(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 675 347 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent:
15.08.2018 Bulletin 2018/33

(21) Application number: **12770539.0**

(22) Date of filing: **26.01.2012**

(51) Int Cl.:
A61B 5/00 *(2006.01)* ***A61B 34/20*** *(2016.01)*

(86) International application number:
PCT/US2012/022678

(87) International publication number:
WO 2012/141775 (18.10.2012 Gazette 2012/42)

(54) SYSTEM FOR REGISTRATION OF MULTIPLE NAVIGATION SYSTEMS TO A COMMON COORDINATE FRAME

SYSTEM ZUR REGISTRIERUNG MEHRERER NAVIGATIONSSYSTEME IN EINEM GEMEINSAMEN KOORDINATENSYSTEM

SYSTÈME D'ENREGISTREMENT DE MULTIPLES SYSTÈMES DE NAVIGATION DANS UN SYSTÈME DE COORDONNÉES COMMUN

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(30) Priority: **14.04.2011 US 201113087203**

(43) Date of publication of application:
25.12.2013 Bulletin 2013/52

(73) Proprietor: **St. Jude Medical, Atrial Fibrillation Division, Inc.**
St. Paul, Minnesota 55117-9913 (US)

(72) Inventor: **OLSON, Eric S.**
Maplewood, Minnesota 55119-5838 (US)

(74) Representative: **Kramer Barske Schmidtchen Patentanwälte PartG mbB**
European Patent Attorneys
Landsberger Strasse 300
80687 München (DE)

(56) References cited:

EP-A1- 2 168 478
EP-A2- 1 743 575
US-A1- 2008 161 681
US-A1- 2008 221 425
US-A1- 2010 152 571
US-A1- 2010 152 571
US-A1- 2010 268 059
US-A1- 2011 062 344

Printed by Jouve, 75001 PARIS (FR)

Description

BACKGROUND OF THE INVENTION

a. Field of the Invention

[0001] The instant invention relates to localization systems, such as those used in cardiac diagnostic and therapeutic procedures. In particular, the instant invention relates to a system and method for registering the coordinate frames of multiple such systems, namely a magnetic-based system and an impedance-based system, to common coordinate frames.

b. Background Art

[0002] The three-dimensional coordinates of a catheter or other medical device moving within a patient's body are often tracked using a localization system (sometimes also referred to as a "mapping system," "navigation system," or "positional feedback system"). These devices typically use magnetic, electrical, ultrasound, and other radiation sources to determine the coordinates of these devices. For example, impedance-based localization systems determine the coordinates of the medical device by interpreting a voltage measured by the medical device as a location within an electrical field.

[0003] Each different type of localization systems offers certain advantages and disadvantages. For example, an impedance-based localization system offers the ability to track numerous localization elements simultaneously, but is susceptible to inhomogeneities in the electrical field and "drift" resulting from varying impedance regions and other external factors. As used herein, the term "drift" refers to a stationary localization element appearing to move due, for example, to patient movement, respiration, electrical noise, varying impedance, and other external factors. Certain solutions to the disadvantages associated with inhomogeneous electrical fields and drift are described in United States application nos. 11/227,580, filed 15 September 2005; 11/715,919, filed 9 March 2007; and 12/986,409, filed 7 January 2011, all of which are incorporated by reference as though fully set forth herein.

[0004] Likewise, a magnetic-based system offers the advantages of improved homogeneity and less drift than an impedance-based system. Such systems, however, require special sensors to be used as localization elements and, as such, are relatively limited in the number of localization elements that can be simultaneously tracked.

[0005] US 2010/0152571 A1 relates to a system for localizing tracked instruments using two or more modalities for localizing the instrument within a volume.

[0006] EP 2 168 478 A1 relates to sensing the position of an object placed within a living body, in particular to detection and compensation of artefacts experiences during position sensing of a probe in a living body.

[0007] US 2008/0161681 A1 relates to the navigation of a medical device through a patient, in particular to a method and system for detecting and controlling for the movement of a reference point utilized in a localization system employed in navigating a medical device through a patient.

[0008] EP 1 743 575 A2 relates to sensing the position of an object placed in a living body, in particular to provide an accurate reference for impedance-based position sensors.

BRIEF SUMMARY OF THE INVENTION

[0009] It would therefore be advantageous to develop a hybrid localization system that leverages the advantages, while minimizing the disadvantages, of several individual localization systems. For example, a hybrid magnetic- and impedance-based localization system could simultaneously track a large number of localization elements using the impedance-based system while minimizing the effect of inhomogeneities and drift by using the magnetic-based system.

[0010] Because each localization system measures the position of its respective localization elements within its respective localization field relative to a unique coordinate frame, however, localization elements that are coincident in real space (that is, they occupy substantially the same physical location) may not appear coincident if rendered on a display device by such a hybrid localization system. It would therefore also be advantageous to provide a transformation that accurately transforms position measurements for the various localization elements to a common coordinate frame.

[0011] Disclosed herein, but not forming part of the claimed invention, is a method of registering two or more localization systems utilizing unique coordinate frames to a common coordinate frame. The method includes the following steps: using a first localization system having a first coordinate frame A to measure position information for a first reference location, the measured position information being A_1; using a second localization system having a second coordinate frame B to measure position information for the first reference location, the measured position information being B_1; associating the position information for the first reference location measured by the first and second localization systems, respectively, as a first fiducial grouping (A_1, B_1); using the first localization system to measure position information for a second reference location, the measured position information being A_2; using the second localization system to measure position information for the second reference location, the measured position information being B_2; associating the position information for the second reference location measured by the first and second localization systems, respectively, as a second fiducial grouping (A_1, B_2); using at least the first and second fiducial groupings (A_1, B_1) and (A_2, B_2) to generate a mapping function f that transforms position measurements made using the second localization system relative to the second coordinate frame *B* to the first coordinate frame *A,* wherein the mapping function *f* is defined such that, for any reference location *r* for which position information is measured using the first and second localization systems as A_r and B_r, respectively, a distance between $f(B_r)$ and A_r is about zero. Preferably, the distance between $f(B_r)$ and A_r is less than about 2 mm. The first and second localization systems can be magnetic-based and impedance-based localization systems, respectively.

[0012] In some aspects, the mapping function *f* employs a non-linear registration algorithm. Suitable non-linear registration algorithms include thin plate splines algorithms and radial basis function networks algorithms.

[0013] Also disclosed herein is a method of measuring position information for a medical device within a patient's body, including the steps of: establishing a first localization field using a first localization system having a first coordinate frame *A*; establishing a second localization field using a second localization system having a second coordinate frame *B*; measuring position information for a plurality of reference locations r relative to the first and second coordinate frames using the first and second localization systems, respectively; associating the measured position information for each of the plurality of reference locations r as a plurality of fiducial groupings, wherein each fiducial grouping comprises position information for a single reference point r measured using the first and second localization systems, respectively, as (A_r, B_r); and using the plurality of fiducial groupings to generate a mapping function *f* such that, for each reference location $r, f(B_r)$ is about equal to A_r. The method optionally includes: measuring position information for the medical device as it moves through the patient's body relative to the second coordinate frame using the second localization system; and converting the measured position information for the medical device as it moves through the patient's body into the first coordinate frame using the mapping function *f.*

[0014] The disclosure further provides methods of monitoring, signaling, and adjusting or mitigating for various anomalies, such as dislodgement or drift of a fixed reference localization element. Thus, the method optionally includes the following steps: defining a fixed reference localization element for the first localization system, the fixed reference localization element for the first localization system having a position measured relative to coordinate frame *A* of R_A; defining a fixed reference localization element for the second localization system, the fixed reference localization element for the second localization system having a position measured relative to coordinate frame *B* of R_B; computing $f(R_B)$; computing a divergence between $f(R_B)$ and R_A; and signaling an anomaly if the divergence between $f(R_B)$ and R_A exceeds a divergence threshold. The fixed reference localization elements for the first and second localization systems may be substantially coincident in real space (*i.e.,* they are physically coincident or nearly coincident). Anomalies may be mitigated by computing offset vectors and/or generating new mapping functions *f'.*

[0015] Another approach to monitoring for anomalies includes the following steps: defining a primary reference localization element; defining a secondary reference localization element; defining a tertiary reference localization element; measuring position information for the primary localization element and the secondary localization element with respect to the coordinate frame *A*; measuring position information for the tertiary reference localization element with respect to both of the coordinate frame *A* and the coordinate frame *B;* using the mapping function f to convert the position information of the tertiary reference localization element measured with respect to coordinate frame *B* to the coordinate frame *A;* computing divergences between the position information for the primary reference localization element measured with respect to the coordinate frame *A* and at least one of: the position information for the secondary reference localization element measured with respect to the coordinate frame *A*; the position information for the tertiary reference localization element measured with respect to the coordinate frame *A*; and the position information for the tertiary reference localization element converted to the coordinate frame *A*; and signaling an anomaly if one or more of the computed divergences exceeds a divergence threshold.

[0016] The present invention also provides a hybrid localization system including: a magnetic-based localization system that measures localization element positions with respect to a coordinate frame *A*; an impedance-based localization system that measures localization element positions with respect to a coordinate frame *B*; a medical device including a plurality of localization elements, the plurality of localization elements comprising at least one localization element detectable by the impedance-based localization system and at least one localization element detectable by the magnetic-based localization system; at least one processor configured to express localization element positions measured by the impedance-based localization system with respect to the coordinate frame *B* in the coordinate frame *A* via application of a non-linear mapping function *f*. The hybrid localization system further includes: a fixed reference localization element for the magnetic-based localization system, the fixed reference localization element for the magnetic-based localization system having a position, measured with respect to the coordinate frame *A*, of R_A; a fixed reference localization element for the impedance-based localization system, the fixed reference localization element for the impedance-based localization system having a position, measured with respect to the coordinate frame *B*, of R_B; and at least one processor configured to monitor a divergence between R_A and $f(R_B)$ and to signal an anomaly when the divergence exceeds a divergence threshold.

[0017] 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

[0018]

Fig. 1 is a schematic diagram of a hybrid localization system, such as may be used in an electrophysiology study.
Fig. 2 depicts an exemplary catheter used in an electrophysiology study.
Fig. 3 illustrates position information of three reference points (*e.g.*, fiducial points) measured relative to two different coordinate frames, as well as the inhomogeneity present in one of the coordinate frames.

DETAILED DESCRIPTION OF THE INVENTION

[0019] The present invention provides a hybrid localization system for registering different coordinate frames to a single, common coordinate frame. The invention will be described in detail in the context of a hybrid localization system that includes both a magnetic-based localization system and an impedance-based localization system.

[0020] Each of the localization systems used in the hybrid localization system described below (*e.g.*, the magnetic-based localization system and the impedance-based localization system) will have a unique coordinate frame in which it expresses position information. For illustrative purposes, the coordinate system of the magnetic-based system will be referred to as coordinate frame *A,* while that of the impedance-based system will be referred to as coordinate frame *B.* Typically, these coordinate frames will express position information as Cartesian coordinates, though the use of other coordinate systems, such as polar, spherical, and cylindrical, is also contemplated, as is the use of multiple coordinate systems (*e.g.*, Cartesian and polar).

[0021] Though the present invention will be described in connection with cardiac procedures, and more particular in connection with a procedure carried out in a heart chamber, it is contemplated that the system according to the present invention may be used to good advantage in other contexts, such as tracking devices for placement of neurostimulation leads in a patient's brain. Further, though the present invention will generally be described in three dimensions and with respect to two localization systems, one of ordinary skill in the art will understand how to apply the principles disclosed herein in any number of dimensions and to any number of localization systems. Accordingly, the illustrative embodiment used herein to describe the invention should not be regarded as limiting.

[0022] Figure 1 shows a schematic diagram of a hybrid localization system 8 for conducting cardiac electrophysiology studies by navigating a cardiac catheter and measuring electrical activity occurring in a heart 10 of a patient 11 (depicted, for simplicity's sake, as an oval) and three-dimensionally mapping the electrical activity and/or information related to or representative of the electrical activity so measured. As one of ordinary skill in the art will recognize, hybrid localization system 8 determines the location (and, in some aspects, the orientation) of objects, typically within a three-dimensional space, and expresses those locations as position information determined relative to at least one reference. System 8 can also be used to measure electrophysiology data at a plurality of points along a cardiac surface, and to store the measured data in association with location information for each measurement point at which the electrophysiology data was measured, for example to create a diagnostic data map of the patient's heart 10.

[0023] Hybrid localization system 8 includes two localization systems: an impedance-based localization system and a magnetic-based localization system. The ordinary artisan will readily appreciate the basic operation of such localization systems. Thus, they will only be explained herein to the extent necessary to understand the present invention.

[0024] In general, and as shown in Figure 1, a localization system, such as an impedance- or magnetic-based localization system includes a plurality of localization field generators (*e.g.*, 12, 14, 16, 18, 19, and 22) that generate an electrical or magnetic field, respectively, across the patient's body. These localization field generators, which may be applied to the patient (internally and/or externally) or fixed to an external apparatus, define three generally orthogonal axes, referred to herein as an x-axis, a y-axis, and a z-axis.

[0025] Figure 1 depicts localization field generators 12, 14, 16, 18, 19, and 22 as coupled to both a current source and a magnetic source. It should be understood that this presentation is for simplicity of illustration. One of ordinary skill in the art will appreciate, of course, that each localization field generator will only be coupled to a source appropriate to the component localization system of which it is a part (*e.g.*, impedance-based localization field generators will be coupled to the current source, while magnetic-based localization field generators will be coupled to the magnetic source).

[0026] For purposes of this disclosure, an exemplary medical device, such as a catheter 13, is shown in Figure 2. In Figure 2, catheter 13 is depicted extending into the left ventricle 50 of the patient's heart 10. Catheter 13 includes a plurality of localization elements (*e.g.*, 17, 52, 54, and 56) spaced along its length. As used herein, the term "localization element" generically refers to any element whose position within a localization field can be measured by that system (*e.g.*, electrodes for an impedance-based system and magnetic sensors for a magnetic-based system).

[0027] Because each localization element lies within the localization field, location data may be collected simultaneously for each localization element. One of ordinary skill in the art will appreciate, of course, that an impedance-based localization system can simultaneously collect from a far larger number of localization elements than can a magnetic-based localization system.

[0028] For impedance-based localization systems, a reference electrode 21 (*e.g.,* a "belly patch") can be used as a reference and/or ground electrode. Alternatively, a fixed intracardiac electrode 31 may be used as a reference electrode. This optional fixed reference electrode 31, which is shown in Figure 1 as carried on a second catheter 29, can be attached to a wall of the heart 10 or anchored within the coronary sinus such that it is either stationary or disposed in a fixed spatial relationship with the localization elements. Thus, reference electrode 31 can be described as a "navigational reference," "local reference," or "fixed reference." Indeed, in many instances, fixed reference electrode 31 defines the origin of the impedance-based localization system's coordinate frame (*e.g.,* coordinate frame *B*).

[0029] A magnetic-based localization system typically includes an element analogous to fixed reference electrode 31 to define the origin of the magnetic-based localization system's coordinate frame (*e.g.,* coordinate frame *A*). That is, a magnetic-based localization system typically includes its own fixed reference relative to which the positions of localization elements 17, 52, 54, and 56 are measured. Such a reference can likewise be in a fixed internal or external location. Likewise, multiple references may be used for the same or different purposes (*e.g.*, to correct for respiration, patient shift, system drift, or the like). Of course, impedance-based and/or magnetic-based localization systems may also include additional fixed references.

[0030] In a preferred embodiment, the impedance-based component of hybrid localization system 8 is the EnSite NavX™ navigation and visualization system of St. Jude Medical, Atrial Fibrillation Division, Inc. Suitable magnetic-based localization systems include the MediGuide Medical Positioning System (mGPS™) of St. Jude Medical, Atrial Fibrillation Division, Inc., the CARTO navigation and location system of Biosense Webster, Inc. and the AURORA® system of Northern Digital Inc.

[0031] A computer, which can comprise a conventional general-purpose computer, a special-purpose computer, a distributed computer, or any other type of computer, and which can comprise one or more processors, such as a single central processing unit (CPU), or a plurality of processing units, commonly referred to as a parallel processing environment, can control hybrid localization system 8 and/or execute instructions to practice the various aspects of the present invention described herein.

[0032] As one of ordinary skill in the art will appreciate, the position information measured by each component of hybrid localization system 8 is context-specific to that localization system. In other words, measurements made using the magnetic-based localization component of hybrid localization system 8 are expressed with respect to coordinate frame *A,* while those made using the impedance-based localization component of hybrid localization system 8 are expressed with respect to coordinate system *B.*

[0033] This is illustrated (in two dimensions) in Figure 3. Figure 3 depicts coordinate axes X_A and Y_A for coordinate frame *A* (associated with the magnetic-based localization system) and coordinate axes X_B and Y_B for coordinate frame *B* (associated with the impedance-based localization system). The origins of coordinate frames *A* and *B,* O_A and O_B, respectively, are offset from each other. In addition, the scales of coordinate frames *A* and *B* differ. Coordinate frames *A* and *B* are also rotated with respect to each other.

[0034] Three reference locations (as described further below) are identified with respect to each coordinate frame as *A1, A2,* and *A3* in coordinate frame *A* and *B1, B2,* and *B3* in coordinate frame *B.* As described in further detail below, the present invention warps coordinate frame *B* such that the locations of these reference locations coincide (that is, such that the coordinates of *B1, B2,* and *B3* numerically match, or nearly match, the coordinates of *A1, A2,* and *A3*).

[0035] It is desirable, of course, to express all position measurements made by hybrid localization system 8 relative to a single, common coordinate frame. This is referred to as "registering" the components of hybrid localization system 8 to the common coordinate frame. For purposes of explanation, the coordinate frame of the magnetic-based localization system (*e.g.,* coordinate frame *A*) will be considered the common coordinate frame (*i.e.,* the frame to which all other localization systems in hybrid localization system 8 will be registered). It should be understood, however, that any coordinate frame may be used as the common coordinate frame.

[0036] The registration process utilizes reference locations for which position information is measured using both components of hybrid localization system 8. For example, the practitioner can navigate catheter 13 to a series of locations within heart 10, and, at each such reference location (denoted herein as *r*), the magnetic-based localization system can be used to measure position information relative to coordinate frame *A* (expressed as A_r) and the impedance-based localization system can be used to measure position information relative to coordinate frame *B* (expressed as B_r).

[0037] The reference locations *r* can be preselected (*e.g.,* designated anatomical landmarks, such as the coronary sinus or pulmonary vein ostium) or arbitrary (*e.g.*, any point on the surface of the heart, any point on a patient's body, any point on a patient table, or any point having a fixed or known relationship to a localization field generator). Similarly, they can be manually identified by the user (*e.g.*, the user "clicks" when desired in order to capture position information for a reference location) or gathered automatically (*e.g.*, hybrid localization system 8 periodically or episodically captures position information for a reference location, such as whenever the registered locations of the components of hybrid localization system 8 diverge by more than a preset tolerance).

[0038] For each reference location *r*, the position information measured with respect to each component of hybrid localization system 8 is associated as a fiducial grouping (A_r, B_r). Preferably, at least two such fiducial groupings (*e.g.,* (A_1, B_1) and (A_2, B_2)) are used to generate a mapping function, denoted *f*, to the common coordinate frame. It is contemplated, however, that a single fiducial grouping may be used to perform an initial registration, particularly where coordinate frames *A* and *B* are not rotated relative to each other *(e.g.,* as shown in Figure 3). The mapping function *f* is defined so as to transform the coordinates of a location, measured with the impedance-based localization system, into the common coordinate frame.

[0039] Of course, the various localization elements (*e.g.*, the electrodes used in an impedance-based localization system and the magnetic sensors used in a magnetic-based localization system) may not be co-located on catheter 13, either by design or by necessity. It may be desirable to take this divergence into account when creating the fiducial groupings (A_r, B_r).

[0040] One method of accounting for this divergence is to interpolate position information measured by neighboring localization elements. For example, consider the case where catheter 13 is constructed such that magnetic sensors lie between neighboring electrodes and vice versa (that is, the localization elements alternate along the length of catheter 13). In the context of Figure 2, suppose that localization elements 17 and 54 are electrodes and localization elements 52 and 56 are magnetic sensors.

[0041] To adjust for the divergence between localization elements, a series of "virtual electrodes" may be placed between neighboring electrodes (*e.g.*, 17 and 54) to coincide with the position of the intervening magnetic sensors (*e.g.*, 52). The location of this virtual electrode may be interpolated based upon the known geometry of catheter 13 and the measured positions of electrodes 17 and 54. The use of B-splines is contemplated. Fiducial groupings may then be created by associating virtual electrode position information with magnetic sensor position information.

[0042] Preferably, the mapping function *f* is defined such that the mapping of a reference point *r* from coordinate frame *B* to coordinate frame *A* is coincident or near-coincident with the actual measured location of reference point *r* in coordinate frame *A* (*e.g.,* A_r). Expressed mathematically, the mapping function *f* is defined such that $|f(B_r)-A_r|\approx 0$ for all reference points *r.* A clinically-acceptable error *(e.g.,* variation from 0 in the mapping function) is about 2 mm.

[0043] For linear and homogeneous localization systems, affine transformations (*e.g.*, translation, rotation, and scaling), such as would result from application of a least mean square error fit (*e.g.,* the Procrustes formulation), would be suitable. Such affine transformations require three or fewer fiducial groupings.

[0044] Because many localization systems - including impedance-based localization systems - are non-linear and non-homogenous, however, affine transformations are not as desirable in connection with the present invention. Preferably, therefore, the mapping function *f* employs a non-linear registration algorithm to locally warp the coordinate frame of the impedance-based localization system at each reference location r to achieve an exact or near-exact match to the magnetic-based localization system. Such non-linear registration algorithms require four or more fiducial groupings.

[0045] There are a number of suitable non-linear registration algorithms for generating the mapping function *f*. One preferred algorithm is the thin plate splines algorithm, which is known for use in fusing images from one modality (*e.g.*, MRI or CT) to a localization system (*e.g.,* the EnSite NavX™ system), such as disclosed in United States application no. 11/715,923. Generally, the thin plate splines algorithm includes summing a fixed number of weighted basis functions. Typically, the number of weighted basis functions will be equal to the number of fiducial groupings. The following articles, which are hereby incorporated by reference as though fully set forth herein, describe the thin plate splines algorithm in further detail:

[0046] Bookstein, FL. Principal Warps: Thin Plate Splines and the Decomposition of Deformations. IEEE Transactions on Pattern Analysis and Machine Intelligence. 1989. 11:567-585.

[0047] Bookstein, FL. Thin-Plate Splines and the Atlas Problem for Biomedical Images. Proceedings of the 12th International Conference on Information Processing in Medical Imaging. July, 1991.

[0048] Another suitable non-linear registration algorithm is a mean value coordinates algorithm. A mean value coordinates algorithm generally transforms individual points in three dimensions to a closed, triangulated surface in three dimensions known as a "control mesh." When the control mesh is deformed, the algorithm can compute a smooth interpolation function through three dimensional space that exactly deforms the vertices and triangles without wildly extrapolating in regions far from the control mesh. The following article, which is hereby incorporated by reference as though fully set forth herein, describes mean value coordinates algorithms in further detail: Ju T, Schaefer S, Warren J, Mean Value Coordinates for Closed Triangular Meshes. ACM Transactions on Graphics. July 2005. 24(3):561-66.

[0049] Still another suitable non-linear registration algorithm is the radial basis function networks algorithm, which is well known in neural networks. The following references describe radial basis function networks algorithms in further detail, and are hereby incorporated by reference as though fully set forth herein:

J. Moody and C. J. Darken, Fast Learning in Networks of Locally Tuned Processing Units. Neural

Computation. 1989. 1, 281-294.
J. Park and I.W. Sandberg, Universal Approximation Using Radial-Basis-Function Networks. Neural Computation. 1991. 3(2):246-257.
A.G. Bors and I. Pitas, Median Radial Basis Function Neural Network, IEEE Trans. On Neural Networks. November 1996. 7(6):1351-1364.
Martin D. Buhmann and M.J. Ablowitz, Radial Basis Functions: Theory and Implementations. 2003.
Paul V. Yee and Simon Haykin, Regularized Radial Basis Function Networks: Theory and Applications. 2001.

[0050] Once the mapping function *f* is generated, hybrid localization system 8 can track the position of catheter 13 within the patient's body using the higher bandwidth of the impedance-based localization system (*e.g.,* measuring relative to coordinate frame *B*) while expressing the position using the more homogenous coordinate frame *A* of the magnetic-based localization system via application of the mapping function *f.* This allows hybrid localization system 8 to exploit the advantages of, while minimizing the disadvantages of, the constituent parts thereof.

[0051] Hybrid localization system 8 can also monitor for and signal various anomalies, such as dislodgement or drift in one or more of the magnetic- and/or impedance-based localization systems. That is, hybrid localization system 8 can keep track of whether the mapping function *f* remains valid, and, if appropriate, correct for any anomalies or compute a new mapping function *f*.

[0052] For example, in one aspect of the disclosure, at least one fixed reference localization element is defined for each of the magnetic-based localization system and the impedance-based localization system. For purposes of illustration, the positions of these reference localization elements will be denoted as R_A and R_B, respectively. Hybrid localization system 8 can continuously, periodically, or episodically compute $f(R_B)$ and compare that computation to R_A.

[0053] Assuming no anomalies (*e.g.*, no drift and/or no dislodgement of one or more of the fixed reference localization elements), the divergence between $f(R_B)$ and R_A should remain relatively constant. Typically, the fixed reference localization elements will be coincident in real space, such that the substantially constant divergence, assuming no anomalies, is approximately zero. It is contemplated, however, to have separate fixed reference localization elements with a non-zero, but known, divergence therebetween.

[0054] If, on the other hand, the divergence exceeds a divergence threshold, it can be considered an indication of an anomaly (*e.g.*, drift in the impedance-based localization system and/or dislodgement of one or more of the fixed reference localization elements). The practitioner can be alerted to this anomaly, for example via audible and/or visible alarms emitted by hybrid localization system 8. Additionally, steps may be taken to mitigate the anomaly. For example, where the anomaly is a dislodgement of one or more fixed reference localization elements, an offset vector may be calculated to account for the dislodgement. (Offset vectors to correct for dislodgement of navigational references are described in United States application nos. 12/972,253, filed 17 December 2010, and 11/647,277, filed 29 December 2006, both of which are hereby incorporated by reference as though fully set forth herein.) Alternatively, the mitigation may take the form of computing a new mapping function *f*, in effect re-doing the calibration described above, using either new fiducial groupings or previously saved fiducial groupings.

[0055] In another aspect, hybrid localization system 8 detects anomalies using three reference localization elements, designated as primary, secondary, and tertiary localization elements. Preferably, the primary reference localization element is rigidly associated with the localization field generators for the magnetic-based localization system, such as by securing it to a structure that carries the localization field generators. Preferably, the secondary reference localization element is disposed on the patient, while the tertiary reference localization element is disposed within the patient.

[0056] Position information for the primary and secondary reference localization elements are measured by the magnetic-based localization system relative to coordinate frame *A.* Position information for the tertiary reference localization element is measured using both the magnetic-based localization system (*e.g.,* relative to coordinate frame *A*) and the impedance-based localization system (*e.g.,* relative to coordinate frame *B*)*,* the latter of which is converted to coordinate frame *A* via application of the mapping function *f*.

[0057] Three quantities in coordinate frame *A* can then be analyzed, relative to respective divergence thresholds, by hybrid localization system 8 to determine whether an anomaly has occurred:

(A) A divergence between the measured position information for the secondary reference localization element and the measured position information for the primary reference localization element;
(B) A divergence between the *measured* position information for the tertiary reference localization element and the measured position information for the primary reference localization element; and
(C) A divergence between the *converted* position information for the tertiary reference localization element and the measured position information for the primary reference localization element.

[0058] These three quantities lead to eight cases, as shown in Table 1 ("N" indicates that the quantity does not exceed the respective divergence threshold, while "Y" indicates that it does):

Table 1

Case	*Quantity A*	*Quantity B*	*Quantity C*
1	N	N	N
2	N	N	Y
3	N	Y	N
4	N	Y	Y
5	Y	N	N
6	Y	N	Y
7	Y	Y	N
8	Y	Y	Y

[0059] The cases are explained below:

Case 1: No anomalies detected; operate as normal.
Case 2: The impedance-based system has changed relative to the magnetic-based system, but there has been no change in the magnetic-based system. The anomaly is limited to the impedance-based system, and is likely drift (if it was dislodgement, Quantity B would also show a "Y" - *see* Case 4). The preferred mitigation is to compute an offset vector to account for this drift.
Case 3: This is an unusual case, as the circumstances under which there would be a divergence in Quantity B but not Quantity C are very narrow (*e.g.*, a dislodgement of the tertiary reference localization element and simultaneous, offsetting drift in the impedance-based localization system). The more likely explanation is that both systems have experienced an unknown anomaly, making navigation unreliable. Accordingly, the preferred mitigation is to compute a new mapping function *f* using newly-collected fiducial groupings.
Case 4: In case 4, the anomaly is likely a physical dislodgement of the tertiary reference localization element. The preferred mitigation is to compute an offset vector to account for the dislodgement.
Case 5: The position of the secondary reference localization element has changed, likely due to movement of the patient on the table. The preferred mitigation is to compute an offset vector to account for patient movement.
Cases 6-8: These cases indicate simultaneous shift of two reference localization elements. Events such as electrical cardioversion could give rise to these cases. The preferred mitigation is to compute a new mapping function *f* using newly-collected fiducial groupings.

[0060] 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.

[0061] Similarly, although the present invention has been described in connection with registration of only two localization systems to a common coordinate system, the teachings herein are equally applicable to the registration of any number of localization systems to a common coordinate system, with each localization system having its own mapping function that transforms position measurements from the coordinate system of that localization system to the common coordinate system.

[0062] 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.

[0063] It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative only and not limiting. Changes in detail or structure may be made without departing from the invention as defined in the appended claims.

Claims

1. A hybrid localization system, comprising:

a magnetic-based localization system that measures localization element positions with respect to a coordinate frame *A*;
an impedance-based localization system that measures localization element positions with respect to a coordinate frame *B*;
a medical device (13) including a plurality of localization elements (17, 52, 54, 56), the plurality of localization elements comprising at least one localization element detectable by the impedance-based localization system and at least one localization element detectable by the magnetic-based localization system;
at least one processor configured to express localization element positions measured by the impedance-based localization system with respect to the coordinate frame *B* in the coordinate frame *A* via application of a non-linear mapping function *f*,
wherein *f* is defined such that, for a plurality of points r, each point r having a location measured with respect to coordinate frame *A* of *Ar,* and a

location measured with respect to coordinate frame *B* of *Br*, *f(Br)≈Ar*, **characterized in that** the system is further comprising:

a fixed reference localization element (31) for the magnetic-based localization system, the fixed reference localization element for the magnetic-based localization system having a position, measured with respect to the coordinate frame *A*, of R_A;
a fixed reference localization element (31) for the impedance-based localization system, the fixed reference localization element for the impedance-based localization system having a position, measured with respect to the coordinate frame *B*, of R_B; and
at least one processor configured to monitor a divergence between R_A and $f(R_B)$ and to signal an anomaly when the divergence exceeds a divergence threshold.

2. The system according to claim 1, wherein at least one processor is adapted for
measuring position information for the medical device (13) as it moves through the patient's body relative to the coordinate frame B using the impedance-based localization system; and
converting the measured position information for the medical device (13) as it moves through the patient's body into the coordinate frame A using the mapping function *f*.

3. The system according to claim 1, wherein the fixed reference localization element for the magnetic-based localization system and the fixed reference localization element for the impedance-based localization system are substantially coincident in real space.

4. The system according to claim 1, wherein at least one processor is adapted to signal that at least one of the fixed reference localization elements has become dislodged or that at least one of the localization systems is experiencing drift.

5. The system according to any one of claims 1 to 4, wherein at least one processor is adapted for mitigating the anomaly by computing an offset vector to account for the anomaly or generating a new mapping function *f'*.

6. The system according to claim 1, wherein at least one processor is configured to:

define a primary reference localization element;
define a secondary reference localization element;
define a tertiary reference localization element;
measure position information for the primary localization element and the secondary localization element with respect to the coordinate frame *A;*
measure position information for the tertiary reference localization element with respect to both of the coordinate frame *A* and the coordinate frame *B;*
use the mapping function *f* to convert the position information of the tertiary reference localization element measured with respect to coordinate frame *B* to the coordinate frame *A;*
compute divergences between the position information for the primary reference localization element measured with respect to the coordinate frame *A* and at least one of:

the position information for the secondary reference localization element measured with respect to the coordinate frame *A;*
the position information for the tertiary reference localization element measured with respect to the coordinate frame *A;* and
the position information for the tertiary reference localization element converted to the coordinate frame *A;* and

signal an anomaly if one or more of the computed divergences exceeds a divergence threshold.

Patentansprüche

1. Hybridlokalisierungssystem mit:

einem magnetbasiertem Lokalisierungssystem, das Lokalisierungselementpositionen bezüglich eines Kooordinatenrahmens A misst;
einem impedanzbasierten Lokalisierungssystem, das Lokalisierungselementpositionen bezüglich eines Koordinatenrahmens B misst;
einer medizinischen Vorrichtung (13), die eine Mehrzahl von Lokalisierungslementen (17, 52, 54, 56) aufweist, wobei die Mehrzahl der Lokalisierungselemente mindestens ein Lokalisierungselement aufweist, das von dem impedanzbasierten Lokalisierungssystem detektierbar ist, und mindestens ein Lokalisierungselement, das von dem magnetbasierten Lokalisierungssystem detektierbar ist;
mindestens einem Prozessor, der konfiguriert ist zum Ausdrücken der Lokalisierungselementpositionen, die von dem impedanzbasierten Lokalisierungssystem bezüglich des Koordinatenrahmens B gemessen worden sind, in dem Koordinatenrahme A durch Anwenden einer nicht linearen Abbildungsfunktion f, wobei

f derart definiert ist, dass für eine Mehrzahl von Punkten r jeder Punkt r einen Ort bezüglich des Koordinatensystems A von Ar und einen Ort, der bezüglich des Koordinatenrahmens B gemessen worden ist, von Br aufweist, f(Br)≈Ar ist, **dadurch gekennzeichnet, dass**
das System ferner aufweist:

ein festes Referenzlokalisierungselement (31) für das magnetbasierte Lokalisierungssystem, wobei das feste Referenzlokalisierungselement für das magnetbasierte Lokalisierungssystem eine Position aufweist, die bezüglich des Koordinatenrahmens A gemessen worden ist, von R_A;
ein festes Referenzlokalisierungselement (31) für das impedanzbasierte Lokalisierungssystem, wobei das feste Referenzlokalisierungselement für das impedanzbasierte Lokalisierungssystem eine Position aufweist, die bezüglich des Koordinatenrahmen B gemessen worden ist, von R_B;
mindestens einen Prozessor, der konfiguriert ist zum Überwachen einer Divergenz zwischen R_A und $f(R_B)$ und zur Signalisierung einer Anomalie, wenn die Divergenz einen Divergenzschwellenwert überschreitet.

2. System nach Anspruch 1, bei dem mindestens ein Prozessor angepasst ist zum
Messen von Positionsinformation für die medizinische Vorrichtung (13), wenn sie sich durch den Patientenkörper bewegt, relativ zu dem Koordinatenrahmen B unter Verwendung des impedanzbasierten Lokalisierungssystems;
Umwandeln der gemessenen Positionsinformation für die medizinische Vorrichtung (13), wenn sie sich durch den Patientenkörper bewegt, in den Koordinatenrahmen A unter Verwendung der Abbildungsfunktion f.

3. System nach Anspruch 1, bei dem das feste Referenzlokalisierungselement für das magnetbasierte Lokalisierungssystem und das feste Referenzlokalisierungselement für das impedanzbasierte Lokalisierungssystem im realen Raum im Wesentlichen übereinstimmen.

4. System nach Anspruch 1, bei dem mindestens ein Prozessor angepasst ist zum Signalisieren, dass mindestens eines der festen Referenzlokalisierungselemente entfernt ist oder mindestens eines der Lokalisierungssysteme eine Verschiebung erfährt.

5. System nach einem der Ansprüche 1 bis 4, bei dem mindestens ein Prozessor angepasst ist zum Mildern der Anomalie durch Berechnung eines Offsetvektors, um der Anomalie Rechnung zu tragen, oder zum Erzeugen einer neuen Abbildungsfunktion f' zu

6. System nach Anspruch 1, bei dem mindestens ein Prozessor konfiguriert ist zum:

Definieren eines primären Referenzlokalisierungselements;
Definieren eines sekundären Referenzlokalisierungselements;
Definieren eines tertiären Referenzlokalisierungselements;
Messen von Positionsinformation für das primäre Lokalisierungselement und das sekundäre Lokalisierungselement bezüglich des Koordinatenrahmens A;
Messen von Positionsinformation für das tertiäre Referenzlokalisierungselement bezüglich beider Rahmen von dem Koordinatenrahmen A und dem Koordinatenrahmen B;
Verwenden der Abbildungsfunktion f, um die Positionsinformation des tertiären Referenzlokalisierungselements, die bezüglich des Koordinatenrahmens B gemessen worden ist, in den Koordinatenrahmen A umzuwandeln;
Berechnen von Divergenzen zwischen der Positionsinformation für das primäre Referenzlokalisierungselement, die bezüglich des Koordinatenrahmens A gemessen worden ist, und mindestens einer von:

der Positionsinformation für das sekundäre Referenzlokalisierungselement, die bezüglich des Koordinatenrahmens A gemessen worden ist;
der Positionsinformation für das tertiäre Referenzlokalisierungselement, die bezüglich des Koordinatenrahmens A gemessen worden ist;
der Positionsinformation für das tertiäre Referenzlokalisierungselement, die in den Koordinatenrahmen A umgewandelt worden ist; und

Signalisieren einer Anomalie, wenn eine oder mehrere der berechneten Divergenzen einen Divergenzschwellenwert überschreitet.

Revendications

1. Système de localisation hybride, comprenant :

un système de localisation magnétique qui mesure des positions d'éléments de localisation par rapport à un système de coordonnées *A* ;
un système de localisation par impédance qui

mesure des positions d'éléments de localisation par rapport à un système de coordonnées *B* ;
un dispositif médical (13) incluant une pluralité d'éléments de localisation (17, 52, 54, 56), la pluralité d'éléments de localisation comprenant au moins un élément de localisation détectable par le système de localisation par impédance et au moins un élément de localisation détectable par le système de localisation magnétique ;
au moins un processeur configuré pour exprimer des positions d'éléments de localisation mesurées par le système de localisation par impédance par rapport au système de coordonnées *B* dans le système de coordonnées *A* par application d'une fonction de mise en correspondance non linéaire *f*,
dans lequel *f* est définie de manière à ce que, pour une pluralité de points r, chaque point r ayant un emplacement mesuré par rapport au système de coordonnées *A* de *Ar,* et un emplacement mesuré par rapport au système de coordonnées *B* de *Br, f*(*Br*)≈*Ar,*
caractérisé en ce que le système comprend en outre :

un élément de localisation de référence fixe (31) pour le système de localisation magnétique, l'élément de localisation de référence fixe pour le système de localisation magnétique ayant une position, mesurée par rapport au système de coordonnées *A,* de R_A ;
un élément de localisation de référence fixe (31) pour le système de localisation par impédance, l'élément de localisation de référence fixe pour le système de localisation par impédance ayant une position, mesurée par rapport au système de coordonnées *B*, de R_B ; et
au moins un processeur configuré pour surveiller une divergence entre R_A et $f(R_B)$ et pour signaler une anomalie lorsque la divergence dépasse un seuil de divergence.

2. Système selon la revendication 1, dans lequel au moins un processeur est adapté pour
mesurer des informations de position pour le dispositif médical (13) lorsqu'il se déplace à travers le corps du patient par rapport au système de coordonnées B en utilisant le système de localisation par impédance ; et
convertir les informations de position mesurées pour le dispositif médical (13) lorsqu'il se déplace à travers le corps du patient dans le système de coordonnées A en utilisant la fonction de mise en correspondance *f.*

3. Système selon la revendication 1, dans lequel l'élément de localisation de référence fixe pour le système de localisation magnétique et l'élément de localisation de référence fixe pour le système de localisation par impédance coïncident sensiblement dans l'espace réel.

4. Système selon la revendication 1, dans lequel au moins un processeur est adapté pour signaler qu'au moins l'un des éléments de localisation de référence fixes a été déplacé ou qu'au moins l'un des systèmes de localisation présente une dérive.

5. Système selon l'une quelconque des revendications 1 à 4, dans lequel au moins un processeur est adapté pour atténuer l'anomalie en calculant un vecteur de décalage pour tenir compte de l'anomalie ou en générant une nouvelle fonction de mise en correspondance *f'*.

6. Système selon la revendication 1, dans lequel au moins un processeur est configuré pour :

définir un élément de localisation de référence primaire ;
définir un élément de localisation de référence secondaire ;
définir un élément de localisation de référence tertiaire ; *mesurer des informations de position pour l'élément de localisation primaire et l'élément de localisation secondaire par rapport au système de coordonnées *A* ;
mesurer des informations de position pour l'élément de localisation de référence tertiaire par rapport à la fois au système de coordonnées *A* et au système de coordonnées *B* ;
utiliser la fonction de mise en correspondance *f* pour convertir les informations de position de l'élément de localisation de référence tertiaire mesurées par rapport au système de coordonnées *B* dans le système de coordonnées *A* ;
calculer des divergences entre les informations de position pour l'élément de localisation de référence primaire mesurées par rapport au système de coordonnées *A* et au moins certaines des :

informations de position pour l'élément de localisation de référence secondaire mesurées par rapport au système de coordonnées *A*;
informations de position pour l'élément de localisation de référence tertiaire mesurées par rapport au système de coordonnées *A* ; et
informations de position pour l'élément de localisation de référence tertiaire converties dans le système de coordonnées *A* ; et
signaler une anomalie si une ou plusieurs des divergences calculées dépasse(nt) un

seuil de divergence.

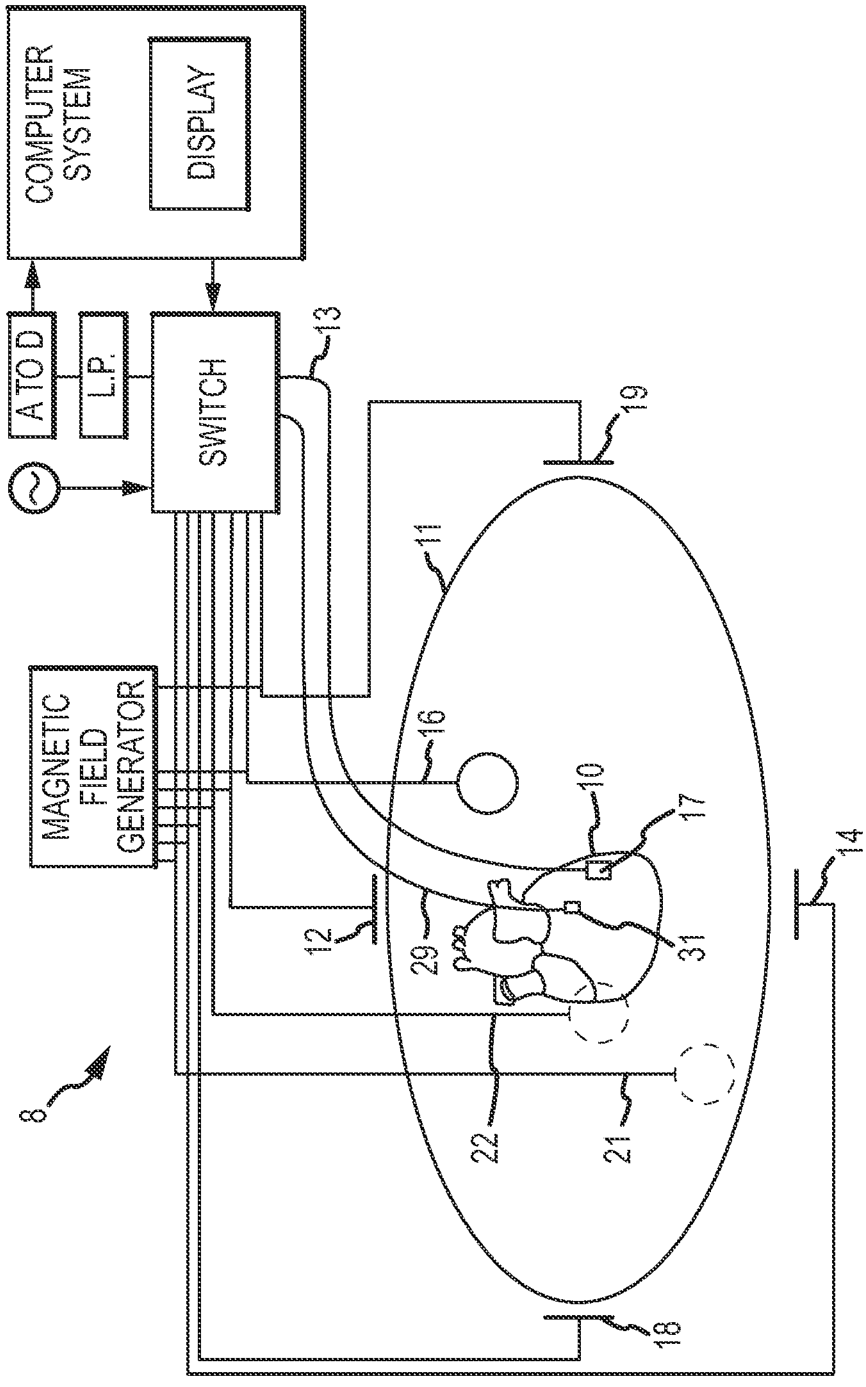
COMPUTER SYSTEM
DISPLAY
A TO D
L.P.
SWITCH
MAGNETIC FIELD GENERATOR
8
10
11
12
13
14
16
17
18
19
21
22
29
31

FIG. 1

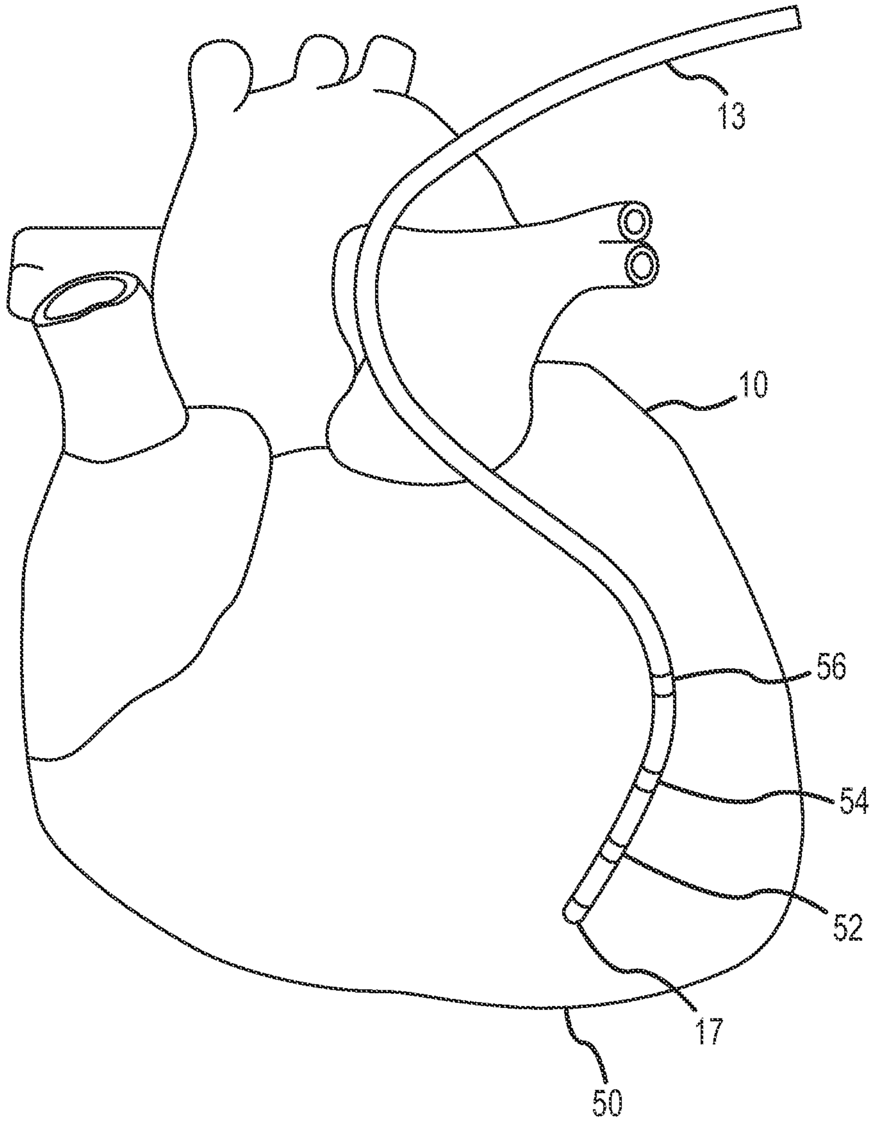

FIG.2

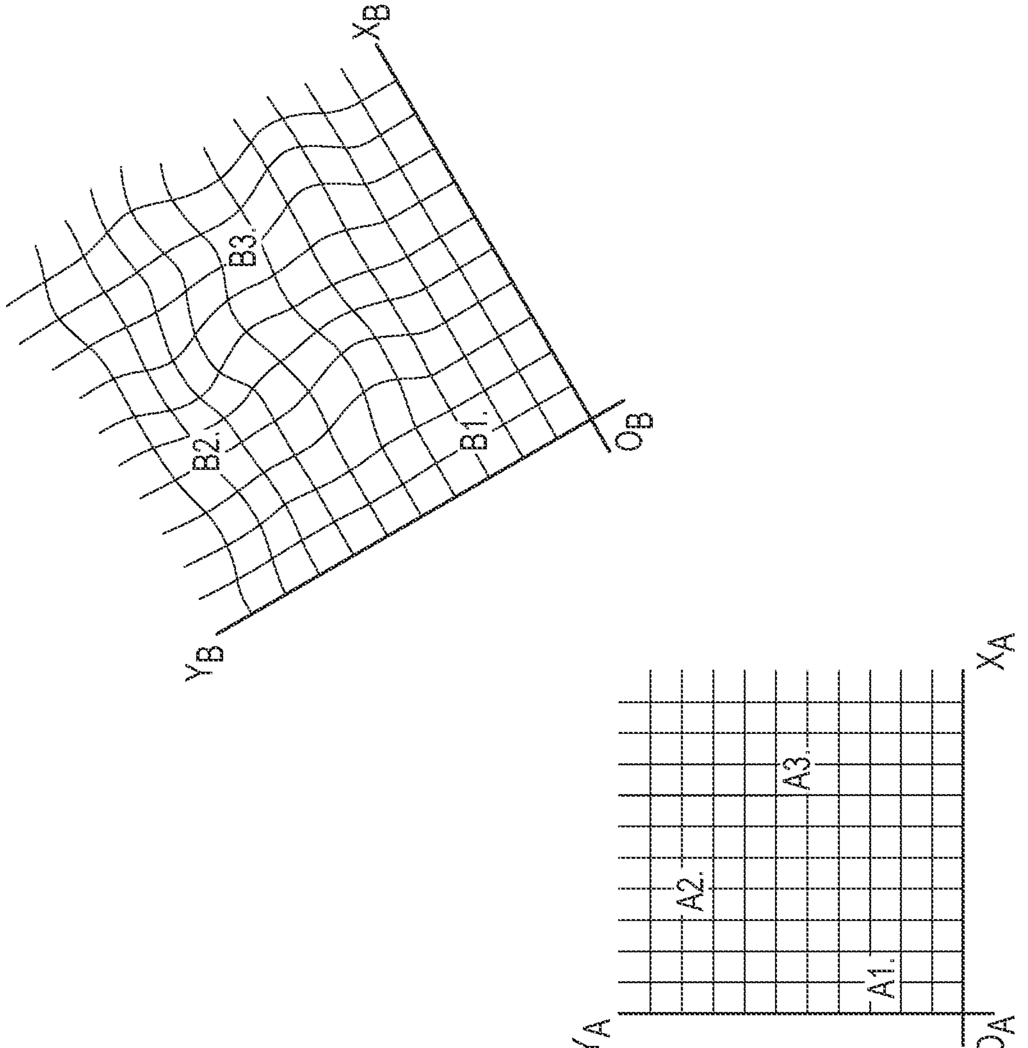

FIG.3

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 11227580 B **[0003]**
- US 11715919 B **[0003]**
- US 12986409 B **[0003]**
- US 20100152571 A1 **[0005]**
- EP 2168478 A1 **[0006]**
- US 20080161681 A1 **[0007]**
- EP 1743575 A2 **[0008]**
- US 11715923 B **[0045]**
- US 12972253 B **[0054]**
- US 11647277 B **[0054]**

Non-patent literature cited in the description

- **BOOKSTEIN, FL.** Principal Warps: Thin Plate Splines and the Decomposition of Deformations. *IEEE Transactions on Pattern Analysis and Machine Intelligence,* 1989, vol. 11, 567-585 **[0046]**
- **BOOKSTEIN, FL.** Thin-Plate Splines and the Atlas Problem for Biomedical Images. *Proceedings of the 12th International Conference on Information Processing in Medical Imaging,* July 1991 **[0047]**
- **JU T ; SCHAEFER S ; WARREN J.** Mean Value Coordinates for Closed Triangular Meshes. *ACM Transactions on Graphics,* July 2005, vol. 24 (3), 561-66 **[0048]**
- **J. MOODY ; C. J. DARKEN.** Fast Learning in Networks of Locally Tuned Processing Units. *Neural Computation,* 1989, vol. 1, 281-294 **[0049]**
- **J. PARK ; I.W. SANDBERG.** Universal Approximation Using Radial-Basis-Function Networks. *Neural Computation,* 1991, vol. 3 (2), 246-257 **[0049]**
- **A.G. BORS ; I. PITAS.** Median Radial Basis Function Neural Network. *IEEE Trans. On Neural Networks,* November 1996, vol. 7 (6), 1351-1364 **[0049]**
- **MARTIN D. BUHMANN ; M.J. ABLOWITZ.** Radial Basis Functions. *Theory and Implementations,* 2003 **[0049]**
- **PAUL V. YEE ; SIMON HAYKIN.** Regularized Radial Basis Function Networks. *Theory and Applications,* 2001 **[0049]**

patsnap

专利名称(译)	用于将多个导航系统登记到公共坐标系的系统		
公开(公告)号	EP2675347B1	公开(公告)日	2018-08-15
申请号	EP2012770539	申请日	2012-01-26
[标]申请(专利权)人(译)	圣犹达医疗用品电生理部门有限公司		
申请(专利权)人(译)	ST.犹达医疗用品，房颤DIVISION，INC.		
当前申请(专利权)人(译)	ST.犹达医疗用品，房颤DIVISION，INC.		
[标]发明人	OLSON ERIC S		
发明人	OLSON, ERIC S.		
IPC分类号	A61B5/00 A61B34/20		
CPC分类号	A61B5/6852 A61B5/062 A61B5/063 A61B34/20 A61B90/39 A61B2034/2051 A61B2034/2053 A61B2090/0818 A61B2090/3995		
优先权	13/087203 2011-04-14 US		
其他公开文献	EP2675347A1 EP2675347A4		
外部链接	Espacenet		

摘要(译)

将唯一坐标系A和B登记到公共坐标系的两个或更多个定位系统的方法包括测量每个坐标系（例如，Ar和Br）中的一个或多个参考位置r的位置信息。对于每个参考位置，从相应的位置测量值（例如，（Ar，Br））创建基准分组。基准分组用于生成映射函数f，其将相对于第二坐标系B表示的位置测量值变换为第一坐标系A.映射函数f被定义为使得f（Br）和Ar之间的距离大约为零。对于每个参考位置r。每个定位系统还可以测量相应固定参考定位元件的位置信息。公共坐标系中的这些固定参考定位元件之间的发散可用于监视，发信号和校正诸如移位和漂移之类的异常。

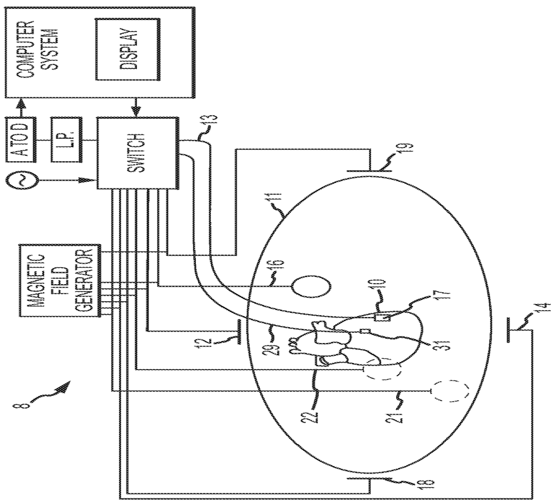

FIG.1