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(54) **SYSTEM AND METHOD FOR LOCALIZING MEDICAL INSTRUMENTS DURING CARDIOVASCULAR MEDICAL PROCEDURES**

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See application file for complete search history.

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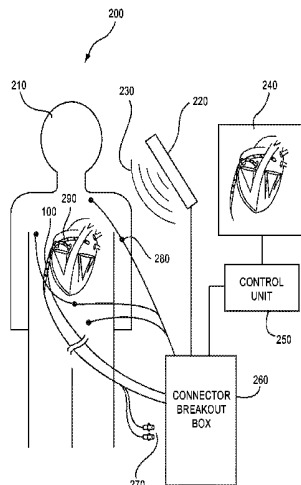
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(57)

ABSTRACT

A system and method for localizing medical instruments during cardiovascular medical procedures is described. One embodiment comprises an electromagnetic field generator; an antenna reference instrument adapted to be introduced into the heart of a subject and including at least one electromagnetic sensor and at least one electrode; at least one roving instrument adapted to be introduced into the thorax cavity of the subject and including at least one electrode; and a control unit configured to determine position coordinates of the antenna reference instrument based on an electromagnetic signal from the electromagnetic field generator sensed by the electromagnetic sensor, measure an electrical-potential difference between the electrode of the antenna reference instrument and the electrode of the roving instrument, and calibrate the measured electrical-potential difference using the determined position coordinates of the antenna reference instrument to determine position coordinates of the roving instrument.

15 Claims, 8 Drawing Sheets



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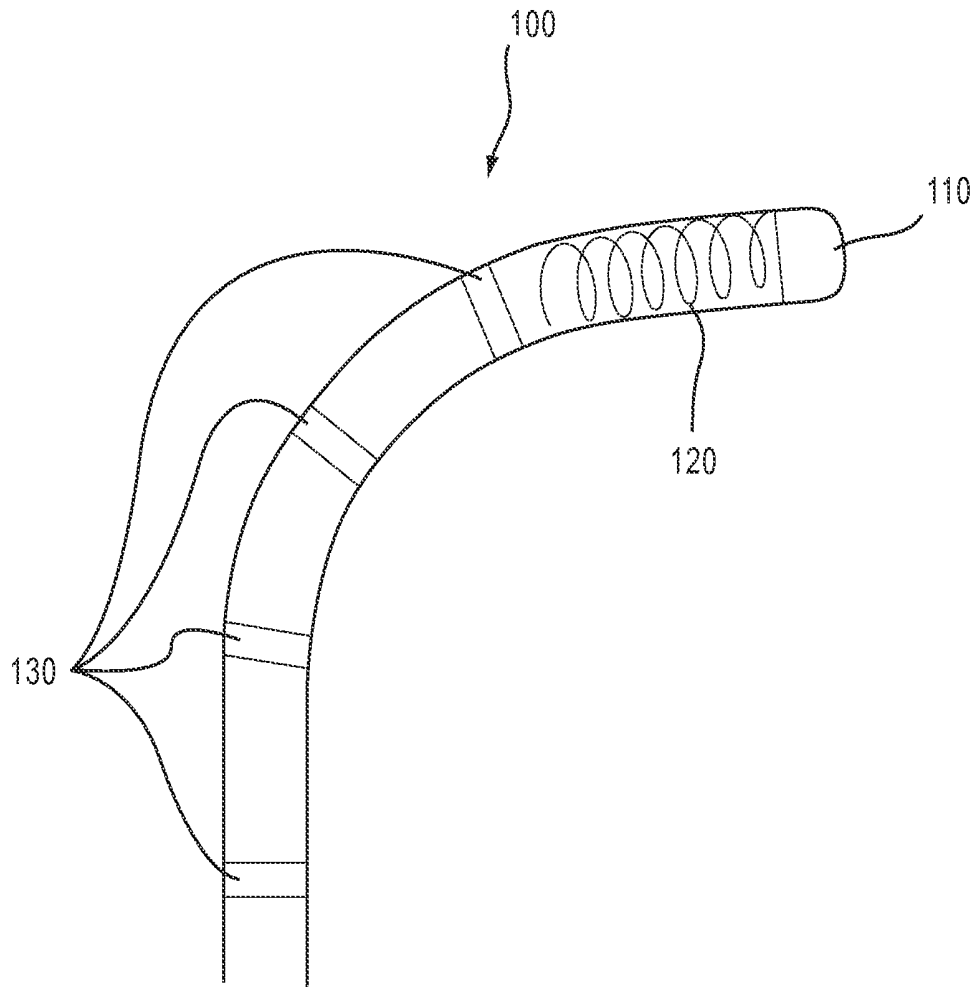


FIG.1

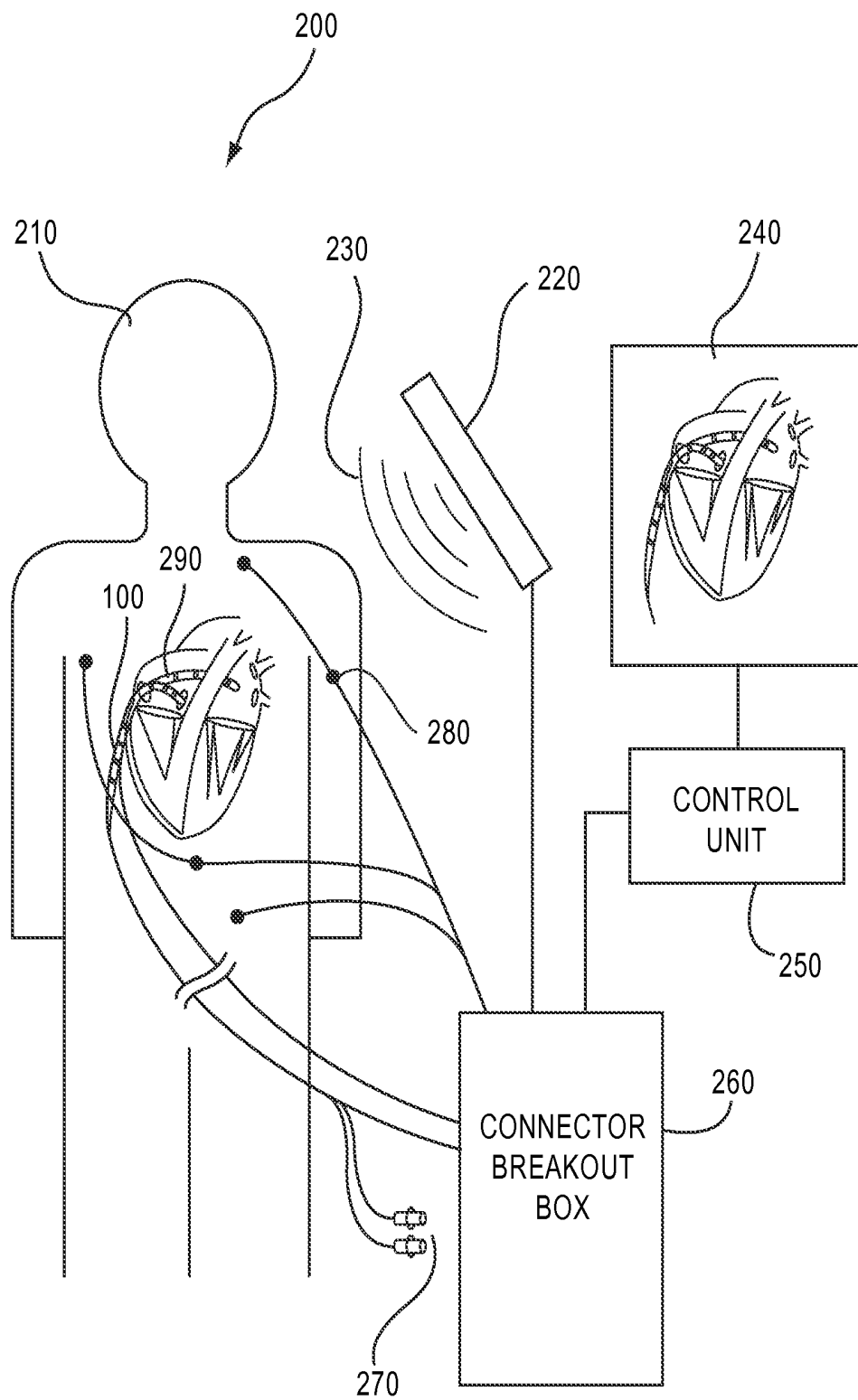


FIG. 2

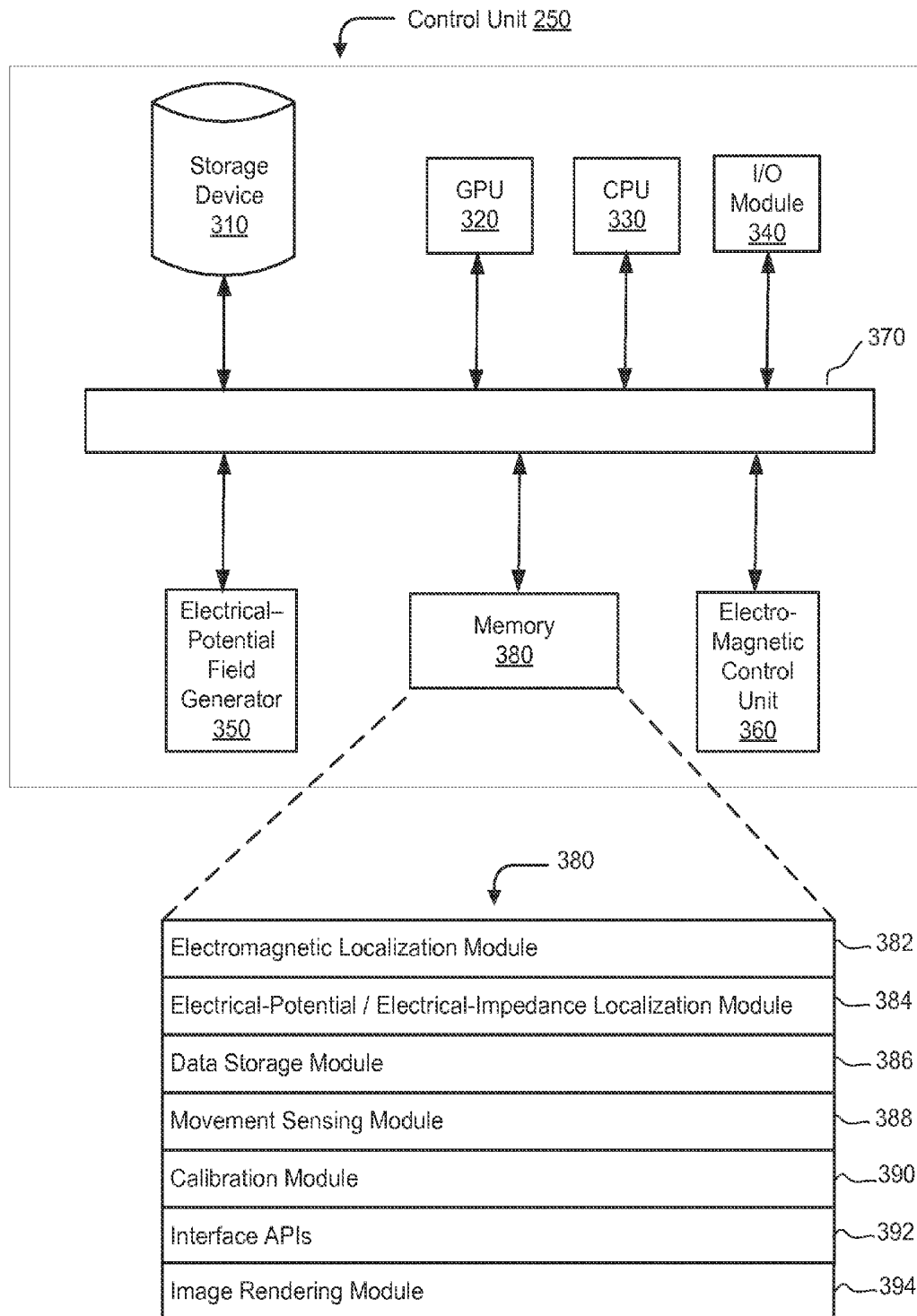


FIG. 3

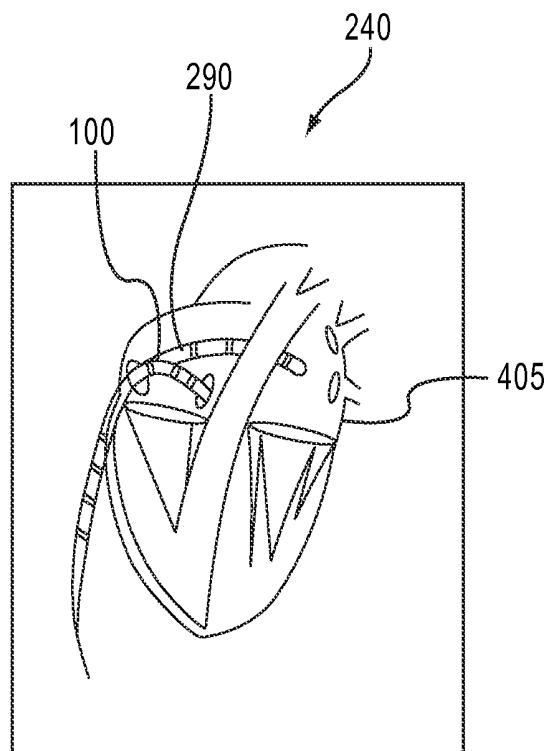


FIG. 4a

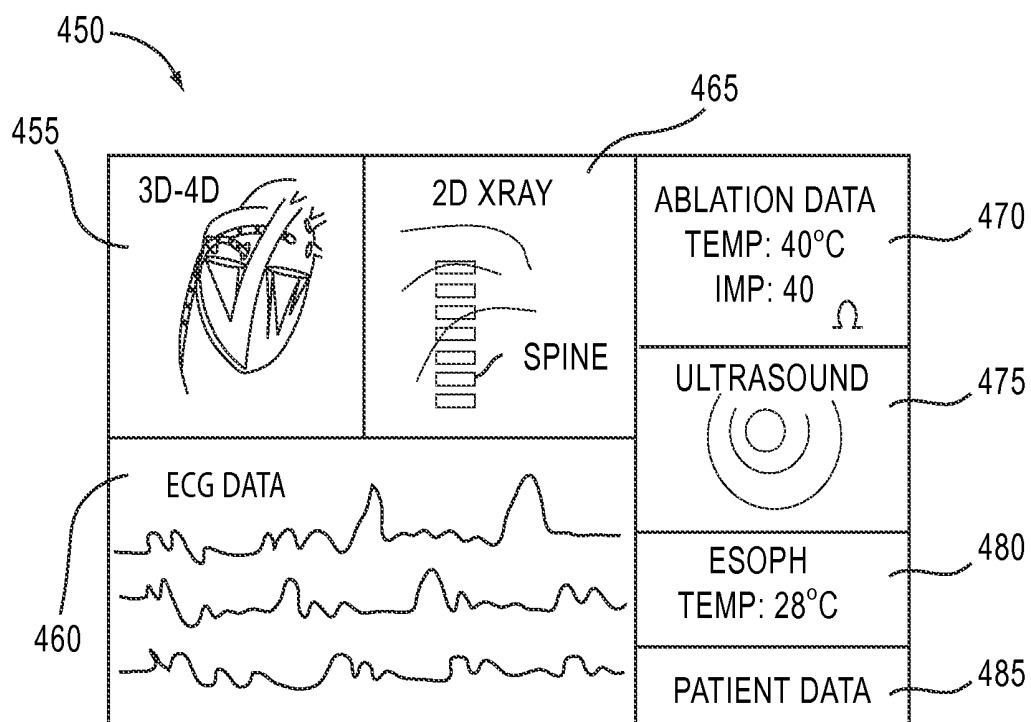


FIG. 4b

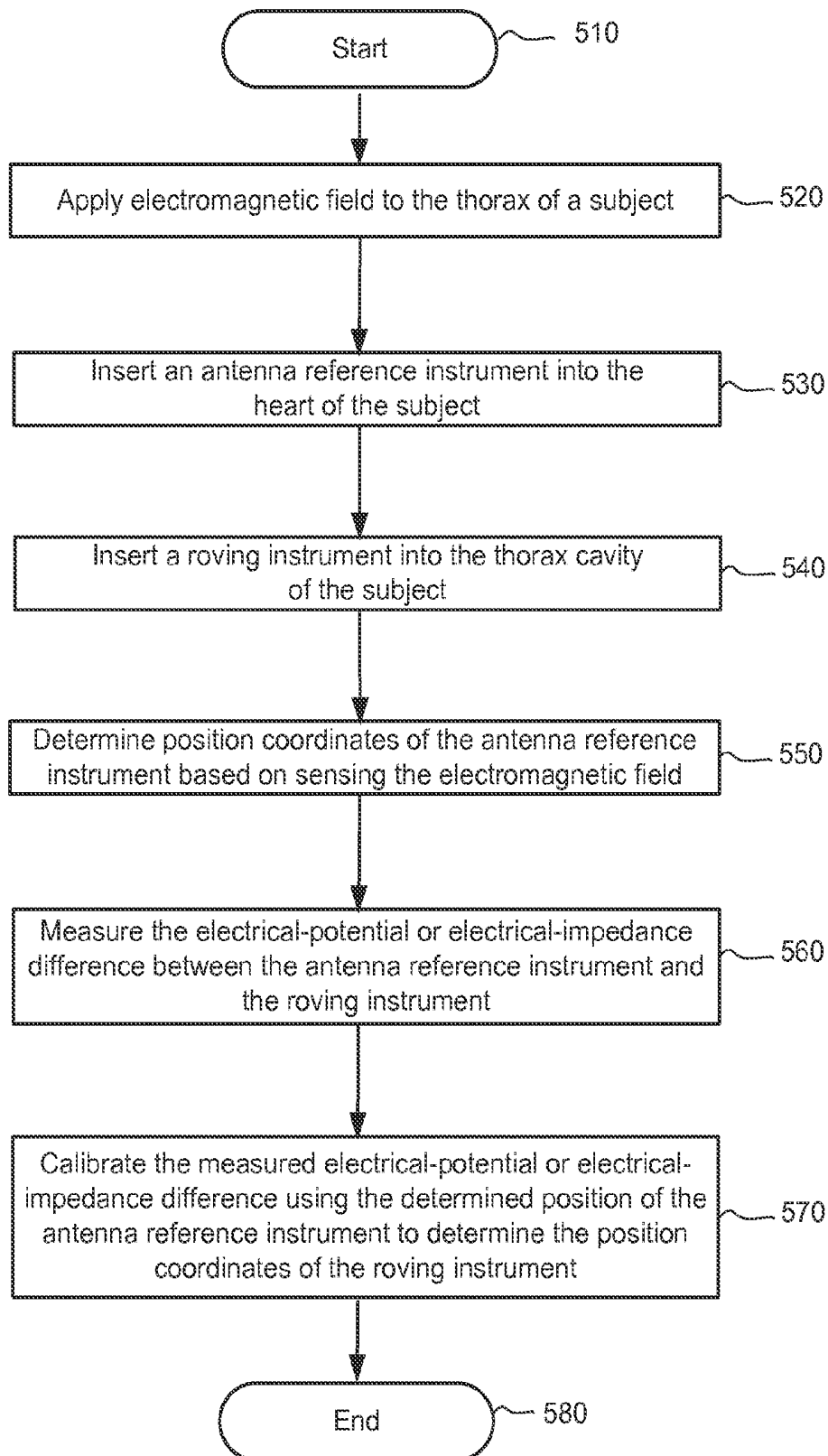


FIG. 5

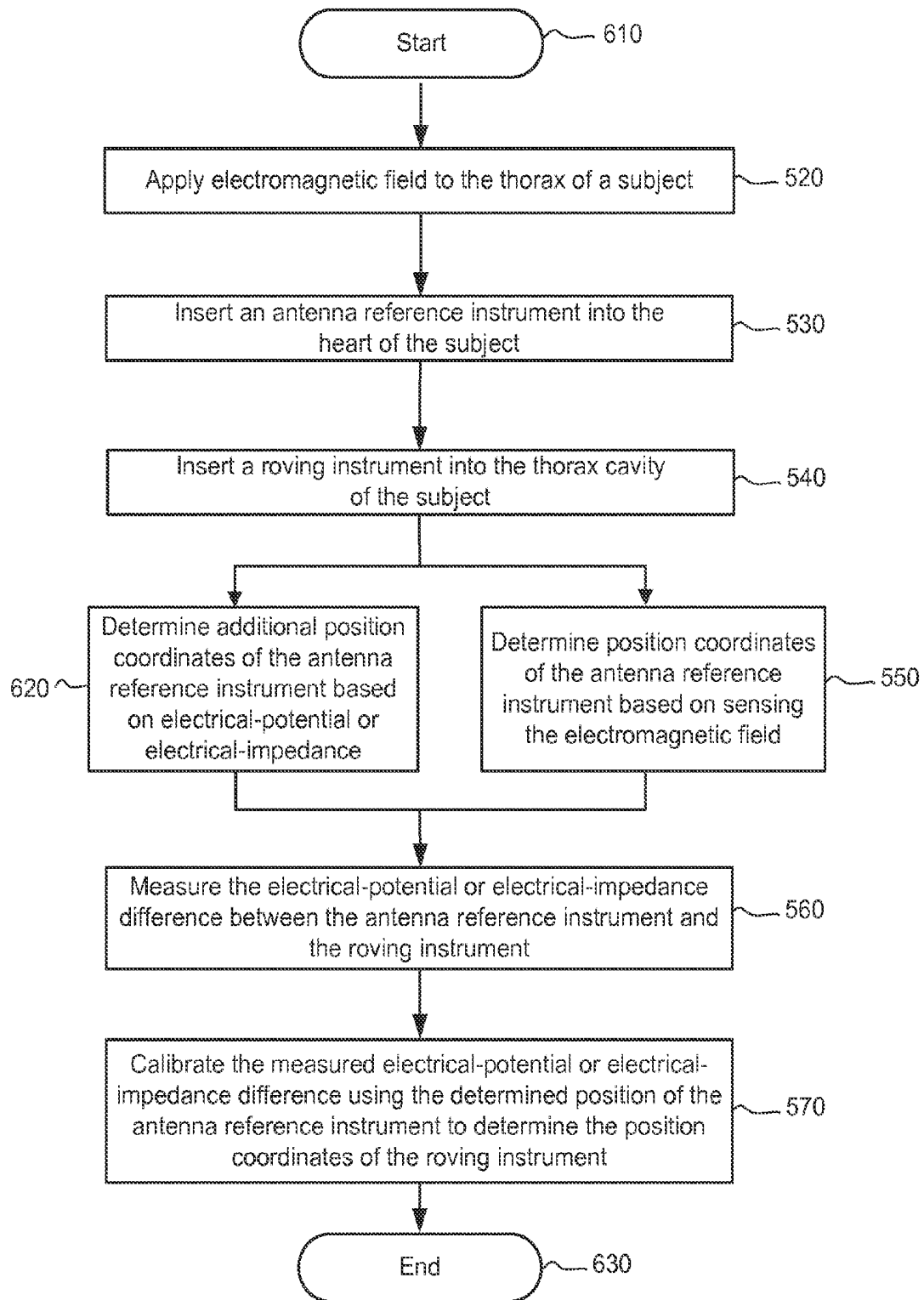


FIG. 6

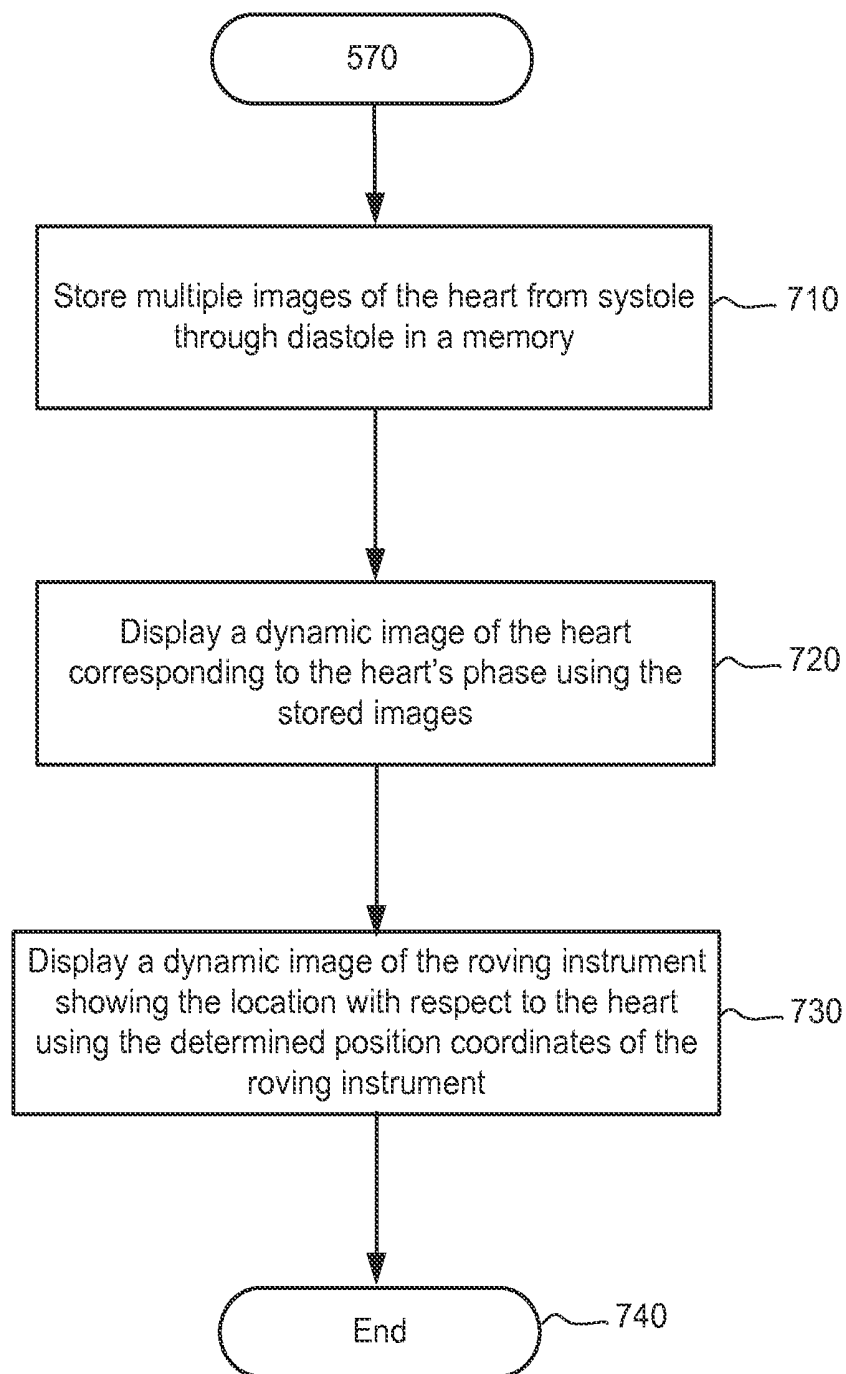


FIG. 7

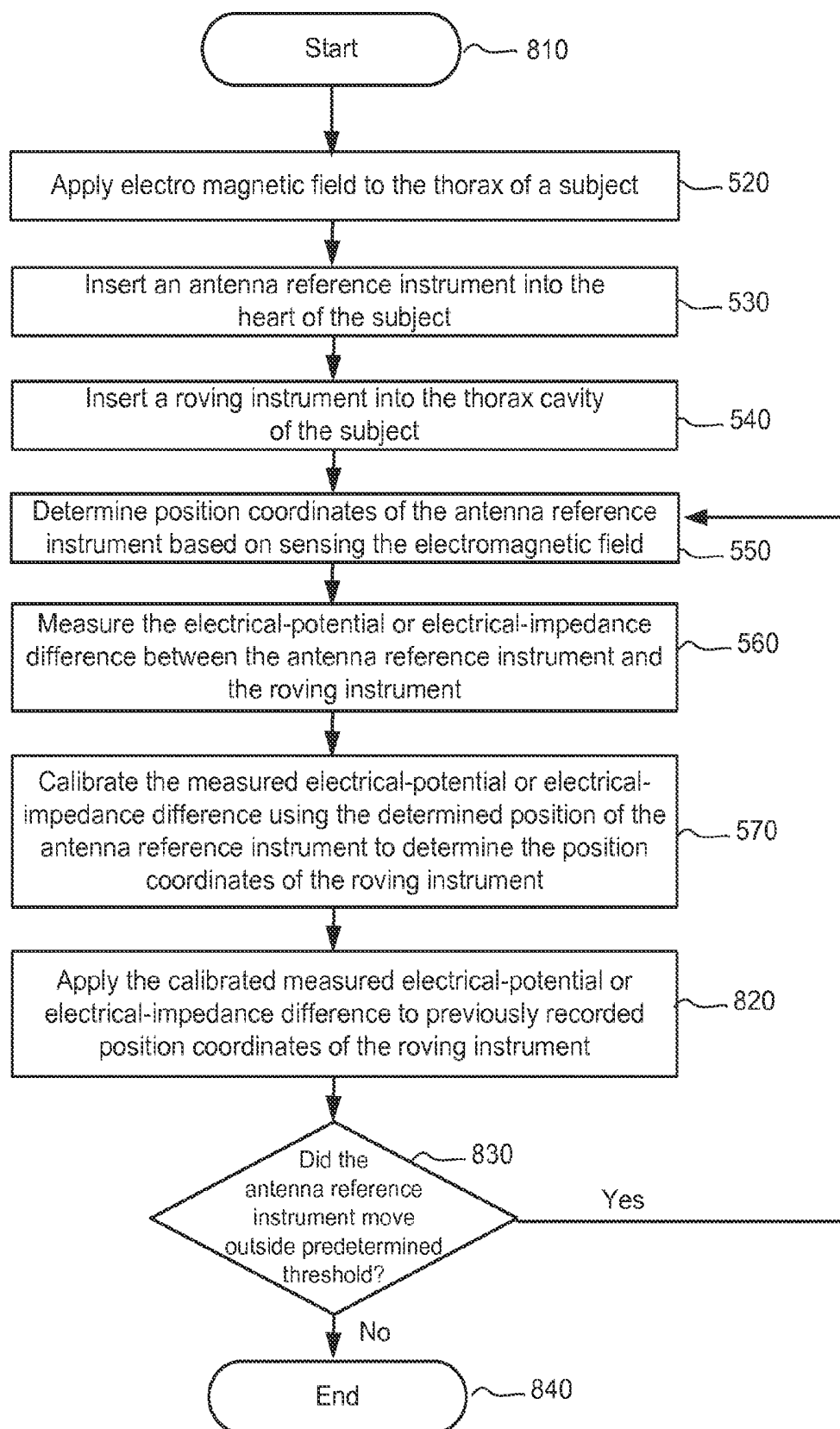


FIG. 8

SYSTEM AND METHOD FOR LOCALIZING MEDICAL INSTRUMENTS DURING CARDIOVASCULAR MEDICAL PROCEDURES

PRIORITY

This application claims priority, under 35 U.S.C. §119(e), to commonly owned and assigned U.S. Provisional Patent Application No. 61/622,220, entitled "Integrated Multi-Localizer Cardiovascular Navigation System and Associated Method," which is incorporated herein by reference in its entirety and for all purposes.

FIELD OF THE INVENTION

The present invention relates generally to systems and methods that aid physicians in performing surgical procedures on patients. More specifically, the invention relates to systems and methods for localizing medical instruments within a subject during cardiovascular medical procedures.

BACKGROUND OF THE INVENTION

Medical procedures to treat cardiovascular diseases are becoming less invasive in nature, such that a physician can insert a small medical device into a subject through a small incision and navigate the device through vasculature to the heart and the specific treatment site. One result is that the physician requires specialized tools to see where the device is travelling as well as the destination treatment location. Stereotactic navigation is the field of taking pre-acquired images of the anatomy of interest and using localization systems to track medical instruments with respect to the pre-acquired imaging. Stereotactic navigation requires position sensing capabilities to be able to locate and track the medical instruments within the human body and display the position with respect to other medical imagery like x-ray, CT, MRI, ultrasound, and electrocardiogram maps.

Current position sensing systems suffer from several issues. Position sensing systems need to provide flexibility to localize many different instruments based on physician preference, and accuracy in inhomogeneous tissues such as bone, air, blood, muscle, and fat, as those tissue characteristics change with breathing and heart beat. The balance of accuracy and flexibility is very difficult to achieve. Electromagnetic position sensing systems are often accurate systems because they do not depend on the tissue characteristics of the living body. However, electromagnetic systems are very proprietary in nature and require proprietary electromagnetic sensors embedded in every instrument used during the procedure that the physician needs to localize. Electrical-potential position sensing systems are typically very flexible in their ability to track different instruments in an open architecture manner using standard electrodes integrated into many medical instruments. However, the accuracy of electrical-potential systems is poor because they are susceptible to the varying tissue impedance changes due to breathing and heartbeat.

Attempts to combine the accuracy of electromagnetic localization and flexibility of electrical-potential localization have so far failed to provide a system that overcomes the issues of the separate systems. Current hybrid position sensing systems aim to calibrate a volume localized by electrical-potential localization to a volume localized by electromagnetic localization with a single instrument with respect to body surface electrodes and use that calibration to

track other instruments in a common calibrated volume. However, any calibration of electromagnetic localization field to electrical-potential localization field calculated by the single instrument is valid only at a particular point in time correlated with a particular point in a breathing cycle and heart beat cycle or is an average over time that is not particularly accurate at any given single point in time. The result is a gated position sensing system that is only accurate periodically.

Thus, a need exists for improved systems and methods of localizing medical instruments within a subject during minimally invasive cardiovascular medical procedures.

SUMMARY OF THE INVENTION

Illustrative embodiments of the present invention that are shown in the drawings are summarized below. These and other embodiments are more fully described in the Detailed Description section. It is to be understood, however, that there is no intention to limit the invention to the forms described in this Summary of the Invention or in the Detailed Description. One skilled in the art can recognize that there are numerous modifications, equivalents, and alternative constructions that fall within the spirit and scope of the invention as expressed in the claims.

In one illustrative embodiment, a position sensing system comprises an electromagnetic field generator; an antenna reference instrument adapted to be introduced into the heart of a subject, the antenna reference instrument including at least one electromagnetic sensor and at least one electrode; at least one roving instrument adapted to be introduced into the thorax cavity of the subject, the at least one roving instrument including at least one electrode; and a control unit configured to determine position coordinates of the antenna reference instrument based on an electromagnetic signal from the electromagnetic field generator sensed by the at least one electromagnetic sensor; measure an electrical-potential difference between the at least one electrode of the antenna reference instrument and the at least one electrode of the at least one roving instrument; and calibrate the measured electrical-potential difference using the determined position coordinates of the antenna reference instrument to determine position coordinates of the at least one roving instrument.

Another illustrative embodiment is a method for sensing the position of a medical instrument, comprising applying an electromagnetic field to the thorax area of a subject; inserting an antenna reference instrument into the heart of the subject, wherein the antenna reference instrument includes at least one electromagnetic sensor and at least one electrode; inserting at least one roving instrument into the thorax cavity of the subject, wherein the at least one roving instrument includes at least one electrode; determining position coordinates of the antenna reference instrument based on sensing the electromagnetic field using the at least one electromagnetic sensor; measuring an electrical-potential difference between the at least one electrode of the antenna reference instrument and the at least one electrode of the at least one roving instrument; and calibrating the measured electrical-potential difference using the determined position coordinates of the antenna reference instrument to determine position coordinates of the at least one roving instrument.

These and other embodiments are described in further detail herein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates an antenna reference instrument, according to an illustrative embodiment of the invention.

FIG. 2 illustrates a position sensing system, according to an illustrative embodiment of the invention.

FIG. 3 is a functional block diagram of a control unit for use in a position sensing system, according to an illustrative embodiment of the invention.

FIG. 4a illustrates a display for tracking instruments relative to a subject's heart, according to an illustrative embodiment of the invention.

FIG. 4b illustrates a display for tracking instruments relative to a subject's heart, according to another illustrative embodiment of the invention.

FIG. 5 is a flowchart of a method for determining the position of a roving instrument, according to an illustrative embodiment of the invention.

FIG. 6 is a flowchart of a method for determining the position of a roving instrument, according to another illustrative embodiment of the invention.

FIG. 7 is a flowchart of a method for displaying the position of a roving instrument, according to yet another illustrative embodiment of the invention.

FIG. 8 is a flowchart of a method for determining the position of a roving instrument, according to yet another illustrative embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

In various illustrative embodiments of the invention, a position sensing system used to navigate medical instruments through a patient's cardiovascular system during a cardiovascular procedure includes an antenna reference instrument that can be inserted into the heart of the patient and localized by at least two different systems. The antenna reference instrument can be inserted into a stable location in the heart by the physician and remain there for the duration of the procedure, providing a stable reference point. This reference point ensures that the images that the physician is viewing during the procedure are accurate. The antenna reference instrument can be localized by an electromagnetic system through its electromagnetic sensor and by an electrical-potential system through its electrodes. The absolute location of the antenna reference instrument is determined by a control unit using an electromagnetic field sensor that is embedded into the antenna reference instrument and the supporting electromagnetic field localization system. The absolute location of the antenna reference instrument is accurate because the electromagnetic system is not dependent on tissue characteristics, the patient's breathing, or the patient's heart beating. Additionally, roving instruments that are used to diagnose diseases and deliver treatments are included. Each roving instrument includes electrodes for localization by the electrical-potential system. Current typical instruments used to diagnose and treat cardiovascular diseases already include electrodes, which makes this a very open-architecture system as it can be used with widely available instruments that are already on the market. The control unit can determine the location of any one of the roving instruments by measuring the electrical-potential difference between the electrodes on the antenna reference instrument and the electrodes on the roving instrument in question. Because the antenna reference instrument location is known and stable, the control unit can calibrate the measurement to determine where the roving instrument is located. The location of the roving instrument is very accurate—even using electrical-potential measurements—because the tissue characteristics that negatively affect those measurements are minimized. Because the roving instru-

ment and antenna reference instruments are in the same tissue, the tissue characteristics can be disregarded, as both instruments are equally affected, and the position location system, in various illustrative embodiments, analyzes the difference between the two.

Referring now to the drawings, where like or similar elements are designated with identical reference numerals throughout the several views, and referring, in particular, to FIG. 1, it is a schematic illustration of the distal portion of antenna reference instrument 100, in accordance with an illustrative embodiment of the invention. Antenna reference instrument 100 can be any medical instrument that can be adapted to be inserted into the thorax of a subject and is associated with at least two location sensing systems. For example, as shown in FIG. 1, antenna reference instrument 100 can include multiple electrodes 130 for sensing current, voltage, or impedance, as well as electromagnetic sensor 120 for sensing an electromagnetic field. Antenna reference instrument 100 can include a catheter system, a pacemaker lead system, an implantable cardioverter defibrillator lead system, or any other suitable medical device, depending on the particular embodiment.

As stated above, antenna reference instrument 100, in some embodiments, includes a catheter system. In some embodiments, the thickness of the catheter lies in the range of 5 to 7 French. As shown in FIG. 1, the distal end of antenna reference instrument 100 can be curved, although this is not required. In some embodiments, the distal end of antenna reference instrument 100 is fixed, and in other embodiments the distal end of antenna reference instrument 100 has an adjustable deflection.

In some embodiments, distal cap electrode 110 is gold, platinum, silver, or any other suitable material for sensing electrical fields and/or applying electrical energy. Distal cap electrode 110 can be located at the distal tip of antenna reference instrument 100 or any other suitable location near the tip of the distal end of antenna reference instrument 100. In some embodiments, antenna reference instrument 100 does not include distal cap electrode 110. In some embodiments, instead of distal cap electrode 110, antenna reference instrument 100 includes a temporary or permanent pacing lead with fixation devices including, but not limited to, screws or permanent implantation anchors. One benefit of using a more permanent lead device is that, in follow-up procedures, a physician can connect to the already implanted lead, which provides a known location for antenna reference instrument 100.

In some embodiments, multiple electrodes 130 are made from gold, platinum, silver, or any other suitable material for sensing electrical fields. While FIG. 1 depicts four electrodes 130, antenna reference instrument 100 can include any number of electrodes 130. A typical range for the number of electrodes 130 is 1 to 21, though, in some embodiments, more than 20 electrodes can be used. Multiple electrodes 130 can be evenly or unevenly spaced along the catheter, depending on the particular embodiment.

Electromagnetic sensor 120 can be a single coil, as shown in FIG. 1, or electromagnetic sensor 120 can include multiple coils. Electromagnetic sensor 120 can be made of copper, platinum, gold, silver, or any other suitable metal for sensing electromagnetic fields.

In use, antenna reference instrument 100 can be inserted into the heart of a subject. The insertion point can be the femoral artery in the groin area or any suitable insertion point for a cardiovascular procedure on the subject. Once antenna reference instrument 100 is inserted into the heart, electromagnetic sensor 120 senses an electromagnetic field

applied, in some embodiments, to the thorax area of the subject. Multiple electrodes **130** can measure current, voltage, or impedance when electrical energy is applied to the thorax area of the subject.

FIG. 2 is a depiction of position sensing system **200**, according to an illustrative embodiment of the invention. FIG. 2 depicts subject **210**, electromagnetic field generator **220**, electromagnetic field **230**, monitor **240**, control unit **250**, connector breakout box **260**, guiding handles **270**, electrical-potential field pads **280**, roving instrument **290**, and antenna reference instrument **100**. In some embodiments, position sensing system **200** is used in a cardiovascular cathlab or operating theatre where other medical instruments, devices, and systems may be present and/or used.

Subject **210** can include a human, animal, or any other suitable subject having a heart.

Electromagnetic field generator **220** emits electromagnetic field **230**. In some embodiments, electromagnetic field generator **220** is aligned near subject **210** such that electromagnetic field **230** emitted from electromagnetic field generator **220** engulfs the thorax area of subject **210**.

As shown in FIG. 2, monitor **240**, in some embodiments, displays a graphical representation of the heart as it beats in subject **210**. Monitor **240** can display where roving instrument **290** and antenna reference instrument **100** are located within subject **210** in relation to the subject's heart. Monitor **240** can be configured to display the subject's heart as it beats (dynamically), statically, or not to show the subject's heart at all. Monitor **240** can be configured to display antenna reference instrument **100** alone, in relation to the subject's heart, in relation to one or more roving instruments **290**, in relation to both the subject's heart and one or more roving instruments **290**, or not at all. Monitor **240** can be configured to display roving instrument **290** alone, in relation to the subject's heart, in relation to antenna reference instrument **100**, in relation to other roving instruments **290**, in relation to the subject's heart and/or one or more other roving instruments **290** and/or antenna reference instrument **100**, or not at all. In some embodiments, position sensing system **200** includes multiple roving instruments **290**, which can also be displayed on monitor **240** in any of the combinations described above.

Monitor **240** can be any suitable monitor for displaying static or dynamic images. In some embodiments, position sensing system **200** may not include monitor **240**. In other embodiments, position sensing system **200** can include multiple monitors **240**.

In some embodiments, monitor **240** can be a touchscreen such that monitor **240** can receive input via options displayed on the screen, allowing the operator to choose the desired display configuration.

Control unit **250** can be connected to monitor **240** and connector breakout box **260**, as shown in FIG. 2. Control unit **250** is described in more detail below in connection with FIG. 3.

As shown in FIG. 2, in some embodiments, connector breakout box **260** is connected to control unit **250**, electromagnetic field generator **220**, electrical-potential field pads **280**, roving instrument **290**, and antenna reference instrument **100**. In other embodiments, connector breakout box **260** can also be connected to other devices and instruments that are used for the procedure. For instance, connector breakout box **260** can be connected to an RF generator, an ultrasound imaging device, an esophageal temperature probe, an electrocardiogram recording device, an x-ray device, a Computed Tomography ("CT") device, a Magnetic

Resonance Imaging ("MRI") device, a Positron Emission Tomography ("PET") device, an Optical Coherence Tomography ("OCT") device, and/or any other device used for the procedure.

As shown in FIG. 2, antenna reference instrument **100** can be a device, the distal end of which can travel through the artery system of subject **210** into the heart while navigation handle **270** remains outside subject **210**. The physician can use navigation handle **270** to guide the distal end of antenna reference instrument **100** to the desired location within subject **210**. The usable length of antenna reference instrument **100** is typically 65 to 110 centimeters, in some embodiments, although in other embodiments antenna reference instrument **100** may be longer than 110 centimeters or shorter than 65 centimeters. As shown in FIG. 1, antenna reference instrument **100** can have multiple sensors, such as one or more electromagnetic sensors **120** and one or more electrodes **130**.

As shown in FIG. 2, roving instrument **290** can also include navigation handle **270**, which can remain outside subject **210**. The physician can use navigation handle **270** to guide the distal end of roving instrument **290** to the desired location within subject **210**. Roving instrument **290** can include at least one electrode for sensing current, voltage, or impedance within subject **210**. While a single roving instrument **290** is shown in FIG. 2, multiple roving instruments **290** may be used in some embodiments.

Electrical-potential field pads **280** can be placed on the surface of subject **210**. FIG. 2 depicts five electrical-potential field pads **280**, however there may be more or fewer than five. Electrical-potential field pads **280** generate electrical current through subject **210**, which generates electrical fields that can be sensed by electrodes **130** on antenna reference instrument **100** and the electrodes on roving instrument **290**. Electrical-potential field pads **280** can be placed on subject **210** such that the electrical fields generated engulf the thorax area of subject **210**. For example, electrical-potential field pads **280** can send current through subject **210** from right armpit to left armpit, neck to groin, and front to back such that there is an effective X,Y,Z coordinate system of electrical current running through subject **210**.

In use, according to one embodiment, control unit **250** can instruct electromagnetic field generator **220** through connector breakout box **260** to generate electromagnetic field **230** that engulfs the thorax area of subject **210**. Control unit **250** can instruct electrical-potential field pads **280** to generate an electrical current through the thorax area of subject **210**, as described above.

Electromagnetic sensor **120** in antenna reference instrument **100** can sense electromagnetic field **230**, and electromagnetic sensor **120** can send a signal to control unit **250** through connector breakout box **260**. Control unit **250** can determine position coordinates of antenna reference instrument **100** based on the signal from electromagnetic sensor **120** in antenna reference instrument **100**. Measurements taken from the electromagnetic localization system can be taken in millimeters. In some embodiments, three-dimensional minimum and maximum locations can also be calculated and recorded. Though antenna reference instrument **100** is in a stable location—often the coronary sinus, but antenna reference instrument **100** may also be located in the fossa ovalis, high right atrium, right ventricular apex, or any other stable location—some movement of antenna reference instrument **100** is normal because of blood flow, heartbeat, and breathing of the subject. The minimum and maximum thresholds can be any number, but the movement typically does not exceed 1 centimeter.

Electrodes **130** in antenna reference instrument **100** can measure the impedance, voltage, and/or current generated by electrical-potential field pads **280**. Electrodes **130** can send an electrical-impedance and/or electrical-potential value to control unit **250** through connector breakout box **260**. Control unit **250** can determine position coordinates of antenna reference instrument **100** based on the electrical-impedance and/or electrical-potential value. In some embodiments, control unit **250** determines absolute position coordinates of antenna reference instrument **100** using electrical-potential.

The electrodes in roving instrument **290** are used to measure the impedance, voltage, and/or current generated by electrical-potential field pads **280**. The electrodes permit control unit **250**, through connector breakout box **260**, to determine a value for the measured electrical impedance and/or electrical potential. In some embodiments, control unit **250** measures the electrical-potential difference and/or the electrical-impedance difference between that measured at antenna reference instrument **100** and that measured at roving instrument **290**. Based on the measured difference, control unit **250** can calibrate the measured difference using the determined position coordinates of antenna reference instrument **100** and determine the position coordinates of roving instrument **290**.

Control unit **250** can convert the position coordinates for antenna reference instrument **100** and roving instrument **290** into an image to be displayed on monitor **240**.

FIG. **3** is a functional block diagram of a computerized control unit **250**, according to an illustrative embodiment of the invention. In FIG. **3**, CPU **330** and GPU **320** communicate over data bus **370** with each other, I/O module **340**, storage device **310**, electrical-potential field generator **350**, electromagnetic control unit **360**, and memory **380**. While FIG. **3** depicts only a single CPU, multiple CPUs, a multi-core CPU, or multiple multi-core CPUs may be present in some embodiments. Similarly, though a single GPU is depicted in FIG. **3**, multiple GPUs, multi-core GPUs, or multiple multi-core GPUs may be present in some embodiments. In some embodiments, CPU **330** and GPU **320** can be configured to process instructions in parallel.

Storage device **310** can include, for example, hard disk drives, storage arrays, network-attached storage, tape-based storage, optical storage, flash-memory-based storage, or any other suitable storage device for use in a computer system. While FIG. **3** depicts a single storage device **310**, multiple storage devices may be present in some embodiments.

I/O Module **340** facilitates communication with external devices that communicate with control unit **250**. For example, I/O module **340** can facilitate communication with monitor **240** or connector breakout box **260**.

In some embodiments, electrical-potential field generator **350** is a module in control unit **250** that controls electrical-potential field pads **280**. For example, electrical-potential field generator **350** can control the current flowing through the subject between electrical-potential field pads **280**, which generates an electrical-potential field in subject **210**. In an illustrative embodiment, electrical-potential field generator **350** can create three separate signals, distinguishable by some characteristic such as frequency, phase, or time so that an X, Y, and Z signal can be separated out to determine position coordinates of the sensing electrode.

Electromagnetic control unit **360** can be a module in control unit **250** that controls electromagnetic field generator **220**. Electromagnetic control unit **360** can control the intensity of electromagnetic field **230**, as well as turn electromagnetic field generator **220** on and off.

Memory **380** may include, without limitation, random access memory ("RAM"), read-only memory ("ROM"), or flash memory. While FIG. **3** shows a single memory, in some embodiments multiple memory devices including combinations of types may be used. In one embodiment, as shown in FIG. **3**, memory **380** includes executable program instructions conceptualized as functional modules, including electromagnetic localization module **382**, electrical-potential/electrical-impedance localization module **384**, data storage module **386**, movement sensing module **388**, calibration module **390**, interface APIs **392**, and image rendering module **394**. In other embodiments, the program instructions may be divided into more or fewer modules, and the functional boundaries among the modules can differ from what is indicated in FIG. **3**.

Electromagnetic localization module **382** determines position coordinates of instruments, including antenna reference instrument **100**, that include electromagnetic sensor **120**. In some embodiments, electromagnetic localization module **382** converts the signals from electromagnetic sensor **120** into X, Y, and Z position coordinates.

Electrical-potential/electrical-impedance localization module **384** determines position coordinates of instruments, including antenna reference instrument **100** and roving instruments **290**, that include one or more electrodes **130**. In some embodiments, electrical-potential/electrical-impedance localization module **384** converts the signals from electrode **130** into X, Y, and Z position coordinates.

Data storage module **386** controls the storage of data, including, without limitation, position coordinates or images and data from the many devices that I/O module **340** communicates with, as described above.

Movement sensing module **388** recognizes movement of antenna reference instrument **100** beyond the predetermined threshold described above. In some embodiments, if antenna reference instrument **100** moves, the physician can be notified through a visual or audio alert. The physician can move antenna reference instrument **100** back to the stable location within the predetermined threshold. In some embodiments, the new location of antenna reference instrument **100** can be used, and an offset can be applied to recalibrate the stored images and data for accurate display of the locations of antenna reference instrument **100** and roving instrument **290**.

Calibration module **390** calibrates the measured differences in electrical-potential or electrical-impedance between antenna reference instrument **100** and roving instrument **290**. Within the calibration module **390**, various mathematical operations are performed. In some embodiments, a three-space coordinate system can be created with voltage values in each orthogonal (anterior-posterior, inferior-superior, and laterally) axis. For example, electrical-potential field pads **280** can send electrical current through subject **210** from right armpit to left armpit, neck to groin, and front to back such that there is an effective X, Y, Z coordinate system of electrical current running through subject **210**. Each axis can have a different carrier frequency. In one embodiment, the X-axis frequency is 30 kHz, the Y-axis frequency is 31 kHz, and the Z-axis frequency is 32 kHz, although other carrier frequencies can be used. A composite voltage can be measured as a difference between an electrode on roving instrument **290** and an electrode **130** on antenna reference instrument **100**. A Fourier transformation can be performed on the composite voltage to extract the separate X, Y, and Z voltage measurements corresponding to the X, Y, Z coordinate system. These real-time X, Y, and Z voltage measurements can be placed into a memory buffer

and averaged over varying periods of time to smooth out any inherent noise in the system and provide the operator with various levels of sensitivity of roving-instrument motion, depending on the operator's haptic preference.

Similarly, in some embodiments, electrical-impedance differences are measured between an electrode on roving instrument 290 and an electrode 130 on antenna reference instrument 100. A Fourier transformation can be performed on the composite impedance measurement to extract the separate X, Y, and Z impedance measurements corresponding to the X, Y, Z coordinate system created by the electrical-potential field pads 280. Buffering and smoothing calculations can be performed to ensure noise cancellation and varying levels of roving instrument motion feedback.

Interface APIs 392 provide interfaces between control unit 250 and other devices, including, without limitation, an x-ray device, an RF generator, an ultrasound imaging device, an esophageal temperature probe, an electrocardiogram recording device, a Computed Tomography ("CT") device, a Magnetic Resonance Imaging ("MRI") device, a Positron Emission Tomography ("PET") device, an Optical Coherence Tomography ("OCT") device, and/or any other device used in a cardiovascular procedure.

FIG. 4a is an illustration, according to an illustrative embodiment of the invention, of monitor 240. Monitor 240 includes a rendered image of antenna reference instrument 100, the subject's heart 405, and roving instrument 290.

In some embodiments monitor 240 can display the heart dynamically such that the subject's heart 405 is shown as beating on monitor 240 substantially in time with the subject's true heartbeat. Monitor 240 can also display the movement of roving instrument 290 in substantially real-time as the physician moves roving instrument 290. The rendered image of antenna reference instrument 100 can also be shown in substantially real-time.

As described above, monitor 240 can be any suitable display monitor for use with a computer system, including without limitation a CRT, a touchscreen, an LCD, a plasma, or an LED display.

FIG. 4b is an illustration, according to another illustrative embodiment, of monitor 450. In this embodiment, the images displayed include not only the subject's heart in the heart display 455, but also include ECG data display 460, x-ray display 465, ablation data display 470, ultrasound display 475, esophageal data display 480, and other patient data display 485.

In one embodiment, the data displays described above are all updated by control unit 250. For example, as control unit 250, via Interface APIs 392, communicates with external devices such as the ultrasound imaging device and receives updated imaging information, GPUs 320 render the images and send the rendered images via I/O module 340 to ultrasound data display 475 on monitor 450.

FIG. 5 is a flowchart of a method for determining the position coordinates of roving instrument 290 in accordance with an illustrative embodiment of the invention. At 520, electromagnetic field 230 is applied to the thorax of a subject. In some embodiments, electromagnetic control unit 360 in control unit 250 sends a signal to electromagnetic field generator 220 that causes electromagnetic field generator 220 to emit electromagnetic field 230.

At 530, antenna reference instrument 100 is inserted into the heart of the subject. In some embodiments, the insertion point is the femoral artery in the groin area of the subject. From there, antenna reference instrument 100 is guided through the vasculature to the subject's heart.

At 540, roving instrument 290 is inserted into the thorax cavity of the subject. In some embodiments, the insertion point is the same as the insertion point for antenna reference instrument 100. However, the insertion point can include any suitable insertion point that allows access to the thorax cavity of the subject.

At 550, position coordinates of antenna reference instrument 100 are determined based on sensing electromagnetic field 230. In some embodiments, electromagnetic sensor 120 in antenna reference instrument 100 detects electromagnetic field 230 that was applied to the thorax area of the subject at 520. The electromagnetic sensor 120 conveys a signal to control unit 250. Electromagnetic localization module 382 interprets the signal and converts the signal into position coordinates of antenna reference instrument 100.

At 560, the electrical-potential and/or electrical-impedance difference between antenna reference instrument 100 and roving instrument 290 is measured. The electrodes 130 in antenna reference instrument 100 and the electrodes in roving instrument 290 each convey a signal to control unit 250. Electrical-potential/electrical-impedance localization module 384 interprets the signal and measures the electrical-potential and/or the electrical-impedance difference.

At 570, the position coordinates of roving instrument 290 are determined by calibrating the electrical-potential difference or the electrical-impedance difference between antenna reference instrument 100 and roving instrument 290 using the determined position coordinates of antenna reference instrument 100. Calibration module 390 uses the position coordinates of antenna reference instrument 100 determined at 550 and the measured electrical-potential and/or electrical-impedance difference measured at 560 to calibrate the difference and determine the position coordinates of roving instrument 290.

FIG. 6 is a flowchart of a method for determining the position coordinates of roving instrument 290 in accordance with an illustrative embodiment of the invention. As in the embodiment discussed in connection with FIG. 5, Blocks 520-570 are preformed. In some embodiments, at 620 additional position coordinates of antenna reference instrument 100 are determined in parallel with Block 550. This can provide redundant absolute location tracking of antenna reference instrument 100. At 620, electrodes 130 in antenna reference instrument 100 convey a signal to control unit 250. Electrical-potential/electrical-impedance localization module 384 interprets the signal and converts it into position coordinates of antenna reference instrument 100.

FIG. 7 is a flowchart of a method for displaying dynamic images of the localized instruments in accordance with an illustrative embodiment of the invention. Starting from Block 570 in FIG. 5 or FIG. 6, at 710, multiple images of the heart from systole through diastole are stored in a memory. The images may be captured from any of the external devices that communicate with control unit 250. For example, the images can be captured from an ultrasound imaging device, an x-ray device, an MRI device, and/or any other imaging device. Once captured by control unit 250, data storage module 386 stores the images on storage device 310.

At 720, the dynamic images of the heart are displayed on monitor (240, 450) corresponding to the subject's heart's phase, such that the images are displayed in substantially real-time with the beating heart of the subject. Image rendering module 394 utilizes GPU 320 to render images for display on monitor (240, 450) and correlates the display to occur in substantially real-time with the heart's phase by

utilizing input from the external devices that provide data indicating the phase of the heart, such as ECG data.

At 730, the roving instrument image is also rendered on monitor (240, 450), in this embodiment. Image rendering module 394 utilizes GPU 320 to render images for display on monitor (240, 450) and correlates the display to occur in substantially real-time as roving instrument 290 moves.

FIG. 8 is a flowchart of a method for correcting the display if antenna reference instrument 100 moves outside of a predetermined threshold, in accordance with an illustrative embodiment. In this embodiment, Blocks 520, 530, 540, 550, 560, and 570 remain the same as in FIGS. 5 and 6. At 820, the calibrated measured electrical-potential and/or electrical-impedance difference is applied to previously recorded position coordinates of roving instrument 290. Calibration module 390 can check for previously recorded position coordinates of roving instrument 290 and apply the calibration such that when the image of roving instrument 290 is rendered, it appears in the proper position because the position coordinates are properly calibrated in reference to antenna reference instrument 100.

At 830, the location of antenna reference instrument 100 is checked to determine whether it moved outside a predetermined threshold. If antenna reference instrument 100 moved sufficiently, the method returns to Block 550 and determines the new position coordinates of antenna reference instrument 100 based on sensing electromagnetic field 230 through electromagnetic sensor 120 in antenna reference instrument 100. In some embodiments, the position of antenna reference instrument 100 is tracked redundantly using both electromagnetic and electrical-potential positioning techniques. As described above, a predetermined threshold can be chosen because the beating of the subject's heart as well as the subject's breathing will cause antenna reference instrument 100 to move approximately 1 centimeter, which is considered normal. However, if antenna reference instrument 100 slips from its substantially stable location, the rendered images of roving instrument 290 will no longer be accurate without a recalibration. Once antenna reference instrument 100 moves, an offset can be applied to calibrate all the images to the new antenna reference instrument 100 location, allowing all location data to be accurate as displayed on monitor (240, 450). In this manner, shifts in position of antenna reference instrument 100 during the procedure can be compensated for.

While various embodiments have been described above, it should be understood that they have been presented by way of example only, and not limitation. Where methods and/or flowcharts described above indicate certain events and/or flow patterns occurring in a certain order, the ordering of certain events and/or flow patterns may be modified. While the embodiments have been particularly shown and described, it will be understood that various changes in form and details may be made.

For instance, in some embodiments multiple roving instruments may be used. In those embodiments, multiple measurement steps can be done to determine each roving instrument's location. Those measurement steps can be done in parallel, but they need not be done in parallel, depending on the embodiment.

Although various embodiments have been described as having particular features and/or combinations of components, other embodiments are possible having a combination of any features and/or components from any of the embodiments as discussed above. For example, while electromagnetic and electrical-potential or electrical-impedance localization methods were used throughout this disclosure, any

combination of those systems may be used. Additionally, other types of localization systems could be used.

In conclusion, the present invention provides, among other things, systems and methods for localizing medical instruments within a subject during cardiovascular medical procedures. Those skilled in the art can readily recognize that numerous variations and substitutions may be made in the invention, its use, and its configuration to achieve substantially the same results as achieved by the embodiments described herein. Accordingly, there is no intention to limit the invention to the disclosed exemplary forms. Many variations, modifications, and alternative constructions fall within the scope and spirit of the disclosed invention as expressed in the claims.

What is claimed is:

1. A position sensing system, comprising:
an electromagnetic field generator;

a distal portion of an antenna reference instrument adapted to be introduced minimally invasively into a living coronary sinus of a beating heart of a subject, the distal portion of the antenna reference instrument including at least one electromagnetic sensor and at least one electrode and having an adjustable deflection when located within the living coronary sinus;

at least one roving instrument adapted to be introduced into a thorax cavity of the subject, the at least one roving instrument including at least one electrode; and
a control unit configured to:

with the distal portion of the antenna reference instrument located within the living coronary sinus, determine position coordinates of the antenna reference instrument based on an electromagnetic signal from the electromagnetic field generator sensed by the at least one electromagnetic sensor when the electromagnetic sensor is disposed within the coronary sinus;

with the distal portion of the antenna reference instrument located within the living coronary sinus, measure an electrical-potential difference between the at least one electrode of the antenna reference instrument and the at least one electrode of the at least one roving instrument; and

with the distal portion of the antenna reference instrument located within the living coronary sinus, calibrate the measured electrical-potential difference using the determined position coordinates of the antenna reference instrument to determine position coordinates of the at least one roving instrument.

2. The position sensing system of claim 1, wherein the antenna reference instrument includes a catheter system designed for placement in and cannulation of the coronary sinus.

3. The position sensing system of claim 2, wherein the catheter system has a usable length of 65-110 centimeters, a thickness of 5-7 French, and one of a fixed and an adjustable deflection of 0-180 degrees, and wherein the catheter system includes 2-20 electrodes for sensing electrocardiograms and an integrated electromagnetic sensor that includes at least one metallic coil.

4. The position sensing system of claim 1, wherein the antenna reference instrument includes at least one of a pacemaker and an implantable cardioverter defibrillator ("ICD") lead system designed for placement in and cannulation of the coronary sinus.

5. The position sensing system of claim 4, wherein at least one of the pacemaker and the ICD lead system has a usable length of 65-110 centimeters, a thickness of 5-7 French, and

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one of a fixed and an adjustable deflection of 0-180 degrees, and wherein at least one of the pacemaker and the ICD lead system includes 2-20 electrodes for sensing electrocardiograms and an integrated electromagnetic sensor that includes at least one metallic coil.

6. The position sensing system of claim 1, wherein the control unit is configured to, with the distal portion of the antenna reference instrument located within the living coronary sinus, determine additional position coordinates of the antenna reference instrument based on electrical-potential sensed by the at least one electrode of the antenna reference instrument to provide redundant tracking of the antenna reference instrument.

7. The position sensing system of claim 1, further comprising a monitor connected to the control unit, wherein the control unit is configured to:

store multiple images of the heart from systole through diastole in a memory;

display, on the monitor and with the distal portion of the antenna reference instrument located within the living coronary sinus, a dynamic image of the heart corresponding to the heart's phase using the stored multiple images of the heart; and

display, on the monitor, a dynamic image of the at least one roving instrument showing the location of the at least one roving instrument with respect to the heart using the determined position coordinates of the at least one roving instrument.

8. The position sensing system of claim 1, wherein the control unit includes:

at least one central processing unit; and

at least two graphical processing units;

wherein the at least two graphical processing units are on separate graphics cards, and the control unit is configured to parallel process mathematical computations on the at least one central processing unit and the at least two graphical processing units.

9. The position sensing system of claim 1, wherein the control unit is configured to:

communicate via an application programming interface with at least one device, the at least one device including at least one of an RF generator, an ultrasound imaging device, an esophageal temperature probe, and an electrocardiogram recording device;

retrieve information from the at least one device; and

store the information in a memory.

10. The position sensing system of claim 1, wherein the control unit is configured to:

determine movement of the antenna reference instrument outside of a predetermined threshold to a new location when the distal portion of the antenna reference instrument is located within the living coronary sinus;

determine position coordinates of the antenna reference instrument at the new location based on (1) sensing an electromagnetic signal from the electromagnetic field generator using the at least one electromagnetic sensor when the electromagnetic sensor is located within the living coronary sinus;

with the distal portion of the antenna reference instrument located within the living coronary sinus, measure an electrical-potential difference between the at least one electrode of the antenna reference instrument at the new location and the at least one electrode of the at least one roving instrument;

with the distal portion of the antenna reference instrument located within the living coronary sinus, calibrate the measured electrical-potential difference using the

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determined position coordinates of the antenna reference instrument at the new location to determine position coordinates of the at least one roving instrument; and

with the distal portion of the antenna reference instrument located within the living coronary sinus, apply the calibrated measured electrical-potential difference to previously recorded position coordinates of the at least one roving instrument.

11. A position sensing system, comprising:

an electromagnetic field generator;

a distal portion of an antenna reference instrument adapted to be introduced minimally invasively into a living coronary sinus of a beating heart of a subject, the distal portion of the antenna reference instrument including at least one electromagnetic sensor and at least one electrode, the distal portion of the antenna reference instrument having an adjustable deflection when located within the living coronary sinus;

at least one roving instrument adapted to be introduced into a thorax cavity of the subject, the at least one roving instrument including at least one electrode; and

a control unit configured to perform the following steps when the distal portion of the antenna reference instrument is disposed in the coronary sinus of the beating heart of the subject:

determine first position coordinates of the antenna reference instrument based on (1) a first electromagnetic signal from the electromagnetic field generator sensed by the at least one electromagnetic sensor when the electromagnetic sensor is disposed within the coronary sinus;

determine second position coordinates of the antenna reference instrument based on (1) a second electromagnetic signal from the electromagnetic field generator sensed by the at least one electromagnetic sensor when the electromagnetic sensor is disposed within the coronary sinus;

identify a reference shift of the antenna reference instrument when a comparison of the first position coordinates to the second position coordinates exceeds a predefined threshold;

measure an electrical-potential difference between the at least one electrode of the antenna reference instrument and the at least one electrode of the at least one roving instrument; and

in response to the identified reference shift, calibrate the measured electrical-potential difference using the determined second position coordinates of the antenna reference instrument to determine position coordinates of the at least one roving instrument.

12. A position sensing system, comprising:

an electromagnetic field generator;

a distal portion of an antenna reference instrument adapted to be introduced minimally invasively into a moving coronary sinus of a living heart of a subject, the distal portion of the antenna reference instrument including at least one electromagnetic sensor and at least one electrode, the distal portion of the antenna reference instrument having an adjustable deflection such that the at least one electromagnetic sensor and the at least one electrode of the antenna reference instrument are deflectable relative to each other;

at least one medical instrument adapted to be introduced into the thorax cavity of the subject, the at least one medical instrument including at least one electrode; and

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a computerized control system configured to:

with the distal portion of the antenna reference instrument disposed within the moving coronary sinus, determine first position coordinates of the antenna reference instrument based on an electromagnetic signal from the electromagnetic field generator sensed by the at least one electromagnetic sensor when the at least one electromagnetic sensor is disposed within the moving coronary sinus;

with the distal portion of the antenna reference instrument disposed within the moving coronary sinus, determine second position coordinates of the antenna reference instrument based on electrical-potential sensed by the at least one electrode of the antenna reference instrument when the at least one electrode of the antenna reference instrument is disposed within the moving coronary sinus;

with the distal portion of the antenna reference instrument disposed within the moving coronary sinus, measure an electrical-potential difference between the at least one electrode of the antenna reference instrument and the at least one electrode of the at least one medical instrument; and

with the distal portion of the antenna reference instrument disposed within the moving coronary sinus, calculate the position of the at least one medical instrument based on the measured electrical-potential difference and the first position coordinates.

13. The position sensing system of claim 12, wherein the computerized control system is further configured to:

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with the distal portion of the antenna reference instrument disposed within the living coronary sinus, detect a reference shift of the antenna reference instrument to a new location based on the electromagnetic signal sensed by the at least one electromagnetic sensor;

with the distal portion of the antenna reference instrument disposed within the living coronary sinus, determine third position coordinates of the antenna reference instrument based on an electromagnetic signal from the electromagnetic field generator sensed by the at least one electromagnetic sensor at the new location;

with the distal portion of the antenna reference instrument disposed within the living coronary sinus, calculate an offset between the first position coordinates and the third position coordinates;

with the distal portion of the antenna reference instrument disposed within the living coronary sinus, apply the offset to the calculated position of the at least one medical instrument; and

with the distal portion of the antenna reference instrument disposed within the living coronary sinus, apply the offset to recorded position coordinates of the at least one medical instrument.

14. The position sensing system of claim 12, wherein the antenna reference instrument includes a pacemaker.

15. The position sensing system of claim 12, wherein the antenna reference instrument includes an implantable cardioverter defibrillator lead.

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专利名称(译)	用于在心血管医疗过程中定位医疗器械的系统和方法		
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[标]申请(专利权)人(译)	EDWARDS JEROME RANJEEV		
申请(专利权)人(译)	EDWARDS , JEROME RANJEEV		
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摘要(译)

描述了一种用于在心血管医疗过程期间定位医疗器械的系统和方法。一个实施例包括电磁场发生器;天线参考仪器,适于引入受试者的心脏并包括至少一个电磁传感器和至少一个电极;至少一个粗纱器,适于引入受试者的胸腔并包括至少一个电极;控制单元,被配置为基于来自电磁传感器感测的电磁场发生器的电磁信号来确定天线参考仪器的位置坐标,测量天线参考仪器的电极与粗纱的电极之间的电势差。仪器,并使用所确定的天线参考仪器的位置坐标校准测量的电势差,以确定粗纱仪器的位置坐标。

