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(54) MEDICAL DEVICE POSITIONING SYSTEM AND METHOD

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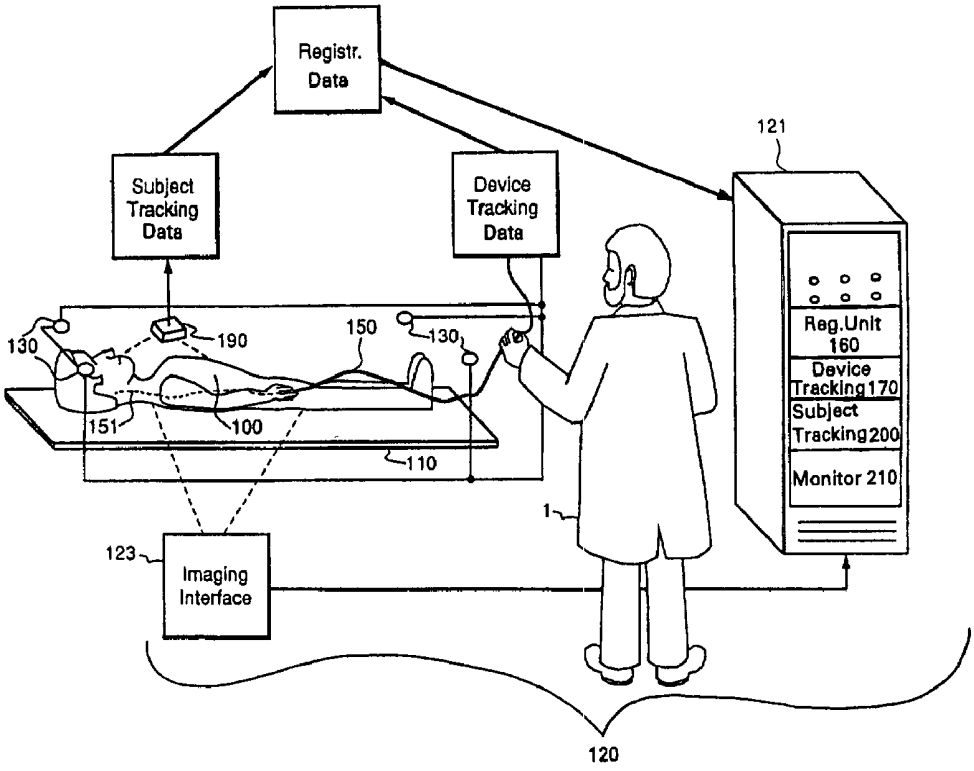
(57) **ABSTRACT**

A medical device positioning system and method for use during a medical procedure on a subject performed during imaging are provided. The system comprises a medical device adapted for internal use within the subject for performing the medical procedure and an imaging device for acquiring image data of a region of interest within the subject. Additionally, the system includes a medical device monitoring subsystem for monitoring position of the medical device relative to a target region of interest within the subject and for providing feedback to an interface unit when the position of the medical device deviates from the target region of interest.



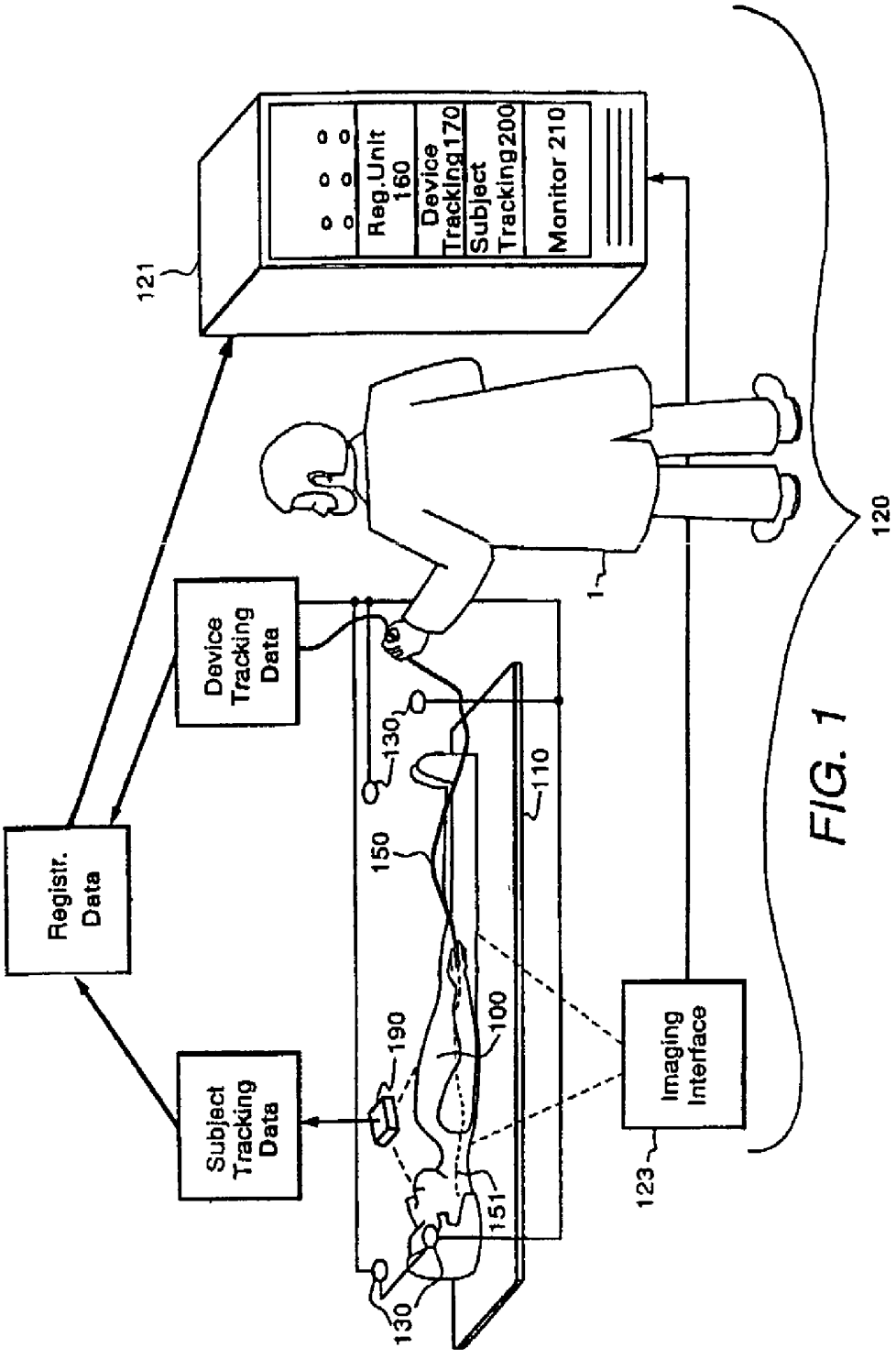

Reg.Unit 160
Device Tracking 170
Subject Tracking 200
Monitor 210
121
120
1
Device Tracking Data
Registr. Data
Subject Tracking Data
Imaging Interface
123
130
110
150
190
100
151

FIG. 1

FIG.2B

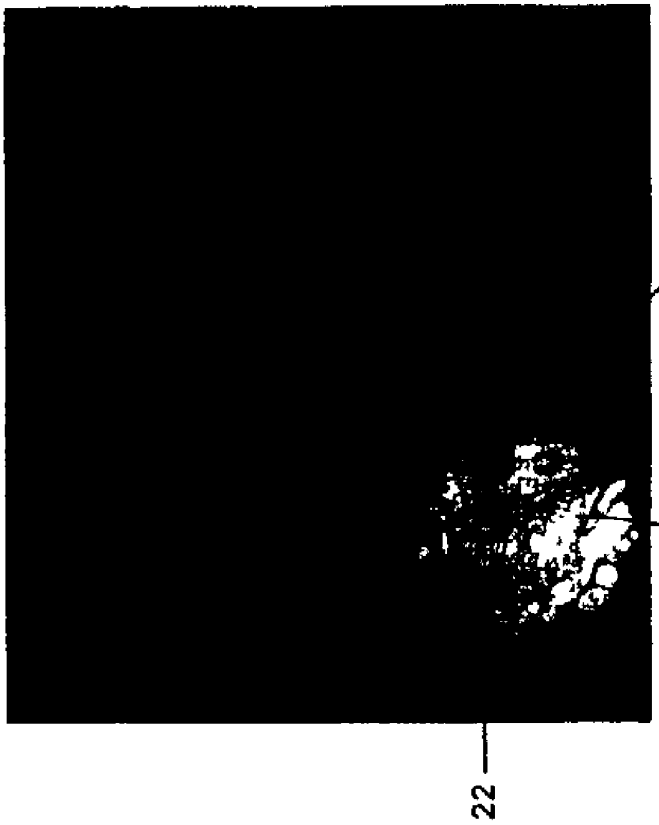


FIG.2A

MEDICAL DEVICE POSITIONING SYSTEM AND METHOD

FEDERAL RESEARCH STATEMENT

[0001] [The U.S. Government may have certain rights in this invention pursuant to contract number DAMD17-99-9008 awarded by the United States Army.]

BACKGROUND OF INVENTION

[0002] This invention relates to systems for image guided interventional medical procedures in which a device is inserted into a body during imaging, and more particularly this invention relates to systems which assist in executing the diagnostic and interventional procedures such as assisting in the positioning of the device during the procedures.

[0003] Image guided medical or surgical procedures generally use an imaging technology such as magnetic resonance imaging (MRI) or compute tomography (CT) for generating images, either prior to the procedure or during the procedure, as a guide for a physician or operator of the system during the procedure. During interactive examinations/interventions with a medical device, such as a biopsy needle, whose guide is localized by a device tracking method, there is a need for a system to provide information to the operator to assist in precise and rapid placement of the guide. Device guides are positioned for the delivery of diagnostic or interventional devices, relative to a feature of interest such as a lesion. Proper placement of the medical device guide results in proper placement of the accompanying medical device, relative to a target.

[0004] During interactive examinations/interventions with a medical device, there is a need for a system to actively monitor the three-dimensional (3D) position of the device, and respond if the device has moved from its target position. Device motion is of importance for procedures where a therapy is applied to carefully selected and circumscribed areas. Device motion is of equal importance for a procedure where a tissue sample must be obtained from a precise location, such as a biopsy procedure.

[0005] Typically, in conventional tracking systems, the location of an interventional device is presented to a physician as a graphic symbol superimposed upon a diagnostic image. Due to time constraints, or the constraint of accumulated radiation dose, diagnostic images are acquired intermittently before tracking of the device commences, or are acquired at a much slower rate than the device is tracked. Consequently, if the subject or device moves after the acquisition of the diagnostic image, the representation of the device displayed to the physician may be misregistered with respect to the diagnostic image.

[0006] What is needed is a system and method that overcomes the problems described above by monitoring and positioning the subject and device. In the event that motion is detected, it is desirable for a system and method to respond to, and correct for, the subject motion.

SUMMARY OF INVENTION

[0007] In a first aspect, a medical device positioning system for use during a medical procedure on a subject performed during imaging is provided. The system comprises a medical device adapted for internal use within the subject for performing the medical procedure and an imaging device for acquiring image data of a region of interest within the subject. Additionally, the system includes a medical device monitoring subsystem for monitoring position of the medical device relative to a target region of interest within the subject and for providing feedback to an interface unit when the position of the medical device deviates from the target region of interest.

[0008] In a second aspect, a method for positioning a medical device is provided. The method includes generating at least one image of a region of interest of a subject including a representation of a medical device superimposed in the image and monitoring a position of the medical device relative to a target region of interest within the subject. Feedback to an interface is provided upon detection of a change in position of the medical device relative to the target region.

BRIEF DESCRIPTION OF DRAWINGS

[0009] The features and advantages of the present invention will become apparent from the following detailed description of the invention when read with the accompanying drawings in which:

[0010] **FIG. 1** is a perspective view of an exemplary medical imaging system in operation for monitoring and positioning the location of an invasive device in a subject to which embodiments of the present invention are applicable; and,

[0011] **FIG. 2** is an illustrative diagram of an acquired image employing embodiments of the present invention.

DETAILED DESCRIPTION

[0012] Referring to **FIG. 1**, there is shown an imaging system to which embodiments of the present invention are applicable. In **FIG. 1, a** subject **100** on a support table **110** is placed in an imaging device **120**, having imaging interface **123** and imaging processor **121**, collectively referred to as imaging device **120**. Imaging device **120** may be a magnetic resonance imaging (MRI) device, an X-Ray imaging device, a computed tomography (CT) scanner, a Positron Emission Tomography system or an ultrasound scanner, or any other conventional medical imaging device. An invasive device **150**, shown in **FIG. 1** as a catheter, is inserted into subject **100**, usually by physician **1**. Device **150** may be a guide wire, a catheter, an endoscope, a laparoscope, a biopsy needle, a laser guide, a device guide, therapeutic laser or similar device.

[0013] Device **150** contains one or more element(s) **151**, which may be easily tracked. For example, in an MR imaging device, it may be an RF coil that detects MR signals generated in subject **100**. The element may also be an MR active substance such as a Fluorine compound that is tracked by MR Imaging. In the case of RF tracking, it may be an RF coil tracked by external RF coils **130**.

[0014] Device tracking unit **170** determines the position of element **151** on device **150** relative to a fixed reference point, such as support table **110**.

[0015] In the case of RF tracking, the location of device **150** is determined by employing several external detection devices, such as RF coils **130** around the perimeter of

subject **100**, and at least one internal coil of element **151** attached to device **150**. The internal coil transmits RF energy that is received by the external RF coils **130** which are connected to device tracking unit **170**. Device tracking unit **170** calculates the position of the internal coil over time. The transmission may be reversed such that external coils **130** transmit RF energy and internal coil of element **151** receives the transmitted RF energy.

[**0016**] In the case of MR tracking, element **151** detects nutation of magnetic resonance in a localized region around element **151**. Device tracking unit **170** determines the location of element **151**.

[**0017**] If more than one coil is used in element **151**, determining the locations of all coils will also allow calculation of the orientation of device **150**.

[**0018**] A position detection means **190**, placed within the imaging device **120**, measures position of one or more reference points of subject **100** over time. A reference image of the subject is acquired by the imaging device **120** at a time ti. The position of the reference points of subject **100** is monitored concurrently by position detection device **190**. The image and corresponding subject location, and position are stored. In another embodiment, position detection means **190** may be comprised of light emitting diodes (LEDs) fixed to subject **100** and an optical detector capable of measuring distance to the LEDs at specified times. Also in another embodiment, position detection means **190** may comprise an ultrasonic tracking device that employs conventional ultrasound distance measurement techniques to determine the position of selected points on subject **100** at different times. In yet a further embodiment, position detection means **190** may comprise a mechanical tracking means such as a mechanical arm physically coupled to the subject to measure the width and height of a portion of the subject's anatomy.

[**0019**] Position information (subject tracking data) over time from motion detection means **190** is sent to a subject tracking unit **200** for processing. Subject tracking unit **200** computes translation and rotation movement of subject **100** from time ti, the time of image acquisition, to time td, the time of device location measurement. This movement information is passed to a registration unit **160**.

[**0020**] Registration unit **160** receives the reference image from imaging device **120** (shown as registration data), the net subject position and orientation change from subject tracking unit **200**, and device **150** position and orientation from device (device tracking data) tracking unit **170**. Registration unit **160** then translates and rotates the reference image to match the position and orientation of subject **100** at the time the location of device **150** location was measured. An image of device **150**, or a graphic symbol of element **151** is synthesized by device tracking unit **170**, or by registration unit **160**. This image is superimposed upon the translated/rotated image of subject **100** at its absolute location and orientation to result in a registered image having both an image of subject **100** and device **150** correctly registered with each other.

[**0021**] Alternatively, registration unit **160** may transform the absolute location/orientation of device **150** in the reverse sense, then superimpose an image of device **150** at the transformed location/orientation on the reference image.

[**0022**] Subject tracking unit **200**, registration unit **160** and device tracking unit **170** are shown as separate units for illustration reasons only. Generally, tracking, registration and device tracking information are sent for further processing by the imaging device (processor **121** of **FIG. 1**). In embodiments of the present invention, processor **121** comprises subject tracking, registration and device tracking processing contained therein.

[**0023**] Proposed is a system where the operator is given active, precise and real-time guidance for positioning of a medical device guide. Such a system could be used for delivery of many different diagnostic and interventional devices. For example, it could be used to guide the placement of a therapeutic laser, or a biopsy needle guide.

[**0024**] Referring further to **FIG. 1**, an embodiment of a medical device positioning system for use during a medical procedure on a subject while imaging the subject is provided herein. The system comprises a medical device, such as invasive device **150**, and corresponding tracking device for example element **151**, an imaging device **120** for acquiring images of the subject and medical device, and a medical device monitoring subsystem **210** for detecting movement of the device relative to a target region of interest on the subject. Monitoring subsystem **210** also provides feedback to an interface unit, such as interface **123**, to assist operator **1** of the positioning system to position the medical device. The medical device **150** is adapted for internal use within the subject for performing the procedure. As used herein, the term medical procedure includes but is not limited to diagnostic procedures such as in vivo imaging, taking biopsies, surgical procedures and therapeutic procedures such as ablation, laser treatments, ultrasonic treatments, brachea-therapy and the like. Also, as used herein, "adapted to", "configured" and the like refer to mechanical or structural connections between elements to allow the elements to cooperate to provide a described effect; these terms also refer to operation capabilities of electrical elements such as analog or digital computers or application specific devices (such as an application specific integrated circuit (ASIC)) that are programmed to perform a sequel to provide an output in response to given input signals.

[**0025**] As described earlier, the medical imaging device **120** may be a magnetic resonance imaging (MRI) device, an X-Ray imaging device, a computed tomography (CT) scanner, a Positron Emission Tomography system or an ultrasound scanner, or any other conventional medical imaging device adapted to obtain medical diagnostic reference images. The device tracking system is a device tracking system capable of real-time localization in three dimensions, such as MR Tracking, RF Tracking and other methods known to one skilled in the art.

[**0026**] The device monitoring subsystem **210** is desirably integrated within processor of **FIG. 1** and is adapted to monitor the position of a medical device relative to a target region of interest in the subject being imaged. In further embodiments of the device monitoring subsystem, the subsystem comprises device-specific configuration information from a configuration file which contains information relative to tracking method, such as position of rf coils, in device coordinates and further contains delivery information, such as position of exit hole and needle length for biopsy needle guide, in device coordinates. The monitoring subsystem is also coupled to interface **123** of **FIG. 1** so that an operator is able to mark the coordinates of a target position on

reference images, either by recording the 3D position of target in system coordinates or by placing an indicator such as an icon on the images. Device monitoring subsystem **210** is adapted to receive input information from various sources and then converts the information to a common coordinate system. For example, target location marked by the operator on reference images, 3D coordinates of tracked locations on device guide or device specific tracking and delivery information.

[**0027**] Desirably, device monitoring subsystem **210** is also adapted to provide advisory feedback, desirably through interface **123** to provide feedback to the operator of the system regarding relative position of the medical device relative to the target region of interest. This capability allows an operator to target the two-dimensional (2D) or three-dimensional (3D) position adjusted for proper delivery of device and also to monitor a current 2D or 3D position of the device guide, in real-time. The advisory feedback is responsive to input from the monitoring subsystem and wherein the output is feedback to the operator for use in navigating or positioning of the device to reach the target location. The feedback may comprise audio instructions such as "rotate guide ten degrees clockwise", text output on a display screen (interface **123**) such as "advance probe one inch" or visual output to show relative position of target and device guide on reference images.

[**0028**] The visual output of the advisory feedback could simply be unique icons on the reference image showing the target position and current position of the device guide, as described in the sample scenario below. When the icons coincide, then the guide has reached the desired position. The output could also be a much more sophisticated display. For example, the device configuration file could also include 3D coordinates of a wire-frame model of the device guide, in device coordinates. The 2D projection of the device guide could be superimposed on the 2D reference image to as an aid in positioning the guide. Additionally, the device configuration file could include the 3D coordinates of a wire-frame model of the medical device, and its 2D projection could be shown superimposed on the reference image. Supplementing this display might be additional device specific information, such as the projected needle track, or laser path.

[**0029**] Referring to **FIG. 2** is an exemplary method in which a pair of 2D images is acquired wherein each image is in-plane with tracked locations of the medical device. The images may be acquired in the same plane, or desirably in two different planes (e.g. axial, sagittal or coronal) in order to be useful in positioning the device. **FIG. 2A** shows an axial planar view of a region of interest **20** within a prostate, a target icon **22** and a sighting icon **24** and **FIG. 2B** shows a second image, a sagittal planar view within the prostate, acquired at a later time and showing the relative position of the sighting icon and the target icon at a different view of region of interest **20**. At the beginning of a medical procedure, the operator marks the location of the target on both of the acquired images with target icon **22**. The result is a unique, stationary target icon **22** superimposed on the reference images. During the procedure to position the needle guide, sighting icon **24** appears on both reference images. In an embodiment for positioning the device, the operator uses the sighting icon and target icon to navigate the device. In this embodiment, the operator moves the device guide in such a way as to bring the sighting icon **24** closer to the target icon **22** in both planes. When the sighting icon **22** coincides with the target icon **24** in both planes, device guide is properly positioned and the medical procedure (e.g. biopsy or therapy) can be performed. The operator may now insert the biopsy needle and perform the biopsy without further positioning. Additionally, projected needle paths or device outlines may be shown as separate visual outputs in order to be used in navigational applications.

[**0030**] In an embodiment for monitoring a device, device monitoring subsystem **210** of **FIG. 1** uses image processing techniques to mathematically compare the most currently acquired image and thereafter outputs to interface **123** an advisory message or output (e.g. audio or predetermined response) if comparison shows the device has moved more than an acceptable or predetermined threshold.

[**0031**] In further embodiments, the monitoring subsystem **210** is adapted to compute the recorded three-dimensional (3D) target position in system coordinates, the device coordinates of three tracking coils embedded in the guide, the device coordinates of the needle exit hole, the needle length and travel in device coordinates, and the real-time system coordinates of the three tracking coils in system coordinates. This information is desirably converted to a common coordinate system and combined to compare the 3D position of the target with the 3D position of the guide to offer advice on positioning the guide for a biopsyin further embodiments, medical device monitoring subsystem **210** is responsive to either movement of the subject or movement of the medical device relative to a specified target region of interest within the subject. In one embodiment, the medical device subsystem **210** is adapted to respond to the movement with a predetermined response if the medical device position deviates by a specified distance from the target region of interest. For example, the monitoring subsystem **210** responds to motion of the medical device in pre-programmed fashion such as terminating therapy, acquiring new reference images, activating a device positioning subsystem to assist operator in repositioning device or alternatively activating advisory feedback.

[**0032**] Advisory feedback includes an output notification to operator, such as through interface **123** of **FIG. 1** that movement of the medical device relative to the target region of interest has occurred. For example, advisory feedback may include audio output such as "Device has moved. Laser has been shut down" text output such as "Device has moved. Do you wish to reposition?"; and, visual output. In one embodiment, visual output may comprise as unique icons corresponding to the target and the device to showing the target position and current position of device. In a further embodiment visual output may show a two-dimensional (2D) projection of a wire-frame model of device or guide superimposed on the reference images. In yet a further embodiment, visual output may comprise a cartoon-like representation of the medical device superimposed on the reference images. Desirably, the visual output also shows device specific information on reference images, such as projected needle track, laser path, exit holes, needle length and similar device delivery information.

[**0033**] Also provided herein is a method for positioning a medical device comprising generating at least one image of a region of interest of a subject including a representation of

a medical device superimposed in the image; monitoring a position of the medical device relative to a target region of interest within the subject; and, providing feedback to an interface upon detection of a change in position of the medical device relative to the target region. As described above, the feedback may include a first visual icon representing position of the device and a second visual icon representing the target region of interest, a text message, an audio advisory or a predetermined response. The predetermined response may include terminating therapy, activating the imaging device to acquire a new image or activating an advisory message to the interface unit. Desirably, the interface is adapted to respond to operator input of coordinates marking a target position of the medical device.

[0034] In further embodiments that are particular to MRI imaging applications, the monitoring subsystem **210** computes inputs from additional device-specific configuration information, such as information related to the tracking method, such as position of RF coils on device or guide, in device coordinates. Further, other inputs that would be useful in monitoring the device may be the static 3D coordinates of the centroid of the medical device or guide, when positioned at the target position which could be recorded when monitoring system activated or computed using a starting 3D position of device or guide from device tracking system, and tracked locations on device or guide. Alternatively, the real-time 3D position of tracked locations on device or guide from device tracking system could be used. In these embodiments, profiling beams (1D projections) are continuously acquired in axial, sagittal, and coronal planes and the profiling beams pass one of the following—3D position of centroid of medical device or guide or the 3D position of each of tracked location on device or guide. The monitoring subsystem thereafter mathematically compares most recently acquired profiling data with previously acquired profiling data and activates a response or feedback if the comparison shows device has moved significantly.

[0035] In a further MRI embodiment, where a MRI scanner is equipped with a MR Tracking system inputs may be from continuously acquired MR Tracking excitation data, such as from a body coil used for excitation or receiving excitation data with surface coil centered about target area, rather than tracking coil as is known in the art. The monitoring subsystem mathematically compares most recently acquired excitations with previously acquired excitations and activates a response or feedback if the comparison shows device has moved significantly. This embodiment allows simultaneous device tracking and motion detection. This is accomplished by using the same pulse sequence to excite spins for both functions. The MR tracking coils receive signals which can be used to determine device location, while the surface coil detects signals that are used to determine the global status and position of the region of interest.

[0036] While the preferred embodiments of the present invention have been shown and described herein, it will be obvious that such embodiments are provided by way of example only. Numerous variations, changes and substitutions will occur to those of skill in the art without departing from the invention herein. Accordingly, it is intended that the invention be limited only by the spirit and scope of the appended claims.

1. A medical device positioning system for use during a medical procedure on a subject performed during imaging, the system comprising:

a medical device adapted for internal use within the subject for performing the medical procedure;

an imaging device for acquiring image data of a region of interest within the subject; and,

a medical device monitoring subsystem for monitoring position of the medical device relative to a target region of interest within the subject and for providing feedback to an interface unit when the position of the medical device deviates from the target region of interest.

2. The system of claim 1 wherein the medical monitoring subsystem is adapted to receive configuration information corresponding to the medical device and wherein the configuration information comprises at least one of three-dimensional (3D) coordinates of the device, tracking method information corresponding to the medical device, physical dimensions of the device and a model representation of the device.

3. The system of claim 1 wherein the medical device monitoring subsystem is responsive to at least one of movement of the subject and movement of the medical device relative to the target region of interest within the subject.

4. The system of claim 3 wherein the medical device monitoring subsystem responds to the movement with a predetermined response if the medical device position deviates by a specified distance from the target region of interest and wherein the predetermined response comprises at least one of terminating therapy, activating the imaging device to acquire a new image and activating an advisory message to the interface unit.

5. The system of claim 1 wherein the medical device monitoring subsystem is further adapted for providing advisory feedback to the interface unit.

6. The system of claim 5 wherein the advisory feedback comprises at least one of a visual icon representing position of the device, a text message and an advisory.

7. The system of claim 1 further comprising a tracking device for tracking a location of the medical device.

8. The system of claim 1 wherein the imaging device comprises at least one of a magnetic resonance imaging (MRI) scanner, a computed tomography (CT) scanner, a X-ray device, a Positron Emission Tomography (PET) system and an ultrasound scanner.

9. The system of claim 1 wherein the medical device comprises at least one of a biopsy needle guide, an invasive probe, an ablation device, a laparoscope and a therapeutic laser.

10. The system of claim 1 wherein the interface is further adapted to respond to operator input of coordinates marking a desired target position for the medical device.

11. The system of claim 2 wherein the medical device configuration information comprises information corresponding to a plurality of medical device types and includes a visual representation of the medical device for superimposing on the images based on the device configuration information for a selected medical device.

12. The system of claim 11 wherein the visual representation of the medical device is a wire-frame model of the medical device.

13. A medical device positioning system for use during a medical procedure on a subject performed during imaging, the system comprising:

a medical device adapted for internal use within the subject for performing a medical procedure;

an imaging device for acquiring image data of a region of interest within the subject;

a tracking device for tracking a location of the medical device; and,

a processor coupled to the medical imaging device and the tracking device for generating images of the region of interest with a visual representation of the medical device superimposed on the images and the processor is further adapted to monitor a position of the medical device relative to the region of interest, the processor responding to change in the position and providing feedback to an interface.

14. The system of claim 13 wherein the medical imaging device comprises at least one of a magnetic resonance imaging (MRI) scanner, a computed tomography (CT) scanner, a X-ray device, a Positron Emission Tomography (PET) system and an ultrasound scanner.

15. The system of claim 13 wherein the medical device comprises at least one of a biopsy needle guide, an invasive probe, an ablation device, a laparoscope and a therapeutic laser.

16. The system of claim 13 wherein the interface is coupled to the processor for displaying the images representing the region of interest and the visual representation of the medical device, the interface being for use in positioning the medical device during the medical procedure and being further adapted to respond to movement of the medical device in real-time.

17. The system of claim 13 wherein the feedback provided comprises at least one of a visual icon representing position of the device, a text message, and an audio advisory.

18. The system of claim 13 wherein the interface is further adapted to respond to operator input of coordinates marking a target position of the medical device.

19. The system of claim 13 wherein the processor is further adapted to provide an advisory response when the medical device deviates from a specified target position.

20. The system of claim 13 wherein the processor further includes medical device configuration information corresponding to a plurality of medical device types and wherein the visual representation of the medical device on the images is based on the device configuration information for a selected medical device.

21. The system of claim 20 wherein the visual representation of the medical device is a wire-frame model of the medical device.

22. The system of claim 13 wherein the processor is further adapted to respond with a predetermined response if the medical device position deviates by a specified distance from the target region of interest and wherein the predetermined response comprises at least one of terminating therapy, activating the imaging device to acquire a new image and activating an advisory message to the interface unit.

23. A method for positioning a medical device comprising:

generating at least one image of a region of interest of a subject including a representation of a medical device superimposed in the image;

monitoring a position of the medical device relative to a target region of interest within the subject; and,

providing feedback to an interface upon detection of a change in position of the medical device relative to the target region.

24. The method of claim 23 wherein the feedback comprises at least one of a first visual icon representing position of the device and a second visual icon representing the target region of interest, a text message, an audio advisory and predetermined response.

25. The method of claim 24 wherein the predetermined response comprises at least one of terminating therapy, activating the imaging device to acquire a new image and activating an advisory message to the interface unit.

26. The method of claim 23 wherein the interface is adapted to respond to operator input of coordinates marking a target position of the medical device.

27. The method of claim 23 wherein image data is acquired using of at least one of a magnetic resonance imaging (MRI) scanner, a computed tomography (CT) scanner, a X-ray device, a Positron Emission Tomography (PET) system and an ultrasound scanner.

28. The method of claim 23 wherein the feedback is used for navigating the medical device to a target region of interest.

29. The system of claim 1 wherein the feedback is used for navigating the medical device during the medical procedure.

30. The system of claim 13 wherein the feedback is used for navigating the medical device during the medical procedure.

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专利名称(译)	医疗设备定位系统和方法		
公开(公告)号	US20040034297A1	公开(公告)日	2004-02-19
申请号	US10/064749	申请日	2002-08-13
[标]申请(专利权)人(译)	通用电气公司		
申请(专利权)人(译)	通用电气公司		
当前申请(专利权)人(译)	通用电气公司		
[标]发明人	DARROW ROBERT DAVID DUMOULIN CHARLES LUCIAN		
发明人	DARROW, ROBERT DAVID DUMOULIN, CHARLES LUCIAN		
IPC分类号	G01T1/161 A61B5/055 A61B5/06 A61B6/03 A61B8/08 A61B17/32 A61B18/20 A61B19/00 A61B5/05		
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外部链接	Espacenet USPTO		

摘要(译)

提供了一种医疗设备定位系统和在成像期间在对象上进行医疗过程期间使用的方法。该系统包括适于在受试者体内内部使用以执行医疗程序的医疗装置和用于获取受试者内感兴趣区域的图像数据的成像装置。另外，该系统包括医疗设备监视子系统，用于监视医疗设备相对于对象内的目标感兴趣区域的位置，并且当医疗设备的位置偏离目标感兴趣区域时向接口单元提供反馈。