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Hauck et al.

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(54) **ROBOTIC SURGICAL SYSTEM AND METHOD FOR AUTOMATED CREATION OF ABLATION LESIONS**

(58) **Field of Classification Search**
CPC A61B 19/2203; A61B 19/5244; A61B 2019/505; A61B 2019/507;
(Continued)

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(73) Assignee: **St. Jude Medical, Atrial Fibrillation Division, Inc.**, St. Paul, MN (US)

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1984 days.

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This patent is subject to a terminal disclaimer.

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Primary Examiner — Boniface Nganga
(74) *Attorney, Agent, or Firm* — Wiley Rein LLP

(57) **ABSTRACT**

Related U.S. Application Data

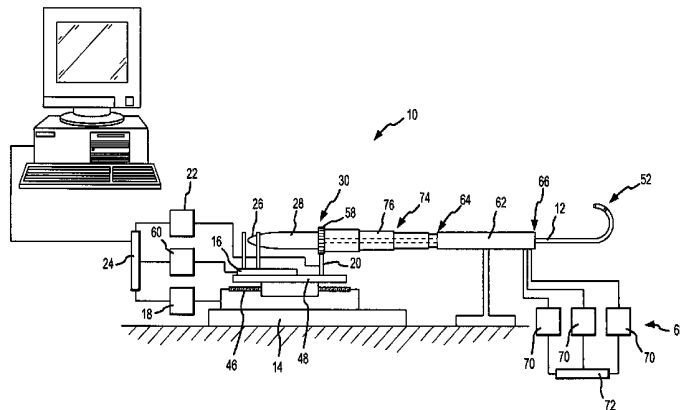
A system for ablating tissue includes an ablation catheter for insertion into the body of a patient and a robotic controller for moving the catheter within the body. The robotic controller advances the catheter until the catheter contacts the tissue surface, maintains contact between the catheter and the tissue surface, and moves the catheter along a predetermined path to create a substantially continuous lesion of ablated tissue. A display device may be used to present a graphical representation of an area of tissue to be ablated. A user interface permits selection of a plurality of treatment points on the graphical representation. The interface is preferably coupled to the controller and catheter such that the controller may cause the catheter to automatically ablate tissue at and between the plurality of treatment points in response to the received user input.

(63) Continuation-in-part of application No. 11/139,908, filed on May 27, 2005, now Pat. No. 7,632,265.
(Continued)

(51) **Int. Cl.**
A61B 18/24 (2006.01)
A61B 5/00 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC *A61B 5/6885* (2013.01); *A61B 34/20* (2016.02); *A61B 34/30* (2016.02); *A61B 34/71* (2016.02);
(Continued)

29 Claims, 20 Drawing Sheets



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	<i>A61B 2019/528</i> ; <i>A61B 2019/464</i> ; <i>A61B 2019/2211</i> ; <i>A61B 2019/2242</i> ; <i>A61B 2019/2276</i> ; <i>A61B 2019/5251</i> ; <i>A61B 5/6885</i> ; <i>A61B 34/20</i> ; <i>A61B 34/30</i> ; <i>A61B 34/71</i> ; <i>A61B 2017/00026</i> ; <i>A61B 2034/105</i> ; <i>A61B 2034/107</i> ; <i>A61B 2034/301</i> ; <i>A61B 2034/742</i> ; <i>A61B 2034/2051</i> ; <i>A61B 2090/064</i> ; <i>A61B 2090/3784</i> ; <i>A61M 25/0105</i>	5,813,991	A	9/1998	Willis et al.
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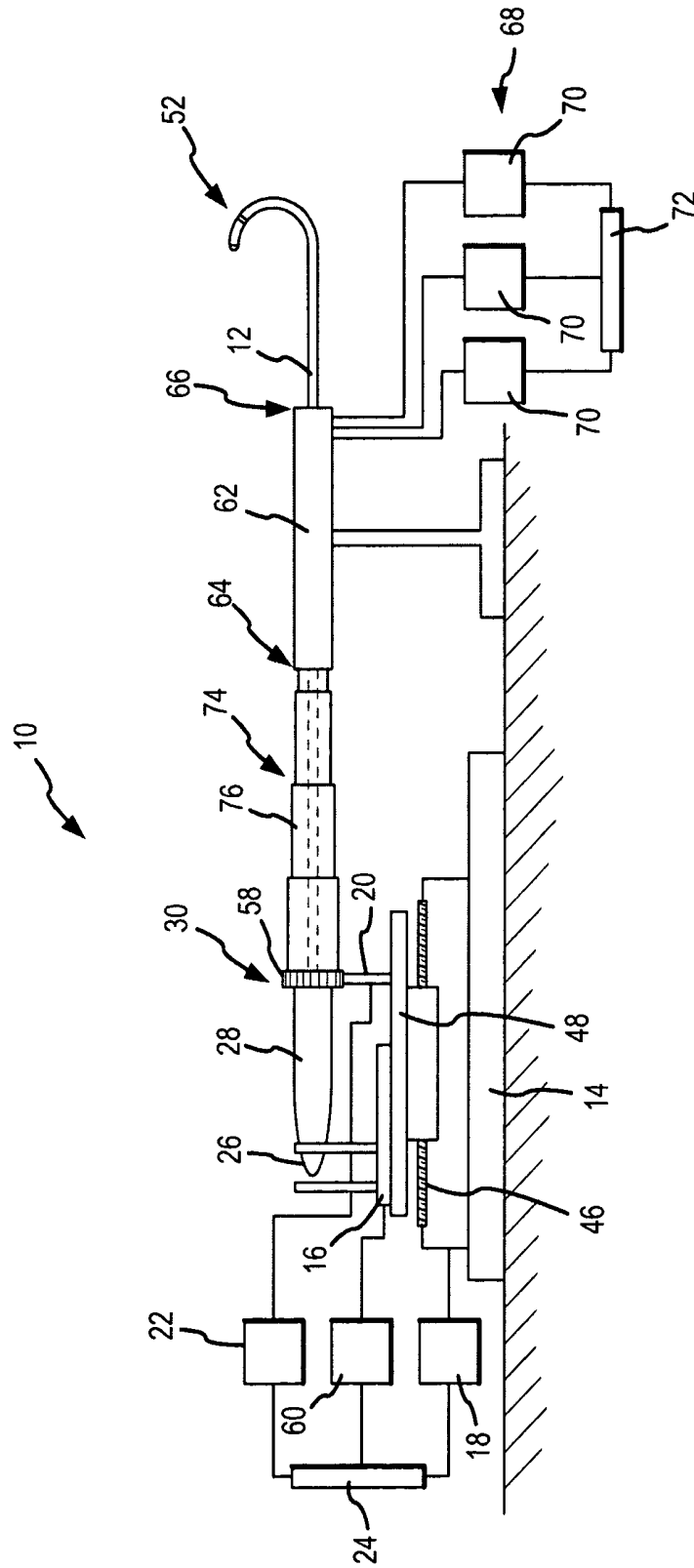


FIG.1

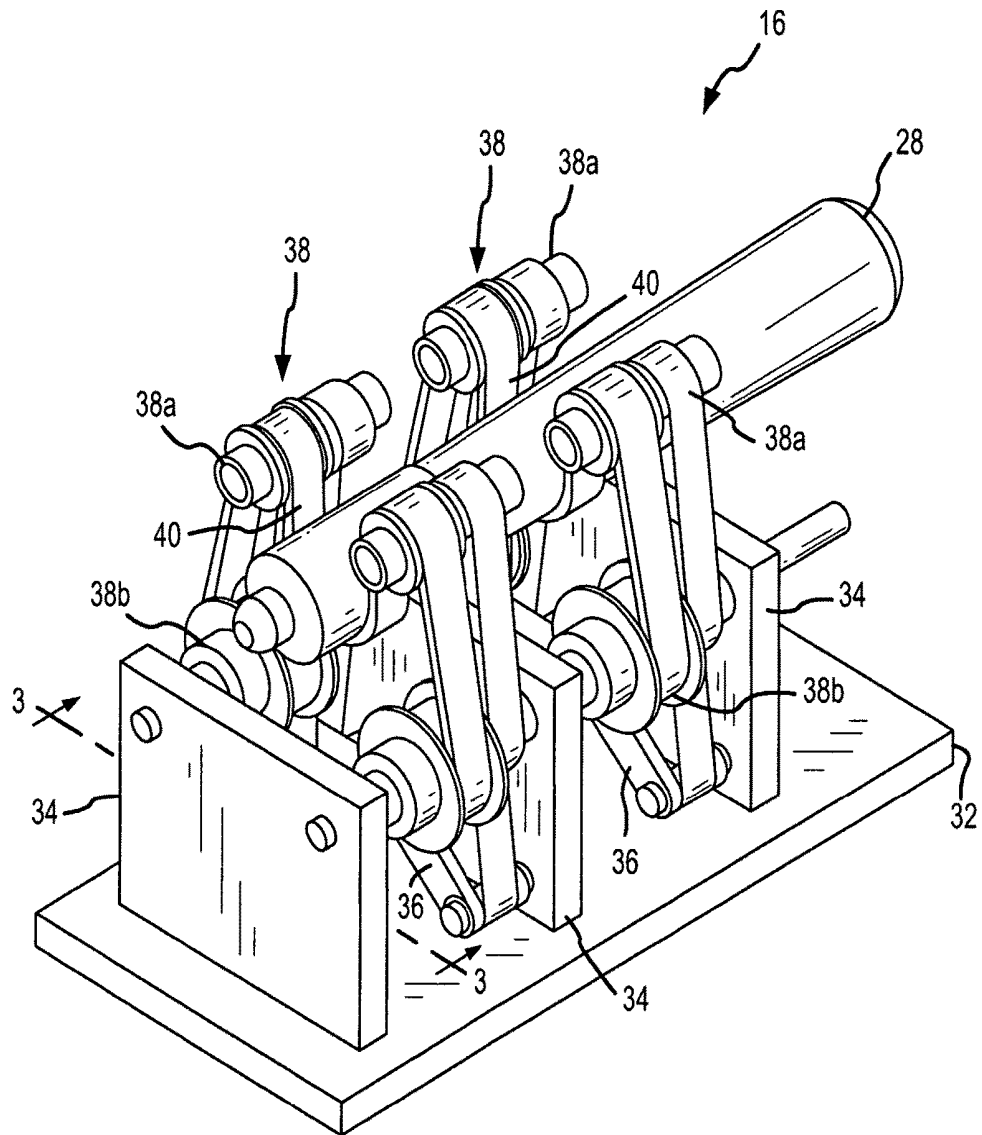


FIG. 2

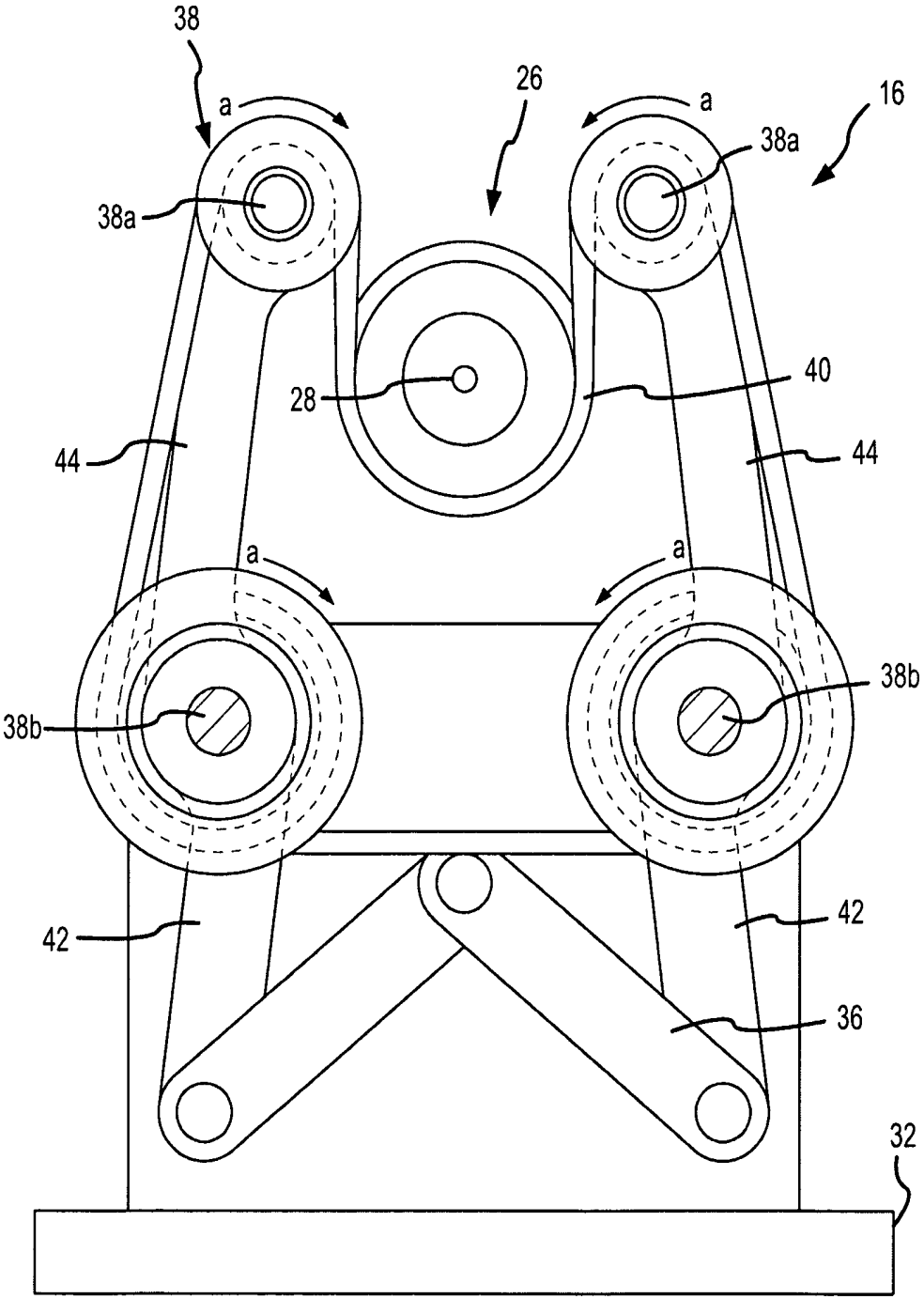


FIG.3

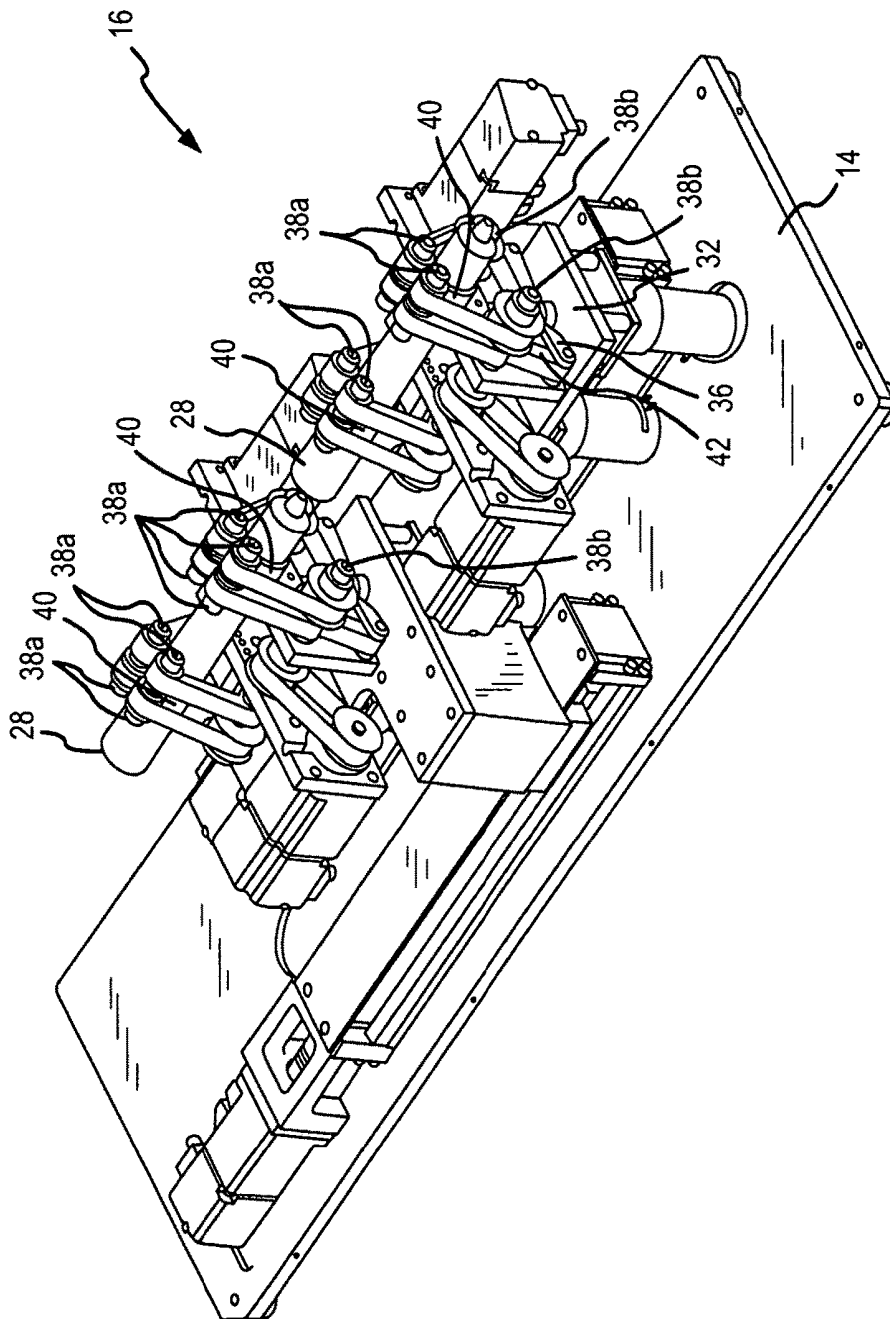


FIG.4

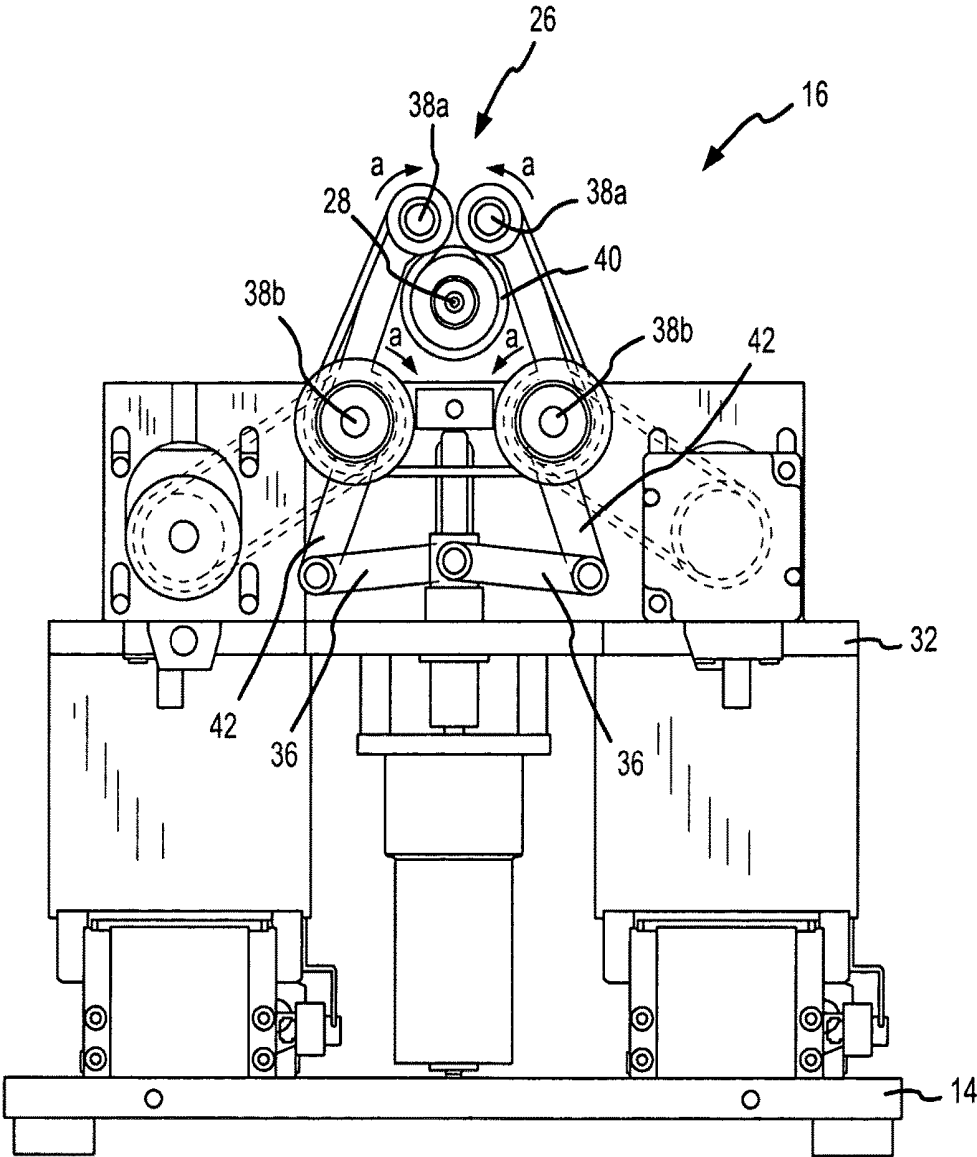


FIG.5

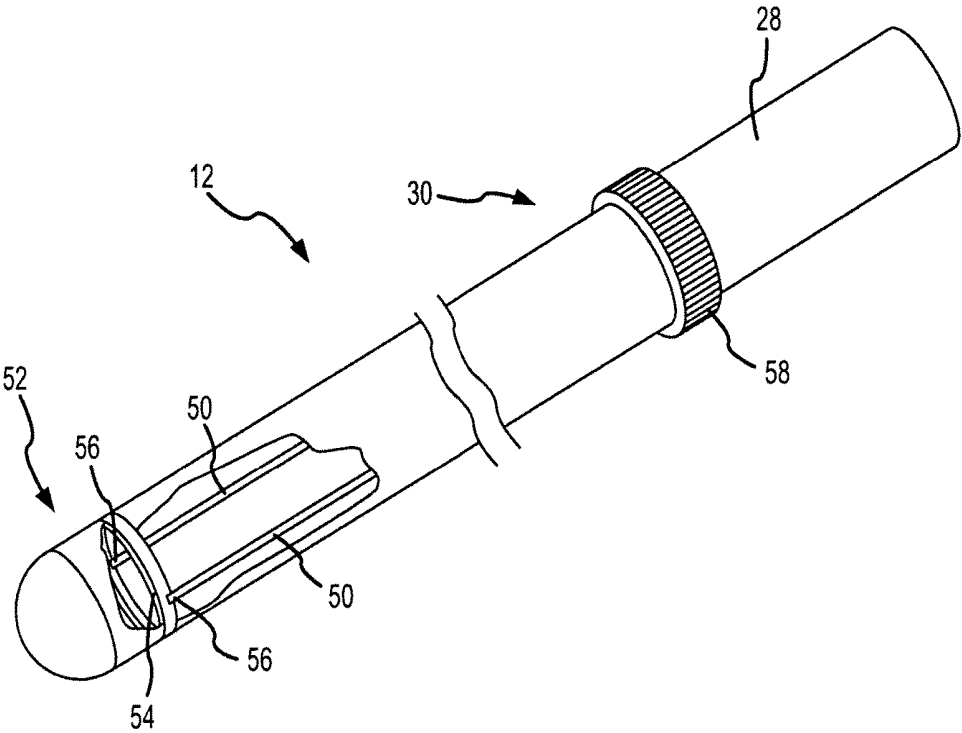


FIG.6

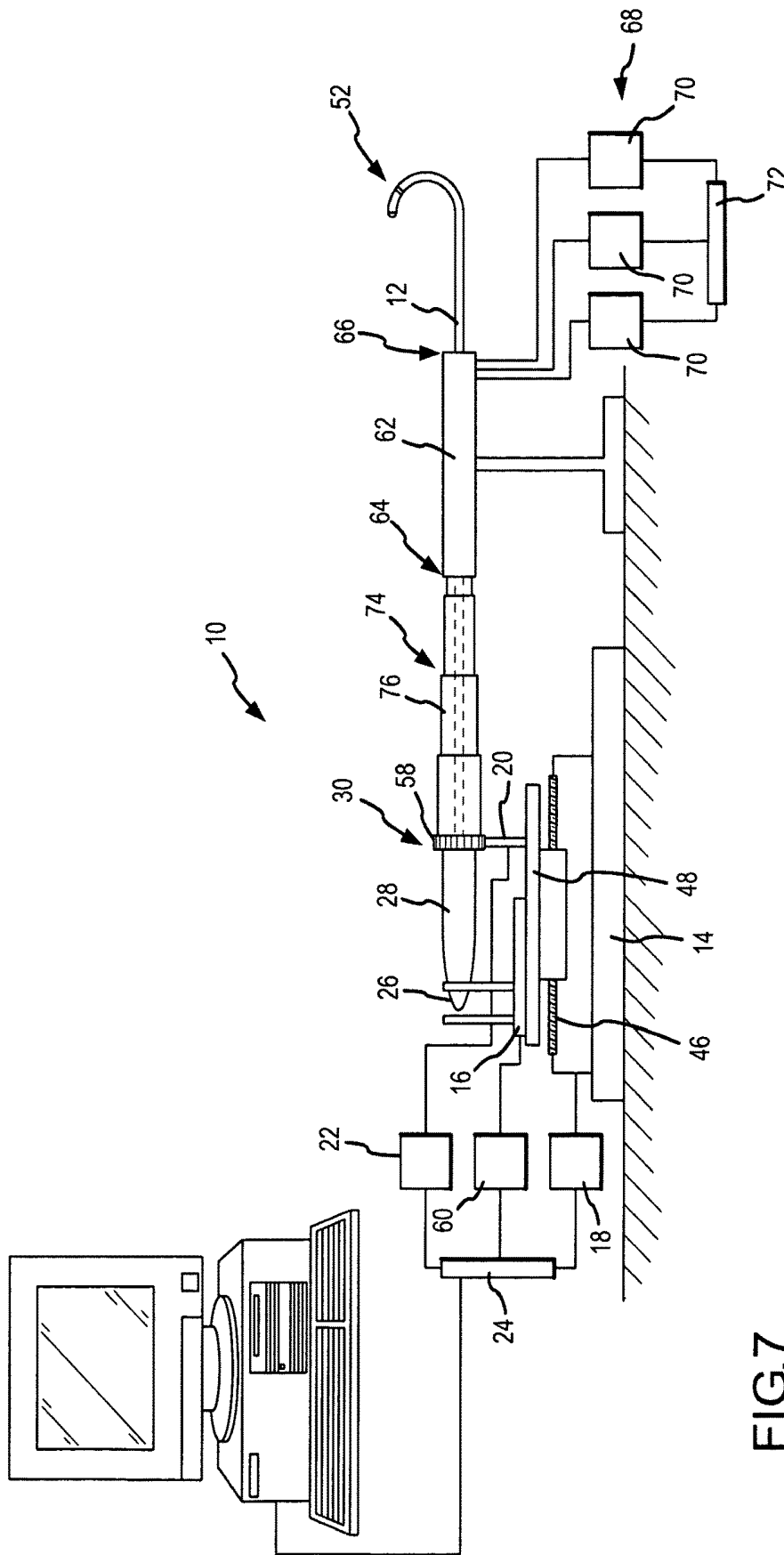


FIG. 7

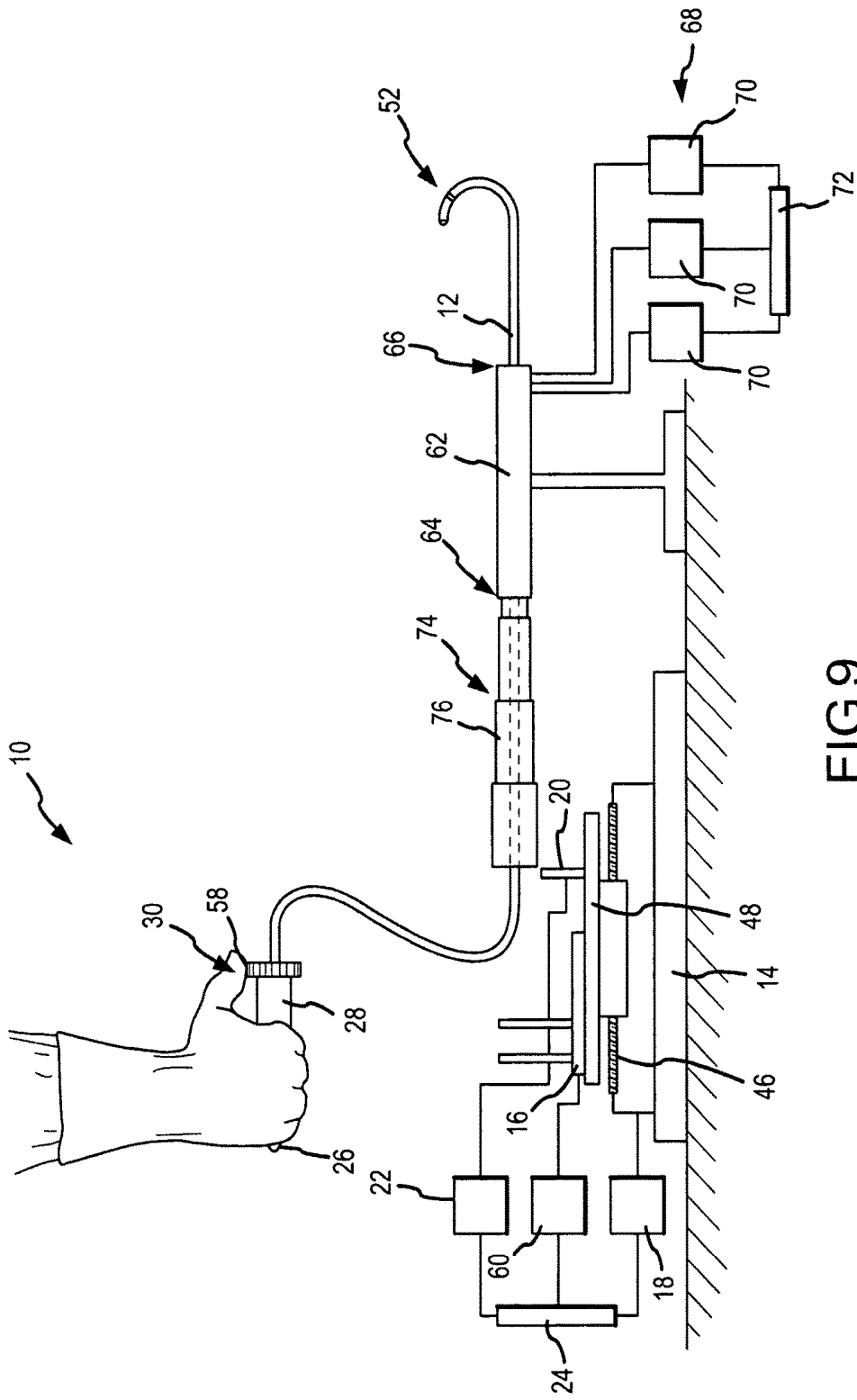


FIG. 9

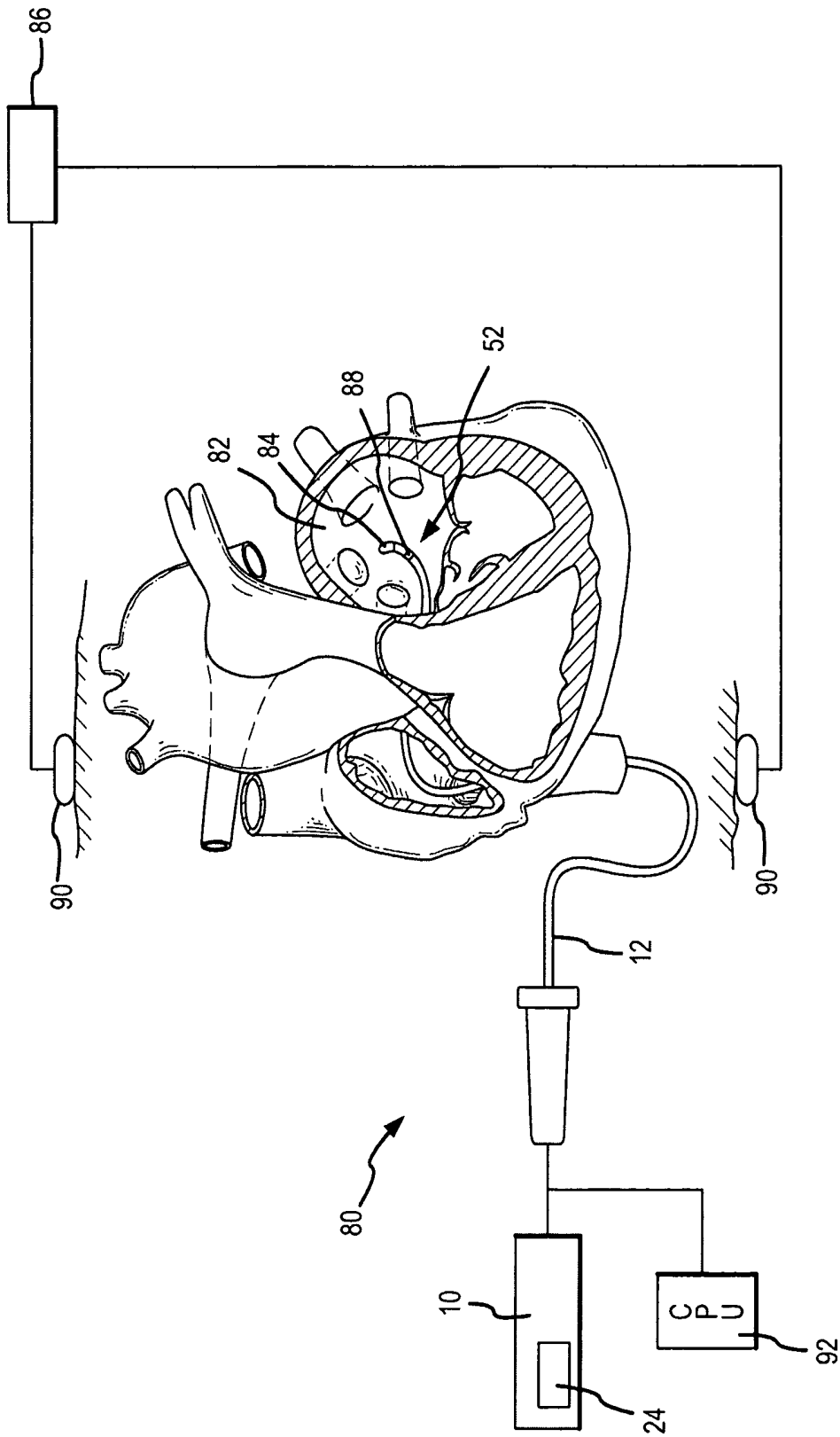


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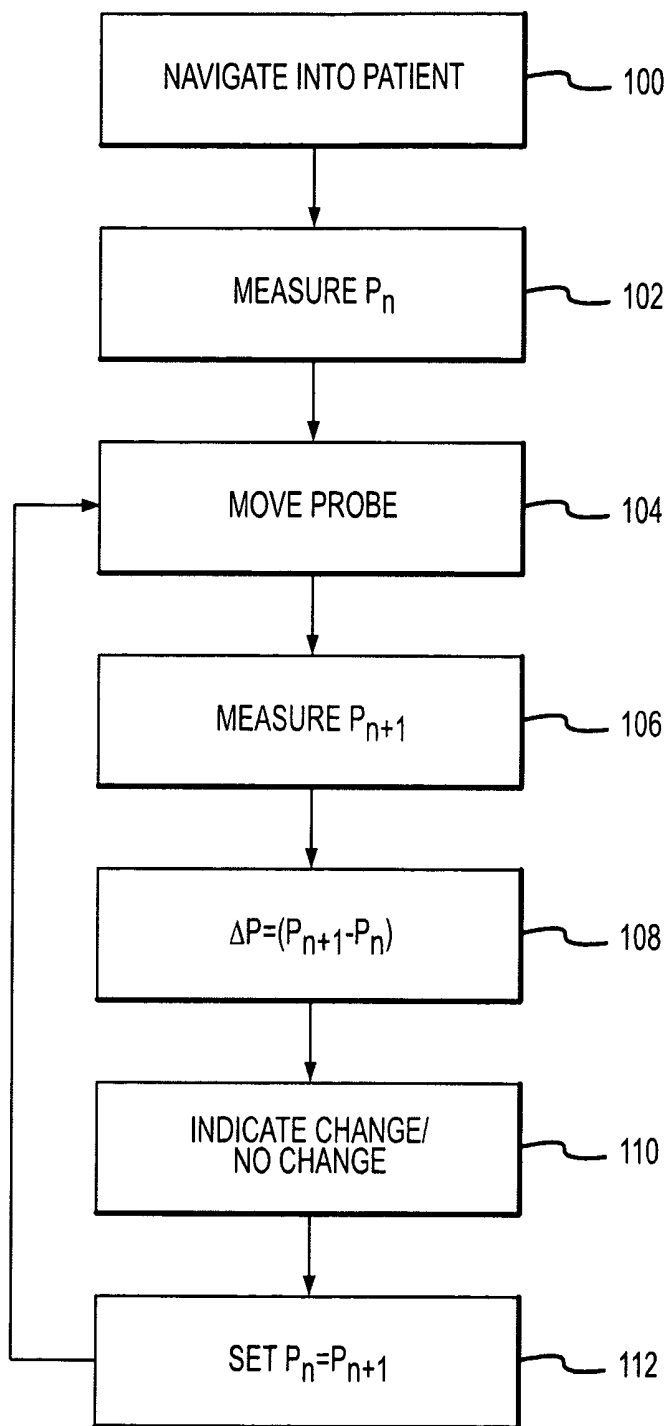


FIG.11

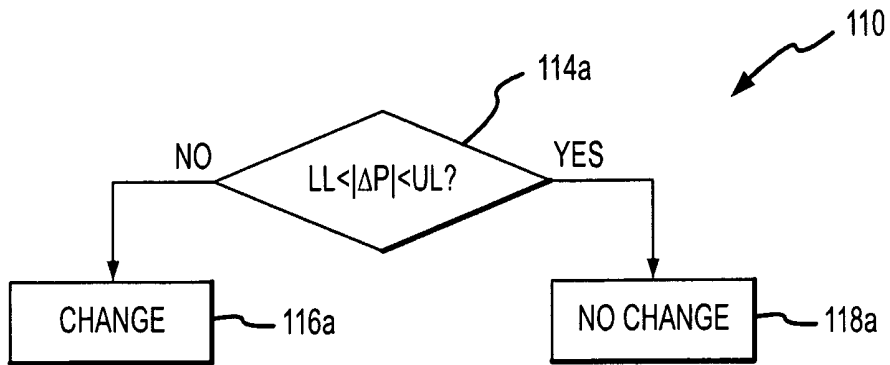


FIG.12a

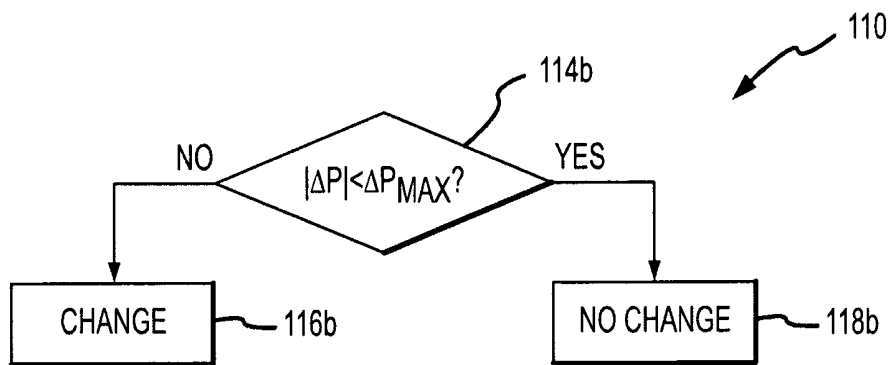


FIG.12b

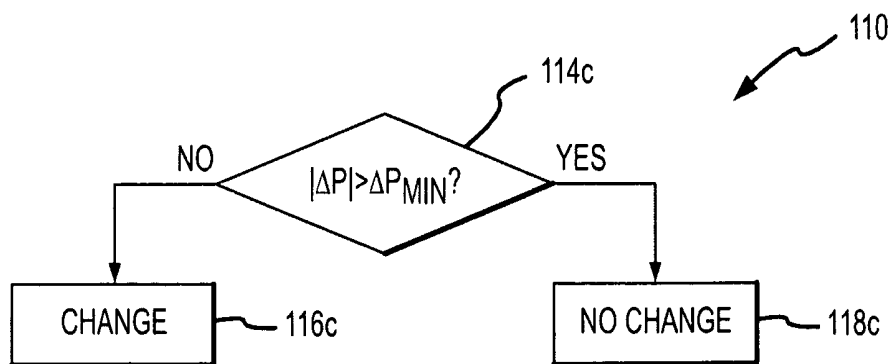


FIG.12c

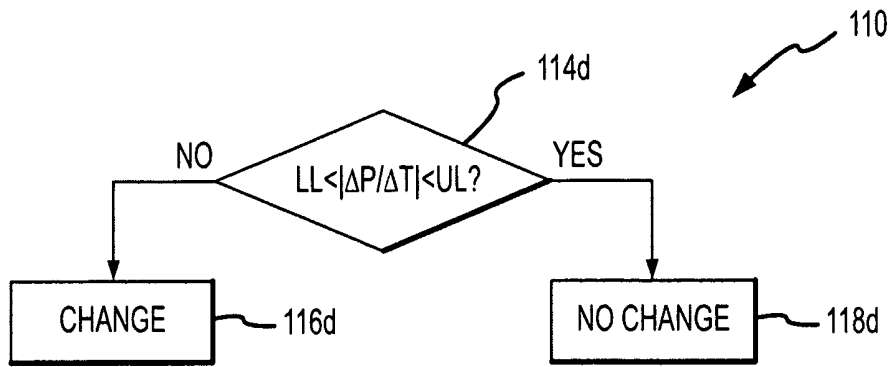


FIG.12d

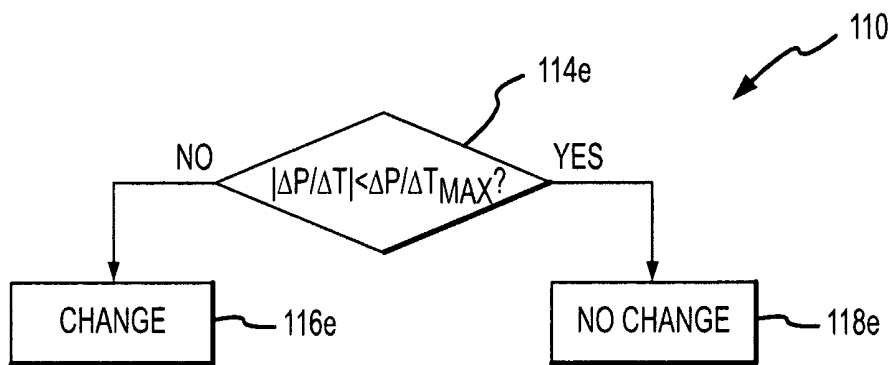


FIG.12e

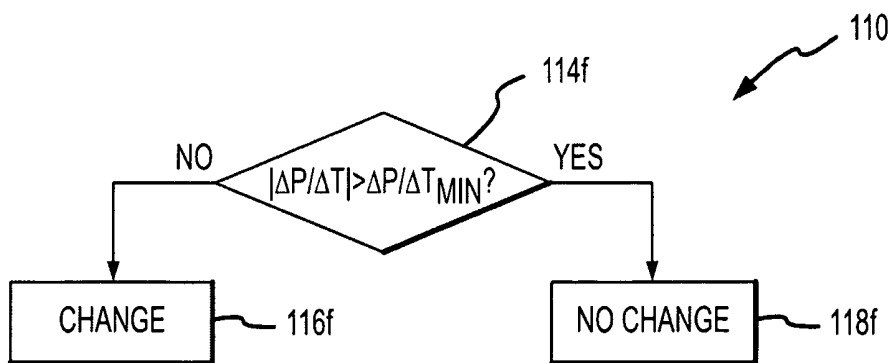


FIG.12f

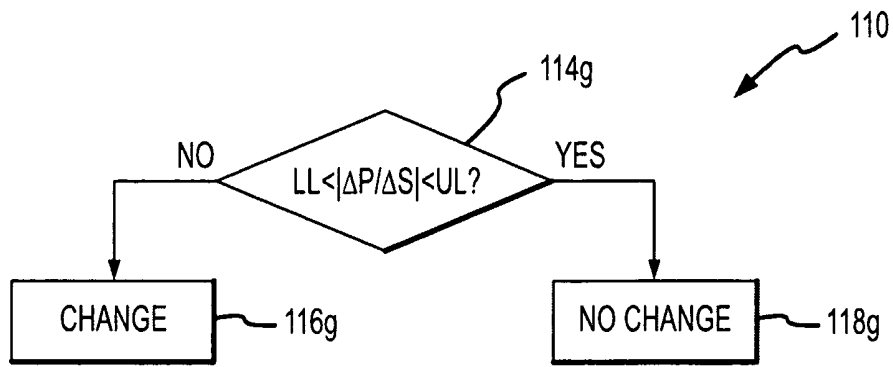


FIG.12g

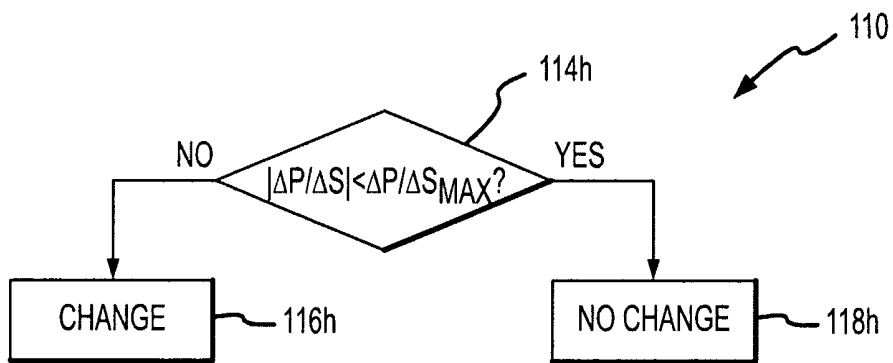


FIG.12h

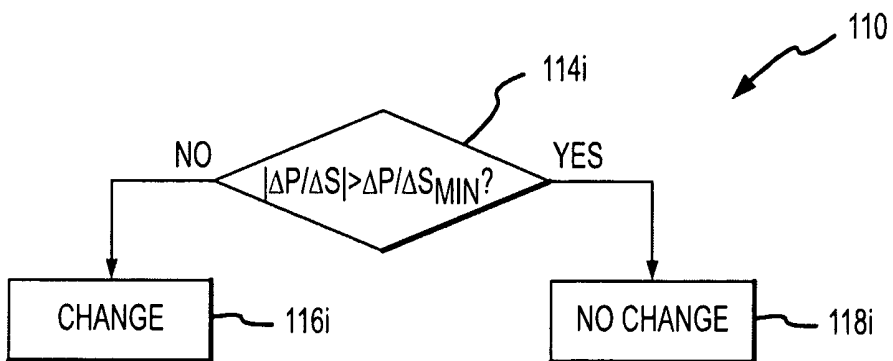


FIG.12i

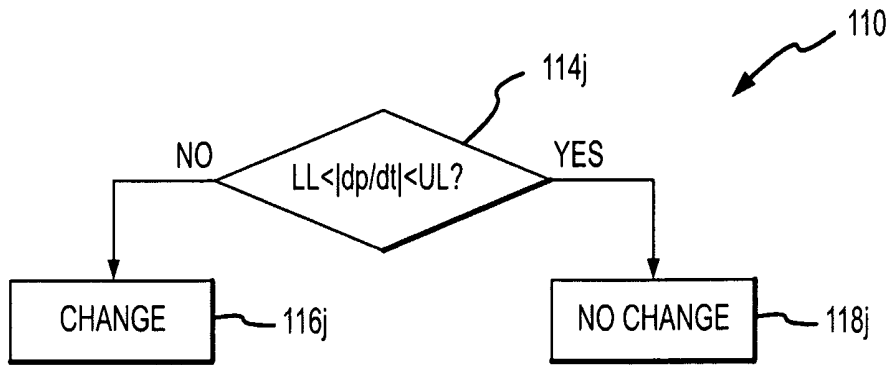


FIG.12j

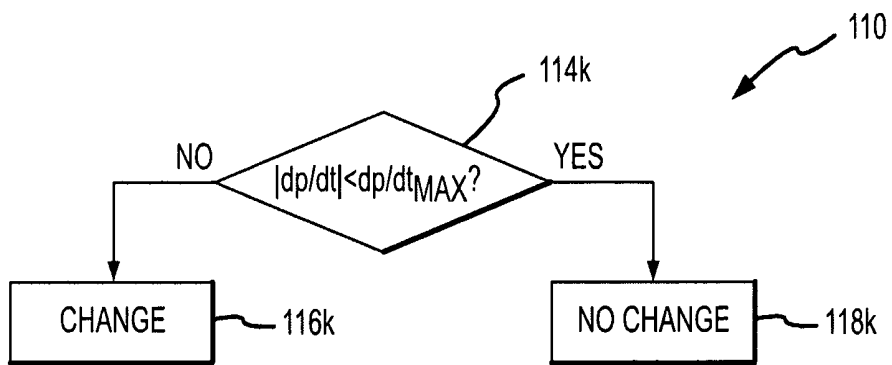


FIG.12k

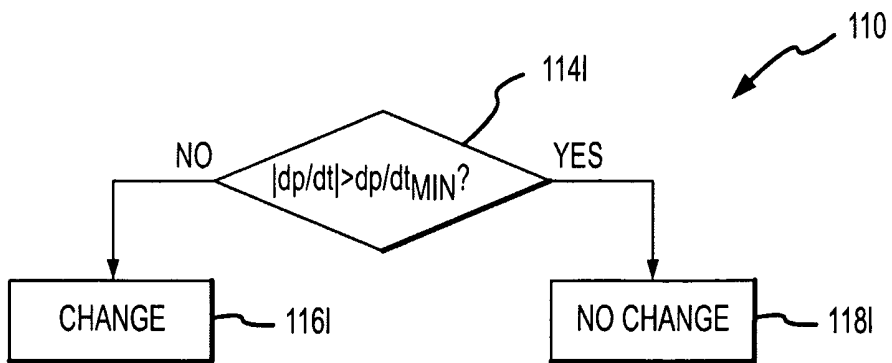


FIG.12l

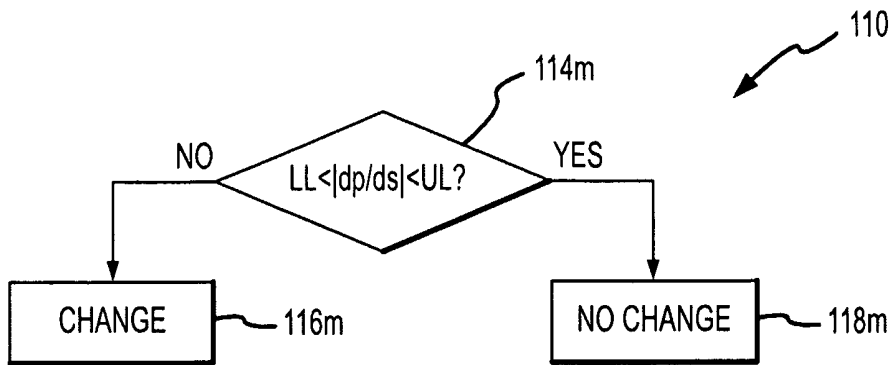


FIG.12m

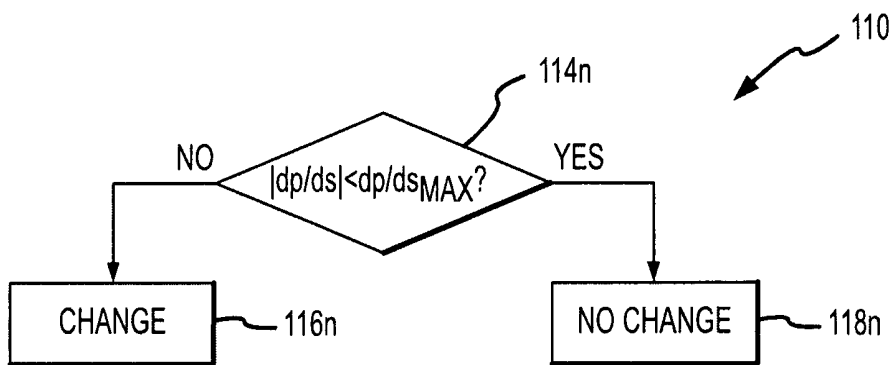


FIG.12n

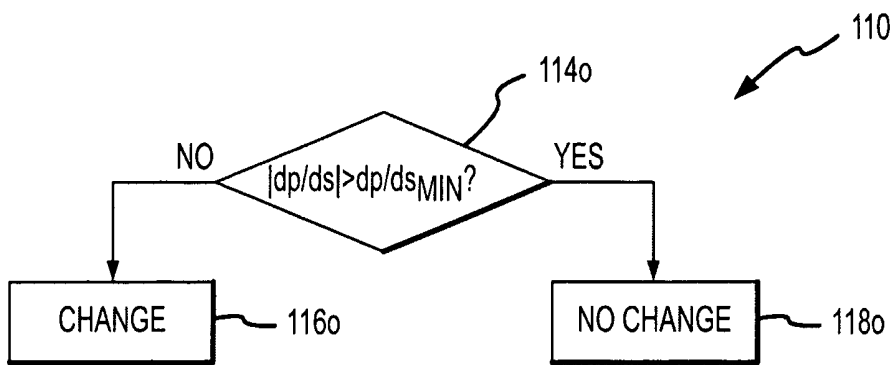


FIG.12o

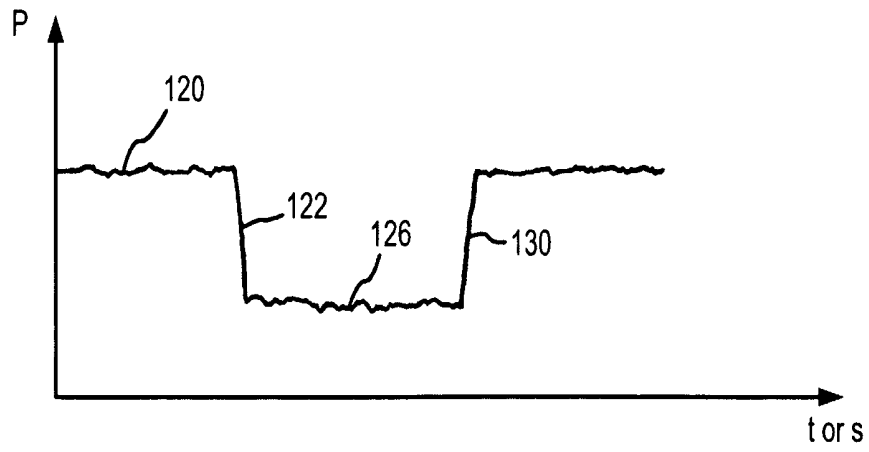


FIG.13a

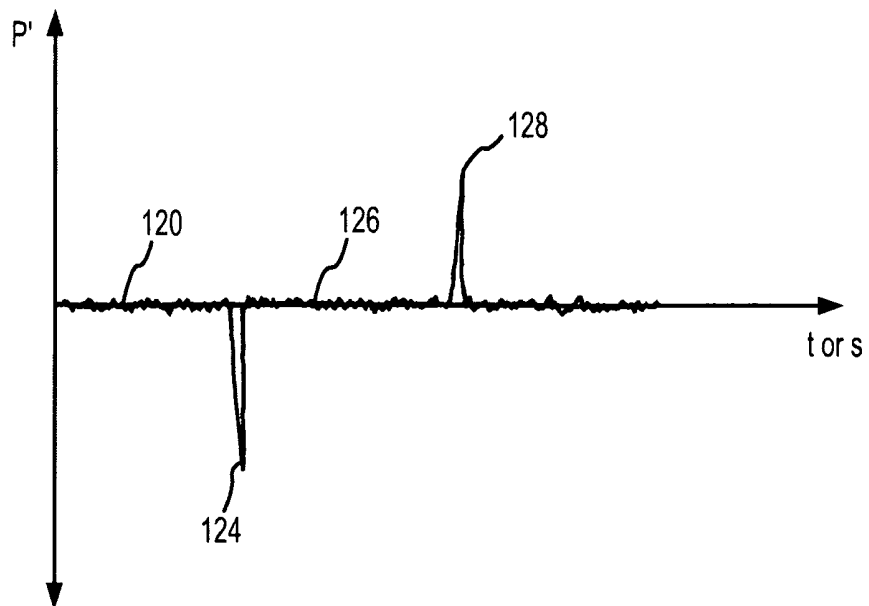


FIG.13b

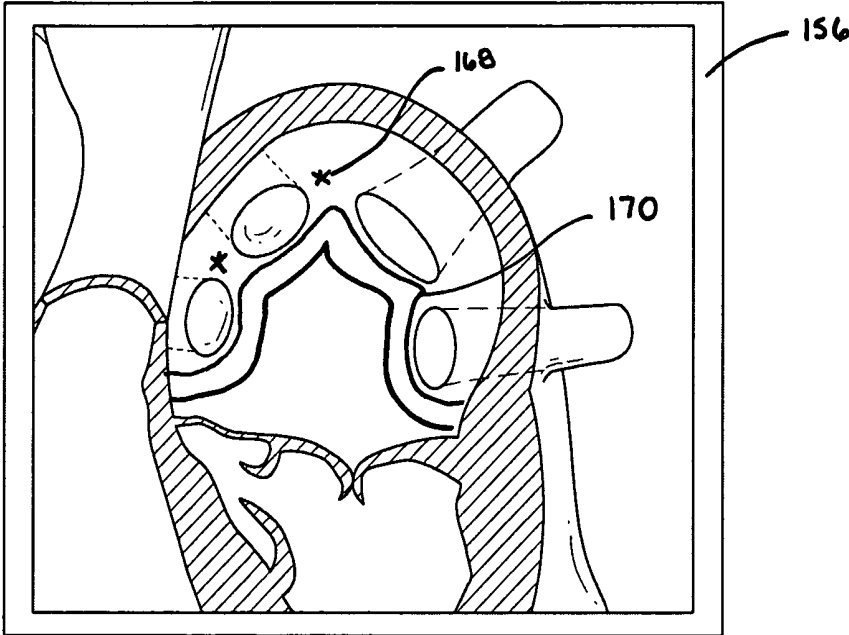


FIG.15

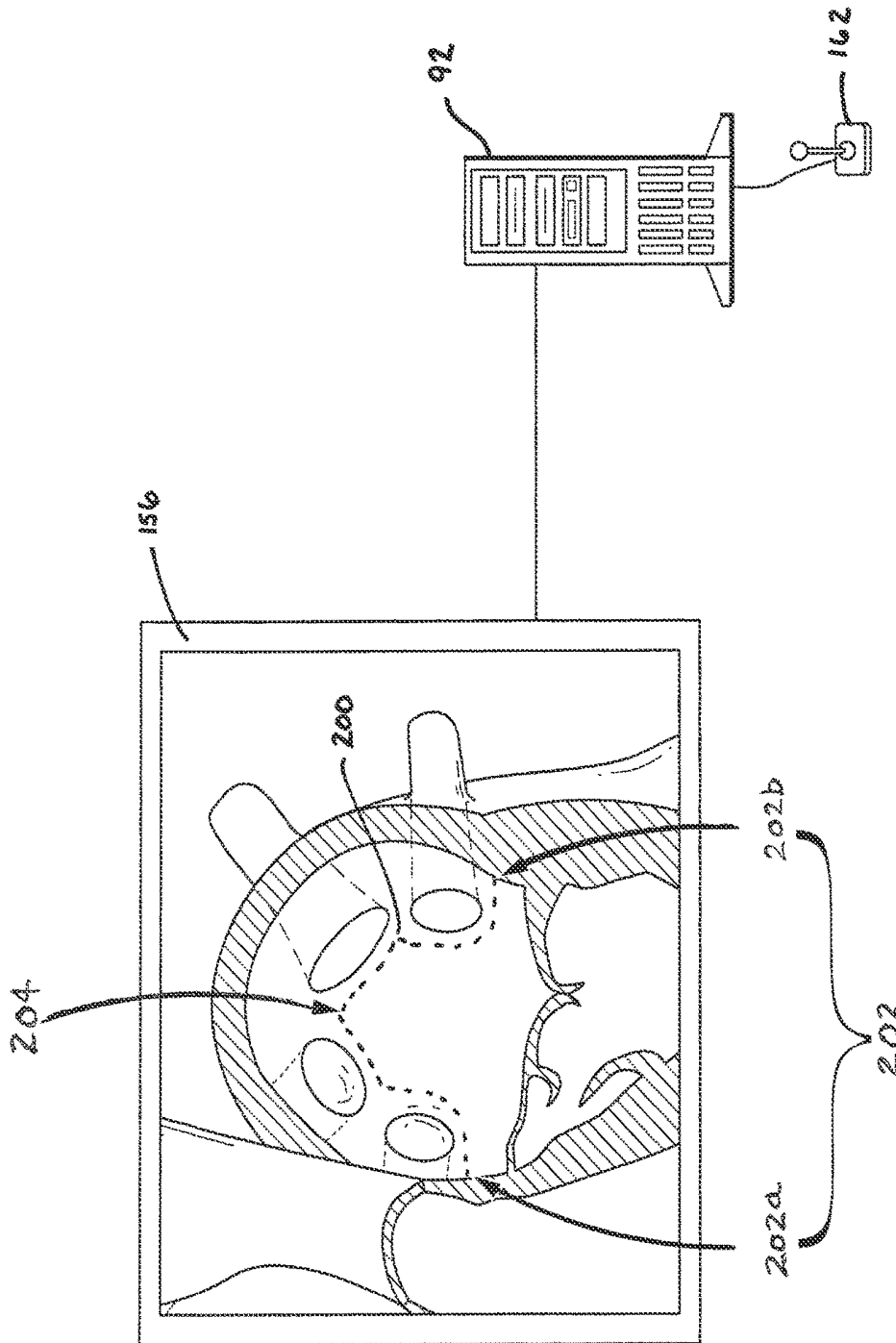


FIG.16

**ROBOTIC SURGICAL SYSTEM AND
METHOD FOR AUTOMATED CREATION OF
ABLATION LESIONS**

CROSS-REFERENCE TO RELATED
APPLICATIONS

This application claims the benefit of U.S. provisional application No. 60/851,042, filed 12 Oct. 2006, which is hereby expressly incorporated by reference as though fully set forth herein.

This application is a continuation-in-part of U.S. application Ser. No. 11/139,908, filed 27 May 2005 (the '908 application), now pending, which claims the benefit of U.S. provisional application No. 60/575,741, filed 28 May 2004 (the '741 application). The '908 and '741 applications are hereby expressly incorporated by reference as though fully set forth herein.

BACKGROUND OF THE INVENTION

a. Field of the Invention

The instant invention relates to robotically controlled medical devices. In particular, the instant invention relates to a robotic surgical system for navigating a medical device through a patient's body for diagnostic and therapeutic purposes.

b. Background Art

Catheters are used for an ever growing number of medical procedures. To name just a few examples, catheters are used for diagnostic, therapeutic, and ablation procedures. Typically, the user manually manipulates the catheter through the patient's vasculature to the intended site, such as a site within the patient's heart. The catheter typically carries one or more electrodes or other diagnostic or therapeutic devices, which may be used for ablation, diagnosis, cardiac mapping, or the like.

It is well known that, to facilitate manipulation of the catheter through the patient's vasculature to the intended site, portions of the catheter shaft, especially the distal regions thereof, may be made steerable. For example, the catheter may be manufactured such that the user can translate, rotate, and deflect the distal end of the catheter as necessary and desired to negotiate the tortuous paths of the patient's vasculature en route to the target site. Navigating a catheter reliably through the patient's body to a precise location, however, is an extremely tedious process requiring a substantial amount of time and skill and potentially causing a high degree of fatigue in the physician, especially where actuation forces are transmitted over large distances.

BRIEF SUMMARY OF THE INVENTION

It is thus desirable to be able to navigate a medical device accurately and precisely through a patient's body to the locations of diagnostic or therapeutic interest.

It is also desirable to be able to reduce the fatigue factor associated with navigating a medical device through a patient's body.

It is further desirable to be able to preserve the ability to manually navigate a medical device when so desired.

It is also desirable that the medical device be able to distinguish proximity or degree of contact between the medical device and a tissue surface.

It is further desirable that the medical device be usable to create a map of a geometry of the patient's body, which map

may include diagnostic information, without the need to distinguish surface points from interior points during the data-gathering phase.

Still further, it is desirable to equip the robotic control system to navigate the catheter according to a predetermined path in order to automatically deliver a therapy, such as a tissue ablation, or perform a diagnostic procedure.

According to a first embodiment of the invention, a system for ablating tissue includes: a catheter for insertion into the body of a patient and a robotic controller for moving the catheter within the body, wherein the controller advances the catheter until the catheter contacts the tissue surface, maintains contact between the catheter and the tissue surface, and moves the catheter along a predetermined path to create a substantially continuous lesion of ablated tissue. The system optionally may include: a display device for presenting a graphical representation of an area of tissue to be ablated; an interface to permit a user to select a plurality of treatment points on the graphical representation, the interface being coupled to the controller and to the catheter such that the controller may cause the catheter to ablate tissue at and between the plurality of treatment points; an instrument for measuring electrophysiology information at a point on the tissue surface; and a processor to cause the controller to move the catheter to a plurality of contact points on the tissue surface, to detect position information for each of the plurality of contact points, and to associate the electrophysiology information with the contact point at which the electrophysiology information was measured, and to generate a three-dimensional surface model of at least a portion of the tissue surface. The display device may present a graphical representation of the three-dimensional surface model of at least a portion of the tissue surface. An optional electrophysiology processor processes the measured electrophysiology information to identify one or more contact points that are potential treatment sites; the processor may be coupled to the display device so that the one or more identified potential treatment sites may be superimposed on the graphical representation of the three-dimensional model and displayed on the display device. An input device may permit a user to designate the predetermined path, while a contact sensor may detect when a distal end of the catheter is in contact with a tissue surface of the body. The contact sensor may be a force sensor that determines when contact has been made between the catheter and the tissue surface using information relating to a force exerted on said catheter by the tissue surface. The controller optionally utilizes feedback from the contact sensor to orient the catheter at a preset orientation relative to the tissue surface, such as substantially orthogonally thereto. Alternatively, the contact sensor may be a sensor that determines when contact has been made between the catheter and the tissue surface using a rate of change in a parameter, such as an electrophysiological characteristic, measured at a location on the catheter. The contact sensor optionally includes an RF filter to filter out any biasing effects caused by RF energy when the system is ablating tissue.

According to another aspect of the invention, a method of ablating tissue includes the steps of: robotically moving a catheter to a treatment area near a tissue surface, the catheter having an ablation electrode located near a distal end of the catheter; monitoring proximity or degree of contact between the catheter and the tissue surface; advancing the catheter until the catheter contacts the tissue surface; activating the ablation electrode to ablate the tissue; robotically moving the catheter, while the ablation electrode is active, along a predetermined path in a way that maintains contact between

the catheter and the tissue surface; and ablating the tissue along the predetermined path. The monitoring step may include monitoring a contact sensor that is located near a distal end of the catheter or monitoring a force sensor that is located at a distal end of the catheter for a degree of force that is indicative of contact between the catheter and the tissue surface. Information from the force sensor may be utilized to orient the catheter relative to the tissue surface. Optionally, the method also includes: analyzing areas of ablated tissue to identify at least a first ablated area and a second ablated area separated by a gap, the gap being characterized by tissue that has not been ablated; advancing the catheter to contact a point in the first ablated area; activating the ablation electrode to ablate the tissue; and robotically moving the catheter to a point in the second ablated area and ablating a path along the gap between the first ablated area and the second ablated area.

According to yet another aspect of the invention, a method of ablating tissue includes the steps of: robotically moving a catheter to a treatment area near a tissue surface, the catheter having an ablation electrode and a contact sensor located near a distal end of the catheter; while monitoring the contact sensor for contact between the catheter and the tissue surface, advancing the catheter until the catheter contacts the tissue surface; activating the ablation electrode to ablate the tissue; robotically moving the catheter along a predetermined path while maintaining contact between the catheter and the tissue surface; and ablating the tissue along the predetermined path. The method optionally includes analyzing areas of ablated tissue to identify at least a first ablated area and a second ablated area separated by a gap, the gap being characterized by tissue that has not been ablated; advancing the catheter to contact a point in the first ablated area; activating the ablation electrode to ablate the tissue; and robotically moving the catheter to a point in the second ablated area, thereby ablating a path along the gap between the first ablated area and the second ablated area. The contact sensor may optionally be a force sensor, and the step of monitoring may include monitoring the force sensor for a degree of force that is indicative of contact between the catheter and the tissue surface. The method may also include: generating a three-dimensional model of at least a portion of the tissue surface; presenting a graphical representation of the three-dimensional model; and receiving input from a user that identifies at least two target locations that define a predetermined path on the graphical representation of the three-dimensional model of the tissue surface, whereby the tissue along the path will be ablated.

In still another aspect of the present invention, a method of ablating tissue includes the steps of: analyzing areas of ablated tissue to identify at least a first ablated area and a second ablated area separated by a gap, the gap being characterized by tissue that has not been ablated; robotically moving a catheter to a point on a surface of the first ablated area, such that the catheter is in contact with the first ablated area; activating an ablation electrode on the catheter to ablate the tissue; and robotically moving the catheter to a point in the second ablated area and ablating a path along the gap between the first ablated area and the second ablated area. The method may include monitoring a degree of contact between the catheter and tissue being ablated, wherein the ablation is carried out while maintaining contact between the catheter and the tissue being ablated. The method may also include: generating a three-dimensional model of a tissue surface to be ablated; presenting a graphical representation of the three-dimensional model of the tissue surface; and receiving input from a user that identifies

at least two target locations that define a path that includes at least a portion of the gap, whereby the tissue along the path will be ablated, wherein the ablation is carried out along the path input by the user.

According to yet another aspect of the invention, a method of ablating tissue includes the steps of: using a probe to measure electrophysiology information for a plurality of measurement points on a surface of a heart, the probe including a measurement device for measuring electrophysiology information; analyzing the measured electrophysiology information to identify areas with previously ablated tissue; generating a three-dimensional surface model of a portion of the heart; presenting a graphical representation of the three-dimensional surface model of the heart; superimposing on the graphical representation information to identify the areas with previously ablated tissue; receiving input from a user that identifies at least two target locations that define a predetermined path on the graphical representation of the three-dimensional model of the heart, whereby tissue along the path will be ablated, said predetermined path including tissue that has not been previously ablated; robotically moving an ablation electrode to one of the at least two target locations along the predetermined path; activating an ablation electrode to ablate the tissue; and robotically moving the ablation electrode along the predetermined path defined by the at least two target locations to ablate tissue along the predetermined path. The method optionally includes monitoring a degree of contact between the catheter and tissue being ablated, wherein the ablation is carried out while maintaining contact between the catheter and the tissue being ablated. The probe may be a catheter, and the ablation electrode may be located on the catheter, and the method may further include the steps of monitoring electrophysiology information of the tissue being ablated during the ablation process and adjusting the position and/or speed of the catheter during the ablation process based on changes in the electrophysiology information being monitored. The electrophysiology information being monitored may be filtered using an RF filter to remove biasing effects caused by RF energy during the ablation process. The monitoring step may include monitoring electrophysiology information for changes in amplitude of the electrophysiology information, changes in fractionation of the electrophysiology information, or changes in another parameter that is indicative of a degree of tissue ablation.

An advantage of the present invention is a reduced exposure to radiation for both the patient and the physician, since the present invention reduces the time required to navigate the catheter to a target location and minimizes the need for fluoroscopy to locate the catheter within the patient.

Another advantage of the present invention is the ability to easily switch between automated robotic control and manual control of the catheter.

Still another advantage of the present invention is the ability to remotely interact with the robotic surgical system controlling the catheter.

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

FIG. 1 is a schematic illustration of an embodiment of a robotic surgical system.

FIG. 2 is a perspective view of one embodiment of a catheter holding device with a catheter placed therein.

FIG. 3 is an end view of the catheter holding device of FIG. 2.

FIG. 4 is a perspective view of one embodiment of a catheter holding device with a catheter secured therein.

FIG. 5 is an end view of the catheter holding device of FIG. 4.

FIG. 6 illustrates an exemplary steerable catheter such as may be used in the robotic surgical system.

FIG. 7 depicts automatic control of the robotic surgical system according to a predetermined program.

FIG. 8 depicts a user manually controlling the robotic surgical system via an input device.

FIG. 9 depicts the user of FIG. 8 manually controlling the steerable catheter after having removed it from the robotic surgical system.

FIG. 10 schematically illustrates a contact sensing surgical system.

FIG. 11 is a high-level flowchart of a contact sensing methodology.

FIGS. 12a through 12o illustrate alternative implementations of the decision process for indicating a change in proximity or degree of contact in the high-level flowchart of FIG. 11.

FIG. 13a is an exemplary plot of tissue parameter versus either time or probe distance as measured by a contact sensing surgical system.

FIG. 13b is the derivative of the plot in FIG. 13a.

FIG. 14 illustrates a system for generating a three-dimensional model of a portion of a patient's body, optionally including diagnostic information.

FIG. 15 illustrates a graphical representation of a three-dimensional model of a heart chamber including diagnostic information superimposed thereon.

FIG. 16 illustrates the definition of a navigation path on a graphical representation of a model of a heart chamber.

DETAILED DESCRIPTION OF THE INVENTION

Robotic Surgical System

FIG. 1 schematically illustrates an embodiment of a robotic surgical system 10 for robotic manipulation and control of a medical device 12. Medical device 12 is preferably a catheter, which may be any type of catheter, including, by way of example only and without limitation, an ablation catheter, a guide wire catheter, an introducer catheter, a probe, or a stylet. It should be understood, however, that any other therapeutic, diagnostic, or assistive medical device may be controlled by robotic surgical system 10 without departing from the scope of the present invention. Such other devices include, but are not limited to, syringes, electrophoresis devices, iontophoresis devices, transdermal pharmaceutical delivery devices, myoblast delivery devices, stem cell delivery devices, ablation devices, stents, and pacemaker leads, which may be carried on or delivered by a catheter. It should further be understood that robotic surgical system 10 may be used to manipulate and control more than one medical device 12 in accordance with the quick installation and removal feature described herein. Accordingly, the terms "medical device," "probe," "therapeutic device," and "catheter" are used interchangeably herein.

Robotic surgical system 10 generally includes a track 14, a catheter holding device 16, a translation servo mechanism 18, a catheter deflection control mechanism 20, a deflection servo mechanism 22, and a controller 24 operatively coupled to at least one of translation servo mechanism 18

and deflection servo mechanism 22. Translation and deflection servo mechanisms 18, 22 may be any type of device for providing mechanical control at a distance, including continuous motors, stepper motors, hydraulic actuators, pulley systems, and other devices known to those of ordinary skill in the art. Catheter deflection control mechanism 20 and deflection servo mechanism 22 are collectively referred to herein as a "catheter deflection mechanism."

Catheter holding device 16 includes a catheter receiving portion 26. Catheter receiving portion 26 is configured to receive catheter 12 by installing a catheter control handle 28, located near a proximal end 30 of catheter 12, into catheter receiving portion 26. Preferably, catheter receiving portion 26 is adapted for quick installation and removal of any type of catheter 12 (or, as noted above, another medical device), thereby facilitating the installation of device 12 for control by robotic surgical system 10 and removal of device 12 for manual control (e.g., user manipulation of catheter control handle 28). Accordingly, catheter control handle 28 may be secured in catheter receiving portion 26 by a frictional fit or with one or more quick-release fasteners. Alternatively, the inner surface of catheter receiving portion 26 and the outer surface of catheter control handle 28 may include mating threaded portions to permit catheter control handle 28 to be screwed into catheter holding device 16. In other embodiments of robotic surgical system 10, catheter control handle 28 is clamped or strapped in place in catheter receiving portion 26. An adapter may also be used to facilitate the reception of catheter control handle 28 within catheter receiving portion 26.

One embodiment of catheter holding device 16 is illustrated in FIGS. 2 and 3 with catheter control handle 28 placed, but not secured, therein. Catheter holding device 16 includes a base plate 32 and a plurality of upstanding support plates 34. Support plates 34 support cams 36, which are connected to pulley systems 38.

Catheter control handle 28 is received downwardly through an opening 40 into the catheter receiving portion 26 and onto belts 40 of pulley systems 38. As catheter control handle is urged downwardly, belts 40 rotate upper and lower pulleys 38a, 38b in the direction of arrows a. This, in turn, urges cams 36 downwards via links 42 and draws upper pulleys 38a, 38b towards one another via links 44, while simultaneously wrapping the belts 40 about catheter control handle 28. Catheter control handle 28 is thereby secured within catheter receiving portion 26 as shown in FIGS. 4 and 5. To remove catheter control handle 28 from catheter holding device 16, the user need only release cams 26, which reverses the process described above and opens catheter receiving portion 26.

Catheter holding device 16 is translatably associated with track 14. The phrase "translatably associated with" encompasses all types of relative lateral motion between catheter holding device 16 and track 14. For example, catheter holding device 16 may slide relative to track 14. Alternatively, catheter holding device 16 may move laterally along a screw mechanism 46, such as a worm gear, a lead screw, or a ball screw, attached to track 14. Preferably, catheter holding device 16 has a translation range relative to track 14 (i.e., the lateral distance that catheter holding device 16 can travel relative to track 14 between extremes) of at least about 5 cm, the approximate width of a human heart. More preferably, the translation range of catheter holding device 16 relative to track 14 is at least about 10 cm.

In the preferred embodiment of the invention, a carriage 48 is translatably mounted on track 14 via screw mechanism 46. Catheter holding device 16 is mounted on carriage 48

such that catheter holding device 16 translates relative to track 14 with carriage 48. For example, base plate 32 may be fixedly or removably mounted on carriage 48. Alternatively, catheter holding device 16 may be integrally formed with carriage 48 as a single assembly (i.e., base plate 32 and carriage 48 may be a single, unitary component). Likewise, in some embodiments of the invention, catheter holding device 16 may be translatably mounted directly on track 14 without an intervening carriage.

Translation servo mechanism 18 is operatively coupled to catheter holding device 16 and adapted to control translation of catheter holding device 16 relative to track 14 in order to adjust the lateral position of catheter holding device 16 along track 14. Preferably, translation servo mechanism 18 is operatively coupled to carriage 48 in order to move carriage 48, and therefore catheter holding device 16 mounted thereon, laterally along track 14. In the embodiment shown in FIG. 1, translation servo mechanism 18 drives screw mechanism 46, thereby moving carriage 48 laterally therealong.

Deflection servo mechanism 22 is operatively coupled to and adapted to control catheter deflection control mechanism 20. In the preferred embodiment of the invention, deflection servo mechanism 22 is operatively coupled to catheter deflection control mechanism 20 such that deflection servo mechanism 22 can rotate catheter deflection control mechanism 20. Either or both of deflection servo mechanism 22 and catheter deflection control mechanism 20 may be mounted on carriage 48 in order to simplify the transmission system linking deflection servo mechanism 22 and catheter deflection control mechanism 20. In some embodiments of robotic surgical system 10, catheter deflection control mechanism 20 is incorporated in catheter holding device 16, for example by utilizing pulley systems 38, and in particular belts 40, as further described below. One of ordinary skill in the art will appreciate, however, that catheter deflection control mechanism 20 may also be separated from catheter holding device 16 without departing from the spirit and scope of the present invention.

Controller 24 is adapted to control at least one of translation servo mechanism 18 and deflection servo mechanism 22 in order to navigate catheter 12 received in catheter holding device 16. It should also be noted that the use of multiple controllers to control translation servo mechanism 18 and deflection servo mechanism 22 is regarded as within the scope of the present invention. Throughout this disclosure, the term "controller" refers to a device that controls the movement or actuation of one or more robotic systems (that is, the component responsible for providing command inputs to the servo mechanisms). One of ordinary skill in the art will understand how to select an appropriate controller for any particular mechanism within robotic surgical system 10. Further, the term "controller" should be regarded as encompassing both a singular, integrated controller and a plurality of controllers for actuating one or more robotic systems.

As shown in FIG. 6, catheter 12 is preferably a steerable catheter including at least one pull wire 50 extending from catheter control handle 28 near proximal end 30 of catheter 12 to a distal end 52 of catheter 12. Pull wires 50 may be coupled to at least one pull ring 54, also located near distal end 52 of catheter 12. When placed in tension, pull wires 50 deflect distal end 52 of catheter 12 into various configurations. As one of skill in the art will understand, additional pull wires 50 will enhance the deflection versatility of distal end 52 of catheter 12. For example, a single pull wire 50 with a single point of attachment to pull ring 54 will permit distal end 52 of catheter 12 to deflect on a single axis, and

perhaps in only one direction, for example upwards relative to FIG. 6. By adding a second pull wire 50 (as shown in FIG. 6), or by looping a single pull wire 50 to have two points of attachment 56 to pull ring 54, distal end 52 of catheter 12 may be deflected in two directions, for example both upwards and downwards relative to FIG. 6. A catheter 12 with four pull wires 50 attached to pull ring 54 at about 90° intervals can deflect in four directions, for example upwards, downwards, and into and out of the plane of the paper relative to FIG. 6.

One or more catheter deflection actuators 58 may be provided on catheter control handle 28 to selectively tension one or more pull wires 50, thereby controlling the direction and degree of deflection of distal end 52 of catheter 12. In some embodiments, one or more knobs may be provided, rotation of which selectively tension one or more pull wires 50. It should be understood, however, that catheter deflection actuators 58 may take many other forms, including, but not limited to, sliders and switches, without departing from the spirit and scope of the present invention. Additionally, it is contemplated that rotating catheter control handle 28 itself may selectively tension pull wires 50 and deflect distal end 52 of catheter 12.

Returning to FIG. 1, when catheter control handle 28 is received within catheter receiving portion 26, catheter 12 translates relative to track 14 with catheter holding device 16, thereby providing a first degree of freedom permitting catheter 12 to be advanced into and retracted from a patient's body. Additionally, catheter 12 is operatively coupled to catheter deflection control mechanism 20 such that actuation of catheter deflection control mechanism 20 causes distal end 52 of catheter 12 to deflect, thereby providing a second degree of freedom to catheter 12. In particular, catheter deflection actuator 58 may be operatively coupled to catheter deflection control mechanism 20 such that catheter deflection control mechanism 20 can actuate catheter deflection actuator 58 to selectively tension one or more pull wires 50 and deflect the distal end 52 of catheter 12 by a desired amount in a desired direction.

In some embodiments of the invention, rotating catheter deflection control mechanism 20 will rotate catheter deflection actuator 58 in turn, thereby selectively tensioning one or more pull wires 50 within catheter 12. The transmission system between catheter deflection control mechanism 20 and catheter deflection actuator 58 may be a frictional fit provided, for example, by rubberized coatings surrounding catheter deflection control mechanism 20 and catheter deflection actuator 58. Alternatively, catheter deflection control mechanism 20 and catheter deflection actuator 58 may be coupled with mating gear teeth or knurling.

Referring specifically to the embodiment of catheter holding device 16 depicted in FIGS. 2-5, when catheter 12 is secured in catheter receiving portion 26, belts 40 frictionally engage catheter control handle 28. They may also engage catheter deflection actuator 58. Thus, if pulley system 38 is driven by deflection servo mechanism 22, belts 40 may rotate catheter control handle 28, catheter deflection actuator 58, or both, in order to selectively tension one or more pull wires 50 and deflect distal end 52 of catheter 12.

It should be understood that the particular configurations of catheter deflection control mechanism 20 and catheter deflection actuator 58 described above are merely exemplary and can be modified without departing from the spirit and scope of the invention. For example, if catheter deflection actuator 58 is a slider rather than a knob, catheter deflection control mechanism 20 may be suitably modified, or even replaced as a modular unit, to actuate a slider. This facilitates

the quick connect/disconnect operation of robotic surgical system 10 by allowing easy installation and interconnection between off-the-shelf medical devices of varying construction and robotic surgical system 10.

As described above, the inclusion of additional pull wires 50 in catheter 12 increases the number of directions in which distal end 52 of catheter 12 can deflect. This is referred to herein as “deflection versatility.” Where relatively few pull wires 50 (e.g., fewer than about four pull wires 50) are used, however, compensation for lost deflection versatility may be had by rotating catheter 12 about its axis. For example, in a catheter using only a single pull wire 50 with a single point of attachment to pull ring 54, permitting the catheter to deflect only in one direction, the catheter may be deflected in the opposite direction simply by rotating it 180° about its axis. Similarly, a catheter that can deflect in two directions 180° apart can be deflected in the directions midway therebetween by rotating the catheter 90° about its axis.

Accordingly, in some embodiments of the invention, catheter receiving portion 26 is rotatable. An example of such a rotatable catheter receiving portion is catheter receiving portion 26 defined by pulley system 38 depicted in FIGS. 2-5. A rotation servo mechanism 60 is operatively coupled to rotatable catheter receiving portion 26 and adapted to control rotatable catheter receiving portion 26. Thus, pulley system 38 may be driven by rotation servo mechanism 60, thereby engaging belts 40 to rotate catheter 12 about its axis.

If desired, rotation servo mechanism 60 may be mounted on carriage 48 or affixed to catheter holding device 16 such that rotation servo mechanism 60 translates relative to track 14 with catheter holding device 16. This arrangement creates a fixed-distance relationship between rotation servo mechanism 60 and catheter holding device 16, which can simplify the transmission system coupling rotation servo mechanism 60 to catheter holding device 16.

When installed in catheter holding device 16, catheter 12 rotates with catheter receiving portion 26, thereby providing a third degree of freedom to catheter 12 and compensating for low deflection versatility attributable to a relatively lower number of pull wires 50. Catheter receiving portion 26 is preferably rotatable at least about 360° about its axis, such that catheter 12 received therein is also rotatable at least about 360° about its axis, thereby facilitating deflection of distal end 52 of catheter 12 in substantially any direction, significantly enhancing the deflection versatility of the distal end 52 of the catheter 12. Catheter receiving portion 26 may also be designed to rotate about 720° or more about its axis.

Rotating catheter 12 by rotating catheter receiving portion 26 may cause inadvertent deflection of distal end 52 of catheter 12. As one skilled in the art will recognize from this disclosure, as catheter receiving portion 26 and catheter 12 rotate, catheter deflection actuator 58 may remain stationary, rather than rotating with catheter control handle 28, if the torque applied by rotation servo mechanism 60 is insufficient to overcome the inertia of catheter deflection control mechanism 20. That is, catheter deflection actuator 58 may bind against catheter deflection control mechanism 20, causing relative rotation between catheter control handle 28 and catheter deflection actuator 58. This relative rotation may result in uncommanded tensioning of one or more pull wires 50, inadvertently deflecting distal end 52 of catheter 12.

To maintain a substantially constant deflection as catheter 12 rotates, therefore, controller 24 may be operatively coupled to both rotation servo mechanism 60 and deflection servo mechanism 22. Controller 24 is adapted to control at least one of deflection servo mechanism 22 and rotation servo mechanism 60, and preferably to simultaneously con-

trol both deflection servo mechanism 22 and rotation servo mechanism 60, to maintain a substantially constant deflection of distal end 52 as catheter receiving portion 26 and catheter 12 rotate. For example, as controller 24 commands rotation servo mechanism 60 to rotate catheter receiving portion 26, controller 24 may simultaneously command deflection servo mechanism 22 to actuate catheter deflection control mechanism 20 to counter-rotate, thereby substantially eliminating relative rotation between the catheter deflection actuator 58 and catheter control handle 28, helping to maintain a substantially constant deflection of catheter 12. Alternatively, as controller 24 commands rotation servo mechanism 60 to rotate catheter receiving portion 26, it may simultaneously command deflection servo mechanism 22 to decouple catheter deflection control mechanism 20 from catheter deflection actuator 58, thereby permitting catheter deflection actuator 58 to rotate freely with catheter control handle 28. In either case, controller 24 may be configured to eliminate the need to couple deflection servo mechanism 22 and rotation servo mechanism 60 through a mechanical transmission system such as a differential. Further, though described herein as a single controller adapted to control the translation, deflection, and rotation servo mechanisms 18, 22, 60, multiple controllers may be used without departing from the spirit and scope of the present invention.

An introducer 62, preferably a steerable introducer, and most preferably an Agilis™ steerable introducer, may be provided as part of robotic surgical system 10. A proximal end 64 of introducer 62 is preferably stationary, while a distal end 66 of introducer 62 extends into a patient (not shown for clarity) to a location proximate a target site (the term “target” is used herein to refer to a location at which treatment or diagnosis occurs). Introducer 62 may be steerable via a robotic control system 68 including at least one servo mechanism 70 adapted to control distal end 66 of introducer 62 in at least one degree of freedom. Preferably, robotic control system 68 includes three servo mechanisms 70 adapted to control distal end 66 of the introducer 62 in three degrees of freedom (translation, deflection, and rotation), resulting in a total of six degrees of freedom for robotic surgical system 10, and at least one controller 72 adapted to control servo mechanisms 70. Similar control principles may be applied to steerable introducer 62 as are described herein with respect to robotic surgical system 10 and medical device 12.

One of ordinary skill in the art will appreciate that the deflection of distal end 52 of catheter 12 is a function not only of the input to catheter deflection actuator 58 (i.e., the selective tensioning of one or more pull wires 50), but also of the extent to which catheter 12 is advanced beyond a generally rigid sheath, such as introducer 62. That is, the further distal end 52 of catheter 12 is advanced beyond distal end 66 of introducer 62, the greater the deflection of distal end 52 of catheter 12 will be for a given input at catheter deflection actuator 58.

It is therefore desirable to calibrate the deflection of distal end 52 of catheter 12 in terms of both catheter deflection control mechanism inputs and extensions of catheter 12 beyond distal end 66 of introducer 62. By robotically actuating catheter deflection control mechanism 20 between extremes (e.g., commanding a complete rotation of catheter deflection actuator 58) and measuring the resulting deflection of distal end 52 of catheter 12 (e.g., using a localization system), catheter deflection control mechanism inputs may be correlated with deflections of distal end 52 for a given extension of catheter 12 beyond distal end 66 of introducer 62. A similar process may be performed for a multiple

different extensions of catheter 12 beyond distal end 66 of introducer 62, resulting in a family of calibration curves relating catheter deflection control mechanism inputs to deflections of distal end 52 of catheter 12. Each curve corresponds to a particular extension of catheter 12 beyond distal end 66 of introducer 62; the amount of extension of catheter 12 beyond distal end 66 of introducer 62 may be derived, at least in part, from the amount of translation of catheter holding device 16 relative to track 14.

To create a substantially sterile field around catheter 12 outside the patient's body, an expandable and collapsible tubular shaft 74 substantially surrounds at least a portion of catheter 12, such as the region of catheter 12 between catheter holding device 16 and proximal end 64 of introducer 62. Preferably, shaft 74 is sterilized before use along with other relevant components of robotic surgical system 10. As catheter holding device 16 translates to advance catheter 12 into the patient (i.e., to the right in FIG. 1), tubular shaft 74 collapses upon itself. Contrarily, as catheter holding device 16 translates to retract catheter 12 from the patient (i.e., to the left in FIG. 1), tubular shaft 74 expands. Preferably, tubular shaft 74 is assembled from a plurality of telescoping tubular elements 76. It is contemplated, however, that tubular shaft 74 may alternatively be an accordion-pleated or other expandable and collapsible structure.

As depicted in FIGS. 7 and 8, robotic surgical system 10 may be employed to robotically navigate catheter 12 into and through the patient and to one or more sites, which may be target sites, within the patient's body by actuating one or more of translation servo mechanism 18, deflection servo mechanism 22, and rotation servo mechanism 60 (if present) via controller 24. Robotic surgical system 10 may operate automatically according to a computerized program as executed by controller 24 (FIG. 7). It is also contemplated that the user, who may be a surgeon, cardiologist, or other physician, may control robotic surgical system 10 through an appropriate set of controls 78, such as a three-dimensional joystick (e.g., a joystick with three input axes), a steering yoke, or another suitable input device or collection of such devices permitting the user to robotically steer catheter 12 (FIG. 8).

As described above, catheter 12 can be quickly and easily disconnected from catheter holding device 16. Thus, if the user desires to manually control catheter 12 at any point during the procedure, the user may disconnect catheter 12 from the catheter holding device 16 as described above. The user may navigate catheter 12 manually for as long as desired, and then replace it into catheter holding device 16 and resume robotic control. FIG. 9 illustrates the user manually operating catheter 12 after having removed it from catheter holding device 16.

In some embodiments of the invention, multiple robotic surgical systems controlling multiple medical devices may be employed during a procedure. For example, a first robotic surgical system may control an ultrasonic imaging transducer, while a second robotic surgical system may control an ablation catheter. A single controller, or multiple cooperating controllers, may coordinate the multiple medical devices and the multiple robotic surgical systems, for example in conjunction with a single localization system, or alternatively by utilizing data from the ultrasonic imaging transducer to control the movement of the ablation catheter.

Robotic surgical system 10 facilitates precise and accurate navigation of medical device 12 within the patient's body. In addition, since medical device 12 is manipulated primarily robotically, the physician will experience considerably less fatigue during the surgical procedure. Furthermore, robotic

control permits a substantially increased degree of complexity in the control and actuation mechanisms that may be incorporated into medical device 12 over those that may be used in a medical device 12 intended solely for human control, enabling an increase in the versatility of medical device 12.

Contact Sensing

FIG. 10 schematically illustrates a surgical system 80 equipped to sense contact between a probe, such as catheter 12, and a tissue surface 82, such as a cardiac wall. Probe 12 includes a sensor or instrument 84 carried thereon, preferably at distal end 52 of probe 12, for measuring the value of a parameter (referred to herein as P) of tissue surface 82 either periodically (that is, with a relatively fixed interval between measurements) or episodically (that is, with a variable interval between measurements). Preferably, sensor 84 is an electrophysiology sensor capable of measuring one or more electrophysiology characteristics, including, but not limited to, impedance, phase angle, electrogram amplitude, optical feedback, and ultrasonic feedback.

To facilitate precise determination of the distance traveled by probe 12 between measurements of the tissue parameter (referred to herein as Δs), a precisely calibrated system is utilized. The precisely calibrated system may be a robotically controlled system to move probe 12 within the patient's body, such as robotic surgical system 10 described herein. It is also contemplated that measurements of the position of probe 12 within the patient's body may be made using a precisely locally- or universally-calibrated positional feedback (i.e., localization) system 86 in conjunction with a location or position electrode 88 carried on probe 12. Preferably, the positional feedback system is the Ensite NavX™ system of St. Jude Medical, Inc., which includes pairs of electrodes 90 defining measurement axes by which the position of probe 12 may be measured. One of ordinary skill in the art will appreciate that other localization systems, such as the CARTO navigation system from Biosense Webster, Inc., may also be employed. Only one pair of electrodes 90 is illustrated; one of skill in the art will appreciate that additional pairs of electrodes 90 may be used if additional measurement axes are desired.

A processor monitors the value of the tissue parameter measured by sensor 84 as probe 12 moves within the patient's body. The processor may be incorporated in a computer system 92. For purposes of this disclosure, a single processor within computer system 92 will be referred to, though it is contemplated that multiple computer systems 92 and/or multiple processors within a single computer system 92 may be used to practice the various aspects of the present invention. Further, one or more processor functions described herein may be integrated in a single processor without departing from the scope of the present invention.

As described above, probe 12 may be moved by a robotically-controlled system capable of precise movements on the order of less than about 5 mm, more preferably on the order of less than about 2 mm, and most preferably on the order of less than about 1 mm. Alternatively, the movements of probe 12 are precisely measured by a positional feedback system 86 with a margin of error of less than about 5 mm, preferably less than about 2 mm, and more preferably less than about 1 mm. For a given, precisely determined Δs (e.g., as precisely moved by robotic surgical system 10 or precisely measured by positional feedback system 86), a corresponding amount and rate of change in the tissue parameter between measurements can be anticipated for a situation where there is no change in the proximity or degree of contact between probe 12 and tissue surface 82.

The processor monitors the tissue parameter for an indicator of proximity or degree of contact between probe **12** and tissue surface **82** and indicates a change in the proximity or degree of contact between probe **12** and tissue surface **82** based on the monitored tissue parameter. In particular, the processor reports the change in either proximity or degree of contact based on either the amount of change in the tissue parameter or the rate of change in the tissue parameter between measurements, and preferably between successive measurements, thereof. The term “proximity” refers to the relationship between probe **12** and tissue surface **82** when probe **12** is not in contact with tissue surface **82**; it is, in lay terms, a measure of how close probe **12** is to tissue surface **82**. The term “degree of contact” refers to the relationship between probe **12** and tissue surface **82** when probe **12** is in contact with tissue surface **82**; it is, in lay terms, a measure of how hard probe **12** is pressing into tissue surface **82**.

A contact sensing method is illustrated in the high-level flowchart of FIG. **11**. Probe **12** is navigated into the patient’s body and into meaningful proximity with tissue surface **82** in step **100**. The term “meaningful proximity” refers to probe **12** being sufficiently close to tissue surface **82** such that sensor **84** can capture useful electrophysiology information about surface **82**, and thus encompasses both contact and non-contact relationships between probe **12** and tissue surface **82**.

Once inside the patient’s body, probe **12** is moved using a calibrated system, such as robotic surgical system **10**, moved and located using a calibrated system, such as positional feedback system **86**, or both. As probe **12** moves, the tissue parameter at distal end **52** of probe **12** is measured, either periodically or episodically, using sensor **84** (steps **102**, **104**, and **106**). An amount of change (ΔP) in the measured tissue parameter between successive measurements (P_n and P_{n+1}) is calculated in step **108**. The processor then indicates a change in proximity or degree of contact between probe **12** and tissue surface **82** based upon the amount of change in the measured tissue parameter in step **110**. That is, the processor provides the user and/or controller **24** controlling robotic surgical system **10** with an indication of either “change” or “no change” in the proximity or degree of contact based upon the amount of change in the measured tissue parameter. If desired, the process may be repeated as probe **12** continues to move through the patient’s body by setting $P_n = P_{n+1}$ (step **112**) and moving probe **12** to a new location (step **104**) where a new P_{n+1} is measured (step **106**).

A number of algorithms may be used to identify the change in proximity or degree of contact between probe **12** and tissue surface **82** in step **110**. In a first algorithm, illustrated in FIG. **12a**, the amount of change in the measured tissue parameter (ΔP) is compared to a predetermined range of values ranging from a lower limit (LL) to an upper limit (UL) in step **114a**. (In FIGS. **12a** through **12o**, absolute values are used in order to account for potential negative values of ΔP .) A change is indicated when the amount of change in the measured parameter falls outside the predetermined range of values (step **116a**); no change is indicated when the amount of change in the measured parameter falls within the predetermined range of values (step **118a**).

The predetermined range of values (that is, either or both of UL and LL) may be user selectable, and may correspond generally to the anticipated amount of change in the measured tissue parameter between measurements when there is no change in the proximity or degree of contact between probe **12** and tissue surface **82** for a given Δs . “Predetermined” is used herein to refer to values that are set in

advance of applying the contact sensing algorithm; for example, the values (i.e., UL and LL) may be based upon a percentage variation in the anticipated change in the measured tissue parameter, which percentage may also be user selectable.

In other algorithms, the amount of change in the measured tissue parameter is compared to a change threshold, with the change indication based upon whether or not the measured tissue parameter crosses the change threshold. For example, as shown in FIG. **12b**, the change threshold may correspond generally to the maximum anticipated amount of change in the measured tissue parameter between successive measurements for a given Δs (ΔP_{MAX}). Thus, no change in proximity or degree of contact would be indicated when the amount of change is less than the change threshold, and a change in proximity or degree of contact would be indicated when the amount of change is greater than the change threshold. It is also contemplated that the algorithm may be modified as shown in FIG. **12c**, such that the threshold corresponds generally to the minimum anticipated amount of change in the measured tissue parameter between successive measurements for a given Δs (ΔP_{MIN}), which would reverse the conditions for indicating change or no change in proximity or degree of contact. The change threshold may be user selectable, and may be calculated as a percentage variation in the anticipated amount of change in the measured tissue parameter for a given Δs , which percentage may itself be user selectable.

In still other algorithms, the change in proximity or degree of contact is indicated based upon a rate of change in the measured tissue parameter with respect to either the time between measurements ($\Delta P/\Delta t$) or the distance traveled by probe **12** between measurements ($\Delta P/\Delta s$). The rate of change may also be calculated as a derivative of the measured tissue parameter with respect to time (dP/dt) or probe distance traveled (dP/ds). The rate of change may be calculated as a first derivative of the tissue parameter, a second derivative of the tissue parameter, or any further derivative of the tissue parameter. One of skill in the art will recognize that any of these variables may be calculated from the amount of change in the measured tissue parameter and the time between measurements or the precisely determined distance traveled by probe **12** between measurements. The decision processes for indicating change in proximity or degree of contact based upon rate of change variables are substantially analogous to the algorithms described with respect to the amount of change in the measured tissue parameter (i.e., comparison to a predetermined range of values or comparison to a rate of change threshold). These alternative algorithms are illustrated in FIGS. **12d-12o**.

FIG. **13a** is a representative chart of the measured tissue parameter as a function of time (t) or probe distance traveled (s), while FIG. **13b** illustrates the derivative of the curve of FIG. **13a**. Initially, in region **120**, there is no change in proximity or degree of contact, so P varies only slightly. ΔP is thus quite small, so $\Delta P/\Delta t$, $\Delta P/\Delta s$, dP/dt , and dP/ds vary slightly about zero (dP/dt and dP/ds are illustrated in FIG. **13b**).

When a change in proximity or degree of contact occurs, such as at point **122**, P experiences a substantial change in a very short interval of time or probe distance traveled. $\Delta P/\Delta t$ and $\Delta P/\Delta s$ are thus quite large, and the curve of FIG. **13b** illustrating the derivative of the measured tissue parameter exhibits a corresponding spike **124** before returning to varying slightly about zero in region **126**. A second spike **128** corresponds to a point **130** where another change in proximity or degree of contact occurs.

The contact sensing methods described above are useful in monitoring for a change indicative of probe **12** making contact with tissue surface **82**, a change indicative of probe **12** breaking contact with tissue surface **82**, or a change indicative of a change in the degree of contact between probe **12** and tissue surface **82**. In the lattermost case, the method may provide an indicator of whether probe **12** is beginning to break contact with tissue surface **82** or is potentially being traumatically driven into tissue surface **82**. This information may be used by the user and/or robotic surgical system **10** (e.g., controller **24**) as feedback to adjust the movement of probe **12** to maintain a particular degree of contact with tissue surface **82** on an ongoing basis in order to improve the quality or efficiency of the medical treatment. For example, in an ablation procedure for the treatment of atrial fibrillation, one of ordinary skill will readily appreciate that a spike in a derivative of the tissue parameter, as shown in FIG. **13b**, may indicate that the ablation catheter has broken contact with the cardiac surface and is therefore no longer creating a substantially continuous lesion and that appropriate corrective action is necessary to bring the ablation catheter back into contact with the cardiac surface. As another example, in a surface modeling procedure, the spike may indicate that the modeling probe has broken contact with the surface being modeled such that the collection of geometry points should be suspended in order to avoid capturing erroneous data.

Surface Modeling

FIG. **14** illustrates a system **150** for generating a three-dimensional model of at least a portion of the patient's body. Though system **150** will be described in the context of generating a three-dimensional model of the patient's heart chamber **152**, it should be understood that system **150** and the method disclosed herein may also be employed to map the volume and tissue surface of any internal organ or other portion of the patient's body in which the user is interested.

Modeling system **150** includes electrode **154** for insertion into a portion of the patient's heart and a controller (once again denoted as controller **24**, though an additional controller or controllers could be used) for robotically moving electrode **154** within the portion of the heart either randomly, pseudo-randomly, or according to one or more predetermined patterns. The term "predetermined pattern" is used to mean any pattern that is not random or pseudo-random, whether that pattern is computer- or user-dictated. Further, with reference to the phrase "within a portion of a heart," it should be appreciated that this does not refer to the movement of electrode **154** within the tissue itself (which could be traumatic), but rather to the movement of electrode **154** within a space that is interior to the patient's body (such as movement within the open space that defines heart chamber **152**).

Electrode **154** may be a position, location, or mapping electrode, with the terms being used interchangeably herein. Controller **24** may be incorporated in robotic surgical system **10** described herein, in which case electrode **154** may be carried on catheter **12**, preferably at or near distal end **52** of catheter **12** such that electrode **154** may be brought into contact with tissue surface **82** of heart chamber **152**. It is also contemplated that electrode **154** may be located more proximally along catheter **12**, for example adjacent to electrode **88**. In the latter configuration, the relationship between electrode **154** and distal end **52** may be used to derive position information for distal end **52** from position information for electrode **154**. It should be understood that carrying electrode **154** on a non-catheter probe, utilizing an alternative robotic control system to move electrode **154**,

and manually moving electrode **154** are all regarded as within the scope of the invention. It should further be understood that the use of both individual and multiple electrodes to practice the various aspects of the present invention is contemplated (i.e., electrode **88** and electrode **154** may be the same electrode).

Positional feedback system **86** detects position information of electrode **154** within heart chamber **152**. Position detector **86** preferably includes a plurality of paired electrodes **90** defining measurement axes for locating electrode **154** within the patient's body by utilizing the electrical potentials measured by electrode **154**. An example of a suitable positional feedback system **86** is disclosed in U.S. application Ser. No. 11/227,006, filed 15 Sep. 2005 (the '006 application) and U.S. provisional application No. 60/800,848, filed 17 May 2006 (the '848 application), both of which are hereby expressly incorporated by reference as though fully set forth herein. The terms "position detector," "positional feedback system," "mapping system," and "navigation system" are used interchangeably herein.

By detecting the position of electrode **154** multiple times as electrode **154** is moved within heart chamber **152**, position detector **86** generates a plurality, or cloud, of location points defining the space occupied by heart chamber **152**. Positional feedback system **86** need not determine whether a particular location point is a surface point or an interior point during the position detection step; the interior points will be resolved during subsequent processing. That is, the cloud of location points is generated indiscriminately, advantageously reducing the overhead and time required to collect the data set from which the three-dimensional model is generated. Thus, the cloud of location points preferably includes at least some location points on the surface of heart chamber **152** ("surface points") and at least some location points not on the surface of heart chamber **152** ("interior points"). The cloud of location points may be stored in a storage medium, such as a hard drive or random access memory (RAM), which may be part of computer system **92**.

A modeling processor, which may be part of computer system **92**, generates a three-dimensional model of heart chamber **152** from the cloud of location points. The three-dimensional model includes position information for a plurality of surface points describing a three-dimensional surface model of heart chamber **152**. That is, after the cloud of location points is generated, the modeling processor identifies, isolates, and either disregards or eliminates the interior points by applying a surface construction or surface modeling algorithm to the plurality of location points. Preferably, the surface modeling algorithm employed is a shrink-wrap algorithm, though numerous other surface modeling algorithms are contemplated, including, but not limited to, convex hull algorithms (e.g., Qhull), alpha shapes, Hoppe's software, CoCone, and Paraform. The three-dimensional surface model may optionally be output as a graphical representation of heart chamber **152** on a display **154**, which may also be part of computer system **92**, or another output device. Further, the three-dimensional surface model may optionally be stored in a storage medium.

In use, electrode **154** is inserted within heart chamber **152**, for example by advancing electrode **154** into heart chamber **152** on catheter **12** controlled by robotic surgical system **10**. Next, electrode **154** is robotically moved within heart chamber **152**. As described above, movement of electrode **154** within heart chamber **152** may be random, pseudo-random, or according to a predetermined pattern. Optionally, the predetermined pattern may include two distinct components: a first predetermined pattern until a determination is made

that electrode **154** is in contact with tissue surface **82** of heart chamber **152**, and a second predetermined pattern after electrode **154** has made contact with surface **82** of heart chamber **152**. The contact sensing methodology described herein may be employed to determine when electrode **154** has made contact with surface **82** of heart chamber **152**; to this end, it is contemplated that electrode **154** may function as sensor **84**. The second predetermined pattern need not be substantially continuous along surface **82** of heart chamber **152**; that is, electrode **154** may occasionally break contact with surface **82** of heart chamber **152** while following the second predetermined pattern such that electrode **154** “bounces” rather than “skates” along surface **82** of heart chamber **152**.

For example, in some embodiments of the invention, electrode **154** may first measure a few initial location points in a region of heart chamber **152**. Electrode **154** may then incrementally approach surface **82** of heart chamber **152**; the contact sensing methodology described herein, or another suitable contact sensing methodology, may be utilized to determine when electrode **154** has contacted surface **82**. A location point may be collected from surface **82** of heart chamber **152**. A section of a model of surface **82** of heart chamber **152** may then be constructed from the initial location points and the surface location point, and electrode **154** may then be moved small distances, such as about 5 mm anti-normal to surface **82** and about 5 mm laterally to an unsampled region. This process may then be repeated as necessary to complete the cloud of location points.

As electrode **154** is moved within heart chamber **152**, position information of electrode **154** is detected in order to generate the plurality of location points defining the space occupied by heart chamber **152**. If electrode **154** is located at or near distal end **52** of catheter **12**, position information may be stored directly; if electrode **154** is located more proximally, position information may be derived from the relationship between electrode **154** and distal end **52** prior to being stored. Detection of position information may be periodic (that is, with a relatively constant interval between successive measurements) or episodic (that is, with a variable interval between successive measurements). Detection may also be event-driven (for example, upon sensing a particular electrophysiological characteristic with sensor **84**).

The three-dimensional model of heart chamber **152** is then generated from the plurality of location points by utilizing a surface construction algorithm, such as a shrink-wrap algorithm, to wrap or otherwise construct a surface around the plurality of location points. The three-dimensional model includes position information for at least some of the plurality of location points within heart chamber **152**, preferably those location points describing a three-dimensional surface model of heart chamber **152**. The model may be generated by processing the plurality of location points using a surface construction algorithm to identify and output the subset of the plurality of location points defining the three-dimensional surface model, and thus surface **82** of heart chamber **152**. Interior points may be eliminated or simply disregarded by the surface construction algorithm. The subset of location points may define vertices for a plurality of triangles representing the three-dimensional surface model of heart chamber **152**, and the triangles themselves may be generated by interconnecting the vertices. Once generated, the three-dimensional model may be presented as a graphical representation on display **156**, permitting the user to interact intuitively with the model through input devices **158**, which may include, but are not

limited to, a mouse, trackball or other pointing device **160**; a two- or three-dimensional joystick or control yoke **162**; and a keyboard or keypad **164**. Input devices **158** may be coupled to computer system **92**. Optionally, one or more of input devices **158** may also serve as controls **78** permitting the user to robotically steer catheter **12**.

As one of ordinary skill in the art will understand from the foregoing description, the present invention facilitates improved collection of location points. For example, manually controlled catheters may tend to follow repetitive or stereotypical patterns during sampling, and thus may not collect location points throughout the volume of the heart chamber. The robotically-controlled catheter of the present invention, however, is less susceptible to this shortcoming, in that it is capable of achieving the necessary control vectors to reach substantially all of the volume of the heart chamber. Further, the robotically-controlled catheter may be programmed to avoid repeat sampling of regions or to exclude repeatedly sampled location points, in the event that it is necessary to travel through a particular region more than once. As a result, the not only may the plurality of location points be improved, but also the time required to create the three-dimensional model may be reduced.

Diagnostic Data Mapping

Modeling system **150** may also be utilized to generate a diagnosis map for surface **82** of heart chamber **152** through the addition of an instrument for measuring physiological information, and preferably an instrument for measuring electrophysiology information, such as sensor **84**. It should be understood that, though described herein as separate components, one or more of sensor **84**, electrode **88**, and electrode **154** may optionally be combined into a single component carried on probe **12**. Sensor **84** measures electrophysiology information at a point on surface **82** of heart chamber **152** that is in meaningful proximity to probe **12**. The diagnosis map contains information about the physiological characteristics of surface **82**, for example the tissue impedance at various locations on surface **82**.

As described above, controller **24** moves probe **12** to a plurality of locations within heart chamber **152**, including into meaningful proximity with a plurality of surface points. A contact sensor, such as a force transducer, or the contact sensing methodology disclosed herein, may be employed to identify proximity or degree of contact between probe **12** and surface **82** of heart chamber **152**, though, as one of ordinary skill in the art will appreciate, contact sensing is not necessary if the geometry of heart chamber **152** is already known, since proximity and contact information between probe **12** and surface **82** can be derived from the known geometry and positional feedback system **86**.

Preferably, a processor, which may be part of computer system **92**, causes probe **12** to automatically move into meaningful proximity with a plurality of surface points, for example by providing instructions to controller **24** incorporated in robotic surgical system **10** to actuate one or more of servo mechanisms **18**, **22**, **60** to translate, deflect, and/or rotate probe **12**. It is also contemplated that the user may robotically steer probe **12** to the plurality of points via a suitable input device **158**, such as joystick **162**.

Sensor **84** detects electrophysiological information for at least some of the surface points, and preferably for each surface point. The processor associates the measured electrophysiological information with the position information for the surface point at which it was measured. As one of skill in the art should appreciate from this disclosure, the position information may be already known (e.g., through application of the surface modeling methodology disclosed

herein) or may be gathered concurrently with the detection of electrophysiological information. Once position and electrophysiological information for the plurality of surface points has been gathered and associated as a plurality of surface diagnostic data points, the processor generates the diagnosis map of heart chamber 152 therefrom.

The diagnosis map may optionally be combined with the three-dimensional surface model of heart chamber 152 generated by the modeling processor or with another model of heart chamber 152 (e.g., an MRI- or CT-generated model). For example, the diagnosis map may be superimposed upon the three-dimensional surface model. If desired, the resultant three-dimensional diagnosis model, including both position information and physiological information, can be output on display 156 as a graphical representation. In addition, the diagnosis map or three-dimensional diagnosis model may be stored in a storage medium, which, as noted above, may be part of computer system 92.

An electrophysiology processor, which also may be incorporated within computer system 92, processes the measured electrophysiology information in order to identify one or more surface points that are potential treatment sites. By way of example only, the electrophysiology processor may identify surface points having abnormal impedance as potential targets for tissue ablation in the diagnosis and treatment of cardiac arrhythmia. The electrophysiology processor may be coupled to display 156 such that the one or more identified potential treatment sites, or other indicia of the measured physiological or electrophysiological information, may be presented to the user by superimposition on the graphical representation of the three-dimensional model. For example, the potential treatment sites may be flagged on display 156 with a special icon or coloration. Alternatively, contour lines may be added to the graphical representation to illustrate the physiological and/or electrophysiological data included in the diagnosis map. FIG. 15 illustrates a graphical representation of heart chamber 152 including both flagged potential treatment sites 168 and contour lines 170.

The user may employ a user interface 166, including display 156 and input devices 158, to select one or more of the identified potential treatment sites as target points (also referred to herein as "treatment points"), for example by pointing to and clicking on the treatment site as superimposed on the graphical representation. In order to permit the user to intuitively designate target points, display 156 may be a touchscreen. User interface 166 is preferably coupled to controller 24, and thus to probe 12, such that, upon selecting one or more target points with user interface 166, controller 24 may cause probe 12 to be relocated thereto for further diagnosis (e.g., the collection of additional electrophysiology information at the target site) or treatment (e.g., the delivery of a therapeutic compound or ablative energy to the target site). It is also contemplated that controller 24 may operate to automatically navigate probe 12 to one or more identified potential treatment sites for further diagnosis or treatment without intervention or target point selection by the user (i.e., controller 24 may be responsive directly to the electrophysiology processor).

In use, electrode 154, which is preferably mounted on medical device 12, is inserted within heart chamber 152. (Recall that this term does not embrace embedding electrode 154 in cardiac tissue.) Robotic controller 24 is used to move electrode 154 within heart chamber 152 either randomly, pseudo-randomly, or according to one or more predetermined patterns, and into meaningful proximity with a plu-

rality of surface points on tissue surface 82 of heart chamber 152 in order to measure electrophysiology information thereat.

Assuming a known geometry of heart chamber 152, for example as generated by the surface modeling methodology disclosed herein, electrophysiology information is measured and associated with the pre-existing position information for a plurality of surface points. If the geometry is unknown, the diagnosis mapping and surface modeling processes may be combined such that, as electrode 154 moves within heart chamber 152, both position information and electrophysiology information are measured, thereby simultaneously generating a plurality of location points defining the space occupied by heart chamber 152, at least some of which are surface points, and electrophysiology information for those surface points. The plurality of location points may be processed as described herein or according to another surface construction algorithm to generate the three-dimensional surface model of heart chamber 152. The measured electrophysiology information is associated with the position information for at least some of the plurality of surface points in order to generate the diagnosis map. It is also contemplated that electrophysiology measurements may be taken after generating the plurality of location points, rather than simultaneously therewith, and either before or after applying the surface construction algorithm to generate the surface model.

The diagnosis map can be generated from the resulting plurality of surface diagnostic data points. The plurality of surface diagnostic data points may also be used to generate a three-dimensional surface model of heart chamber 152 including both position and electrophysiology information for the plurality of surface points. The diagnosis map and/or surface model may optionally be stored in a storage medium, either individually or as a composite, or presented as a graphical representation on display 156, either with or without an accompanying three-dimensional model of heart chamber 152.

Once the diagnosis map is generated, it may be used as an intuitive interface for the user to select one or more target points, for example by using an input device 158 to point and click on the graphical representation of the three-dimensional model of heart chamber 152 with the diagnosis map superimposed thereon. Medical device 12 may subsequently be navigated to the target points so selected in order to provide treatment, such as ablation of tissue, or for further diagnosis, such as making additional electrophysiology measurements. It is contemplated that the user selecting the one or more target points may be remote from robotic surgical system 10. For example, an expert physician in one city may access the three-dimensional model of heart chamber 152 via a computer network, such as the Internet, and select the target points, which may then be delivered to robotic surgical system 10 in a second city for execution.

Automated Therapy Delivery

Robotic surgical system 10 may be adapted for automated delivery of therapy, such as ablation of cardiac or other tissue or the delivery of a therapeutic agent to a cardiac or other tissue surface. As shown in FIG. 16, user interface 166 permits the user to define a navigation path 200 (also referred to herein as a "predetermined path" or "treatment path") on tissue surface 82, preferably by utilizing input devices 158 to designate navigation path 200 on the graphical representation of heart chamber 152 shown on display 156. As described above, the user may be remote from robotic surgical system 10, providing the advantage of expert consultation over even long distances during a pro-

cedure. It should be understood that the graphical representation may or may not include physiological information measured by sensor 84 as described herein; the user may choose whether or not this information is depicted on display 156.

In some embodiments, the user designates a plurality of waypoints 202, including a first waypoint 202a (i.e., a starting point) and a final waypoint 202b (i.e., an endpoint), on the graphical representation of heart chamber 152. The first and final waypoints 202a, 202b may be substantially co-located such that navigation path 200 is a substantially closed loop (e.g., a closed loop around a the pulmonary veins). Alternatively, the user may utilize input devices 158 to trace a substantially continuous treatment path 200 on the graphical representation without defining individual waypoints 200. The user may further identify at least one target point 204 on the navigation path where a therapy is to be administered or a diagnosis is to be performed. The at least one target point 204 may, but need not, correspond to a waypoint 202, and may be input as described herein in connection with the diagnostic data mapping aspect of the present invention.

Controller 24 actuates robotic surgical system 10 to navigate medical device 12 along the navigation path “inbound” from first waypoint 202a to final waypoint 202b, optionally through one or more intermediate waypoints 202. If the user has designated target points 204, controller 24 actuates robotic surgical system 10 to navigate medical device 12 thereto. Controller 24 may utilize positional feedback measured by positional feedback system 86 to navigate medical device 12 and to position medical device 12 to the at least one treatment or diagnosis location (i.e., target points 204).

Controller 24 may include software to further refine the navigation of medical device 12. For example, controller 24 may include software to automate navigation of medical device 12. As another example, controller 24 may include software to automatically maintain contact between medical device 12 and tissue surface 82, perhaps by automatically synchronizing movement of medical device 12 to movement of tissue surface 82. This will improve the efficiency of therapy delivery along treatment path 200 by ensuring that medical device 12 remains in contact with tissue surface 82 as it moves, rather than bouncing along tissue surface 82 as the patient’s heart beats or the patient breathes. The contact sensing methodology disclosed herein may be utilized to maintain contact between medical device 12 and tissue surface 82.

As one skilled in the art will recognize, advancing (i.e., pushing) medical device 12 into a patient with precision is more difficult than retracting (i.e., pulling) it from the patient with precision. It may therefore be desirable to administer treatment or perform a diagnostic procedure as device 12 is being retracted rather than as device 12 is being advanced. Accordingly, a memory device, which, in embodiments, is part of computer system 92, may store a plurality of reference points generated by making periodic measurements of the position of medical device 12 as it is navigated along navigation path 200. A processor, which may also be part of computer system 92, generates a return path for medical device 12 from the plurality of reference points. Controller 24 can actuate robotic surgical system 10 to navigate medical device 12 along the return path. In effect, the reference points are used as reverse waypoints, or virtual breadcrumbs, permitting an “outbound” medical device 12 to retrace its steps during retraction from the patient. Alternatively, the memory device may store a plurality of robotic

settings or commands used by controller 24 to actuate robotic surgical system 10 to robotically place medical device 12 at waypoints 202 defining navigation path 200. These commands may thereafter be executed in reverse to retract medical device 12 from the patient along navigation path 200 in reverse. The use of a return path defined by a plurality of reference points or the reversed robotic settings may improve the precision of the navigation of medical device 12 as it is retracted, which in turn may improve the quality of the therapy delivered to tissue surface 82 (i.e., by creating a substantially continuous, smooth ablation lesion).

In use, a topography (i.e., a surface model) of at least a portion of the patient’s body is provided. The topography may be generated as described herein, and may be depicted graphically on display 156, either with or without diagnostic data superimposed thereon. Next, user input is accepted to define navigation path 200 on the topography as described above. User input may be accepted on the graphical representation through a pointing device, such as mouse 160 or a trackball, joystick 162, a touchpad, or another suitable device. Alternatively, display 156 may be a touchscreen permitting more direct interaction with the graphical representation.

Medical device 12 is then robotically navigated to first waypoint 202a, preferably by automatically actuating robotic surgical system 10. From first waypoint 202a, medical device 12 is robotically actuated to move along navigation path 200 to final waypoint 202b. It should be understood that navigation path 200 may incorporate one or more other waypoints 202 between first waypoint 202a and final waypoint 202b. Once final waypoint 202b is reached, medical device 12 may be robotically navigated along navigation path 200 in reverse, or alternatively navigated along a return path from final waypoint 202b to first waypoint 202a, for withdrawal from the patient.

As described above, the return path may be created by periodically measuring a position of medical device 12 as it is navigated along navigation path 200 from first waypoint 202a to final waypoint 202b. These periodic measurements become reference points, which may be thought of as reverse waypoints or virtual breadcrumbs defining the return path. Medical device 12 can then be robotically actuated to navigate the return path by following the virtual breadcrumbs.

As one of skill in the art will understand, the higher the sampling rate for measuring the position of medical device 12 as it navigates navigation path 200, the more reference points will be collected, and the more reference points collected, the smoother the return path will be. Accordingly, the resolution (e.g., the relative smoothness) of the return path may be user-adjustable; the user-selected resolution can be used to adjust the sampling rate to an appropriate value. Alternatively, the sampling rate may be directly user-adjustable.

As an alternative to navigating from final waypoint 202b to first waypoint 202a along a virtual breadcrumb return path, medical device 12 may be navigated waypoint-to-waypoint in reverse along navigation path 200. To implement this reverse navigation, a plurality of robotic settings corresponding to the robotic settings used to robotically place medical device 12 at each of the plurality of waypoints 202 defining navigation path 200 are recorded in a memory device. These robotic settings are then utilized to improve accuracy of travel of medical device 12 along navigation path 200 in reverse, for example by playing them back in

reverse (i.e., retracting 0.5 mm and rotating counter-clockwise 30 degrees rather than advancing 0.5 mm and rotating clockwise 30 degrees).

Navigation path **200** may be entirely in contact with tissue surface **82**, or may include segments not in contact with tissue surface **82**. Where navigation path **200** is entirely in contact with tissue surface **82**, medical device **12** is navigated from first waypoint **202a** to final waypoint **202b** while maintaining contact between medical device **12** and tissue surface **82**. Thus, controller **24** may advance medical device **12** to a location proximate starting point **202a** and periodically sense for contact between medical device **12** and the moving cardiac surface. Upon sensing contact with the moving cardiac surface, movement of medical device **12** may be synchronized with the movement of the cardiac surface.

Synchronization may be accomplished by measuring a contact force between medical device **12** and tissue surface **82** and robotically actuating medical device **12** to maintain the contact force at a substantially constant level or within a predetermined range of values. It should be recognized that the maximum contact force is associated with orthogonal positioning of medical device **12** against tissue surface **82**; as orthogonal contact is the preferred orientation for maximum efficacy of treatment, it is desirable to also robotically actuate medical device **12** to maintain the contact force at a substantially constant maximum level. It is also contemplated, however, that contact force feedback, for example from a three-axis force sensor, may be utilized to robotically actuate medical device **12** to maintain other preset orientations relative to tissue surface **82**.

Alternatively, the contact sensing methodology disclosed herein could be utilized to monitor the proximity or degree of contact between medical device **12** and tissue surface **82**. For example, robotic surgical system **10** may advance medical device **12** relative to the cardiac surface when the rate of change in the contact force is indicative of the cardiac surface moving away from medical device **12** and retract medical device **12** relative to the cardiac surface when the rate of change in the contact force is indicative of the cardiac surface moving towards medical device **12**.

Medical device **12** may be used to administer a therapy or perform a diagnostic procedure as it is navigated along navigation path **200**, either going forwards (i.e., while being introduced into the patient) or in reverse (i.e., while being retraced from the patient), or as medical device **12** is navigated along the return path. Medical device **12** may be an ablation device, and the therapy may be ablating tissue along navigation path **200** with the ablation device. Alternatively, the therapy may involve utilizing medical device **12** to deliver a therapeutic agent to a tissue surface at one or more target points **204** along navigation path **200**. Therapy may be administered at one or more discrete locations or substantially continuously along navigation path **200**. Other therapies and diagnostic procedures are also contemplated.

Automatic Creation of Ablation Lesions

Robotic surgical system **10** and the automatic therapy delivery methodology disclosed herein, as well as one or more of the contact sensing, surface modeling, and diagnostic data mapping methodologies, may be advantageously utilized in combination to automatically create ablation lesions on the cardiac surface. An ablation probe is installed into robotic surgical system **10** as medical device **12**. The ablation probe carries thereon one or more ablation elements, which may be RF elements, ultrasound elements, thermal elements, cryogenic elements, laser elements,

microwave elements, or any other type of element for delivering ablative energy or chemicals to tissue.

As described above, display **156** preferably presents a graphical representation of an area of tissue to be ablated, such as a portion of the patient's heart. User interface **166** may be used to select a plurality of target points **204** thereon as described herein. For example, the user may identify at least two target points **204** defining the predetermined path on the graphical representation of surface **82** of heart chamber **152**. Alternatively, the user may trace a substantially continuous treatment path **200** on the graphical representation.

User interface **166** is coupled to controller **24** such that controller **24** may cause the ablation probe to ablate tissue along predetermined path **200** at and between the plurality of target points **204**. Path **200** may span a gap between first and second areas of ablated tissue as superimposed on the graphical representation of the cardiac surface.

Though the predetermined path is preferably user-designated through user interface **166** as described above, it is also contemplated that path **200** may be computer-determined. For example, the electrophysiology processor may analyze the cardiac surface in order to identify one or more gaps between ablated tissue, and define path **200** accordingly, in order to create a substantially continuous lesion.

Controller **24** robotically moves the ablation probe to an area near a tissue surface. The controller **24** then advances the ablation probe into contact with the cardiac surface and activates the ablation element (or elements) thereon. Once in contact with tissue surface **82** and active, the ablation probe is robotically moved along predetermined path **200** while maintaining contact between the probe and the cardiac surface to create a substantially continuous ablation lesion. For example, controller **24** may advance the ablation probe to a point in the first ablated area, activate the ablation element or elements, and robotically move the ablation probe to a point in the second ablated area, thereby ablating a path along the gap between the first ablated area and second ablated area. The result is a substantially continuous ablation lesion between the first and second ablated areas.

Alternatively, controller **24** may advance the ablation probe to a first target point **204** or waypoint **202**, from the first target point to a second target point **204** or waypoint **202**, from the second target point to a third target point **204** or waypoint **202**, and so on until reaching a final target point or waypoint. The result is a substantially continuous ablation lesion following the plurality of target points **204** or waypoints **202**.

In order to maintain contact between the ablation probe and the cardiac surface, the ablation probe may include a contact sensor, the output of which is monitored for proximity or degree of contact between the ablation probe and tissue surface **82**. The contact sensor may be a force sensor or a sensor **84** employed by the contact sensing methodology disclosed herein. Feedback from the contact sensor may be used by controller **24** to orient the ablation probe at any desired angle to tissue surface **82**, including substantially orthogonal thereto, in order to improve lesion quality.

In some embodiments of the invention, the movement of the ablation probe is synchronized to the movement of tissue surface **82** caused by patient movement, patient respiration, and/or the beating of the heart. Synchronization may be accomplished by monitoring a parameter at tissue surface **82** and actuating the ablation probe to maintain the parameter within a predetermined range of values. Synchronization may also be accomplished by monitoring a rate of change in the parameter. When the rate of change in the parameter

indicates that tissue surface **82** is moving away from the ablation probe, the ablation probe can be automatically actuated to advance relative to tissue surface **82**; when the rate of change in the parameter indicates that tissue surface **82** is moving towards the ablation probe, the ablation probe can be automatically actuated to retract relative to tissue surface **82**.

Electrophysiology information may be collected via sensor **84** and monitored during the ablation process in order to measure lesion quality. Typical electrophysiology information includes, without limitation, changes in amplitude, changes in fractionation, changes in impedance, peak power delivered, average power delivered, peak temperature achieved, and average temperature achieved. Other parameters indicative of lesion quality, diameter, or depth may also be measured without departing from the spirit and scope of the present invention. In order to ameliorate biasing effects in the electrophysiology information caused by RF ablation energy, an RF filter may be utilized. Based on the feedback in the measured electrophysiology information, robotic surgical system **10** may dynamically adjust one or more aspects of the treatment, including, without limitation, probe speed, probe orientation relative to the tissue surface, probe position, the degree of contact between the probe and the tissue surface, and the distance the probe moves along the tissue surface.

Further, according to the methods disclosed herein, the ablation lesion may be created as the ablation probe is withdrawn from the patient. An ablation lesion created as the ablation probe is withdrawn may be of better continuity, higher quality, and greater precision than an ablation lesion created as the ablation probe is advanced. This benefit is particularly useful in more elongate lesions.

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. For example, the robotic surgical system **10** may be modified to incorporate additional servo mechanisms and controllers operating on additional degrees of freedom.

Further, though the contact sensing methodology has been described in connection with a robotically controlled medical device, it could also be implemented in a manually controlled medical device. It should also be understood that, rather than utilizing absolute values in the various contact sensing algorithms described herein, the thresholds or limits may be appropriately adjusted to compensate for negative values of ΔP , for example by taking the opposite of all thresholds or limits and reversing the comparator (i.e., changing $<to>$) upon detecting that ΔP is less than zero.

In addition, one of ordinary skill in the art will appreciate that, though the devices and methods disclosed herein have been described in connection with the treatment of atrial fibrillation, and in particular in connection with the creation of lesions of ablated tissue, they may be used to administer other therapies or to perform other diagnostic procedures. For example, the automatic therapy delivery method disclosed herein could be utilized to emplace a pacemaker lead or a stent or to perform a balloon angioplasty. It is also contemplated that the ablation lesions may be automatically created without utilizing one or more of the methods disclosed herein. For example, rather than creating the surface model of the patient's heart chamber utilizing the surface modeling methodology disclosed herein, navigation path **200** may be defined on an MRI- or CT-generated surface model.

Further, the devices and methods disclosed herein are capable of use both epicardially and endocardially.

All directional references (e.g., upper, lower, upward, downward, left, right, leftward, rightward, top, bottom, above, below, vertical, horizontal, clockwise, and counter-clockwise) 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.

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.

What is claimed is:

1. A method of ablating tissue, comprising the steps of: analyzing areas of ablated tissue to identify at least a first ablated area and a second ablated area separated by a gap of unablated tissue; robotically moving a catheter to a treatment area near a tissue surface, said catheter having an ablation electrode located near a distal end of the catheter; monitoring proximity or degree of contact between the catheter and the tissue surface; robotically advancing the catheter to contact a point in the first ablated area; automatically robotically moving the catheter to a point in the second ablated area in a way that maintains contact between the catheter and the tissue surface, thereby defining a path along the gap between the first ablated area and the second ablated area; activating the ablation electrode to ablate the tissue after the catheter reaches the point in the second ablated area; and automatically robotically withdrawing the catheter along the path along the gap between the first ablated area and the second ablated area from the point in the second ablated area to the point in the first ablated area while the ablation electrode is active, thereby ablating the tissue along the path along the gap between the first ablated area and the second ablated area.
2. The method of claim 1, wherein the step of monitoring comprises monitoring a contact sensor that is located near a distal end of the catheter.
3. The method of claim 1, wherein the step of monitoring comprises monitoring a force sensor that is located at a distal end of the catheter for a degree of force that is indicative of contact between the catheter and the tissue surface.
4. The method of claim 3, further comprising utilizing information from the force sensor to orient the catheter in a preset orientation relative to the tissue surface.
5. The method of claim 4, further comprising utilizing information from the force sensor to orient the catheter substantially orthogonally to the tissue surface.
6. A method of ablating tissue, comprising the steps of: analyzing areas of ablated tissue to identify at least a first ablated area and a second ablated area separated by a gap of unablated tissue; robotically moving a catheter to a treatment area near a tissue surface within the first ablated area, said catheter

having an ablation electrode and a contact sensor located near a distal end of the catheter; while monitoring the contact sensor for contact between the catheter and the tissue surface, advancing the catheter until the catheter contacts the tissue surface at a point in the first ablated area; automatically robotically moving the catheter from the point in the first ablated area, through the gap of unablated tissue, and to a point in the second ablated area while maintaining contact between the catheter and the tissue surface, thereby defining a path between the point in the first ablated area and the point in the second ablated area; activating the ablation electrode to ablate the tissue after reaching the point in the second ablated area; robotically moving the catheter from the point in the second ablated area, along the path between the point in the first ablated area and the point in the second ablated area, to the point in the first ablated area with the ablation electrode active, thereby ablating the tissue along the path between the point in the first ablated area and the point in the second ablated area.

7. The method of claim 6, wherein the contact sensor is a force sensor, and wherein the step of monitoring comprises monitoring the force sensor for a degree of force that is indicative of contact between the catheter and the tissue surface.

8. The method of claim 6, further comprising: generating a three-dimensional model of at least a portion of the tissue surface; presenting a graphical representation of the three-dimensional model; and receiving input from a user that identifies at least two target locations that define the point in the first ablated area and the point in the second ablated area.

9. A method of ablating tissue, comprising the steps of: analyzing, using an electrophysiology processor, areas of ablated tissue to identify at least a first ablated area and a second ablated area separated by a gap, the gap being characterized by tissue that has not been ablated; robotically moving a catheter to a point on a surface of the first ablated area, such that the catheter is in contact with the first ablated area; robotically moving the catheter to a point in the second ablated area along a path between the first ablated area and the second ablated area; activating an ablation electrode on the catheter to ablate the tissue after reaching the point in the second ablated area; and robotically moving the catheter from the point in the second ablated area, along the path between the first ablated area and the second ablated area, to the point on the surface of the first ablated area with the ablation electrode active.

10. The method of claim 9, further comprising: monitoring a degree of contact between the catheter and tissue being ablated; wherein the ablation is carried out while maintaining contact between the catheter and the tissue being ablated.

11. The method of claim 9, further comprising: generating a three-dimensional model of a tissue surface to be ablated; presenting a graphical representation of the three-dimensional model of the tissue surface; and

receiving input from a user that identifies at least two target locations that define the path between the first ablated area and the second ablated area that includes at least a portion of the gap, whereby the tissue along the path will be ablated, wherein the ablation is carried out along the path input by the user.

12. A method of ablating tissue, comprising the steps of: receiving, from a probe and at an electrophysiology processor, measured electrophysiology information for a plurality of measurement points on a surface of a heart, the probe including a measurement device for measuring electrophysiology information; analyzing, using the electrophysiology processor, the measured electrophysiology information to identify areas with previously ablated tissue; generating a three-dimensional surface model of a portion of the heart; presenting a graphical representation of the three-dimensional surface model of the heart; superimposing on the graphical representation information to identify the areas with previously ablated tissue; receiving input from a user that identifies at least two target locations that define a predetermined path on the graphical representation of the three-dimensional model of the heart, whereby tissue along the path will be ablated, said predetermined path including tissue that has not been previously ablated; robotically moving an ablation electrode to one of the at least two target locations along the predetermined path; robotically moving the ablation electrode along the predetermined path defined by the at least two target locations; and robotically moving the ablation electrode along the predetermined path defined by the at least two target locations in reverse with the ablation electrode activated to ablate tissue along the predetermined path.

13. The method of claim 12, further comprising: monitoring a degree of contact between the catheter and tissue being ablated; and wherein the ablation is carried out while maintaining contact between the catheter and the tissue being ablated.

14. The method of claim 12, wherein the probe is a catheter, and wherein the ablation electrode is located on the catheter, said method further comprising: monitoring electrophysiology information of the tissue being ablated during the ablation process; adjusting the position and/or speed of the catheter during the ablation process based on changes in the electrophysiology information being monitored.

15. The method of claim 14, wherein the electrophysiology information being monitored is filtered using an RF filter to remove biasing effects caused by RF energy during the ablation process.

16. The method of claim 14, wherein the monitoring of electrophysiology information comprises monitoring electrophysiology information for changes in amplitude of the electrophysiology information.

17. The method of claim 14, wherein the monitoring of electrophysiology information comprises monitoring electrophysiology information for changes in fractionation of the electrophysiology information.

18. The method of claim 14, wherein the monitoring of electrophysiology information comprises monitoring electrophysiology information for changes in a parameter that is indicative of a degree of tissue ablation.

19. A robotic system for tissue ablation, comprising:
 an electrophysiology processor configured to analyze
 measured electrophysiology information from a cardiac
 surface and to identify, from the measured electro-
 physiology information, a first ablated area on the
 cardiac surface and a second ablated area on the cardiac
 surface, wherein the first ablated area and the second
 ablated area are separated by an unablated gap; and
 a robotic controller for moving a catheter within a
 patient's body, wherein the robotic controller automati-
 cally:
 advances the catheter to an initial waypoint within the
 first ablated area;
 maintains contact between the catheter and the cardiac
 surface while moving the catheter to a final waypoint
 within the second ablated area along a lesion path-
 way that crosses the unablated gap; and
 withdraws the catheter from the final waypoint, along
 the lesion pathway; to the initial waypoint.
20. The robotic system of claim 19, further comprising a
 contact sensor to detect when a distal end of the catheter is
 in contact with the cardiac surface.
21. The robotic system of claim 20, wherein the contact
 sensor is a force sensor that determines when contact has
 been made between the catheter and the cardiac surface
 using information relating to a force exerted on said catheter
 by the cardiac surface.
22. The robotic system of claim 20, wherein the robotic
 controller utilizes feedback from the contact sensor to orient
 the catheter in a preset orientation relative to the cardiac
 surface.

23. The robotic system of claim 22, wherein the controller
 utilizes feedback from the contact sensor to orient the
 catheter substantially orthogonally to the cardiac surface.
24. The robotic system of claim 20, wherein the contact
 sensor is a sensor that determines when contact has been
 made between the catheter and the cardiac surface using a
 rate of change in a parameter measured at a location on the
 catheter.
25. The robotic system of claim 24, wherein the parameter
 is an electrophysiological characteristic.
26. The robotic system of claim 20, wherein the contact
 sensor comprises an RF filter to filter out any biasing effects
 caused by RF energy when the system is ablating tissue.
27. The robotic system of claim 19, further comprising:
 a display device for presenting a graphical representation
 of the cardiac surface; and
 an interface to permit a user to define the initial waypoint
 and the final waypoint on the graphical representation
 of the cardiac surface.
28. The robotic system of claim 27, wherein the interface
 further permits the user to define a plurality of waypoints
 including the initial waypoint and the final waypoint on the
 graphical representation of the cardiac surface, wherein the
 plurality of waypoints defines the lesion pathway.
29. The robotic system of claim 19, wherein the electro-
 physiology processor is configured to determine the initial
 waypoint, the final waypoint, and the lesion pathway.

* * * * *

专利名称(译)	用于自动产生消融损伤的机器人手术系统和方法		
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摘要(译)

用于消融组织的系统包括用于插入患者体内的消融导管和用于在体内移动导管的机器人控制器。机器人控制器使导管前进直到导管接触组织表面，保持导管与组织表面之间的接触，并沿预定路径移动导管以产生基本上连续的消融组织损伤。显示装置可用于呈现待消融的组织区域的图形表示。用户界面允许在图形表示上选择多个治疗点。界面优选地耦合到控制器和导管，使得控制器可以使导管响应于所接收的用户输入而自动地消融多个治疗点处和之间的组织。

