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(2013.01)
USPC **600/444**

(57) **ABSTRACT**

Related U.S. Application Data

A system and a method related to improving ultrasound examination of a patient, specifically of a patient's breast by sensing and controlling the pressure/force that an ultrasound probe and/or a compression/scanning assembly housing the probe exert on the breast and/or the chest wall of the patient.

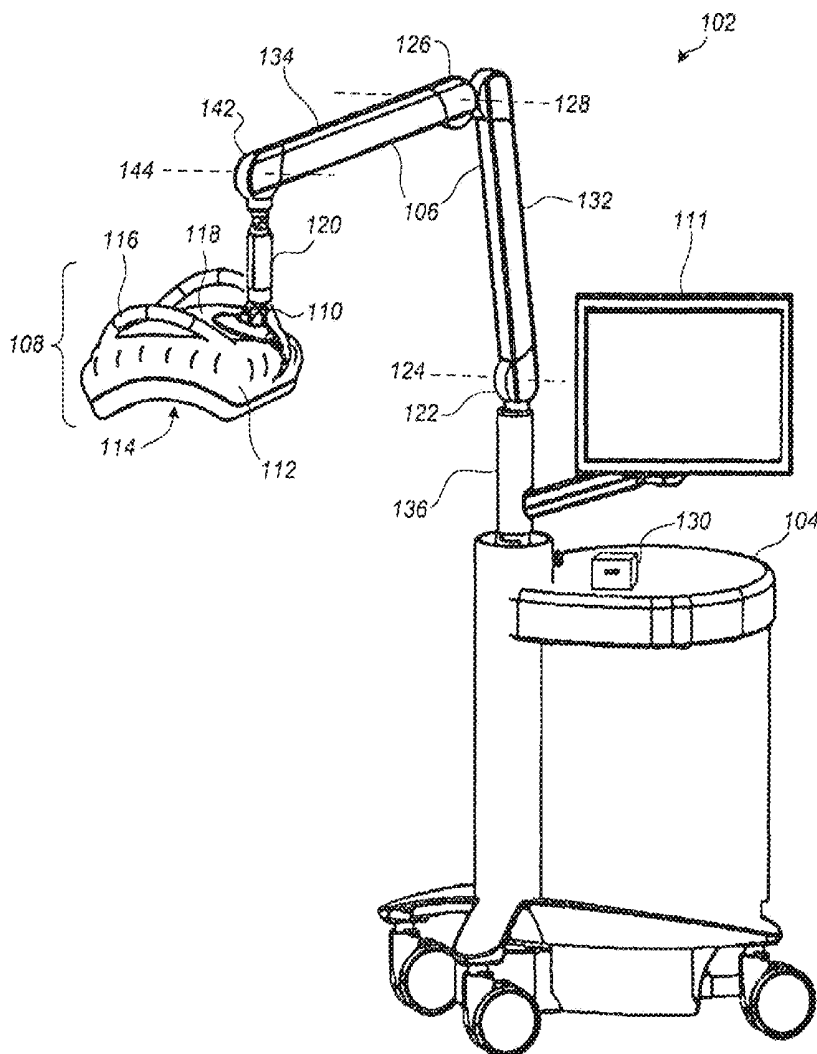


FIG. 1

FIG. 2

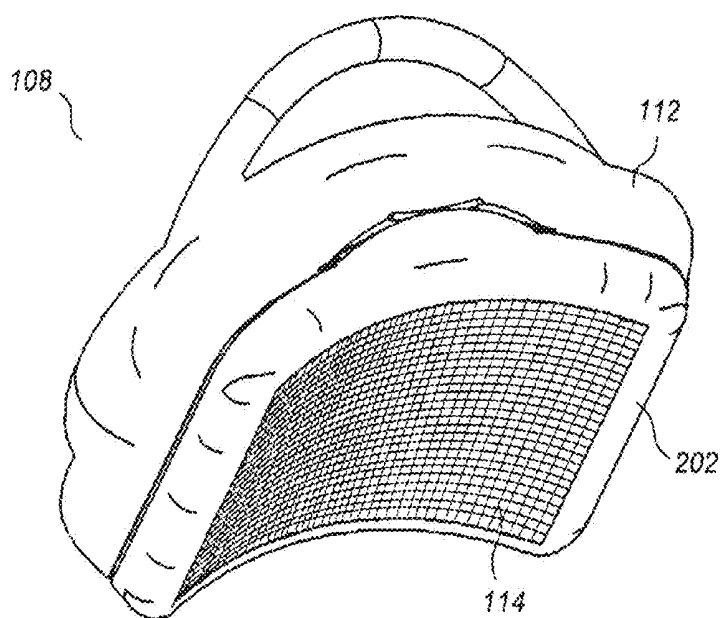


FIG. 3

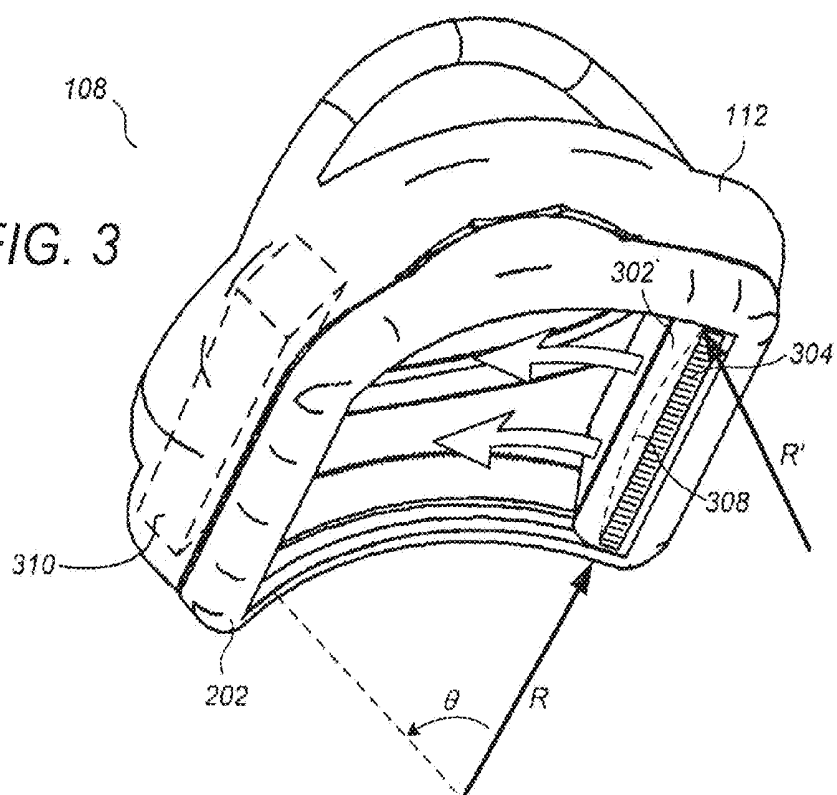


FIG. 4

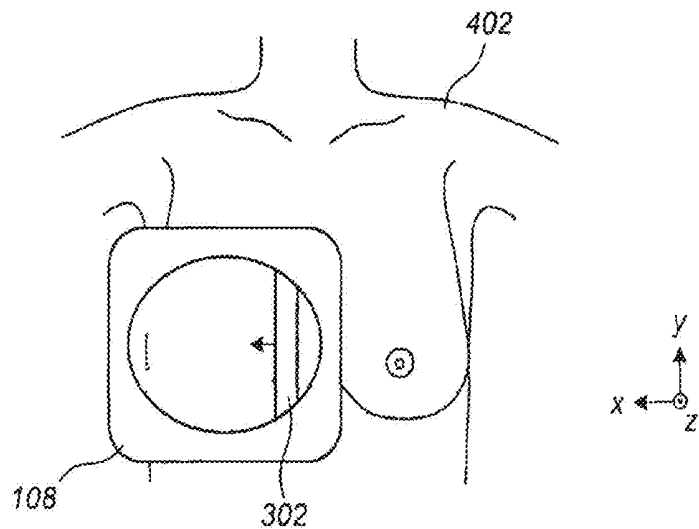
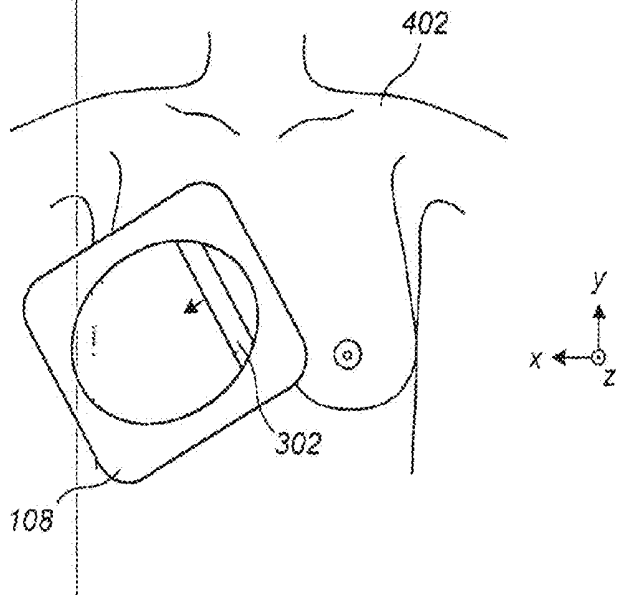


FIG. 5



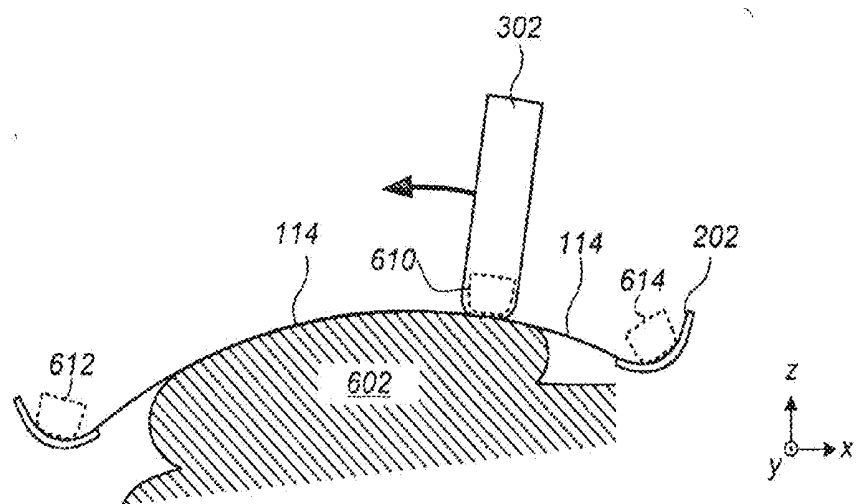


FIG. 6

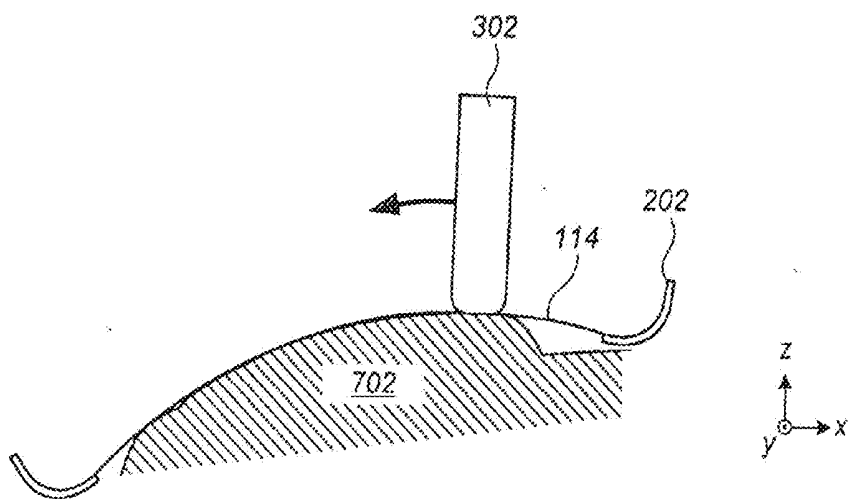


FIG. 7

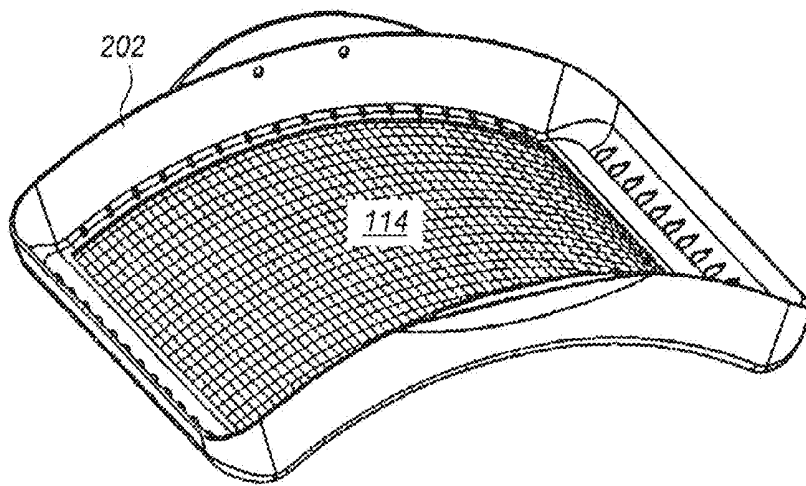


FIG. 8

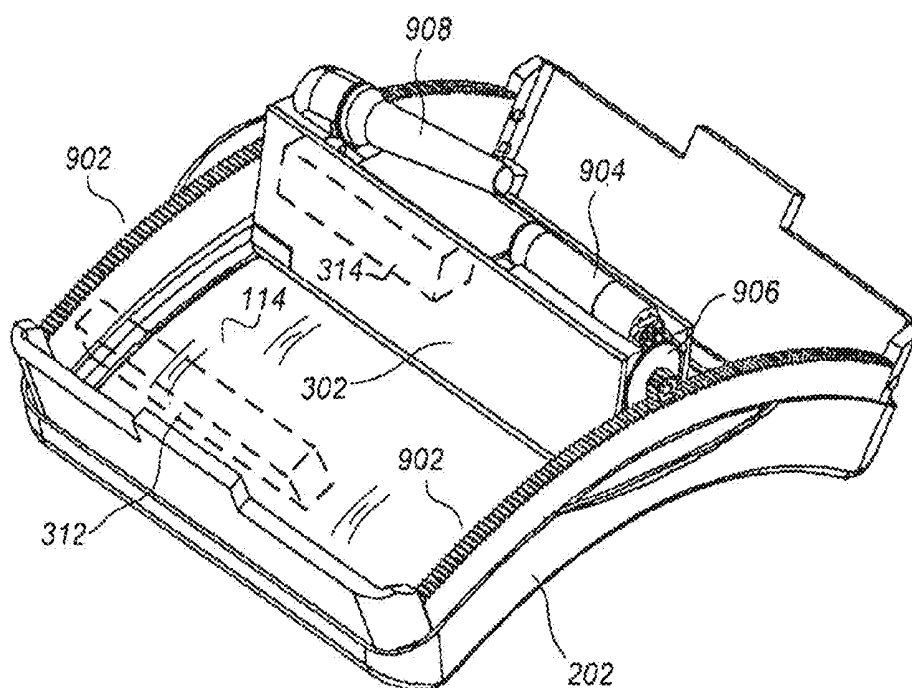


FIG. 9

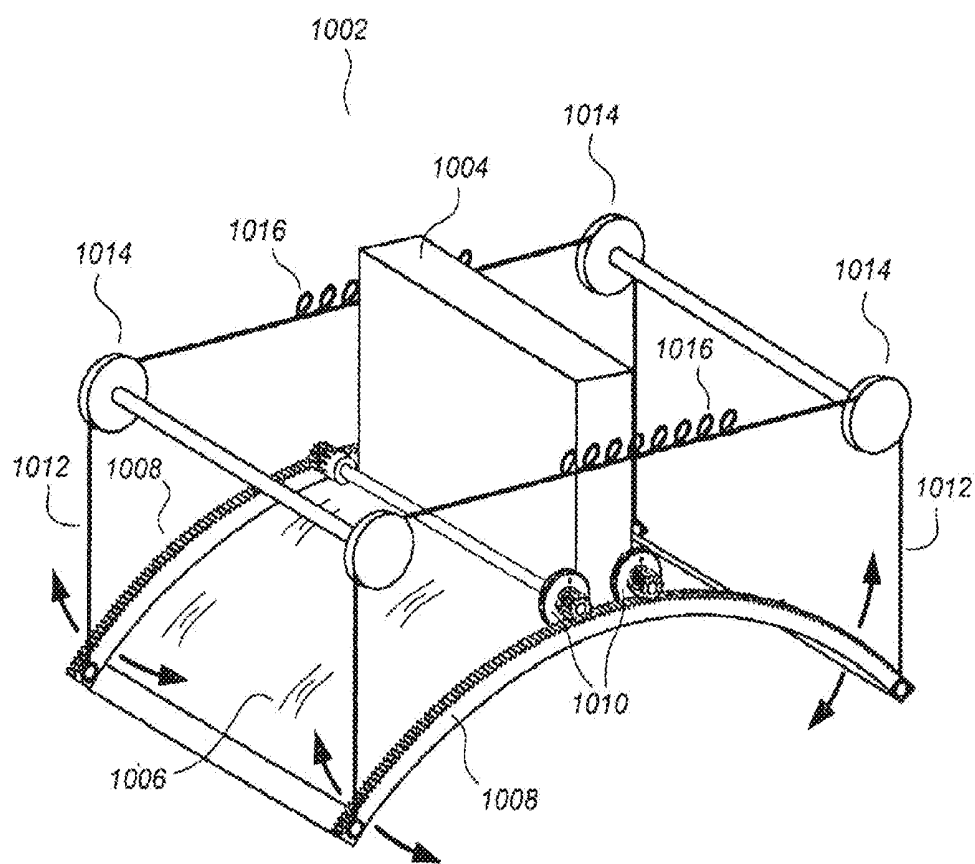


FIG. 10

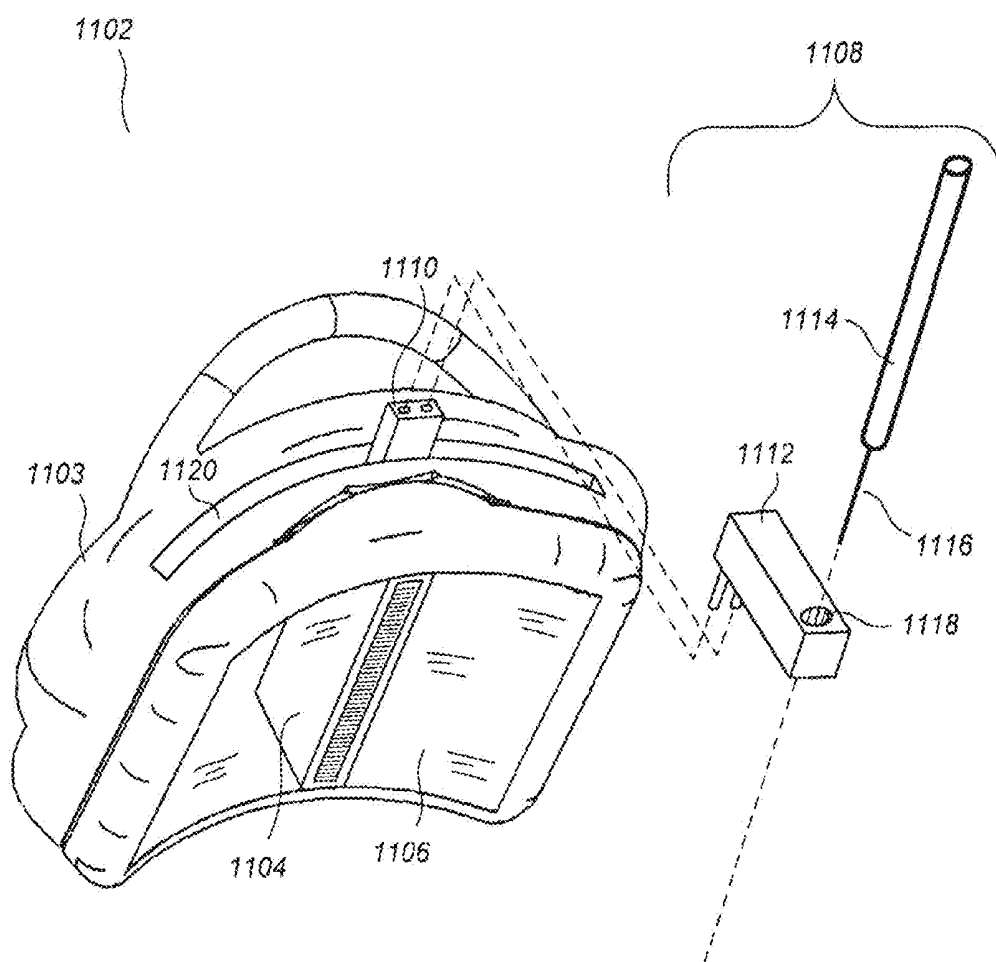


FIG. 11

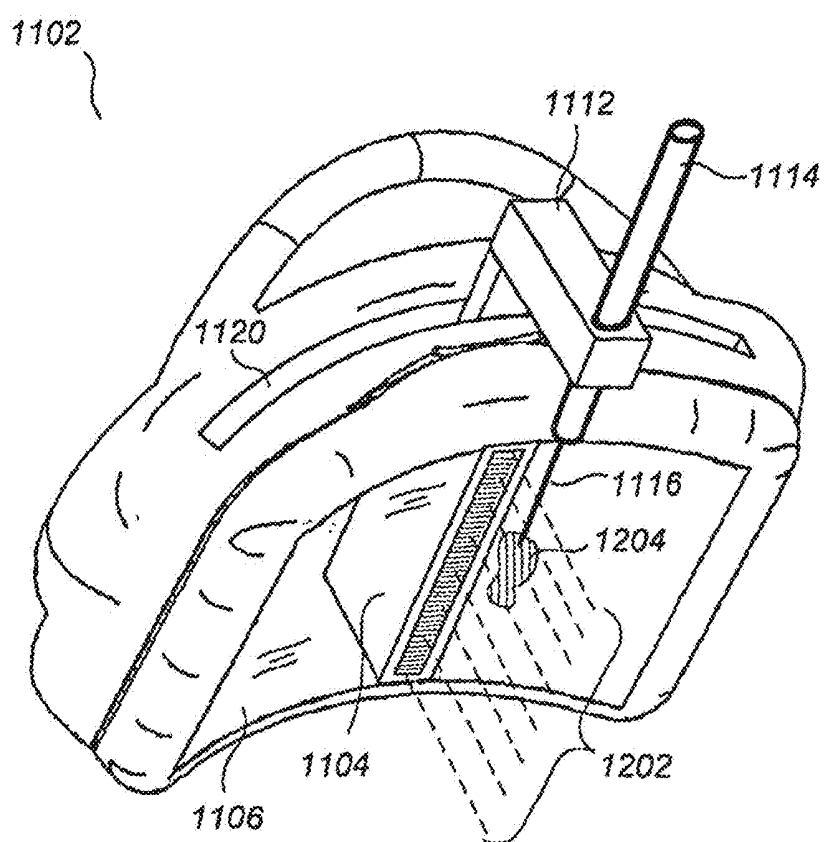


FIG. 12

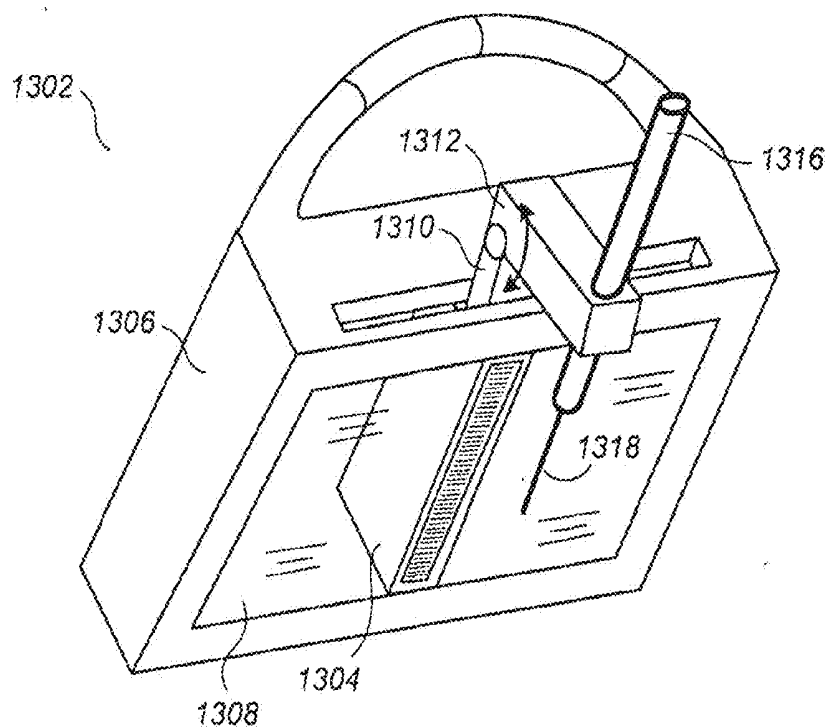


FIG. 13

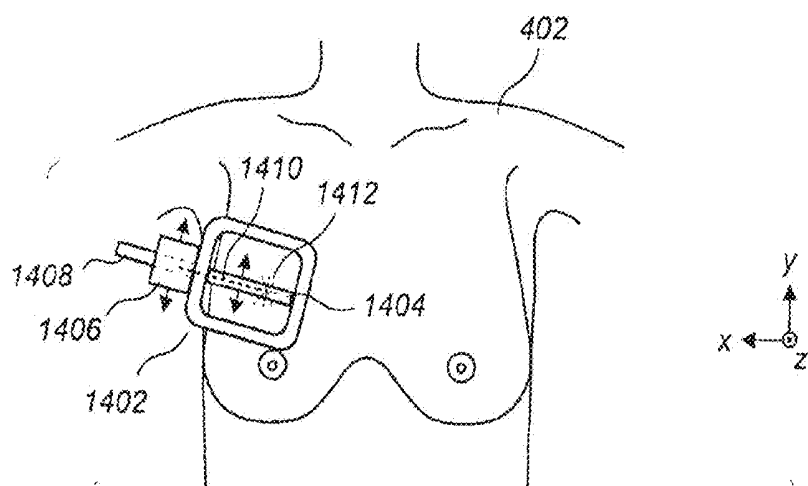


FIG. 14

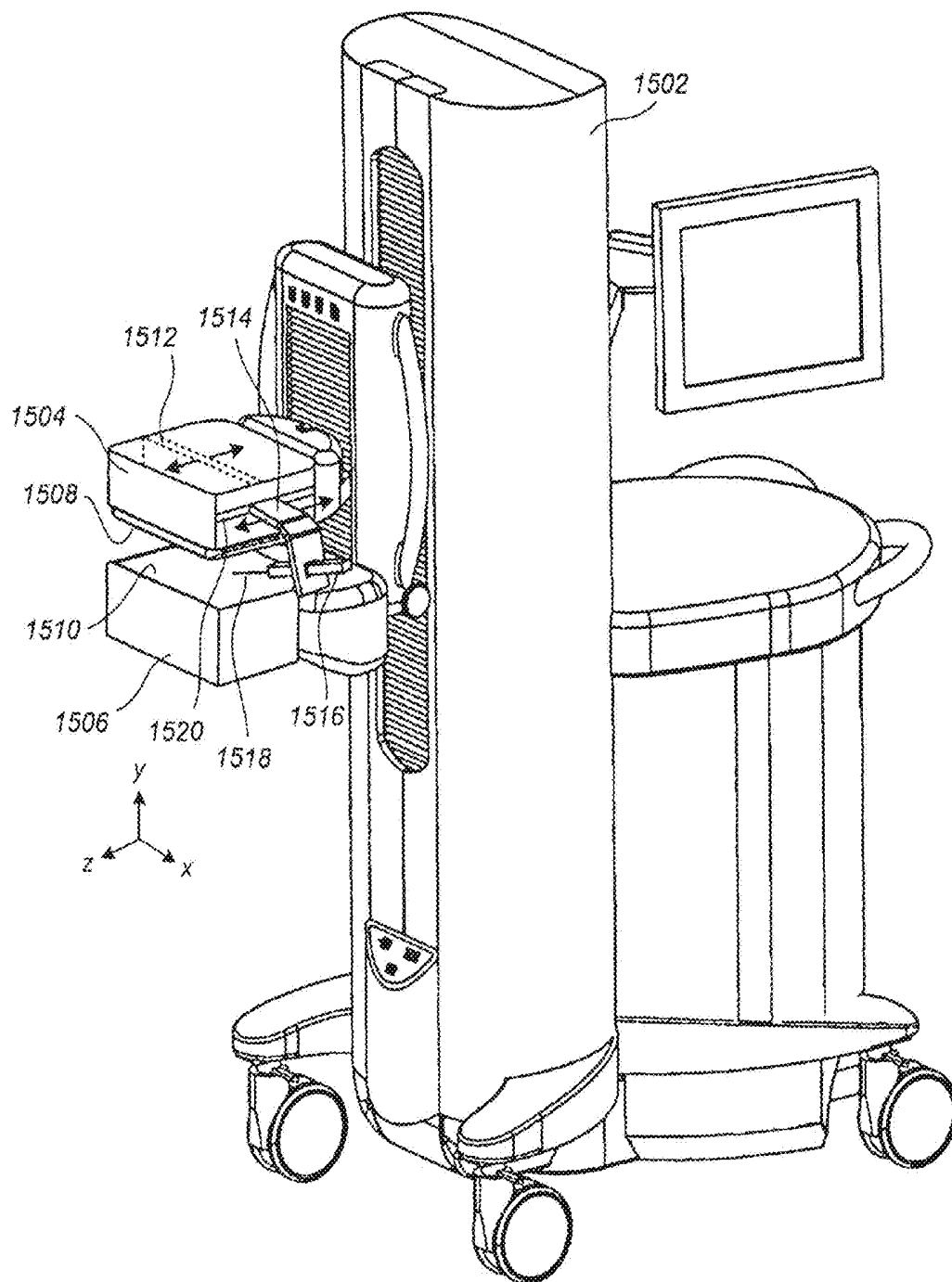


FIG. 15

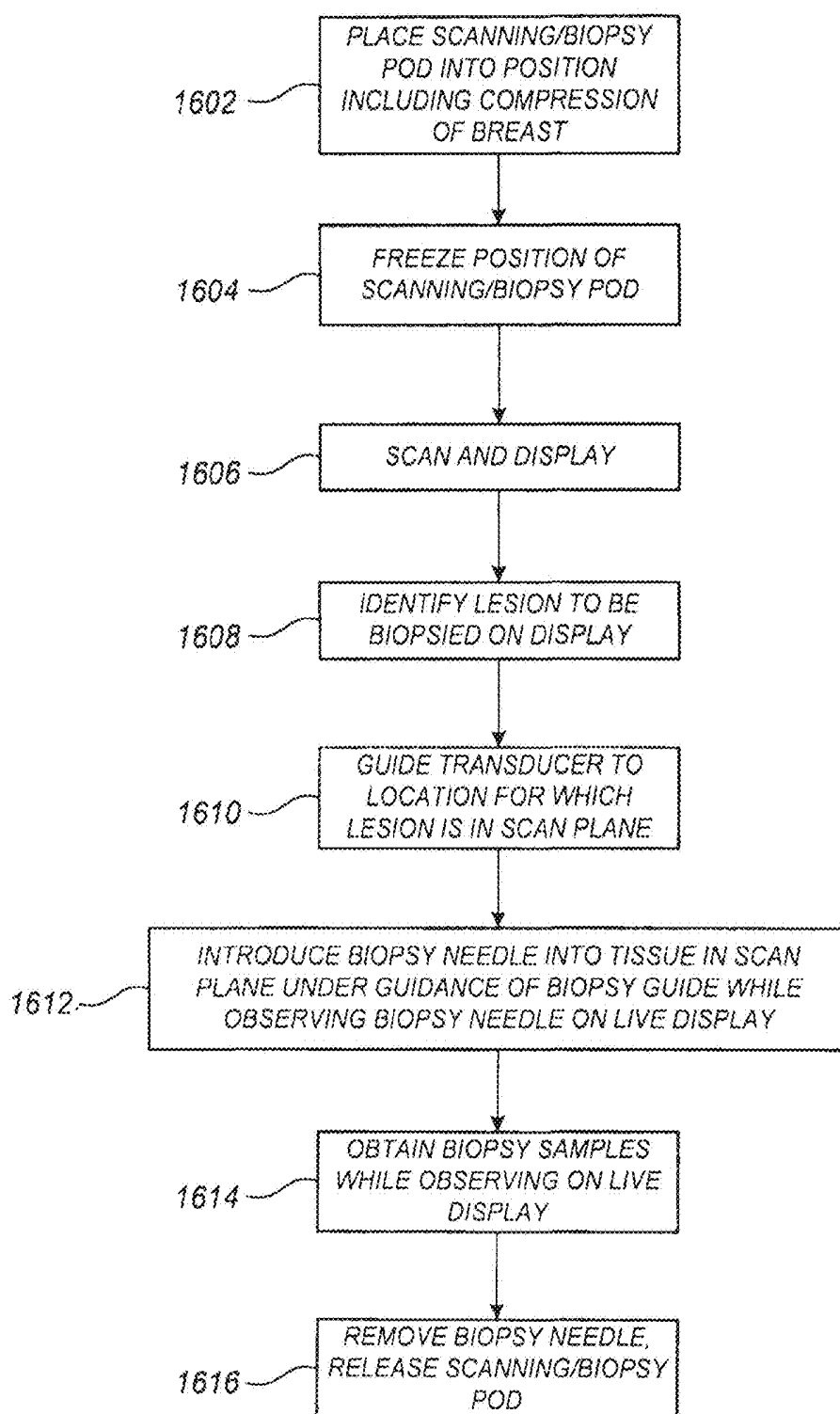


FIG. 16

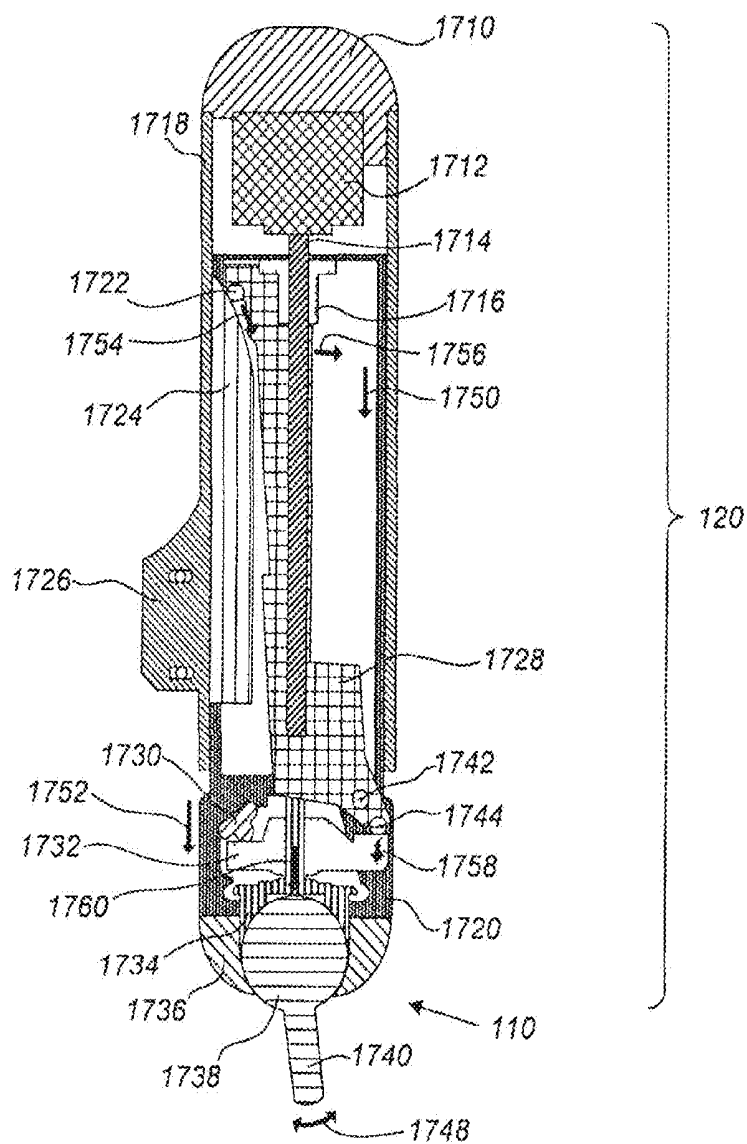


FIG. 17

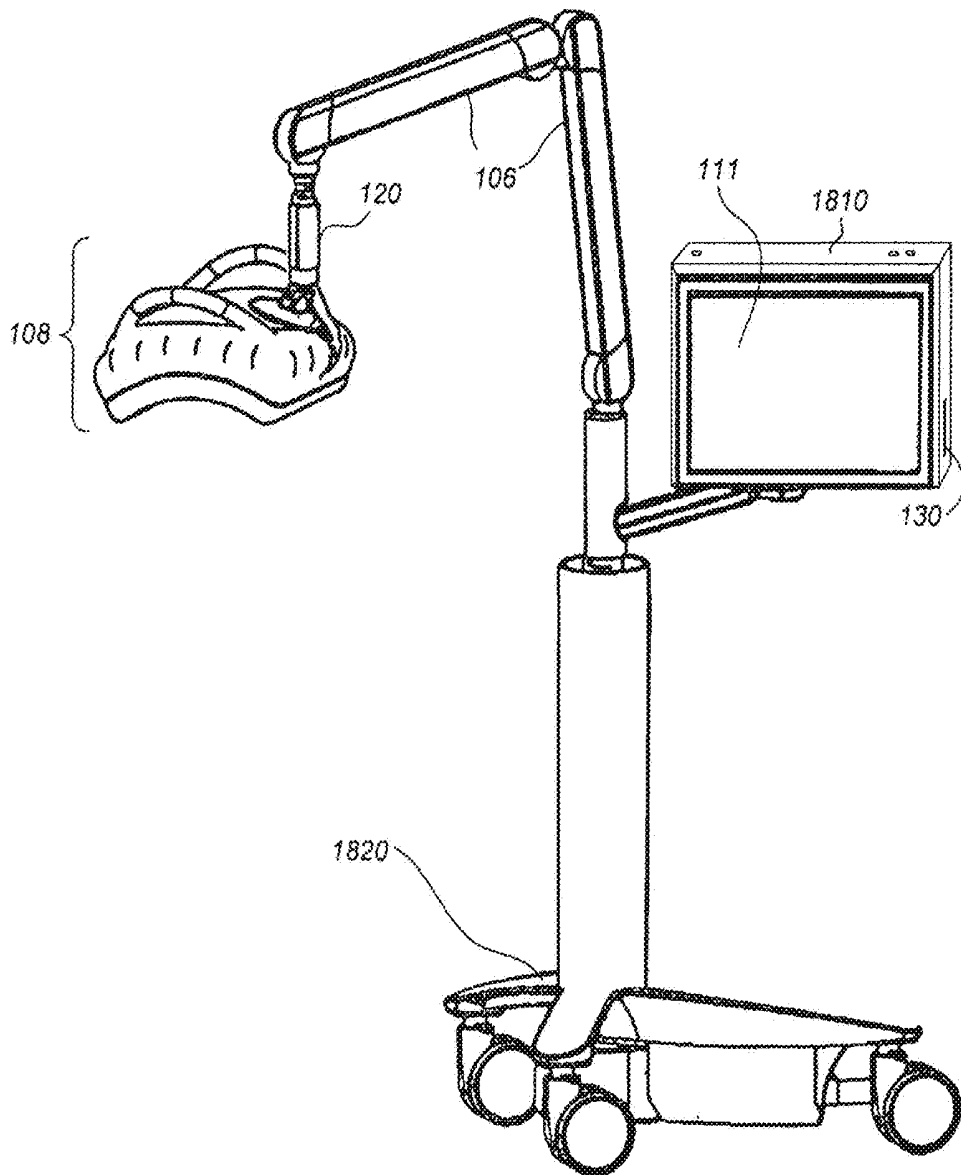


FIG. 18

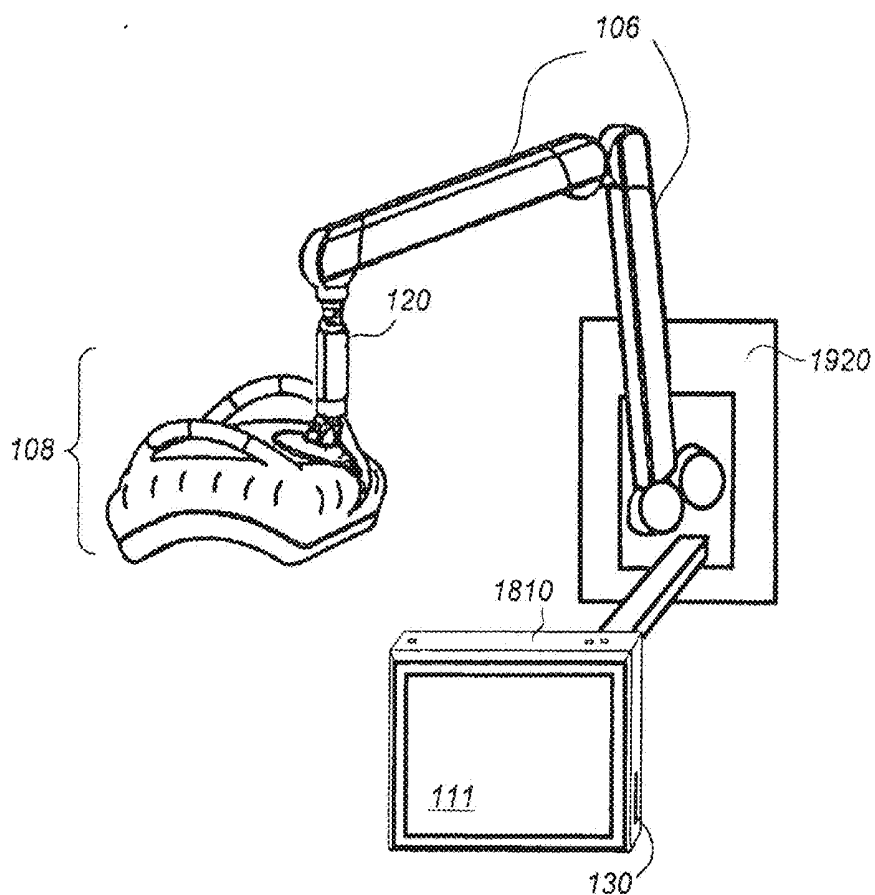


FIG. 19

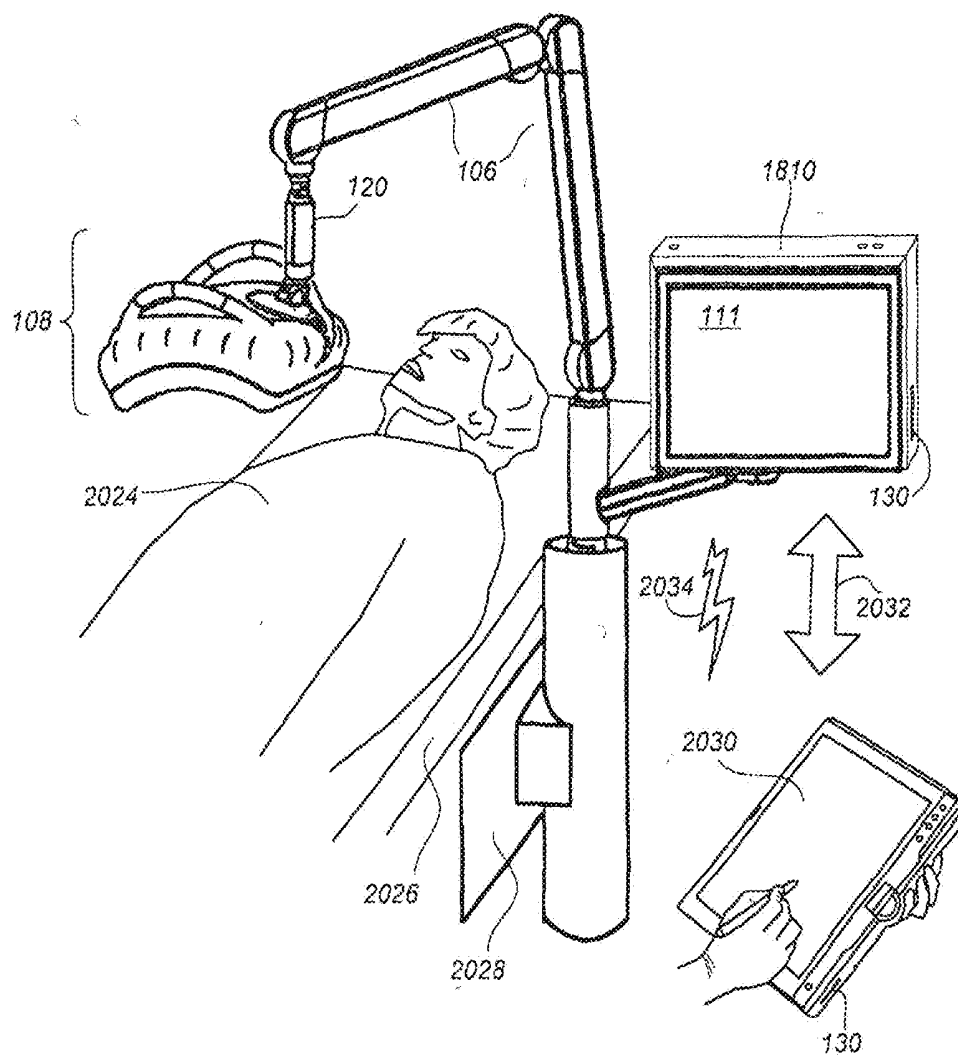


FIG. 20

FIGURE 21

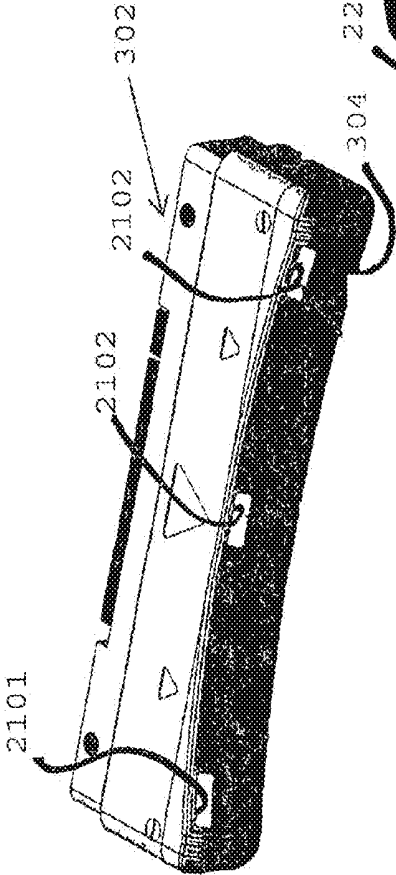
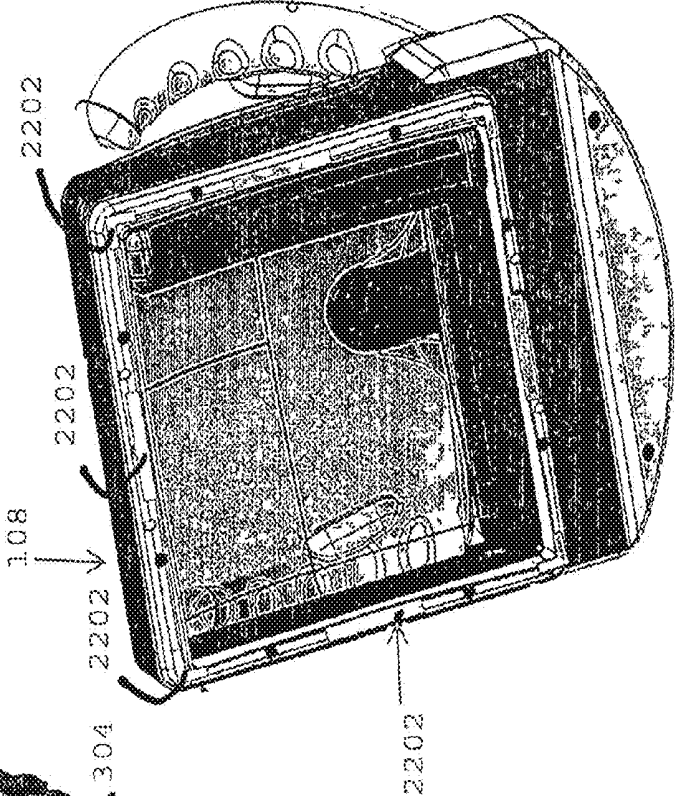


FIGURE 22



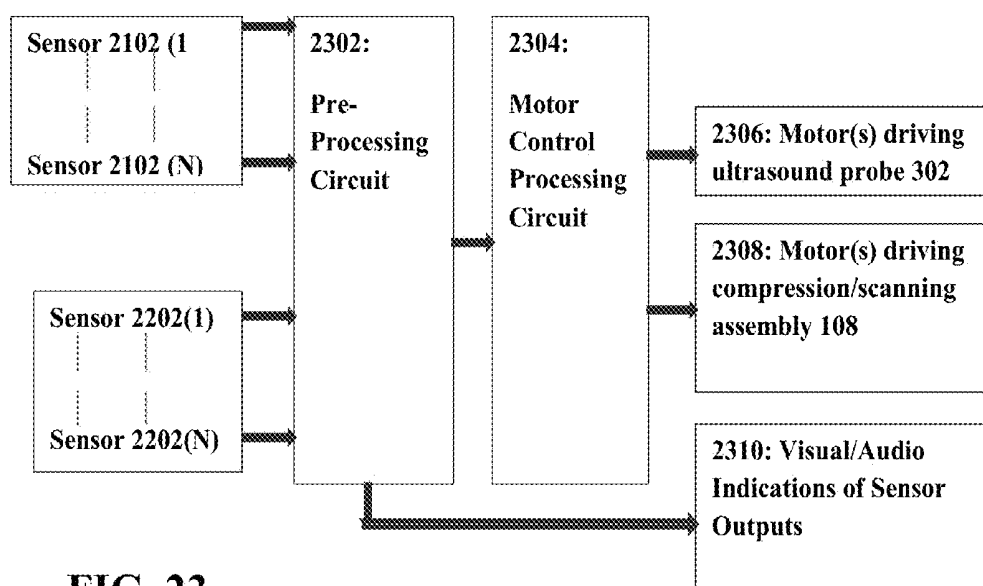


FIG. 23

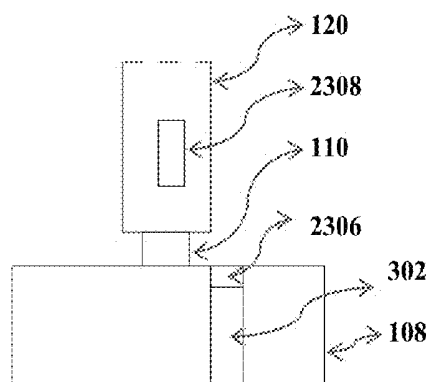


FIG. 24

**MEDICAL ULTRASOUND SCANNING WITH
CONTROL OVER PRESSURE/FORCE
EXERTED BY AN ULTRASOUND PROBE
AND/OR A COMPRESSION/SCANNING
ASSEMBLY**

**CROSS REFERENCE TO RELATED
APPLICATIONS**

[0001] This application is a continuation-in-part of Ser. No. 12/299,275 (published as US 2010/0174185 A1), filed 19 Mar. 2010, which claims the benefit of U.S. Provisional Application No. 60/746,259, filed 2 May 2006. These applications are hereby incorporated by reference herein.

FIELD

[0002] This patent specification relates to medical imaging. More particularly, this patent specification relates to ultrasound scanning and ultrasound-assisted biopsy. One of the features relates to sensing the pressure or force that a compression/scanning assembly exerts on the patient (e.g., chest and/or breast) and using the results to improve imaging.

BACKGROUND

[0003] Volumetric ultrasound scanning usually involves the movement of an ultrasound transducer relative to a tissue sample and the processing of resultant ultrasound echoes to form a data volume representing at least one acoustic property of the tissue sample. Although several examples herein are presented in the particular context of human breast ultrasound, it is to be appreciated that the present teachings are broadly applicable for facilitating ultrasonic scanning of any externally accessible human or animal body part (e.g., abdomen, legs, feet, arms, neck, etc.). Moreover, although several examples herein are presented in the particular context of mechanized scanning (i.e., in which the ultrasound transducer is moved by a robot arm or other automated or semi-automated mechanism), it is to be appreciated that one or more aspects of the present teachings can be advantageously applied in a handheld scanning context.

[0004] Volumetric ultrasound scanning of the breast has been proposed as a complementary modality for breast cancer screening as described, for example, in the commonly assigned US 20031007598A1 published Jan. 9, 2003, which is incorporated by reference herein. The commonly assigned WO 20041030523A2 published Apr. 15, 2004, which is incorporated by reference herein, describes a full-field breast ultrasound (FFBU) scanning apparatus that compresses a breast along planes such as the craniocaudal (CC) plane, the mediolateral oblique (MLO) plane, etc., and ultrasonically scans the breast. One side of an at least partially conformable, substantially taut membrane or film sheet compresses the breast. A transducer translation mechanism maintains an ultrasound transducer in contact with the other side of the film sheet while translating the ultrasound transducer thereacross to scan the breast.

[0005] Other FFBU scanning devices that compress the breast in other directions, such as in generally chestward or "head-on" directions, are described in one or more of the following commonly assigned applications, each of which is incorporated by reference herein: U.S. Ser. No. 60/565,698 filed Apr. 26, 2004; U.S. Ser. No. 60/577,078 filed Jun. 4, 2004; U.S. Ser. No. 60/629,007 filed Nov. 17, 2004; U.S. Ser. No. 60/702,202 filed Jul. 25, 2005; U.S. Ser. No. 60/713,322

filed Aug. 31, 2005; WO 2005/104729A2 published Nov. 10, 2005; and WO 2005/120357A1 published Dec. 22, 2005.

[0006] Among other useful applications, ultrasound imaging systems can be used to facilitate percutaneous biopsy procedures in which a needle or other fine biopsy instrument is used to extract a tissue sample. More specifically, ultrasound imaging systems can be used to locate a lesion and to assist the radiologist in guiding a biopsy instrument to the lesion. In such applications, it is necessary to keep the biopsy needle positioned within the imaged plane in order for it to remain visible on the ultrasound monitor during the procedure. As used herein, the terms radiologist and physician are used interchangeably and generically to refer to medical professionals that analyze medical images and make clinical determinations therefrom, and/or that perform medical procedures under the at least partial guidance of medical imaging systems, it being understood that such person might be titled differently, or might have differing qualifications, depending on the country or locality of their particular medical environment.

[0007] Percutaneous ultrasound-guided biopsy of the breast is a procedure that can be quickly performed free-handed by a "skilled" physician, using a hand-held ultrasound imaging system, in an out-patient environment. Because this procedure would take less physician time, it is less expensive than other breast biopsy procedures, such as x-ray guided stereotactic BIOPSY and surgical biopsy. Thus, percutaneous ultrasound-guided biopsy has become a highly popular breast biopsy procedure.

[0008] However, this procedure could become even more popular if it were easier to perform. This is because many physicians may find it difficult to do the free-handed procedure, which requires the physician to hold a hand-held ultrasound transducer in one hand and the biopsy needle in the other hand, while looking at both the display monitor and the patient breast (usually placed three feet apart) and trying to visualize simultaneously the thin biopsy needle (approximately 1 mm in diameter) and the breast lesion in the thin (approximately 1 mm thick) scan plane of the ultrasound imaging system.

[0009] One type of ultrasound-assisted biopsy guide is described in the commonly assigned U.S. Pat. No. 6,695,786, issued Feb. 24, 2004, which is incorporated by reference herein. Although one or more preferred embodiments are herein presented in the particular context of needle biopsy procedures for the breast such as fine needle aspiration biopsy, core-needle biopsy, vacuum-assisted biopsy, and/or other single-cylinder excision alternatives, it is to be appreciated that one or more aspects of the present teachings can be advantageously applied in a variety of different image-guided surgical contexts.

[0010] It would be desirable to facilitate ultrasound scanning of a tissue volume (such as, but not limited to, a breast) in a manner that further improves at least one of image quality, volumetric thoroughness, patient comfort, and overall quickness of the scanning process. It would be further desirable to provide assistance to physicians in performing ultrasound-guided biopsy of the breast. It would be further desirable to provide for ultrasound scanning of a tissue volume in a manner that facilitates at least one of guidance, positioning, and operation of a biopsy instrument. Other issues arise as would be readily apparent to one skilled in the art in view of the present disclosure. It would be further desirable to sense

the force or pressure that a compression/scanning assembly exerts on a patient and to use the resulting information to improve imaging.

SUMMARY

[0011] In one embodiment, an apparatus and related methods for ultrasonically scanning a tissue sample are provided, the apparatus comprising an ultrasound transducer and a membranous sheet, the membranous sheet compressing the tissue sample, the ultrasound transducer contacting the membranous sheet and ultrasonically scanning the tissue sample therethrough, wherein the membranous sheet has a generally arcuate shape and the ultrasound transducer is movable in a generally arcuate trajectory therealong during the ultrasonic scan. Preferably, the membranous sheet comprises one or more of a fabric and a vented membrane that is at least partially porous to a liquid or gel acoustic coupling agent. Alternatively, the membranous sheet may comprise material available under the trade name Mylar or other non-porous sheet-like material, or may comprise thin, sheet-like versions of solid materials such as 40-mil polycarbonate plastic. The tissue sample is compressed in an at least partially conformal manner toward an underlying anatomical structure during the ultrasonic scan.

[0012] In one particular example, the tissue sample may be a breast of a human patient and the underlying anatomical structure may be the patient's rib cage. In the context of ultrasonic scanning in which a transducer scans the breast through a compressing membranous sheet, it has been found advantageous to compress the breast along a generally arcuate surface, and still more advantageous to have the generally arcuate surface positioned to compress the breast conformally toward the rib cage. Among other advantages, volumetric thoroughness and patient comfort are promoted while maintaining good image quality. Also promoted is an ability to better accommodate a variety of different breast sizes ranging from larger fatty breasts to smaller dense breasts.

[0013] According to another embodiment, an apparatus for facilitating a medical procedure is provided, comprising a membranous sheet compressing a tissue sample, an ultrasound transducer contacting the membranous sheet to ultrasonically scan the tissue sample therethrough, and a biopsy guide operably coupled to the ultrasound transducer for maintaining a biopsy instrument in a scan plane of the ultrasound transducer to facilitate a percutaneous biopsy of a lesion located in the scan plane. The ultrasound transducer is preferably translatable along a scanning trajectory as it scans the tissue sample through the membranous sheet, to provide for volumetric imaging of the tissue sample so that a position of the lesion within the tissue sample can be determined prior to the percutaneous biopsy. In one particular example, the tissue sample is a human breast and the biopsy instrument is a biopsy needle for fine needle aspiration biopsy, core-needle biopsy, or vacuum-assisted biopsy. However, it is to be appreciated that one or more aspects of the present teachings can be advantageously applied for other single-cylinder excision alternatives and in other image-guided surgical contexts.

[0014] For one embodiment, the ultrasound transducer is movably disposed within a housing, and the biopsy guide is coupled to the ultrasound transducer through an opening in the housing. The biopsy guide is thereby movable with the ultrasound transducer and maintainable in the scan plane for many or all transducer positions along the scanning trajectory.

[0015] In one embodiment, the biopsy guide is provided as an addable and removable accessory to the above-described curved-membrane ultrasonic scanning apparatus. For this embodiment, and with particular applicability to the breast, the part of the tissue sample near an apex of the scanning trajectory becomes raised relative to the other parts of the tissue sample, and side entry of the needle or other biopsy instrument into that raised portion of the tissue sample becomes particularly convenient. In other embodiments, the biopsy guide is provided as an addable/removable accessory for ultrasound scanners having planar (i.e., flat, non-curved) compression surfaces that compress the breast in a generally chestward direction. In still other embodiments, the biopsy guide is provided as an addable/removable accessory for dual compression-plate scanning devices. For another preferred embodiment applicable to each of these cases, the biopsy guide is configured such that the biopsy instrument can have different angular orientations within the scan plane, such as by using a multi-link assembly analogous to that described in the commonly assigned U.S. Pat. No. 6,695,786, *supra*.

[0016] In another embodiment, the apparatus senses pressure or force that a compression/scanning assembly exerts on the patient and uses the results to improve imaging.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. 1 illustrates a perspective view of a breast ultrasound scanning apparatus according to an embodiment;

[0018] FIGS. 2-3 illustrate a perspective view of a compression/scanning assembly of the ultrasound scanning apparatus of FIG. 1;

[0019] FIGS. 4-5 illustrate a top view of breast ultrasound scanning according to an embodiment;

[0020] FIGS. 6-7 illustrate an axial cut-away view of breast ultrasound scanning according to an embodiment;

[0021] FIG. 8 illustrates a perspective view of a curved frame and membranous sheet as removed from a compression/scanning assembly according to an embodiment;

[0022] FIG. 9 illustrates a perspective view of an ultrasound transducer, a curved membranous sheet, a rigid frame, and a transducer translation apparatus according to an embodiment;

[0023] FIG. 10 illustrates a perspective view of a flexible curved compression/scanning assembly according to an embodiment;

[0024] FIG. 11 illustrates a perspective view of a compression/scanning assembly and a biopsy attachment according to an embodiment;

[0025] FIG. 12 illustrates a conceptual perspective view of the biopsy guide of FIG. 11 guiding a biopsy instrument into a lesion located in a scan plane of an ultrasound transducer;

[0026] FIG. 13 illustrates a perspective view of a compression/scanning assembly and a biopsy guide attachment according to an embodiment;

[0027] FIG. 14 illustrates a top view of a compression/scanning assembly and a biopsy guide attachment according to an embodiment;

[0028] FIG. 15 illustrates a perspective view of a breast ultrasound scanning apparatus with biopsy guide attachment according to a preferred embodiment;

[0029] FIG. 16 illustrates ultrasound scanning and ultrasound-assisted breast biopsy according to an embodiment;

[0030] FIG. 17 illustrates a locking and actuating support column according to certain embodiments;

[0031] FIG. 18 illustrates a perspective view of a breast ultrasound scanning apparatus according to an alternative embodiment;

[0032] FIG. 19 illustrates a perspective view of a wall mounted breast ultrasound scanning apparatus according to a further alternative embodiment;

[0033] FIG. 20 illustrates a perspective view of a chair or bed-mounted breast ultrasound scanning apparatus according to further alternative embodiments;

[0034] FIG. 21 illustrates a perspective view of an ultrasound transducer with pressure or force sensing elements;

[0035] FIG. 22 illustrates in perspective view a compression scanning assembly with pressure or force sensing elements;

[0036] FIG. 23 is a functional block diagram illustrating an example of using force/pressure sensing results to improve imaging; and

[0037] FIG. 24 illustrates in schematic form motors for driving an ultrasound probe and a compression/scanning assembly.

DETAILED DESCRIPTION

[0038] FIG. 1 illustrates a perspective view of a breast ultrasound scanning apparatus 102 according to an embodiment, comprising a frame 104 that may contain an ultrasound processor including beamforming electronics, and other processors and electronics including user interface devices and processors, data management and control, and power supplies, a movable support arm 106, a compression/scanning assembly 108 connected to the support arm 106 via a ball-and-socket connector 110, and a monitor 111 connected to the frame 104 as shown. A housing 112 supports a membranous sheet 114 that is disposed across a bottom opening thereof and that compresses the breast, usually toward the rib cage. An ultrasound transducer inside the housing 112 is swept across the top of the membranous sheet 114 in a generally arcuate trajectory to ultrasonically scan the compressed breast there-through. A top surface 118 of the compression/scanning assembly 108 is preferably translucent to visible light to allow the user to see therethrough and onto the top of the membranous sheet 114, for facilitating ease of positioning. For embodiments in which the membranous sheet 114 is also translucent to visible light, the skin of the compressed breast can itself be seen through the top surface 118.

[0039] Preferably, the support arm 106 is configured and adapted such that the compression/scanning assembly 108 is either neutrally buoyant in space, or has a relatively light net downward weight for breast compression, while allowing for easy user manipulation. According to one embodiment, the amount of net downward force exerted onto the patient can be user-adjusted and maintained using actuation and feedback control devices. For example, the user may set the downward force for “8 pounds”, and the net amount of downward force maintained (at joint 110, for example) would be automatically maintained at 8 pounds.

[0040] According to another embodiment, the current position of the support arm 106 and compression/scanning assembly 108 can be substantially stabilized or “frozen” preferably at the press of a single button (not shown) located near a handle 116 or a foot pedal (not shown). This can be achieved by stepper motors that actuate the support arm 106, or by any of a variety of electronically controlled seizing mechanisms operating at the various joints of the support arm 106. In one embodiment, the positional freezing or stabilization can be

absolute, wherein the compression/scanning assembly 108 is kept absolutely at the fixed position and orientation regardless of any forces applied or released subsequent to freezing. In another embodiment, the positional freezing can be non-absolute with a constant downward force, wherein the compression/scanning assembly 108 is kept generally at the fixed or “frozen” position, but wherein a small amount of vertical movement is allowed so as to keep the downward force on the breast constant at the “frozen” amount. The latter embodiment is particularly advantageous because it allows the patient to breathe while at the same time curbing the amount of resulting disturbance to the imaging and/or biopsy procedures being performed.

[0041] Support arm 106 is comprised of arm section 132 that is attached to support column 136 via joint 122 such that section 132 can both rotate about the axis of column 136 and about axis 124 of joint 122. Arm section 134 is attached to section 132 via joint 126 so as to allow rotation about axis 128 of joint 126. Section 134 is also attached to column 120 via joint 142 so as to allow movement about axis 144 of joint 142. According to an embodiment arm sections 132 and 134, and joints 122, 126 and 142 are constructed in a four-bar link arrangement that maintains columns 120 and 136 substantially parallel. Neutral buoyancy of compression/scanning assembly 108 so as to allow ease of positioning of assembly 108 upon the patient is preferably achieved using hydraulic cylinders within arm sections 132 and 134. The hydraulic cylinders are preferably electronically lockable using solenoid actuated locking valves. In this way, column 120 can be substantially frozen or fixed along the axis of column 120 electronically. It has been found that locking of arm 106 about the axis of column 136 is not critical in many applications. However, in applications where such movement stabilization is needed, an additional electronically actuated clamp is added within column 136.

[0042] Scanning consistency is important ultrasound breast imaging in a number of ways. First, it is important that a scanning system be capable of generating a good image generally free of artifacts due to relative movements between the ultrasound transducer and the patient's breast. Second, it is important that scans of a patient at one time are consistent with scans of the same patient at a later date, thus allowing for useful temporal comparisons. Finally, it is important that a scanning system achieves relatively consistent scans between different patients. It has been found a scanning system in which applies a relatively constant force on the patient's breast during ultrasound scanning, in a direction towards the patient's chest wall, is useful in achieving the types of scanning consistency described above. In order to provide for relatively constant force during scanning, a low spring constant of mechanical scanning system in the direction of the patient's chest wall is desirable. In the example shown in FIG. 1, the spring constant of the scanning system includes the flexibility of arm sections 132, 134, columns 136 and 120, and joints 122, 126, 142 and 110. It has been found that a spring constant of less than 100 lbs/inch (17.52 N/mm) is desirable for most applications. According to embodiments, the mechanical scanning system is arranged and designed such that it has a spring constant that preferably is less than 25 lbs/inch (4.38 N/mm). According to an even further preferred embodiment, the scanning system is arranged and designed such that it has a spring constant in the direction towards the chest wall of the patient of less than about 2 lbs/inch (0.35 N/mm).

[0043] Column 120 is attached to assembly 108 via locking ball joint 110. According to certain embodiments, column 120 also provides linear actuation (e.g., telescoping) along the axis of column 120. It has been found that in many applications, applying such linear actuation in column 120 provides sufficient net downward force if the actuation occurs after the compression/scanning assembly 108 is correctly positioned on the patient's breast and arm 106 and ball joint 110 are locked. With the spring constant designed into the scanning system as described above, the amount of force can be controlled by the amount of linear actuation of column 120. Further detail of the design of column 120 is provided below with respect to FIG. 17. In still other embodiments, the compression/scanning assembly 108 is not supported by the support arm 106 or other support mechanism, but instead is handheld by the operator. Optionally, battery power and wireless communication technology can be used to make the compression/scanning assembly 108 entirely tether-free.

[0044] Optionally, the support arm 106 may comprise potentiometers (not shown) to allow position and orientation sensing for the compression/scanning assembly 108, or other types of position and orientation sensing (e.g., gyroscopic, magnetic, optical, radio frequency (RF)) can be used. Within frame 104 may be provided a fully functional ultrasound engine for driving an ultrasound transducer and generating volumetric breast ultrasound data from the scans in conjunction with the associated position and orientation information. The volumetric scan data can be transferred to another computer system for further processing using any of a variety of data transfer methods known in the art. A general purpose computer, which can be implemented on the same computer as the ultrasound engine, is also provided for general user interfacing and system control. The general purpose computer can be a self-contained stand-alone unit, or can be remotely controlled, configured, and/or monitored by a remote station connected across a network.

[0045] According to certain embodiments, sensor 130 is provided to aid in operator log-in procedures and to increase security. Sensor 130 can be a smart card reader which is adapted to scan the identification badge of the operator. The system can be programmed to automatically load and display the operator's preferred system setup. Sensor 130 can alternatively be implemented as an RFID reader that communicates with the operator's RFID tag, or it may be any of a number of known biometric sensors such as a fingerprint scanner. Sensor 130 can also be integrated into monitor 111.

[0046] FIG. 2 illustrates a perspective view of a bottom of the compression/scanning assembly 108. Preferably, the membranous sheet 114 is disposed across a rigid frame 202 that is removably coupled to the housing 112. The membranous sheet 114 comprises one or more of a fabric (as described in Ser. No. 60/702,202, supra) and a vented membrane (as described in Ser. No. 60/713,322, supra) that is at least partially porous to a liquid or gel acoustic coupling agent. Alternatively, the membranous sheet may comprise Mylar or other non-porous sheet-like material, or may comprise thin, sheet-like versions of solid materials such as 40-mil polycarbonate plastic. When the compression/scanning assembly 108 is not compressing a breast, the degree of tautness of the membranous sheet 114 will depend on the specific characteristics of the material used. For non-elastic or minimally elastic materials, the membranous sheet 114 may have very low tautness when the compression/scanning assembly 108 is not compressing a breast.

[0047] FIG. 3 illustrates a perspective view of a bottom of the compression/scanning assembly 108, with the membranous sheet 114 omitted to display overlying elements. More particularly, an ultrasound probe 302 including a 15-cm, 768-element linear transducer array 304 is provided that sweeps across the breast in an arcuate scanning trajectory. For one preferred embodiment, the arcuate scanning trajectory is roughly circular, such that the surface traversed by the linear transducer array 304 resembles a cylindrical sector having a radius R and a subtended angle θ (theta). In one embodiment, the radius R is between about 6 inches and 36 inches, and the subtended angle θ is between 45 degrees and 135 degrees. In another embodiment, the radius R is between 8-18 inches. In yet another embodiment, the radius R is about 12 inches. In yet another embodiment, the radius R is about 8 inches and the subtended angle θ is about 105°. In other embodiments, the arcuate shape can be elliptical, hyperbolic, or with a profile reminiscent of any of a variety of other shapes that have at least one apex and at least one downward-facing concavity.

[0048] According to certain embodiments, the lower face of transducer array 304 is concave as indicated by broken line 308 having radius R' . With a concave face, transducer array 304 can move along a more linear direction while still creating a cylindrical surface. In other words, the radius R as shown in FIG. 3 can be larger. In some embodiments the radius R is greater than 36 inches, or is essentially infinite (i.e. there is no arc along the direction of motion of transducer array 304). In cases where the transducer array is both concave and moves in an arcuate trajectory, an approximately spherical scanned surface (radius R is about equal to radius R') or ellipsoidal scanned surface can be generated.

[0049] According to certain embodiments, compact ultrasound electronics 310, including ultrasound beamformer electronics is integrated into compression/scanning assembly 108. Examples of compact ultrasound electronics include products commercially available from Terason, A Division of Teratech Corporation, a corporation of Massachusetts. Placing the ultrasound electronics 310 in compression/scanning assembly 108 allows for a much shorter path between electronics 310 and transducer array 304 compared with the electronics positioned in frame 104 as shown in FIG. 1.

[0050] FIGS. 4-5 illustrate a top view of breast ultrasound scanning according to an embodiment. Generally speaking, the arcuate contour of the compression/scanning assembly 108 will be positioned to follow the rib cage of the patient, although a variety of other orientations are possible depending on the breast size, breast shape, and other factors. Thus, while the concavity of the scanning surface and corresponding scanning direction will most commonly point in the range of 0° to 40° relative to the x-z plane in FIGS. 4-5, the range of possibilities is within the full range of rotation around the z-axis in FIGS. 4-5.

[0051] FIG. 6 illustrates an axial cut-away view of a relatively large breast 602 being scanned by the compression/scanning assembly 108, while FIG. 7 illustrates an equivalent view for a relatively small breast 702. As illustrated in FIGS. 6-7, it has been found that the at-least rough conformity of the compression and scanning surface to the shape of the rib cage can provide for more thorough volumetric scanning for a larger variety of breast sizes and shapes. According to certain embodiments, pressure sensors are included within compression/scanning assembly 108. In FIG. 6, pressure sensor 610 is integrated with the transducer array 302 and is

preferably a piezo-electric type pressure sensor, although other types of sensors could be used including strain gauges and/or MEMs based pressure sensors. Pressure sensor **610** measures the pressure being applied to the patient's breast by transducer array **302**, thereby aiding in scanning consistency. A feedback control loop can be added with the stepper motor within column **120** (described infra with respect to FIG. 17) so as to provide a more constant force to the patient's breast and/or chest wall, thereby further increasing consistency of scans. Sensor **610** can also be linked to an audio and/or visual indicator that aids the operator in correct positioning and pressure of compression/scanning assembly **108**. Also shown in FIG. 6 are alternative locations **612** and **614** for sensors which are mounted on the sides of compression/scanning assembly **108** in order to measure the tension on membrane **114**.

[0052] FIG. 8 illustrates a perspective view of the curved frame **202** and membranous sheet **114** affixed thereto as removed from a compression/scanning assembly according to an embodiment. The curved frame **202** is designed to easily snap in and out of the housing **112** of the compression/scanning assembly **108**. In one embodiment, the curved frame **202** and membranous sheet **114** are permanent or semi-permanent components of the overall apparatus and are sterilized after each patient. In another embodiment, the curved frame **202** and membranous sheet **114** are disposable or recyclable and are replaced after each patient.

[0053] FIG. 9 illustrates a perspective view of the membranous sheet **114** and the curved frame **202** in conjunction with the ultrasound probe **302**. Also shown in FIG. 9 is a probe translation assembly comprising rigid, curved racks **902**, a motor **904**, and a gear/pinion **906** configured such that the ultrasound probe **302** moves along the curved racks **902** according to actuation of the motor **904**. Also shown in FIG. 9 is a connector **908** that connects to electrical cabling driving the transducer elements. It is to be appreciated that many different mechanical configurations achieving similar mechanical goals would be apparent to one skilled in the art in view of the present disclosure and are within the scope of the embodiments. Also shown in FIG. 9 are alternative locations **312** and **314** for compact ultrasound electronics **310** as described in connection with FIG. 6 supra.

[0054] FIG. 10 illustrates a perspective view of a flexible curved compression/scanning assembly **1002** for which the particular shape of the compression surface can vary according to the particular body part being compressed and the forces being applied. An ultrasound probe **1004** is mechanically swept across a curved membranous sheet **1006** that is disposed across a frame, the frame being conformal with two flexible racks **1008**. The two flexible racks **1008** are themselves used in conjunction with multiple motor-driven pinions **1010** to translate the ultrasound probe **1004** (the motors are not shown). The flexible assembly is mechanically supported and stabilized by wires **1012** coupled to pulleys **1014** secured to assembly **108**, and springs **1016** as shown, to selectively change the curvature of racks **1008**. It is to be appreciated that many different mechanical configurations achieving similar mechanical goals would be apparent to one skilled in the art in view of the present disclosure and are within the scope of the embodiments.

[0055] FIGS. 11-12 illustrate a perspective view of a compression/scanning assembly **1102** and a biopsy attachment **1108** according to an embodiment. An ultrasound probe **1104** is mechanically swept in an arcuate trajectory across a curved

membranous sheet **1106** disposed across a bottom opening of a housing **1103**, in a manner similar to that shown for FIGS. 2-3, supra. A coupler **1110** is affixed to the ultrasound probe **1104** through a slot **1120** formed in the housing **1103**, the slot **1120** having the same shape as the arcuate trajectory of the ultrasound probe **1104**. The biopsy attachment **1108** comprises a guide **1112** and a biopsy instrument comprising a needle holder **1114** and a biopsy needle **1116**. A biopsy guide is formed when the guide **1112** is inserted into the coupler **1110**, the biopsy guide restricting the biopsy needle **1116** to a scan plane **1202** that intersects a lesion **1204** during the biopsy procedure.

[0056] Preferably, the guide **1112** is extendable in a lengthwise direction such that the depth of the biopsy instrument into the scan plane (i.e., the downward distance from the linear transducer array within the scan plane in FIGS. 11-12) can be varied. By way of example, the guide **1112** may be provided with a telescoping and retracting capability, analogous to that of a retractable radio antenna. Alternatively, a selection of guides **1112** of different lengths can be provided so that a suitable guide can be used for each patient. It is to be appreciated that many different mechanical configurations achieving similar mechanical goals would be apparent to one skilled in the art in view of the present disclosure and are within the scope of the embodiments, including embodiments with motorized positioners and needle insertion mechanisms.

[0057] FIG. 13 illustrates a perspective view of a compression/scanning assembly **1302** and a biopsy guide **1310/1312** according to an embodiment. An ultrasound probe **1304** is mechanically swept in a flat, planar trajectory across a flat membranous sheet **1308** disposed across a flat bottom opening of a housing **1306**, in a manner similar to that described in Ser. Nos. 60/702,202 and/or 60/713,322, supra. A coupler **1310** is affixed to the ultrasound probe **1304** through a straight slot formed in the housing **1306**. The biopsy guide couples to a needle holder **1316** such that a biopsy needle **1318** is maintained in the scan plane of the ultrasound probe **1304**. For the embodiment of FIG. 13, the biopsy guide **1310/1312** comprises two links hingeably coupled to allow the biopsy needle **1318** to have varying angles of attack into the lesion within the scan plane.

[0058] Preferably, the biopsy guide **1310/1312** is extendable in an outward direction such that the depth of the biopsy instrument into the scan plane (i.e., the downward distance from the linear transducer array within the scan plane in FIG. 13) can be varied, e.g., by having a telescoping/retracting capability. In still other embodiments, in a manner analogous to that disclosed in the commonly assigned U.S. Pat. No. 6,695,786, supra, a multi-link assembly having 3 or more links is provided for permitting a broader range of angular orientations of the biopsy needle **1116** within the scan plane. Also, such multi-link assembly would inherently provide a depth-varying functionality for moving the biopsy instrument to shallower and deeper depths in the scan plane. It is to be appreciated that many different mechanical configurations achieving similar mechanical goals would be apparent to one skilled in the art in view of the present disclosure and are within the scope of the embodiments, including embodiments with motorized positioners and needle insertion mechanisms.

[0059] FIG. 14 illustrates a top view of a smaller, specialized compression/scanning assembly **1402** including an integrated biopsy guide **1406** according to an embodiment. The size and trajectory of an ultrasound probe **1404** are substantially smaller, perhaps as small as three inches, for particu-

larly performing percutaneous breast biopsies using the biopsy needle **1410** and needle holder **1408**. The integrated biopsy guide **1406** is configured and adapted to restrict the biopsy needle **1410** to the scan plane of the ultrasound probe **1404**, while allowing multiple depths and angles within the scan plan for attacking a breast lesion **1412** over which the ultrasound probe **1404** has been positioned. In one embodiment, the compression/scanning assembly **1402** is entirely handheld, while in other embodiments it is mechanically supported by a support arm.

[0060] FIG. **15** illustrates a perspective view of a breast ultrasound scanning apparatus **1502** with biopsy guide attachment according to an embodiment. The apparatus comprises an upper compression/scanning assembly **1504** and a lower compression/scanning assembly **1506**, the breast of an upright patient being inserted therebetween for scanning and/or biopsy (the patient is facing the $-z$ axis). Upper compression/scanning assembly **1504** comprises a compressive surface **1508**, such as a membranous sheet described supra, and a probe **1512** that is swept thereover in the z direction. A biopsy guide **1514** is affixed to the ultrasound probe **1512** through a slot **1520** as shown. The biopsy guide **1514** couples to a needle holder **1516** such that a biopsy needle **1518** is restricted to the scan plane of the ultrasound probe **1512** while allowing multiple depths and angles within the scan plan for attacking a breast lesion over which the ultrasound probe **1512** has been positioned. The lower compression/scanning assembly **1506** may simply comprise a compression plate **1510**, or alternatively may be a duplicate of the upper compression/scanning assembly **1504** for allowing two-sided scans and other advantageous applications. In other embodiments, one or more aspects of the breast ultrasound scanning apparatus, with the exception of the biopsy guide attachment, can be found in the commonly assigned WO 2004/030523A2, which is incorporated by reference herein.

[0061] FIG. **16** illustrates ultrasound scanning and ultrasound-assisted breast biopsy according to an embodiment. As used hereinbelow, the term biopsy/scanning pod is used to refer to the compression/scanning assembly **1102** of FIG. **11** together with the attached biopsy guide attachment **1108**, or to other compression/scanning assemblies such as those of FIG. **10**, FIG. **13**, and FIG. **14** together with similar biopsy guide attachments. At step **1602**, the scanning/biopsy pod is compressibly positioned on the breast. Generally speaking, the curved contour of the scanning/biopsy pod will be positioned to follow the rib cage of the patient, with the scan plane (and therefore the plane of needle movement) being at least roughly in the head-to-toe direction, although a variety of other orientations are possible as well depending on the breast size, breast shape, lesion location, and other factors. Prior to step **1602**, the breast is preferably wetted with a liquid or gel acoustic couplant. If the nipple of the breast protrudes or is recessed by substantial amounts, it should be generously wetted with a relatively large amount of couplant so that air pocket formation is avoided when the nipple is contacted by the membranous sheet.

[0062] At step **1604**, the position of the scanning/biopsy pod is frozen in place using the above-described position-freezing capability. Notably, it is the overall housing of the scanning/biopsy pod that is frozen in place, and not the ultrasound transducer itself, which is still movable inside the scanning/biopsy pod. At step **1606**, the breast is scanned to generate a three-dimensional volumetric representation thereof, and results therefrom are displayed to the radiologist.

Any of a variety of different two-dimensional and three-dimensional images are displayed as may be required by the radiologist to properly identify, locate, and visualize the lesion and the surrounding tissue including, without limitation, thin-slice views, thick-slice views, maximum-intensity projection views, or other views as described in the commonly assigned US2003/0212327A1 and US2005/0171430A1, which are incorporated by reference herein. At step **1608**, the lesion is identified by the radiologist.

[0063] At step **1610**, the ultrasound transducer is guided until the lesion is located in the scan plane. The movement of the transducer can be fully automatic, semi-automatic, or hand-controlled by the radiologist (e.g., using buttons, mouse, joystick, etc.) without departing from the scope of the embodiments. At the end of step **1610**, the plane of confinement of the biopsy needle corresponds to a live planar image of the scan plane being displayed, which includes the lesion.

[0064] At step **1612**, the biopsy needle is introduced into the breast, under mechanical guidance of the biopsy guide and under visual monitoring by the radiologist using the live planar image. The movement of the biopsy needle may be fully automatic, semi-automatic, or hand-controlled by the radiologist, although at all times it is under visual observation by the radiologist because the needle is confined to the scan plane. For embodiments in which the biopsy needle is fully- or semi-automatically actuated, the controlling processor can be provided with image information from the scanned images from which the needle and the lesion can be segmented to facilitate control of the biopsy needle position. The rib cage can also be segmented and hardware or software limits/stops placed on the range of motion, to avoid accidental puncture of the underlying anatomy. Even for manually actuated embodiments in which the needle is guided and actuated by the radiologist, automated sensing and mechanical limiting can be used to avoid accidental punctures based on the relative positions of the lesion, needle, rib cage, etc., as detected from the real-time ultrasonically-obtained image information.

[0065] In another embodiment, predictive biopsy needle highlighting is provided on the user display in a manner analogous to that described in U.S. Pat. No. 6,695,786, supra. Regardless of the current position of the biopsy needle—even if it has not yet been inserted into the patient—a needle projection image is superimposed on the ultrasound display to represent the trajectory that the needle would have if it were to follow the exact direction in which it is currently pointing. Optionally, the “throw” of a spring-loaded biopsy needle can be marked on the needle projection image, representing the future needle depth when the spring-loaded trigger has been released.

[0066] At step **1614**, biopsy samples are collected as the radiologist continues to monitor the display. As known in the art, where the lesion is hard, the biopsy needle is springably “shot” into the lesion using a spring-trigger mechanism. At step **1616**, the biopsy needle is removed and the scanning/biopsy pod is released. It is to be appreciated that equivalent procedures using other compression/scanning assemblies, such as those having dual compression paddles (see FIG. **15**, for example) are also within the scope of the embodiments.

[0067] FIG. **17** illustrates a locking and actuating support column according to certain embodiments. Column **120** includes ball joint **110** which comprises of socket **1736**, ball **1738** and member **1740**. Compression/scanning assembly **108** of FIG. **1** is fixedly attached to member **1740** such that ball joint **110** provides assembly **108** with pitch, roll and yaw

motions as indicated by arrow 1748. Socket 1736 is fixedly attached to lower housing 1720. Lower housing 1720 slides along the axis of column 120 within upper housing 1718. Upper housing 1718 is attached to cap 1710 to which arm 106 is attached via joint 142 as shown in FIG. 1. Alternatively, arm 106 can be attached via joint 142 to flange 1726 which is part of upper housing 1718. Relative actuation between housings 1718 and 1720 is accomplished using stepper motor 1712 which is fixedly mounted on cap 1710. Motor 1712 turns lead screw 1714 which is engaged with nut 1716. Nut 1716 is fixedly mounted on the upper end of lower housing 1720. Thus stepper motor 1712 causes lower housing 1720 to move relative upper housing 1718 along the axis of column 120 in the direction indicated by arrows 1750 and 1752. According to an embodiment, locking of ball joint 110 is provided automatically as part of the actuation process through the use of ramp 1724 which is fixedly mounted on the inner wall of upper housing 1718 and which protrudes through a slot in lower housing 1720. When lower housing is pushed downwards by stepper motor 1712, roller 1722 rolls along ramp 1724 in a direction indicated by arrow 1754. Roller 1722 is attached to lever 1728 which is mounted to lower housing 1720 at pivot 1742. When roller 1722 moves along ramp 1724 in the direction indicated by arrow 1754, lever 1728 pivots and moves in directions indicated by arrows 1756 and 1758. Attached to lever 1728 is roller 1744 which pushes upon inner lever 1732 in the direction indicated by arrow 1758. Inner lever 1732 pivots on fulcrum 1730, and when pushed in the direction indicated by arrow 1758, pushes on ball clamp 1734 which in turn pushes on ball 1738 in the direction indicated by arrow 1760. In this way, due to the contour of ramp 1724, ball clamp 1734 is engaged with and automatically locks the movement of ball 1738 at the beginning portion of downward movement of inner housing 1720.

[0068] FIG. 18 illustrates a perspective view of a breast ultrasound scanning apparatus according to an alternative embodiment. Compression/scanning assembly 108 has integrated ultrasound electronics as described supra, thus allowing for a much more compact system. As mentioned, the integration of compact ultrasound electronics greatly decreases the path length between the beamformer and the transducer. Compact electronics also greatly reduced the need for large power supplies. Monitor 111 is also integrated with computer processor system 1810 which handles the user interface and data management and control functions. Processor system 1810 can be based on a laptop PC design or other small format computer platform such as a tablet PC, mini-box PC, thin-profile PC or all-in-one PC processor system 1810 also integrates sensor 130 as described supra. The ultrasound scanning apparatus is mounted on wheel assembly 1820 for ease of positioning and flexibility of use.

[0069] FIG. 19 illustrates a perspective view of a wall mounted breast ultrasound scanning apparatus according to a further alternative embodiment. The ultrasound scanning apparatus of FIG. 19 is similar to that shown and described in FIG. 18, except that it is wall mounted on mount 1920 instead of wheel mounted. Wall mounting advantageously saves floor space and is preferred for some settings.

[0070] FIG. 20 illustrates a perspective view of a chair or bed-mounted breast ultrasound scanning apparatus according to further alternative embodiments. The ultrasound scanning apparatus of FIG. 20 is similar to that shown and described in connection with FIGS. 18-19, except that is mounted on bed 2026 via mount 2028. Bed 2026 may alternatively be a den-

tist-style chair for the comfort and flexibility of positioning of patient 2024. According to yet further embodiments, computer processing system 1810 can be a tablet-type PC 2030. The tablet-type PC 2030 is preferably removable and dockable as indicated by arrow 2032. While undocked, PC 2030 can communicate with the rest of the scanning apparatus via Bluetooth, Wi-Fi or other suitable wireless communication technology, tablet-type PC 2030 provides greater flexibility in the user interface and allows for the operator to more easily share the images with the patient or with other personnel such as a radiologist so as to aid in decision making.

[0071] FIG. 21 illustrates ultrasound probe 302 incorporating several sensors 2102 for parameters such as pressure, force, or other properties. While only three sensors 2102 on one side of transducer array 304 are visible, it should be understood that similar sensors can be included at the other side of array 304, and that sensors can be utilized that are different in number or are differently positioned than those illustrated in FIG. 21. For example, sensors can be positioned at the ends of the length of probe 302 instead of or in addition to sensors along the length of probe 302. The several sensors 2102 can output measurements of the same parameter related to force or pressure, or different sensors can output measurements related to respective different parameters related to force or pressure. In addition, some of sensors 2102 can output measurements related to orientation, motion, acceleration, or other properties. As described below, the outputs of sensors 2102 can be used to improve imaging by improving scanning consistency, patient comfort, and ease of operating the imaging system.

[0072] FIG. 22 illustrates in perspective view the underside of compression/scanning assembly 108 incorporating several sensors 2202 for similar parameters. For clarity, membrane sheet 114 is not shown. Sensors 2202 are configured such that at least some of them contact the patient when assembly 108 is in position for imaging a patient's breast. Typically, sensors 2202 contact the patient's chest wall but some may contact the breast in case the breast extends beyond the outline of assembly 108, and some may make no contact with the patient due to the patient's size or body shape. As illustrated, there is a sensor 2202 at each corner of assembly 108 and in the mid-section of each of the sides. Again, a different number of sensors 2202 can be used, in a different spatial arrangement, in different implementation of assembly 108, and different sensors 2202 can output measurements for the same or different parameters.

[0073] FIG. 23 illustrates an example of a configuration utilizing the outputs of probe sensors 2102 and 2202 to improve imaging. As noted in several paragraphs above, scanning consistency is desirable, and it is advantageous for pressure/force on the patient to be consistent from one patient to another and also for imaging the same patient at different times. It also is advantageous to select the pressure/force on the patient automatically or under convenient control by the professional imaging the patient or setting up the equipment. To this end, as illustrated in FIG. 23, the outputs of sensor 2102(1) through 2102(N), and 2202(1) through 2202(N) are supplied to a pre-processing circuit 2302. The index designation for the sensors signifies that each of the sensor sets can include 1, 2, . . . , N sensors, where N is a positive integer. Sensors 2102 can be arranged on ultrasound probe as illustrated in FIG. 21, or in a different arrangement, and can be different in number in different implementations, from a single sensor to many sensors. Sensors 2202 can be arranged

as in FIG. 22, or in a different arrangement, and also can be different in number in different implementations.

[0074] Pre-processor circuit 2302 performs functions such as converting analog outputs to digital values, correcting for sensitivity differences between sensor, setting baselines and limits in sensor outputs, multiplexing the signals from different sensors, etc. Such pre-processing is known in the pertinent technology and need not be described in detail. Typically it is computer-implemented and can be under the control of a program of the same computer doing other signal processing in the overall system of FIG. 1, or it can be implemented in a processor or a circuit board that can be housed, for example, in assembly 108 or in column 120 supporting assembly 108.

[0075] Motor control processing circuit 2304 receives from circuit 2302 the pre-processed output of sensors 2102 on ultrasound probe 302 and sensors 2202 on compression/scanning assembly 108 and carries out programmed operations to generate control signals and deliver them to one or more motors 2306 driving probe 302 and thus serving as a motorized probe drive, and motors 2308 driving assembly 108 and thus serving as a motorized probe or assembly control. Processing circuit 2304 also typically is computer-implemented and can be under the control of a program running in the same computer doing other signal processing in the overall system of FIG. 1, or it can be implemented in a processor or a circuit board that can be housed, for example, in assembly 108 or in column 120 supporting assembly 108. Circuit 2304 can calculate the current state of the measured parameters and issue corrective control signals to motor(s) 2306 and 2308 repeatedly and frequently, thus achieving feedback loop control to maintain or vary the parameters as desired. Circuit 2304 and motor(s) 2306 form a motorized probe control, and circuit 2304 and motor(s) 2308 form a motorized assembly control.

[0076] FIG. 24 illustrates in schematic form that motor(s) 2306 can be coupled with probe 302 inside housing 112 of assembly 108, and motor(s) 2308 can be located inside column 120 that supports assembly 108. FIG. 24 represents a portion of the system illustrated in FIG. 1, but for clarity omits the other portions of the entire system. Like numerals refer to the same or similar components in FIGS. 1 and 24.

[0077] In one implementation, processing circuit 2304 maintains at a desired constant or varying level the pressure/force that ultrasound probe 302 exerts on the patient's breast while scanning, and/or the pressure/force that compression/scanning assembly 108 exerts on the patient's body. One example of pressure control is illustrated in FIG. 6, where pressure sensor 610 is mounted on probe 302 and thus is comparable to sensors 2102 in that it senses the pressure that probe 302 exerts on breast 602, and pressure sensors 612 and 614 that measure the tension on membrane 114 and thus provide information related to the pressure that scanning assembly 108 exerts on the patient. The example of FIG. 23 provides more sophisticated control over pressure/force in that it allows control over a greater number of parameters, such as separate controls over pressure/force by probe 302 and by assembly 108, two- or three-dimensional orientation of probe 302 and of assembly 108, and changes in pressure/force during scanning if desirable.

[0078] Processing circuit 2304 can exercise control based only on output from sensors 2102, or only from sensors 2202, or from both sensors 2102 and 2202. In one example, using only the pre-processed output from a single sensor 2102, circuit 2304 can compare the sensor output with a preset value and control a motor such as motor 1712 in FIG. 17 to reduce

the difference between the current value from sensor 2102 and the preset value, to thereby maintain constant the pressure/force that probe 302 exerts on the patient's breast. In another example, circuit 2304 additionally uses the pre-processed outputs of several sensors 2102 that are spaced along the length of probe 302 to make the pressure/force more uniform along the probe's length by reducing differences between the outputs of the several sensors. In another example that may be used in combination with or in place of the prior example, circuit 2304 additionally uses sensors 2102 that are at opposite sides of transducer array 304 to maintain or vary the angle of probe 302 to the patient's breast or chest wall to thereby make the pressure/force more uniform across the probe's width. These controls over the position/orientation of probe 302 relative to the patient's breast and to assembly 108 can be similarly used in the case of a compression/scanning assembly that is hand-held, such as assembly 1402 in FIG. 14. In another example, circuit 2304 uses only the pre-processed outputs of sensors 2202, which are on assembly 108, to control the pressure/force that assembly 108 exerts on the patient, or the pressure/force that specific portions of assembly 108 exert, or the orientation of assembly 108 to the patient's chest wall. In the case of using only the outputs of sensors 2202, in one example, circuit 2304 repeatedly operates to reduce the difference between the average current outputs of the sensors and a pre-set value, acting as a part of a feedback circuit. In another example, circuit 2304 operates to repeatedly reduce the difference between the pre-processed outputs of two or more sensors 2202 that are at different locations along the periphery of assembly 108 to thereby change the orientation of assembly 108 so that it more uniformly presses against the patient's breast and chest wall. This operation can ignore the outputs of some sensors 2202 that provide outputs sufficiently different from those of other sensors to indicate that a portion (such as a corner) or assembly 108 extends outside the patient's chest wall. In other examples, circuit 2304 can use the pre-processed output of both sensors 2102 and 2202 to control both the position of probe 302 relative to assembly 108 and the patient, and the position of assembly 108 relative to the patient, and thus control pressure/force exerted on the breast and patient. Many variations in a program written to implement the operations of processing circuit 2304 are possible, which a skilled programmer can provide without undue experimentation based on the principles described in this patent specification.

[0079] As in the example of FIG. 6, sensors 2102 and/or 2202 can be used to provide visual and/or audible indications of the measured parameters, in addition to controlling the parameters. For example, as illustrated in FIG. 23 pre-processing circuit supplies actual pressure/force outputs of sensors 2102 and/or 2202 to a circuit 2310 that provides visual and/or audio indications of pressure/force, for example by providing visual indications in the form of numerical or graphical display on a monitor and/or providing audio indications in the form of sound level or pitch indicative of level of pressure/force, or of pressure/force exceeding a specified level, or an imbalance of outputs of different sensors.

[0080] The discussion above regarding FIGS. 21-24 refers to probe 302 but it should be clear that it also applies to the use of the ultrasound probes identified by different reference numerals in other FIGS., such as probe 1004 in FIG. 10, probe 1104 in FIGS. 11 and 12, etc. Similarly, the discussion above of assembly 108 regarding FIGS. 21-24 also applies to com-

pression/scanning assemblies identified by other reference numerals in other FIGS., such as **1002** in FIG. **10**, **1102** in FIG. **11**, etc.

[0081] Whereas many alterations and modifications of the present invention will no doubt become apparent to a person of ordinary skill in the art after having read the foregoing description, it is to be understood that the particular embodiments shown and described by way of illustration are in no way intended to be considered limiting. By way of example, it is to be appreciated that any of a variety of different frame assemblies can be used that position, tension, and otherwise manipulate the membranous sheet, whether the membranous sheet is permanently used and re-used for different patients or is disposable for each patient, without departing from the scope of the present teachings. By way of further example, while in the above-described embodiments the biopsy guide is translatable in conjunction with the ultrasound transducer, in other embodiments the biopsy guide is fixably coupled to the housing around the ultrasound transducer, the biopsy instrument only being maintained in the scan plane when the ultrasound transducer is positioned adjacent to the biopsy guide within the housing. In still other embodiments, the biopsy guide is not fixably attached to the ultrasound probe, yet is also decoupled from the ultrasound transducer, i.e., the ultrasound probe and the biopsy guide are independently translatable relative to the housing. By way of even further example, although described primarily in terms of breast ultrasound and percutaneous biopsy, one or more of the above-described embodiments are readily applicable and/or adaptable for compressive ultrasonic imaging and/or percutaneous biopsy for the arm, the leg, the neck, the abdomen, or other human or animal body part.

[0082] By way of still further example, in other embodiments there are provided dual scanning pods, i.e., dual compression/scanning assemblies (optionally with biopsy attachments) mounted on a common support arm in a butterfly-wing configuration. The dual scanning pods are configured such that they can be simultaneously placed over both breasts for simultaneous scanning. By way of even further example, in other embodiments the provided scanning pod is equipped to have the biopsy guide attachment placed on either side of the transducer, and/or to have two biopsy guides simultaneously attached to both sides of the transducer. By way of still further example, although embodiments are described supra in the context of linear ultrasound transducers, it is to be appreciated that other transducer types including 1.25D, 1.5D, and 2D transducers can be used without departing from the scope of the embodiments. Therefore, references to the details of the embodiments are not intended to limit their scope.

[0083] Thus, it should be further understood that the new subject matter described in this patent specification is not limited to any one embodiment or combination of embodiments described herein, but instead encompasses numerous alternatives, modifications, and equivalents. In addition, while numerous specific details are set forth in the description in order to provide a thorough understanding, some embodiments can be practiced without some or all of these details. Moreover, for the purpose of clarity, certain technical material that is known in the related art has not been described in detail in order to avoid unnecessarily obscuring the new subject matter described herein. It should be clear that individual features of one or several of the specific embodiments described herein can be used in combination with features or

other described embodiments. Further, like reference numbers and designations in the various drawings indicate like elements.

[0084] The foregoing has been described in some detail for purposes of clarity, but it will be apparent that certain changes and modifications may be made without departing from the principles thereof. It should be noted that there are many alternative ways of implementing both the processes and apparatuses described herein. Accordingly, the present embodiments are to be considered as illustrative and not restrictive, and the body of work described herein is not to be limited to the details given herein, which may be modified within the scope and equivalents of the appended claims

[0085] The patents or other publications, including patent applications identified above, are hereby incorporated by reference in this patent specification as though fully set out herein.

1. A system for ultrasonically scanning a patient, comprising:

- an ultrasound probe configured to scan the patient along a scanning trajectory;
- a motorized probe drive configured to drive the probe along the scanning trajectory in contact with the patient;
- one or more probe sensors associated with the probe and configured to provide probe sensor measurements of probe pressure/force that the probe exerts on the patient while scanning the patient;
- a processing circuit configured to receive information regarding said probe sensor measurements and utilize them to calculate and provide probe motor control signals that maintain selected parameters related to the pressure/force at selected levels; and
- a motorized probe control coupled with the processing circuit and configured to respond to said probe motor control signals to thereby maintain the pressure/force that the probe exerts on the patient during the scan at said selected levels.

2. The system of claim 1 in which the probe drive is configured to drive the probe along the scanning trajectory while the probe is in contact with a breast of the patient.

3. The system of claim 2 in which the probe is elongated and the probe sensors comprise plural sensor at locations spaced from each other along the length of the probe, and the processing circuit is further configured to provide control signals equalizing the pressure/force at locations related to those of the probe sensors.

4. The system of claim 1 further including:

- a compression/scanning assembly that carries the probe and contacts the patient during the scan, said probe drive driving the probe relative to said assembly;
- one or more assembly sensors coupled with the assembly and configured to provide assembly sensor measurements of assembly pressure/force that the assembly exerts on the patient while scanning the patient;
- said processing circuit being further configured to receive information regarding said assembly sensor measurements and utilize them to calculate and provide assembly motor control signals that maintain selected parameters related to said assembly pressure/force at selected levels; and
- a motorized assembly control coupled with the processing circuit and configured to respond to said assembly motor control signals to thereby maintain the assembly pres-

sure/force that the assembly exerts on the patient during the scan at said selected levels.

5. The system of claim 4 in which the compression/scanning assembly comprises a frame having a periphery contacting the patient in said scan, and the assembly sensors comprise plural sensors arranged along at least two locations that are spaced from each other along the periphery of the frame.

6. The system of claim 4 in which the assembly frame is rectangular and the assembly sensors comprise sensors located at least at two of the sides of the frame.

7. The system of claim 4 in which the frame is rectangular and at least one of the assembly sensors is located at a corner of the frame.

8. The system of claim 4 in which the processing circuit is further configured to provide assembly motor control signals that equalize the pressure/force the assembly exerts on the patient at locations matching those of the plural assembly sensors.

9. The system of claim 8 in which the assembly is configured for three-dimensional motion relative to the patient, and the processing circuit is configured to control said three-dimensional motion to thereby equalize the pressure/force that the assembly exerts on the patient at said locations.

10. The system of claim 4 including an articulated arm supporting the compression/scanning assembly for motion toward and away from the patient and while the probe scans along the scanning trajectory.

11. A system for ultrasonically scanning a patient, comprising:

- a compression/scanning assembly and an ultrasound probe supported in the assembly and configured to scan the patient along a scanning trajectory;

- a motorized probe drive configured to drive the probe along the scanning trajectory in contact with the patient and relative to the compression/scanning assembly while the assembly maintains contact with the patient;

- one or more sensors configured to provide measurements of pressure/force that at least one of the probe and the assembly exerts on the patient;

- a processing circuit configured to receive information regarding the sensor measurements and utilize them to calculate and provide motor control signals that maintain at selected levels selected parameters related to said pressure/force; and

- a motorized control coupled with the processing circuit and configured to respond to said motor control signals to thereby maintain the pressure/force at said selected levels.

12. The system of claim 1 in which the compression/scanning assembly comprises a frame having a periphery contacting the patient, and the sensors comprise plural sensors arranged along at least two locations that are spaced from each other along the periphery of the frame.

13. The system of claim 12 in which the assembly frame is rectangular and the sensors comprise sensors located at least at two of the sides of the frame.

14. The system of claim 12 in which the frame is rectangular and at least one of the assembly sensors is located at a corner of the frame.

15. The system of claim 12 in which the processing circuit is further configured to provide motor control signals that equalize the pressure/force the assembly exerts on the patient at locations matching those of the plural assembly sensors.

16. The system of claim 11 in which the assembly is configured for three-dimensional motion relative to the patient, and the processing circuit is configured to control said three-dimensional motion to thereby equalize the pressure/force that the assembly exerts on the patient at said locations.

17. The system of claim 11 including an articulated arm supporting the compression/scanning assembly for motion toward and away from the patient and while the probe scans along the scanning trajectory.

18. The system of claim 11 in which the probe is configured to scan a patient's breast while at least a portion of the compression/scanning assembly contacts the patient's chest wall.

19. The system of claim 1 in which the probe is elongated and is configured to rotate about an axis transverse to the direction of the pressure/force that the probe exerts on the patient, and said processing circuit is further configured to move the probe about said axis to thereby equalize the pressure/force exerted on the patient by portions of the probe that are spaced along the probe length.

20. A method of examining a patient's breast with ultrasound, comprising:

- compressing the breast with a compression/scanning assembly;

- scanning the breast with an elongated ultrasound probe that is supported by the assembly, contacts the breast through a compression sheet mounted to the assembly, and scans the breast while maintaining said contact and moving related to the breast and the assembly along a scanning trajectory and while at least a portion of the assembly presses against the patient's chest wall;

- sensing compression/force that at least one of the probe and the assembly and controlling at least one of the pressure/force that the probe exerts on the breast during the scan and the pressure/force that at least a portion of the assembly exerts on the patient's chest wall during the scan to thereby maintain the pressure/force at selected levels during the scan.

21. The method of claim 20 including sensing the pressure/force at least in two locations of the probe.

22. The method of claim 20 including sensing the pressure/force at least at two locations of the compression/scanning assembly that are spaced from each other.

23. A system for ultrasonically scanning a patient, comprising:

- an ultrasound probe configured to scan the patient along a scanning trajectory;

- a motorized probe drive configured to drive the probe along the scanning trajectory in contact with the patient;

- one or more sensors coupled with the probe and configured to provide probe sensor measurements of probe pressure/force that the probe exerts on the patient while scanning the patient;

- a processing circuit configured to receive information regarding said probe sensor measurements and utilize them to calculate and provide probe motor control signals that maintain selected parameters related to the pressure/force at selected levels; and

- a motorized probe control coupled with the processing circuit and configured to respond to said probe motor control signals to thereby maintain the pressure/force that the probe exerts on the patient during the scan at said selected levels.

24. A system for ultrasonically scanning a patient, comprising:

an ultrasound probe configured to scan the patient along a scanning trajectory;
a motorized probe drive configured to drive the probe along the scanning trajectory in contact with the patient;
a compression/scanning assembly that carries the probe and contacts the patient during the scan, said probe drive driving the probe relative to said assembly;
one or more sensors coupled with the assembly and configured to provide sensor measurements of pressure/force that the assembly exerts on the patient while scanning the patient;
a processing circuit configured to receive information regarding said sensor measurements and utilize them to calculate and provide motor control signals that maintain selected parameters related to the pressure/force at selected levels; and
a motorized control coupled with the processing circuit and configured to respond to said motor control signals to thereby maintain the pressure/force that the assembly exerts on the patient during the scan at said selected levels.

25. A system for ultrasonically scanning a patient, comprising:

an ultrasound probe configured to scan the patient along a scanning trajectory;
a motorized probe drive configured to drive the probe along the scanning trajectory in contact with the patient;
a compression/scanning assembly that carries the probe and contacts the patient during the scan, said probe drive driving the probe relative to said assembly;
one or more sensors associated with each of the probe and the assembly and configured to provide sensor measurements of pressure/force exerted on the patient while scanning the patient;
a processing circuit configured to receive information regarding said sensor measurements and utilize them to calculate and provide motor control signals that maintain selected parameters related to the pressure/force at selected levels; and
a motorized control coupled with the processing circuit and configured to respond to said motor control signals to thereby maintain the pressure/force at said selected levels.

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专利名称(译)	医疗超声扫描，其控制由超声探头和/或压缩/扫描组件施加的压力/力		
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申请(专利权)人(译)	U-SYSTEMS INC.		
当前申请(专利权)人(译)	U-SYSTEMS INC.		
[标]发明人	WANG SHIH PING ANDERSON TOR C CHEN JIAYU SUMMERS DOUGLAS G		
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摘要(译)

一种系统和方法，涉及通过感测和控制超声探头和/或容纳探头的压缩/扫描组件施加在乳房和/或乳房上的压力/力来改善患者，特别是患者乳房的超声检查。病人的胸壁。

