysiology procedure, comprising:

inserting a catheter including at least one magnetic localization sensor into a patient's heart;

generating a cardiac model using the catheter, wherein the cardiac model comprises magnetic localization data measured using the at least one magnetic localization sensor;

removing the catheter from the patient's heart; and, after removing the catheter from the patient's heart:

inserting an electrophysiology catheter including at least one magnetic localization sensor into the patient's heart;

placing the electrophysiology catheter in an initial location within the heart;

localizing the electrophysiology catheter within a coordinate system common to the cardiac model using the at least one magnetic localization sensor of the electrophysiology catheter; and

performing the electrophysiology procedure using the electrophysiology catheter.

2. The method according to claim 1, wherein the electrophysiology procedure comprises an electrophysiology mapping procedure.

3. The method according to claim 1, wherein the electrophysiology device comprises a multi-electrode electrophysiology mapping catheter.

4. The method according to claim 3, wherein the electrophysiology device comprises a non-contact electrophysiology mapping catheter.

5. The method according to claim 1, wherein the electrophysiology procedure comprises an ablation procedure.

6. The method according to claim 1, further comprising:

monitoring for movement of the electrophysiology catheter from the initial location to a subsequent location; and

re-localizing the electrophysiology catheter within the coordinate system common to the cardiac model using the at least one magnetic localization sensor of the electrophysiology catheter.

7. The method according to claim 1, wherein localizing the electrophysiology catheter within a coordinate system common to the cardiac model using the at least one magnetic localization sensor of the electrophysiology catheter further comprises determining a rotation angle of the at least one magnetic localization sensor of the electrophysiology catheter.

8. The method according to claim 7, wherein the electrophysiology catheter comprises at least one radiopaque marker, and wherein determining the rotation angle of the at least one magnetic localization sensor of the electrophysiology catheter comprises using the at least one radiopaque marker to determine the rotation angle of the at least one magnetic localization sensor of the electrophysiology catheter.

9. The method according to claim 7, wherein the electrophysiology device comprises a multi-electrode electrophysiology mapping catheter, and wherein determining the rotation angle of the at least one magnetic localization sensor of the electrophysiology catheter comprises using the multiple electrodes of the electrophysiology mapping catheter to determine the rotation angle of the at least one magnetic localization sensor of the electrophysiology catheter.

10. The method according to claim 1, wherein the at least one magnetic localization sensor of the electrophysiology catheter is positioned on a shaft of the electrophysiology catheter.

11. A method of performing an electrophysiology procedure, comprising:

generating a model of an anatomical region using a probe, wherein the probe comprises at least one magnetic localization sensor, and wherein the model comprises magnetic localization data measured using the at least one magnetic localization sensor;

placing an electrophysiology device within the anatomical region, wherein the electrophysiology device comprises at least one magnetic localization sensor;

localizing the electrophysiology device within a common coordinate system to the model using the at least one magnetic localization sensor of the electrophysiology device; and

performing the electrophysiology procedure using the electrophysiology device.

12. The method according to claim 11, further comprising compensating for movement of the electrophysiology device during the electrophysiology procedure using the at least one magnetic localization sensor of the electrophysiology device.

13. The method according to claim 12, wherein compensating for movement of the electrophysiology device during the electrophysiology procedure comprises repeating the localizing step when the electrophysiology device moves.

14. The method according to claim 11, wherein the electrophysiology procedure comprises a diagnostic procedure.

15. The method according to claim 11, wherein the electrophysiology procedure comprises a therapeutic procedure.

16. The method according to claim 11, wherein the electrophysiology device comprises a plurality of electrodes, and wherein localizing the electrophysiology device within a coordinate system common to the model using the at least one magnetic localization sensor of the electrophysiology device further comprises using the plurality of electrodes to determine a rotation angle of the electrophysiology device.

17. The method according to claim 11, wherein the electrophysiology device comprises a radiopaque marker, and wherein localizing the electrophysiology device within a coordinate system common to the model using the at least one magnetic localization sensor of the electrophysiology device further comprises using the radiopaque marker to determine a rotation angle of the electrophysiology device.

18. A method of performing an electrophysiology procedure, comprising:

inserting a probe carrying at least one magnetic localization sensor into an anatomical region;

generating a model of the anatomical region by measuring a plurality of positions of the at least one magnetic localization sensor as it moves through the anatomical region;

removing the probe from the anatomical region; and, after removing the probe from the anatomical region:

positioning an electrophysiology device including at least one magnetic localization sensor at an initial position within the anatomical region;

localizing the initial position of the electrophysiology device within a coordinate system common to the model of the anatomical region using the at least one magnetic localization sensor of the electrophysiology device; and

performing the electrophysiology procedure using the electrophysiology device.

19. The method according to claim 18, further comprising:

monitoring for movement of the electrophysiology device from the initial position to a subsequent position; and

localizing the subsequent position of the electrophysiology device within the coordinate system common to the model of the anatomical region using the at least one magnetic localization sensor of the electrophysiology device.

20. The method according to claim 18, wherein localizing the initial position of the electrophysiology device within a coordinate system common to the model of the anatomical region using the at least one magnetic localization sensor of the electrophysiology device further comprises determining a rotation angle of the electrophysiology device.

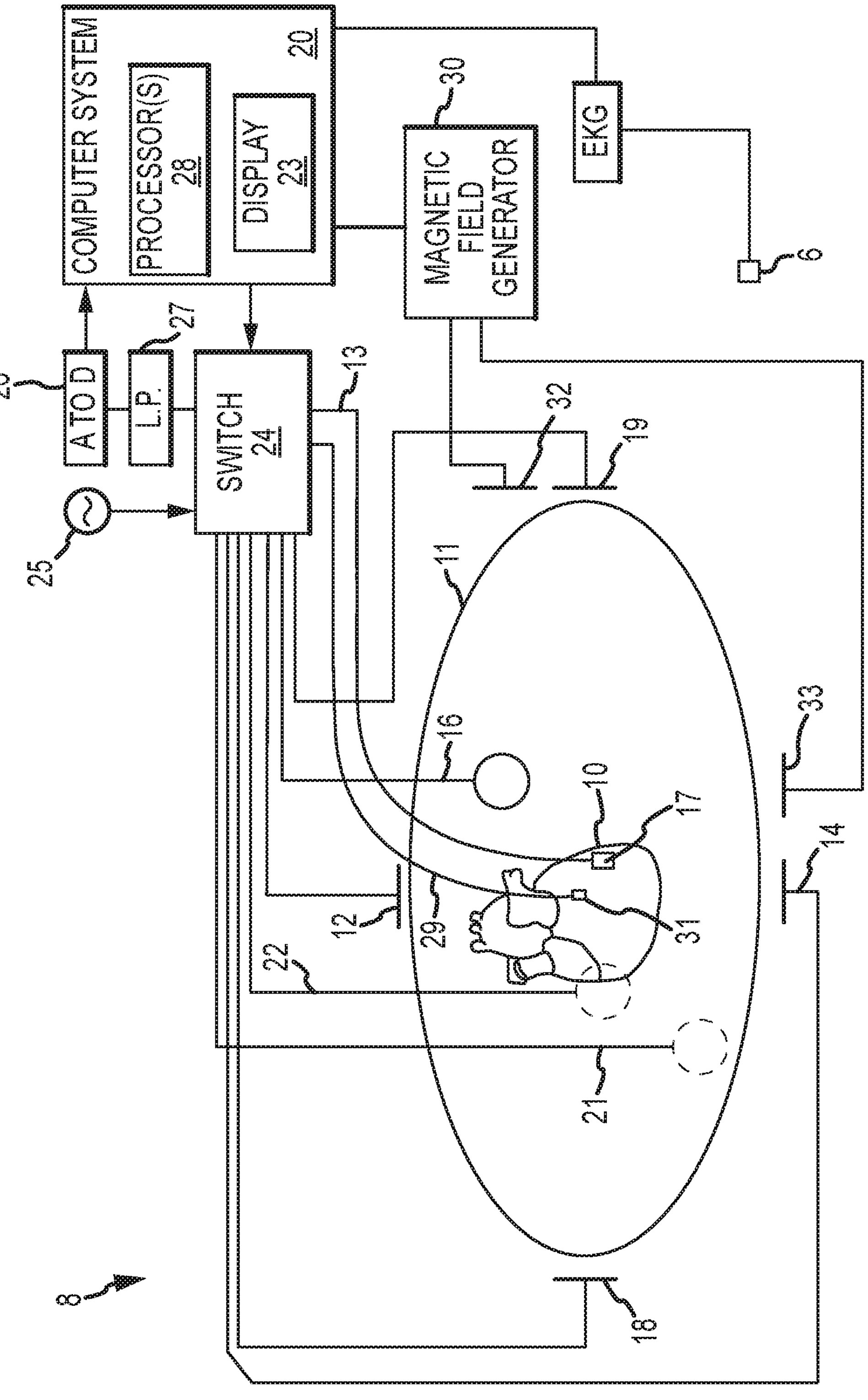
COMPUTER SYSTEM
PROCESSOR(S) 28
DISPLAY 23
20
30
MAGNETIC FIELD GENERATOR
EKG
6
26
A TO D
27
L.P.
SWITCH 24
13
25
32
19
11
16
10
17
33
14
12
29
31
22
21
8
18

FIG.1

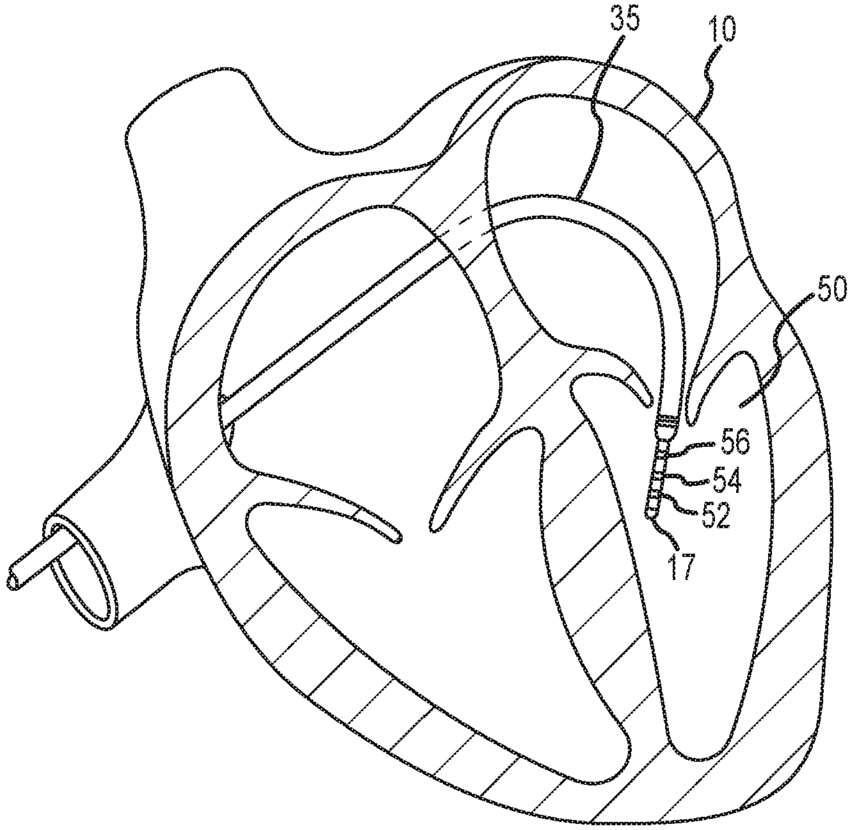

FIG.2

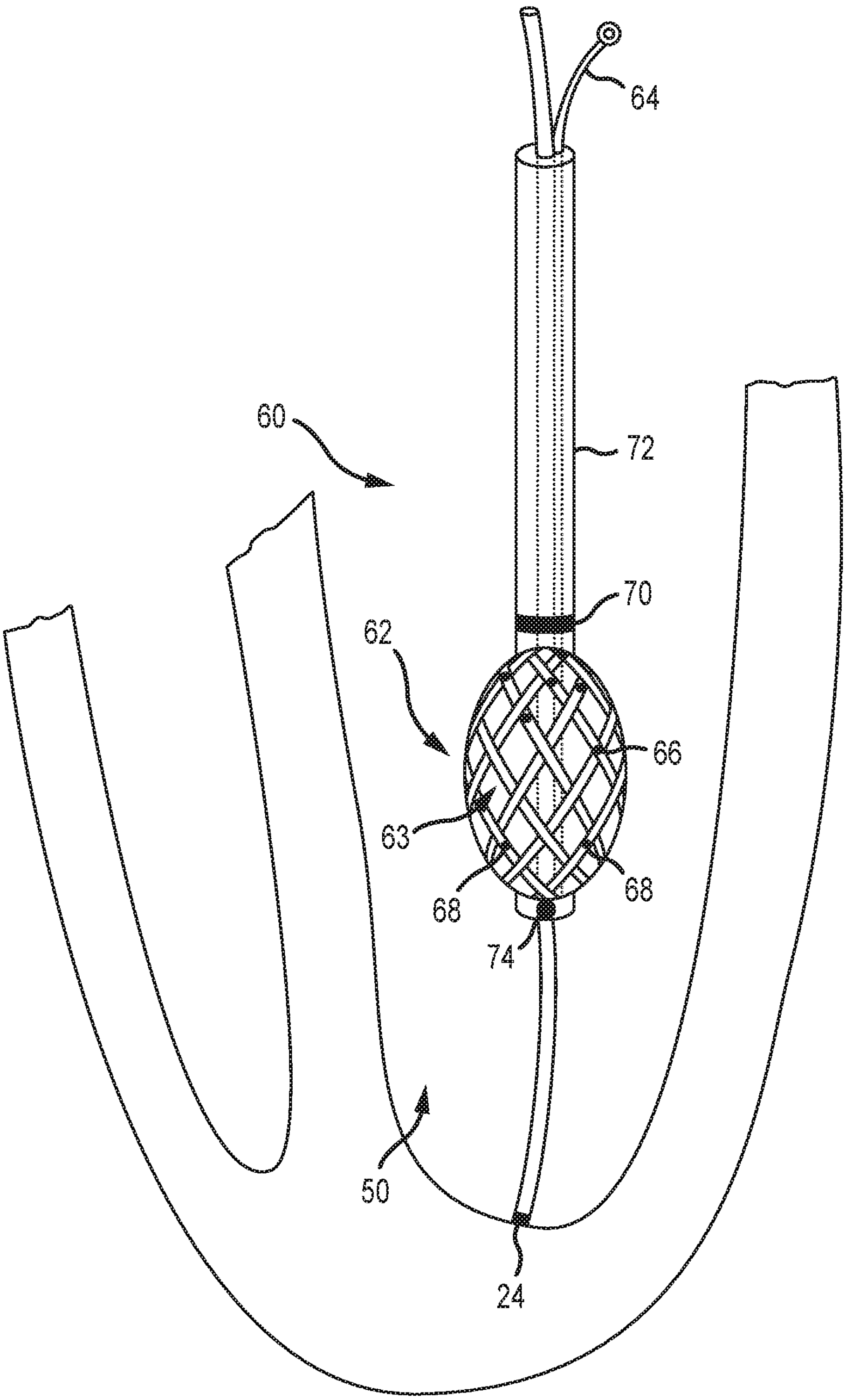

FIG.3

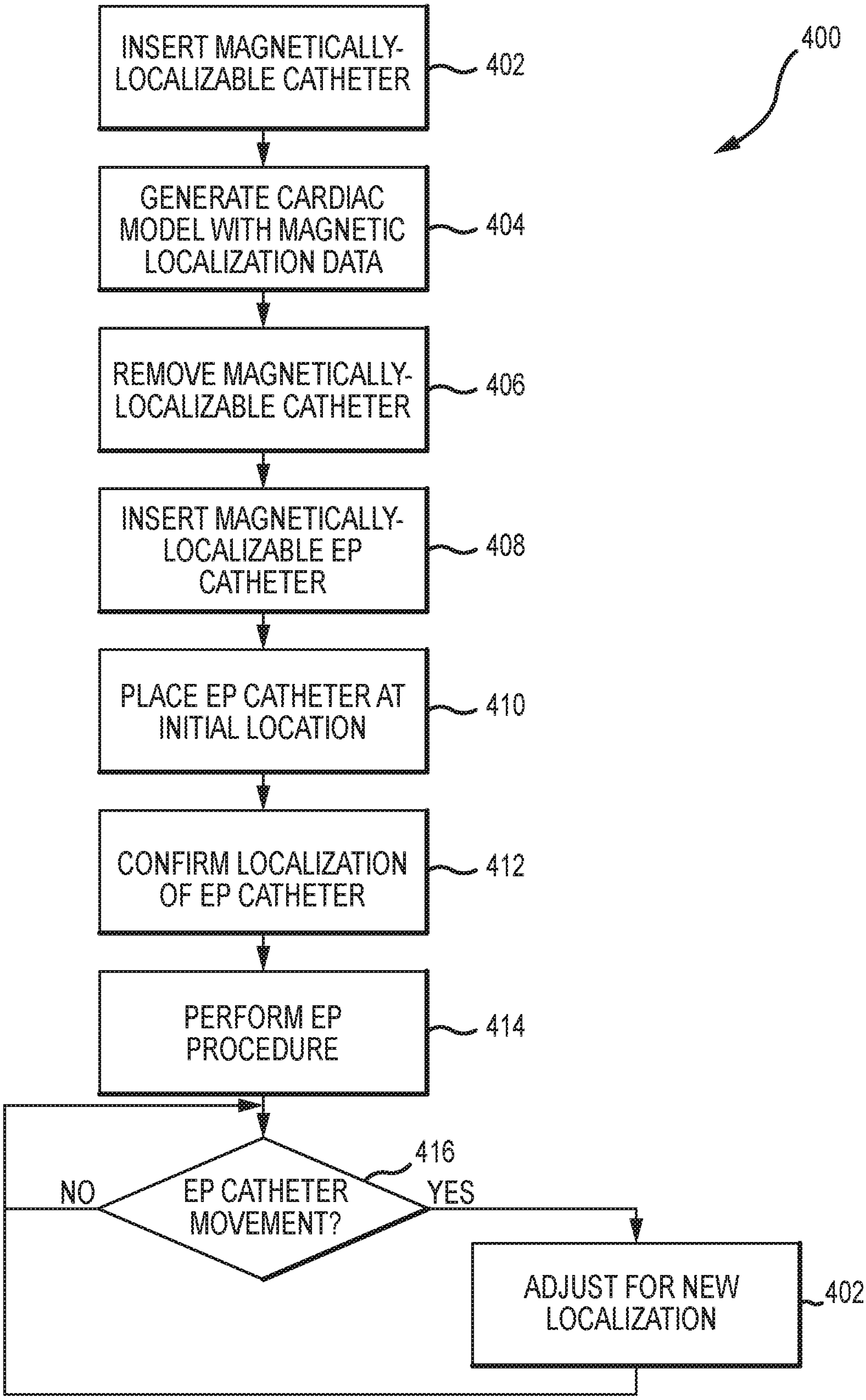
400
INSERT MAGNETICALLY-LOCALIZABLE CATHETER
402
GENERATE CARDIAC MODEL WITH MAGNETIC LOCALIZATION DATA
404
REMOVE MAGNETICALLY-LOCALIZABLE CATHETER
406
INSERT MAGNETICALLY-LOCALIZABLE EP CATHETER
408
PLACE EP CATHETER AT INITIAL LOCATION
410
CONFIRM LOCALIZATION OF EP CATHETER
412
PERFORM EP PROCEDURE
414
EP CATHETER MOVEMENT?
416
NO
YES
ADJUST FOR NEW LOCALIZATION
402

FIG.4

PATENT COOPERATION TREATY

PCT

DECLARATION OF NON-ESTABLISHMENT OF INTERNATIONAL SEARCH REPORT

(PCT Article 17(2)(a), Rules 13ter.1(c) and Rule 39)

Applicant's or agent's file reference CD-1243WO01	IMPORTANT DECLARATION	Date of mailing *(day/month/year)* 11 August 2017 (11-08-2017)
International application No. PCT/US2017/029428	International filing date *(day/month/year)* 25 April 2017 (25-04-2017)	(Earliest) Priority date *(day/month/year)* 22 June 2016 (22-06-2016)
International Patent Classification (IPC) or both national classification and IPC A61B5/042 A61B5/00 A61B5/06		
Applicant ST JUDE MEDICAL, CARDIOLOGY DIVISION, INC		

This International Searching Authority hereby declares, according to Article 17(2)(a), that **no international search report will be established** on the international application for the reasons indicated below

1. [X] The subject matter of the international application relates to:
   - a. [ ] scientific theories.
   - b. [ ] mathematical theories
   - c. [ ] plant varieties.
   - d. [ ] animal varieties.
   - e. [ ] essentially biological processes for the production of plants and animals, other than microbiological processes and the products of such processes.
   - f. [ ] schemes, rules or methods of doing business.
   - g. [ ] schemes, rules or methods of performing purely mental acts.
   - h. [ ] schemes, rules or methods of playing games.
   - i. [X] methods for treatment of the human body by surgery or therapy.
   - j. [X] methods for treatment of the animal body by surgery or therapy.
   - k. [ ] diagnostic methods practised on the human or animal body.
   - l. [ ] mere presentations of information.
   - m. [ ] computer programs for which this International Searching Authority is not equipped to search prior art.

2. [ ] The failure of the following parts of the international application to comply with prescribed requirements prevents a meaningful search from being carried out:

   [ ] the description   [ ] the claims   [ ] the drawings

3. [ ] The failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions prevents a meaningful search from being carried out:

   [ ] the written form has not been furnished or does not comply with the standard.

   [ ] the computer readable form has not been furnished or does not comply with the standard.

4. Further comments:

Name and mailing address of the International Searching Authority	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040 Fax: (+31-70) 340-3016	KLUG, Desirée Tel: +31 (0)70 340-4520

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 203

The present application does not meet the criteria of Article 17(2)(a)(i) and Rule 39.1(iv) PCT, because the subject-matter of independent claims 1, 11, 18 discloses a surgical method (see also PCT Guidelines 9.10) for the following reasons:
Independent claims 1, 11, 18 define surgical method steps practiced on the human or animal body in the meaning of Rule 39.1(iv) PCT ("inserting a catheter [...] into a patient's heart", "removing the catheter", "placing the catheter").
Furthermore, independent claims 1, 11, 18 disclose the step of "performing a electrophysiology procedure" which, according to the description (see [0002]) includes cardiac diagnostic and therapeutic procedures.
Therefore, according to Article 17(2)(a)(i) PCT no written opinion regarding novelty, inventive step or industrial applicability is given for all claims on file.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

patsnap

专利名称(译)	用于电生理学程序的系统和方法		
公开(公告)号	EP3474744A2	公开(公告)日	2019-05-01
申请号	EP2017722288	申请日	2017-04-25
[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.		
当前申请(专利权)人(译)	ST.犹达医疗用品，心脏病DIVISION，INC.		
[标]发明人	MARKOVITZ CRAIG QU FUJIAN LI WENWEN MCSPADDEN LUKE		
发明人	MARKOVITZ, CRAIG QU, FUJIAN LI, WENWEN MCSPADDEN, LUKE		
IPC分类号	A61B5/042 A61B5/00 A61B5/06		
CPC分类号	A61B5/0422 A61B5/062 A61B5/6858 A61B5/05 A61B5/0538 A61B5/1076 A61B5/6852 A61B18/1492 A61B34/10		
优先权	62/353252 2016-06-22 US		
外部链接	Espacenet		

摘要(译)

一种执行心脏电生理学过程的方法包括使用可磁性定位的导管来产生心脏模型，然后从患者的心脏移除导管。然后将电生理学导管（例如多电极，非接触式标测导管）插入心脏中。电生理导管也是可磁性定位的，因此可以定位在模型内。电生理学导管用于执行电生理学过程，例如电生理学绘图或消融。有利地，因为电生理学导管是可磁性定位的，所以它可以在电生理学过程期间有意或无意地移动，而不会使任何先前收集的数据无效或需要重建心脏模型。