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(54) **WEARABLE 3D ULTRASOUND-BASED WHOLE BREAST IMAGING SYSTEM**

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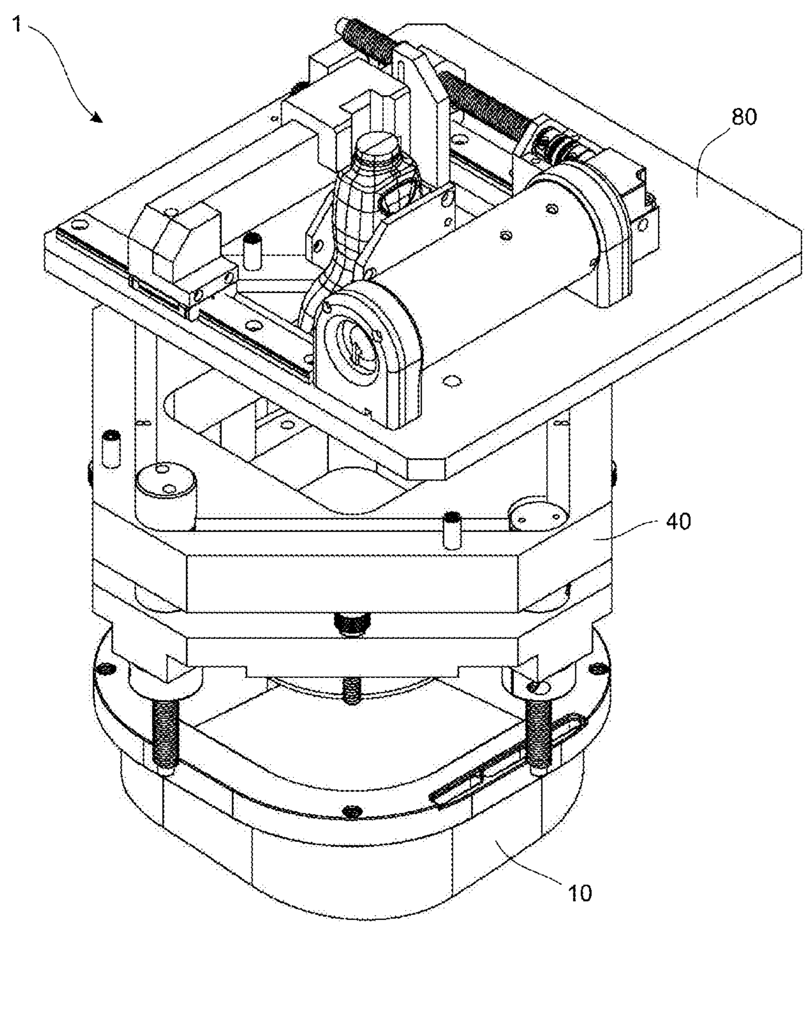
(57) **ABSTRACT**

A whole breast 3D ultrasound imaging system involves a wearable adapter subassembly, a compression plate subassembly releasably mountable on the wearable adapter subassembly and a motor plate subassembly releasably mountable on the compression plate subassembly so that the compression plate subassembly is between the wearable adapter subassembly and the motor plate subassembly. The wearable adapter subassembly acts as a dam to contain ultrasound fluid around a subject's breast. The compression plate subassembly has an ultrasound compression plate in a frame, whereby the ultrasound compression plate is height adjustable. The motor plate subassembly has an ultrasound transducer and an actuator operatively coupled to the ultrasound transducer to translate the ultrasound transducer in a plane parallel to the ultrasound compression plate. The imaging system is cost-effective, portable and hands-free and can be used for bedside point-of-care imaging to acquire clear, sharp 3D ultrasound images of dense and/or small breasts.



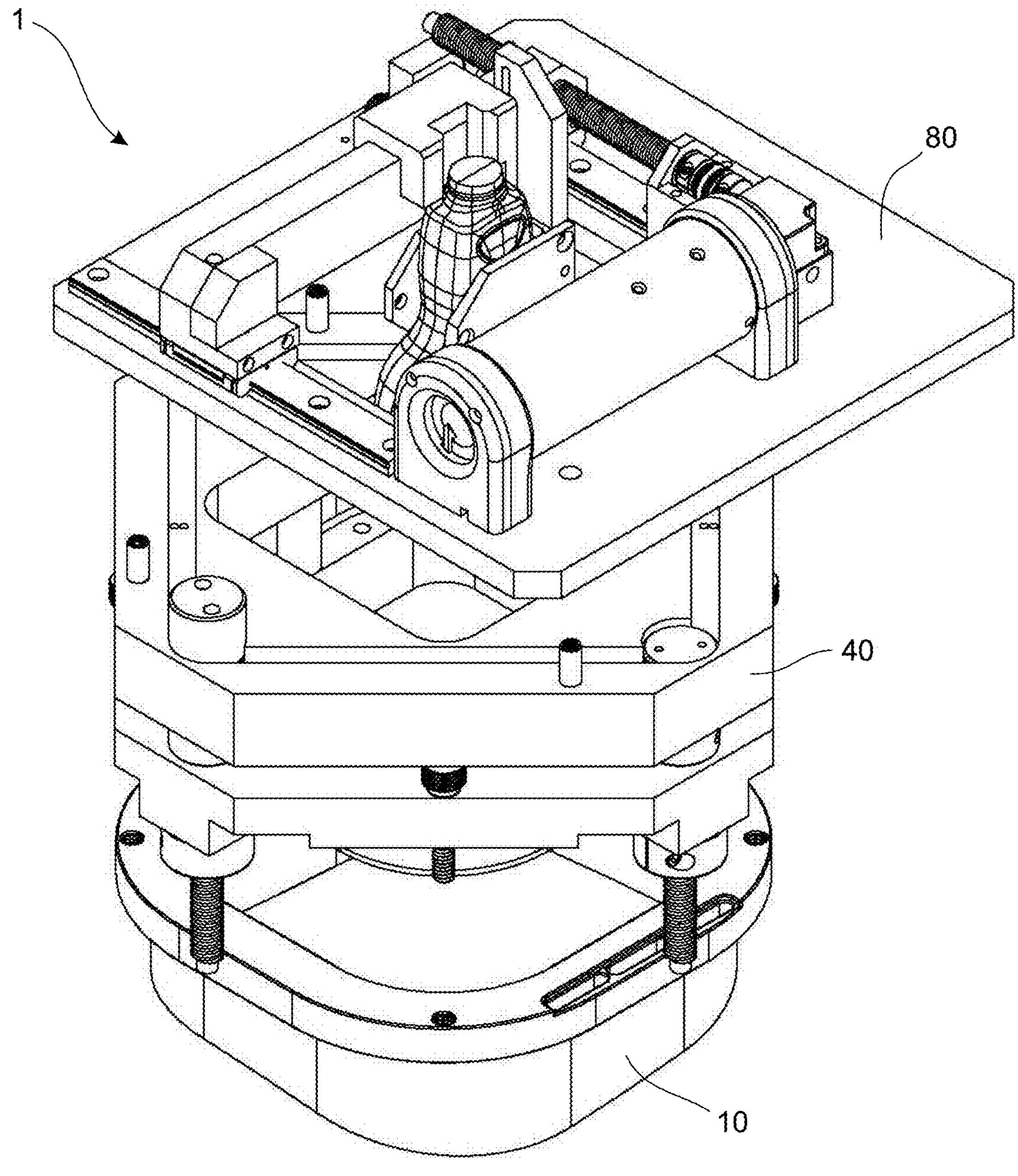


FIG. 1

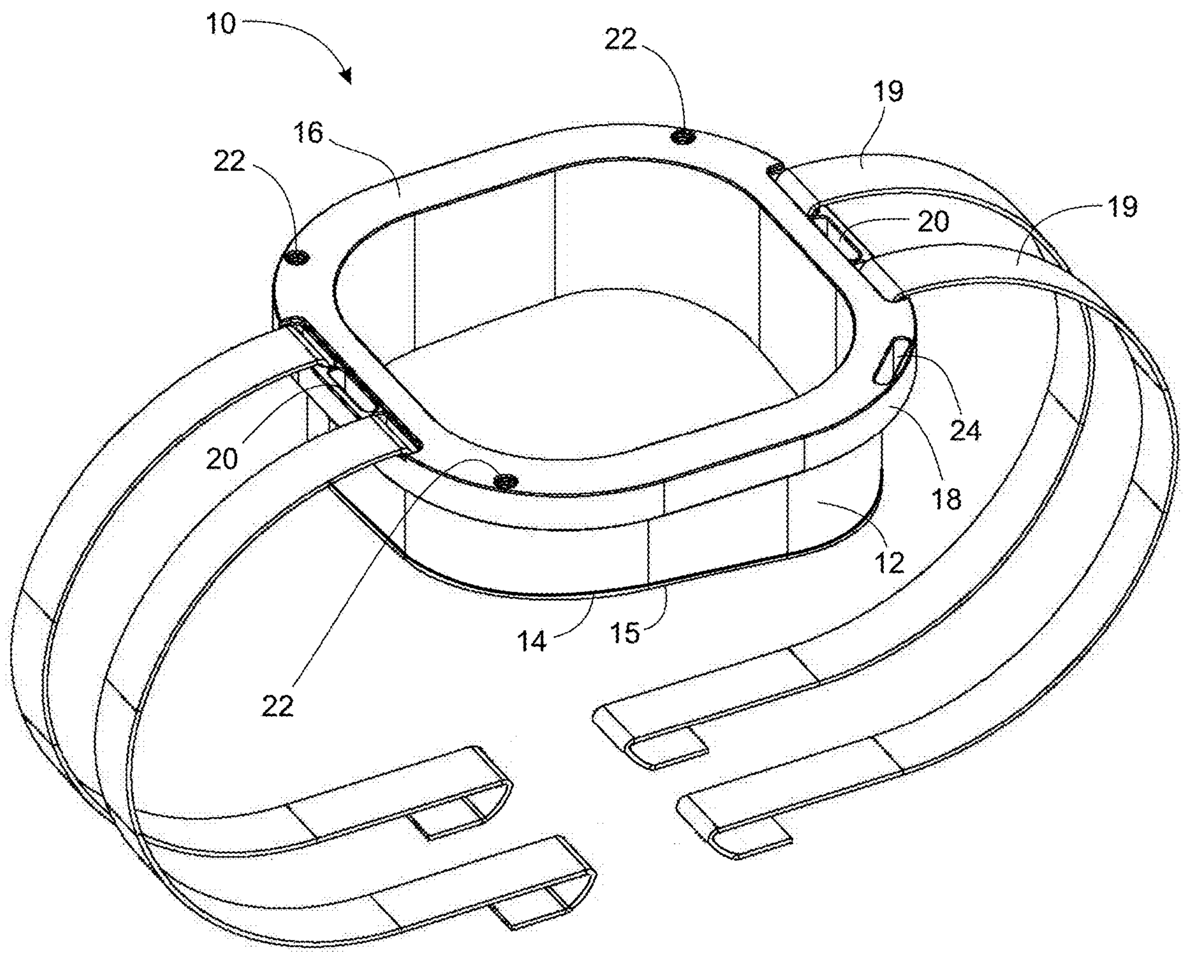


FIG. 2A

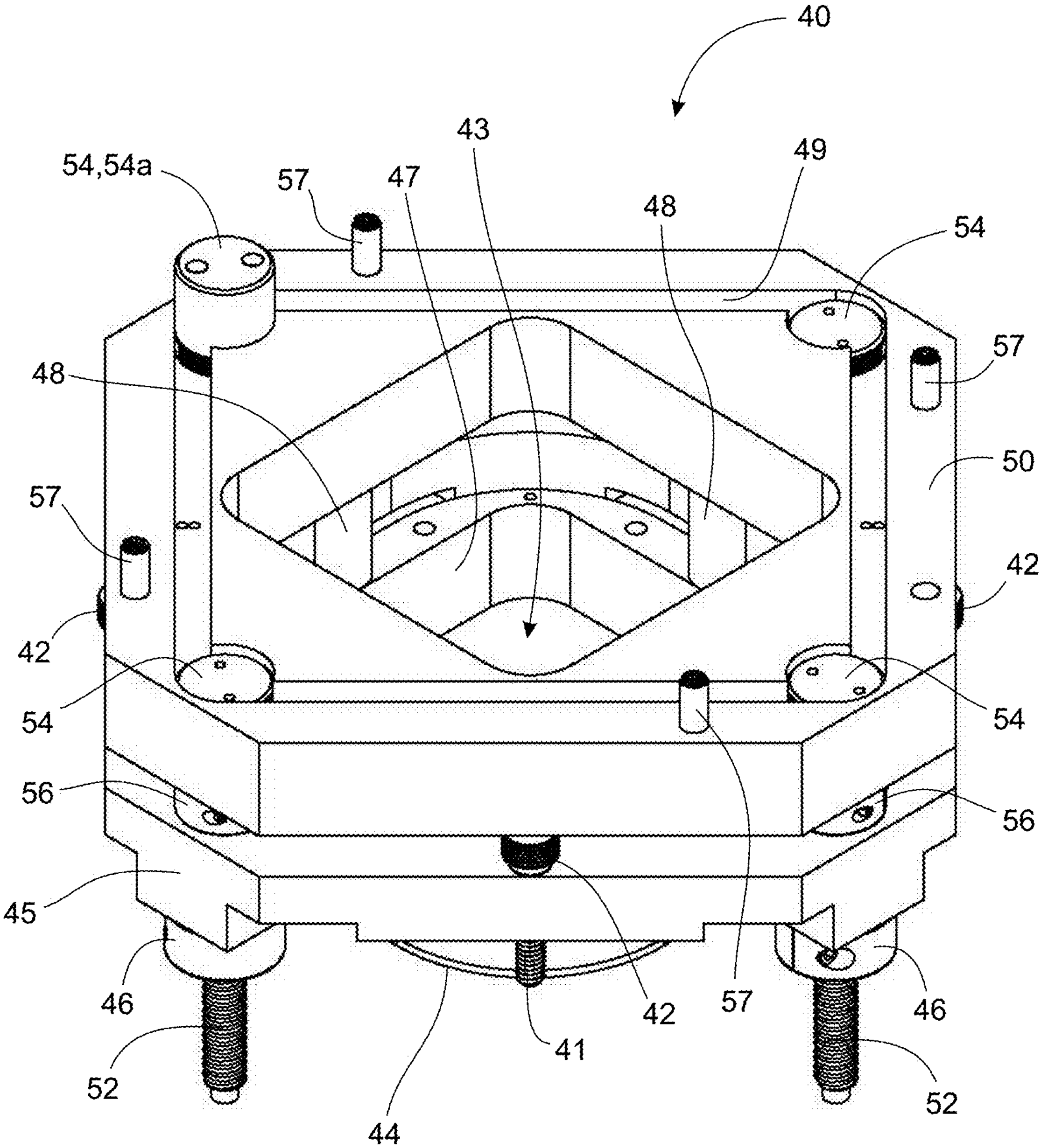

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FIG. 2B

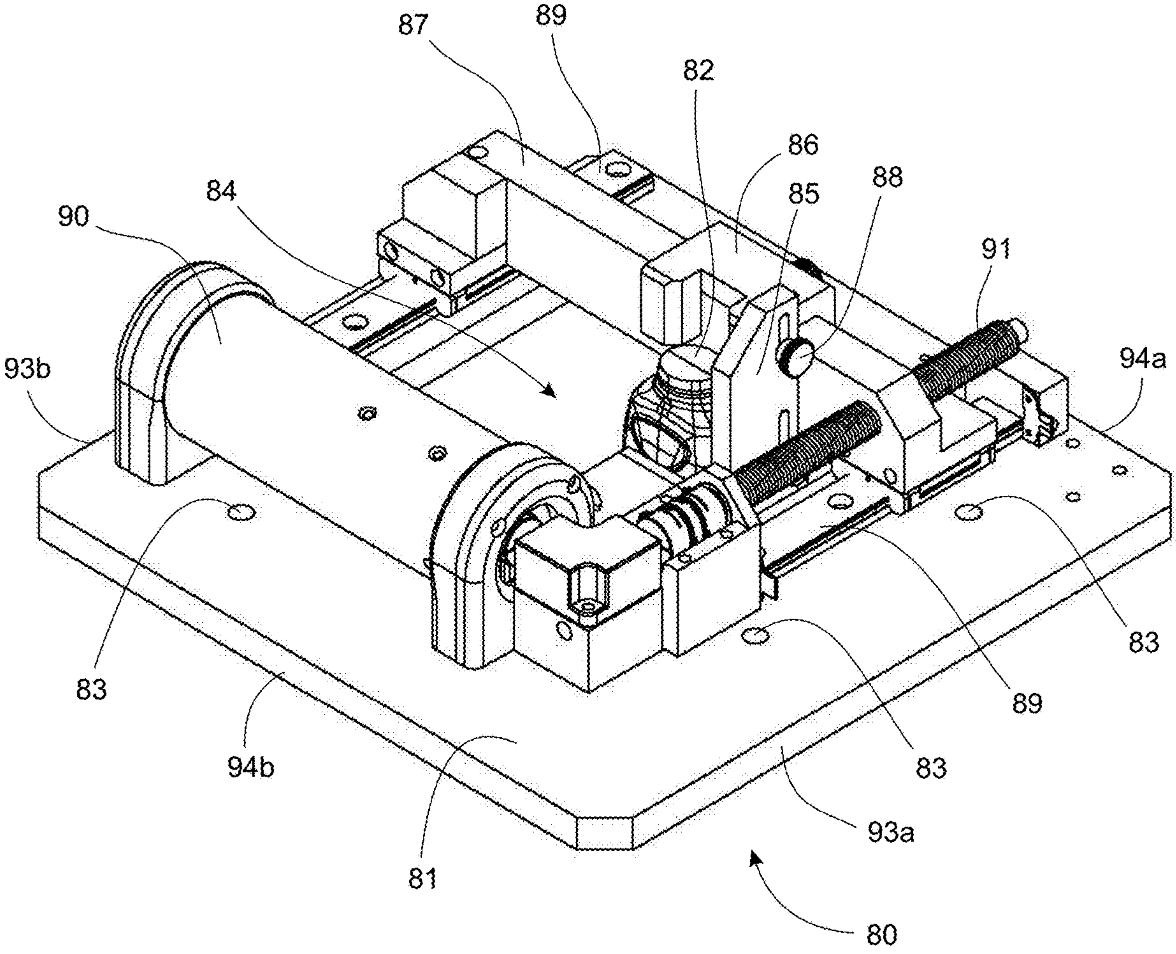

FIG. 2C

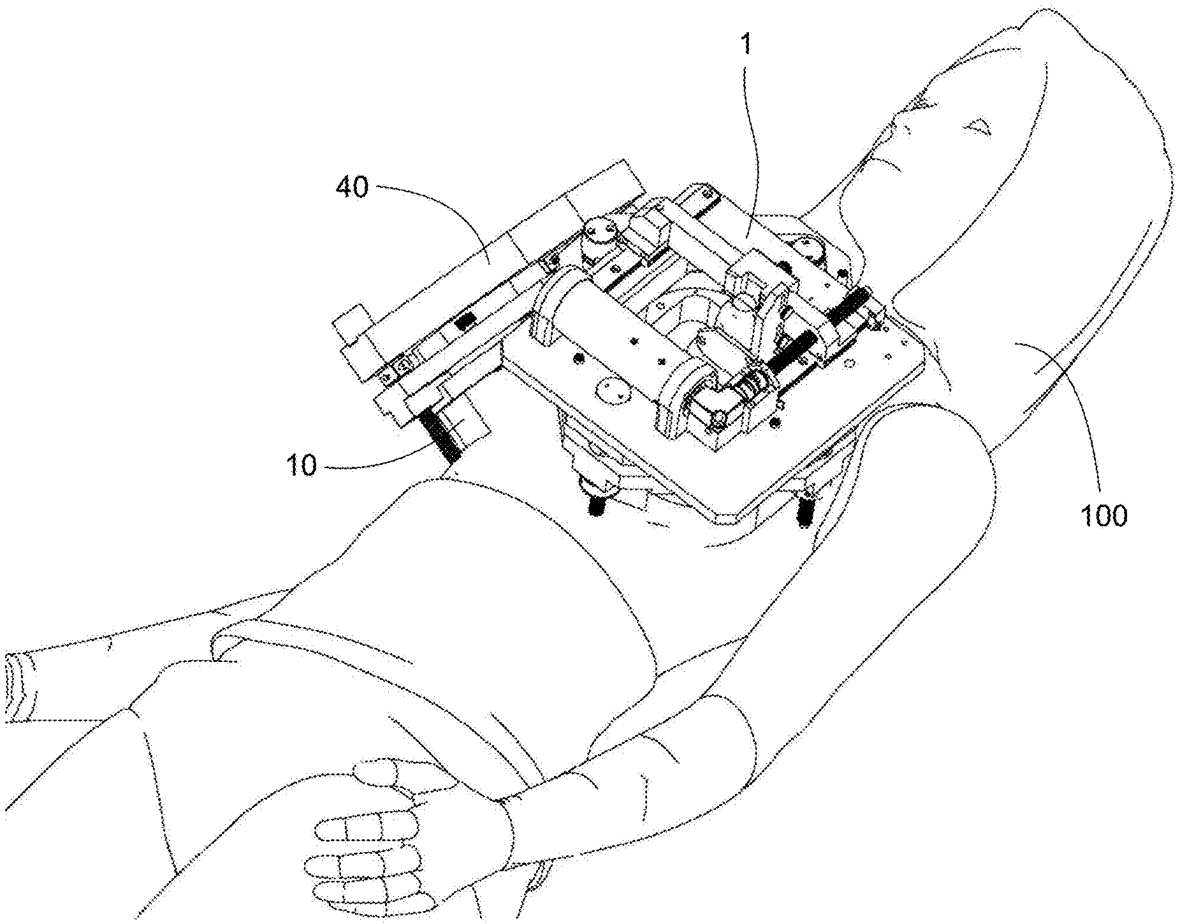

FIG. 3A

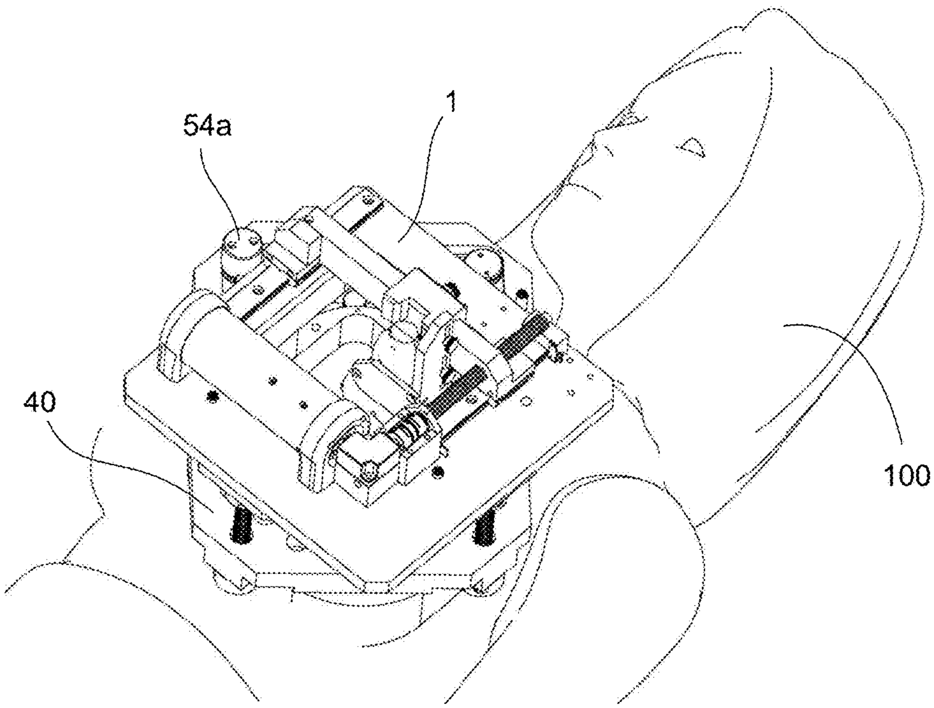

FIG. 3B

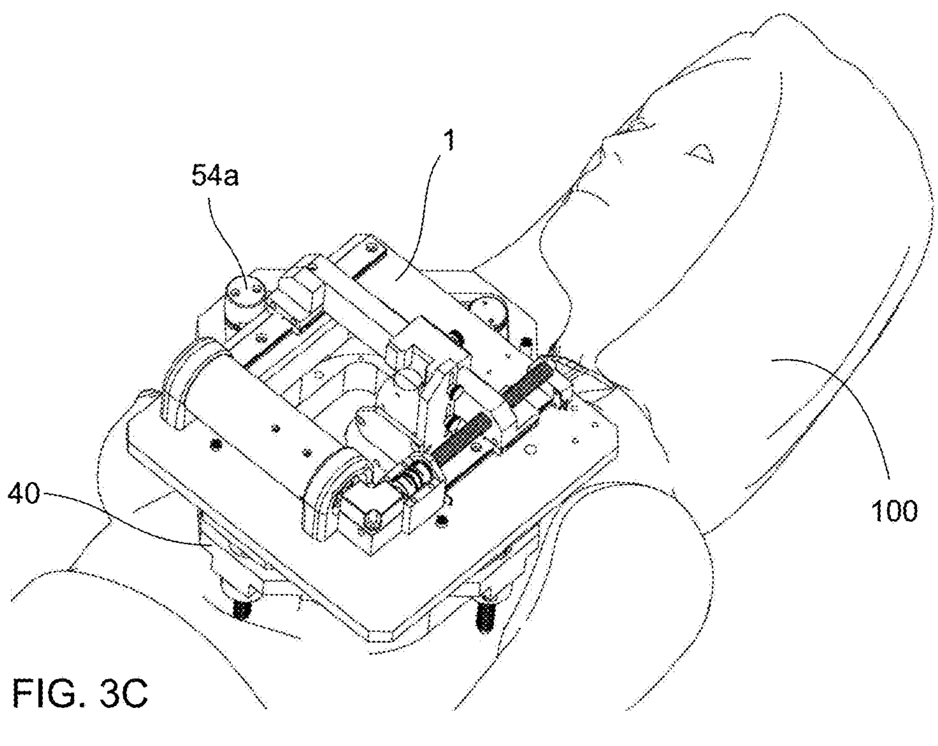

FIG. 3C

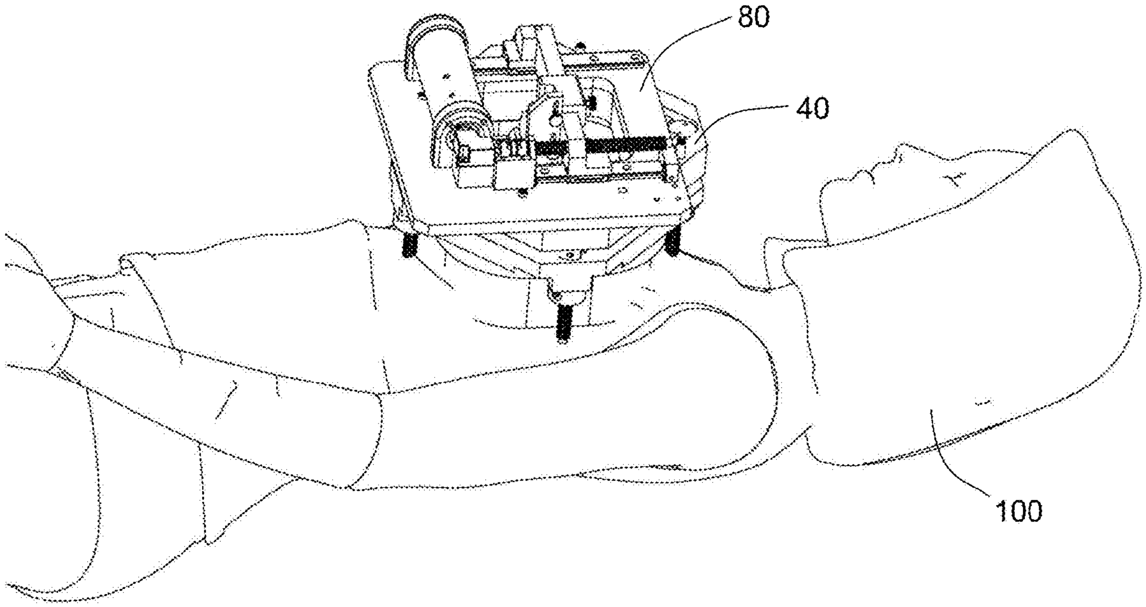

FIG. 4A

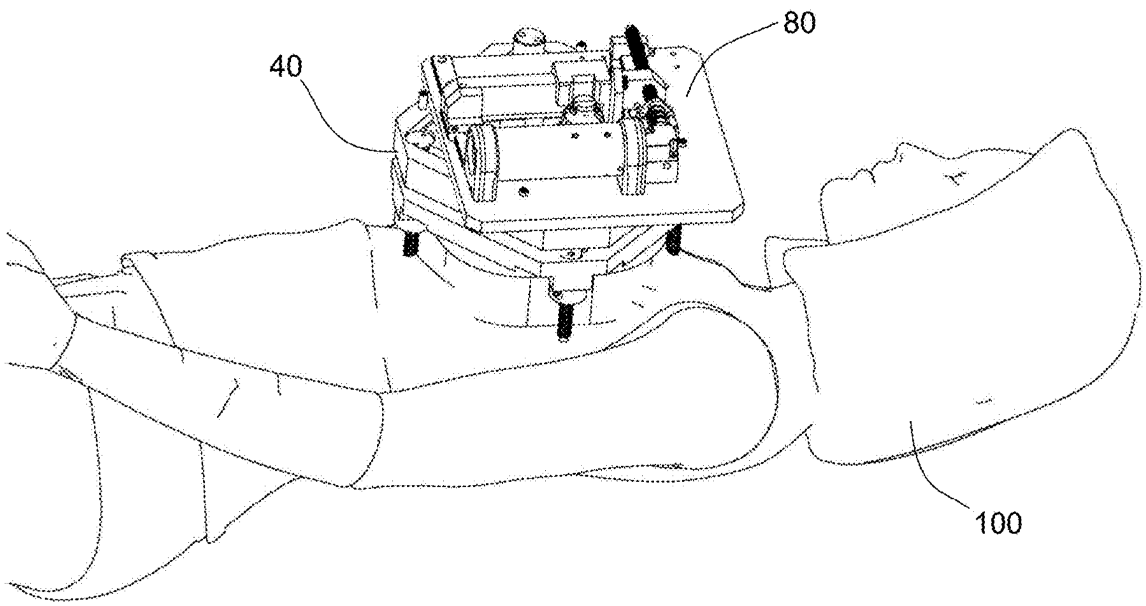

FIG. 4B

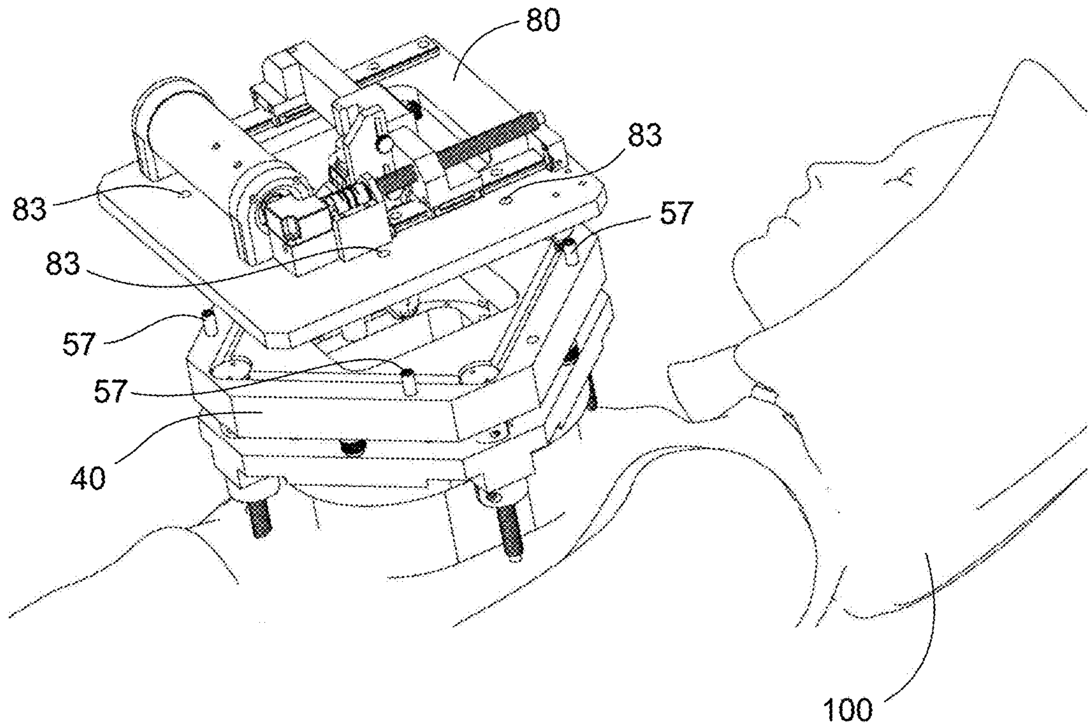

FIG. 5A

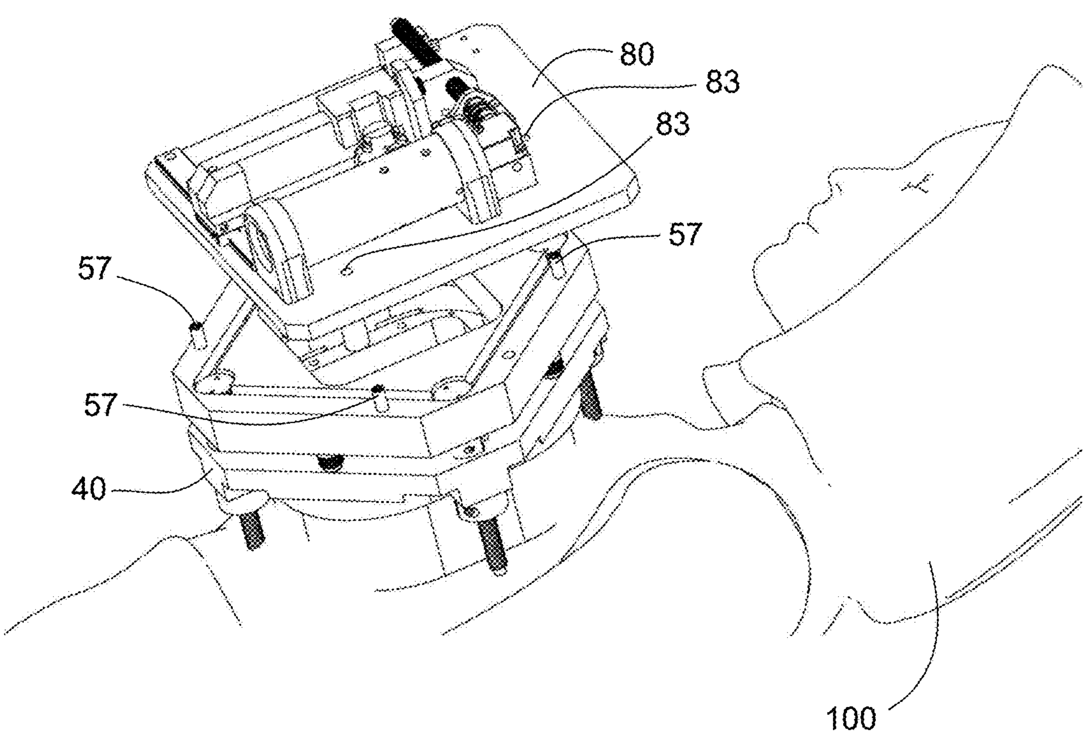

FIG. 5B

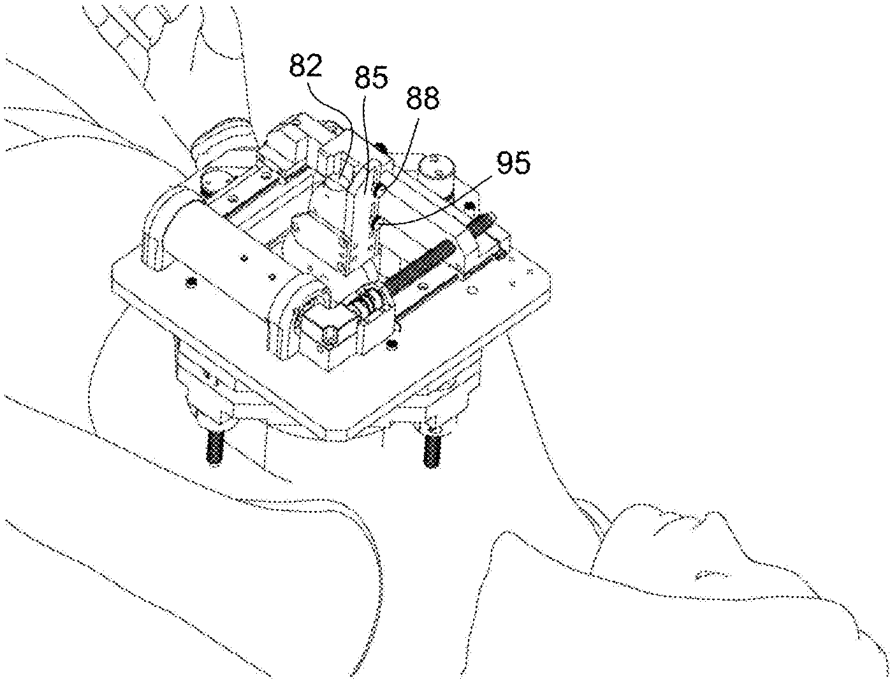

FIG. 6A

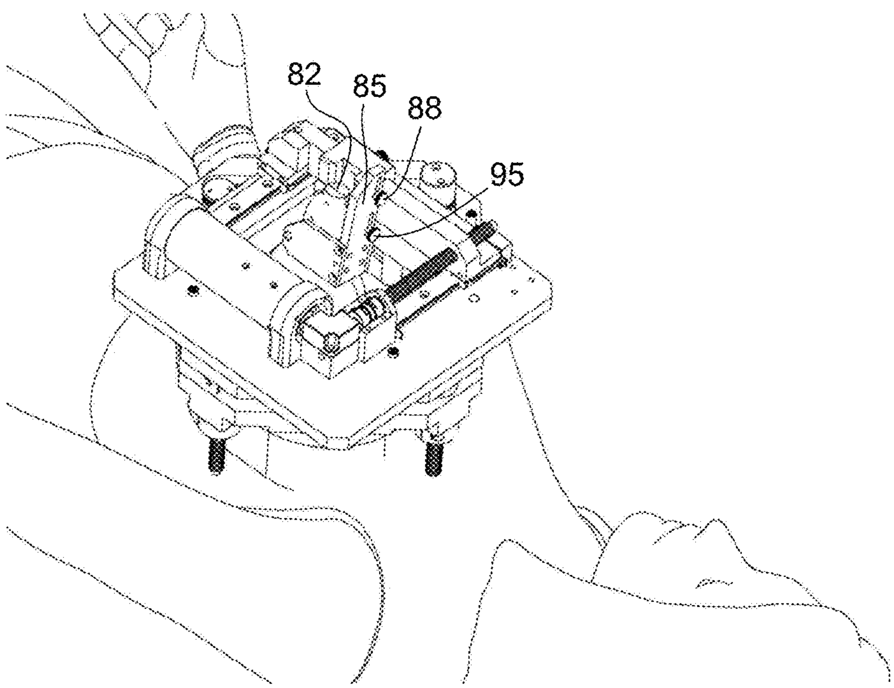

FIG. 6B

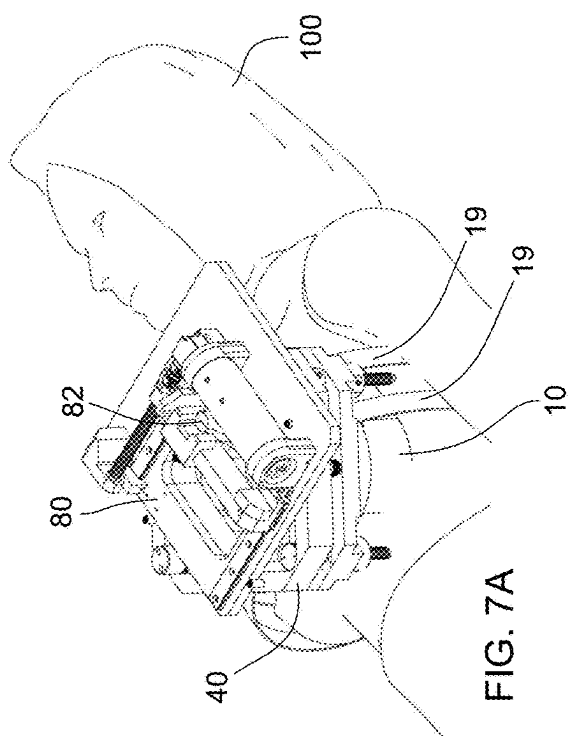

FIG. 7A

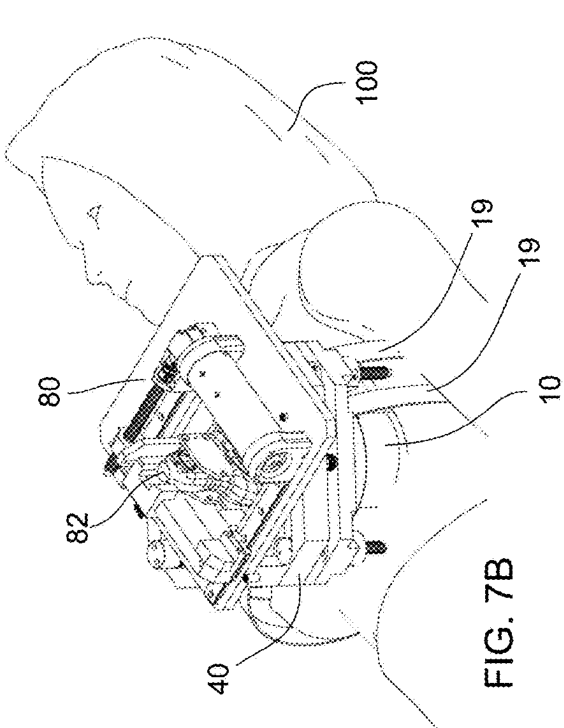

FIG. 7B

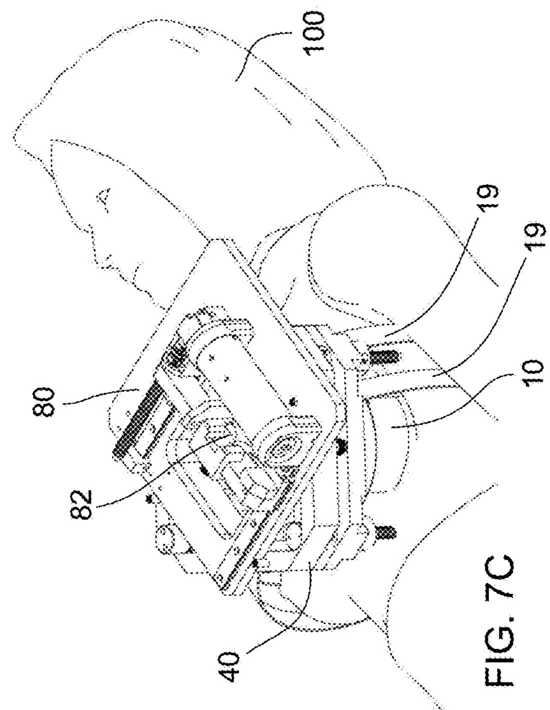

FIG. 7C

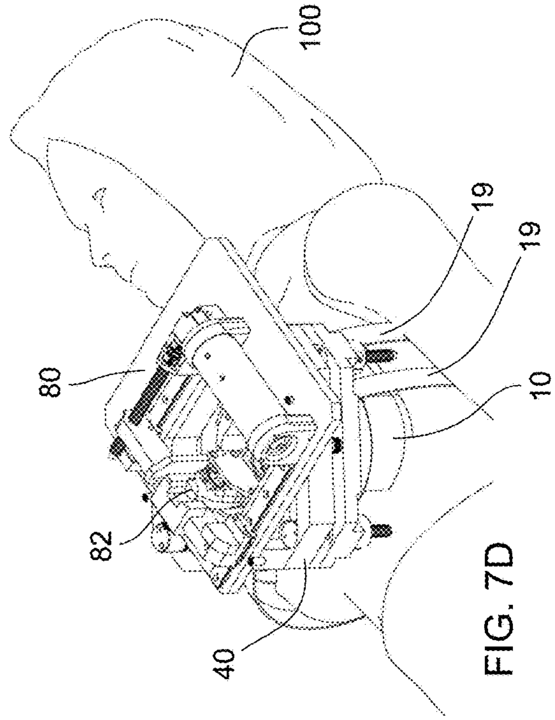

FIG. 7D

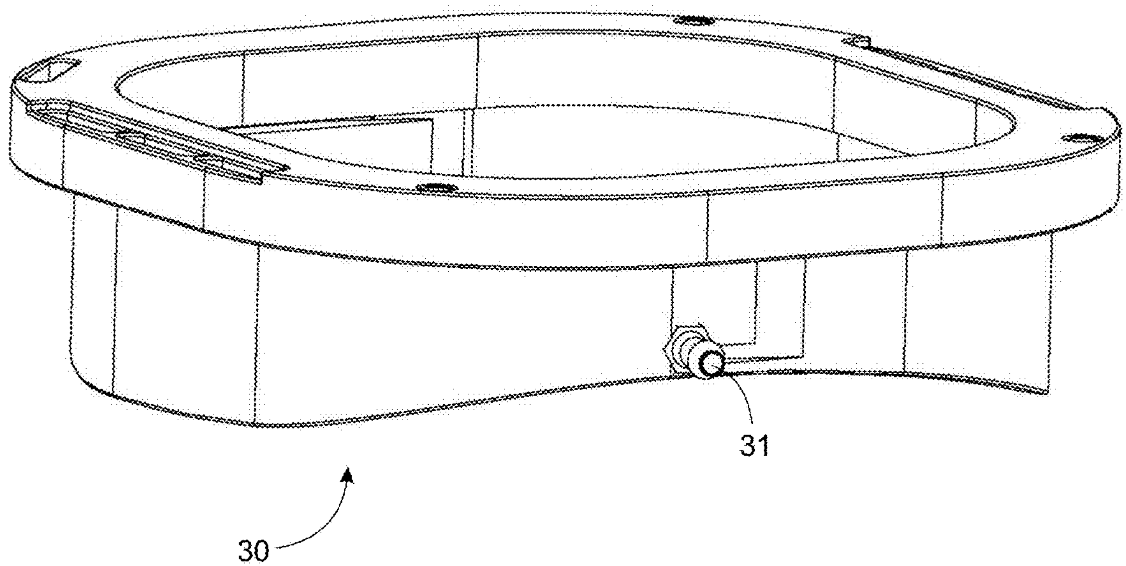

FIG. 8A

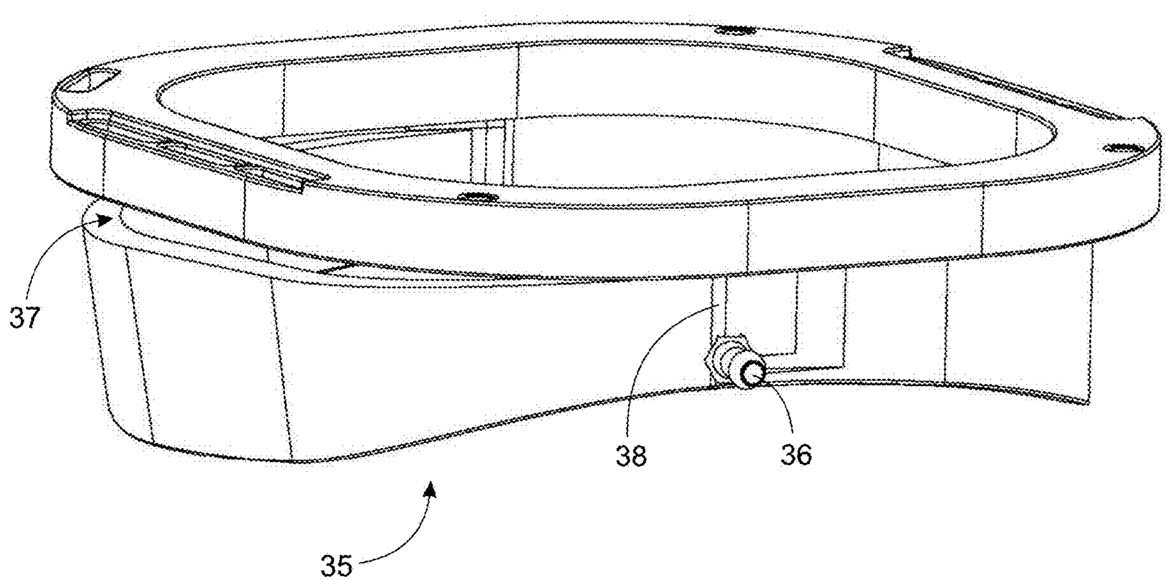

FIG. 8B

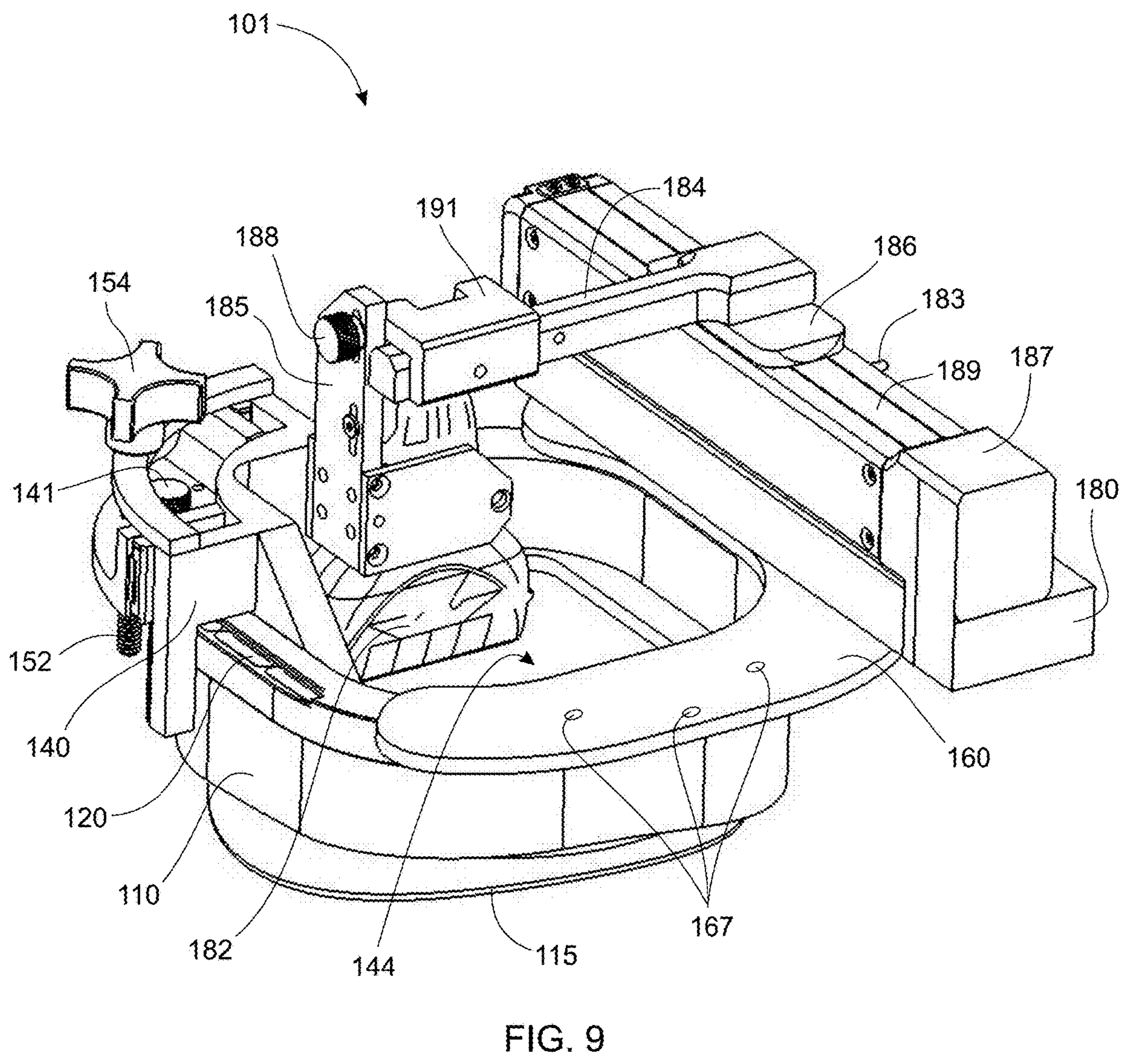
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FIG. 9

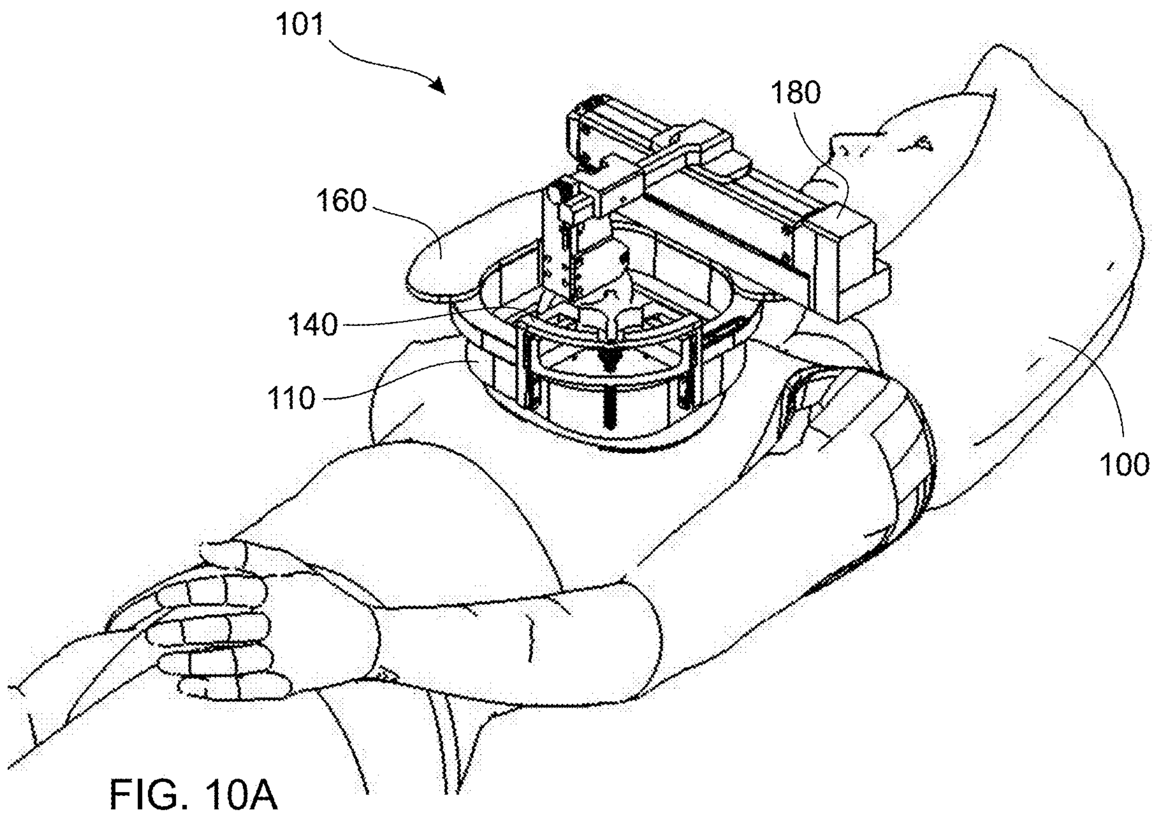

FIG. 10A

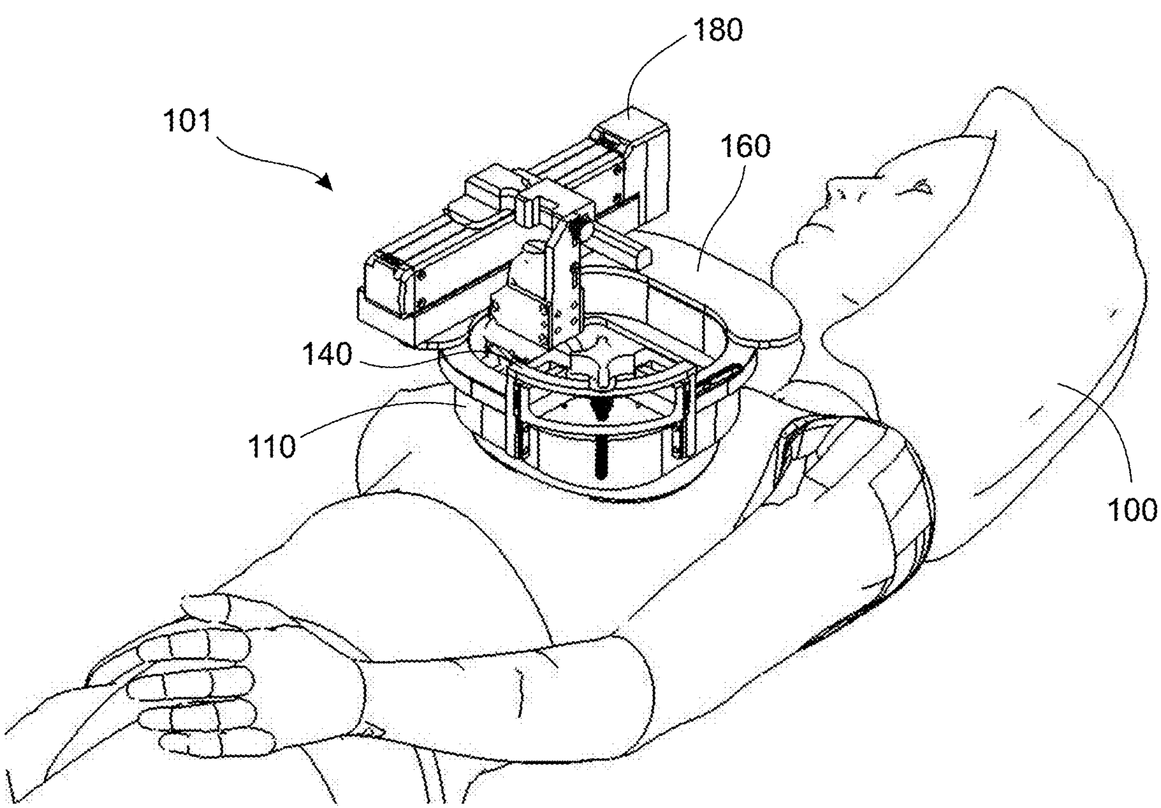

FIG. 10B

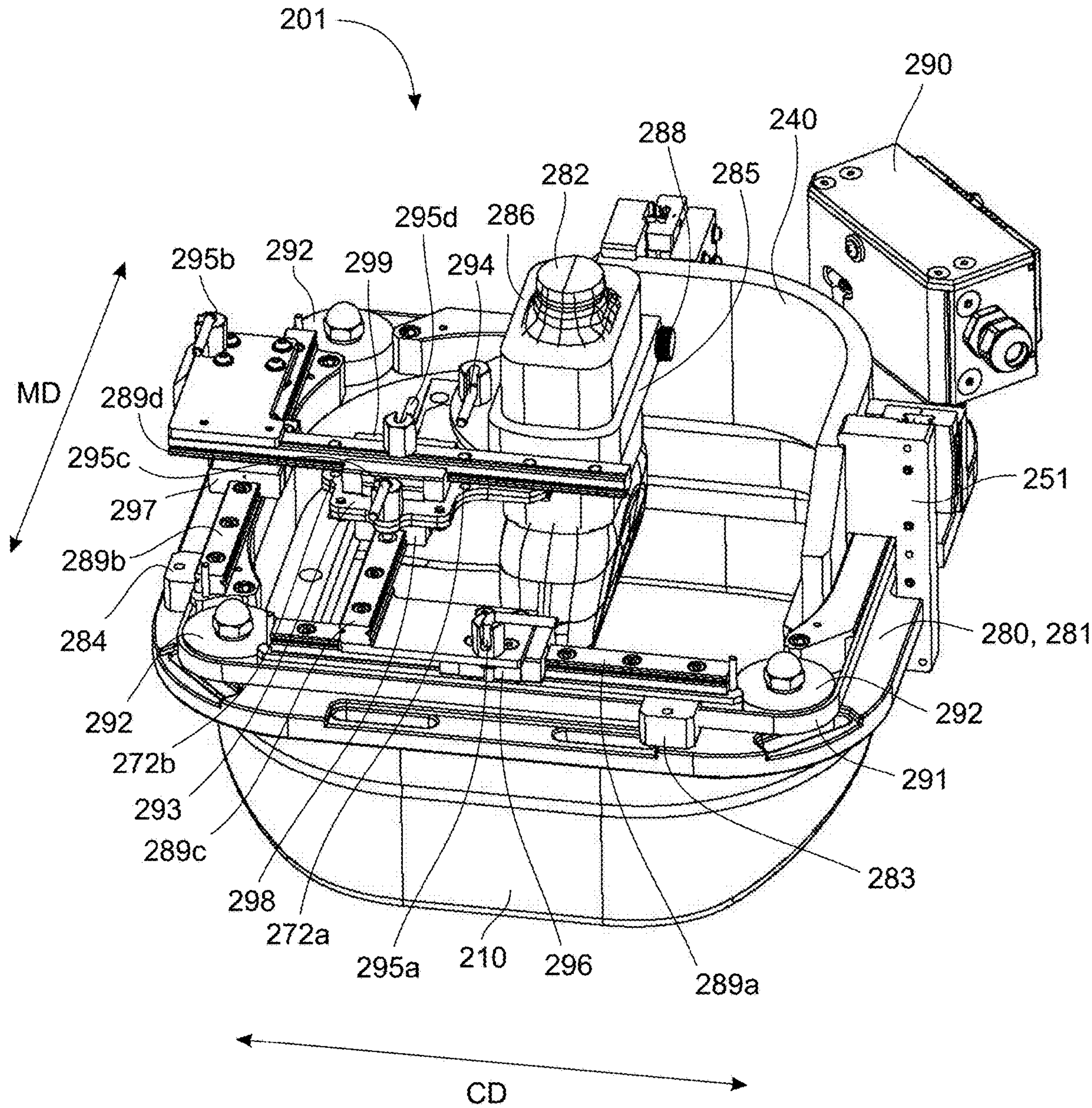
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FIG. 11A

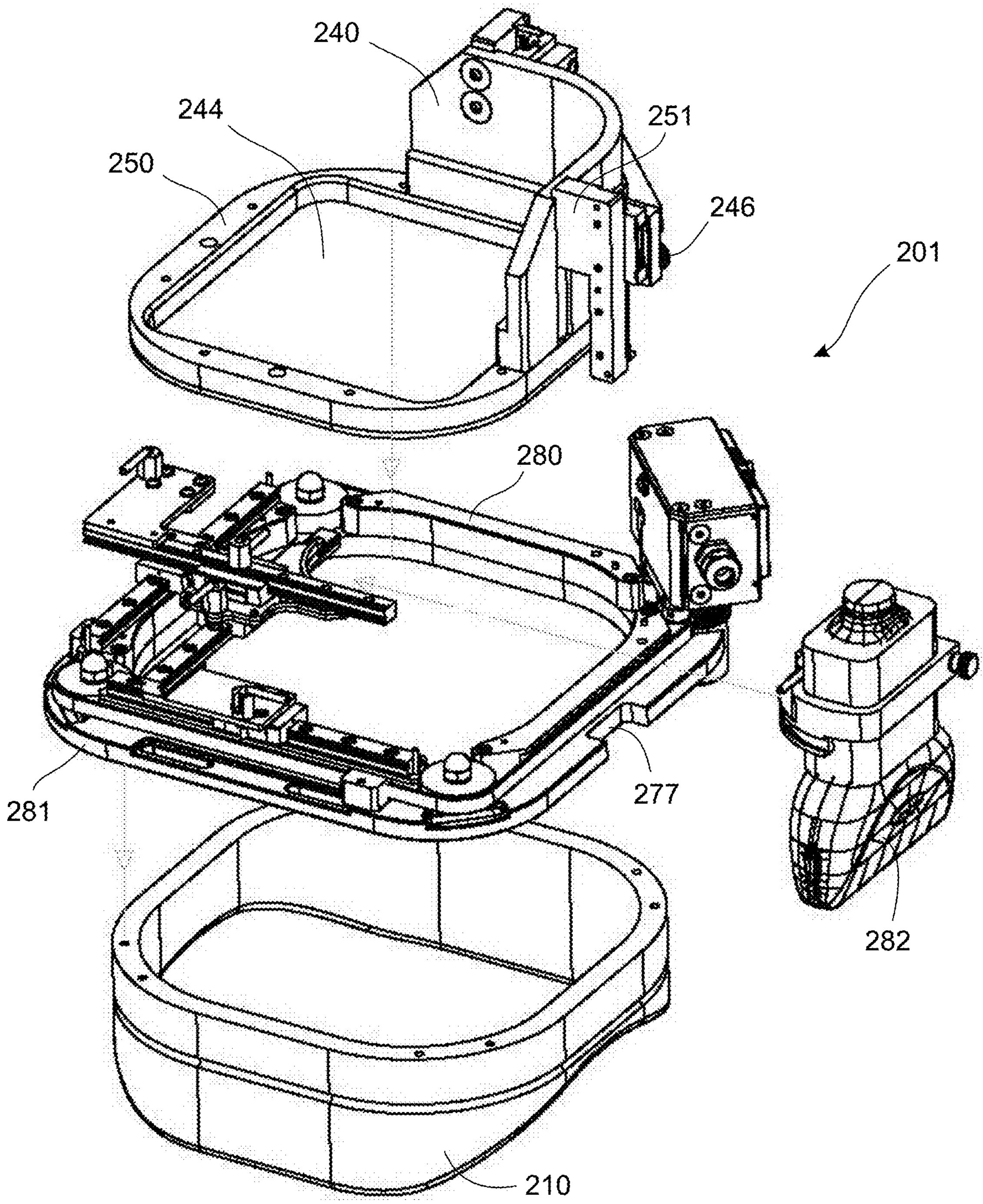

FIG. 11B

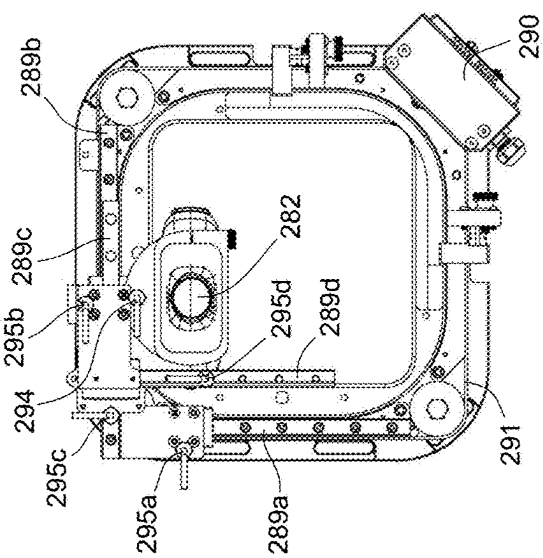

FIG. 12A

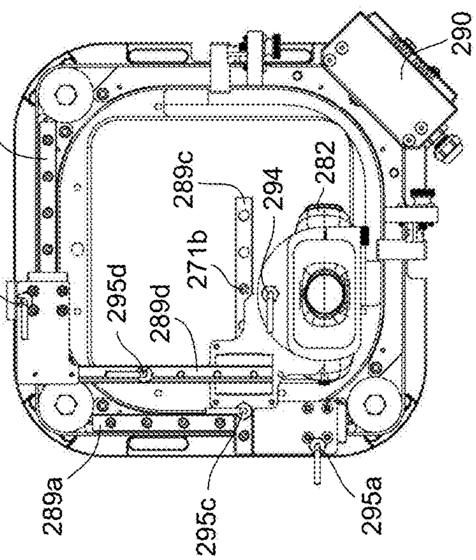

FIG. 12B

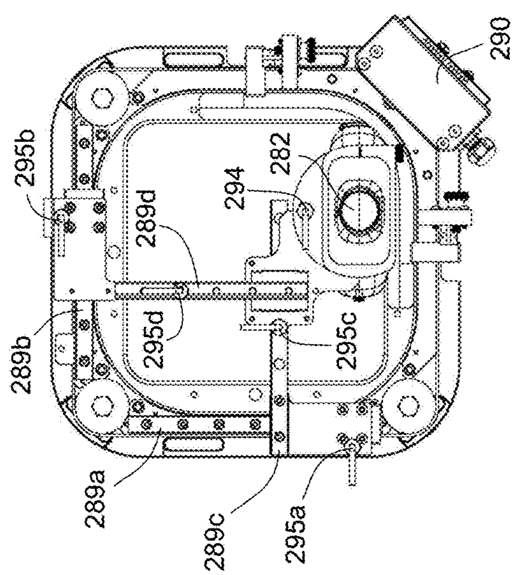

FIG. 12C

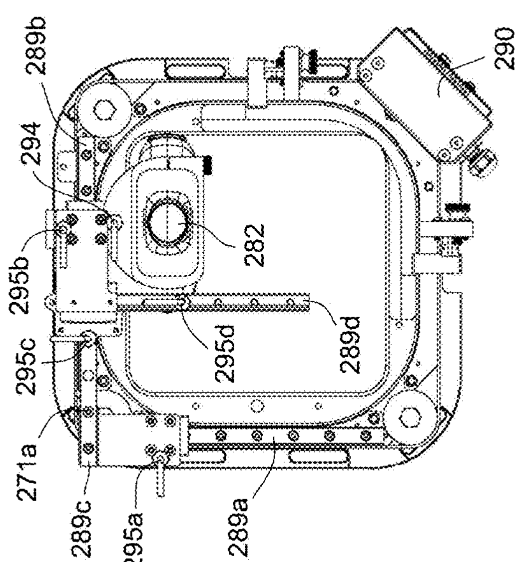

FIG. 12D

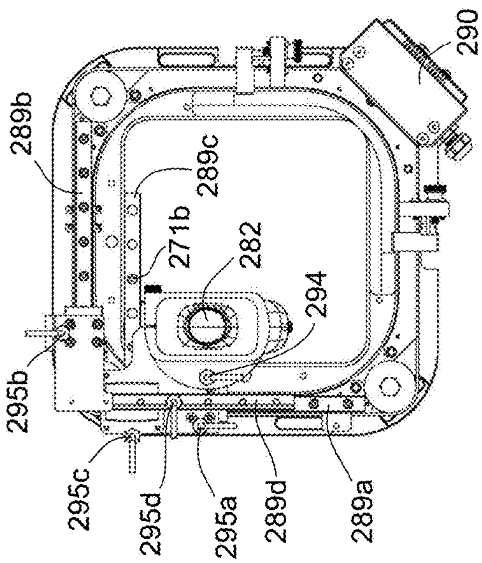

FIG. 13B

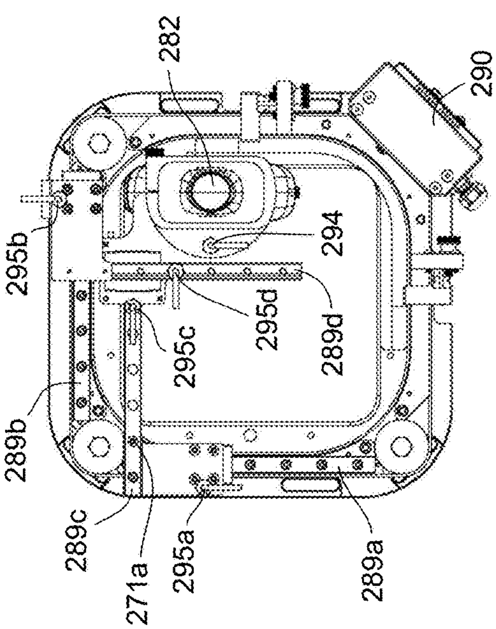

FIG. 13A

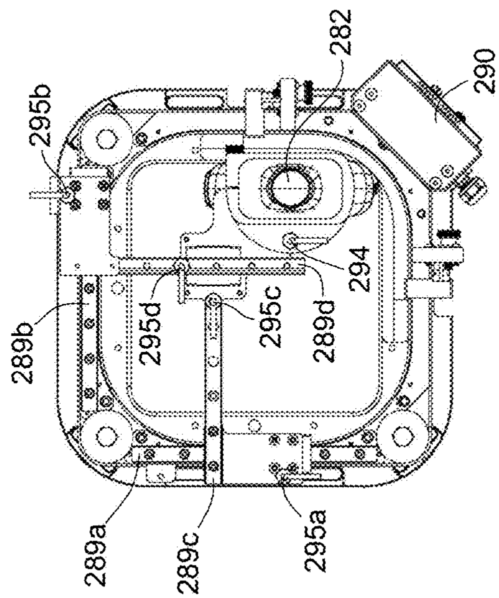

FIG. 13D

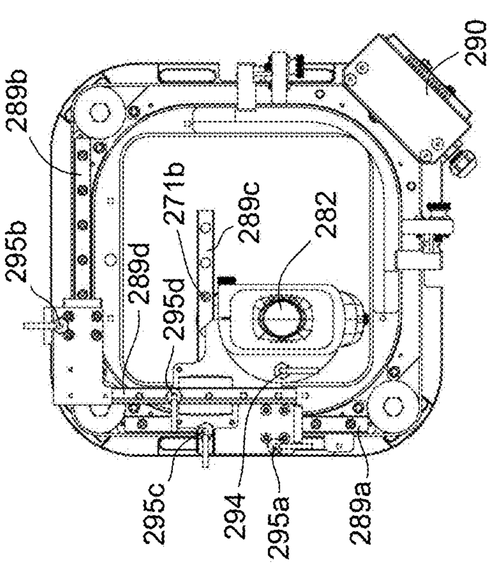

FIG. 13C

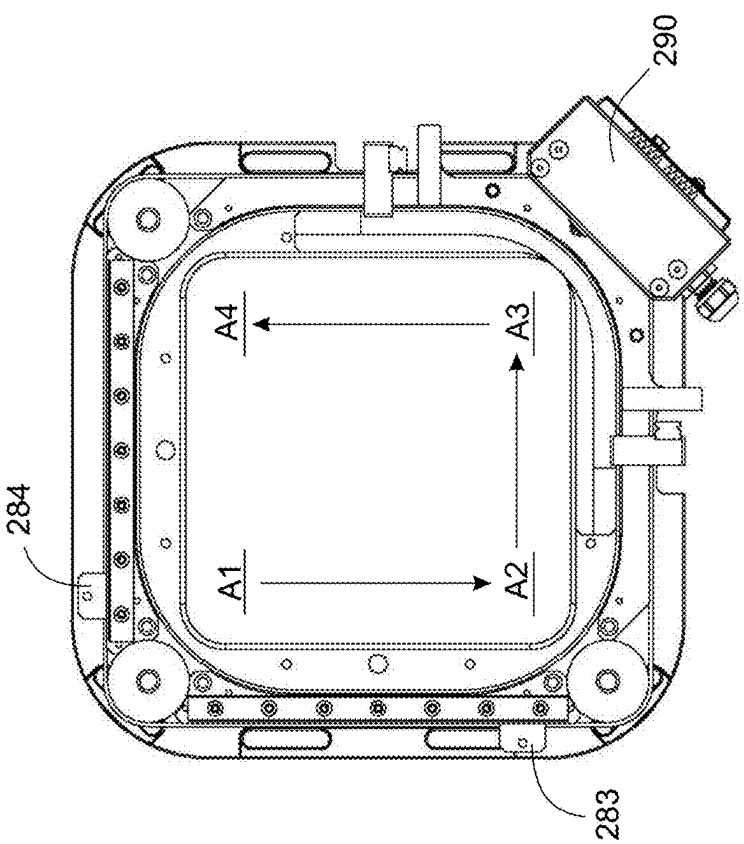

FIG. 14A

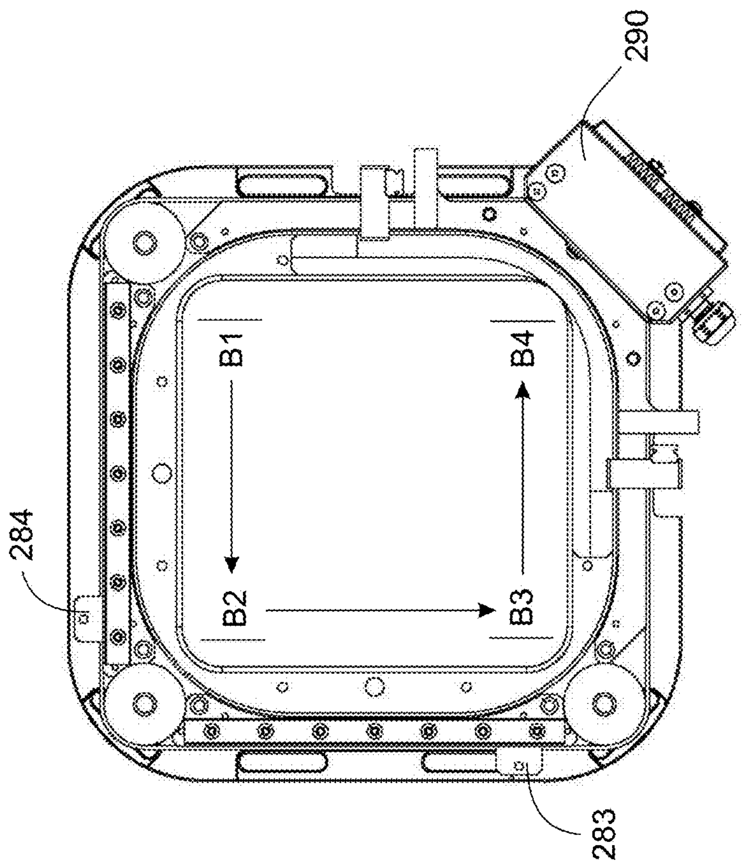

FIG. 14B

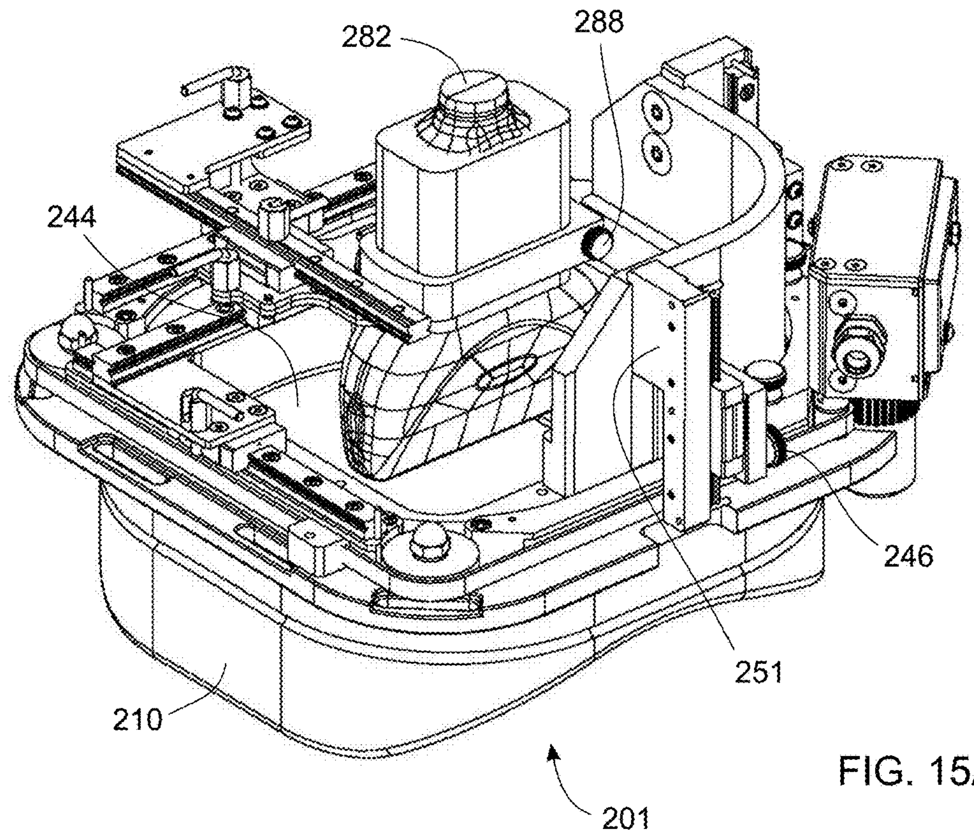

FIG. 15A

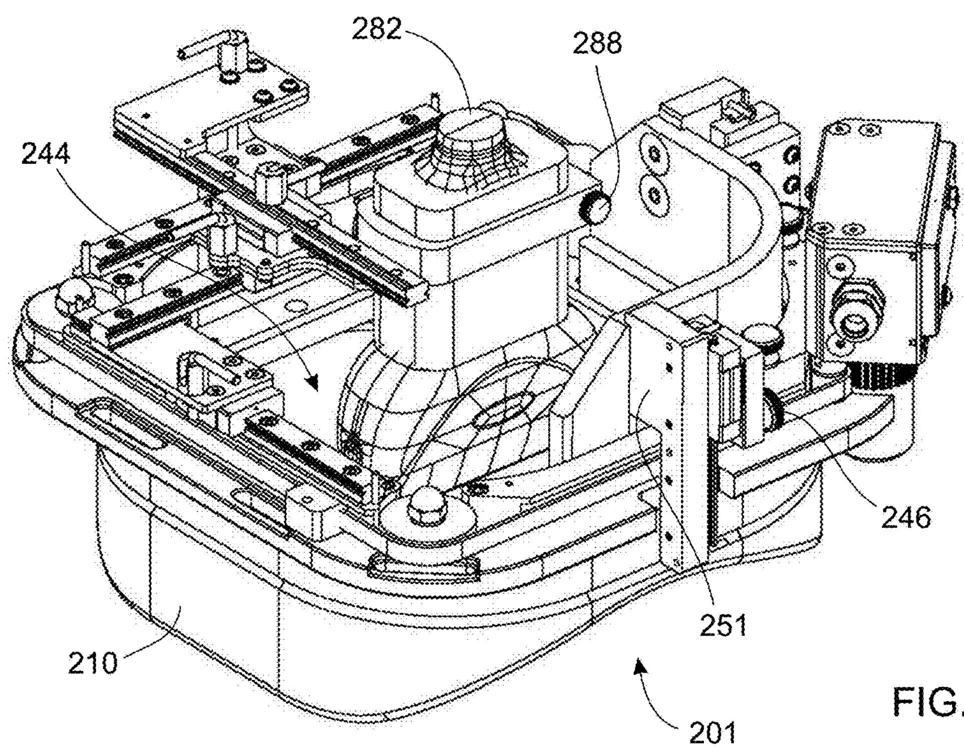

FIG. 15B

WEARABLE 3D ULTRASOUND-BASED WHOLE BREAST IMAGING SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. Ser. No. 18/136,926 filed Apr. 20, 2023, which claims the benefit of U.S. Provisional Patent Application 63/335,857 filed Apr. 28, 2022, the entire contents of both of which are herein incorporated by reference.

FIELD

[0002] This application relates to medical devices and methods, in particular to a wearable whole breast three-dimensional (3D) ultrasound imaging system.

BACKGROUND

[0003] Breast cancer is the leading cause of cancer incidence and cancer-related deaths in women worldwide. Widely employed mammographic screening methods for breast cancer have improved treatment outcomes and reduced mortality in this population through the early detection of breast cancer. However, the diagnostic sensitivity for detecting small, early-stage breast cancer is significantly reduced in women with dense (small) breasts. Furthermore, mammographic density (MD) alone has been established as a strong, independent risk factor for developing invasive breast cancer, with a four to six times increased risk in women with dense breasts. The complex dynamic between risk factors such as age, body mass index (BMI), reproductive factors, hormonal status, menopausal status, and increased mammographic density over time may further increase the uncertainty of breast cancer detection at the time of imaging. These variable uncertainties may increase the number of false-positive findings, resulting in unnecessary breast biopsy procedures and interventions. Additionally, under current mammographic screening recommendations, the associated exposure due to ionizing radiation may not be ideal for screening younger, high-risk women with dense breasts. Due to these aforementioned challenges, there is still an urgent need for improved screening methods in the intermediate to high-risk women with dense breasts.

[0004] 3D ultrasound (3D US) is one technique used for imaging whole breasts to screen for cancer. In some prior art approaches to 3D ultrasound, a subject is supine lying face up, and a mechanical arm holding an ultrasound transducer is deployed over the subject. The transducer is then swept across the surface of the breast. One issue with this approach is movement of the subject due to breathing causing blurry images and image artefacts. In another prior art approach, called the “pendulous” approach, a subject lies prone face down over a cavity in an imaging table with the breast hanging into the cavity. The cavity is filled with ultrasound transmission fluid, for example ultrasound gel or water, and an ultrasound transducer is manipulated over the exterior of the cavity from underneath the table. The image quality is not good in the pendulous approach, particularly for smaller, denser breasts.

[0005] Improving accessible, cost-effective methods for the early detection of breast cancer remains a challenge in development and clinical practice, particularly in the intermediate to high-risk population of women with dense breasts. Specifically, with supine detection systems, removing the need for medical cart-based systems and mechanical arms for automated scanning may provide a cost-effective, portable and hands-free whole-breast 3D ultrasound imaging technique. Furthermore, systems with the capability for bedside point-of-care (POC) imaging would be useful.

[0006] Thus, there remains a need for whole breast 3D ultrasound imaging systems, especially for dense breasts, which are cost-effective, portable and hands-free and can be used for bedside point-of-care imaging.

SUMMARY

[0007] A whole breast 3D ultrasound imaging system comprises: a wearable adapter subassembly comprising an annular wall for containing an ultrasound transmission fluid around a breast of a subject, the annular wall comprising a first edge configured to conform to a body surface around the breast of the subject to reduce leakage of the ultrasound fluid between the first edge and the body of the subject, and a second edge; a compression plate subassembly releasably mountable on the second edge of the wearable adapter subassembly, the compression plate subassembly comprising an ultrasound compression plate that is height adjustable relative to the wearable adapter subassembly; and, a motor plate subassembly releasably mountable on the wearable adapter subassembly, the motor plate subassembly comprising an ultrasound transducer movable on the motor plate subassembly in a plane parallel to the ultrasound compression plate.

[0008] In some embodiments, a whole breast 3D ultrasound imaging system comprises: a wearable adapter subassembly comprising an annular wall for containing an ultrasound transmission fluid around a breast of a subject, the annular wall comprising a first edge configured to conform to a body surface around the breast of the subject to reduce leakage of the ultrasound fluid between the first edge and the body of the subject, and a second edge; a compression plate subassembly releasably mountable on the second edge of the wearable adapter subassembly, the compression plate subassembly comprising a securement portion configured to be releasably secured to the second edge of the annular wall of the wearable adapter, and a frame with an ultrasound compression plate mounted to the frame, whereby the ultrasound compression plate is height adjustable relative to the securement portion; and, a motor plate subassembly releasably mountable on the compression plate subassembly so that the compression plate subassembly is between the wearable adapter subassembly and the motor plate subassembly, the motor plate subassembly comprising an ultrasound transducer movably mounted thereon, and an actuator operatively coupled to the ultrasound transducer to translate the ultrasound transducer in a plane parallel to the ultrasound compression plate.

[0009] The whole breast 3D ultrasound imaging system is cost-effective, portable and hands-free and can be used for bedside point-of-care imaging. The whole breast 3D ultrasound imaging system is particularly useful for acquiring clear, sharp 3D ultrasound images of dense and/or small breasts. The whole breast 3D ultrasound imaging system provides for a wearable device in which a conventional hand-held 3D ultrasound transducer or a motorized sweeping assembly with a 2D ultrasound transducer moves with the subject while the subject is breathing resulting in clearer 3D ultrasound images, while facilitating scanning with the ultrasound transducer over a surface of a conventional ultrasound compression plate. The imaging system is further provided with hardware and software to capture and store the relative 3D position and orientation of multiple 3D ultrasound images, or 2D ultrasound images in the case of a 2D ultrasound transducer on the motorized sweeping assembly, for reconstruction in a single volume for increased image size and/or resolution.

[0010] In some embodiments, the wearable adapter subassembly comprises a flexible gasket on the first edge to assist with conforming the first edge to the body surface of the subject. In some embodiments, the wearable adapter subassembly comprises a hinge permitting the annular wall to flex to assist with conforming the first edge to the body surface of the subject. In some embodiments, the wearable adapter subassembly further comprises a flexible membrane covering an open face thereof. The flexible membrane is preferably deformable by the breast when the breast is housed within the wearable adapter subassembly to prevent the breast from directly contacting the ultrasound transmission fluid within the wearable adapter subassembly, although a small amount of ultrasound fluid may be required to couple the subject to the flexible membrane. In some embodiments, the wearable adapter subassembly comprises a fastener for fastening the wearable adapter subassembly to the subject.

[0011] In some embodiments, the frame comprises mounting bolts secured thereon. In some embodiments, the mounting bolts engage the securement portion to connect the frame to the securement portion. In some embodiments, at least one of the mounting bolts is rotatable in a threaded aperture in the securement portion to cause the frame and the ultrasound compression plate to move relative to the securement portion when the securement portion is secured to the wearable adapter subassembly. In some embodiments, the securement portion comprises mounting screws that are threadingly mated with corresponding threaded mounting apertures in the second edge of the wearable adapter subassembly to releasably secure the compression plate subassembly to the wearable adapter subassembly.

[0012] In some embodiments, the motor plate subassembly is mountable on the frame and moves with the compression plate during height adjustment of the compression plate. In some embodiments, the motor plate subassembly is mountable on the compression plate subassembly with mounting pins inserted in locating apertures. In some embodiments, the frame comprises mounting pins and the motor plate subassembly comprises a mounting plate having locating apertures therein, the locating apertures aligning with the mounting pins so that the motor plate subassembly is mountable on the frame by insertion of the mounting pins into the locating apertures. In some embodiments, the mounting pins and the locating apertures are configured so that the motor plate subassembly can be rotated 90° and still be mountable on the mounting pins.

[0013] In some embodiments, the motor plate subassembly comprises a plurality of rails on which the ultrasound transducer is mountable. In some embodiments, the plurality of rails comprises one or more fixed rails. In some embodiments, the plurality of rails comprises one or more translatable rails. In some embodiments, the fixed rails comprise a first fixed rail orthogonal to a second fixed rail. In some embodiments, the translatable rails comprise a first translatable rail orthogonal to a second translatable rail. In some embodiments, one of the fixed rails extends in a craniocaudal direction and another of the fixed rails extends in a mediolateral direction, with respect to the breast when the imaging system is in use. In some embodiments, one of the translatable rails extends in a craniocaudal direction and another of the translatable rails extends in a mediolateral direction, with respect to the breast when the imaging system is in use. In some embodiments, the motor plate subassembly comprises a motor operatively connected to the one or more translatable rails, whereby operation of the motor causes translation of at least one of the one or more translatable rails. In some embodiments, the motor operatively connected to the one or more translatable rails through a timing belt (e.g., a chain or a strap) driven by a motor to translate the one or more translatable rails. However, other operative linkages such as gears may be used. In some embodiments, the motor plate subassembly comprises one or more quick-release mechanisms (e.g., spring-loaded pins, clamps, hooks and the like) to prevent or allow translation of the one or more translatable rails and/or rotation of the ultrasound transducer.

[0014] The plurality of rails allows a user to scan in two orthogonal directions without removing the entire motor plate subassembly during scanning. To save time and eliminate the need to remove and reposition the entire motor plate subassembly at **90** degrees for a second scan set, the timing belt may be situated to encircle a perimeter of the wearable adapter subassembly. Incorporation of the one or more quick-release mechanisms permits changing orientation of and direction of travel of the ultrasound transducer. In some embodiments, the ultrasound transducer is rotatable to change the orientation of the ultrasound transducer between the craniocaudal direction and the mediolateral direction. In some embodiments, the ultrasound transducer is translatable in the craniocaudal and mediolateral directions by virtue of the being mountable on the translatable rails. Selective engagement of the one or more quick-release mechanisms determines the direction in which the translatable rails, and therefore the ultrasound transducer, moves. Thus, the motor plate subassembly only needs to be dismounted between patients who require a different wearable adapter subassembly to accommodate varying patient breast geometry (e.g., cup sizes).

[0015] Further features will be described or will become apparent in the course of the following detailed description. It should be understood that each feature described herein may be utilized in any combination with any one or more of the other described features, and that each feature does not necessarily rely on the presence of another feature except where evident to one of skill in the art.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] For clearer understanding, preferred embodiments will now be described in detail by way of example, with reference to the accompanying drawings, in which:

[0017] FIG. **1** depicts an exploded view of a whole breast 3D ultrasound imaging system.

[0018] FIG. **2**A depicts a rigid wearable adapter subassembly of the imaging system of FIG. **1**.

[0019] FIG. **2**B depicts a perspective view of a compression plate subassembly of the imaging system of FIG. **1**.

[0020] FIG. **2**C depicts a perspective view of a motor plate subassembly of the imaging system of FIG. **1**.

[0021] FIG. **3**A depicts a subject having the imaging system of FIG. **1** mounted on the subject's left breast, and the compression plate subassembly of FIG. **2**B with the wearable adapter subassembly of FIG. **2**A mounted on the subject's right breast.

[0022] FIG. **3**B depicts the imaging system of FIG. **1** mounted on the subject's left breast with the compression plate subassembly in an up configuration.

[0023] FIG. **3**C depicts the imaging system of FIG. **1** mounted on the subject's left breast with the compression plate subassembly in a down configuration.

[0024] FIG. **4**A depicts a subject having the imaging system of FIG. **1** mounted on the subject's left breast with the motor plate subassembly oriented as shown in FIG. **3**B.

[0025] FIG. **4**B depicts a similar view as FIG. **4**A except that the motor plate subassembly is oriented at 90° to the orientation shown in FIG. **4**A.

[0026] FIG. **5**A depicts the motor plate and compression plate subassemblies showing pins and matching apertures for orienting the motor plate subassembly as shown in FIG. **4**A.

[0027] FIG. **5**B depicts the motor plate and compression plate subassemblies showing pins and matching apertures for orienting the motor plate subassembly as shown in FIG. **4**B.

[0028] FIG. **6**A depicts the imaging system with an ultrasound transducer configured in a non-tilted position.

[0029] FIG. **6**B depicts the imaging system with an ultrasound transducer configured in a tilted position.

[0030] FIG. **7**A, FIG. **7**B, FIG. **7**C and FIG. **7**D illustrate four different positions of an ultrasound transducer on the motor plate subassembly when the imaging system of FIG. **1** is used to acquire ultrasound images.

[0031] FIG. **8**A depicts a rigid wearable adapter subassembly design for the imaging system.

[0032] FIG. **8**B depicts a flexible wearable adapter subassembly design for the imaging system.

[0033] FIG. **9** depicts another embodiment of a whole breast 3D ultrasound imaging system.

[0034] FIG. **10**A depicts the imaging system of FIG. **9** mounted on a left breast of a subject.

[0035] FIG. **10**B depicts a similar view as FIG. **10**A except that a motor plate subassembly is oriented at 90° to the orientation shown in FIG. **10**A.

[0036] FIG. **11**A depicts another embodiment of a whole breast 3D ultrasound imaging system.

[0037] FIG. **11**B depicts an exploded view of FIG. **11**A.

[0038] FIG. **12**A, FIG. **12**B, FIG. **12**C and FIG. **12**D depict a series of top views of the whole breast 3D ultrasound imaging system of FIG. **11**A showing how an ultrasound transducer is translated in a craniocaudal direction during a scan.

[0039] FIG. **13**A, FIG. **13**B, FIG. **13**C and FIG. **13**D depict a series of top views of the whole breast 3D ultrasound imaging system of FIG. **11**A showing how an ultrasound transducer is translated in a mediolateral direction during a scan.

[0040] FIG. **14**A and FIG. **14**B illustrate schematically how multiple scans can be created with the whole breast 3D ultrasound imaging system of FIG. **11**A.

[0041] FIG. **15**A depicts the whole breast 3D ultrasound imaging system of FIG. **11**A with a compression plate and an ultrasound transducer in a raised position.

[0042] FIG. **15**B depicts the whole breast 3D ultrasound imaging system of FIG. **11**A with a compression plate and an ultrasound transducer in a lowered position.

DETAILED DESCRIPTION

[0043] With reference to the Figures, a whole breast 3D ultrasound imaging system **1** comprises three subassemblies including a wearable adapter subassembly **10**, a compression plate subassembly **40** and a motor plate subassembly **80** releasably stackable on each other with the compression plate subassembly **40** between the wearable adapter subassembly **10** and the motor plate subassembly **80**. The ultrasound imaging system **1** is particularly useful for capturing images of a breast of a supine subject **100** where the wearable adapter subassembly **10** is in contact with the subject and the compression plate subassembly **40** and the motor plate subassembly **80** are stacked on the wearable adapter subassembly **10** with the wearable adapter subassembly **10** at a bottom of the stack and the motor plate subassembly **80** at a top of the stack.

[0044] With reference to FIG. **2**A, the wearable adapter subassembly **10** comprises an annular wall **12** forming a hollow ring having opposed lower and upper open faces, the annular wall **12** defining a volume for containing ultrasound transmission fluid (e.g., ultrasound gel) around a breast of a subject during operation of the ultrasound imaging system **1**. During operation of the ultrasound imaging system **1**, the breast of the subjects is housed within the annular wall **12**. Thus, the wearable adapter **10** acts as a dam for containing ultrasound transmission fluid around the breast of the subject. The annular wall **12** comprises a lower edge **14** and an upper edge **16**, the upper edge **16** having a lip **18** that overhangs the annular wall **12** toward an outside of the wearable adapter subassembly **10**. The lower edge **14** is configured to conform to a body surface around the breast of the subject to reduce leakage of the ultrasound transmission fluid between the lower edge **14** and the body of the subject **100**. The lower edge **14** is thus shaped to follow contours of the subject's body in a region around the subject's breast. To facilitate sealing the lower edge **14** to the subject's body, the lower edge **14** is provided with a compressible gasket **15** (e.g., silicone tubing or other elastomeric material), which forms a better seal with skin.

[0045] The upper edge **16** is flat and has features for mounting additional structures thereon. The lip **18** of the upper edge **16** comprises slots **20** on opposite sides of the wearable adapter subassembly **10**, in which adjustable straps **19** are accommodated to be able to strap the wearable adapter subassembly **10** to the subject **100**. Being able to strap the wearable adapter subassembly **10** to the subjects makes the ultrasound imaging system **1** wearable and further helps seal the wearable adapter subassembly **10** to the skin of the subject **100**. The upper edge **16** further comprises mounting apertures **22** therein that align with and receive mounting screws **41** on the compression plate subassembly **40** for securely but releasably mounting the compression plate subassembly **40** on the wearable adapter subassembly **10**. The mounting apertures **22** are threaded and the mounting screws on the compression plate subassembly **40** are matingly threaded to be able to secure the compression plate subassembly **40** on the wearable adapter subassembly **10**. The upper edge **16** further comprises an index slot **24** that helps align the mounting apertures **22** of the wearable adapter subassembly **10** with the mounting screws **41** of the compression plate subassembly **40** to be able to mount the compression plate subassembly **40** on the wearable adapter subassembly **10** in the proper orientation. The index slot **24**

can also accommodate the adjustable straps **19** to further facilitate strapping the wearable adapter subassembly **10** to the subject **100**.

[0046] In some embodiments, the wearable adapter subassembly **10** further comprises a flexible membrane covering the lower open face, which is deformable by the breast when the breast is housed within the annular wall **12**. The membrane conforms to the breast to prevent the breast from directly contacting the ultrasound transmission fluid, which simplifies clean-up and permits re-use of most of the ultrasound transmission fluid.

[0047] With reference to FIG. **8**A and FIG. **8**B, variations of the wearable adapter subassembly are illustrated. In one variation, the wearable adapter subassembly is a rigid wearable adapter subassembly **30** having a fluid port **31** in the annular wall. The fluid port **31** permits draining the ultrasound transmission fluid in a controlled manner after the ultrasound imaging operation is completed. In another variation, the wearable adapter subassembly is a flexible wearable adapter subassembly **35** having a fluid port **36** in the annular wall and both a transverse cut **37** proximate the upper edge below the lip running about halfway along the annular wall and a longitudinal cut **38** running down the annular wall from an end of the transverse cut **37** to the fluid port **36** to form a flexible hinge that permits the annular wall to flex at the fluid port **36**. The flexible hinge facilitates conforming the lower edge of the flexible wearable adapter subassembly **35** to the body surface of the subject. The fluid port **36** may be used to drain unwanted ultrasound transmission fluid from the wearable adapter subassembly **35**.

[0048] With reference to FIG. **2**B, the compression plate subassembly **40** comprises a securement portion **45** and an upper frame **50** height adjustably mounted on the securement portion **45** so that the securement portion **45** is between the wearable adapter subassembly **10** and the upper frame **50** when the compression plate subassembly **40** is mounted on the wearable adapter subassembly **10**. The securement portion **45** is releasably mounted on and secured to the upper edge **16** of the wearable adapter subassembly **10** by the mounting screws **41** (only one shown) mounted in the securement portion **45** and insertable into the mounting apertures **22** in the upper edge **16** of the wearable adapter subassembly **10**. To releasably secure the securement portion **45**, and therefore the entire compression plate subassembly **40**, to the wearable adapter subassembly **10**, the mounting screws **41** are threadingly mated with the corresponding threaded mounting apertures **22** and can be screwed into the threaded mounting apertures **22** by operation of knurled knobs **42** attached to the mounting screws **41**. The securement portion **45** comprises connected frame elements that bound an opening **43** through which an ultrasound compression plate **44** can move. The compression plate **44** is rigidly connected ultimately to the upper frame **50**, the upper frame **50** being the same general size and shape as the securement portion **45** and situated above the securement portion **45**. To connect the ultrasound compression plate **44** to the upper frame **50**, the upper frame **50** is rigidly connected to mounting posts **48**, which extend downwardly to, and are rigidly connected to, a window frame **47**. The window frame **47** is a square frame with rounded corners, the window frame **47** being smaller than the upper frame **50**. The ultrasound compression plate **44** is rigidly connected to the window frame **47** below the window frame **47**. The ultrasound compression plate **44** and the window frame **47** are sized to fit within the confines of the annular wall **12** of the wearable adapter subassembly **10**. The compression plate **44**, window frame **47**, mounting posts **48** and upper frame **50** form a single rigid part. The window frame **47** forms a seal with an inside surface of the annular wall **12** by minimizing, without closing, an air gap between the inside surface of the annular wall **12** and an outside surface of the window frame **47** to inhibit leakage of the ultrasound transmission fluid between the wearable adapter subassembly **10** and the compression plate subassembly **40** when the compression plate **44** presses down toward or on the breast of the subject **100**. The small air gap between annular wall **12** and the window frame **47** allows air bubbles to escape from the wearable adapter subassembly **10** but prevents the ultrasound transmission fluid from escaping due to large friction forces created from the relatively large viscosity of the ultrasound transmission fluid being forced through a small air gap compared to air which can flow freely through the small air gap.

[0049] The ultrasound compression plate **44**, for example a TPX plate (made from a 4-methylpentene-1-based polyolefin plastic), is ultimately mounted to and underneath the upper frame **50**. The ultrasound compression plate **44** together with the window frame **47** move with the upper frame **50** during height adjustment of the upper frame **50**. Height adjustment of the upper frame **50** relative to the securement portion **45** is accomplished with threaded mounting bolts **52**. The threaded mounting bolts **52** are mounted in bores through the upper frame **50**, upper ends of the mounting bolts **52** having grooved bolt heads **54** seated in the bores. The mounting bolts **52** extend out a bottom of the upper frame **50** through corresponding threaded holes in the securement portion **45** and through lockable bosses **46** on a lower face of the securement portion **45**. The lockable bosses **46** can be loosened to permit height adjustability of the upper frame **50** or tightened to secure the upper frame **50** in position relative to the securement portion **45**. Mounted on the mounting bolts **52** between the securement portion **45** and the upper frame **50** are lockable stops **56** to hold the mounting bolts **52** in place in the upper frame **50**. One of the bolt heads **54** is an adjustment knob **54***a*, whereby all of the bolt heads **54**, are mechanically linked to each other via a timing belt (not shown) located in a groove **49** in an inner face of the upper frame **50**, the timing belt operatively linking the grooved bolt heads **54**, including the knob **54***a*. When the lockable bosses **46** are loosened, rotation of the adjustment knob **54***a* causes the mounting bolt (not shown) and all of the other mounting bolts **52** connected to the adjustment knob **54***a* via the timing belt to turn in the corresponding threaded holes thereby causing the upper frame **50** to move up and down relative to the securement portion **45**. In use, height adjustment of the upper frame **50** is adjusted so that the compression plate **44** compresses the ultrasound transmission fluid slightly in order to cause the transmission fluid to flow and fill any voids around the breast, thereby ensuring that the compression plate **44** continuously engages either the breast or the ultrasound transmission fluid. A flat scanning surface in “sonic engagement” with the breast is thereby achieved.

[0050] The compression plate subassembly **40** further comprises mounting pins **57** extending from an upper surface of the upper frame **50**. The mounting pins **57** permit releasably mounting of the motor plate subassembly **80** on the compression plate subassembly **40**.

[0051] With reference to FIG. **2**C, the motor plate subassembly **80** comprises a mounting plate **81** on which an ultrasound transducer **82** is mounted. The motor plate subassembly **80** is releasably mountable on the compression plate subassembly **40** by virtue of locating apertures **83** (only three of four shown) in the mounting plate **81**, which are positioned to align with at least two of the mounting pins **57** on the frame **50** of the compression plate subassembly **40**. The motor plate subassembly **80** can be simply placed on and lifted off the mounting pins **57** to permit changing the orientation of the the motor plate subassembly **80** by 90° or 180°.

[0052] The mounting plate **81** comprises a large through-aperture **84** within which the ultrasound transducer **82** is situated and through which the ultrasound transducer **82** extends to contact the ultrasound compression plate **44** when the motor plate subassembly **80** is mounted on the compression plate subassembly **40**. The ultrasound transducer **82** is mounted on a mounting bracket **85**, which is mounted on a cradle **86**. The cradle **86** is slidingly mounted on a carriage **87**. The carriage **87** is slidingly mounted on rails **89**, the rails **89** fixed to an upper surface of the mounting plate **81**. The carriage **87** is operatively connected to an actuator comprising a motor **90** and a threaded drive rod **91** extending through a matingly threaded through-aperture in the carriage **87**. The drive rod **91** is rotatably connected to a drive shaft of the motor **90** through appropriate gears or other linkages. Operation of the motor **90** rotates the threaded drive rod **91** in the matingly threaded through-aperture of the carriage **87** thereby driving the carriage **87** linearly along the rails **89** between opposed sides **94***a* and **94***b* of the motor plate subassembly **80**. The cradle **86** is manually slidable linearly on the carriage **87** between opposed sides **93***a* and **93***b* of the motor plate subassembly **80**. Thus, linear motion of the carriage **87** on the rails **89** is perpendicular to linear motion of the cradle **86** on the carriage **87**.

[0053] Therefore, the ultrasound transducer **82** can be driven automatically by the motor to perform a sweep along a first sweep axis, and can be moved manually transversely to the first sweep axis so that the ultrasound transducer **82** can be automatically driven along a second sweep axis parallel to the first sweep axis in order to image more of the breast. Thus, the motor **90** is used to sweep the ultrasound transducer **82** linearly across the the compression plate **44** in a direction perpendicular to a long dimension of the ultrasound transducer **82** and acquire a first 3D image that is rectangular in plan view. To acquire an image of a larger area, the ultrasound transducer **82** is manually re-positioned laterally on the carriage **87** to acquire a second 3D image, and the second image can be stitched together with the first image.

[0054] The ultrasound transducer **82** is mounted on the mounting bracket **85** by a height adjusting fitting **88** comprising a tightenable bolt disposed through a slot in the mounting bracket **85**. Loosening the bolt permits the ultrasound transducer **82** to be raised and lowered relative to the mounting plate **81**. While this could be useful, it is a particular advantage of the ultrasound imaging system **1** that a height of the ultrasound transducer **82** itself does not need to be adjusted to contact the compression plate **44** during operation of the ultrasound imaging system **1** because the entire motor plate subassembly **80** moves up and down in tandem with the compression plate **44** by virtue of being mounted on the upper frame **50** of the compression plate subassembly **40**. The height adjustable upper frame **50** has a structurally defined depth between the compression plate **44** and the upper surface of the upper frame **50** so that, when the ultrasound transducer **82** is mounted on the cradle **86**, the ultrasound transducer **82** engages the surface of the compression plate **44** and is at 90° (i.e., perpendicular) to the compression plate **44**.

[0055] The ultrasound imaging system **1** has a number of advantages arising from the system's modularity and portability.

[0056] With reference to FIG. **3**A, the subject **100** can wear on one breast (e.g., the right breast), the wearable adapter assembly **10** with the compression plate subassembly **40** secured thereon at the same time as wearing the entire ultrasound imaging system **1** on the other breast (e.g., the left breast). After finishing ultrasound imaging on one breast, the motor plate assembly can be quickly lifted off the compression plate subassembly **40** over that breast and placed on the compression plate subassembly **40** over the other breast, thereby speeding up overall workflow when imaging two breasts.

[0057] With reference to FIG. **3**B and FIG. **3**C, the height adjustability of the upper frame **50** of the compression plate subassembly **40** between a raised position (FIG. **3**B) and a lowered position (FIG. **3**C) permits accommodating different breast sizes and fine tuning the position of the compression plate **44** without needing to do anything except turn the adjustment knob **54***a* and preferably the lock the lockable bosses **46** once the desired position of the compression plate **44** is attained. For a portable system, such a feature avoids time-consuming reconfiguration of the components.

[0058] With reference to FIG. **4**A, FIG. **4**B, FIG. **5**A and FIG. **5**B, the orientation, in plan view, of the motor plate subassembly **80** on the compression plate subassembly **40** can be changed quickly and simply by just lifting the motor plate subassembly **80** off the compression plate subassembly **40**, turning the motor plate subassembly **80** 90° and setting the motor plate subassembly **80** back on the compression plate subassembly **40** as permitted by the modular design of the ultrasound imaging system **1** and the design of the locating apertures **83** and the mounting pins **57**. Being able to change the orientation of the motor plate subassembly **80** on the compression plate subassembly **40** by 90° permits sweeping the ultrasound transducer **82** in a perpendicular direction. Thus, scans of a target volume can be taken in a first direction (e.g., head to toe direction), then, following angular re-positioning of the motor plate subassembly **80**, in a second direction (e.g., left to right). Further, because the motor plate subassembly **80** is separable from the compression plate subassembly **40**, the ultrasound transducer **82** can be positioned at any desired angle relative to compression plate subassembly **40** by providing a suitably indexable structure. For example, in an alternative embodiment, the mounting pins **57** can be replaced by an arcuate track that allows the motor plate subassembly **80** to be rotated (as seen in plan view) relative to the compression plate subassembly **57** and locked at any desired angle relative to the compression plate subassembly **57**.

[0059] With reference to FIG. **6**A and FIG. **6**B, the ultrasound transducer **82** can also be tilted from an orientation where a longitudinal axis of the ultrasound transducer **82** is in a vertical orientation (FIG. **6**A) into an orientation where the longitudinal axis of the ultrasound transducer **82** is in a non-vertical orientation (FIG. **6**B). By loosening the tightenable bolt of the height adjusting fitting **88** and loosening a tightenable bolt of a tilt adjusting fitting **95**, the mounting bracket **85**, and the ultrasound transducer **82** mounted thereon, can be tilted with a bottom thereof moving up out of the plane of the sheet as illustrated in FIG. **6**B. Once the desired tilt is achieved, the two tightenable bolts are re-tightened.

[0060] With reference to FIG. **7**A, FIG. **7**B, FIG. **7**C and FIG. **7**D, the ultrasound imaging system **1** may be used to acquire 3D images or a series of 3D images in the following manner.

[0061] The wearable adapter assembly **10** is strapped to the subject **100** over one of the breasts. Once the straps are in place, and the wearable adapter assembly **10** is secure, a sufficient amount of ultrasound transmission fluid is poured into the volume defined by the annular wall **12** for containing the ultrasound transmission fluid to cover the whole breast and the surrounding volume.

[0062] The compression plate assembly **40** is then placed on top of the wearable adapter assembly **10** is and secured in place using the mounting screws **41**. The adjustment knob **54***a* is then turned to lower the frame **50** of the compression plate assembly **40** until the breast is stabilized and the ultrasound transmission fluid is occupying the volume around the breast. A sufficient amount of ultrasound transmission fluid is added on top of the compression plate **44** so that the ultrasound transducer **82** is sonically coupled to both the subject **100** and the compression plate **44**.

[0063] The motor plate subassembly **80** is placed on the compression plate subassembly **40** in one of the two possible orientations, for example the orientation shown in FIG. **7**A. The cradle **86** with the ultrasound transducer **82** mounted thereon is manually moved along the carriage **87** to one of the fixed locations, for example the fixed location in FIG. **7**A, so that the images overlap in the same volume. The actuator is actuated, for example from a computer, so that the motor **90** drives the carriage **87** linearly along the rails **89** until the ultrasound transducer **82** reaches the position shown in FIG. **7**B to create a 3D ultrasound image of the scanned volume. Additional 3D images are then acquired to increase the image volume by driving the carriage **87** in reverse and then manually relocating the cradle **86**, and the ultrasound transducer **82** mounted thereon, to another fixed location as shown in FIG. **7**C. The carriage **87** is then driven linearly along the rails **89** until the ultrasound transducer **82** reaches the position shown in FIG. **7**D to create another 3D ultrasound image. Alternatively, or additionally, image resolution can be improved by repositioning the motor plate subassembly to the other of the two orientations at 90° to the first, and then acquire images in a manner where the images acquired at both orientations overlap each other completely.

[0064] With reference to FIG. **9**, FIG. **10**A and FIG. **10**B, another embodiment of a whole breast 3D ultrasound imaging system **101** comprises three subassemblies including a wearable adapter subassembly **110**, a compression plate subassembly **140** and a motor plate subassembly **180**. The compression plate subassembly **140** is releasably mountable on the wearable adapter subassembly **110**. The motor plate subassembly **180** is also releasably mountable on the wearable adapter subassembly **110**. Thus, the imaging system **101** is modular in a similar manner to the imaging system **1**.

[0065] The wearable adapter subassembly **110** is essentially the same as the wearable adapter subassembly **10** of the imaging system **1**. The wearable adapter subassembly **110** therefore comprises an annular wall defining a volume for containing ultrasound transmission around a breast of a subject during operation of the ultrasound imaging system **101**. The wearable adapter subassembly **110** is also worn by the subject **100** using adjustable straps through slots **120** in a lip of the upper edge of the annular wall. A lower edge of the annular wall is also provided with a compressible gasket **115**.

[0066] The compression plate subassembly **140** is releasably mounted on an upper edge of the annular wall of the wearable adapter subassembly **110** and secured to the upper edge via a clamping screw **141** through a threaded mounting aperture in the lip of the upper edge. The compression plate subassembly **140** comprises a compression plate **144** mounted to a threaded mounting bolt **152** connected to an adjustment knob **154**, the compression plate **144** mounted within the volume defined by the annular wall of the wearable adapter subassembly **110**. The mounting bolt **152** is threaded through a threaded aperture in an upper surface of the compression plate subassembly **140** whereby rotation of the adjustment knob **154**, and therefore rotation of the mounting bolt **152** in the threaded aperture, causes the compression plate **144** to raise and lower as desired. Because the compression plate subassembly **140** is small, occupying only a small portion of the upper edge of the annular wall of the wearable adapter subassembly **110**, only a single clamping screw **141** and a single mounting bolt **152** are required.

[0067] The motor plate subassembly **180** is releasably mounted on the wearable adapter subassembly **110** instead of the compression plate subassembly **140**. The motor plate subassembly **180** may be mounted directly to the upper edge of the annular wall of the wearable adapter subassembly **110**, but in the illustrated embodiment, the motor plate subassembly **180** is mounted on an interface plate **160**, which is releasably mounted on the upper edge of the annular wall of the wearable adapter subassembly **110**. The interface plate **160** may be fixedly mounted or releasably mounted on the wearable adapter subassembly **110**. The motor plate subassembly **180** is releasably mounted on the interface plate **160** by virtue of mounting pins (not shown) on a lower face of the motor plate subassembly **180** indexed to locating apertures **167** in an upper surface of or through the interface plate **160**. The interface plate **160** is curved and comprises locating apertures **167** on both transverse and longitudinal sections of the curve so that the motor plate subassembly **180** can be simply picked up, after operating a release pin **183**, and re-oriented by 90° on the interface plate **160**, as seen in FIG. **10**A and FIG. **10**B. The release pin **183** holds the motor plate subassembly **180** to the interface plate **160**.

[0068] In some embodiment, the interface plate **160** can be considered a non-moving part of the compression plate subassembly **140**, especially if the interface plate **160** is directly connected to the compression plate subassembly **140**. However, it is a feature of the imaging system **101** that the motor plate subassembly **180** does not move synchronously with the compression plate **144**. Thus, wherever the motor plate subassembly **180** is mounted, the motor plate subassembly **180** is stationary when the compression plate **144** is adjusted to contact the breast.

[0069] The motor plate subassembly **180** comprises a carriage **187** having a track **189** thereon. A slider block **186** is slidably mounted on the track **189** and is capable of being slid manually along a longitudinal axis of the carriage **187**. In some embodiments, the slider block may be motorized.

The slider block **186** supports a slider arm **186** that extends away from the carriage **187** to a position over the compression plate **144**. The slider arm **186** supports a cradle **191**, which is connected to a mounting bracket **185** to which an ultrasound transducer **182** is mounted. A long axis of the ultrasound transducer **182** is mounted perpendicular to a direction of travel of the slider block **186** do that sliding the slider block **186** translates the ultrasound transducer **182** along the compression plate **144** to acquire 2D images or a series of 2D images. Because the motor plate subassembly **180** does not move with the compression plate **144**, height adjustment of the ultrasound transducer **182** may be required to make ultrasonic contact with the breast of the subject **100**. Height adjustment can be accomplished by the operating a height adjusting fitting **188**, which is a knobbed screw holding the ultrasound transducer **182** to the mounting bracket **185**, the knobbed screw loosenable and tightenable in a slot in the mounting bracket **185**. By changing the orientation of the motor plate subassembly **180** on the wearable adapter subassembly **110** by 90° (see FIG. **10**A and FIG. **10**B), the orientation of the ultrasound transducer **182** can be changed by 90° so that a second scan can be taken orthogonally to a first scan and the scan results stitched together by a computer to produce 3D images or a series of 3D images.

[0070] Another embodiment of a whole breast 3D ultrasound imaging system **201** is illustrated in FIG. **11**A to FIG. **15**B where the whole breast 3D ultrasound imaging system **201** comprises three subassemblies including a wearable adapter subassembly **210** made from a rapid-prototype 3D-printed dam, a compression plate subassembly **240** and a motor plate subassembly **280** releasably stackable with each other with the compression plate subassembly **40** situated above the wearable adapter subassembly **210**.

[0071] The compression plate subassembly **240** comprises a generally rectangular frame **250** and an ultrasound compression plate **244** mounted to and underneath the frame **250**. The frame **250** comprises a mounting bracket **251** that engages the motor plate subassembly **280** at a detent **277** in the motor plate subassembly **280**. The position of the frame **250**, and therefore the position of the ultrasound compression plate **244**, relative to the positions of the wearable adapter subassembly **210** and the motor plate subassembly **280** can be adjusted by clamping the frame **250** at different positions on the motor plate subassembly **280** using a clamping knob **246**.

[0072] The motor plate subassembly **280** comprises a motor plate **281** having a generally rectangular shape. The motor plate **281** has a motor **290** mounted thereon at one of the corners of the motor plate **281**. The motor **290** drives a timing belt **291** around three pullies **292** situated at each of the other corners of the mounting plate **281**. Rigidly attached to the timing belt **291** are a craniocaudal coupling **283** and a mediolateral coupling **284**. An ultrasound transducer **282** may be coupled to either the craniocaudal coupling **283** or the mediolateral coupling **284**. Coupling the ultrasound transducer **282** to the craniocaudal coupling **283** permits creating multiple scans in a craniocaudal direction CD without removing the ultrasound transducer **282** or motor plate **281** between scans. Coupling the ultrasound transducer **282** to the mediolateral coupling **283** permits creating multiple scans in a mediolateral direction MD without removing the ultrasound transducer **282** or the motor plate **281** between scans.

[0073] The ultrasound transducer **282** is held in place by a cradle **286**, which is slidably connected to a cradle adapter **285** along a long axis of the ultrasound transducer **282** (i.e., same direction as the cord of the ultrasound transducer). The cradle **286** can be fixed in place by cradle knob **288** once the ultrasound transducer **282** is in contact with the compression plate **244** which in turn is in contact with a patient's skin. The cradle adapter **285** is coupled to a cross rail mounting block **293** in a manner where the ultrasound transducer **282** can pivot about the long axis of the transducer **282** allowing a maximum of 90 degrees of adjustment needed to scan either in the craniocaudal direction CD or the mediolateral direction MD where the ultrasound imaging plane is at right angles to the direction of the scan. A spring-loaded locking pin **294** constrains the ultrasound transducer **282** in one of two possible orientations as best shown in FIG. **12***d* and FIG. **13**A.

[0074] The cross rail mounting block **293** is rigidly connected to two linear bearing blocks **298**, **299** which are mounted to each other at right angles and are parallel to rails **289***a* and **289***b* which define the scanning directions CD and MD. The bearing blocks **298** and **299** are slidably connected to two rails **289***c* and **289***d* which in turn are rigidly connected to bearing blocks **296** and **297**. The two rails **289***c* and **289***d* are mounted at right angles to the direction of travel of rails **289***a* and **289***b*. This gives the ultrasound transducer **282** the ability to move freely with 2 degrees of freedom in either of the scan directions CD and MD unless constrained by one of a plurality of spring-loaded locking pins **295***a*. **295***b*, **295***c*, **295***d* associated with the respective rails **289***a*, **289***b*, **289***c*, **289***d* when the imaging system **201** is used for scanning. The location of the bearing block **298** is constrained on the rail **289***c* when the locking pin **295***c* engages with one of two apertures **271***a* or **271***b* and the location of the bearing block **299** is constrained on the rail **289***d* when the locking pin **295***d* engages with one of two apertures **272***a* or **272***b*. The locking pins **295***a* and **295***b* are used to couple transducer motion to either the craniocaudal direction CD or the mediolateral MD direction, which is driven by the motor **290**. The locking pins **295***c* and **295***d* are used to constrain the ultrasound transducer **282** in one of two positions along the rails **289***c* and **289***d*.

[0075] FIG. **12**A to FIG. **12**D, FIG. **13**A to FIG. **13**D, FIG. **14**A and FIG. **14**B illustrate how multiple scans can be created. FIG. **12**A to FIG. **12**D and FIG. **14**A show how two parallel scans can be created along the craniocaudal direction CD where the user would set the ultrasound transducer **282** in position A**1** (see FIG. **12**A for detail) where the locking pin **295***a* is engaged with the craniocaudal coupling **283**. The first 3D scan is created when the motor **290** moves the ultrasound transducer **282** from position A**1** to position A**2**. The user would then reposition the ultrasound transducer **282** to positions A**3** by releasing the locking pin **295***c* from the aperture **271***a* and then engaging the locking pin **295***c* with the aperture **271***b*. The second scan is created when the ultrasound transducer **282** is moved from position A**3** to position A**4**, thus creating two parallel scans that can be stitched together electronically to form one larger image.

[0076] With reference to FIG. **12**A to FIG. **12**D, details of ultrasound transducer positioning and locking pin engagement during a craniocaudal scan are summarized as follows:

[0077] FIG. **12**A: Craniocaudal scan, ultrasound transducer **282** upper right (near the patient head): detail of the ultrasound transducer **282** in position A**1** as shown in FIG. **14**A. Locking pins **295***c* and **295***a* are engaged while locking pins **295***b* and **295***d* are released. The locking pin **295***c* is engaged in a position defined by aperture **271***a*.

[0078] FIG. **12**B: Craniocaudal scan, ultrasound transducer **282** lower right (away from the patient head): detail of the ultrasound transducer **282** in position A**2** as shown in FIG. **14**A. Locking pins **295***c* and **295***a* are engaged while locking pins **295***b* and **295***d* are released.

[0079] FIG. **12**C: Craniocaudal scan, ultrasound transducer **282** lower left: detail of the ultrasound transducer **282** in position A**3** as shown in FIG. **14**A. Locking pins **295***c* and **295***a* are engaged while locking pins **295***b* and **295***d* are released. The locking pin **295***c* is engaged in a position defined by aperture **271***b*.

[0080] FIG. **12**D: Craniocaudal scan, ultrasound transducer **282** upper left: detail of the ultrasound transducer **282** in position A**4** as shown in FIG. **14**A. Locking pins **295***c* and **295***a* are engaged while locking pins **295***b* and **295***d* are released.

[0081] FIG. **13**A to FIG. **13**D and FIG. **14**B show how two parallel scans can be created along the mediolateral direction MD. To create two additional scans at right angles to the first two images, the ultrasound transducer **282** is set up in position B**1** as shown in FIG. **14**B. The ultrasound transducer **282** is rotated 90 degrees relative to position A**4** by releasing the locking pin **294**, turning the ultrasound transducer **282**, and re-engaging the locking pin **294** to lock the orientation. To engage transducer motion into the mediolateral direction MD, the locking pins **295***a* and **295***c* are released, the locking pin **295***b* is engaged in an aperture in the mediolateral coupling **284**, and the locking pin **295***d* is locked in aperture **272***a*. The third 3D scan is created when the motor **290** moves the ultrasound transducer **282** from position B**1** to position B**2**. The user would then reposition the ultrasound transducer **282** in position B**3** by releasing the locking pin **295***d* from the aperture **272***a* and engaging the locking pin **295***d* with aperture **272***b*. The fourth scan is created when the ultrasound transducer **282** is moved from position B**3** to position B**4**, thus creating two parallel scans that can be stitched together electronically to form one larger image and can be merged with the first two scans to improve the resolution of the final image by combining two 3D images where the scan directions are at right angles.

[0082] With reference to FIG. **13**A to FIG. **13**D, details of ultrasound transducer positioning and locking pin engagement during a mediolateral scan are summarized as follows:

[0083] FIG. **13**A: Mediolateral scan, ultrasound transducer **282** upper left: detail of the ultrasound transducer **282** in position B**1** as shown in FIG. **14**B. Locking pins **295***c* and **295***a* are released while locking pins **295***b* and **295***d* are engaged. The locking pin **295***d* is engaged in a position defined by aperture **272***a*. In addition, the ultrasound transducer **282** is rotated 90 degrees relative to position A**4** by releasing the locking pin **294**, repositioning the ultrasound transducer **282**, and re-engaging the locking pin **294**.

[0084] FIG. **13**B: Mediolateral scan, ultrasound transducer **282** upper right: detail of the ultrasound transducer **282** in position B**2** as shown in FIG. **14**B. Locking pins **295***c* and **295***a* are released while locking pins **295***b* and **295***d* are engaged.

[0085] FIG. **13**C: Mediolateral scan, ultrasound transducer **282** lower right: detail of the ultrasound transducer **282** in position B**3** as shown in FIG. **14**B. Locking pins **295***c* and **295***a* are released while locking pins **295***b* and **295***d* are engaged. The locking pin **295***d* is engaged in a position defined by the aperture **272***b*.

[0086] FIG. **13**D: Mediolateral scan, ultrasound transducer **282** lower left: detail of the ultrasound transducer **282** in position B**4** as shown in FIG. **14**B. Locking pins **295***c* and **295***a* are released while locking pins **295***b* and **295***d* are engaged.

[0087] FIG. **15**A and FIG. **15**B illustrate the imaging system **201** with the ultrasound transducer **282** and the compression plate **244** in raised and lowered positions, respectively. The ultrasound transducer **282** and the compression plate **244** can be raised and lowered to accommodate different breast sizes. The cradle knob **288** is used to unlock and lock the cradle **286** to permit and prevent sliding of the cradle **286** in the cradle adapter **285** to raise and lower the ultrasound transducer **282**. Likewise, the clamping knob **246** is used to unlock and lock the mounting bracket **251** of the frame **250** to permit and prevent movement of the frame **250** to raise and lower the compression plate **244**.

[0088] The novel features will become apparent to those of skill in the art upon examination of the description. It should be understood, however, that the scope of the claims should not be limited by the embodiments but should be given the broadest interpretation consistent with the wording of the claims and the specification as a whole.

1. A method of obtaining a whole breast 3D ultrasound image, the method comprising:

placing an adapter subassembly of a whole breast 3D ultrasound imaging system around a whole breast of a subject, the adapter subassembly comprising an annular wall for containing an ultrasound transmission fluid around the breast of the subject;

fastening the adapter subassembly to the subject to provide a seal between a first edge of the annular wall and a body surface around the breast of the subject to reduce leakage of the ultrasound fluid between the first edge and the body surface of the subject;

providing the ultrasound transmission fluid inside the annular wall of the adapter subassembly around the breast of the subject;

releasably mounting a compression plate subassembly of the whole breast 3D ultrasound imaging system on a second edge of the adapter subassembly thereby positioning an ultrasound compression plate of the compression plate subassembly above the breast with the ultrasound fluid between the compression plate and the body surface of the subject;

adjusting a height of the compression plate to compress the breast;

releasably mounting a motor plate subassembly of the whole breast 3D ultrasound imaging system on the adapter subassembly or the compression plate subassembly, the motor plate subassembly comprising an ultrasound transducer movable relative to the motor plate subassembly; and,

scanning the breast with the ultrasound transducer by moving the ultrasound transducer in a plane parallel to the ultrasound compression plate.

2. The method of claim **1**, wherein the ultrasound fluid directly contacts the breast.

3. The method of claim **1**, wherein the adapter subassembly further comprises a flexible membrane covering a lower open face of the adapter subassembly, the flexible membrane deformed by the breast when the breast is housed within the annular wall.

4. The method of claim **1**, wherein the adapter subassembly comprises a compressible gasket on the first edge to assist with providing the seal between the first edge and the body surface of the subject.

5. The method of claim **1**, wherein the adapter subassembly comprises a hinge permitting the annular wall to flex to assist with providing the seal between the first edge and the body surface of the subject.

6. The method of claim **2**, wherein the adapter subassembly comprises a compressible gasket made of an elastomeric material on the first edge to assist with providing the seal between the first edge and the body surface of the subject.

7. The method of claim **6**, wherein the adapter subassembly comprises a hinge permitting the annular wall to flex to assist with providing the seal between the first edge and the body surface of the subject.

8. The method of claim **1**, wherein the adapter subassembly is fastened to the subject with adjustable straps.

9. The method of claim **6**, wherein the adapter subassembly is fastened to the subject with adjustable straps and wherein the straps are adjusted to compress the compressible gasket relative to the body surface of the subject.

10. The method of claim **7**, wherein the adapter subassembly is fastened to the subject with adjustable straps, wherein the straps are adjusted to compress the compressible gasket relative to the body surface of the subject, and wherein the straps are adjusted to cause the annular wall to flex.

11. The method of claim **1**, wherein the adapter subassembly moves with the subject when the subject moves in any direction.

12. The method of claim **1**, wherein the compression plate subassembly is between the adapter subassembly and the motor plate subassembly.

13. The method of claim **1**, wherein the motor plate subassembly further comprises an actuator operatively coupled to the ultrasound transducer to translate the ultrasound transducer.

14. The method of claim **1**, wherein the compression plate subassembly comprises:

a securement portion configured to be releasably secured to the second edge of the annular wall of the adapter subassembly, and

a frame with the ultrasound compression plate mounted to the frame, whereby the ultrasound compression plate is height adjustable relative to the securement portion,

wherein the frame comprises mounting bolts secured thereon, the mounting bolts engaging the securement portion to connect the frame to the securement portion,

wherein to adjust the height of the compression plate, at least one of the mounting bolts is rotated in a threaded aperture in the securement portion to cause the frame and the ultrasound compression plate to move relative to the securement portion when the securement portion is secured on the adapter subassembly.

15. The method of claim **14**, wherein the mounting bolts are all threaded and the mounting bolts are linked to each other by a timing belt so that rotation of one of the mounting bolts causes all the mounting bolts to rotate thereby causing the frame and the ultrasound compression plate to move relative to the securement portion.

16. The method of claim **15**, wherein the securement portion comprises mounting screws that are threadingly mated with corresponding threaded mounting apertures in the second edge of the adapter subassembly to releasably secure the compression plate subassembly to the adapter subassembly.

17. The method of claim **14**, wherein the motor plate subassembly is mounted on the frame and moves with the compression plate while adjusting the height of the compression plate.

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