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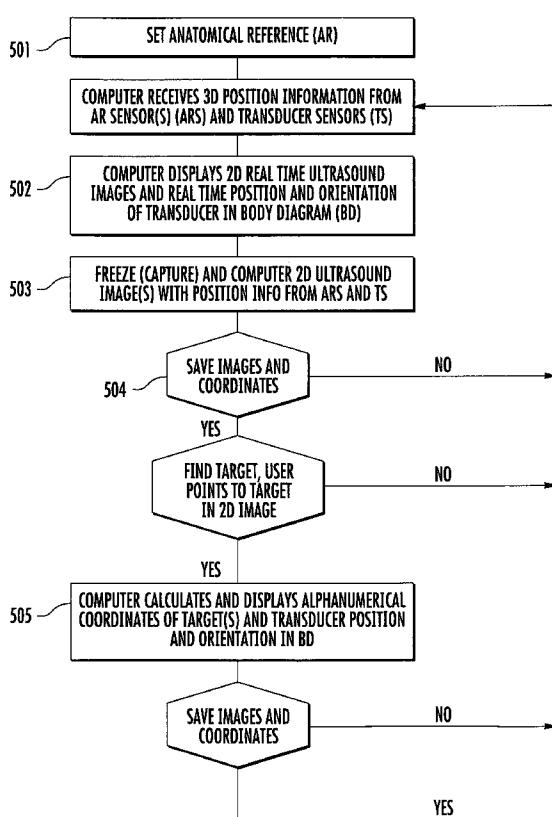
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(54) Title: THREE DIMENSIONAL MAPPING DISPLAY SYSTEM FOR DIAGNOSTIC ULTRASOUND MACHINES AND METHOD



(57) **Abstract:** An apparatus, system, and method where the ultrasound transducer position registration is automated, calculates the position of each pixel in the ultrasound image in reference to the predetermined anatomical reference points (AR) and can store the information on demand. The graphic interface associated with the ultrasound image allows for the instant display of selected targets position coordinates relative to anatomical reference points, in the ultrasound images. This system would significantly reduce the ultrasound examination time, by eliminating the time consuming manual labeling of images and speeding up the target finding at subsequent examinations, enhance correlation capability with other diagnostic imaging modalities like CT scans, MRI, mammograms, decrease human errors and fatigue, provide an easy, uniform, method of communicating the target position among healthcare providers.

FIG. 9



*for restoration is pending and will be published separately
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Invention: Three Dimensional Mapping Display System for Diagnostic Ultrasound Machines and Method

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Inventor: Calin Caluser

Priority Claim

This application claims the priority of provisional application number 60/999,789 filed October 19, 2007 in the United States of America.

15

**Computer Program
Incorporation by Reference**

This Specification incorporates by reference the material contained on the enclosed compact disc (Appendix A) that includes the source code of the computer program for use with the inventive apparatus. The submission comprises a single compact disc, submitted in duplicate (labeled Copy 1 and Copy 2 and identical in content), created on October 18, 2008 from files created October 14, 2008, entitled Three Dimensional Mapping Display System for Diagnostic Ultrasound Machines and Method and containing the following files:

25

	<u>File</u>	<u>Size</u>
	CapturePCIBird	4.87kb
	DShowNET	81.60kb
	FileBirdNETApi	17.30kb
	FileBirdNETApiProvider	9.68kb
30	Math3D	23.30kb
	MSSQLDBStorageProvider	7.74kb

	MTMDController	288.00kb
	MTMDDatabaseManager	71.80kb
	MTMDFakeVideoCaptureProvider	3.44kb
	MTMDPostgreDBStorageProvider	10.90kb
5	MTMDVideoCaptureCardProvider	38.90kb
	MTMDWindowDisplayProvider	21.10kb
	NetBirdApiProvider	205.00kb
	NETBirdCommon	30.90kb
	PCIBirdNET	25.40kb
10	PCINetBirdProvider	5.58kb
	TestPCIBird	58.70kb
	WildCard.Database	<u>15.00kb</u>
	Total Size on Disk	1,067.00kb

I. Technical Field

15 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 20 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

Ultrasound is an important imaging modality for medical diagnostic purposes 25 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 5 associated health risks.

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.

10 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 15 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.

Two dimensional ("2D") ultrasound imaging, the most common technique used today, represents a slice through the region of interest. Three-dimensional 20 ("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.

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.

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.

5 As a result, precise positional registration of the targets is important.

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

10 take advantage of the increased capabilities.

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

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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 5 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.

The American College of Radiology (ACR) recommends that all ultrasound images be properly labeled. For example, for breast ultrasound images, the position, 10 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, 15 difficult for the user.

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. It 20 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 25 to the art.

III. Objects and Advantages of the Present Invention

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.

5 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.

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

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 15 patients for repeat examination.

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 20 the ultrasound transducer position in relation to the target coordinates from a previous examination.

IV. Summary of the Invention

The present invention provides an apparatus and method of use for automated ultrasound probe position registration, calculating the position of each pixel in the 25 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.

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

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

- 10 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,
- 15 providing orientation help for the ultrasound operator.

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

- 20 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.

- 25 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.

For the accurate automated recording of body targets and transducer position related to certain anatomical references, a user continuously obtains positional 5 information from the preset anatomical references and the motion correction instantly applied to the transducer positional coordinates.

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 10 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.

There has been outlined, rather broadly, the more important features of the 15 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

20 **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.

25 **Fig.3** depicts an alternate embodiment illustrating an overhead infrared or 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.

5 **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.

10 **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

Before explaining the preferred embodiment of the present invention in detail, 15 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 20 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.

Turning to Figure 1, an over view of the physical aspects of an ultrasound 25 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.

Inventive apparatus (also referred to as three dimensional mapping display, 5 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 10 magnetic sensor 52 connected to TDMD 20 by second magnetic sensor cord 56.

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

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 15 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.

20 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, endocavitory, endoluminal or otherwise placed in the body 25 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.

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.

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.

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.

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 shows 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.

5 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 10 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.

Additionally, each target is displayed with the associated position (hourly representation or degrees to longitudinal axis and anatomical reference as center) and 15 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 20 degrees (here, 15° for F and 0° 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.

Additionally, an additional display function is to show a cumulative area of 25 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.

In the preferred embodiment, any off the shelf generic PC computer with Windows XP® (by Microsoft Corporation, Redmond, WA) can be used to run 5 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.

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 10 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. 15 The inventive device enabling a user to accurately review, evaluate, and compare examination results by having anatomical reference point guides to isolate target sites.

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 20 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.

Additionally, the preferred 3D position registration system is based on 25 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

5 (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.

10 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-
15 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.

In any of the above configurations, initial calibration is needed to register the ultrasound probe scanning plane orientation and position. The initial calibration may
20 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, scanhead 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
25 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 5 position aligned with the scanning plane of the transducer.

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 10 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 15 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 20 calibration process is then exited 78.

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 25 method is to hold the ultrasound transducer scanhead 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, 5 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 10 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 15 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.

Continuing with Figure 8, at 502 the transducer 34 position and orientation and anatomical reference point are continuously displayed in TDMD computer 20 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 25 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).

- 5 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
- 10 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.

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.

- 15 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 alphanumerical format as distance and angle from the anatomical reference, hourly coordinates, where the position of a target is assigned an hour from
- 20 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 5 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.

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 10 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.

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 15 preset anatomical reference point, when performing an ultrasound examination. The system allows for automatic correction for body or anatomical reference motion during the examination.

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 20 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 25 the separate computer can be stored as hardcopy or it can be digitally stored.

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 5 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

I claim:

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

a controller further comprising at least one sensor port, an ultrasound data port, and a processor port;

at least one sensor for transmitting data operatively connected to the at least one sensor port;

10 a source of ultrasound data production operatively connected to the ultrasound data port; and,

a processor operatively connected to the processor port for receiving and sensor data and ultrasound data,

15 wherein the processor receives ultrasound data and sensor data from the controller, using the data to automate ultrasound probe position registration and determine the position in ultrasound image pixels in reference to one or more predetermined anatomical reference points for identifying target site location to generate processing results.

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2) The apparatus of claim 1 further including a display for displaying processor registration and calculation data.

3) The apparatus of claim 1 further including a memory operatively connected to the processor.

5

4) The memory of claim 3 wherein the memory stores data for the processor comprises processed sensor data and processed ultrasound data.

10 5) The apparatus of Claim 3 wherein the memory stores data for later retrieval and overlay with subsequent ultrasound data to facilitate anatomical reference point correlation and target site location.

15 6) The apparatus of Claim 1 further comprising a second sensor for identifying and transmitting to the processor the location of the anatomical reference point.

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25 7) The apparatus of Claim 1 wherein the at least one sensor is magnetic.

8) The apparatus of Claim 1 wherein the at least one sensor is selected
5 from the group of ultrasound, optical, infrared, and inertial.

9) The apparatus of Claim 1 wherein the at least one sensor is located
10 overhead to track transducer location and anatomical reference point location for
transmission to the processor.

10) The apparatus of Claim 1 wherein the processor generates a three
15 dimensional mapping of the processing results.

20

11) A system for automating ultrasound probe position registration and
calculating the position in an ultrasound image pixels in reference to one or more
25 predetermined anatomical reference points comprising:

a controller further comprising at least one tracking sensor port, an ultrasound data port, and a processor port;

at least one tracking sensor operationally connected to the at least one tracking port;

5 an ultrasound device operationally connected to the ultrasound port;

a processor operationally connected to the processor port;

processing for capturing data transmitted to the computing member from the ultrasound and the at least one tracking member to create images and positional data;

10 a display for displaying the images and positional data; and,

memory operatively connected to the processor.

12) The apparatus of Claim 11 wherein the memory stores data for later retrieval and overlay with subsequent ultrasound data to facilitate anatomical reference point correlation and target site location.

13) The apparatus of Claim 11 wherein the at least one sensor is magnetic.

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14) The apparatus of Claim 11 wherein the at least one sensor is selected from the group of ultrasound, optical, and inertial.

25

15) The apparatus of Claim 11 wherein the processor generates a three dimensional mapping of the processing results.

5 16) The apparatus of Claim 11 further comprising a second sensor for identifying and transmitting to the processor the location of the anatomical reference point.

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17) A method for real time tracking and capturing target sites in reference to selected anatomical positions during ultrasound procedures comprising the steps of:

selecting one or more anatomical reference points;
20 using at least one tracking sensor to locate and track the position of an ultrasound transducer with respect to the selected anatomical reference points;
performing an ultrasound procedure using the transducer wherein the transducer transmits data to an ultrasound device and the tracking sensor transmits data to a processor;

25

transmitting data from the ultrasound device 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
5 position in an ultrasound image pixels by processor from the data
transmitted to the processor by at least one tracking member and
the
ultrasound device.

10

18) The method of Claim 17 comprising the further step of reviewing on a
display.

15

20 19) The method of Claim 17 comprising the further step of storing the
processor data in memory.

20) The method of Claim 19 comprising the further step of retrieving the stored processor data for review.

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21) A method for facilitating the real time tracking and capturing target sites in reference to selected anatomical positions during ultrasound procedures comprising the steps of: a) selecting one or more anatomical reference points; b) 15 receiving ultrasound transducer location data from an electronic sensor and receiving ultrasound examination data regarding a target site; and c) creating data identifying the location of the target site with respect to the anatomical location.

20 22) The method of Claim 21 including the further step of storing the data.

23) The method of Claim 21 including the further step of retrieving the data to compare target site changes by comparative analysis at a later date.

5

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24) An automated process for using ultrasound data and anatomical reference point data to perform real time tracking and capturing of target site information in reference to the anatomical reference point positions comprising:

selecting a target site for study on a patient;

15 selecting at least one anatomical point on the patient for use as a reference point;

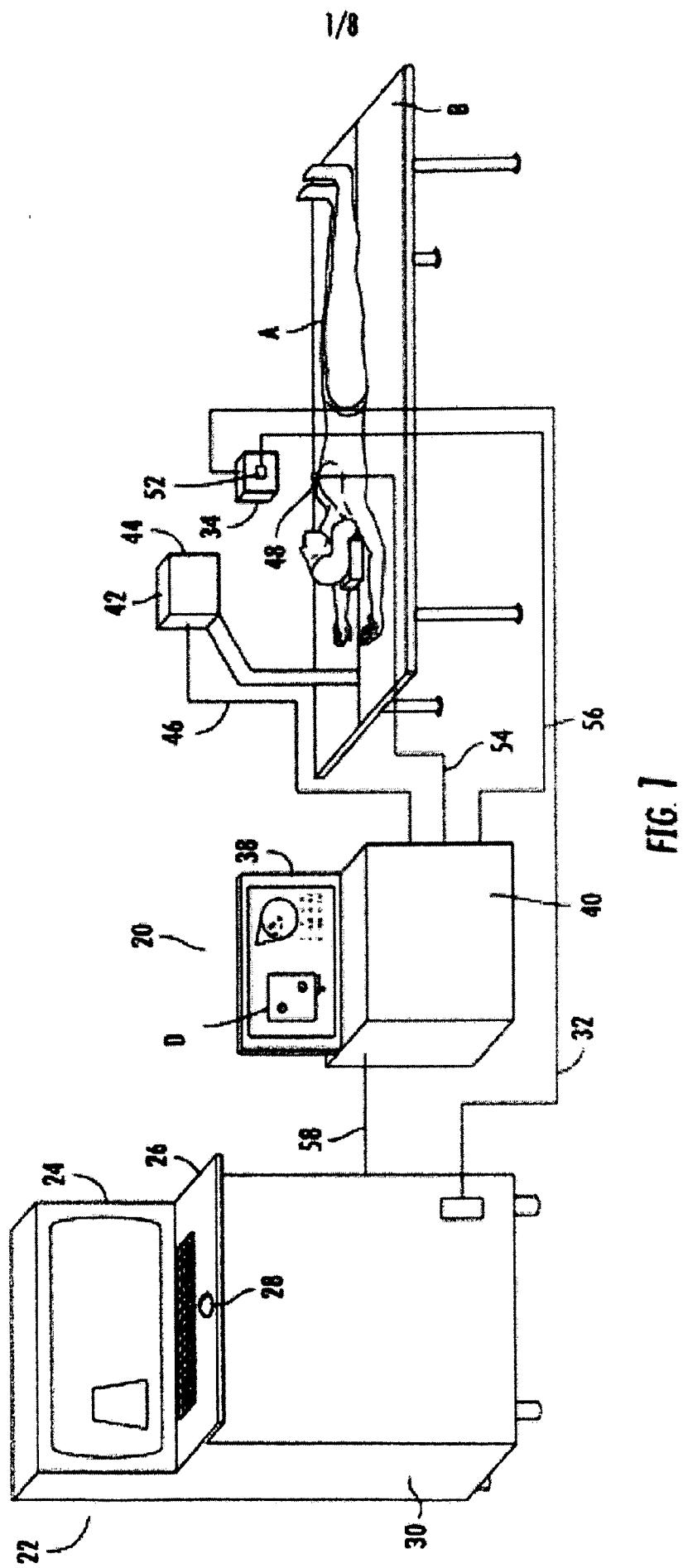
providing an ultrasound device having at least one transducer, a processor, a tracking sensor, and a controller having an ultrasound data port for operatively

20 connecting to the ultrasound device, a processor port for operatively connecting to a processor that receives data from the ultrasound device and tracking sensor in relation to the anatomical reference point at least one sensor

port for operatively connecting to a transducer tracking sensor;

- calibrating the location of the transducer in relation to the at least one anatomical reference point using the tracking sensor and transmitting the calibration data
- 5 to the processor;
- performing an ultrasound examination during which ultrasound data is transmitted to the ultrasound device and then to the processor and transducer location data
- 10 is transmitted to the processor;
- receiving from the processor results data in which data received from the ultrasound device and from the tracking sensor are coordinated to track and capture target site relational data with reference to the at least one anatomical reference point.
- 20
- 25) The process of Claim 24 further comprising a second sensor for identifying and transmitting to the processor the location of the anatomical reference point.
- 25

- 26) The process of Claim 24 further comprising storing the processor results data.
- 5 27) The method of Claim 24 including the further step of retrieving the data to compare target site changes by comparative analysis at a later date.
- 10 28) A method for reviewing transducer position of an ultrasound examination comprising the steps of a) recording transducer locations in real time, b) storing the transducer locations, and c) retrieving the results for review wherein the location and completeness of an examination can be determined.



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FUNCTIONAL BLOCK DIAGRAM TDMD

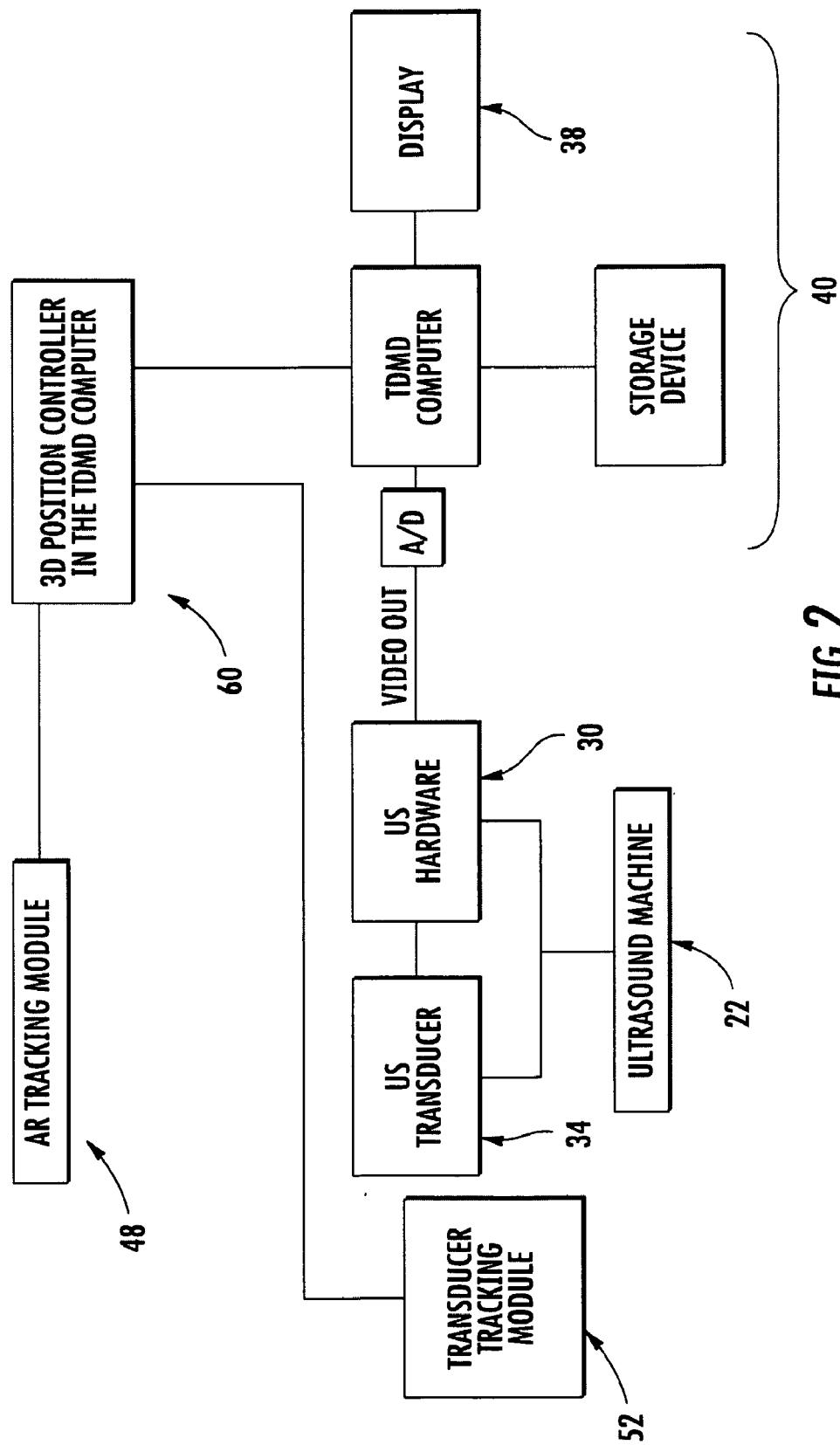


FIG. 2

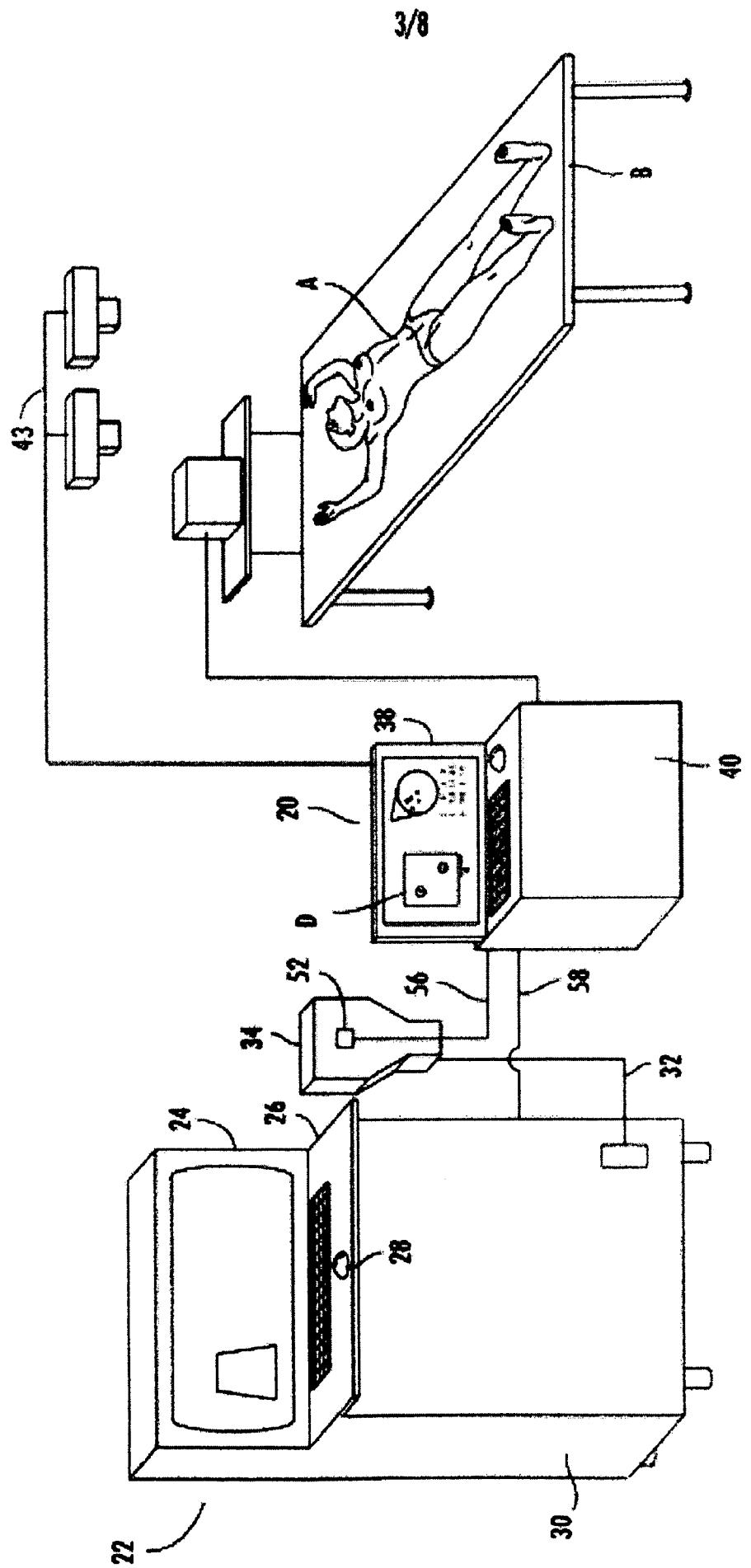


FIG. 3

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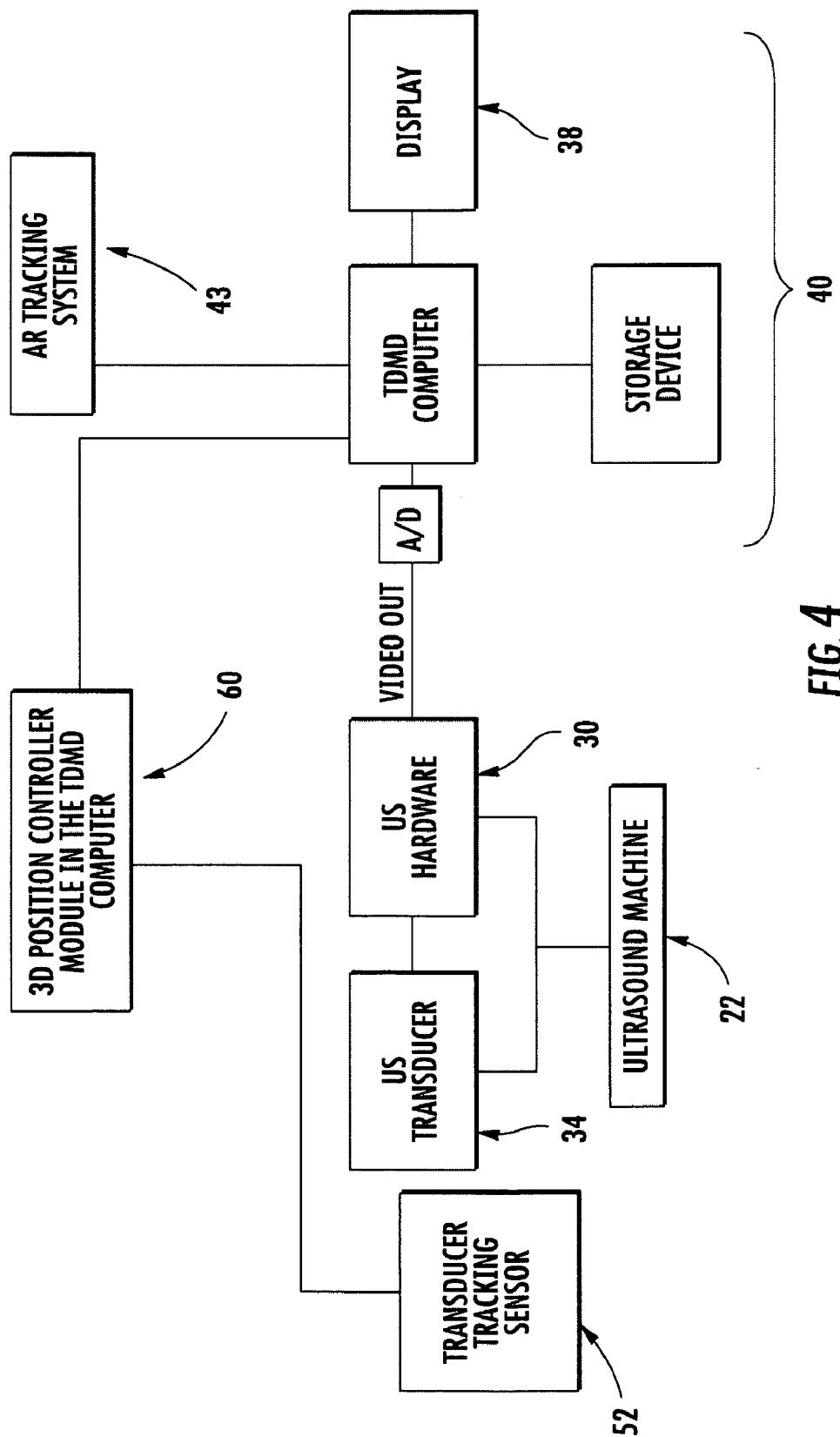
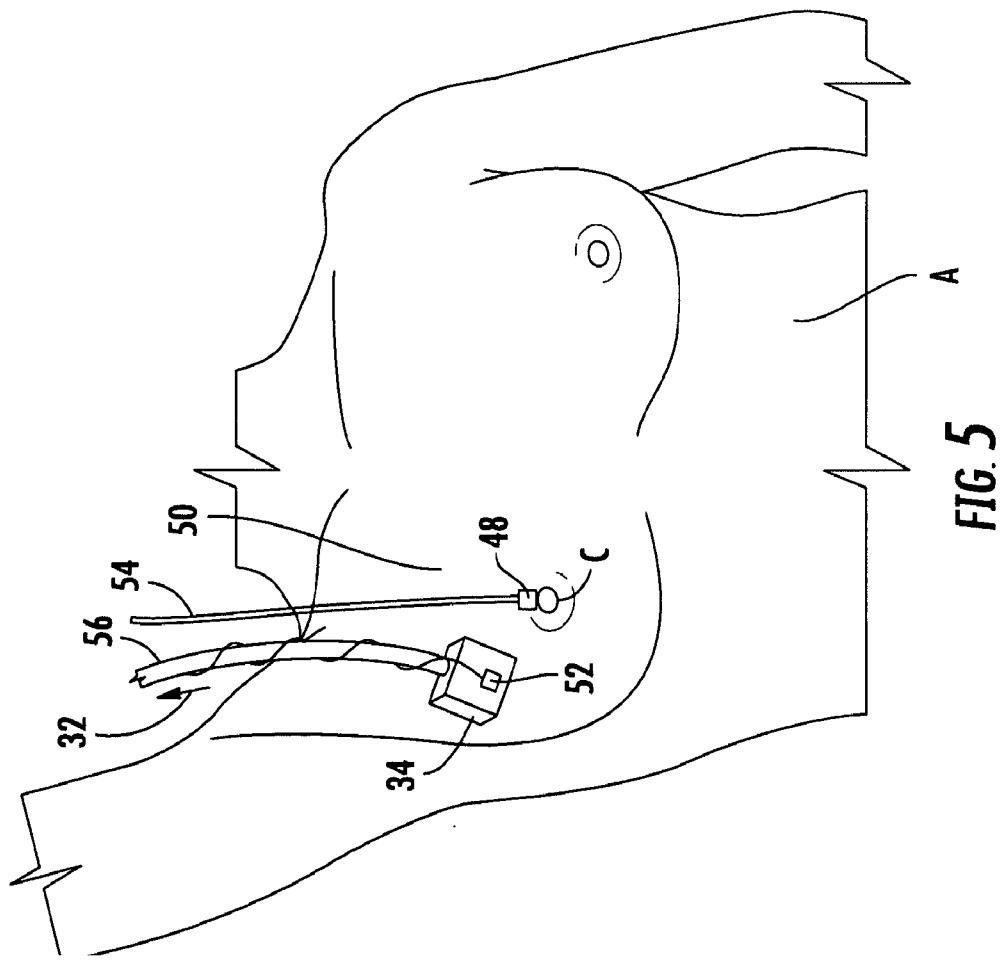
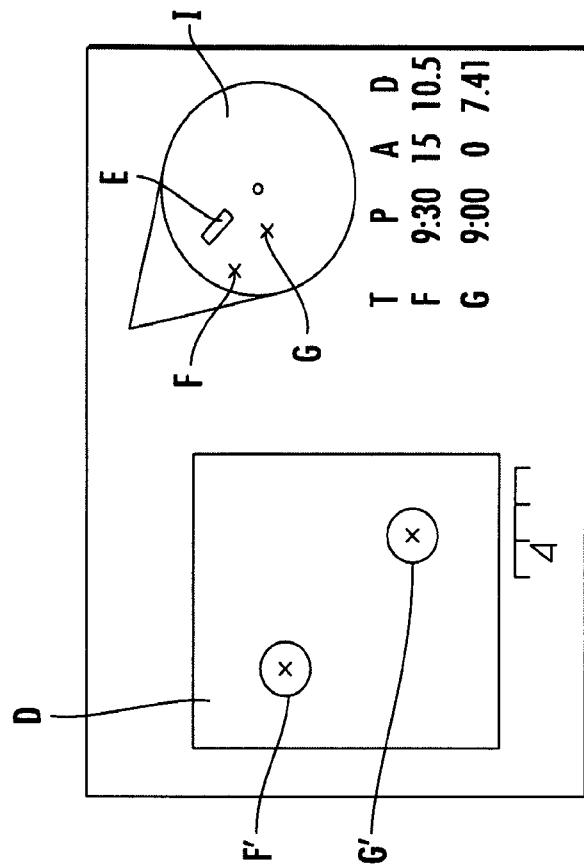


FIG. 4

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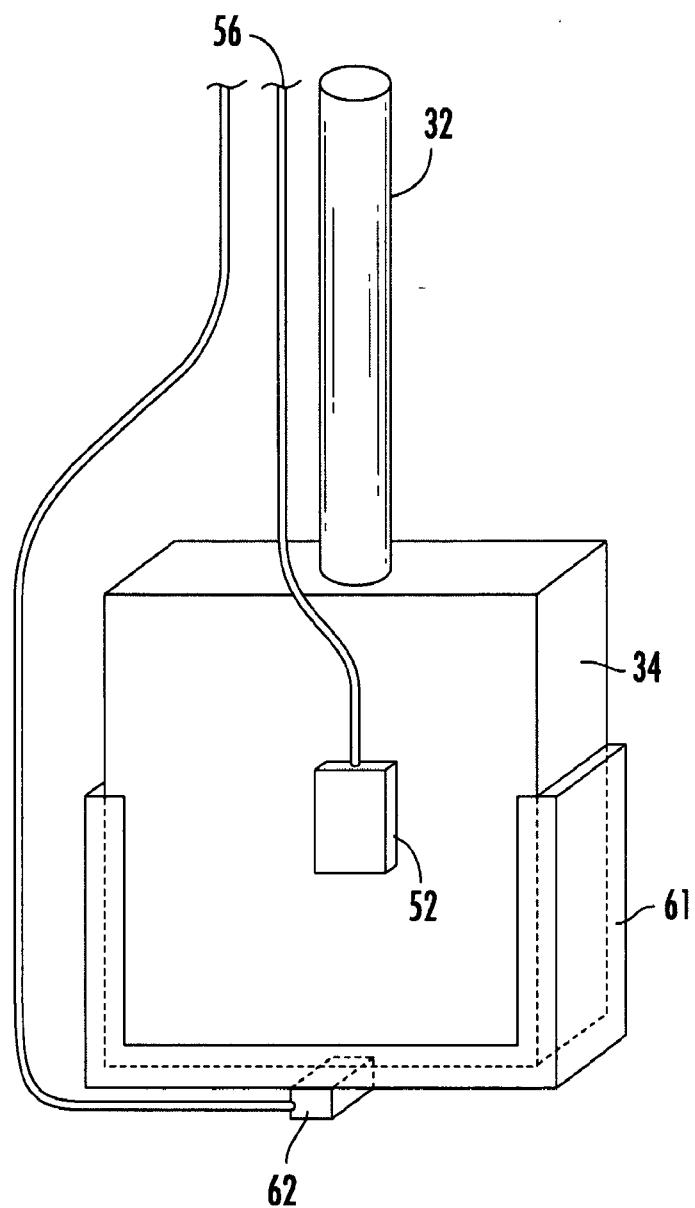


FIG. 7

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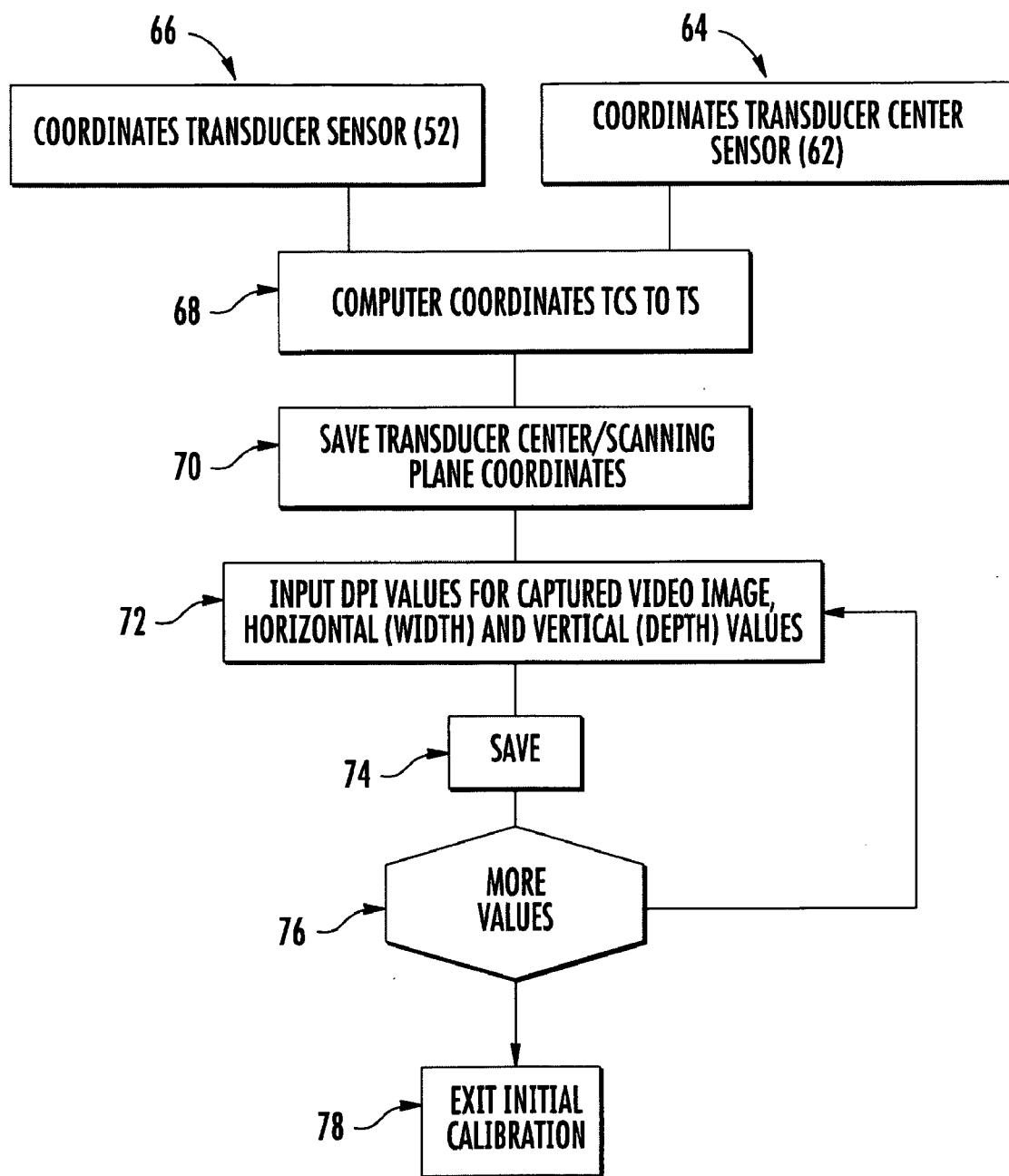


FIG. 8

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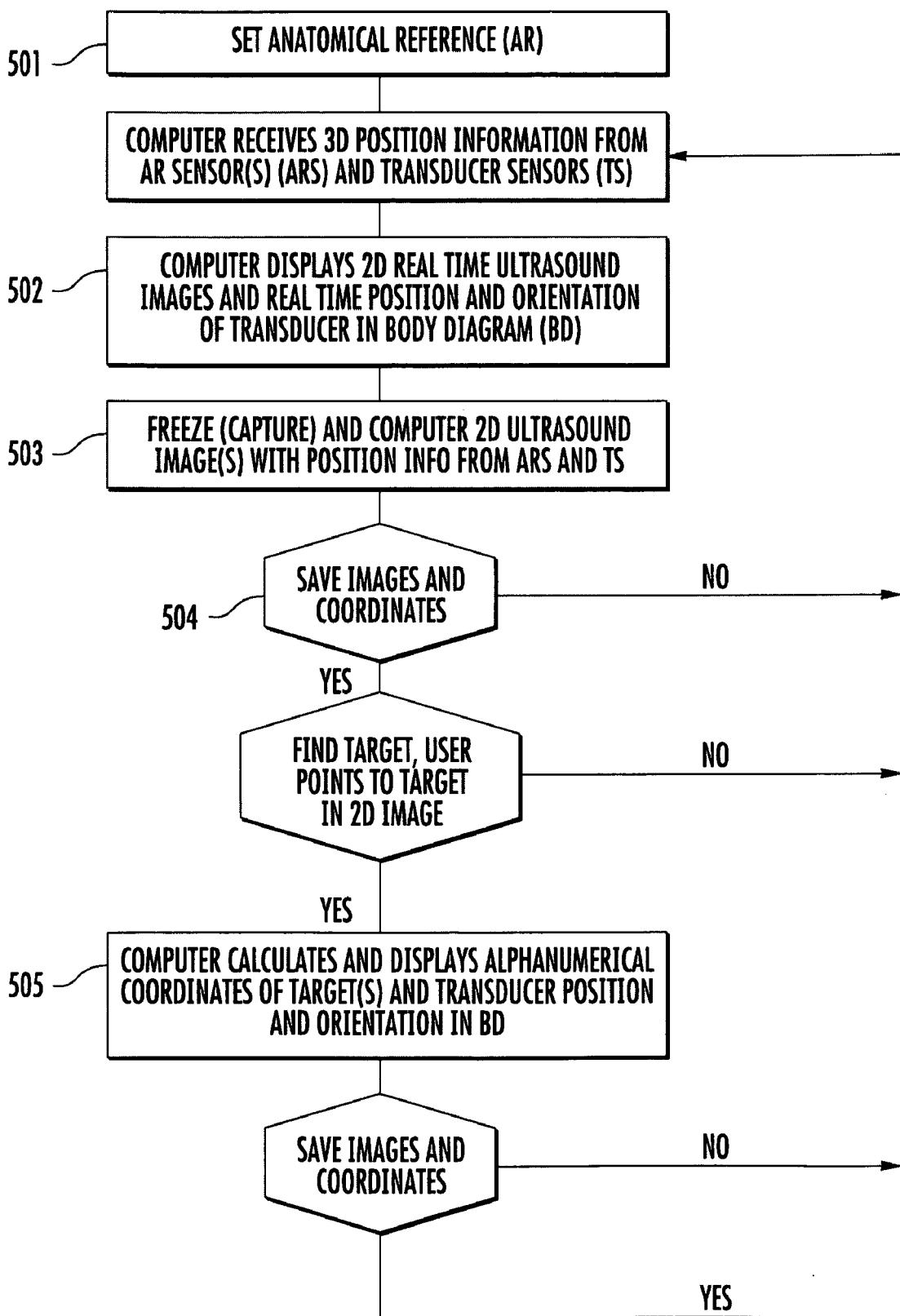


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/11973

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 8/00 (2008.04)

USPC - 600/443

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61B 8/00 (2008.04)

USPC - 600/443

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC(8) - A61B 8/00 (2008.04)

USPC - 600/407,437,443,444,463; 382/131; 128/916

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest: US PAT, US PGPUB, US OCR, EPO, JPO; Google Scholar; Keywords: ultrasound, acoustic, transducer, display, memory, sensor, infrared, inertial, magnetic, optical, fiducial, reference point or position, overlay or overlaid image, image registration, real-time, PAC, image or data retrieval

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/0083117 A1 (SAKAS, et al.) 12 April 2007 (12.04.2007), para [0003], [0009], [0022], [0027], [0028], [0032], [0039], [0052]-[0056], [0066], [0072]	1-28
A	US 2006/0262970 A1 (BOESE, et al.) 23 November 2006 (23.11.2006), entire document	1-28
A	US 2005/0015005 A1 (BARTHE, et al.) 03 February 2005 (03.02.2005), entire document	1-28
A	US 2007/0167801 A1 (WEBLER, et al.) 19 July 2007 (19.07.2007), entire document	1-28
A	US 2004/0097805 A1 (VERARD, et al.) 20 May 2004 (20.05.2004), entire document	1-28

Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

- “A” document defining the general state of the art which is not considered to be of particular relevance
- “E” earlier application or patent but published on or after the international filing date
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- “O” document referring to an oral disclosure, use, exhibition or other means
- “P” document published prior to the international filing date but later than the priority date claimed
- “T” later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- “X” document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- “Y” document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- “&” document member of the same patent family

Date of the actual completion of the international search

04 December 2008 (04.12.2008)

Date of mailing of the international search report

22 DEC 2008

Name and mailing address of the ISA/US

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Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
 PCT OSP: 571-272-7774

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其他公开文献	EP2207483B1 EP2207483A4		
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，显着缩短超声检查时间，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。