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(54) System for determining the position of a medical device within a body

System zur Bestimmung der Position einer medizinischen Vorrichtung in einem Körper

Système pour déterminer la position d'un dispositif médical dans un corps

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EP 2 471 454 B1

Description

BACKGROUND OF THE INVENTION

a. Field of the Invention

[0001] This invention relates to a system for determining the position of a medical device within a body. In particular, the invention relates to a system that establishes a reference origin of a position coordinate system nearer the medical device to reduce errors in position measurements and that may also simplify the system by integrating components and functions of the system.

b. Background Art

[0002] US 2007/060833 A1 relates to systems for positioning and mapping electrophysiology catheters and ablation catheters in the heart of a patient, wherein no electronic control unit is disclosed configured to determine a position of a medical device responsive to a position signal generated by a device electrode and reflecting changes in voltage levels on the device electrode and a voltage output by a common reference node.

[0003] EP 2 204 120 A1 relates to a system and a method for multiple shell construction to emulate chamber contraction with a mapping system.

[0004] US 2009/0264739 A1 relates to surgical navigation systems and in particular to a system and a method for determining a position or a location of a sheath within an anatomy.

[0005] It is desirable to track the position of medical devices as they are moved within a body so that, for example, drugs and other forms of treatment are administered at the proper location and medical procedures can be completed more efficiently and safely. One conventional means to track the position of medical devices within the body is fluoroscopic imaging. Fluoroscopy is disadvantageous, however, because it subjects the patient and clinician to undesirable levels of electromagnetic radiation. As a result, medical device navigation systems have been developed to track the position of medical devices within the body. These systems typically rely on the generation of electrical or magnetic fields and the detection of induced voltages and currents on position sensors attached to the medical device and/or external to the body. The information derived from these systems is then provided to a clinician through, for example, a visual display.

[0006] One conventional medical device navigation system is offered for sale under the trademark "ENSITE NAVX" by St. Jude Medical, Inc. The system is based on the principal that when electrical currents are passed through the thorax a voltage drop occurs across internal organs such as the heart and this voltage drop can be measured and used to determine the position of a medical device within the body. The system includes three pairs of patch electrodes that are placed on opposed surfaces of the body (e.g., chest and back, left and right sides of the thorax, and neck and leg) and form generally orthogonal x, y, and z axes as well as a reference electrode that is typically placed near the stomach and provides a reference value and acts as the origin of the coordinate system for the navigation system. Sinusoidal currents are driven through each pair of patch electrodes and voltage measurements for one or more electrodes associated with the medical device are obtained. The measured voltages are proportional to the distance of the device electrodes from the patch electrodes. The measured voltages are compared to the potential at the reference electrode and a position of the device electrodes within the coordinate system of the navigation system is determined. Referring to Figure 1, the inventors herein have identified a simplified zero-order circuit 10 that illustrates the system for any given axis. Although the following description refers to impedances within circuit 10, only the real or resistive portion of a given impedance is used. In the illustrated circuit 10, the medical device within the body includes three electrodes represented by impedances 12_1, 12_2, 12_3. Amplifiers, filters and other signal processing circuitry for each electrode create impedances 14_1, 14_2, 14_3. The position of each electrode along the axis is determined responsive to the voltage at nodes 16_1, 16_2, 16_3 which, when divided by the drive current, will yield resistances. The resistance generated by the body is represented by resistance 20, denoted as R_b. The position (P) of an electrode along an axis may be obtained using the following equation (1):

$$P = \frac{S_f * R_b * R_i}{R_i + R_e}$$

where R_e is the resistance of the individual electrode (typically 100-500 ohms, but may exceed 1000 ohms with specialty electrodes), R_i is the input resistance of the amplifier (typically 200-1000 kilo ohms), S_f is a scale factor (e.g., 25mm/ohm), and R_b is the resistance of the body along the axis (typically 5-30 ohms).

[0007] The above-described system can be used to provide a substantially accurate indication of the position of the medical device. As indicated in the above-recited formula, however, the position determination along each axis is generally proportional to the resistance R_b of the body between the anatomical region of interest and the reference electrode. This resistance R_b varies along each axis. The varying body resistance R_b contributes to a variety of position measurement errors including: (1) drift resulting from a changing position of the medical device over time relative to the original measured position; (2) shift resulting from a changes to certain parameters (e.g., connection or disconnection of the medical device or movement of the reference electrode); (3) scatter resulting from variation of electrode impedances or the amplifiers and related circuitry; and (4) offset resulting from differences in impedance among the electrodes and amplifiers and related circuitry among multiple catheters. For example, in one realistic scenario the body resistance R_b between the location of the reference electrode and the anatomical region of interest may be 12 ohms with an input resistance R_i along the sense amplifier channel of 200 kilo ohms and a scale factors S_f of 25 mm/ohm. In the case of a specialty electrode having a nominal resistance R_e of 2 kilo ohms, the resistance may vary within a range of +/- 30%, or between 1.4 and 2.6 kilo ohms. If electrodes having 1.4 and 2.6 kilo ohms are placed at an identical location, the position of the electrode along the axis calculated using equation (1) would yield different results at 297.9 millimeters and 296.2 millimeters, respectively—a difference of 1.7 millimeters. In the case where multiple electrodes are separate by, for example, 5 millimeters on a catheter, 1 deviation of 1.7 millimeters about a mean along any of the three axes will result in a visible error. A linear catheter may be erroneously depicted with electrode locations creating a saw tooth pattern instead of a smooth pattern. As another example, the body resistance R_b may change over time due to, for example, a saline infusion received by a patient which will generally lower body resistance. If the initial body resistance R_b is again 12 ohms, a 2% reduction in R_b would change the 297.9 millimeter position location of the electrode referred to above to 291.9 millimeters-a 6 millimeter drift.

[0008] The use and placement of the reference electrode is also disadvantageous because clinicians are required to locate and place a separate electrode and facilities must likewise maintain an inventory of the electrodes. Medical device navigation systems employ special purpose electrodes, sensors and other components that are separately connected to the body surface. Oftentimes, these systems are used simultaneously with, and even cooperatively with, other systems employing different electrodes and sensors that are also connected to the body surface. For example, electrocardiography (ECG) electrodes are typically connected to the body during the same procedures in which navigation systems are used in order to monitor critical vital signs and as an input to the navigation system to compensate for motion of the heart. Similarly, magnetic navigation systems typically employ a sensor to monitor movement of the patient in order to compensate for this movement in determining the position of the medical device. The proliferation of electrodes, sensors and other components connected to the body increases the chance of error in setting up the various systems and increases the time required to prepare and complete a procedure.

[0009] The inventors herein have recognized a need for a system for determining the position of a medical device within a body that will minimize and/or eliminate one or more of the above-identified deficiencies.

BRIEF SUMMARY OF THE INVENTION

[0010] It is desirable to provide a system for determining the position of a medical device within a body. In particular, it is desirable to provide a system that will reduce errors in position measurements by establishing a reference origin for a coordinate system of the positioning system nearer the medical device to reduce the impact of body resistance and/or to simplify the system by integrating components and functions of the system.

[0011] A system in accordance with one embodiment of the invention for determining a position of a medical device within a body, the system defining a coordinate system, includes first and second drive electrodes. The first and second drive electrodes are configured to be affixed to opposed external surface of the body so as to create a first pathway for transmission of current through the body and thereby generate a voltage on a device electrode having a known positional relationship to the medical device. The system further includes first and second reference electrodes disposed proximate the first and second drive electrodes, respectively. The first and second reference electrodes and coupled to a common reference node. The common reference node outputs a reference signal establishing an origin of the coordinate system. An electronic control unit is configured to determine the position of the medical device responsive to a position signal generated by the device electrode and the reference signal.

[0012] A system in accordance with the above-described embodiment of the present invention is advantageous because it establishes a virtual reference electrode nearer to the medical device and more centrally located relative to axes on which currents are transmitted. As a result, body resistance between the medical device and the reference electrode is reduced or eliminated and measurement position errors resulting from drift, shift, scatter and offset are likewise reduced or eliminated. With reference to the example described above, for example, a reduction in the body resistance R_b from 12 ohms to 1.2 ohms will cause a corresponding order of magnitude reduction in the potential measurement errors. Thus, the 1.7 millimeter deviation resulting from the different resistance values of the electrodes becomes 0.17 millimeters. Similarly, the 6 millimeter drift resulting from variations in body resistance over time becomes 0.6 millimeters. As a result, the potential errors are brought within clinically acceptable measures.

[0013] Another embodiment of the system for determining a position of a medical device within a body, which does not form part of the invention, the system defining a coordinate system, includes a field generator and a position sensor generating a position signal indicative of a position of the medical device in the coordinate system. One of the field generator and the position sensor is disposed outside of the body and another of the field generator and the position sensor has a known positional relationship to the medical device. The system further includes a patch comprising a flexible and unitary base layer configured for attachment to an external surface of the body. The patch further includes a first device supported on the base layer and configured to perform a first function and a second device supported on the base layer and configured to perform a second function different from the first function. In one embodiment, which does not form part of the invention, for example, one of the devices comprises an electrode configured to establish an electrical pathway with another electrode disposed on an opposed surface of the body while the other device comprises an electrode configured to output a reference signal against which the position signal is compared. The second device is electrically isolated from the first device. The system further includes an electronic control unit configured to determine the position of the medical device responsive to the position signal and an output of at least one of the first and second devices.

[0014] According to a further development of the above-described embodiment, which does not form part of the invention, said second device comprises an electrode configured to detect electrical activity in a heart of said body.

[0015] According to a further development of the above-described embodiment, which does not form part of the invention, said second device comprises an electrode configured to establish an electrical pathway with another electrode disposed on a surface of said body.

[0016] According to a further development of the above-described embodiment, which does not form part of the invention, said second device comprises an electrode configured to output a reference signal against which said position signal is compared.

[0017] According to a further development of the above-described embodiment, which does not form part of the invention, said patch further includes a third device supported on said base layer and configured to perform a third function different from said first and second functions, said third device electrically isolated from said first and second devices.

[0018] A system in accordance with above-described embodiment, which does not form part of the invention is advantageous relative to conventional systems because it integrates component and/or functions that require separate components in conventional systems. As a result, fewer components are required for procedures thereby reducing inventory and procedural time and complexity.

[0019] The foregoing and other aspects, features, details, utilities and advantages of the present invention will be apparent from reading the following description and claims, and from reviewing the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020]

Fig. 1 is schematic diagram illustrating resistances in a circuit in a conventional medical position and navigation system.

Fig. 2 is a diagrammatic view of a system in accordance with the present teachings.

Fig. 3 is a diagrammatic representation of a patch in accordance with one embodiment of the present teachings.

Fig. 4 is a schematic diagram illustrating a circuit coupling drive and reference electrodes to other components of a system in accordance with the present teachings.

Fig. 5 is a diagrammatic representation of a system in accordance with another embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0021] Referring now to the drawings wherein like reference numerals are used to identify identical components in the various views, Fig. 2 illustrates one embodiment of a system 22 for determining the position of a medical device 24 in a body 26. System 22 may include a plurality of patch electrodes 28 applied to body 26, an electronic control unit (ECU) 30 and a display 32.

[0022] In the illustrated embodiment, system 22 is used to determine the position of medical device 24 within a heart 34. Medical device 24 may, for example, comprise a deformable catheter of the type used to allow removal of bodily fluids or injection of fluids and medicine into body 26 and/or for transporting surgical tools or instruments within body 16 including those use for pacing or tissue ablation of heart 34. The catheter may be manipulated by manually by a clinician or automatically through, for example, robotic controls and may be inserted within a vessel located near the surface of a body (e.g., in an artery or vein in the leg, neck, or arm) in a conventional manner and maneuvered to a region of interest in body 26 such as heart 34 under the guidance of system 22. Device 24 may, for example, comprise an electrophysiology (EP) mapping catheter for use in gathering EP data associated with heart 34 to enable generation of an image of the geometry of the heart surface and related EP data. Device 24 may alternatively comprise an intracardiac echocardiography (ICE) catheter used to generate an image of a region of interest within body 26 such as heart 34. Device 24 may alternatively comprise an ablation catheter used to ablate tissue within heart 34 to treat abnormal heart rhythms such as atrial fibrillation, ventricular tachycardia and similar conditions. Although examples of specific medical devices 24 associated with diagnosis and treatment of conditions associated with heart 34 have been described, it should be understood that the inventive system 22 may find application in connection with determining the position of a variety of medical devices in varying locations within human and non-human bodies. Medical device 24 includes one or more position sensors 36. In the illustrated embodiment, positions sensors 36 are electrodes configured to generate an induced voltage responsive to the transmission of current by patch electrodes 28.

[0023] Patch electrodes 28 are provided to generate electrical signals used in determining the position of device 24 within a three dimensional coordinate system 38 of system 22. Electrodes 28 may also be used to generate EP data regarding heart 34. Electrodes 28 are placed orthogonally on the surface of body 26 and are used to create axes specific electric fields within body 26. Electrodes 28_{X1}, 28_{X2} may be placed along a first (x) axis. Similarly, electrodes 28_{Y1}, 28_{Y2} may be placed along a second (y) axis and electrodes 28_{Z1}, 28_{Z2} may be placed along a third (z) axis. Each of the electrodes 28 may be coupled to a multiplex switch 40. ECU 30 is configured through appropriate software to provide control signals to switch 40 and thereby sequentially couple pairs of electrodes 28 to a signal generator 42. Excitation of each pair of electrodes 28 generates an electromagnetic field within body 26 and within an area of interest such as heart 34. Voltage levels at non-excited electrodes 28 may be filtered and converted and provided to ECU 30 for use as reference values.

[0024] Electronic control unit (ECU) 30 provides a means for controlling the operation of various components of system 22 including device 24, display 32 and switch 40. ECU 30 also provides a means for determining the position and orientation of medical device 24. ECU 30 may comprise a programmable microprocessor or microcontroller or may comprise an application specific integrated circuit (ASIC). ECU 30 may include a central processing unit (CPU) and an input/output (I/O) interface through which ECU 30 may receive a plurality of input signals including signals generated by device 24 (and particularly sensors 36) and patch electrodes 28 and generate a plurality of output signals including those used to control and/or provide data to device 24, display 32, and switch 40.

[0025] In operation, ECU 30 generates signals to control switch 40 and thereby selectively energize patch electrodes 28. ECU 30 receives position signals from position sensors 36 on device 24 reflecting changes in voltage levels on sensors 36 and from the non-energized patch electrodes 28. ECU 30 uses the raw location data produced by sensors 36 and electrodes 28 and corrects the data to account for respiration and other artifacts. ECU 30 then generates display signals to generate a display on display 32.

[0026] Display 32 is provided to convey information to a physician to assist in diagnosis and treatment. Display 32 may comprise a conventional computer monitor or other display device. Display 32 presents a graphical user interface (GUI) to the physician. The GUI may include a variety of information including, for example, an image of the geometry of heart 34, EP data associated with heart 34, graphs illustrating voltage levels over time for various electrodes, and images of medical device 24 and related information indicative of the position of device 24 relative to heart 34 and coordinate system 38.

[0027] As discussed hereinabove, conventional position and navigation systems based on the principal of passing electric currents through the thorax using electrodes 28 and measuring the resulting voltage drops on sensors 36 employ a reference electrode that is typically located near the stomach of body 26. The reference electrode serves as the origin of coordinate system 38 and the voltage measurements on sensors 36 are compared to the voltage at the reference electrode. In accordance with one embodiment of the present invention, the reference electrode is moved to a location on the surface of the body nearer heart 34. In yet another embodiment of the invention, a virtual reference electrode is established within body 26 and, preferably, within heart 34 as described hereinbelow.

[0028] Referring to Figure 3, in accordance with one embodiment of the invention, at least one of the electrodes-in this case patch electrode 28_{Z1}—is configured to perform multiple functions. In particular, patch electrode 28_{Z1} includes a device 44 comprising an electrode configured to establish an electrical pathway with another electrode (in this case 28_{Z2}) disposed on an opposed surface of body 26. Electrode 28_{Z1} also includes a device 46 comprising an electrode configured to act as a reference electrode and output a reference signal against which the voltage measurements on position sensors 36 are compared. Devices 44 and 46 are electrically isolated from one another. In the illustrated embodiment, devices 44 and 46 are mechanically connected to one another through the support of a common flexible base layer with an electrical insulator 48 separating devices 44 and 46. It should be understood, however, that devices 44 and 46 need not be mechanically connected and could be mechanically separate with an air gap serving as an insulator between devices 44, 46. In the illustrated embodiment, device 46 surrounds device 44 and is concentric with device 44. In this manner, devices 44 and 46 have a common geometric center. It should be understood, however, that device 44 may alternatively be arranged to surround device 46. Further, it should be understood that, while preferable, devices 44, 46 need not be arranged so as to be concentric and having a common geometric center and that the benefits of the invention are achieved by moving the reference electrode (here device 46) nearer to heart 34 and the location of positions sensors 36. Accordingly, for example, devices 44, 46 may be arranged to be side by side with their geometric centers offset from one another. Finally, although patch electrode 28_{Z1} is shown as a multi-function patch in the illustrated embodiment, it should be understood that any of patches 28_{X1}, 28_{X2}, 28_{Y1}, 28_{Y2}, or 28_{Z2} could be configured in the same manner.

[0029] Referring now to Figure 4, in accordance with another embodiment of the invention both of patches 28_{Z1} and 28_{Z2} may be configured as multi-function patches as discussed hereinabove. The devices 46 serving as a reference electrode on each of patches 28_{Z1} and 28_{Z2}

are tied to a common reference node 50. In this manner a virtual reference electrode is established within body 26 nearer to heart 34 and position sensors 36 as opposed to remaining on the surface of body 26. As a result, the origin of coordinate system 38 to which voltage measurements on sensors 36 are referenced is moved even closer to sensors 36 to further reduce position measurement errors. Devices 46 on patches 28_{Z1} and 28_{Z2} may be tied to reference node 50 through impedance devices 52, 54, respectively. Impedance devices may comprise a resistor or another conventional impedance device such as a capacitor or inductor. Impedance devices 52, 54 may have the same impedance value. Impedance devices 52, 54 preferably have different impedance values, however, to allow the virtual reference electrode and system origin to be located at a point other than the geometric center of a line connecting devices 46 of patches 28_{Z1} and 28_{Z2}. The heart 34, for example, is typically located nearer the chest than the back. Accordingly, impedance device 52 may have a lower impedance value relative to device 54 to move the virtual reference electrode and system origin to a location nearer the chest. In yet another embodiment of the invention, impedance devices 52, 54 have variable impedance values. Impedance devices 52, 54 may, for example, comprise potentiometers or variable resistors or rheostats. In this configuration, impedance devices 52, 54 may be adjusted to establish a reference electrode and system origin in an appropriate location despite anatomical differences among humans or across species. A method for establishing the virtual reference electrode and system origin may, for example, include the steps of introducing a medical device 24 with a position sensor 36 into an anatomical region of interest and adjusting the impedance values on devices 52, 54 until the difference in voltages generated by position sensor 36 and output at reference node 50 and is at a predetermined minimum level such that the location of position sensor 36 is established as the virtual reference electrode and system origin. Although the illustrated embodiment shows patches 28_{Z1} and 28_{Z2} configured as multi function patches and used to establish the reference electrode, it should be understood that patch pairs 28_{X1} and 28_{X2} or 28_{Y1} and 28_{Y2} could alternatively be configured in the same manner. Further, multiple patch pairs could be configured in the same manner and collectively or individual (through, e.g., one or more switches controlled by ECU 30) to reference node 50 in order to establish a virtual reference electrode and system origin at a precise location along multiple axes.

[0030] A system in accordance with the above-identified embodiments of the invention as defined in the claims represents an improvement relative to conventional systems. The inventive system locates the reference electrode serving as the origin of the navigation system's coordinate system 38 nearer to the anatomical region of interest, such as heart 34, and nearer to the position sensors 36 on medical device 24. Locating the reference electrode in this way reduces or eliminates the impact of the body's resistance on the position measurements and, particularly, in the inter axis variability of this resistance. Eliminating this resistance results in significant improvement in reducing or eliminating measurement errors due to drift resulting from a changing position of medical device 24 over time relative to the original measured position, shift resulting from a changes to certain parameters (e.g., connection or disconnection of medical device 24 or movement of the reference electrode, scatter resulting from variation of impedance among position sensors 36 and related circuitry and offset resulting from differences in impedance among the position sensors 36 and related circuitry among different devices 24. In the case of scatter for example, and with reference to equation (1) hereinabove, differences in impedance among individual electrodes will result in different determinations of electrode position even if the electrodes are actually located in the same position within the coordinate system 38. A reduction in body resistance, however, will cause a proportion reduction in the position values for the two electrodes and reduce the overall error in the measured difference in positions.

[0031] As discussed hereinabove, in one embodiment of the invention devices 44, 46 are integrated and supported on a common base layer of a patch electrode 28 affixed to the surface of body 26. Referring to Figure 5, in another aspect of the present invention, this concept can be extended to permit the integration of additional or different components and functions and use with other types of position and navigation systems. As shown in Figure 5, a system 56 for determining the position of a medical device 24 within a body 26 in accordance with another embodiment not forming part of the invention includes a field generator 58, a position sensor 60, a patch 62 affixed to the surface of body 26 and an electronic control unit (ECU) 64.

[0032] Field generator 58 generates an electrical and/or magnetic field used in determining the position of device 24 and navigating device 24. Field generator 58 may comprise an electric field generator as described hereinabove in system 22 in which electric currents are directed from a signal generator 42 through patch electrodes 28. Alternatively, field generator 58 may comprise a magnetic field generator such as those in the systems sold under the trademarks "GMPS" by Mediguide Ltd. or "CARTO" by Biosense Webster, Inc.

[0033] Position sensor 60 generates a position signal indicative of a position of medical device 24 in a coordinate system 66 of system 56. Sensor 60 may be mounted on device 24. Alternatively, sensor 60 may be physically separate from device 24 and offset from device 24 at a fixed distance. In any event, sensor 60 has a known positional relationship to device 24 such that the output of sensor 60 is indicative of the position of device 24. The type of position sensor 60 employed will depend on the type of field generator 58. If the field generator 58 is an electric field generator as in system 22, position sensor 60 may comprise a conventional electrode. If the field generator 58 is a magnetic field generator, position sensor 60 may comprise a conventional coil on which a current is induced. Sensor 60 will generate a voltage and/or current that is indicative of the position of sensor 60 and device 24 and provide a corresponding position signal to ECU 64. Although position sensor 60 is shown on or near device 24 in the illustrated embodiment while field generator 58 is disposed outside of the body, it should be understood that these roles may be reversed with field generator 58 within body 26 in a known positional relationship relative to device 24 and position sensor 60 disposed outside of body 26.

[0034] Patch 62 is used to affix various components of system 56 to body 26 and may perform a plurality of functions as described below. Patch 62 includes a base layer 66 and multiple devices such as devices 68, 70, 72, 74 configured to perform different functions and electrically isolated from one another on patch 62.

[0035] Base layer 66 comprises a flexible and unitary structure on which devices 68, 70, 72, 74 are supported. Base layer 66 is conventional in the art and may be made from conventional materials such as polytetrafluoroethylene (PTFE). Base layer 66 may be made from an electrically conductive material and may include an adhesive on one side configured to allow base layer 66 to attach and adhere to the external surfaces of body 26. Base layer 66 may also include insulation separating devices 68, 70, 72, 74 from one another to electrically isolate devices 68, 70, 72, 74.

[0036] Devices 68, 70, 72, 74 may be configured to provide a variety of functions. In accordance with the present invention, one or more of devices 68, 70, 72, 74 generate an output that is used by ECU 64 together with the position signal generated by position sensor 60 to determine the position of position sensor 60 and device 24. As discussed hereinabove, devices 68 and 70 may (similar to devices 44, 46) comprise electrodes configured to establish an electrical pathway with another electrode disposed on an opposed surface of body 26 and configured to output a reference signal against which the position signal from sensor 60 is compared, respectively. Devices 72, 74 may perform additional functions relied upon in assessing the position of sensor 60 and/or providing additional information regarding system 22. Device 72, for example, may comprise an electrode configured to detect electrical activity in heart 34 (i.e. an ECG electrode). This information can be used to compensate for change s in position of sensor 60 due to movement of heart 34 and/or to provide information regarding electrical activity of heart 34. Device 74 may comprise a position sensor for detecting movement of body 26. In the case where field generator 58 is a magnetic field generator, for example, device 74 may comprise a coil whose output is indicative of a change in position of the body within the generated magnetic field such as the body position sensor used in the magnetic position and navigation system sold under the trademark "GMPS" by Mediguide, Ltd. This information can be used to compensate for change in position of sensor 60 due to movement of body 26 relative to the generated magnetic field.

[0037] Although patch 62 is shown in the illustrated embodiment with four devices 68, 70, 72, 74, it should be understood that the number and type of devices employed on patch 62 will depend on the nature of the position and navigation system employed. For example, patch 62 may include only devices 72, 74 if a magnetic position and navigation system is used while patch 62 may include devices 68, 70, 72 if a system such as system 22 is used.

[0038] ECU 64 provides a means for controlling the operation of various components of system 56 including device 24, display 32 and field generator 58. ECU 64 also provides a means for determining the position and orientation of medical device 24. ECU 64 may comprise a programmable microprocessor or microcontroller or may comprise an application specific integrated circuit (ASIC). ECU 64 may include a central processing unit (CPU) and an input/output (I/O) interface through which ECU 64 may receive a plurality of input signals including signals generated by device 24 (and particularly sensors 60) and devices 68, 70, 72, 74 on patch 62 and generate a plurality of output signals including those used to control and/or provide data to device 24, display 32, and field generator 58.

[0039] In operation, ECU 64 generates signals to control field generator 58. ECU 64 receives position signals from position sensors 60 on device 24 reflecting changes in voltage or current levels on sensors 60 and other sensors within system 56. ECU 64 uses the raw location data produced by sensors 60 and corrects the data to account for respiration and other artifacts. ECU 64 then generates display signals to generate a display on display 32.

[0040] A system 56 for determining a position of medical device 24 within body 26 is advantageous relative to conventional systems because it integrates component and/or functions that are separate in conventional systems. As a result, fewer components are required for procedures thereby reducing inventory and procedural time and complexity.

[0041] 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 scope of this invention as defined in the claims. All directional references (e.g., upper, lower, upward, downward, left, right, leftward, rightward, top, bottom, above, below, vertical, horizontal, clockwise and counterclockwise) are only used for identification purposes to aid the reader's understanding of the present invention, and do not create limitations, particularly as to the position, orientation, or use of the invention. Joinder references (e.g., attached, coupled, connected, and the like) are to be construed broadly and may include intermediate members between a connection of elements and relative movement between elements. As such, joinder references do not necessarily infer that two elements are directly connected and in fixed relation to each other. 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 as limiting.

[0042] It is explicitly stated that all features disclosed in the description and/or the claims are intended to be disclosed separately and independently from each other for the purpose of original disclosure as well as for the purpose of restricting the claimed invention independent of the composition of the features in the embodiments and/or the claims. It is explicitly stated that all value ranges or indications of groups of entities disclose every possible intermediate value or intermediate entity for the purpose of original disclosure as well as for the purpose of restricting the claimed invention, in particular as limits of value ranges.

Claims

1. A system for determining a position of a medical device (24) within a body (26), said system defining a coordinate system (38) and comprising:

first and second drive electrodes (44) configured to be affixed to opposed external surface of said body (26) so as to create a first pathway for transmission of current through said body (26) and thereby causing a device electrode (36) having a known positional relationship to said medical device (24) to generate an induced voltage responsive to the transmission of current through the body (26);
first and second reference electrodes (46) disposed proximate said first and second drive electrodes (44), respectively, and coupled to a common reference node (50) for establishing a virtual reference electrode, said common reference node (50) outputting a voltage establishing an origin of said coordinate system (38);
an electronic control unit (30) configured to determine said position of said medical device (24) responsive to a position signal generated by said device electrode (36) and reflecting changes in voltage levels on the device electrode (36) and said voltage output by the common reference node (50).

2. The system of claim 1 further comprising a first impedance device (52) disposed between said first reference electrode (46) and said common reference node (50).

3. The system of claim 2 further comprising a second impedance device (54) disposed between said second reference electrode (46) and said common reference node (50).

4. The system of claim 3 wherein said first and second impedance devices (52, 54) have the same impedance value or wherein said first and second impedance devices (52, 54) have different impedance values.

5. The system of any one of claims 2 to 4 wherein an impedance value of said first impedance device (52) is variable.

6. The system of any one of claims 2 to 5 wherein said first impedance device (52) comprises a resistor.

7. The system of any one of claims 1 to 6 further comprising
third and fourth drive electrodes (44) configured to be affixed to opposed external surface of said body (26) so as to create a second pathway for transmission of current through said body orthogonal to said first pathway;
third and fourth reference electrodes (46) disposed proximate said third and fourth drive electrodes, respectively, and coupled to said common reference node (50).

8. The system of claim 7 further comprising
fifth and sixth drive electrodes (44) configured to be affixed to opposed external surface of said body so as to create a third pathway for transmission of current through said body (26) orthogonal to each of said first and second pathways;
fifth and sixth reference electrodes (46) disposed proximate said fifth and sixth drive electrodes, respectively, and coupled to said common reference node (50).

9. The system of any one of claims 1 to 8 wherein one of said first drive electrode and said first reference electrode surrounds the other of said first drive electrode and said first reference electrode.

10. The system of any one of claims 1 to 9 wherein said first drive electrode (28) and said first reference electrode (46) have a common geometric center.

11. The system of any one of claims 1 to 10 wherein said first drive electrode (28) and said first reference electrode (46) are supported on a unitary flexible base.

12. The system of claim 1 wherein said first drive electrode (44) and an ECG electrode are supported on a unitary base.

13. The system of claim 1 wherein said first drive electrode (44) and said first reference electrode (46) are electrically isolated from one another.

Patentansprüche

1. System zum Bestimmen einer Position einer medizinischen Vorrichtung (24) innerhalb eines Körpers (26), wobei das System ein Koordinatensystem (38) definiert und enthält:

   eine erste und zweite Treiberelektrode (44), die ausgelegt sind, um an gegenüberliegenden äußeren Flächen des Körpers (26) befestigt zu werden, um einen ersten Pfad zu erzeugen zur Übertragung eines Stroms durch den Körper (26), und um dadurch eine Vorrichtungselektrode (36), die eine bekannte Positionsbeziehung zu der medizinischen Vorrichtung (24) hat, zu veranlassen eine in Antwort auf die Übertragung des Stroms durch den Körper (26) induzierte Spannung zu erzeugen;
   eine erste und zweite Referenzelektrode (46), die benachbart zu der ersten bzw. zweiten Treiberelektrode (44) angeordnet und mit einem gemeinsamen Referenzknoten (50) gekoppelt sind zum Bilden einer virtuellen Referenzelektrode, wobei der gemeinsame Referenzknoten (50) eine Spannung ausgibt, die einen Ursprung des Koordinatensystems (38) bildet;
   eine elektronische Steuerungseinheit (30), die ausgelegt ist zum Bestimmen der Position der medizinischen Vorrichtung (24) in Antwort auf ein Positionssignal, das von der Vorrichtungselektrode (36) erzeugt wird, und zum Reflektieren von Änderungen in Spannungspegeln der Vorrichtungselektrode (36) und der von dem gemeinsamen Referenzknoten (50) ausgegebenen Spannung.

2. System nach Anspruch 1, ferner enthaltend eine erste Impedanzvorrichtung (52), die zwischen der ersten Referenzelektrode (46) und dem gemeinsamen Referenzknoten (50) angeordnet ist.

3. System nach Anspruch 2, ferner enthaltend eine zweite Impedanzvorrichtung (54), die zwischen der zweiten Referenzelektrode (46) und dem gemeinsamen Referenzknoten (50) angeordnet ist.

4. System nach Anspruch 3, bei dem die erste und die zweite Impedanzvorrichtung (52, 54) den gleichen Impedanzwert haben, oder bei dem die erste und die zweite Impedanzvorrichtung (52, 54) unterschiedliche Impedanzwerte haben.

5. System nach einem der Ansprüche 2 bis 4, bei dem ein Impedanzwert der ersten Im-pedanzvorrichtung (52) variabel ist.

6. System nach einem der Ansprüche 2 bis 5, bei dem die erste Impedanzvorrichtung (52) einen Widerstand enthält.

7. System nach einem der Ansprüche 1 bis 6, ferner enthaltend
   eine dritte und vierte Treiberelektrode (44), die ausgelegt sind, um an gegenüberliegenden äußeren Flächen des Körpers (26) befestigt zu werden, um so einen zweiten Pfad zur Übertragung eines Stroms durch den Körper senkrecht zu dem ersten Pfad zu erzeugen;
   eine dritte und vierte Referenzelektrode (46), die benachbart zu der dritten bzw. vierten Treiberelektrode angeordnet und mit dem gemeinsamen Referenzknoten (50) gekoppelt sind.

8. System nach Anspruch 7, ferner enthaltend
   eine fünfte und sechste Treiberelektrode (44), die ausgelegt sind, um an gegenüberliegenden äußeren Flächen des Körpers befestigt zu werden, um so einen dritten Pfad zur Übertragung eines Stroms durch den Körper (26) senkrecht zu jeweils dem ersten und zweiten Pfad zu erzeugen;
   eine fünfte und sechste Referenzelektrode (46), die benachbart zu der fünften bzw. sechsten Treiberelektrode angeordnet und mit dem gemeinsamen Referenzknoten (50) gekoppelt sind.

9. System nach einem der Ansprüche 1 bis 8, bei dem eine von der ersten Treiberelektrode und der ersten Referenzelektrode die andere von der ersten Treiberelektrode und der ersten Referenzelektrode umgibt.

10. System nach einem der Ansprüche 1 bis 9, bei dem die erste Treiberelektrode (28) und die erste Referenzelektrode (46) ein gemeinsames geometrisches Zentrum haben.

11. System nach einem der Ansprüche 1 bis 10, bei dem die erste Treiberelektrode (28) und die erste Referenzelektrode (46) auf einer unitären flexiblen Basis abgestützt sind.

12. System nach Anspruch 1, bei dem die ersten Treiberelektrode (44) und eine EKG-Elektrode auf einer unitären Basis abgestützt sind.

13. System nach Anspruch 1, bei dem die erste Treiberelektrode (44) und die erste Referenzelektrode (46) elektrisch voneinander isoliert sind.

Revendications

1. Système pour déterminer une position d'un dispositif médical (24) dans un corps (26), ledit système définissant un système de coordonnées (38) et comprenant :

des première et deuxième électrodes de commande (44) configurées pour être fixées à une surface extérieure opposée dudit corps (26) de manière à créer une première voie de passage pour la transmission de courant à travers ledit corps (26) et amenant ainsi une électrode de dispositif (36) ayant un rapport de position connu avec ledit dispositif médical (24) à générer une tension induite en réponse à la transmission de courant à travers le corps (26) ;
des première et deuxième électrodes de référence (46) disposées respectivement à proximité desdites première et deuxième électrodes de commande (44) et couplées à un noeud de référence commun (50) pour établir une électrode de référence virtuelle, ledit noeud de référence commun (50) produisant une tension établissant une origine dudit système de coordonnées (38) ;
une unité de commande électronique (30) configurée pour déterminer ladite position dudit dispositif médical (24) en réponse à un signal de position généré par ladite électrode de dispositif (26) et reflétant des changements des niveaux de tension sur l'électrode de dispositif (36) et ladite tension produite par le noeud de référence commun (50).

2. Système de la revendication 1 comprenant en outre un premier dispositif d'impédance (52) disposé entre ladite première électrode de référence (46) et ledit noeud de référence commun (50).

3. Système de la revendication 2 comprenant en outre un deuxième dispositif d'impédance (54) disposé entre ladite deuxième électrode de référence (46) et ledit noeud de référence commun (50).

4. Système de la revendication 3 dans lequel lesdits premier et deuxième dispositifs d'impédance (52, 54) ont la même valeur d'impédance ou dans lequel lesdits premier et deuxième dispositifs d'impédance (52, 54) ont des valeurs d'impédance différentes.

5. Système de l'une quelconque des revendications 2 à 4 dans lequel une valeur d'impédance dudit premier dispositif d'impédance (52) est variable.

6. Système de l'une quelconque des revendications 2 à 5 dans lequel ledit premier dispositif d'impédance (52) comprend une résistance.

7. Système de l'une quelconque des revendications 2 à 6 comprenant en outre
des troisième et quatrième électrodes de commande (44) configurées pour être fixées sur une surface extérieure opposée dudit corps (26) de manière à créer une deuxième voie de passage pour la transmission de courant à travers ledit corps orthogonale à ladite première voie de passage ;
des troisième et quatrième électrodes de référence (46) disposées respectivement à proximité desdites troisième et quatrième électrodes de commande et couplées audit noeud de référence commun (50).

8. Système de la revendication 7 comprenant en outre des cinquième et sixième électrodes de commande (44) configurées pour être fixées à une surface extérieure opposée dudit corps de manière à créer une troisième voie de passage pour la transmission de courant à travers ledit corps (26) orthogonale à chacune desdites première et deuxième voies de passage ;
des cinquième et sixième électrodes de référence (46) disposées respectivement à proximité desdites cinquième et sixième électrodes de commande et couplées audit noeud de référence commun (50).

9. Système de l'une quelconque des revendications 1 à 8 dans lequel une de ladite première électrode de commande et de ladite première électrode de référence entoure l'autre de ladite première électrode de commande et de ladite première électrode de référence.

10. Système de l'une quelconque des revendications 1 à 9 dans lequel ladite première électrode de commande (28) et ladite première électrode de référence (46) ont un centre géométrique commun.

11. Système de l'une quelconque des revendications 1 à 10 dans lequel ladite première électrode de commande (28) et ladite première électrode de référence (46) sont supportées sur une base flexible unitaire.

12. Système de la revendication 1 dans lequel ladite première électrode de commande (44) et une électrode ECG sont supportées sur une base unitaire.

13. Système de la revendication 1 dans lequel ladite première électrode de commande (44) et ladite première électrode de référence (46) sont isolées électriquement l'une de l'autre.

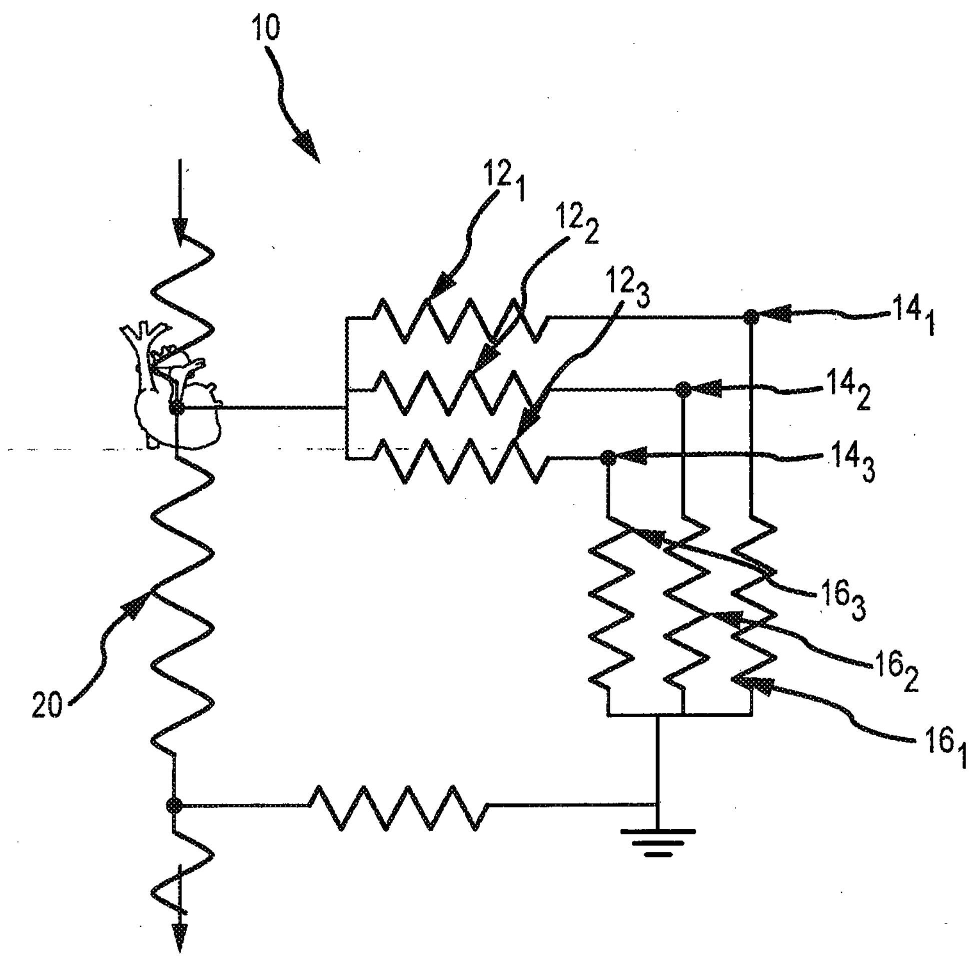

FIG.1

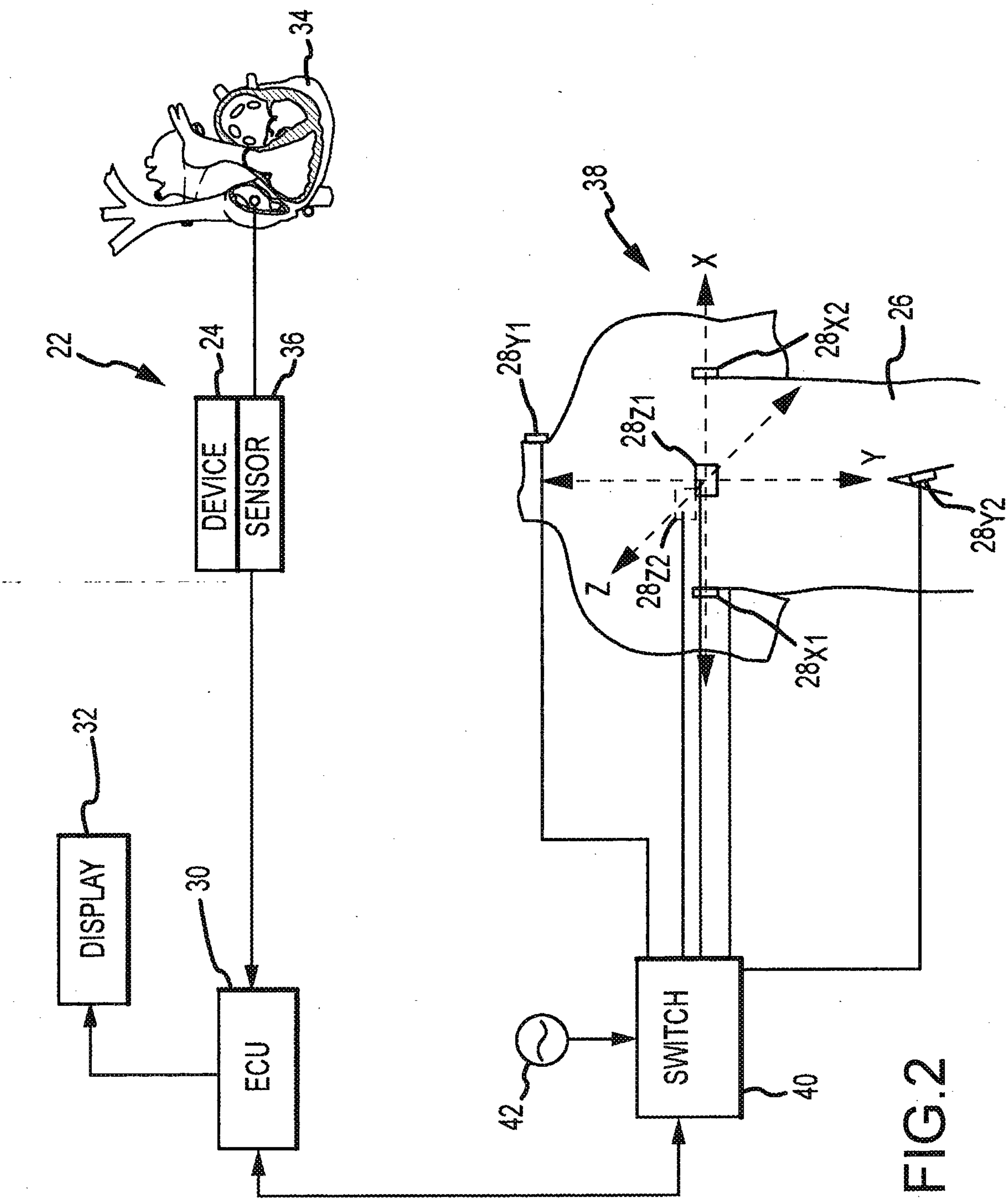
22
DEVICE
24
SENSOR
36
34
38
X
Y
Z
28Y1
28X2
26
28Z1
28Z2
28Y2
28X1
DISPLAY
32
ECU
30
SWITCH
40
42

FIG.2

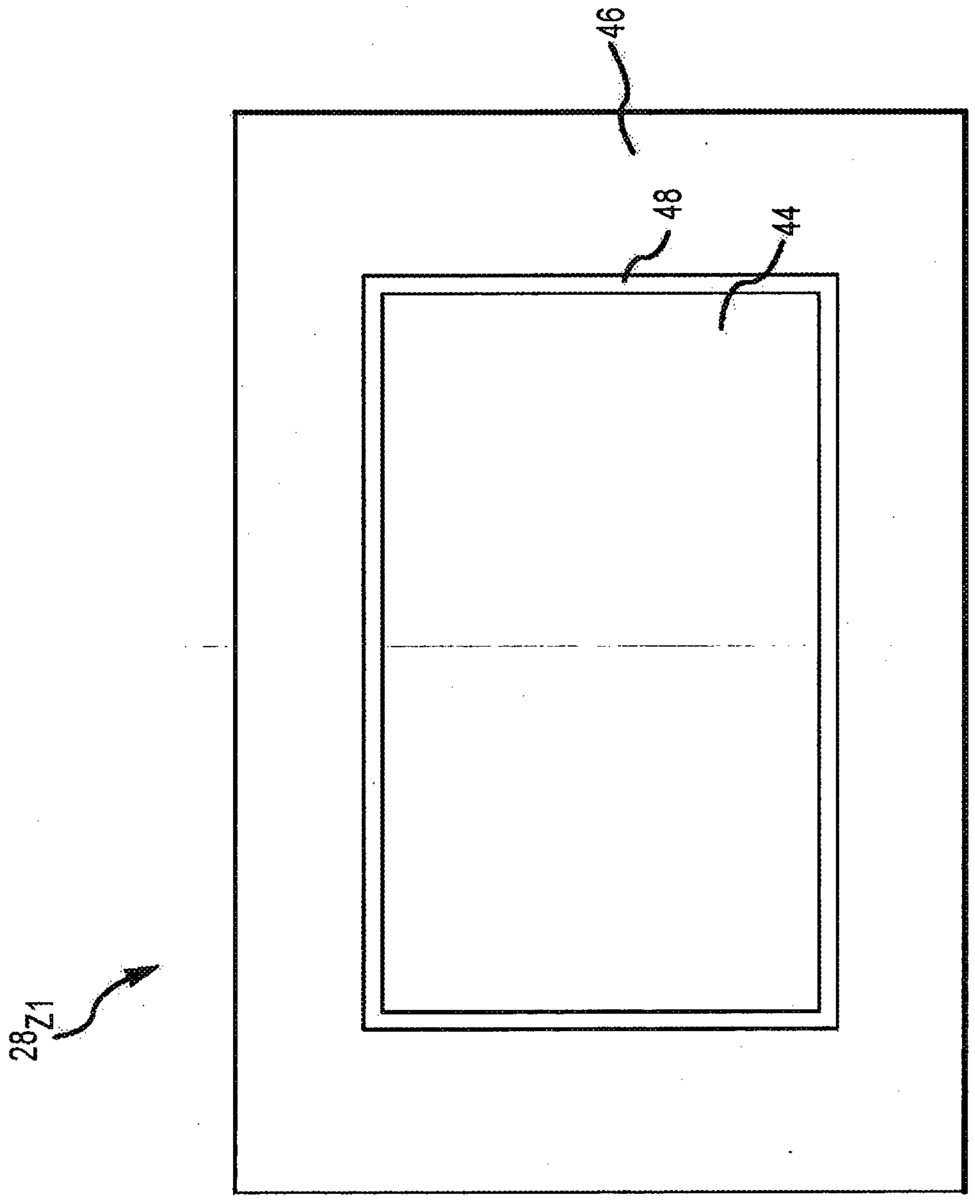

FIG.3

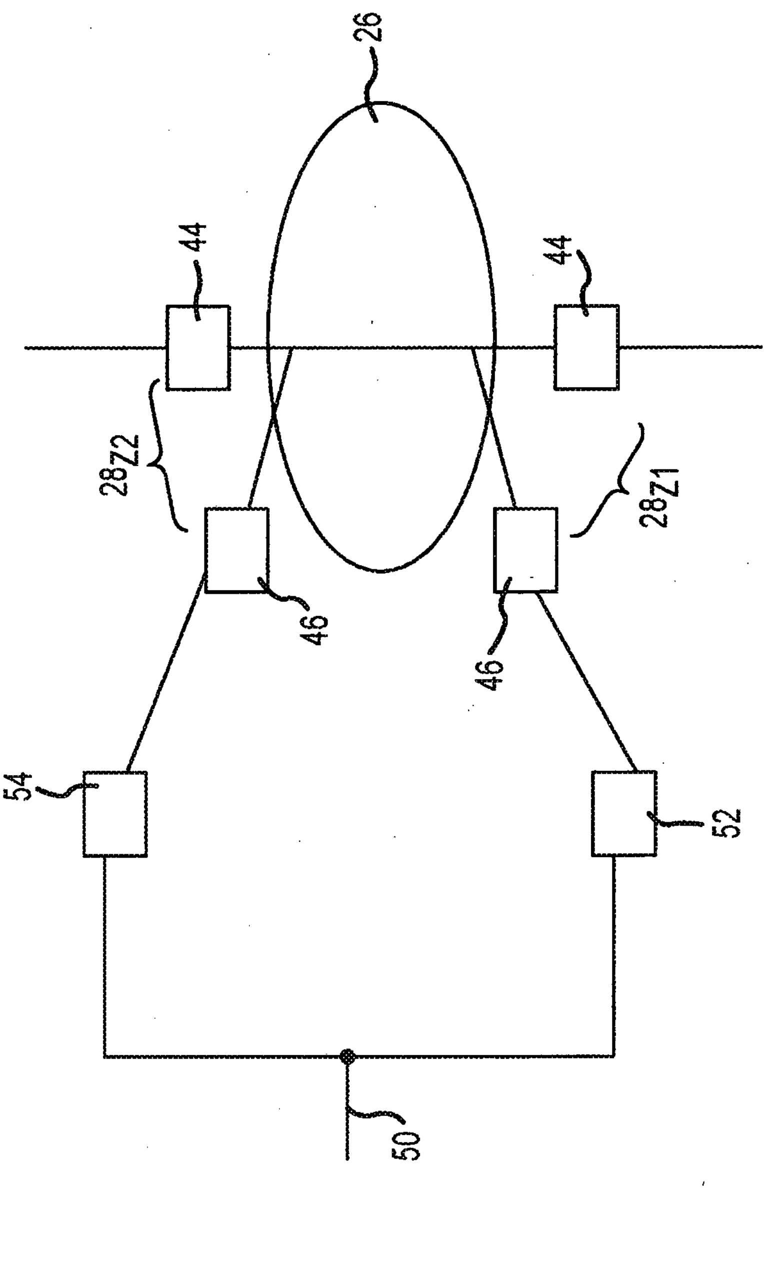

FIG.4

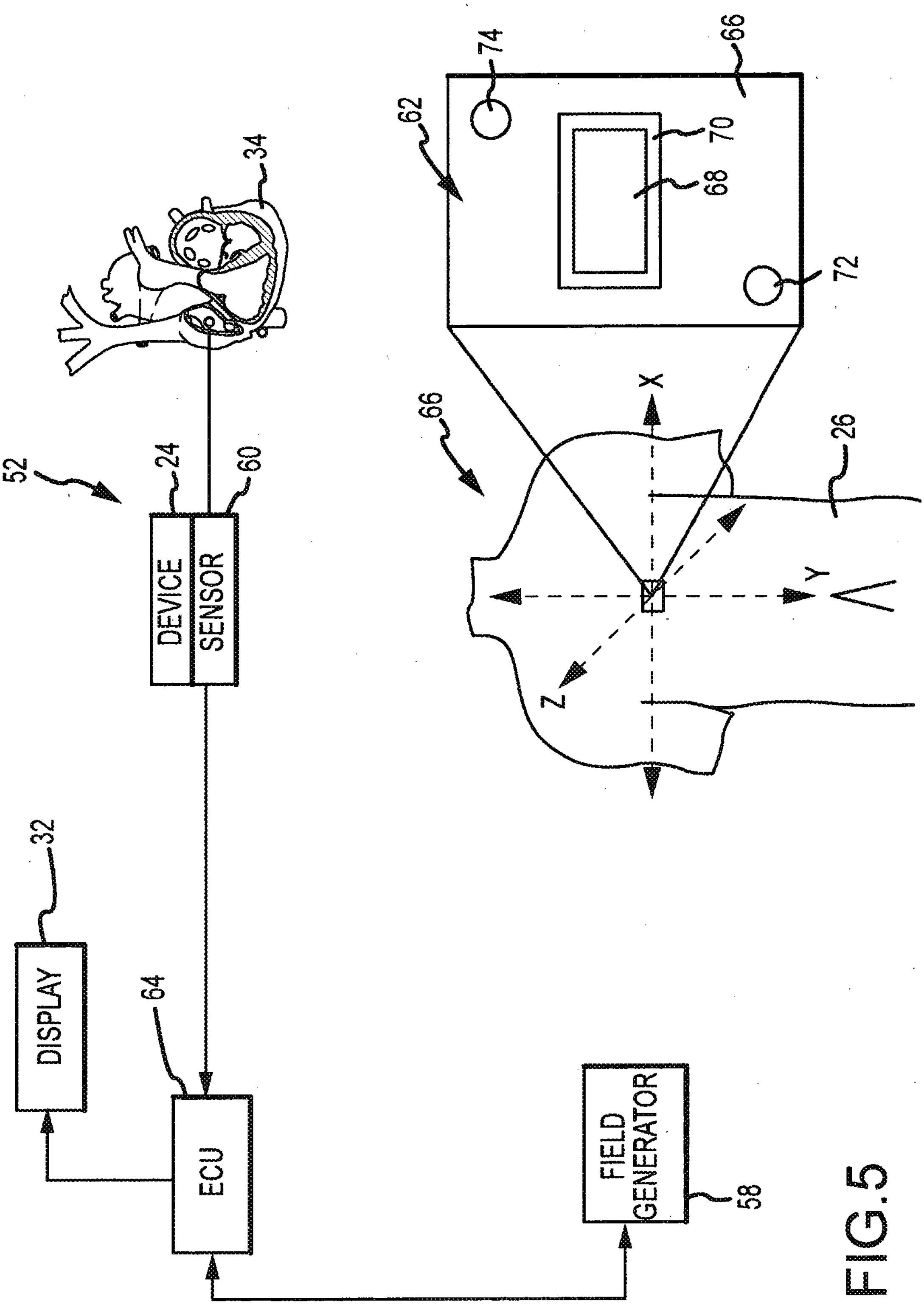
52
24
DEVICE
SENSOR
60
34
62
74
66
70
68
72
66
X
Y
Z
26
32
DISPLAY
64
ECU
FIELD GENERATOR
58

FIG.5

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 2007060833 A1 **[0002]**
- EP 2204120 A1 **[0003]**
- US 20090264739 A1 **[0004]**

专利名称(译)	用于确定医疗设备在体内的位置的系统		
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IPC分类号	A61B5/06 A61B18/14 A61B5/00 A61B5/042 A61B5/0408 A61B5/053 A61B19/00 A61B17/00		
CPC分类号	A61B5/065 A61B5/04085 A61B5/0422 A61B5/063 A61B5/6833 A61B5/6869 A61B34/20 A61B2034/2053		
代理机构(译)	KRAMER - HARSH - 施密特陈		
优先权	12/981150 2010-12-29 US		
其他公开文献	EP2471454A2 EP2471454A3		
外部链接	Espacenet		

摘要(译)

提供了一种用于确定医疗设备（24）在主体（26）内的位置的系统，其通过建立更靠近设备的参考原点（38）来减少位置误差和/或通过集成组件和功能来简化系统。在一个实施例中，一对驱动电极（28）固定到主体（26）的相对表面上，并形成用于通过与医疗装置（24）相关的位置传感器（36）传输电流的通路。靠近驱动电极（28）的一对参考电极（46）耦合到公共参考节点（50），输出建立参考原点（38）的参考信号。电子控制单元（30）响应于由位置传感器（36）产生的位置信号和参考信号确定医疗设备（24）的位置。在另一个实施例中，固定到主体外表面的贴片（62）具有基层（66）和支撑在基层（66）上的多个装置（68,70,72,74），彼此电隔离。 ，并配置为执行不同的功能。

$$P = \frac{S_f * R_b * R_i}{R_i + R_e}$$