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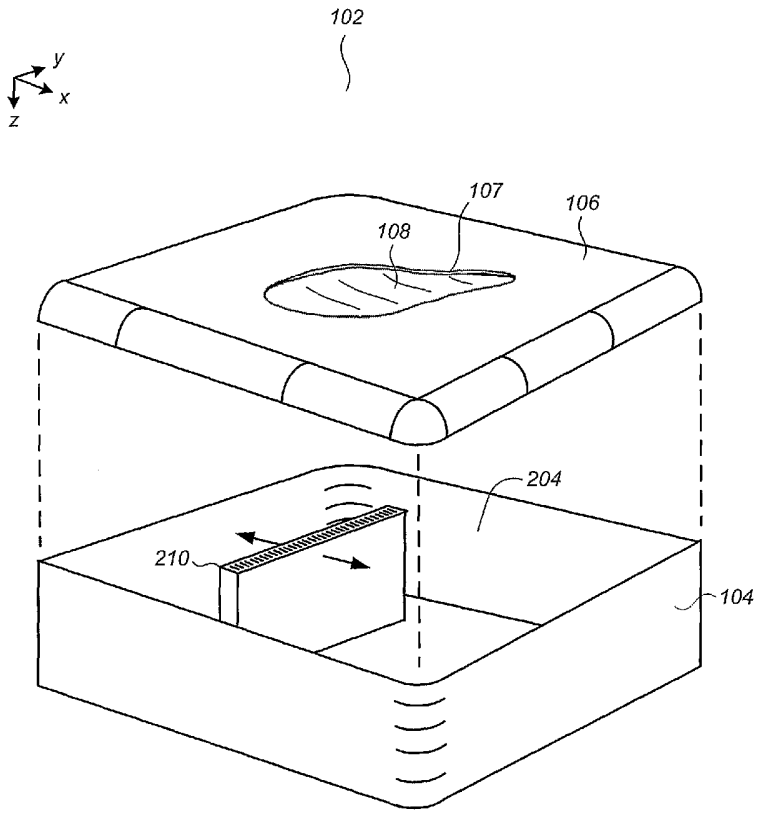

(57) Abstract: An apparatus and related methods for scanning a breast are described, the apparatus comprising a frame defining an orifice shaped to allow the breast to be received therein, a compressive member secured to the frame across the orifice that compresses the received breast toward the patient's chest wall, and a transducer positioned in acoustic communication with the compressive member for imaging the breast therethrough. The frame holds a reservoir of acoustically conductive fluid that maintains the transducer in acoustic communication with the compressive member. In different preferred embodiments having different advantages, the compressive member comprises a flexible elastic membrane, a flexible inelastic membrane, or a rigid sonolucent plastic preformed into the shape of a chestwardly-compressed breast. Where the transducer comprises one or more linear array probes, various probe orientations and trajectories are described for generating a three-dimensional volumetric representation of the breast having reduced nipple shadow effects.

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BREAST ULTRASOUND SCANNING PROMOTING PATIENT COMFORT AND IMPROVED IMAGING NEAR CHEST WALL

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/577,388, filed June 4, 2004, which is incorporated by reference herein.

FIELD

[0002] This patent specification relates to medical ultrasound imaging. More particularly, the present specification relates to an apparatus and related methods for obtaining volumetric ultrasound scans of a breast in a manner that promotes both patient comfort and improved ultrasonic imaging of breast tissue near the chest wall.

BACKGROUND

[0003] 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 2003/007598A1 and US2003/0212327A1, each of which is incorporated by reference herein. Whereas a conventional two-dimensional x-ray mammogram only detects a summation of the x-ray opacity of individual slices of breast tissue over the entire breast, ultrasound can separately detect the sonographic properties of individual slices of breast tissue, and therefore may allow detection of breast lesions where x-ray mammography alone fails. Another well-known shortcoming of x-ray mammography practice is found in the case of dense-breasted women, including patients with high content of fibroglandular tissues in their breasts. Because fibroglandular tissues have higher x-ray absorption than the surrounding fatty tissues, portions of breasts with high fibroglandular tissue content are not well penetrated by x-rays and thus the resulting mammograms contain reduced information in areas where fibroglandular tissues reside.

[0004] It is believed that preventive health care policy should progress toward the adoption of regular breast cancer screening procedures for increasingly younger women, for example, women under the age of 40, and perhaps even under the age of 30 if there is a family history of cancer. Because younger women generally have denser breasts, the shortcomings of conventional two-dimensional x-ray mammography are

expected to become especially apparent and lead to the increased adoption of ultrasound mammography as an adjunctive screening modality. Even further, because the dangers of x-ray radiation exposure are cumulative over a lifetime, ultrasound mammography could well become a sole breast cancer screening modality for women in these younger age groups. Other demographics indicating higher breast densities among certain groups, regions, or countries may also lead to the increased adoption of breast ultrasound as a sole or adjunctive screening modality for those groups, regions, or countries.

[0005] Criteria that can be used to characterize the effectiveness of any particular breast ultrasound scanning method include image quality, image resolution, volumetric completeness, repeatability, patient comfort, per-patient costs, and patient throughput, many of these factors being inter-related. For example, higher-frequency ultrasound scans (e.g., 10 MHz or greater) generally yield higher image resolution, but do so at a reduced scanning depth which can compromise volumetric completeness of the scan. As another example, real-time hand-held scanning of the breast by a screening radiologist would promote volumetric completeness and patient comfort, but would result in compromised repeatability, low patient throughout, and high per-patient costs.

[0006] Although various automated breast ultrasound scanning devices have been proposed, it is believed that each possesses one or more drawbacks that make it less useful than the preferred embodiments described herein with respect to one or more of the above effectiveness criteria, particularly for dense-breasted patients. For example, many proposals depend, at least in part, on the "pendulous" properties of a breast for their effectiveness in imaging the diagnostically relevant breast volume. Some of these proposals require the breast to hang downwardly away from a prone patient's body and into a chamber containing an ultrasound probe, such as WO 02/089672 (see Fig. 1 thereof), US 4,298,009 (see Fig. 3 thereof), and US 6,102,866 (see Fig. 1 thereof). Others require the breast to project outwardly away from an upright patient's body for compression between two compressive members, an ultrasound probe scanning the breast from underneath (WO 83/02053 at Fig. 1, US 5,851,180 at Fig. 4A), from the side (US 5,479,927 at Fig. 12), or from the top (US 5,479,927 at Fig. 1).

[0007] The above-referenced proposals that depend, at least in part, on the pendulous properties of the breast have limited effectiveness with respect to at least two important aspects of breast imaging. First, there are difficulties in imaging breast tissue near the chest wall of the patient. Because a large number of cancers are known to

occur within 3 cm of the chest wall, this represents a serious problem with respect to completeness of the ultrasound screening apparatus. Second, such proposals also bring about difficulties with small breasts, which are generally not pendulous. For small breasts, much of the diagnostically relevant breast tissue is physically unable to hang down into a chamber or project outwardly onto a compression plate, thereby limiting the completeness of the ultrasound scans.

[0008] Some proposals have been made that at least partially address the problem of small-breasted patients. In these proposals, a water bag or gel bag is lowered onto the breast of a supine patient and an ultrasound probe disposed within the water bag or gel bag scans the breast volume. Examples can be found in a brochure by Labsonics, Inc., "Labsonics Ultrasound Breast Scanner: Accurate, High-Performance Investigation of the Breast for Confident Diagnosis," Mooresville, Indiana (1983), and in the commonly assigned WO02/43801A2 at Fig. 14. However, it is believed that substantial improvements in one or more of repeatability, patient throughout, volumetric completeness, image quality near the chest wall, per-patient cost, reduced shadowing effects, and even patient comfort is provided by one or more of the preferred embodiments described *infra*.

[0009] Accordingly, it would be desirable to provide a breast ultrasound scanning apparatus and related methods that achieve high-quality ultrasound imaging even near the chest wall of the patient.

[0010] It would be further desirable to provide such a breast ultrasound scanning apparatus that can imaging the entire diagnostically relevant breast volume even for small-breasted and/or dense-breasted patients.

[0011] It would be further desirable to provide such a breast ultrasound scanning apparatus that is comfortable for the patient while also having a cost-efficient patient throughput rate.

[0012] It would be still further desirable to provide a breast ultrasound scanning apparatus that is cost-efficient to fabricate, that obviates nipple shadow effects, and that provides substantially repeatable scans.

SUMMARY

[0013] An apparatus and related methods for scanning a breast of a patient are provided, the apparatus comprising (i) a frame defining an orifice shaped to allow at least a portion of the breast to extend therethrough, (ii) a compressive member secured

to the frame across the orifice that compresses the breast toward a chest wall of the patient when the breast is extended through the orifice, and (iii) a transducer positioned in acoustic communication with the compressive member for imaging the breast therethrough. The frame holds a reservoir of acoustically conductive fluid that maintains the transducer in acoustic communication with the compressive member. Preferably, the orifice has an oblong shape with a major axis corresponding to an axillary axis of the breast.

[0014] According to one preferred embodiment, the orifice is defined within an approximately horizontal, rigid surface of the frame so as to receive the breast while the patient is in a substantially prone position, and the compressive member comprises a flexible membrane. In one preferred embodiment, the flexible membrane comprises a stretchable material that elastically compresses the breast upward, while in another preferred embodiment the flexible membrane comprises a non-stretchable material that tensionably compresses the breast upward.

[0015] According to another preferred embodiment, the compressive member comprises a substantially rigid, acoustically conductive plastic pre-molded into a shape corresponding to a chestwardly-flattened breast. In this preferred embodiment, the orifice can optionally be positioned in an approximately vertical plane to receive the breast while the patient is in a substantially upright position. A array of differently-sized orifices for receiving differently-sized breasts can be provided for optimal acoustic contact and patient comfort.

[0016] According to a preferred embodiment, the transducer is a linear array probe that is physically offset from the compressive member, and the linear array probe is offsetably swept across the compressive member while obtaining a set of ultrasound sufficient to construct a three-dimensional volumetric representation of the breast. Alternatively, the linear array probe is maintained in floatable physical contact with the compressive member when swept thereacross. Preferably, the linear array probe is oriented parallel to the axillary axis of the patient for that breast.

[0017] According to one preferred embodiment, the linear array probe is maintained substantially perpendicular to a coronal plane throughout the sweep. Nipple shadow effects in the three-dimensional volumetric representation can be reduced by sweeping an additional linear array probe having a different scanning direction within the imaged plane across the compressive member, and/or by using beamsteering in the linear array probe(s).

[0018] Alternatively, nipple shadow effects can be reduced by maintaining the linear array probe a skewed plane during the sweep, by sweeping an additional linear array probe oriented in a different skewed plane, and/or by sweeping the linear array probe(s) at a multiplicity of skewed angles during an arcuate or other irregular scanning trajectory.

[0019] Preferably, there is no additional external downward force applied to the patient other than their natural body weight. Patient comfort is thereby promoted while still flattening of the breast toward the chest wall such that the required imaging depth is substantially reduced. This, in turn, provides an ability to higher-frequency ultrasound transducers known to result in superior image resolution.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG. 1 illustrates a perspective exterior view of a breast scanning apparatus according to a preferred embodiment;

[0021] FIG. 2 illustrates an exploded perspective view of the breast scanning apparatus of FIG. 1;

[0022] FIGS 3A, 3B, and 4 illustrate a perspective view of the breast scanning apparatus of FIG. 1 as being used by a patient;

[0023] FIG. 5 illustrates a perspective view of a breast scanning apparatus according to a preferred embodiment as being used by a patient;

[0024] FIGS. 6A and 6B illustrate perspective views of a breast being compressed toward a chest wall according to a preferred embodiment;

[0025] FIG. 7A illustrates a top view of a breast scanning apparatus according to a preferred embodiment;

[0026] FIGS. 7B, 8, 9, 10, 11, 12, 13, and 14A illustrate conceptual side views of chestwardly compressed breasts being scanned using breast scanning apparatuses according to various preferred embodiments;

[0027] FIG. 14B illustrates a top view of a breast scanning apparatus in accordance with the preferred embodiment of FIG. 14A;

[0028] FIGS. 15A and 15B illustrate top views of a breast scanning apparatus according to a preferred embodiment;

[0029] FIG. 16 illustrates a conceptual side view of a chestwardly compressed breast being scanned using a breast scanning apparatus according to a preferred embodiment; and

[0030] FIG. 17 illustrates a top view of a breast scanning apparatus according to a preferred embodiment.

DETAILED DESCRIPTION

[0031] FIG. 1 illustrates a perspective exterior view of a breast scanning apparatus 102 according to a preferred embodiment, comprising a frame including a lower housing 104 and a substantially rigid surface 106, the surface 106 defining an orifice 107 across which is sealably secured a compressive member in the form of a flexible membrane 108. The orifice 107 is an opening in the surface 106 that is shaped to correspond to the general outline of a breast of a patient, preferably including the diagnostically important tissue near the axilla or axillary region of the patient for that breast. For clarity of description the scanning apparatus 102 is described herein in the context of scanning the right breast only, it being understood that corresponding structure is also provided for the left breast as would be readily apparent to one skilled in the art. As indicated, in the convention of FIG. 1, the +x direction points to the patient's right side within the coronal plane, the +y direction points toward the head within the coronal plane, and the +z direction points outward toward the front of the patient in a direction perpendicular to the coronal plane.

[0032] FIG. 2 illustrates an exploded perspective view of the scanning apparatus 102 in which the surface 106 is removed from the lower housing 104. The lower housing 104 and surface 106 form a reservoir casing that maintains a sonically conductive fluid therein. The sonically conductive fluid is not specifically drawn in FIG. 2 but its presence is to be understood, as pointed to by element 204. The reservoir casing formed by the lower housing 104 and surface 106 should be sufficiently filled with sonically conductive fluid such that the flexible membrane is maintained in bubble-free contact with the sonically conductive fluid during the insertion of the breast through the orifice 107. A pressure/volume relief valve system (not shown) can be provided to facilitate proper fluid volumes within the reservoir casing during breast insertion.

[0033] Disposed within the sonically conductive fluid 204 is a transducer in the form of a linear array probe 210. Although a linear array probe is generally preferred because of their relatively low cost, it is to be appreciated that many different kinds of 1D, 1.25D, 1.5D, and 2D probes can be used without departing from the scope of the preferred embodiments. The sonically conductive fluid 204 can comprise water,

mineral oil, Jojoba oil, or generally any kind of couplant, gel, oil, or cream that is acoustically conductive, substantially bubble-free, and sufficiently nonviscous to maintain acoustic coupling between the probe 210 and the flexible membrane 108 when the probe is in motion without distortion of the breast contours. When the breast is inserted into the orifice 107, the probe 210 is swept across the frame within the sonically conductive fluid while obtaining ultrasound slices sufficient to construct a three-dimensional volumetric representation of the breast.

[0034] The sonically conductive fluid 204 should also be selected with acoustic matching in mind with respect to the probe and the compressive member, to minimize the effects of reflections. One advantage of using a thinner membranous substance for the flexible membrane 108 is that there is less back-and-forth reflection between its two surfaces as compared to when a thicker material is used as, for example, with the alternative preferred embodiments of FIGS. 16-17, *infra*. Undesirable back-and-forth reflections at surface interfaces lying between the probe and the target can cause regularly-spaced reverberation artifacts in the resulting images. In the cases of FIGS. 16-17, however, it has been found that using a rigid material with a modest degree of attenuation can reduce the reverberation artifacts, because the reverberations would die out before causing too much harm to the resulting images.

[0035] FIGS. 3A-3B illustrates the scanning apparatus 102 as integrated into a table 306 for receiving a breast 304 of a patient 306. The patient stands next to the table 306 and then bends over to insert the breast 304 through the orifice 107. The breast 304 is preferably coated with a layer of acoustic couplant prior to insertion through the orifice 107. Alternatively or in conjunction therewith, the flexible membrane 108 can maintain a small pool of acoustic couplant or an be outfitted with a prefabricated couplant sheet such as the Hydroscan Sterile Couplant Sheet available from Cone Instruments, Inc. of Solon, Ohio.

[0036] FIG. 4 illustrates the scanning apparatus 102 as integrated into a cot 402 for receiving the breast of the patient 302. In the preferred embodiments of FIGS. 3 and 4, it is preferable that no external downward forces are exerted on the breast area of the patient other than the natural body weight of the patient. As part of this natural body weight, the patient may be asked to mildly urge the axilla region of the breast downward toward the orifice 107. A highly comfortable patient experience is provided while also allowing substantially all clinically relevant breast tissue to be imaged at a very high frequencies, *e.g.*, 10-15 MHz and even up to 20 MHz, for patients with

generally smaller breasts. However, the scanning apparatus 102 is also operative for patients with larger breasts as well when used according to one or more of the preferred embodiments described further *infra*. Optionally, the orifice 107 may be contoured out-of-plane relative to the rest of the surface 106 to further increase patient comfort and scanning thoroughness.

[0037] FIG. 5 illustrates a perspective view of a breast scanning apparatus 102' according to a preferred embodiment as being used by the patient 302 in an upright position. A C-arm and backplane arrangement 404, or other suitable mechanical assembly, is used to urge the scanning apparatus 102' toward the chest wall of the patient. Preferably, the C-arm and backplane arrangement 404 is configured to springably maintain a constant compression force that is reminiscent of the force that would be exerted by operation of the natural body weight of the patient if they were in a prone position as in FIGS. 3 or 4 *supra*. By way of example, and not by way of limitation, a suitable range of forces may lie in the range of approximately 2 pounds (8.9 Newtons) to 12 pounds (53.4 Newtons).

[0038] The breast scanning apparatus 102' of FIG. 5 is generally similar to the scanning apparatus 102 of FIGS. 1-4, except that it is preferable for the compressive member secured across the orifice 107 to comprise a rigid, acoustically conductive plastic element pre-molded into a shape corresponding to a chestwardly-compressed breast. This element is described further *infra* with respect to FIG. 16.

[0039] FIGS. 6A and 6B illustrate perspective views, taken at different angles from "within" the reservoir casing, of the breast 304 as it is extended into the orifice 107 and chestwardly compressed by the flexible membrane 108. The breast 304 is urged into a state of flattened compression generally corresponding to a coronal plane of the patient. According to a preferred embodiment, the total upward force exerted by the flexible membrane 108 lies in the range of approximately 2 pounds (8.9 Newtons) to 12 pounds (53.4 Newtons).

[0040] For patients with very small breasts, it has been found that good results are obtained when the flexible membrane 108 comprises a substantially inelastic material such as a 2-mil (0.051 mm) thick sheet of Mylar® polyester film. The Mylar is secured across the orifice 107 in a substantially taut manner such that it is roughly coplanar with the orifice 107 itself. Even though it is substantially inelastic, the Mylar will yield by a small amount as it tensionably compresses the breast upward, resulting in a

smooth surface with very few gaps or wrinkles, making an ideal surface for ultrasonically imaging the breast from underneath.

[0041] Alternatively, the flexible membrane 108 can comprise a modestly stretchable material such as the latex, vinyl, nitrile, polyurethane, and/or neoprene rubbers that are used in medical exam gloves. When used in thicknesses on the orders used for medical exam gloves (*e.g.*, 5-15 mils = 0.127-0.381 mm) suitable compression of the breast can be experienced with tolerable amounts (*e.g.*, on the order of 3 dB or less) of attenuation. Silicone rubber on the order of 5-15 mils (0.127-0.381 mm) can also be used. Similarly performing materials can be used without departing from the scope of the preferred embodiments. The stretchable material causes the flexible membrane 108 to elastically compress the breast upward, which results in a smooth surface with very few gaps or wrinkles while also promoting patient comfort. Generally speaking, higher degrees of stretchability are desired as the breast size increases, for promoting patient comfort while still providing substantial chestward compression, minimization of wrinkles/gaps in the material, and minimization of skin folds at the breast periphery.

[0042] FIG. 7A illustrates a top view of a breast scanning apparatus 702 according to a preferred embodiment that is similar to that of scanning apparatus 102 of FIG. 2, except that a linear probe 710 is oriented along an axillary axis and swept in a direction perpendicular thereto. As used herein, axillary axis generally refers to an imaginary line extending roughly from the nipple to the axilla of the breast. The preferred embodiment of FIG. 7A has a particular advantage brought about by a known characteristic of linear array probes. In particular, a three-dimensional volumetric representation built from raw ultrasound slices obtained by a swept linear array probe will have generally superior resolution in planes parallel to the raw ultrasound slices, and generally inferior resolution in planes perpendicular to the raw ultrasound slices along the direction of the probe sweep. This is generally an outgrowth of a spatial integration effect that occurs along the elevation beamwidth of linear array probes. Advantageously, MLO thick-slice images computed by integrating the raw ultrasound slices captured parallel to the axillary axis according to the preferred embodiment of FIG. 7A will generally be of superior quality.

[0043] FIG. 7B illustrates a conceptual side view of the chestwardly compressed breast 304 being scanned in accordance with the preferred embodiment of FIG. 7A. The flexible membrane 108 compresses the breast 304 upward toward a chest wall 714

such that a maximum distance "d" between the flexible membrane 108 and the chest wall 714, *i.e.* the required ultrasonic penetration depth, is usually no more than 2-3 cm for small-sized breasts. This allows very high probe frequencies to be used for greater image resolution as may be harnessed, for example, for the visual and/or computer-assisted detection (CAD) of microcalcifications in the three-dimensional breast volume. Even for larger-sized breasts the distance "d" has been found to be relatively modest due to lateral spreading of the breast.

[0044] Also shown in FIG. 7B is some non-breast tissue 712 on the anterior side of the chest wall 714 and interior non-breast tissue 716 in the posterior side of the chest wall 714. As indicated in FIG. 7B, the sonically conductive fluid 204 maintains acoustic communication between the linear probe 710 and the flexible membrane 108 as the probe is offsetably translated across the face of the breast. Small gaps that may occur near an orifice 107 boundary are found to be generally filled in by the acoustic couplant pool and/or prefabricated couplant sheet described *supra* with respect to FIGS. 3A-3B. Alternatively, even if some of these small gaps remain, their negative effects can be controlled by the effects of the skewed orientations and trajectories described *infra*, and/or by beamsteering, that also obviate nipple-shadow effects.

[0045] FIG. 8 illustrates a conceptual side view of the chestwardly compressed breast 304 being scanned in accordance with a preferred embodiment designed to minimize the occurrence of nipple shadow that could be caused by nipple 305. A first linear probe 810a is skewed relative to both (i) the coronal plane, and (ii) a plane perpendicular to the coronal plane, while a second linear probe 810b is skewed relative to (i) the coronal plane, and (ii) the plane perpendicular to the coronal plane, and (iii) the plane of the first linear probe 810a. The skew angle can be anywhere from 15-75 degrees depending on the particular implementation, with one particularly useful skew angle being near 45 degrees. When compounded to form the three-dimensional volume using principles known in the art, the effects of nipple shadow are reduced in comparison to the scenario of FIG. 7B.

[0046] FIG. 9 illustrates a conceptual side view of the chestwardly compressed breast 304 being scanned in accordance with another preferred embodiment, wherein a single linear probe 910 is swept in a circularly-shaped trajectory 912. When individual ultrasound frames are compounded to form the three-dimensional volume, nipple shadow effects are also reduced in comparison to the scenario of FIG. 7B. FIG. 10 illustrates a conceptual side view of the chestwardly compressed breast 304 being

scanned in accordance another preferred embodiment, wherein a single linear probe 1010 is swept in a cam follower-like trajectory 1012, with similar nipple shadow reduction effects.

[0047] FIG. 11 illustrates a conceptual side view of the chestwardly compressed breast 304 being scanned in accordance with another preferred embodiment, wherein a single linear probe 1110 maintains floatable contact with the flexible membrane 108 during the probe sweep. Means for translating the linear probe 1110 in such a floatable fashion can be used that are analogous to those described, albeit in different contexts, in U.S. 6,574,499 and JP2003310614A2, each of which is incorporated by reference herein.

[0048] FIGS. 12 and 13 illustrate conceptual side views of the chestwardly compressed breast 304 being scanned in accordance with preferred embodiment designed to minimize the occurrence of nipple shadow. In these preferred embodiments, a plurality of linear probes 1210a/1210b and 1310a/1310b/1310c, respectively, lie in a common plane but are oriented at different directions within that common plane. The common plane can be perpendicular to, or skewed relative to, the coronal plane. For clarity of description, the trajectory of the linear probe assembly is "into" the paper in FIGS. 12 and 13. The ultrasound slices are first compounded in a planar fashion for a given probe assembly location, then assembled into the desired three-dimensional volumetric representation. Instead of tilting the probe segments 1210a/1210b and 1310a/1310c, in-plane beamsteering using a straight horizontal multiple-segment probe assembly can alternatively be used to achieve similar nipple-shadow reduction results.

[0049] FIG. 14A illustrates a conceptual side view of the chestwardly compressed breast 304 being scanned in accordance with another preferred embodiment, wherein a single linear probe 1410 is rotated about an axis perpendicular to the coronal plane while capturing ultrasound slices in planes also perpendicular to the coronal plane. FIG. 14B illustrates a top view of the apparatus of FIG. 14A. Instead of tilting the linear probe 1410, in-plane beamsteering using a horizontally-oriented probe can alternatively be used to achieve similar nipple-shadow reduction results.

[0050] FIGS. 15A and 15 B illustrate a top view of a breast ultrasound scanning apparatus 1502 having two linear probes 1510 and 1511 with orthogonal trajectories in the x-y plane. Image quality of the resultant compounded three-dimensional representation is enhanced, with lower resolutions in the elevation beamwidth direction

of one probe being compensated by the higher in-plane resolution of the other probe for both the x and y directions. In an alternative preferred embodiment, with reference to FIG. 7A *supra*, the two scanning directions are parallel to the axillary axis and perpendicular to the axillary axis, respectively.

[0051] FIG. 16 illustrates a conceptual side view of the chestwardly compressed breast 304 being scanned while compressed against a substantially rigid compressive member 1608. The compressive member 1608 comprises a rigid, acoustically conductive plastic element pre-molded into a shape corresponding to a chestwardly-compressed breast. This preferred embodiment has an advantage in that the breast scanning apparatus can be tilted at different angles, *e.g.*, in the vertical orientation of FIG. 5, *supra*, such tilting being generally more difficult for flexibly-membraned orifices due to vertical fluid pressure variations.

[0052] FIG. 17 illustrates a top view of a breast scanning apparatus 1702 comprising an array of orifices 1707a-1707d and associated substantially rigid compressive members 1708a-d, respectively, each being similar to that of FIG. 16 except having differing sizes.. According to a preferred embodiment, the medical clinician selects the properly-sized orifice according to the size of patient's breast prior to the scan. One example of suitable material for the substantially rigid compressive members 1608/1708a-d is polycarbonate plastic having a thickness in the range of approximately 0.5 mm to 2 mm. However, other materials of similar rigidity and sonolucence can be used, for example, polymethylpentene (PMP), which is also known by the trade name of TPX plastic. Among other advantages, a breast ultrasound scanner according to the preferred embodiments is robust against breathing motion by the patient during the sweep of the ultrasound probe. As best appreciated with respect to FIG. 7B, breathing action by the patient has minimal impact on the probe-to-tissue distance, which is substantially fixed by abutment of the orifice 107 against the chest wall 714 (through the small amount of skin/tissue 712). Instead, the breathing action mainly affects vertical movement of the patient at internal tissues 716 (which includes the lungs), this tissue lying above the chest wall 714.

[0053] Preferably, a breast ultrasound scanner according to the preferred embodiments is further equipped to facilitate identification of the nipple position in the acquired three-dimensional volumes. In a simplest preferred embodiment, the nipple position may be identified manually by the technician at the time of scanning, e.g., by ensuring that the nipple falls on a predetermined point on the compression plate. In

another preferred embodiment, the technician can interact with the scanning system based on a quick exploratory sweep across the breast by the probe, followed by a manual selection (such as by a mouse click) on a display of the observed position of the nipple. In another preferred embodiment, the technician can manually position the center of the ultrasound probe (*e.g.*, by joystick control) to the nipple location and press a nipple identification button, thereby identifying the nipple location within the subsequent three-dimensional scans. Any of a variety of other nipple identification schemes can be used without departing from the scope of the preferred embodiments.

[0054] 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. Therefore, reference to the details of the preferred embodiments are not intended to limit their scope, which is limited only by the scope of the claims set forth below.

CLAIMS

What is claimed is:

1. An apparatus for scanning a breast of a patient, comprising:

a frame defining an orifice, said orifice being shaped to allow at least a portion of the breast to extend therethrough;

a compressive member secured to said frame across said orifice, a first side of said compressive member compressing the breast toward a chest wall of the patient when said breast is extended through said orifice; and

a transducer positioned in acoustic communication with a second side of said compressive member opposite said first side for imaging the breast therethrough.

2. The apparatus of claim 1, said orifice and compressive member being positioned in an approximately horizontal plane to receive the breast while the patient is in a substantially prone position.

3. The apparatus of claim 2, wherein said compressive member comprises a stretchable membrane elastically compressing the breast upward toward the chest wall.

4. The apparatus of claim 3, wherein said stretchable membrane exerts a total upward force on the breast in the range of approximately 2 pounds (8.9 Newtons) to 12 pounds (53.4 Newtons).

5. The apparatus of claim 3, wherein said stretchable membrane comprises an elastomer selected from the group consisting of: silicone, latex, vinyl, nitrile, polyurethane, and neoprene rubbers.

6. The apparatus of claim 2, wherein said compressive member comprises a flexible, non-elastic membrane tensionably compressing the breast upward toward the chest wall.

7. The apparatus of claim 6, wherein said flexible, non-elastic membrane comprises a high-strength polyester film.

8. The apparatus of claim 1, wherein said compressive member comprises a substantially rigid plastic having relatively high acoustic transparency, said substantially rigid plastic being pre-molded into a shape corresponding to a compressed breast.

9. The apparatus of claim 8, further comprising an orifice array including said orifice and a plurality of similar orifices, each orifice being sized differently for receiving differently-sized breasts, each orifice having a corresponding pre-molded rigid plastic member corresponding to a breast size for that orifice.

10. The apparatus of claim 8, wherein said substantially rigid plastic comprises a polycarbonate plastic having a thickness in the range of approximately 0.5 mm to 2 mm.

11. The apparatus of claim 8, said orifice and compressive member being positioned in an approximately vertical plane to receive the breast while the patient is in a substantially upright position.

12. The apparatus of claim 1, said transducer comprising a first linear array probe maintained in floatable physical contact with said compressive member, said first linear array probe being moved to successive positions across said compressive member while obtaining successive ultrasound slices sufficient to reconstruct a three-dimensional volumetric representation of the breast.

13. The apparatus of claim 1, said transducer comprising a first linear array probe physically offset from said compressive member, said apparatus further comprising an enclosed reservoir at least partially defined by said frame and said compressive member, said enclosed reservoir maintaining an acoustically conductive fluid between said first linear array probe and said compressive member for establishing said acoustic communication therebetween, said first linear array probe being offsetably moved across said compressive member while obtaining a first set of ultrasound slices for constructing a three-dimensional volumetric representation of the breast.

14. The apparatus of claim 13, said first linear array probe being oriented such that said first set of ultrasound slices corresponds to planes substantially perpendicular to a coronal plane.

15. The apparatus of claim 14, said first linear array probe being oriented such that said first set of ultrasound slices also corresponds to planes substantially parallel to an axillary axis for that breast.

16. The apparatus of claim 13, said first linear array probe being oriented such that said first set of ultrasound slices corresponds to planes at a first skewed angle, said first skewed angle being neither substantially parallel to nor substantially perpendicular to said coronal plane, whereby nipple shadow effects in said three-dimensional volumetric representation are at least partially reduced for locations underlying a nipple of the breast.

17. The apparatus of claim 16, further comprising a second linear array probe physically offset from said compressive member and being offsetably moved across said compressive member while obtaining a second set of ultrasound slices for use in constructing said three-dimensional volumetric representation in conjunction with said first set of ultrasound slices, said second linear array probe being oriented such that said second set of ultrasound slices corresponds to planes at a second skewed angle, said second skewed angle being neither substantially parallel to nor substantially perpendicular to said coronal plane, said second skewed angle being substantially nonparallel to said first skewed angle, whereby nipple shadow effects in said three-dimensional volumetric representation are further reduced.

18. The apparatus of claim 16, said offsetable movement of said first linear array probe having an arcuate trajectory such that said first set of ultrasound slices corresponds to planes at a multiplicity of skewed angles neither substantially parallel to nor substantially perpendicular to said coronal plane, whereby nipple shadow effects in said three-dimensional volumetric representation are at least partially reduced.

19. The apparatus of claim 1, said orifice and compressive member being positioned in an approximately horizontal plane to receive the breast while the patient

is in a substantially prone position, said orifice having an oblong shape with a major axis corresponding to an axillary axis of the patient for that breast.

20. The apparatus of claim 1, said compressive member comprising a substantially rigid plastic having relatively high acoustic transparency, said substantially rigid plastic having pre-molded contours in the form of a compressed breast. said orifice having an oblong shape with a major axis corresponding to an axillary axis of the patient for that breast.

21. A method for scanning a breast of a patient, comprising:

receiving at least a portion of the breast through an orifice defined by a frame, the orifice being shaped to allow at least a portion of the breast to extend therethrough;

compressing the breast toward a chest wall of the patient using a first side of a compressive member secured to the frame across the orifice; and

scanning the breast with a transducer positioned in acoustic communication with a second side of the compressive member opposite the first side of the compressive member.

22. The method of claim 21, said orifice and compressive member being positioned in an approximately horizontal plane to receive the breast while the patient is in a substantially prone position.

23. The method of claim 22, wherein said compressive member comprises a stretchable membrane elastically compressing the breast upward toward the chest wall.

24. The method of claim 23, wherein said stretchable membrane exerts a total upward force on the breast in the range of approximately 2 pounds (8.9 Newtons) to 12 pounds (53.4 Newtons).

25. The method of claim 23, wherein said stretchable membrane comprises an elastomer selected from the group consisting of: silicone, latex, vinyl, nitrile, polyurethane, and neoprene rubbers.

26. The method of claim 22, wherein said compressive member comprises a flexible, non-elastic membrane tensionably compressing the breast upward toward the chest wall.

27. The method of claim 26, wherein said flexible, non-elastic membrane comprises a high-strength polyethylene film.

28. The method of claim 21, wherein said compressive member comprises a substantially rigid plastic having relatively high acoustic transparency, said substantially rigid plastic being pre-molded into a shape corresponding to a compressed breast.

29. The method of claim 28, further comprising:

identifying, according to a size of the breast, a suitable member of an orifice array including said orifice and a plurality of similar orifices, each orifice being sized differently for receiving differently-sized breasts, each orifice having a corresponding pre-molded rigid plastic member corresponding to a breast size for that orifice;

and

receiving said portion of the breast through the identified orifice.

30. The method of claim 28, wherein said substantially rigid plastic comprises a polycarbonate plastic having a thickness in the range of approximately 0.5 mm to 2 mm.

31. The method of claim 28, said orifice and compressive member being positioned in an approximately vertical plane to receive the breast while the patient is in a substantially upright position.

32. The method of claim 21, the transducer comprising a first linear array probe, further comprising maintaining the first linear array probe in floatable physical contact with the compressive member while moving the first linear array probe across the compressive member, the first linear array probe obtaining ultrasound slices sufficient to reconstruct a three-dimensional volumetric representation of the breast.

33. The method of claim 21, the transducer comprising a first linear array probe, the frame and compressive member at least partially defining an enclosed reservoir that maintains an acoustically conductive fluid between the first linear array probe and the compressive member for establishing the acoustic communication therebetween, further comprising offsetably moving the first linear array probe across said compressive member while obtaining a first set of ultrasound slices for constructing a three-dimensional volumetric representation of the breast.

34. The method of claim 33, further comprising orienting said first linear array probe during said offsetable movement such that said first set of ultrasound slices corresponds to planes substantially perpendicular to a coronal plane.

35. The method of claim 34, further comprising orienting said first linear array probe during said offsetable movement such that said first set of ultrasound slices also corresponds to planes substantially parallel to an axillary axis for that breast.

36. The method of claim 33, further comprising orienting said first linear array probe during said offsetable movement such that said first set of ultrasound slices corresponds to planes at a first skewed angle, said first skewed angle being neither substantially parallel to nor substantially perpendicular to said coronal plane, whereby nipple shadow effects in said three-dimensional volumetric representation are at least partially reduced for locations underlying a nipple of the breast.

37. The method of claim 36, further comprising offsetably moving a second linear array probe across said compressive member while obtaining a second set of ultrasound slices for use in constructing said three-dimensional volumetric representation in conjunction with said first set of ultrasound slices, said second linear array probe being oriented during said offsetable movement such that said second set of ultrasound slices corresponds to planes at a second skewed angle, said second skewed angle being neither substantially parallel to nor substantially perpendicular to said coronal plane, said second skewed angle being substantially nonparallel to said first skewed angle, whereby nipple shadow effects in said three-dimensional volumetric representation are further reduced.

38. The method of claim 36, said offsetable movement of said first linear array probe having an arcuate trajectory such that said first set of ultrasound slices corresponds to planes at a multiplicity of skewed angles neither substantially parallel to nor substantially perpendicular to said coronal plane, whereby nipple shadow effects in said three-dimensional volumetric representation are at least partially reduced.

39. The method of claim 21, wherein the orifice and the compressive member are positioned in an approximately horizontal plane to receive the breast while the patient is in a substantially prone position, and wherein the orifice has an oblong shape with a major axis corresponding to an axillary axis of the patient for that breast.

40. The method of claim 21, wherein the compressive member comprises a substantially rigid plastic having relatively high acoustic transparency, the substantially rigid plastic having pre-molded contours in the form of a compressed breast, and wherein the orifice has an oblong shape with a major axis corresponding to an axillary axis of the patient for that breast.

41. An ultrasound scanning apparatus, comprising:

a reservoir casing holding a sonically conductive fluid and having a substantially rigid upper surface, said upper surface having an opening generally shaped to receive a breast of a prone patient;

a flexible membrane sealably secured across said opening, said flexible membrane having a lower surface in contact with said sonically conductive fluid and an upper surface pressing upward against the breast when the breast is extended through said opening; and

a transducer disposed within said sonically conductive fluid for imaging the breast through said flexible membrane.

42. The ultrasound scanning apparatus of claim 41, said transducer comprising a first linear array probe, further comprising means for translating said first linear array probe within said sonically conductive fluid to obtain a first set of ultrasound slices sufficient to construct a three dimensional representation of the breast.

43. The ultrasound scanning apparatus of claim 42, wherein said flexible membrane comprises a stretchable material that at least partially stretches while compressing upward against the breast.

44. The ultrasound scanning apparatus of claim 42, wherein said flexible membrane comprises a non-elastic material that does not stretch while compressing upward against the breast.

45. The ultrasound scanning apparatus of claim 42, further comprising means for maintaining said first linear array probe in floatable physical contact with said flexible membrane during said translation of said linear probe in a manner that exerts substantially negligible upward force on the breast.

46. The ultrasound scanning apparatus of claim 42, further comprising means for offsetably maintaining said first linear array probe at least 1 cm from said flexible membrane during a majority of said linear probe translation, said first linear array probe maintaining sonic communication with said flexible membrane through said sonically conductive fluid.

47. The ultrasound scanning apparatus of any of claims 42-46, said first linear array probe being oriented such that said first set of ultrasound slices corresponds to planes substantially perpendicular to a coronal plane.

48. The ultrasound scanning apparatus of claim 47, said first linear array probe being oriented such that said first set of ultrasound slices also corresponds to planes substantially parallel to an axillary axis for that breast.

49. The ultrasound scanning apparatus of any of claims 42-46, said first linear array probe being oriented such that said first set of ultrasound slices corresponds to planes at a first skewed angle, said first skewed angle being neither substantially parallel to nor substantially perpendicular to said coronal plane, whereby nipple shadow effects in said three-dimensional representation are at least partially reduced for locations underlying a nipple of the breast.

50. The ultrasound scanning apparatus of claim 49, further comprising:

a second linear array probe;

means for translating said second linear array probe within said sonically conductive fluid to obtain a second set of ultrasound slices for use in constructing said three dimensional representation of the breast;

means for offsetably maintaining said second linear array probe at least 1 cm from said flexible membrane during a majority of said linear probe translation, said second linear array probe maintaining sonic communication with said flexible membrane through said sonically conductive fluid, said second linear array probe being oriented such that said second set of ultrasound slices corresponds to planes at a second skewed angle, said second skewed angle being neither substantially parallel to nor substantially perpendicular to said coronal plane, said second skewed angle being substantially nonparallel to said first skewed angle, whereby nipple shadow effects in said three-dimensional representation are further reduced.

51. The ultrasound scanning apparatus of any of claims 42-46, first linear array probe having an arcuate-trajectory translation such that said first set of ultrasound slices corresponds to planes at a multiplicity of skewed angles neither substantially parallel to nor substantially perpendicular to said coronal plane, whereby nipple shadow effects in said three-dimensional representation are at least partially reduced.

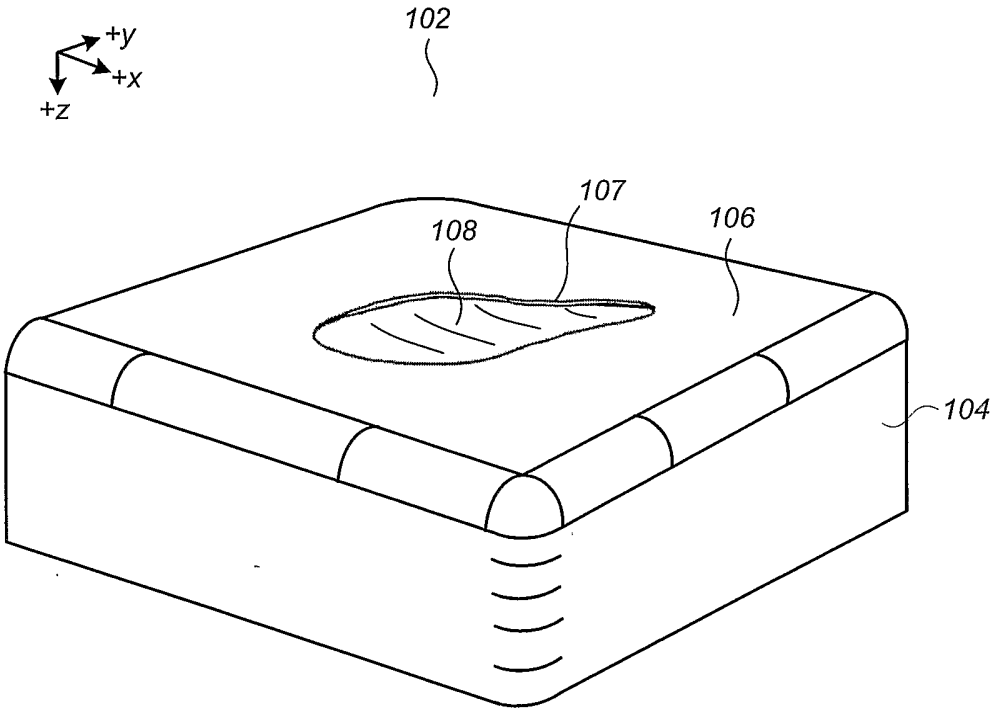


FIG. 1

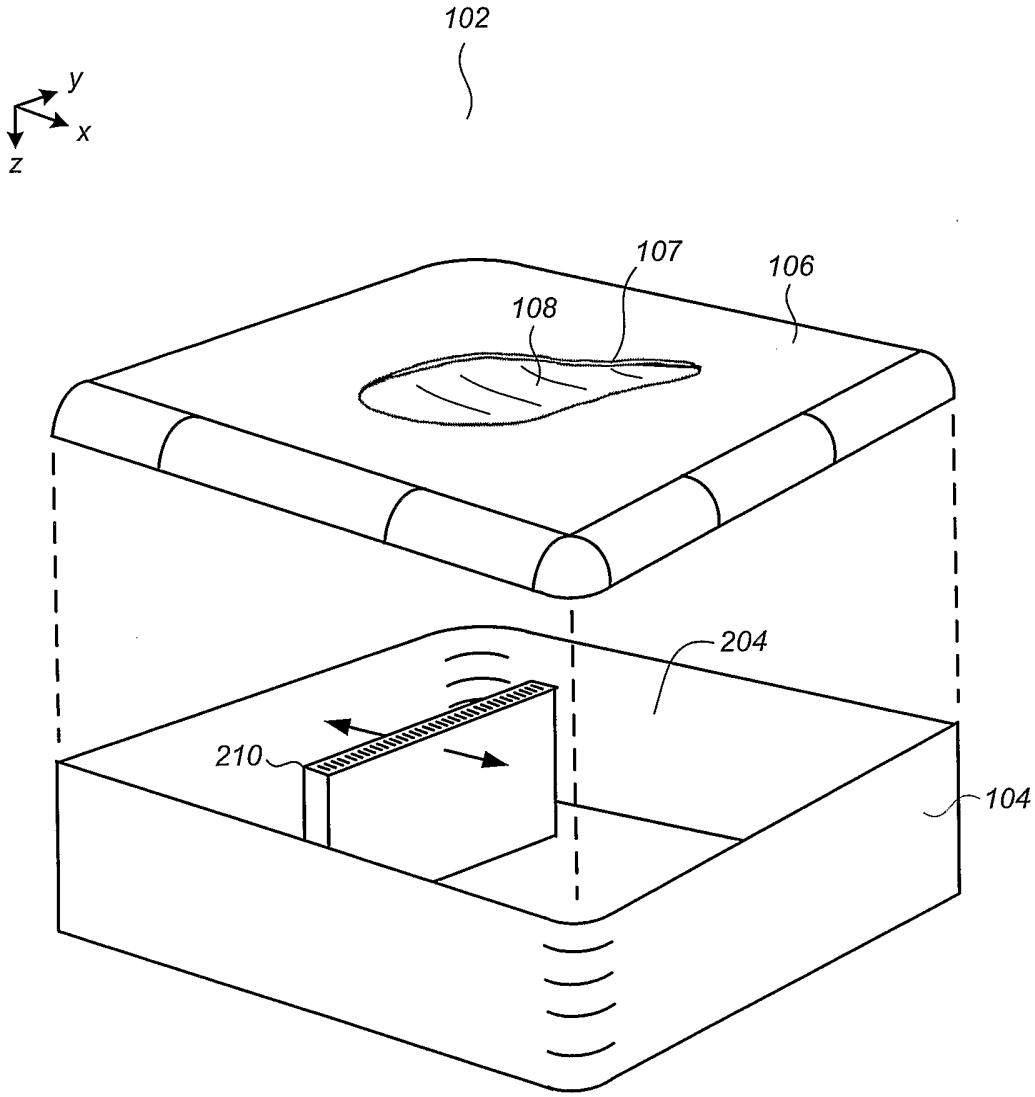


FIG. 2

FIG. 3A

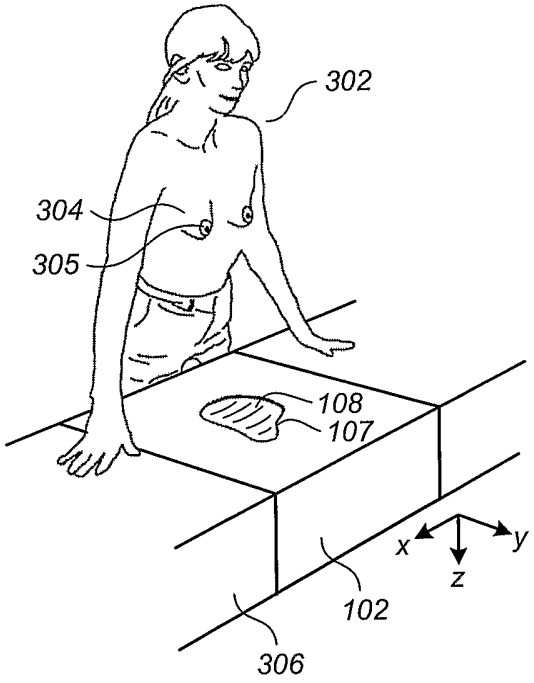
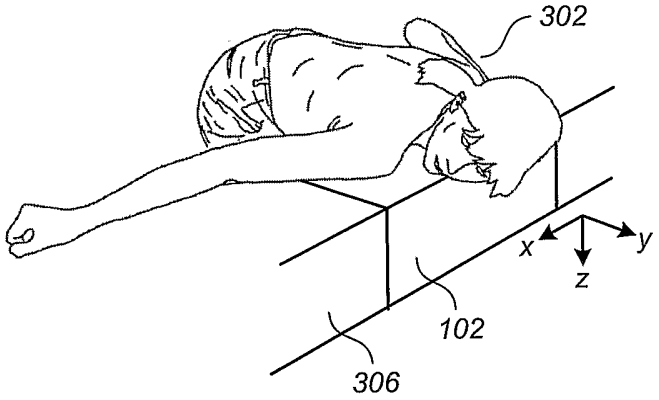


FIG. 3B



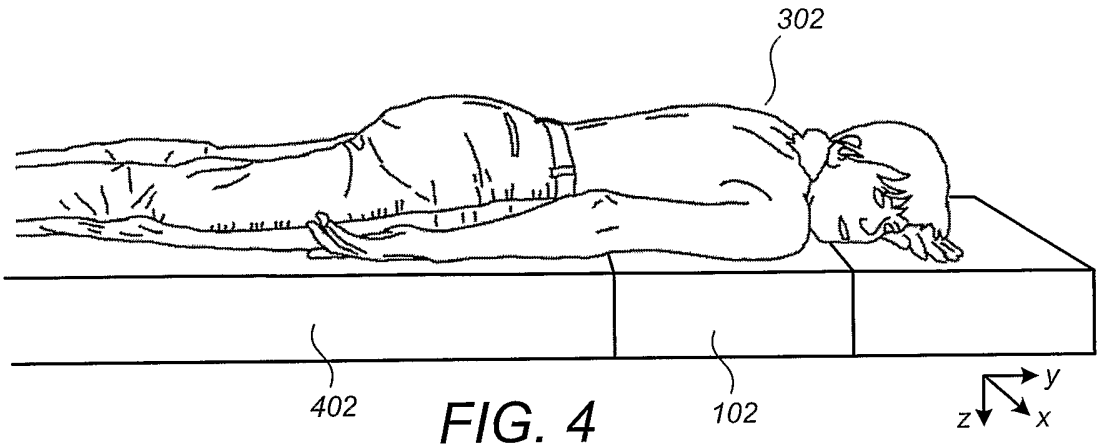


FIG. 4

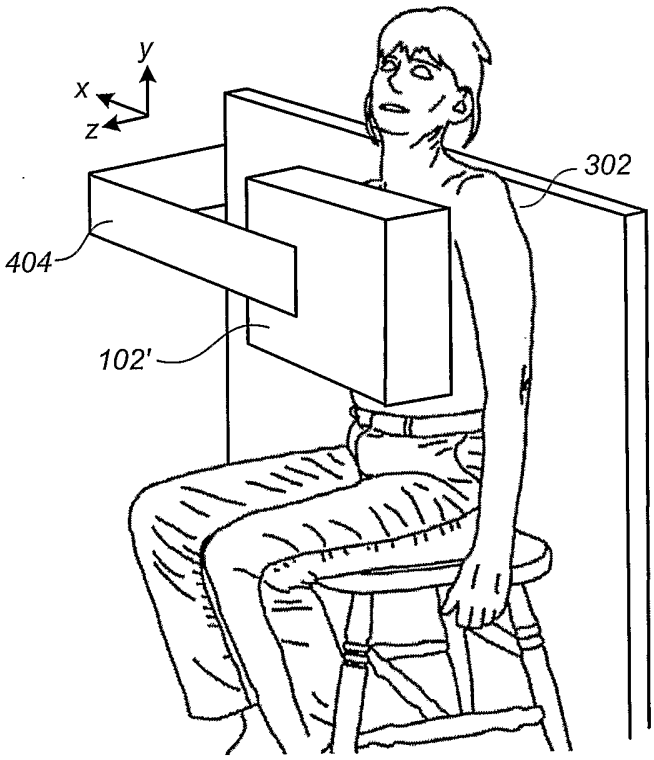


FIG. 5

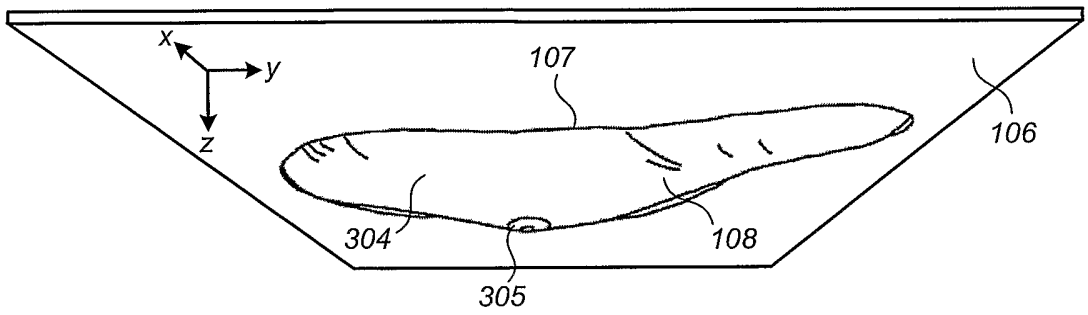


FIG. 6A

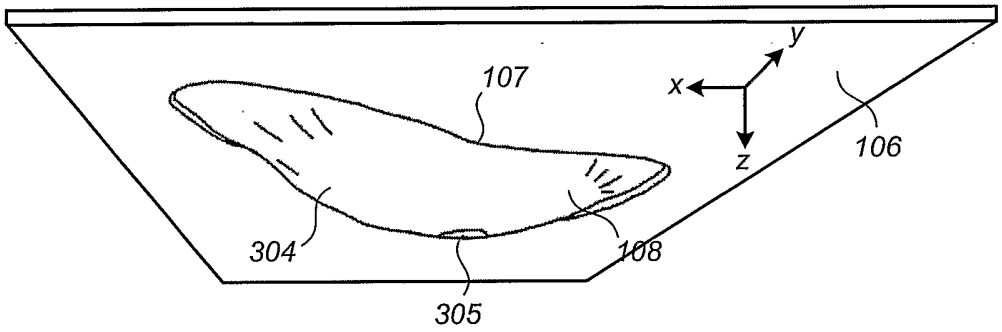


FIG. 6B

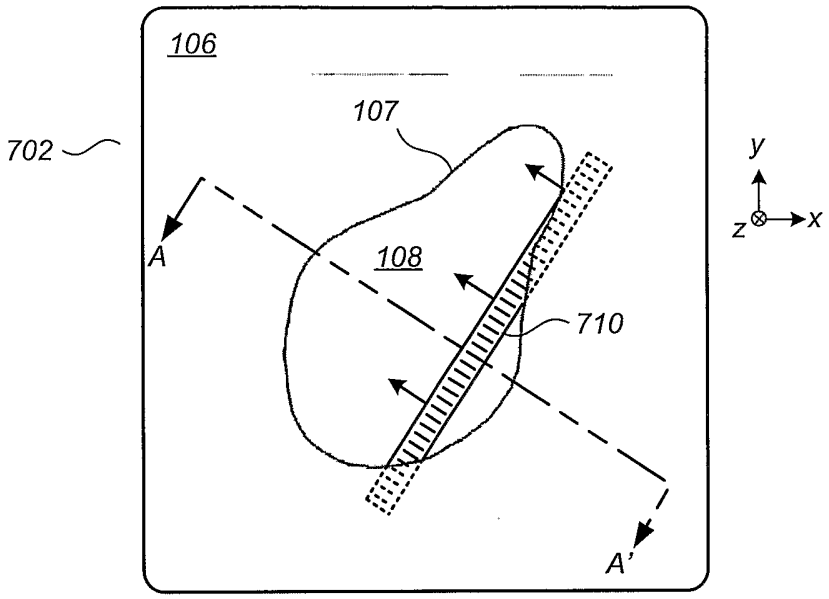

106
107
702
y
z
x
A
108
710
A'

FIG. 7A

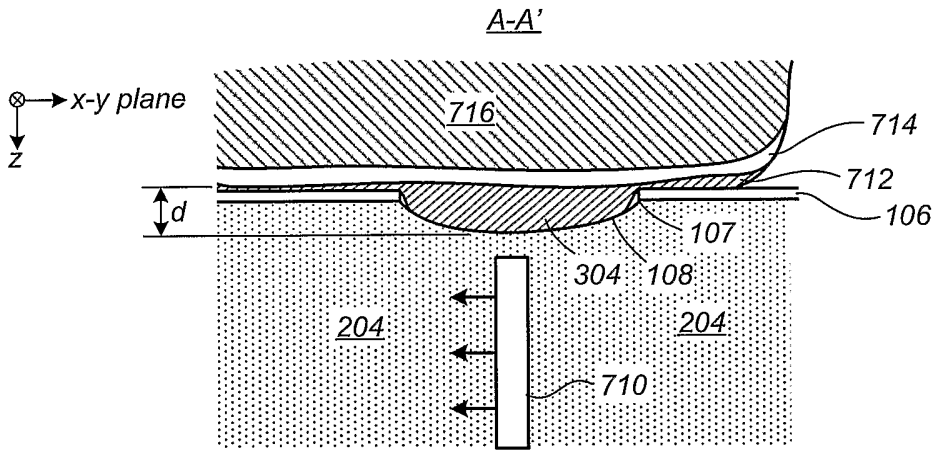

A-A'
x-y plane
z
716
714
712
106
d
107
304
108
204
204
710

FIG. 7B

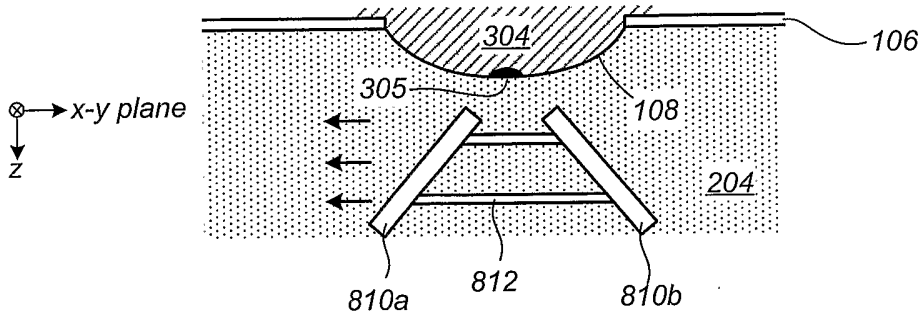


FIG. 8

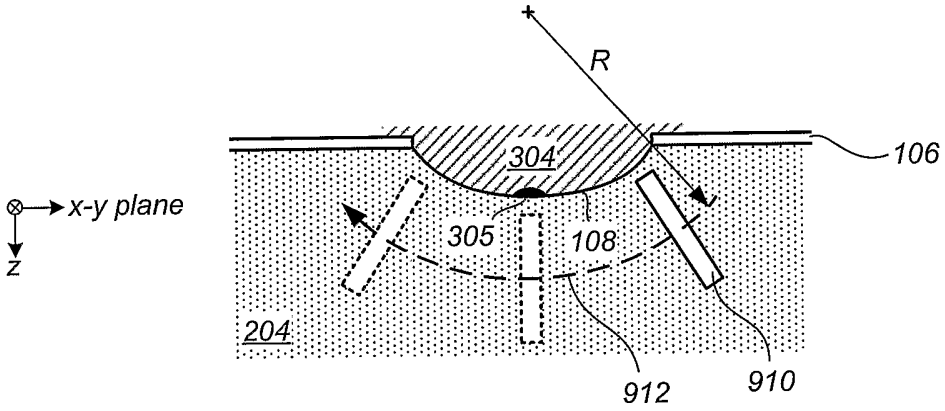


FIG. 9

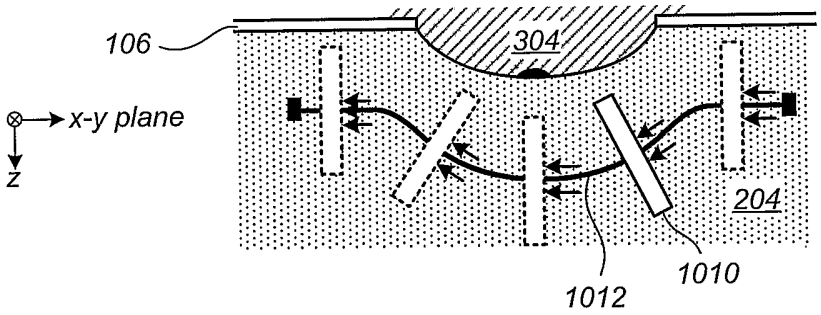


FIG. 10

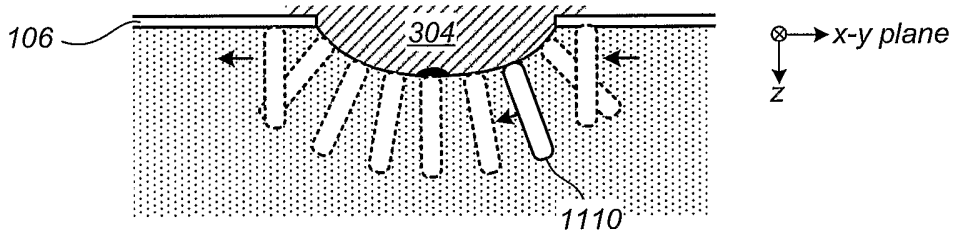


FIG. 11

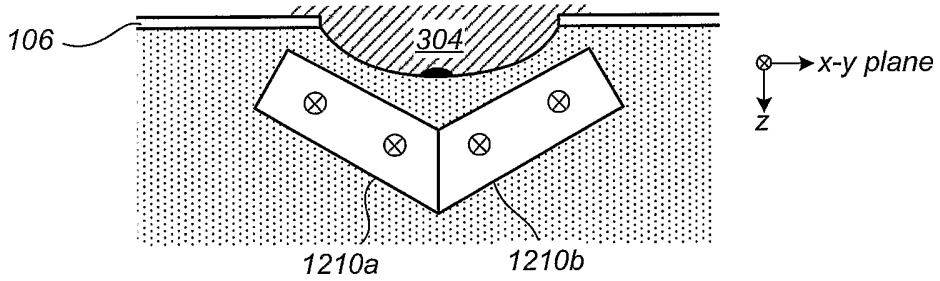


FIG. 12

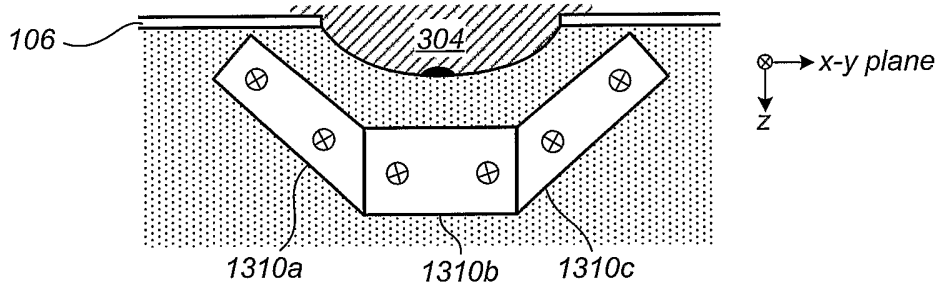


FIG. 13

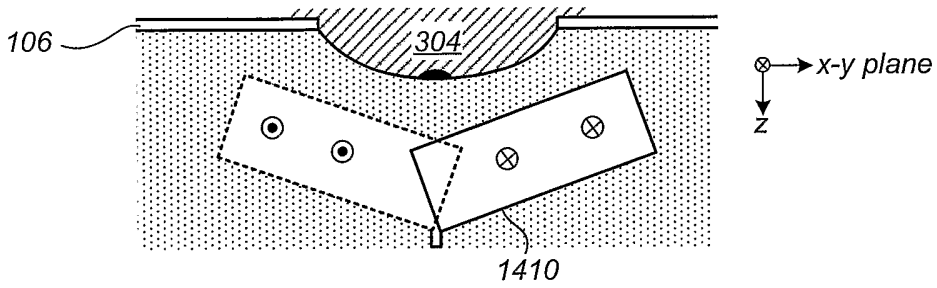


FIG. 14A

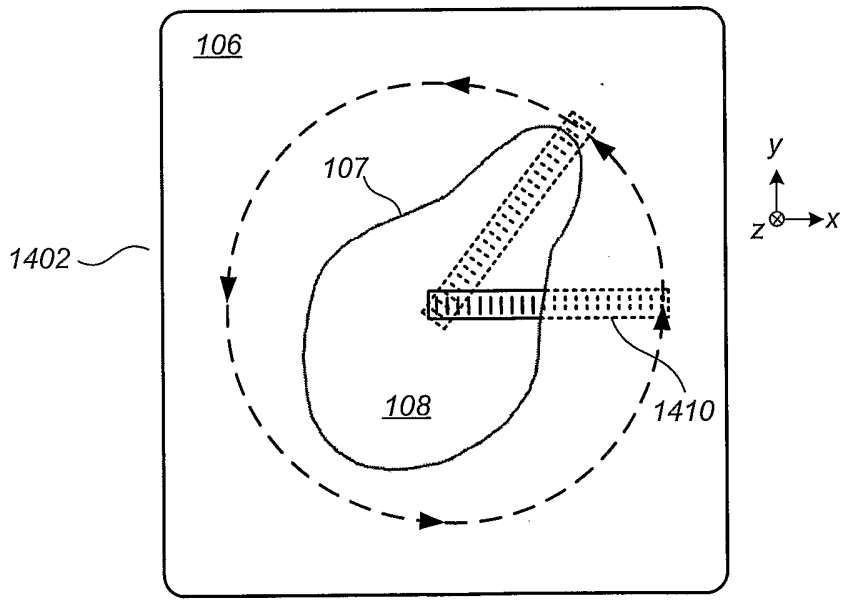


FIG. 14B

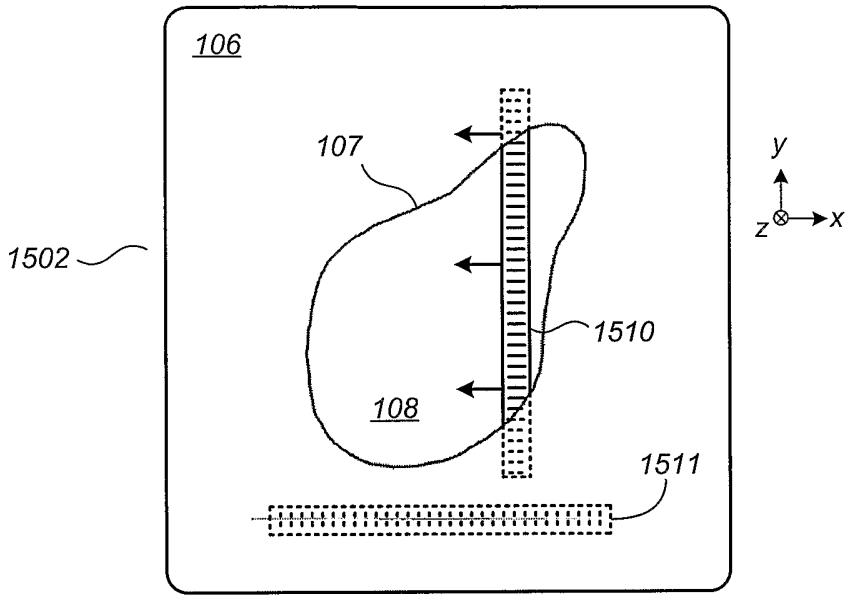


FIG. 15A

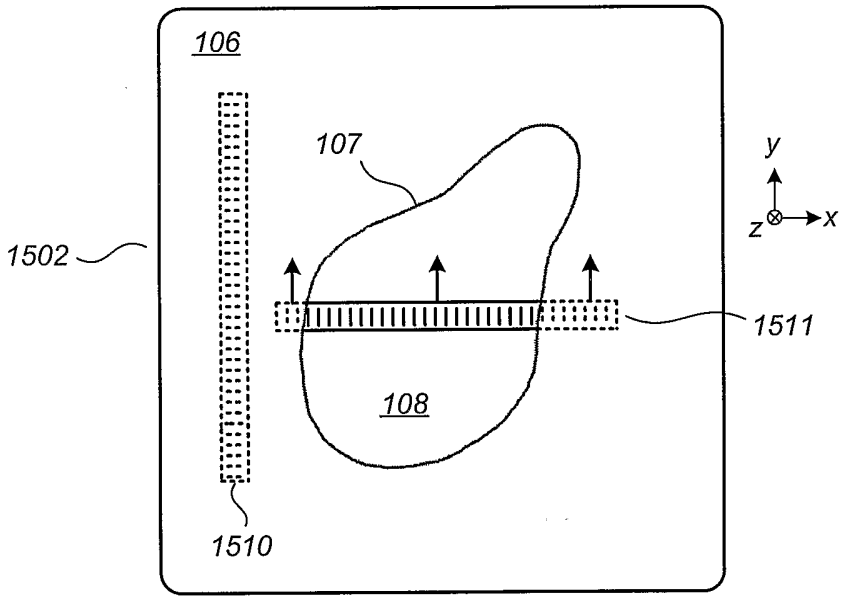
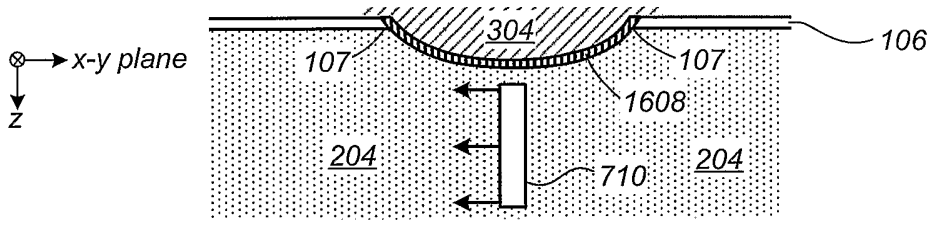


FIG. 15B


x-y plane
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204

FIG. 16

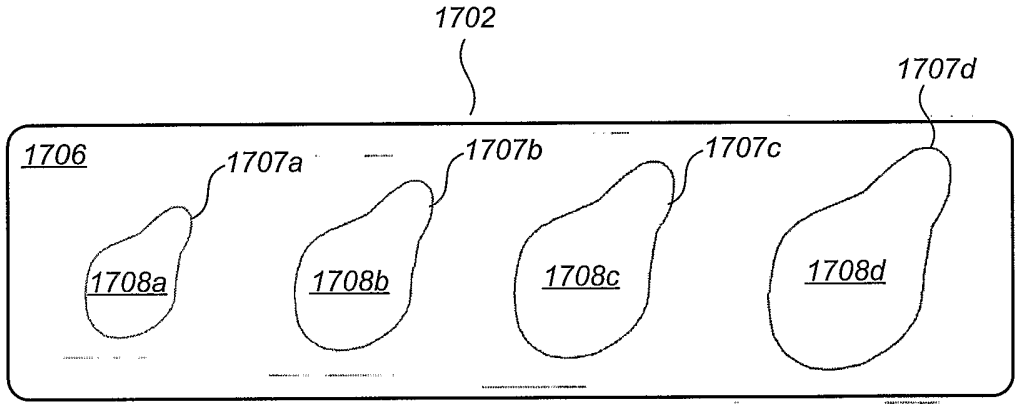
1702
1707d
1706
1707a
1707b
1707c
1708a
1708b
1708c
1708d

FIG. 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/18316

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61B 8/00
US CL : 600/437; 128/915
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)
U.S. : 600/437-443; 128/915

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6,254,614 B1 (JESSEPH) 03 July 2001 (03.07.2001), entire document.	1-51
A	US 5,833,633 A (SARVAZYAN) 10 November 1998 (10.11.1998), entire document.	1-51

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* 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 published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"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	Date of mailing of the international search report
30 September 2005 (30.09.2005)	31 OCT 2005
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Ali Imam Telephone No. 703-308-1148

Form PCT/ISA/210 (second sheet) (April 2005)