

(19)



(11)

EP 2 207 483 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:

01.06.2016 Bulletin 2016/22

(21) Application number: **08840319.1**

(22) Date of filing: **20.10.2008**

(51) Int Cl.:

A61B 8/00 (2006.01)

(86) International application number:

PCT/US2008/011973

(87) International publication number:

WO 2009/051847 (23.04.2009 Gazette 2009/17)

(54) THREE DIMENSIONAL MAPPING DISPLAY SYSTEM FOR DIAGNOSTIC ULTRASOUND MACHINES AND METHOD

DREIDIMENSIONALES MAPPING-DISPLAY-SYSTEM FÜR DIAGNOSTISCHE
ULTRASCHALLGERÄTE UND VERFAHREN

SYSTÈME D'AFFICHAGE À MAPPAGE TRIDIMENSIONNEL POUR DES MACHINES DE
DIAGNOSTIC À ULTRASONS ET PROCÉDÉ

(84) Designated Contracting States:

**AT BE BG CH CY CZ DE DK EE ES FI FR GB GR
HR HU IE IS IT LI LT LU LV MC MT NL NO PL PT
RO SE SI SK TR**

(30) Priority: **19.10.2007 US 999789 P**

(43) Date of publication of application:

21.07.2010 Bulletin 2010/29

(73) Proprietor: **METRITRACK, INC.**

Hillside, IL 60162 (US)

(72) Inventor: **Caluser, Calin**

Glen Ellyn, IL 60137 (US)

(74) Representative: **Schäfer, Matthias W.**

Patentanwalt

Schwanseestrasse 43

81549 München (DE)

(56) References cited:

WO-A1-2006/008300

US-A1- 2004 097 805

US-A1- 2005 015 005

US-A1- 2006 262 970

US-A1- 2007 083 117

US-A1- 2007 167 801

US-A1- 2007 239 004

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description

I. Technical Field

[0001] The present invention relates to diagnostic ultrasound technology and, more particularly, to a diagnostic ultrasound system in which ultrasound probe position registration is automated, the position of each pixel in the ultrasound image in reference to predetermined anatomical reference points is calculated, and specified information is stored on command. Moreover, the system, during real time ultrasound scanning enables the ultrasound probe position and orientation to be continuously displayed over a body or body part diagram, thereby facilitating the storage of information.

II. Background of the Invention

[0002] Ultrasound is an important imaging modality for medical diagnostic purposes and as a guidance tool for diagnostic or therapeutic procedures, like soft tissue needle biopsy, tumor ablation, etc. Ultrasound can be used over the entire human body and has certain advantages over other modalities, including, among others: the ability to locate and characterize medical problems; lower cost compared to modalities such as MRI and CT; real time operation; and, the lack of ionizing radiation with the known associated health risks.

[0003] Ultrasound imaging systems transmit sound waves of very high frequency (e.g., 1 MHz to 20 MHz) into the patient's body and the echoes scattered from structures in the patient's body are processed to create and display images and information related to these structures.

[0004] Ultrasound imaging can be applied to various regions or organs in the body. For example, a breast ultrasound procedure involves the placement of an ultrasound transducer over a region of interest of the breast, with the radiologist or other medical professional (the "user") viewing a real-time ultrasound image output on a display. The ultrasound machine monitor usually displays relevant text and/or graphical information next to the ultrasound image for simultaneous viewing by the user. The user can freeze the display, and the corresponding image can be printed on a printer or stored in digital format.

[0005] Two dimensional ("2D") ultrasound imaging, the most common technique used today, represents a slice through the region of interest. Three-dimensional ("3D") ultrasound scanning is available; however, it is usually used in conjunction with 2D scanning techniques. Currently, most diagnostic studies are performed using 2 D scanning technique.

[0006] The vast majority of ultrasound guided biopsies and other invasive ultrasound guided invasive procedures done by free hand and other more automated modes use the ultrasound machine 2D display mode. Therefore, it is desirable to have a fast and accurate way

to find the target during such invasive procedures.

[0007] It is important to accurately store positional annotations for later evaluation, since this is essential for final interpretation, diagnosis, and treatment. As digital storage and communication of medical information replace hard copy based storage and communication technologies, the accurate and consistent annotation of ultrasound and other medical images is critical. Correlation of ultrasound images with images of the same body region obtained with other modalities (MRI, CT, mammograms, PET, etc.) becomes increasingly important for medical diagnostic and therapeutic purposes. As a result, precise positional registration of the targets is important.

[0008] This importance is illustrated by noting that finding a small tumor can save a patient's life. The smaller the tumor is before treatment, the higher the probability of long term patient survival; however, a small tumor is difficult to find in a patient's body and differentiate from other structures in the same region. Many times a suspicious small finding can coexist in the same region with multiple benign findings (cysts, solid benign nodules, etc), which may create confusion during a follow up exam and may lead to missing the suspicious lesion. As imaging diagnostic devices provide ever greater detail and sub-millimeter resolution, accurate position registration and mapping of lesions is becoming increasingly important in order to take advantage of the increased capabilities.

[0009] Ultrasound procedures are highly dependent on the device user's experience and training. Position recording of certain findings is important, especially for the small targets and /or multiple targets. Most frequently, an ultrasound user will hold the ultrasound transducer in one hand and use the other hand to operate the ultrasound machine controls. It is desirable to obtain the instant recording of target coordinates

[0010] seen in the ultrasound image in relation to the anatomical reference (for example, a nipple) and the simultaneous recording of the transducer position. Currently, the automated recording of the transducer position in real time scanning is limited due to the motion of the pre-selected anatomical reference secondary to body and transducer induced motion. Therefore, it is desirable to continuously update the position of the anatomical references, or landmarks, and apply the correction to the obtained measurements.

[0011] The American College of Radiology (ACR) recommends that all ultrasound images be properly labeled. For example, for breast ultrasound images, the position, in hourly format or other format, and distance from nipple should be displayed with each diagnostic image containing significant findings. Currently, ultrasound findings are manually labeled by an operator, which is time consuming and prone to errors. Manual labeling involves the typing of an approximate position in the organ or part of the body, since an accurate position registration is time consuming and, importantly, difficult for the user.

[0012] Although multiple ultrasound guidance systems

and devices already exist, they do not offer a practical and accurate solution to mapping patient findings in 2D or 3D images in relation to set anatomical reference point(s), which is operator independent during a routine examination, with real time correction for the patient's motion.

[0013] US patent application US 2007/039004 A1 to Kakee, et al discloses and claims an apparatus and method for indicating locus of an ultrasound probe. This example enables an operator to determine the completeness of an examination through periodic mapping of a body part through the anatomical referencing of probe position. The shortcoming of Kakee is that it does so in a static environment without correcting for body or tissue movement. Another shortcoming is that mapping is done on a timed basis; there is no opportunity for an operator to select when to mark an image.

[0014] International application WO 2006/008300 A1 to Politecnico di Milano discloses and apparatus for navigation and fusion of images using optical markers. This prior art example does include a feature of dynamic referencing to body tissue. However, a shortcoming of this example is that it relies on preexisting images for co-registration. Another shortcoming of this example is that it is useful using optical markers only.

[0015] A significant shortcoming of all prior art is that any reference data is in a format not useful to an operator. The data must be, at a later time than an examination, be converted into readable data.

[0016] It would be beneficial, therefore, to obtain the accurate position of selected targets in the ultrasound images in relation to set anatomical reference point(s) with the corresponding ultrasound transducer position and orientation by selecting the target in the ultrasound image at the time of examination or at a later date in the stored images with attached positional information. The present invention provides such an advance to the art.

III. Objects and Advantages of the Present Invention

[0017] It is an object of the present invention to significantly reduce the time of the examination by eliminating the time consuming manual labeling of images and speeding up the target finding at subsequent examinations.

[0018] It is a further object of the present invention to obtain the accurate position of selected targets in ultrasound images in relation to set anatomical reference point(s) with the corresponding ultrasound transducer position and orientation by selecting the target in the ultrasound image at the time of examination or at a later date in the stored images with attached positional information in both 2D or 3D imaging techniques.

[0019] It is a further object of the present invention to enhance correlation capability with other diagnostic imaging modalities like CT scans, MRI, mammograms etc.

[0020] It is yet a further object of the present invention to eliminate or minimize errors due to inaccurate position

labeling, therefore reducing the risk of costly lawsuits due to missed diagnosis and decrease the number of callbacks for the patients for repeat examination.

[0021] One advantage, among the many that will be appreciated by those skilled in the arts, is that the present invention provides an easy, uniform, method of communicating the target position among healthcare providers by guiding the ultrasound to a previously recorded target through following the real time display of the ultrasound transducer position in relation to the target coordinates from a previous examination.

IV. Summary of the Invention

[0022] The present invention provides an apparatus and method of use for automated ultrasound probe position registration, calculating the position of each pixel in the ultrasound image in reference to the predetermined anatomical reference points (AR), and storing selected information on demand. The present invention further enables, during real time ultrasound scanning, continuous ultrasound probe position and orientation display, which display be permanently stored in the system's memory at the users command.

[0023] The Present invention comprises a hardware/software application and real time commercial 3D position registration system interfaced with an ultrasound machine.

[0024] After initial calibration and selection of one or more anatomical reference (nipple, umbilicus etc), positional information associated with each individually recorded image frame or each image in a cine loop is stored with the corresponding image. Using a pointing device with the system display, spatial numerical coordinates of the selected pixel or region, including the distance from the anatomical reference, depth, angle to the body axis and a graphical representation, are displayed next to the ultrasound image. Also displayed are the real time position of the ultrasound probe and target position in a diagram shown next to the real time ultrasound image, providing orientation help for the ultrasound operator.

[0025] Each ultrasound saved image or set of images in a cine loop will have attached the positional information corresponding to each pixel in the ultrasound frame and the diagram with the body part with the ultrasound transducer position and orientation in reference to the anatomical reference(s) and position of a target pixel(s), if any are selected. Other body parts or regions can be recorded with corresponding anatomical reference points, ex.: liver with umbilicus, neck with thyroid cartilage etc. Target pixel selection can be made at the time of the image capture, before saving the image, or at a later time at the review station.

[0026] During future examinations, the user is guided to the target by entering the target coordinates obtained at the previous examination, display the target in the body diagram and adjust the transducer position in the real time body diagram to overlap the target.

[0027] For the accurate automated recording of body targets and transducer position related to certain anatomical references, a user continuously obtains positional information from the preset anatomical references and the motion correction instantly applied to the transducer positional coordinates.

[0028] This is achieved by continuously monitoring the preset anatomical reference point(s) position, which in the preferred embodiment can be achieved with a magnetic sensor placed next to the anatomical reference on the skin. In an alternate embodiment the anatomical reference tracking can be obtained with an overhead tracking system using digital infrared or optical cameras with or without skin markers. In this embodiment, one camera can be used, or two or more cameras can be also used to achieve a three dimensional stereoscopic effect.

[0029] There has been outlined, rather broadly, the more important features of the invention in order that the detailed description thereof that follows may be better understood, and in order that the present contribution to the art may be better appreciated. There are, of course, additional features of the invention that will be described hereinafter and that will form the subject matter of the invention.

V. Brief description of the drawings

[0030]

Fig.1 depicts an overview illustration of the inventive apparatus placed in an ultrasound system.

Fig.2 illustrates the functional block diagram for the inventive device preferred embodiment with a magnetic sensor used for anatomical reference tracking.

Fig.3 depicts an alternate embodiment illustrating an overhead infrared or 25 optical anatomical reference tracking system.

Fig.4 illustrates the functional block diagram for the inventive device in the alternate embodiment with an overhead infrared or optical anatomical reference tracking system.

Fig.5 depicts the inventive apparatus in a breast ultrasound examination

Fig 6 depicts the image created during a breast examination as illustrated in Figure 5.

Fig.7 illustrates the ultrasound transducer with the sensors in the calibrating tool.

Fig.8 illustrates the steps of initial calibration.

Fig.9 illustrates the steps needed to measure and record the positional information associated with the diagnostic ultrasound images.

VI. Detailed Description of the Preferred Embodiment

[0031] Before explaining the preferred embodiment of the present invention in detail, it is to be understood that the present invention is not limited in its application to the details of arrangements of the components set forth

in the following description. As will be appreciated by those skilled in the arts, the present invention is capable of other embodiments and of being practiced and carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein are for the purpose of description and should not be regarded as limiting. It is also to be understood that where ranges are provided for various aspects of the invention and for examples, they are approximate ranges and are not to be limiting except where noted otherwise.

[0032] Turning to Figure 1, an over view of the physical aspects of an ultrasound device employing the inventive apparatus 20 is seen. Ultrasound machine 22 is a standard device including display 24, interface with keyboard 26 and pointer 28, chassis containing operating hardware (not seen) 30, transducer connecting cord 32, and transducer 34.

[0033] Inventive apparatus (also referred to as three dimensional mapping display, or TDMD) 20 is depicted and comprises TDMD display 38, TDMD Chassis 40 containing hardware (also referred to as a "processor") and software (not seen; described in detail below), 3D magnetic tracking member 42 with the transmitter 44 connected to TDMD 20 by 3D magnetic tracking member cord 46, first magnetic sensor 48 connected to TDMD 20 by first magnetic sensor cord 54 and second magnetic sensor 52 connected to TDMD 20 by second magnetic sensor cord 56.

[0034] For completeness in explaining Figure 1, Patient A is situated on examining table B.

[0035] Turning to Figure 2, a block diagram illustrating the various general working aspects of inventive device 20 are shown. First magnetic sensor 48 and second magnetic sensor 52 provide the positional information to the TDMD 20 3D position board/module 60 (not seen). Video output 24 from ultrasound device 22 is digitized by the dedicated TDMD module/board 40. It should be noted that the analog to digital image conversion is not needed if the ultrasound machine can be interfaced and it can directly provide the digital images to the TDMD 22.

[0036] TDMD can continuously track one or several anatomical reference markers or positional body markers, which can increase the overall accuracy of the system. If multiple positional body markers are used, not all of them need to be continuously tracked. The positional body markers may be surface markers, attached at the skin, or may be internal markers, endocavitary, endoluminal or otherwise placed in the body at a known position. A known internal structure, like vessel crossing, may also serve as an anatomical reference point but without the advantage of having the position continuously tracked.

[0037] Other configurations will work as well. For non-limiting example, Figure 3 illustrates an alternate configuration in which second magnetic sensor 52 provides the 5 positional information to the TDMD 3D position board/module 60. The overhead infrared or optical anatomical reference (AR) tracking system 43 provides the positional information to the TDMD computer 40. Video

output 24 from the ultrasound device 22 is digitized by the dedicated TDMD module/board 40. Again, analog to digital image conversion is not required if the ultrasound device 22 can be 10 interfaced and directly provide the digital images to TDMD computer 40. The digital ultrasound images with the associated positional information are displayed in the TDMD computer display 38 or stored for review and processing at a later time.

[0038] Turning to Figure 4, a block diagram illustrating the various general working aspects of inventive device 20 are shown. Second magnetic sensor 52 provides the 15 positional information to the TDMD 20 3D position board/module 60 and overhead infrared position detector 43 transmits positional information to TDMD computer 40. Video output 24 from ultrasound device 22 is digitized by the dedicated TDMD module/board 40. It should be noted that the analog to digital image conversion is not needed if the ultrasound machine can be interfaced and it can directly provide the 20 digital images to the TDMD 22.

[0039] Returning to Figure 1, second magnetic sensor 52 is attached to the exterior of transducer 34 and, as seen in more detail in Figure 5, first magnetic sensor 48 is positioned at the anatomical reference, here, the breast nipple C of Patient A.

[0040] Ultrasound device 22 video output 24 is directed to TDMD video capture 25 board at TMDS Chassis 40 through video output cord 58 as is 3D magnetic tracking member 42 through 3D magnetic tracking member cord 46. TDMS display 38 is then enabled to show images D captured by ultrasound device 22 and associated positional data as collected from 3D tracking member 42, first magnetic sensor 48 and second magnetic sensor 52. Turning to Figure 5, a detailed view of transducer 34 with the second magnetic sensor 52 and first magnetic sensor 48 applied at the upper margin of the right nipple. First magnetic sensor 48 continuously tracks the anatomical reference position, the nipple in this case, to compensate for motion artifacts during the ultrasound exam. Figure 6 illustrates TDMD display 38 with the captured video image D from the ultrasound machine and the body diagram of Figure 5 with the transducer 34 position and orientation at the time of image capture D and two different targets F and G in body part diagram I, and F' and G' as selected in image D image capture.

[0041] Additionally, each target is annotated in a display with the associated position (hourly representation or degrees to longitudinal axis and anatomical reference as center) and distance (cm) from the selected anatomical reference F and G. Positional coordinates are displayed under body part diagram I in Figure 6. While the inventive device enable any number of coordinates to be displayed, here the example includes Target number (T), example F and G, Positional in reference to anatomical reference in hour format (here, 9:30 for F and 9:00 for G), position from anatomical reference point in degrees (here, 15[deg.] for F and 0[deg.] for G), and distance from anatomical reference point in centimeters(cm) (here,

10.5cm for F and 7.41cm for G). Also, transducer 34 position location is identified at transducer position Icon E.

[0042] Additionally, an additional display function is to show a cumulative area of the transducer positions (via icon E) over the body diagram, where the ultrasound images were recorded during patient examination. This will allow for the quick evaluation of an ultrasound examination completeness, at the time of the examination or at a later time.

[0043] In the preferred embodiment, any off the shelf generic PC computer with Windows XP® (by Microsoft Corporation, Redmond, WA) can be used to run instructions compiled in C++ and dotnet languages. While preferred, those skilled in the arts will understand that the invention can be implemented on any other computer platform and operating system.

[0044] The software to run the program is that incorporated by reference above. The software substantially used to process the data received by the processor form the at least one sensor and data from the ultrasound to manipulate the data for identifying, and storing in memory as selected by the user, target site location and size information in relation to selected anatomical reference points for simultaneous review and interpretation and later retrieval for comparative purposes with later examination, whether compared in real time or a later time based upon saved data. The inventive device enabling a user to accurately review, evaluate, and compare examination results by having anatomical reference point guides to isolate target sites.

[0045] The body diagram representation is not limited to the "bird's eye view" type like the "clock" representation for the breast, but more complex and realistic three dimensional representations of the body or body regions, including images obtained using contour rendering algorithms, can be used. The calculated and recorded positional data can be displayed in these representations. The ultrasound transducer position, orientation, can be depicted in a realistic appearance in space so it can be easily reproduced at subsequent examinations.

[0046] Additionally, the preferred 3D position registration system is based on magnetic tracking technology (for example, like that manufactured by Ascension Technology, Burlington, VT); however, any other suitable technology, such as optical or ultrasound, may be employed. Moreover, the inventive device can be deployed as an add on to any existing ultrasound unit, and can outfit DICOM compatible and non DICOM machines as well. The magnetic sensors, also commercially available (Natural Point inc., Corvallis, OR), comprise at least one infrared cameras with the dedicated hardware and software receiving reflected infrared light from the reflectors applied over the anatomical references. The infrared cameras can be replaced with optical cameras and the infrared reflectors with optical markers. One or more infrared or optical cameras can also be used.

[0047] The ultrasound probe and anatomical reference point real time tracking is not limited to the above solution,

but other tracking modalities like ultrasound, optical, inertial etc. can be used for the ultrasound probe and optical/pattern recognition, magnetic, etc. for the anatomical reference point real time tracking. It should also be noted that tracking modalities can be used in combination with one another, for non-limiting example, ultrasound tracking with optical tracking. It is also notable that the described TDMD system and method can optionally be used with the anatomical reference tracking feature disabled.

[0048] In any of the above configurations, initial calibration is needed to register the ultrasound probe scanning plane orientation and position. The initial calibration may be performed with or without the use of a second positional sensor 62 (Fig. 7), however the use of a second magnetic sensor makes the calibration task easier and more precise. Without second positional sensor 62, scan-head center of transducer 34 and plane orientation need to be manually entered. This initial calibration is done once only, unless a different ultrasound probe is used or the fixed magnetic sensor position on the ultrasound transducer is modified. As those skilled in the arts will understand, there are many ways and methods to calibrate ultrasound equipment. For non-limiting example, one method includes placing ultrasound transducer 34 in a dedicated holder 61 which has the calibrating magnetic sensor 62 attached to correspond exactly to the center of the ultrasound transducer 34 scanning head, in a position aligned with the scanning plane of the transducer.

[0049] The initial system calibration steps are shown in Fig. 8. When performing the second magnetic sensor 52 calibration, TDMD computer 40 registers the 3D position of sensor 52 in relation to the center of the transducer 34 scanning head 64 and in relation to the transducer scanning plane 68, so it can accurately define the position of each pixel in the ultrasound image in relation to the transducer scanning head and first magnetic sensor 48. That coordinate is then saved 70. In addition to the above sensor initial calibration, the ultrasound image size calibration is needed for each transducer 72, in dots per inch (dpi) or per mm and it can be done automatically in systems where this information is passed from the ultrasound machine, 22, to the TDMD computer. For systems where this is not possible, the manual calibration for image size: depth and width, is needed and can be performed by manually entering the calculated values, obtained by dividing the number of pixels to the size of markers of known size in the ultrasound image. This information is then saved 74. The process is repeated 76 until all required values are calculated and saved 76. The initial calibration process is then exited 78.

[0050] Turning to Figure 9, the TDMD operation steps required to record the 3D position of targets in relation to anatomical reference points are shown. For each patient, at the beginning of examination the anatomical reference spatial position and the ultrasound probe orientation relative to the body is defined and recorded, 501.

One method is to hold the ultrasound transducer scan-head center at the anatomical reference, for ex. on the nipple, with the transducer held in the preset orientation, ex. sagittal plane, horizontal, parallel to the patient and examination table long axis (Fig 1). At least one anatomical reference point needs to be defined at the beginning of each examination, however more than one anatomical reference points can be defined, which can increase the measurements accuracy. When a second magnetic sensor is used to track the anatomical reference position, the first magnetic sensor 48 position in relation to the anatomical reference point is recorded and computed by the TDMD 40 during the anatomical reference setting step, so it can continuously track the anatomical reference point. This additional calculation is necessary when the first magnetic sensor 48 is applied in close proximity, but slightly off the selected anatomical reference. In other embodiments where the anatomical reference sensor or marker, for example when using the overhead anatomical reference tracking system with infrared reflectors or markers or optical markers, is applied exactly at the anatomical reference point, this additional correction is not necessary and can be skipped. If the magnetic anatomical reference marker can be applied exactly at the anatomical reference point, this additional correction is not necessary and can be skipped.

[0051] Continuing with Figure 8, at 502 the transducer 34 position and orientation and anatomical reference point are continuously displayed in TDMD computer display 38 or ultrasound display 24, as a moving icon over the body part diagram, in reference to the anatomical reference point, with an "out of range" warning when the transducer is moved out of the scanning region range or too far from the magnetic transmitter. The frame images are entered and displayed in the TDMD display 38 or if implemented at the ultrasound machine host computer, ultrasound display 24. In the preferred embodiment, the ultrasound user can "freeze" the 2D still image of interest or capture short video cine loops or 3D images, 503 (Fig. 8). The "frozen" image or the video clip can be saved in TDMD computer 40 or a host computer with the positional information associated to each frame or set of frame images, in a local database, 504, (Fig. 9).

[0052] The coordinates associated with a target in a still image, in relation to the anatomical reference point, can be displayed by pointing to the target (image pixel/region of pixels) with a pointing device in the image displayed on the TDMD display 38 or Ultrasound display 24, step 505 (Fig. 9). The target position can be also determined at a later time in the same TDMD computer or a remote computer with the TDMD software, from the saved ultrasound images with the associated positional information. The target positional information can be displayed at the time of the ultrasound examination or at a later date, it also can be printed and stored in digital format at any time after the acquisition.

[0053] For the images in cine loops, the position display process is similar to the still images, after the cine

loop is "frozen" at a certain frame. For 3D ultrasound probes, the same principle applies when a 2D image is reconstructed from the recorded 3D data and the positioning information is applied to the ultrasound 2D image.

[0054] The position of each pixel in an ultrasound image in reference to the anatomical reference(s) is calculated from the ultrasound probe tracking system data and corrections applied to the anatomical reference points from the secondary tracking system that monitors the anatomical reference points. Both tracking systems provide 3D positional data. The positional information displayed for each image is presented in alphanumeric format as distance and angle from the anatomical reference, hourly coordinates, where the position of a target is assigned an hour from 1 to 12 o'clock, when the region (breast or abdomen) is viewed from above as a clock, with the anatomical reference, nipple or umbilicus respectively, imagined in the middle of the clock and also as a graphic diagram of the region, see, e.g., Figure 6. Additional data fields are also available, including the position of the patient during the examination (supine, lateral decubitus, etc). The graphic diagram points to the relative position of a target over a diagram of a body part, the breast, for example. Accordingly, it is easy to see that multiple targets can be selected/displayed or erased.

[0055] The TDMD computer allows for the manual or automatic entry and display of target coordinates from previous exams over the body diagram or body part diagram, with the ultrasound probe icon position and orientation in relation to the anatomical reference point and body axis, represented in real time in the diagram. This feature allows for ultrasound device operator orientation and guidance to help moving the ultrasound transducer and find a known target from a previous examination.

[0056] Accordingly, the present invention is a system and method where a target position in a human or animal body can be automatically recorded in reference to any preset anatomical reference point, when performing an ultrasound examination. The system allows for automatic correction for body or anatomical reference motion during the examination.

[0057] It is to be understood that while the invention has been described as being implemented on the ultrasound machine itself, it is capable of other deployments as well. For non-limiting example, it could be deployed at the level of a host computer or a separate computer from the ultrasound system where the separate computer is connected to the ultrasound machine so it can simultaneously display the image outputs from the ultrasound machine and the diagnostic image positional information in graphic and alphanumeric modes from the TDMD device. The information from the separate computer can be stored as hardcopy or it can be digitally stored.

[0058] It is also to be understood, that even though numerous characteristics and advantages of the preferred and alternative embodiments have been set forth in the foregoing description, together with details of the structure and function of the embodiments, the disclosure

is illustrative only, and changes may be made in detail within the principles of the invention to the full extent indicated by the broad general meaning of the terms in which the appended claims are expressed.

Claims

1. An apparatus for processing ultrasound data and anatomical reference point data comprising:

a controller comprising at least one sensor port, an ultrasound data port, and a processor port; an ultrasound machine (22) with an ultrasound probe comprising an imaging transducer (34) for capturing ultrasound image data during an examination, the ultrasound machine being operatively connected to the ultrasound data port; a processor operatively connected to the processor port for receiving sensor data and ultrasound data; and a sensor (52) for identifying the positional information of the ultrasound probe;

characterized in that the apparatus further comprises

at least a second sensor (48) or an overhead position detector (43) for identifying, continuously tracking and transmitting to the processor the location of at least one anatomical reference point, the at least one second sensor (48) or the overhead position detector (43) being operatively connected to the at least one sensor port; wherein the processor receives ultrasound data and sensor data from the controller and uses the data to determine the ultrasound probe position in reference to one or more anatomical reference points, to determine the position of each pixel in the ultrasound image in reference to one or more predetermined anatomical reference points and to associate the positional information of the ultrasound probe with each corresponding captured ultrasound image, wherein the ultrasound probe and the at least one reference point are tracked in real time during examination.

2. The apparatus of claim 1, further including a display for displaying ultrasound images and the corresponding associated positional information.

3. The apparatus of claim 2, further including a pointing device and being adapted to display on the display next to the ultrasound image spatial numerical coordinates of the selected pixel or region, including the distance from at least one anatomical reference point, depth, angle of the body axis and a graphical

representation.

of:

4. The apparatus of claim 1, 2 or 3, further including a memory operatively connected to the processor. 5
 5. The apparatus of claim 4 wherein the memory stores data for the processor comprising processed sensor data and processed ultrasound data.
 6. The apparatus of Claim 4 or 5, wherein the memory stores data for later retrieval and overlay with subsequent ultrasound data to facilitate anatomical reference point correlation and target site location. 10
 7. The apparatus according to any one of the preceding claims, wherein the sensor for identifying the positional information of the ultrasound probe is magnetic. 15
 8. The apparatus according to any one of the preceding claims, wherein at least one sensor is selected from the group of ultrasound, optical, infrared, and inertial. 20
 9. The apparatus according to any one of the preceding claims, wherein the overhead position detector (43) is located overhead to track ultrasound probe location and anatomical reference point location for transmission to the processor. 25
 10. The apparatus according to any one of the preceding claims, wherein the processor generates a three dimensional mapping of the processing results. 30
 11. The apparatus according to any one of the preceding claims wherein the sensor (52) for identifying the positional information of the ultrasound probe is attached to the exterior of the transducer (34) of the ultrasound probe. 35
 12. The apparatus according to any one of the preceding claims wherein the ultrasound machine (22) operatively connected to the ultrasound data port provides directly digital image data to the apparatus. 40
 13. The apparatus according to any one of the preceding claims wherein the positional information of the ultrasound probe comprises the location and the orientation of the ultrasound probe when capturing the corresponding ultrasound image. 45
 14. The apparatus according to any one of the preceding claims comprising a further positional sensor (62) for calibration of the center and plane orientation of the transducer (34). 50
 15. A method for real time tracking and capturing target sites in reference to selected anatomical positions during ultrasound procedures comprising the steps 55
- selecting one or more anatomical reference points;
 - using a tracking sensor (52) to locate and track the position of an ultrasound transducer (34) with respect to the selected anatomical reference points;
 - using at least another sensor (48) or an overhead detector (43) for continuously tracking and transmitting to the processor the location of the one or more anatomical reference points;
 - performing an ultrasound procedure using the transducer (34) wherein the transducer (34) transmits image data to an ultrasound machine (22) and the tracking sensor (52) transmits data to a processor;
 - transmitting data from the ultrasound machine (22) to the processor; and
 - obtaining from the processor data regarding ultrasound probe position in reference to the one or more anatomical reference points and the position in an ultrasound image of each pixel in reference to the one or more anatomical reference points from the data transmitted to the processor by at least one of the tracking sensor (52), the at least another sensor (48) or the overhead detector (43), and the ultrasound device; and
 - associating the obtained positional information of the ultrasound probe with each corresponding captured ultrasound image, wherein the ultrasound probe and the at least one anatomical reference point are tracked in real time during examination.
 16. The method of Claim 15 comprising the further step of reviewing on a display.
 17. The method of Claim 15 or 16, wherein the ultrasound probe position and orientation are displayed over a body or body part diagram.
 18. The method of Claim 17 wherein the body or body part diagram is a medical image of the same body region obtained with another medical modality.
 19. The method according to any one of the preceding claims 15 to 18, wherein displaying occurs continuously during real-time ultrasound examination.
 20. The method according to any one of the preceding claims 15 to 19, comprising the further step of storing the processor data in memory.
 21. The method of Claim 20 comprising the further step of retrieving the stored processor data for review.

22. The method according to any one of the preceding claims 15 to 21 comprising the step of defining and recording the anatomical reference spatial position and the ultrasound probe orientation relative to the body at the beginning of examination.

Patentansprüche

1. Gerät zur Verarbeitung von Ultraschalldaten und Daten anatomischer Bezugspunkte, welches Folgendes aufweist:

eine Regeleinrichtung, welche mindestens einen Sensoranschluss, einen Ultraschall-Datenanschluss und einen Prozessoranschluss aufweist;

ein Ultraschallgerät (22) mit einem Ultraschallkopf, welcher einen bildgebenden Messwertgeber (34) zum Erfassen von Ultraschall-Bilddaten während einer Untersuchung aufweist, wobei das Ultraschallgerät mit dem Ultraschall-Datenanschluss operativ verbunden ist;

einen operativ mit dem Prozessoranschluss verbundenen Prozessor zum Empfangen von Sensordaten und Ultraschalldaten; und einen Sensor (52) zum Identifizieren der Informationen über die Position des Ultraschallkopfes;

dadurch gekennzeichnet, dass das Gerät weiter mindestens einen zweiten Sensor (48) oder einen Überkopf-Positionsdetektor (43) zum Identifizieren, fortlaufenden Verfolgen und Übermitteln des Ortes von mindestens einem anatomischen Bezugspunkt an den Prozessor aufweist, wobei der mindestens eine zweite Sensor (48) oder der Überkopf-Positionsdetektor (43) wirksam mit dem mindestens einen Sensoranschluss verbunden ist; wobei der Prozessor Ultraschalldaten und Sensordaten von der Regeleinrichtung empfängt und die Daten verwendet, um die Position des Ultraschallkopfes in Bezug auf einen oder mehrere anatomische Bezugspunkte zu bestimmen, um die Position jedes Pixels in dem Ultraschallbild in Bezug auf einen oder mehrere anatomische Bezugspunkte zu bestimmen und um die Information über die Position des Ultraschallkopfes mit jedem entsprechenden erfassten Ultraschallbild zu verknüpfen, wobei der Ultraschallkopf und der mindestens eine Bezugspunkt während der Untersuchung in Echtzeit verfolgt werden.

2. Gerät nach Anspruch 1, welches weiter eine Anzeige zum Anzeigen von Ultraschallbildern und der entsprechenden verknüpften Information über die Position aufweist.

3. Gerät nach Anspruch 2, welches weiter eine Zeigevorrichtung aufweist und dafür angepasst ist, auf der Anzeige neben dem Ultraschallbild räumliche Zahlenkoordinaten des ausgewählten Pixels oder Gebiets, einschließlich des Abstands von mindestens einem anatomischen Bezugspunkt, der Tiefe, des Winkels der Körperachse und einer graphischen Darstellung, anzuzeigen.

4. Gerät nach Anspruch 1, 2 oder 3, welches weiter einen Speicher aufweist, welcher mit dem Prozessor wirksam verbunden ist.

5. Gerät nach Anspruch 4, wobei der Speicher Daten für den Prozessor abspeichert, welche verarbeitete Sensordaten und verarbeitete Ultraschalldaten aufweisen.

6. Gerät nach Anspruch 4 oder 5, wobei der Speicher Daten für späteren Abruf und Überlagerung mit nachfolgenden Ultraschalldaten abspeichert, um Korrelation mit einem anatomischen Bezugspunkt und Standortbestimmung des Zielortes zu erleichtern.

7. Gerät nach einem der vorhergehenden Ansprüche, wobei der Sensor zum Identifizieren der Information über die Position des Ultraschallkopfes magnetisch ist.

8. Gerät nach einem der vorhergehenden Ansprüche, wobei mindestens ein Sensor aus der Gruppe von Ultraschall, optisch, Infrarot und Trägheit ausgewählt wird.

9. Gerät nach einem der vorhergehenden Ansprüche, wobei der Überkopf-Positionsdetektor (43) über Kopf angeordnet ist, um einen Standort des Ultraschallkopfes und einen Standort eines anatomischen Bezugspunktes zur Übermittlung an den Prozessor zu verfolgen.

10. Gerät nach einem der vorhergehenden Ansprüche, wobei der Prozessor eine dreidimensionale Abbildung der Verarbeitungsergebnisse erzeugt.

11. Gerät nach einem der vorhergehenden Ansprüche, wobei der Sensor (52) zum Identifizieren der Information über die Position des Ultraschallkopfes am Außenbereich des Messwertgebers (34) des Ultraschallkopfes angebracht ist.

12. Gerät nach einem der vorhergehenden Ansprüche, wobei das Ultraschallgerät (22), welches mit dem Ultraschall-Datenanschluss operativ verbunden ist, dem Gerät direkt digitale Bilddaten bereitstellt.

13. Gerät nach einem der vorhergehenden Ansprüche,

wobei die Information über die Position des Ultraschallkopfes den Standort und die Orientierung des Ultraschallkopfes aufweist, wenn das entsprechende Ultraschallbild erfasst wird.

14. Gerät nach einem der vorhergehenden Ansprüche, welches einen weiteren Positionssensor (62) zur Kalibrierung der mittigen und flächigen Ausrichtung des Messwertgebers (34) aufweist.

15. Verfahren zum Verfolgen und Erfassen von Zielorten in Bezug auf ausgewählte anatomische Positionen in Echtzeit während Ultraschalluntersuchungen, aufweisend die folgenden Schritte:

Auswählen eines oder mehrerer anatomischer Bezugspunkte;

Verwenden eines Verfolgungssensors (52), um die Position eines Ultraschallmesswertgebers (34) in Bezug auf die ausgewählten anatomischen Bezugspunkte aufzufinden und zu verfolgen;

Verwenden von mindestens einem weiteren Sensor (48) oder eines Überkopf-Detektors (43) zum fortlaufenden Verfolgen und Übermitteln des Standortes des einen oder der mehreren anatomischen Bezugspunkte an den Prozessor;

Durchführen einer Ultraschalluntersuchung unter Verwendung des Messwertgebers (34), wobei der Messwertgeber (34) Bilddaten an ein Ultraschallgerät (22) übermittelt und der Verfolgungssensor (52) Daten an einen Prozessor übermittelt;

Übermitteln von Daten von dem Ultraschallgerät (22) an den Prozessor; und

Erhalten von Daten vom Prozessor in Hinsicht auf eine Position des Ultraschallkopfes in Bezug auf den einen oder die mehreren anatomischen Bezugspunkte und die Position in einem Ultraschallbild jedes Pixels in Bezug auf den einen oder die mehreren anatomischen Bezugspunkte von den Daten, welche von dem mindestens einen Verfolgungssensor (52), dem mindestens einen weiteren Sensor (48) oder dem Überkopf-Detektor (43) und dem Ultraschallgerät an den Prozessor übermittelt wurden; und

Verknüpfen der erhaltenen Information über die Position des Ultraschallkopfes mit jedem entsprechenden erfassten Ultraschallbild, wobei der Ultraschallkopf und der mindestens eine anatomische Bezugspunkt während der Untersuchung in Echtzeit verfolgt werden.

16. Verfahren nach Anspruch 15, welches den weiteren Schritt des Überprüfens auf einer Anzeige aufweist.

17. Verfahren nach Anspruch 15 oder 16, wobei die Po-

sition und Ausrichtung des Ultraschallkopfes über einer schematischen Darstellung eines Körpers oder eines Körperteils angezeigt wird.

18. Verfahren nach Anspruch 17, wobei die schematische Darstellung eines Körpers oder eines Körperteils ein medizinisches Bild desselben Körperbereiches ist, welches mit einer anderen medizinischen Methode erzielt wurde.

10

19. Verfahren nach einem der vorhergehenden Ansprüche 15 bis 18, wobei das Anzeigen fortlaufend während der Ultraschalluntersuchung in Echtzeit geschieht.

15

20. Verfahren nach einem der vorhergehenden Ansprüche 15 bis 18, welches den weiteren Schritt des Abspeicherns der Prozessordaten in einem Speicher aufweist.

20

21. Verfahren nach Anspruch 20, welches den weiteren Schritt des Abrufens der gespeicherten Prozessordaten zur Überprüfung aufweist.

25

22. Verfahren nach einem der vorhergehenden Ansprüche 15 bis 21, welches den Schritt des Definierens und Aufzeichnens der anatomischen, räumlichen Bezugsposition und der Orientierung des Ultraschallkopfes in Bezug auf den Körper zu Beginn der Untersuchung aufweist.

30

Revendications

1. Un dispositif pour le traitement de données ultrasoniques et de données relatives à un point de référence anatomique comprenant :

un dispositif de commande comprenant au moins port de capteur, un port de données ultrasoniques, et un port de processeur;
un appareil à ultrasons (22) avec une sonde à ultrasons comprenant un transducteur d'imagerie (34) pour capturer des données d'image ultrasonique pendant un examen, l'appareil à ultrasons étant connecté de manière opérationnelle au port de données ultrasoniques ;

40

45

50

un processeur connecté de manière opérationnelle au port de processeur pour recevoir des données du capteur et des données ultrasoniques; et
un capteur (52) pour identifier les informations relatives à la position de la sonde à ultrasons ;

55

caractérisé en ce que le dispositif comprend de plus

- au moins un second capteur (48) ou un détecteur de position suspendu (43) pour identifier, suivre de manière continue et transmettre la position d'au moins un point de référence anatomique au processeur, le second capteur (48) ou le détecteur de position suspendu (43) étant au moins connecté de manière opérationnelle au port de capteur ;
où le processeur reçoit des données ultrasoniques et des données du capteur de la part du dispositif de commande et utilise les données pour déterminer la position de la sonde à ultrasons par rapport à un ou plusieurs points de référence anatomiques, de façon à déterminer la position de chaque pixel dans l'image ultrasonique par rapport à un ou plusieurs points de référence anatomiques prédéterminés et à associer les informations relatives à la position de la sonde ultrasonique avec chaque image ultrasonique capturée correspondante,
où la sonde à ultrasons et l'un au moins des points de référence sont suivis en temps réel durant l'examen.
2. Le dispositif de la revendication 1 comprenant de plus un affichage pour afficher les images ultrasoniques et les informations associées relatives à la position correspondantes.
 3. Le dispositif de la revendication 2 comprenant de plus un dispositif de pointage et étant adapté à afficher les coordonnées numériques spatiales du pixel ou de la région sélectionnée à côté de l'image ultrasonique sur l'affichage, y compris la distance entre au moins un point de référence, une profondeur, un angle de l'axe corporel et une représentation graphique.
 4. Le dispositif de la revendication 1, 2 ou 3 comprenant de plus une mémoire connectée de manière opérationnelle au processeur.
 5. Le dispositif de la revendication 4 où la mémoire sauvegarde des données pour le processeur comprenant des données de capteur traitées et des données ultrasoniques traitées.
 6. Le dispositif de la revendication 4 ou 5, où la mémoire sauvegarde des données pour une restitution ultérieure et une superposition avec des données ultrasoniques ultérieures de façon à faciliter la corrélation d'un point de référence anatomique et d'une position de site ciblée.
 7. Le dispositif selon l'une des revendications précédentes, où le capteur pour identifier les informations relatives à la position de la sonde ultrasonique est magnétique.
 8. Le dispositif selon l'une des revendications précédentes, où au moins un capteur est choisi dans le groupe constitué par ultrasonique, optique, infrarouge, et inertiel.
 9. Le dispositif selon l'une des revendications précédentes, où le détecteur de position suspendu (43) est placé en surplomb de façon à pouvoir suivre la position de la sonde ultrasonique et la position d'un point de référence anatomique pour transmission au processeur.
 10. Le dispositif selon l'une des revendications précédentes, où le processeur génère une cartographie tridimensionnelle des résultats traités.
 11. Le dispositif selon l'une des revendications précédentes, où le capteur (52) pour identifier les informations relatives à la position de la sonde ultrasonique est attaché à l'extérieur du transducteur (34) de la sonde ultrasonique.
 12. Le dispositif selon l'une des revendications précédentes, où l'appareil à ultrasons (22) connecté de manière opérationnelle au port de données ultrasoniques fournit directement des données d'image digitale au dispositif.
 13. Le dispositif selon l'une des revendications précédentes, où les informations relatives à la position de la sonde ultrasonique comprennent la position et l'orientation de la sonde à ultrasons lors de la capture de l'image ultrasonique correspondante.
 14. Le dispositif selon l'une des revendications précédentes comprenant un capteur de position (62) supplémentaire pour calibrer le centre et le plan d'orientation du transducteur (34).
 15. Un procédé pour suivre en temps réel et capturer des sites ciblés par rapport à des positions anatomiques sélectionnées lors de procédures ultrasoniques comprenant les étapes consistant à :
sélectionner un ou plusieurs points de référence anatomiques ;
utiliser un capteur de suivi (52) pour localiser et suivre la position d'un transducteur ultrasonique (34) par rapport aux points de référence anatomiques sélectionnés ;
utiliser au moins un autre capteur (48) ou un détecteur de position suspendu (43) pour suivre de manière continue et transmettre la position du ou des points de référence anatomiques au processeur ;
effectuer une procédure ultrasonique utilisant le transducteur (34), où le transducteur (34) transmet des données d'image à un appareil à ultra-

- sons (22) et le capteur de suivi (52) transmet des données à un processeur ; transmettre des données de l'appareil à ultrasons (22) au processeur; et obtenir du processeur des données relatives à la position de la sonde ultrasonique par rapport au ou aux points de référence anatomiques ainsi qu'à la position dans une image ultrasonique de chaque pixel par rapport au ou aux points de référence anatomiques à partir des données transmises au processeur par l'un au moins du capteur de suivi (52), d'un autre capteur (48) ou du détecteur de position suspendu (43), ou du dispositif ultrasonique ; et associer les informations relatives à la position de la sonde ultrasonique obtenues avec chaque image ultrasonique capturée correspondante ; où la sonde ultrasonique et l'un au moins des points de référence anatomiques sont suivis en temps réel pendant l'examen.
16. Le procédé selon la revendication 15 comprenant l'étape supplémentaire consistant à passer en revue sur un affichage.
17. Le procédé selon la revendication 15 ou 16, où la position et l'orientation de la sonde ultrasonique sont affichées sur un diagramme corporel ou sur un diagramme corporel partiel.
18. Le procédé selon la revendication 17, où le diagramme corporel ou le diagramme corporel partiel est une image médicale de la même région corporelle obtenue avec une autre modalité médicale.
19. Le procédé selon l'une des revendications précédentes 15 à 18, où l'affichage a lieu de manière continue pendant un examen ultrasonique en temps réel.
20. Le procédé selon l'une des revendications précédentes 15 à 19 comprenant l'étape supplémentaire consistant à sauvegarder les données du processeur en mémoire.
21. Le procédé selon la revendication 20 comprenant l'étape supplémentaire consistant à restituer les données du processeur sauvegardées pour revue.
22. Le procédé selon l'une des revendications précédentes 15 à 21 comprenant l'étape consistant à définir et à enregistrer la position spatiale de la référence anatomique et l'orientation de la sonde ultrasonique par rapport au corps au début de l'examen.

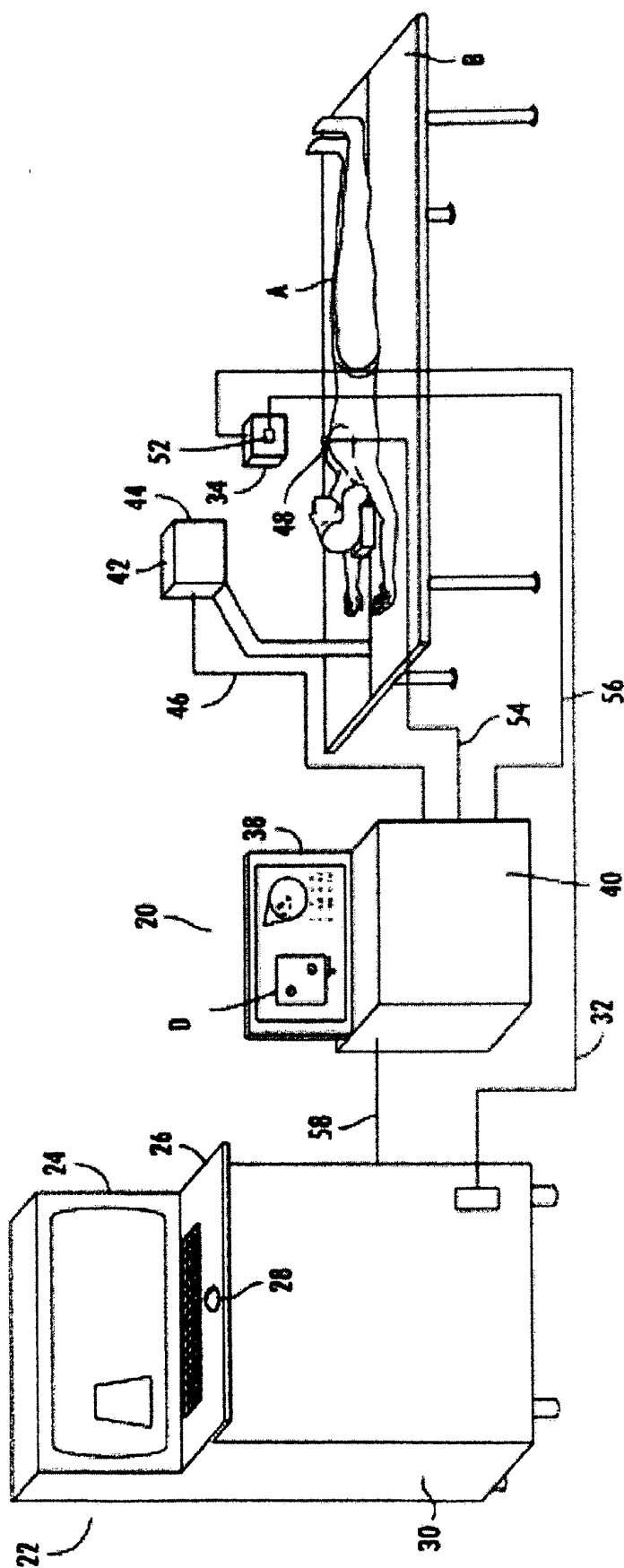
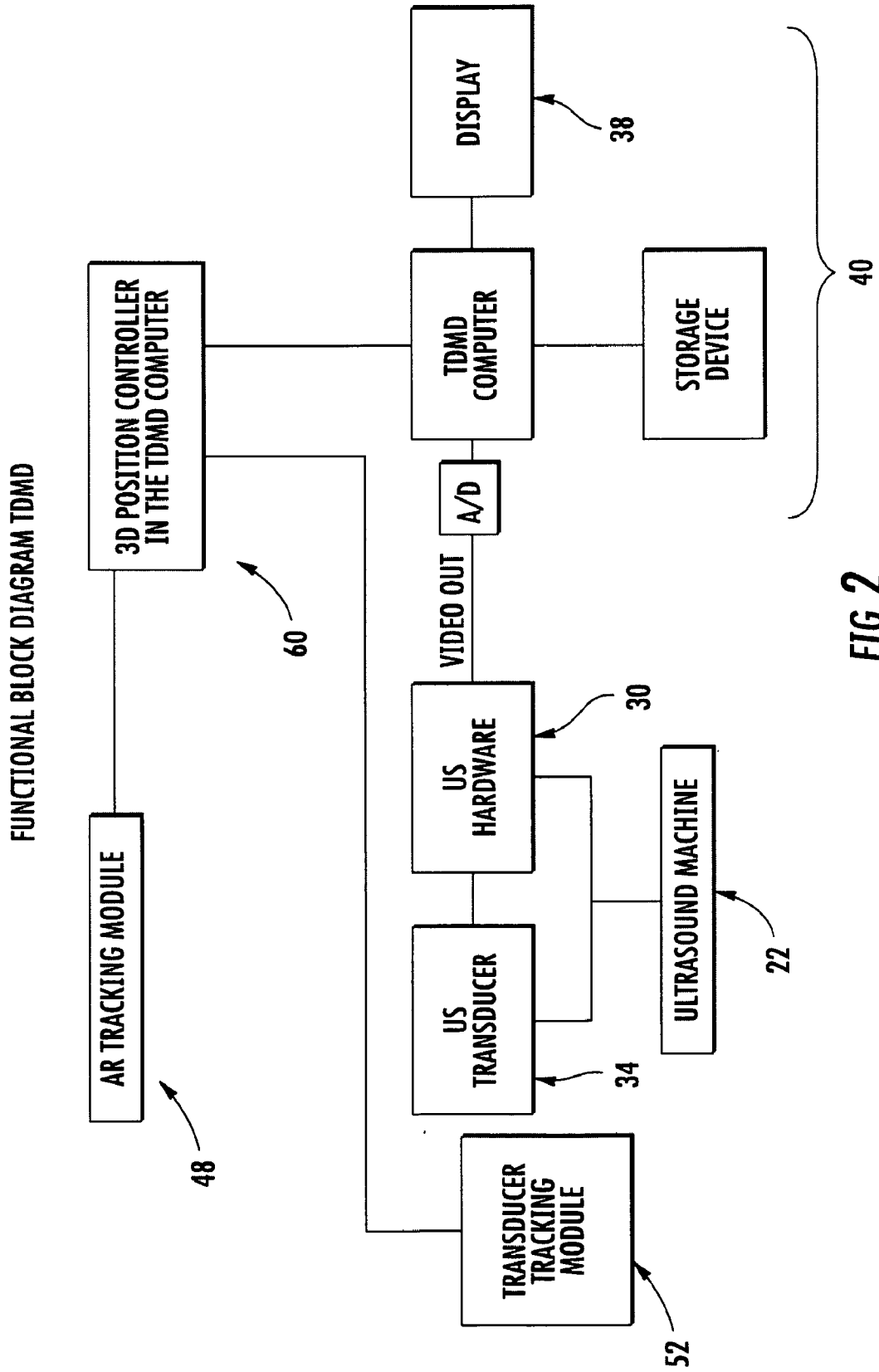


FIG. 1



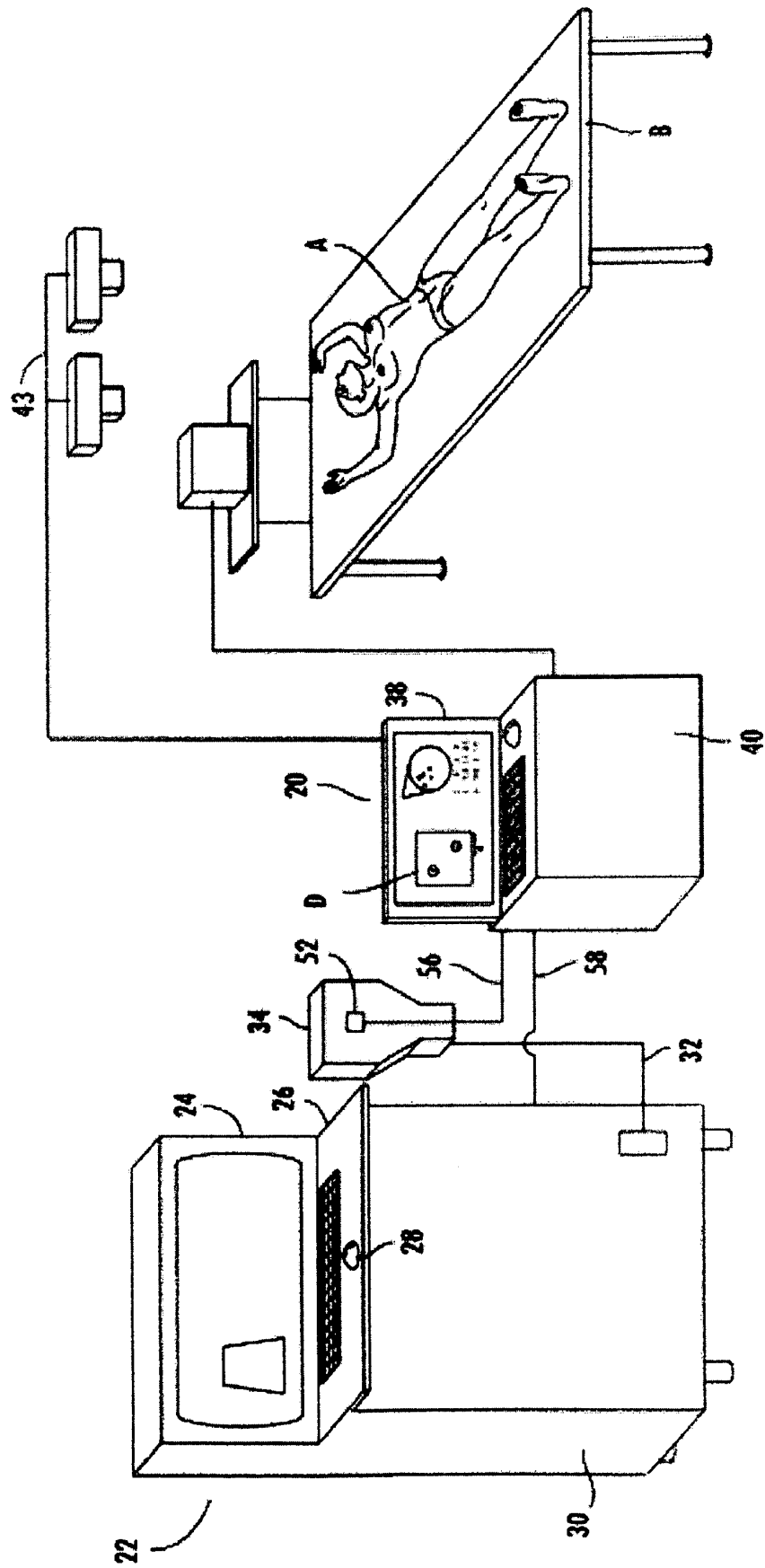
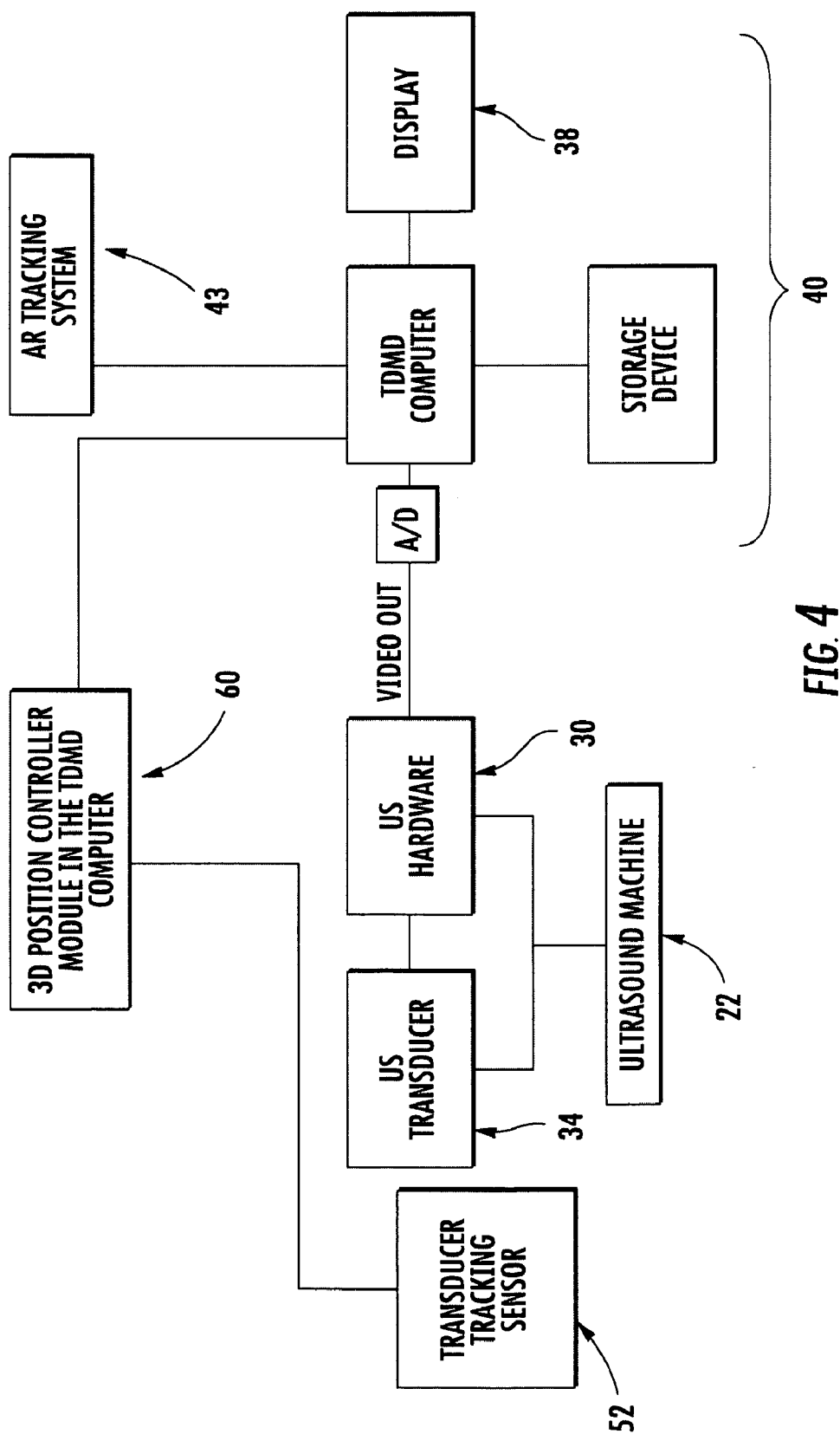
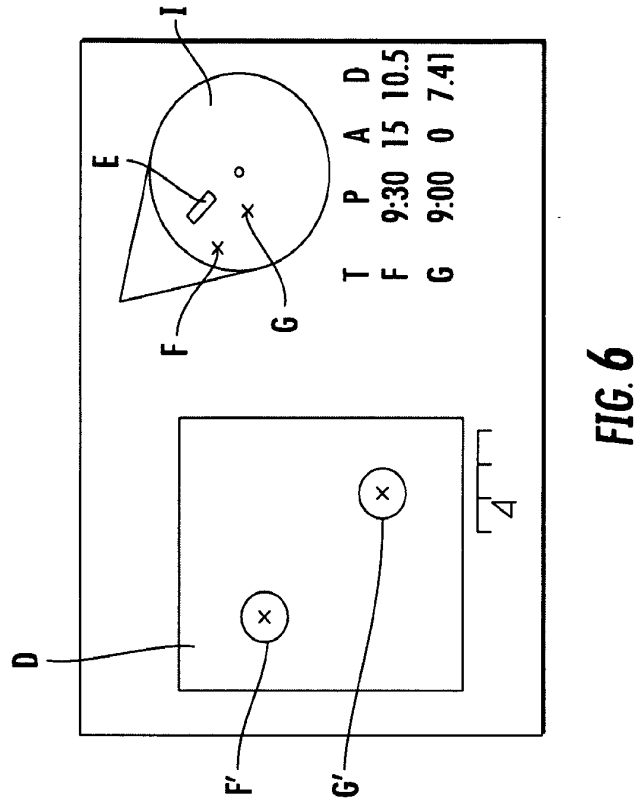
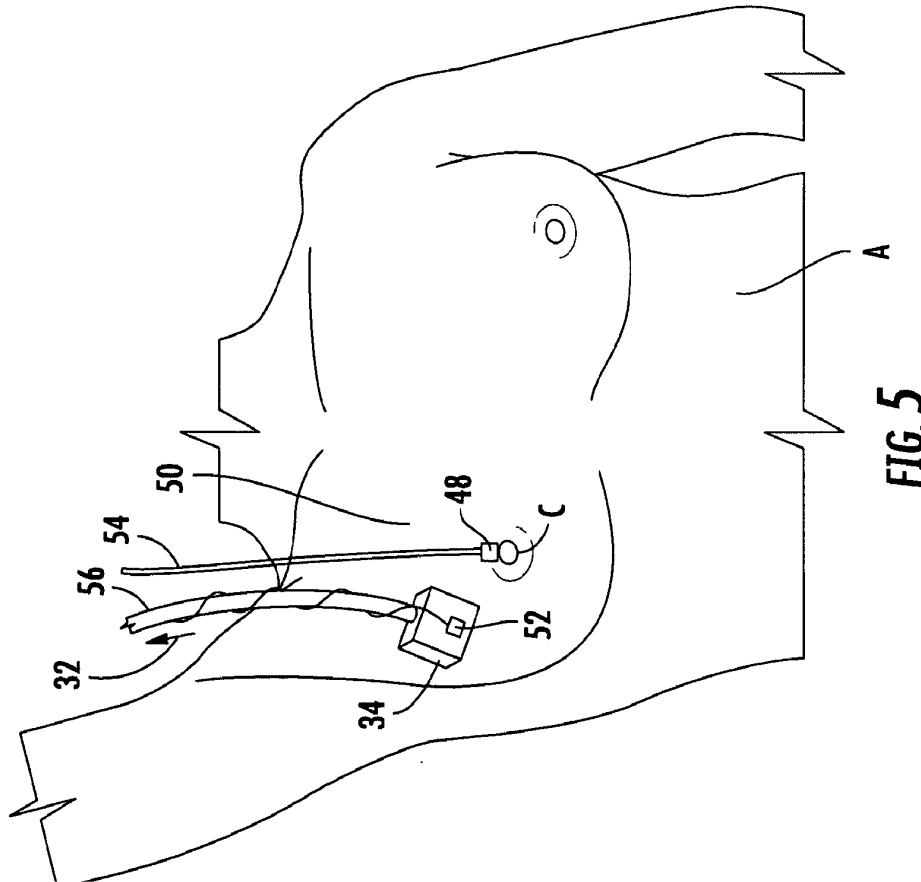


FIG 3





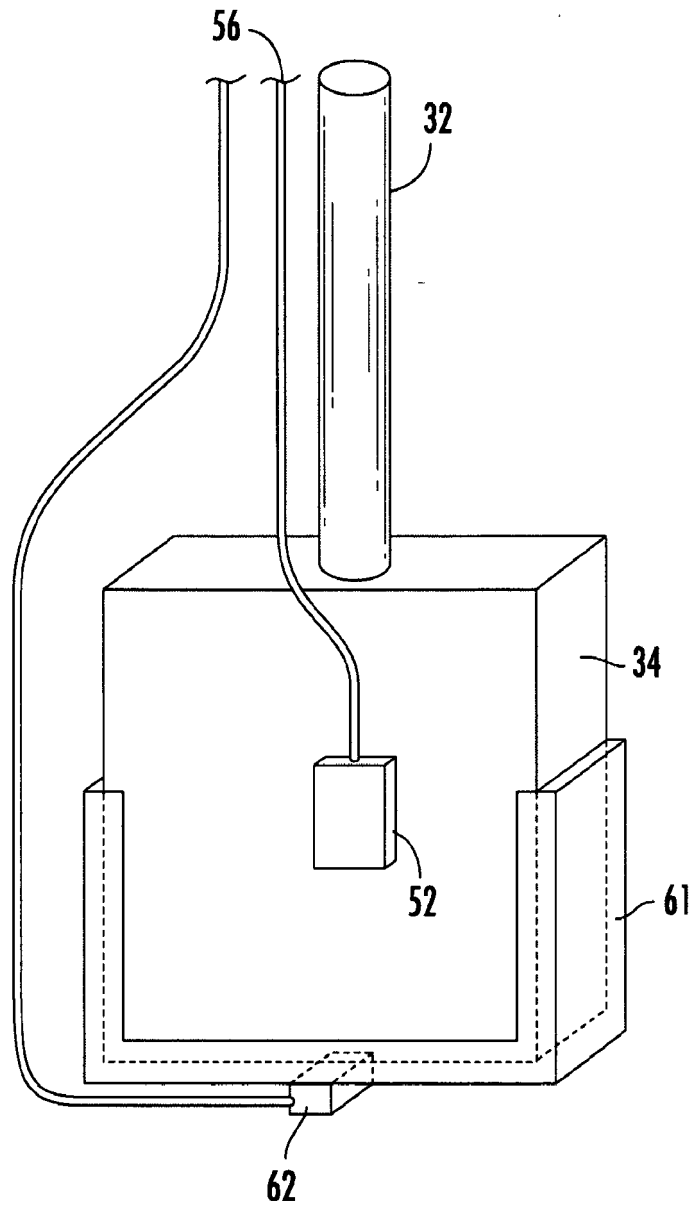
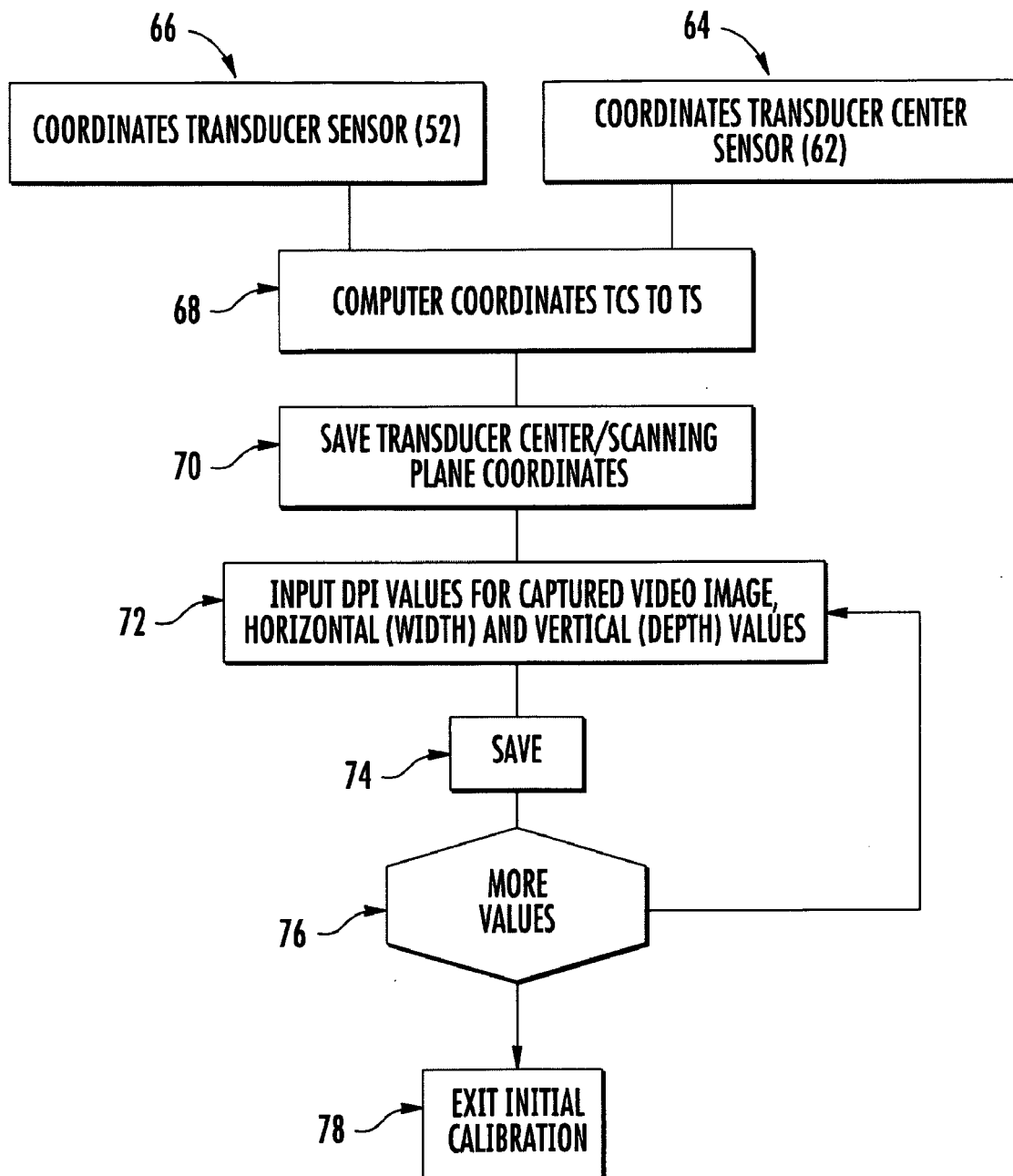


FIG. 7

**FIG. 8**

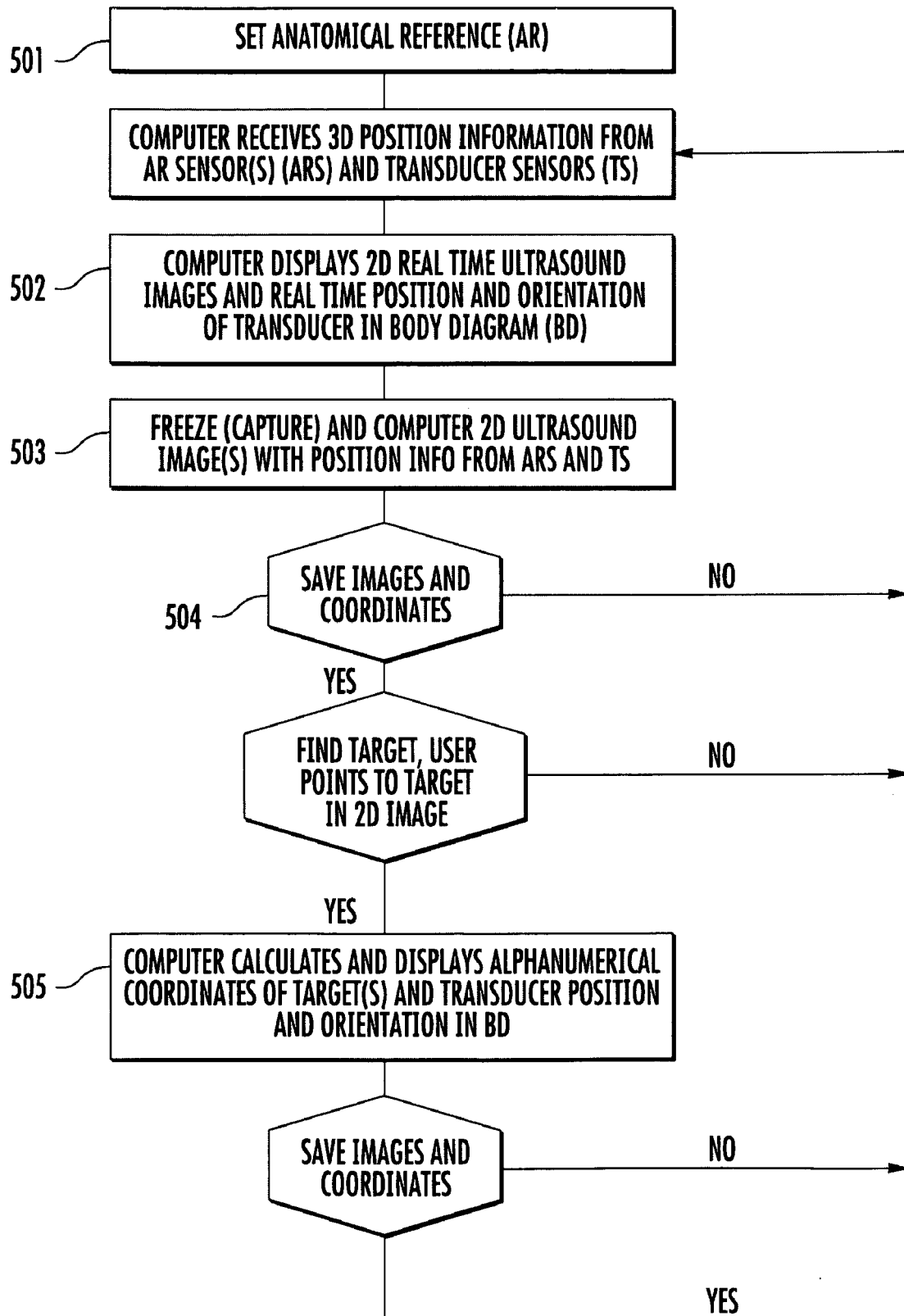


FIG. 9

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 2007039004 A1, Kakee [0013]
- WO 2006008300 A1, Politecnico [0014]

专利名称(译)	用于诊断超声机的三维映射显示系统和方法		
公开(公告)号	EP2207483A4	公开(公告)日	2011-08-10
申请号	EP2008840319	申请日	2008-10-20
[标]申请(专利权)人(译)	CALUSER CALIN		
申请(专利权)人(译)	CALUSER , CALIN		
当前申请(专利权)人(译)	CALUSER , CALIN		
[标]发明人	CALUSER CALIN		
发明人	CALUSER, CALIN		
IPC分类号	A61B8/00		
CPC分类号	A61B5/062 A61B5/064 A61B8/00 A61B8/4245 A61B8/4254 A61B8/483 G06F19/321 G16H40/63 A61B5/06 A61B8/4263 G16H30/20		
代理机构(译)	法思博事务所		
优先权	60/999789 2007-10-19 US		
其他公开文献	EP2207483B1 EP2207483A1		
外部链接	Espacenet		

摘要(译)

超声换能器位置配准自动化的装置，系统和方法参考预定的解剖学参考点（AR）计算超声图像中的每个像素的位置，并且可以按需存储信息。与超声图像相关联的图形界面允许在超声图像中即时显示相对于解剖参考点的所选目标位置坐标。该系统通过消除耗时的手动标记图像并加快后续检查中的目标发现，显著缩短超声检查时间，增强与其他诊断成像模式（如CT扫描，MRI，乳房X线照片，减少人为错误和疲劳）的相关能力，提供一种简单，统一的方法，在医疗服务提供者之间传达目标位置。