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Ning et al.

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(54) **CONE BEAM BREAST COMPUTED TOMOGRAPHY WITH PIVOTAL GANTRY SUBSYSTEM**

(71) Applicant: **Koning Corporation**, Norcross, GA (US)

(72) Inventors: **Ruola Ning**, Atlanta, GA (US); **Shaohua Liu**, Atlanta, GA (US)

(73) Assignee: **KONING CORPORATION**, Norcross, GA (US)

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A61B 6/04	(2006.01)
A61B 6/40	(2024.01)
A61B 6/50	(2024.01)
A61B 8/08	(2006.01)
G06T 7/00	(2017.01)

(52) **U.S. Cl.**
CPC ***A61B 6/502*** (2013.01); ***A61B 6/032*** (2013.01); ***A61B 6/035*** (2013.01); ***A61B 6/0435*** (2013.01); ***A61B 6/0478*** (2013.01); ***A61B 6/0487*** (2020.08); ***A61B 6/4085*** (2013.01); ***A61B 8/0825*** (2013.01); ***G06T 7/00*** (2013.01); *G06T 2207/30068* (2013.01)

(58) **Field of Classification Search**
CPC A61B 6/025; A61B 6/032
See application file for complete search history.

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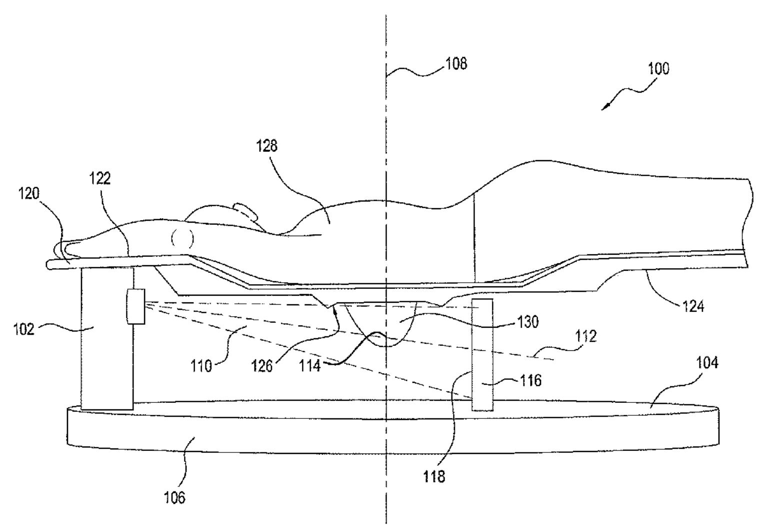
Primary Examiner — Dani Fox
(74) *Attorney, Agent, or Firm* — Bergman LLC; Michael Bergman

(57) **ABSTRACT**

A cone beam breast computed tomography scanning system includes a vertical plane gantry subsystem pivotally connected to a foundation element for ergonomic patient positioning.

9 Claims, 13 Drawing Sheets



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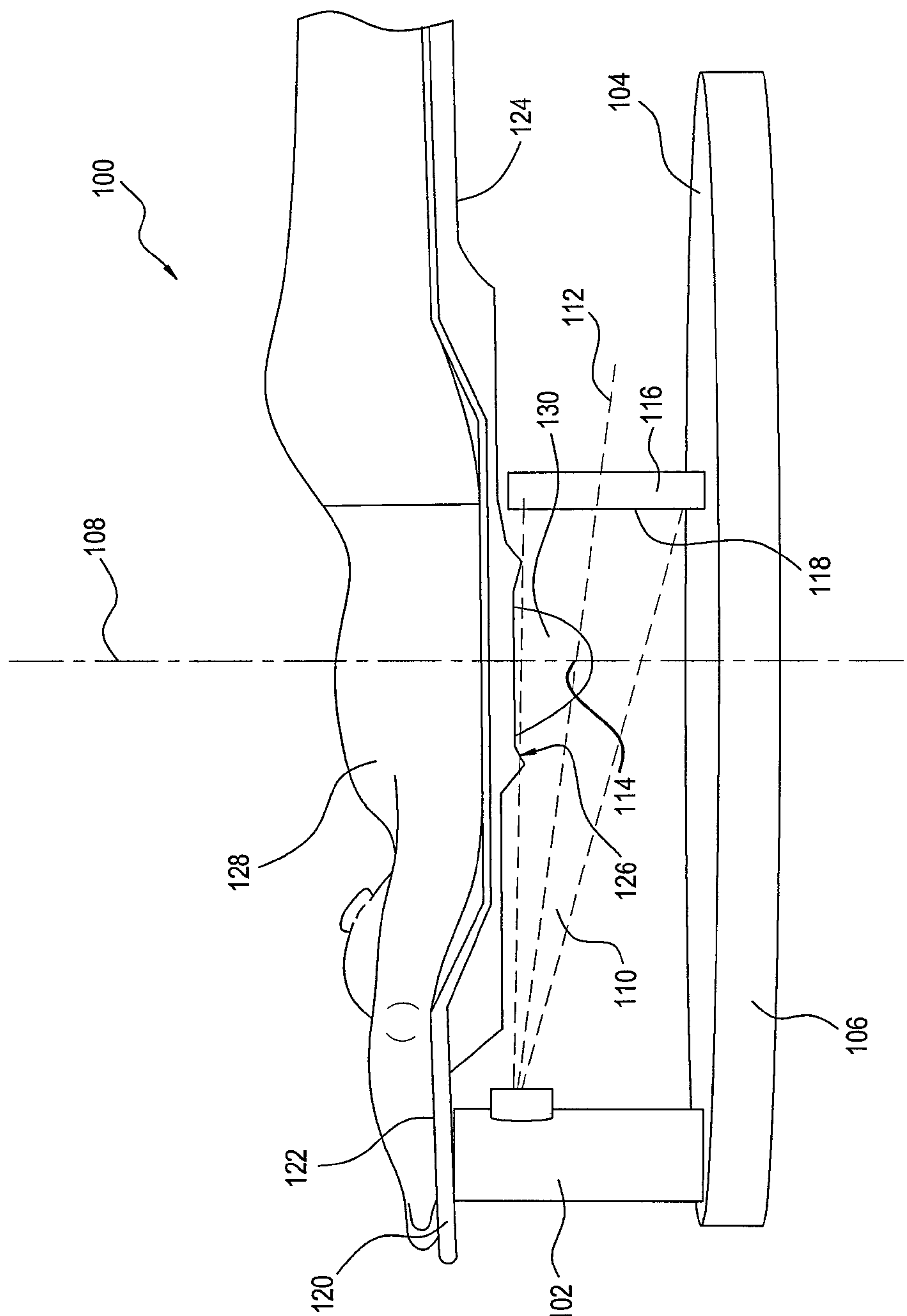

FIG. 1

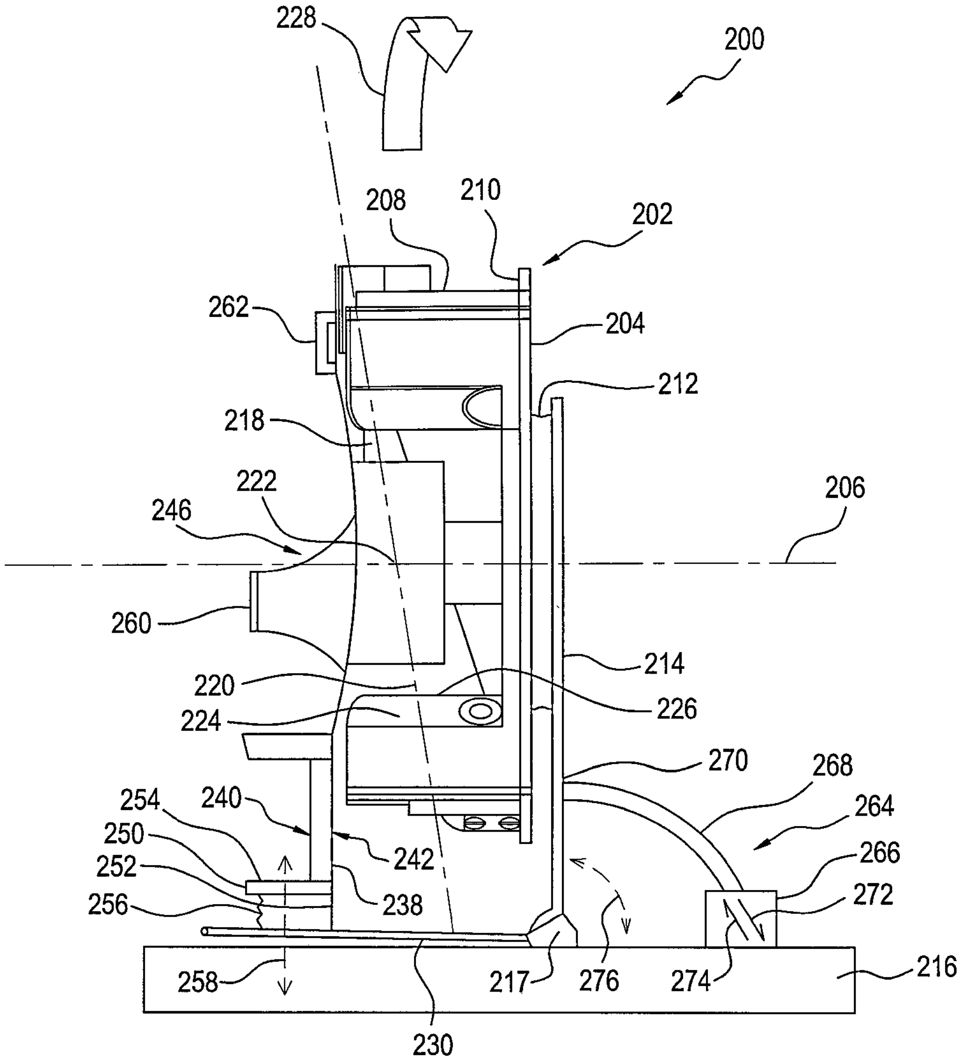
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FIG. 2A

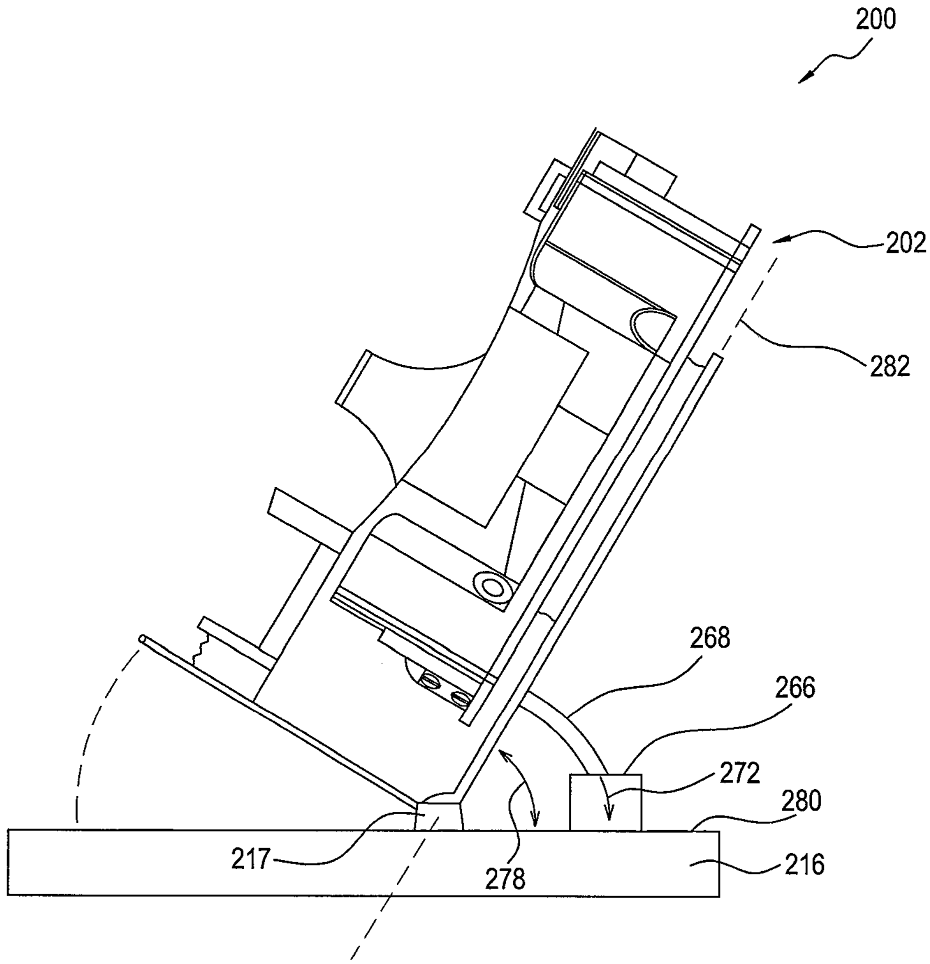

FIG. 2B

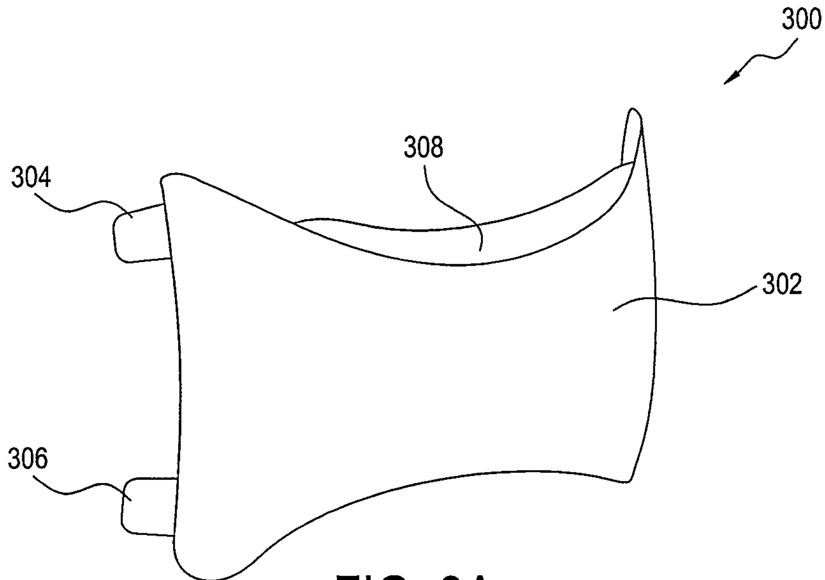

FIG. 3A

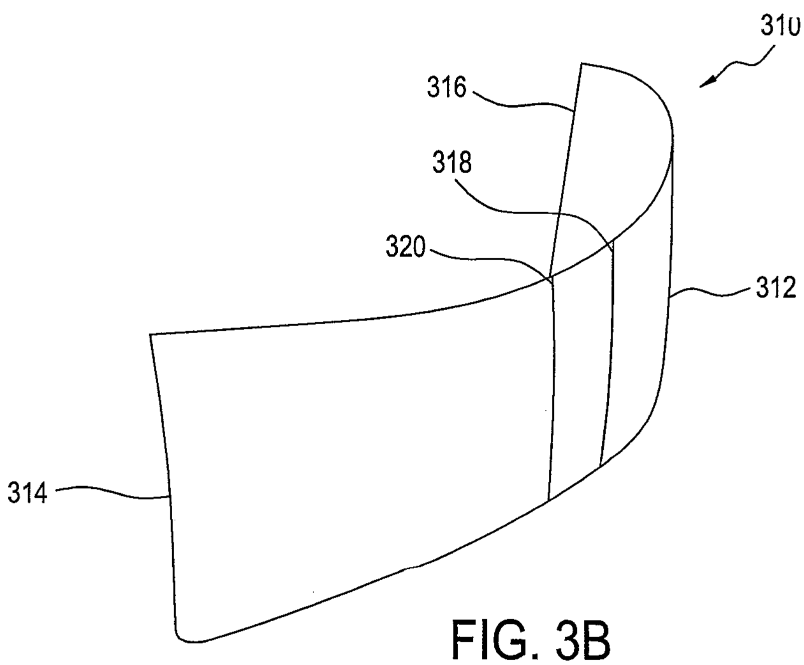

FIG. 3B

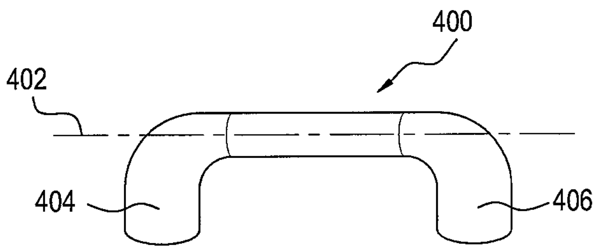

FIG. 4A

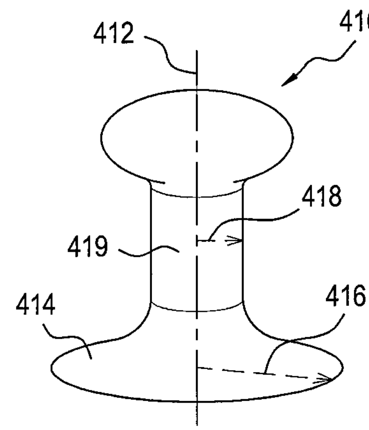

FIG. 4B

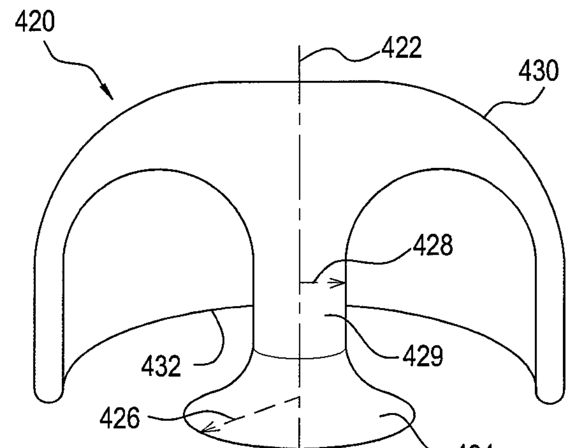

FIG. 4C

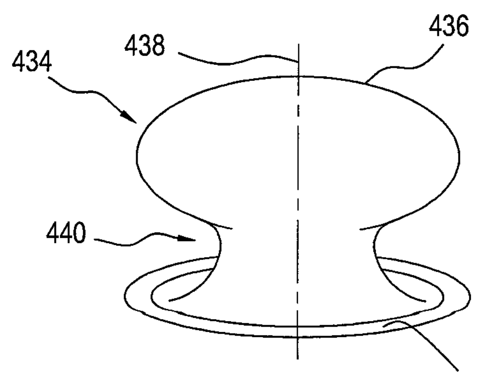

FIG. 4D

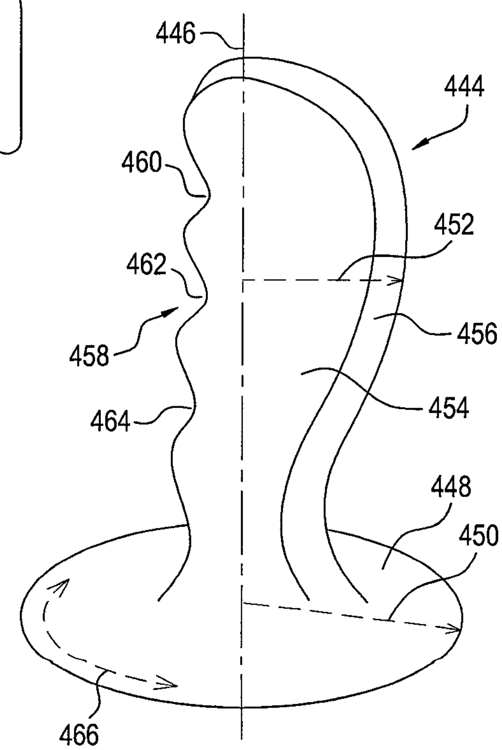

FIG. 4E

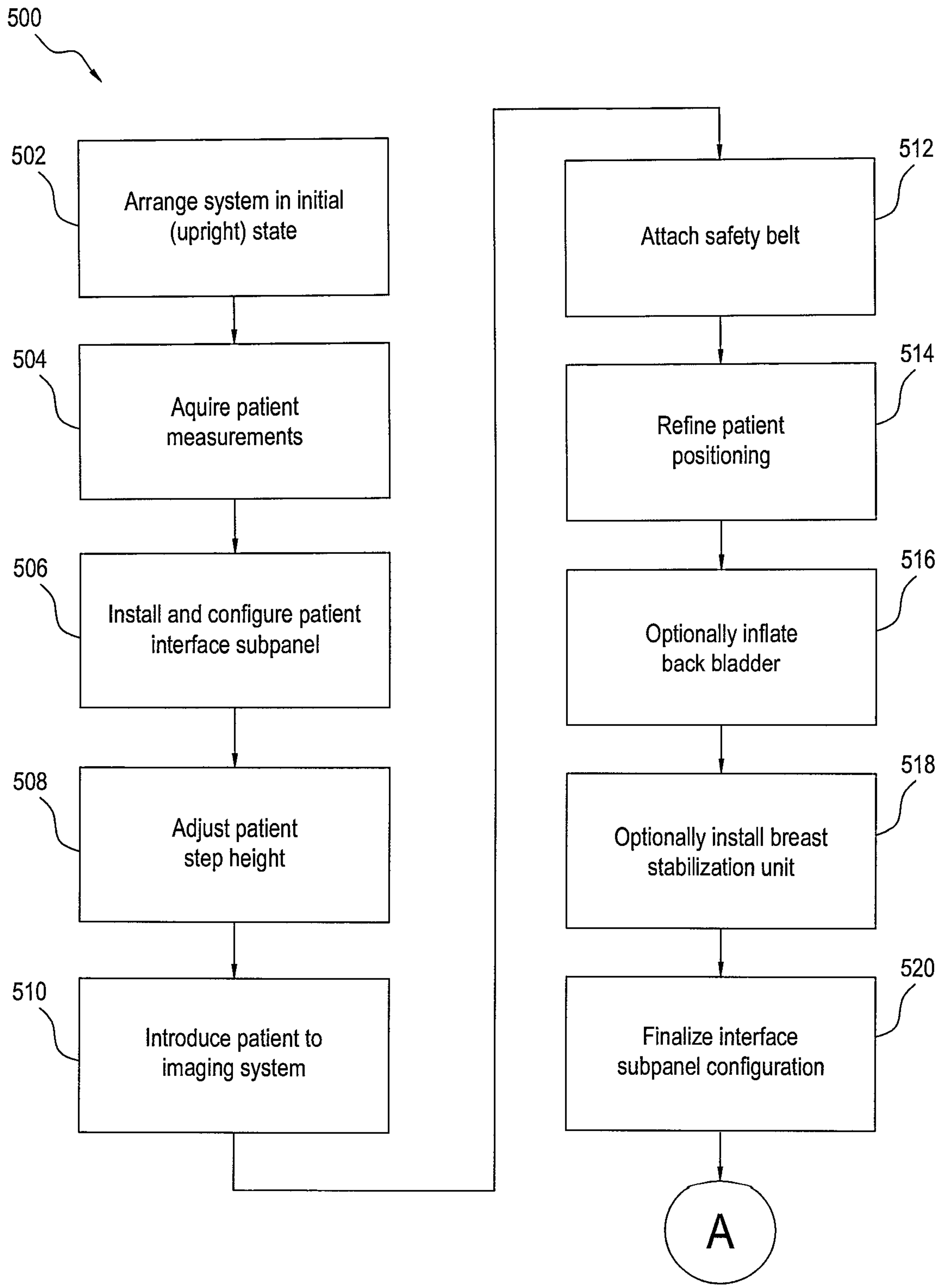
500
502
Arrange system in initial (upright) state
504
Aquire patient measurements
506
Install and configure patient interface subpanel
508
Adjust patient step height
510
Introduce patient to imaging system
512
Attach safety belt
514
Refine patient positioning
516
Optionally inflate back bladder
518
Optionally install breast stabilization unit
520
Finalize interface subpanel configuration
A

FIG. 5A

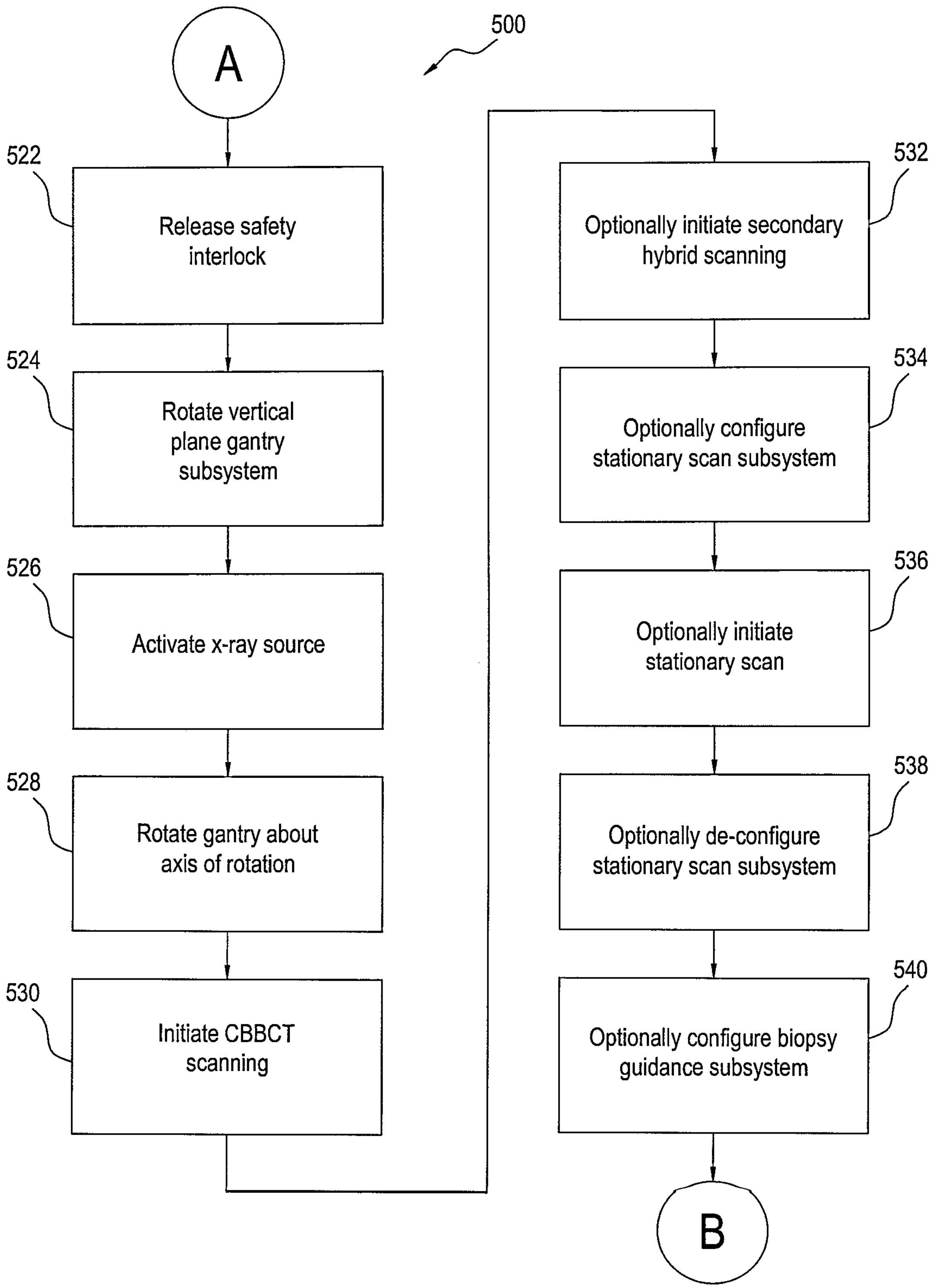
A
500
522
Release safety interlock
524
Rotate vertical plane gantry subsystem
526
Activate x-ray source
528
Rotate gantry about axis of rotation
530
Initiate CBBCT scanning
532
Optionally initiate secondary hybrid scanning
534
Optionally configure stationary scan subsystem
536
Optionally initiate stationary scan
538
Optionally de-configure stationary scan subsystem
540
Optionally configure biopsy guidance subsystem
B

FIG. 5B

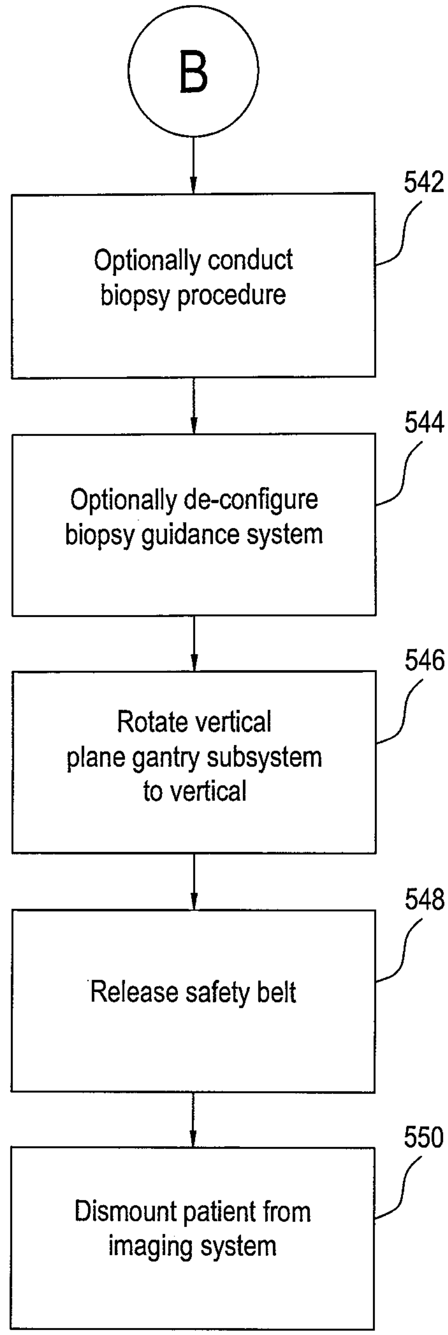
B
Optionally conduct biopsy procedure
542
Optionally de-configure biopsy guidance system
544
Rotate vertical plane gantry subsystem to vertical
546
Release safety belt
548
Dismount patient from imaging system
550

FIG. 5C

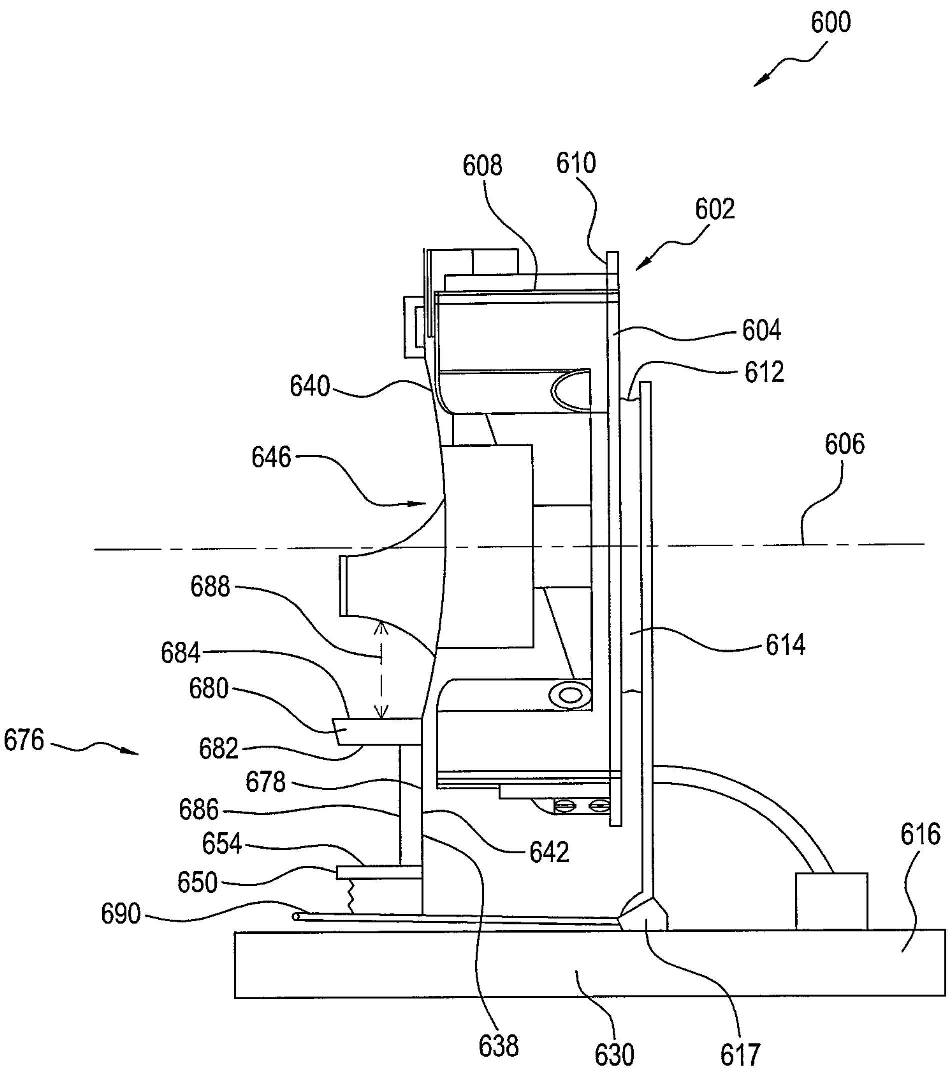
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FIG. 6

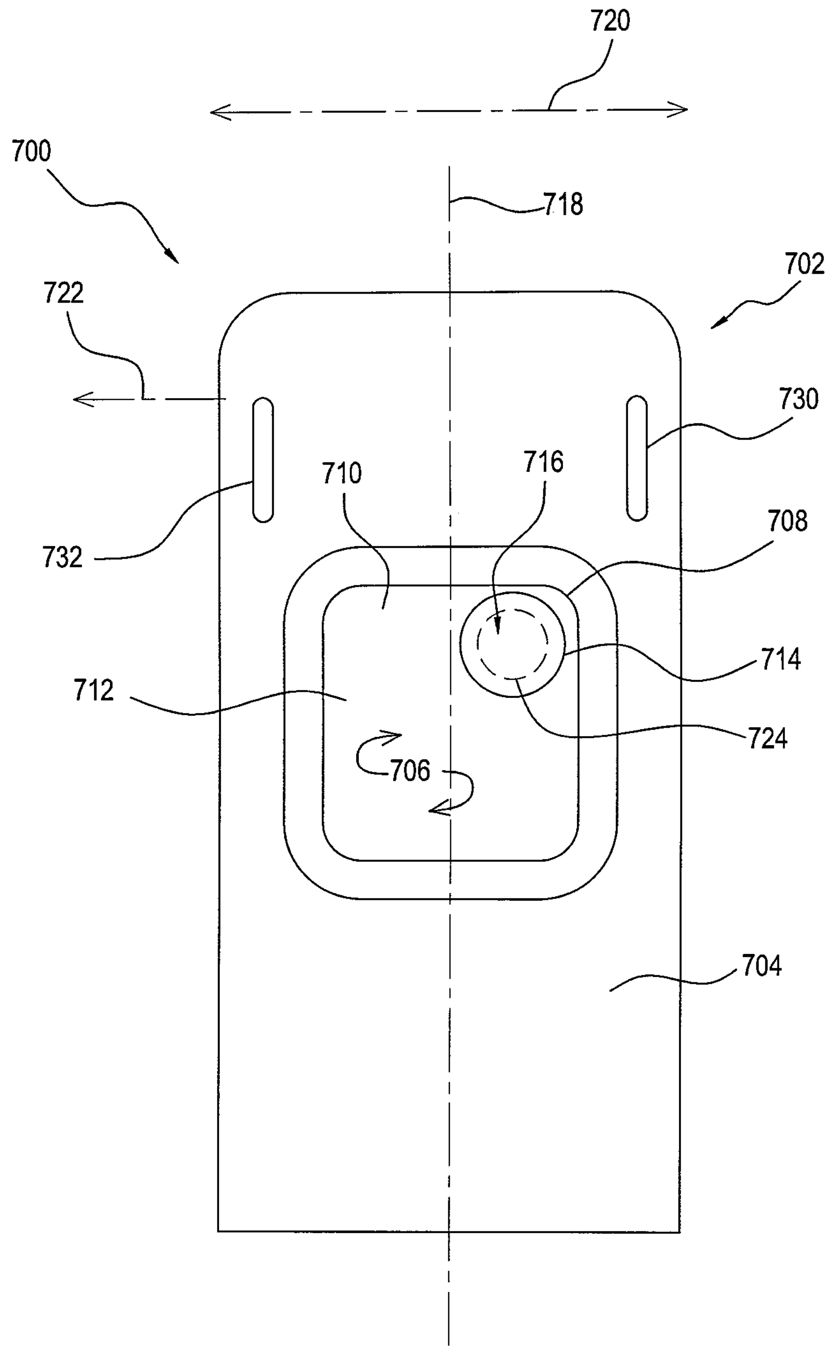

FIG. 7

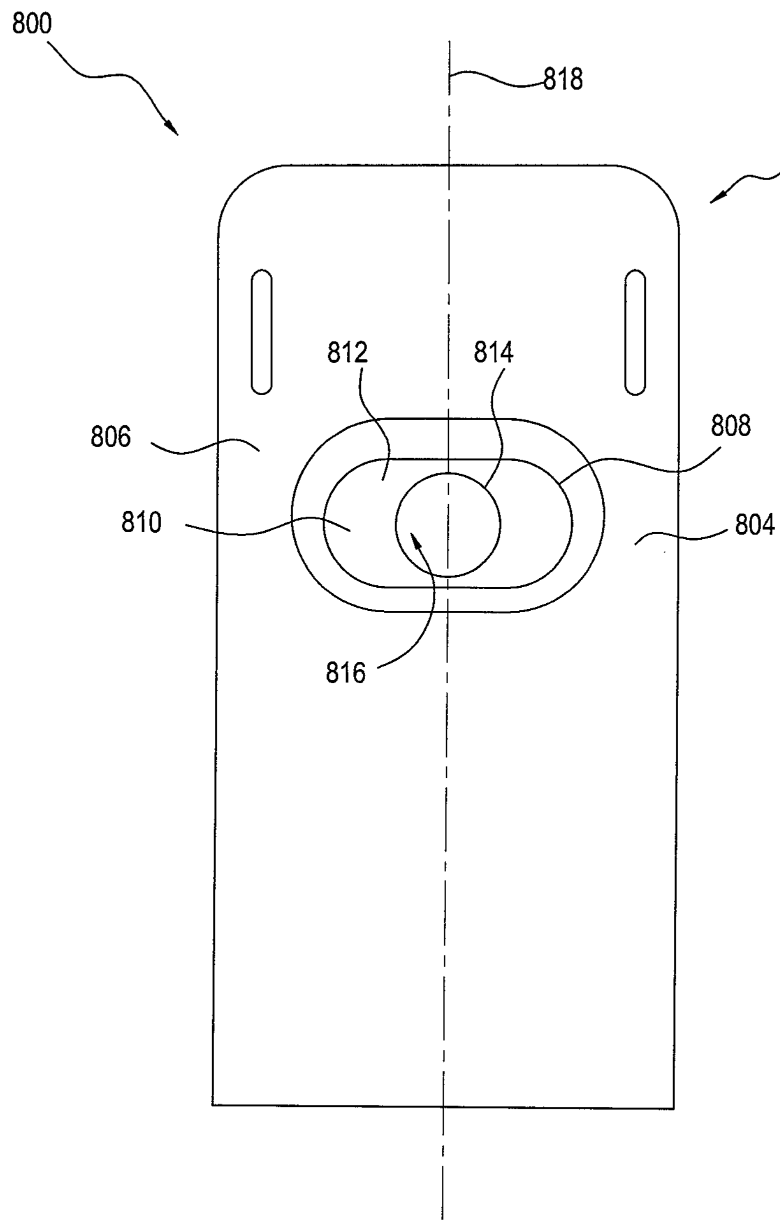

FIG. 8

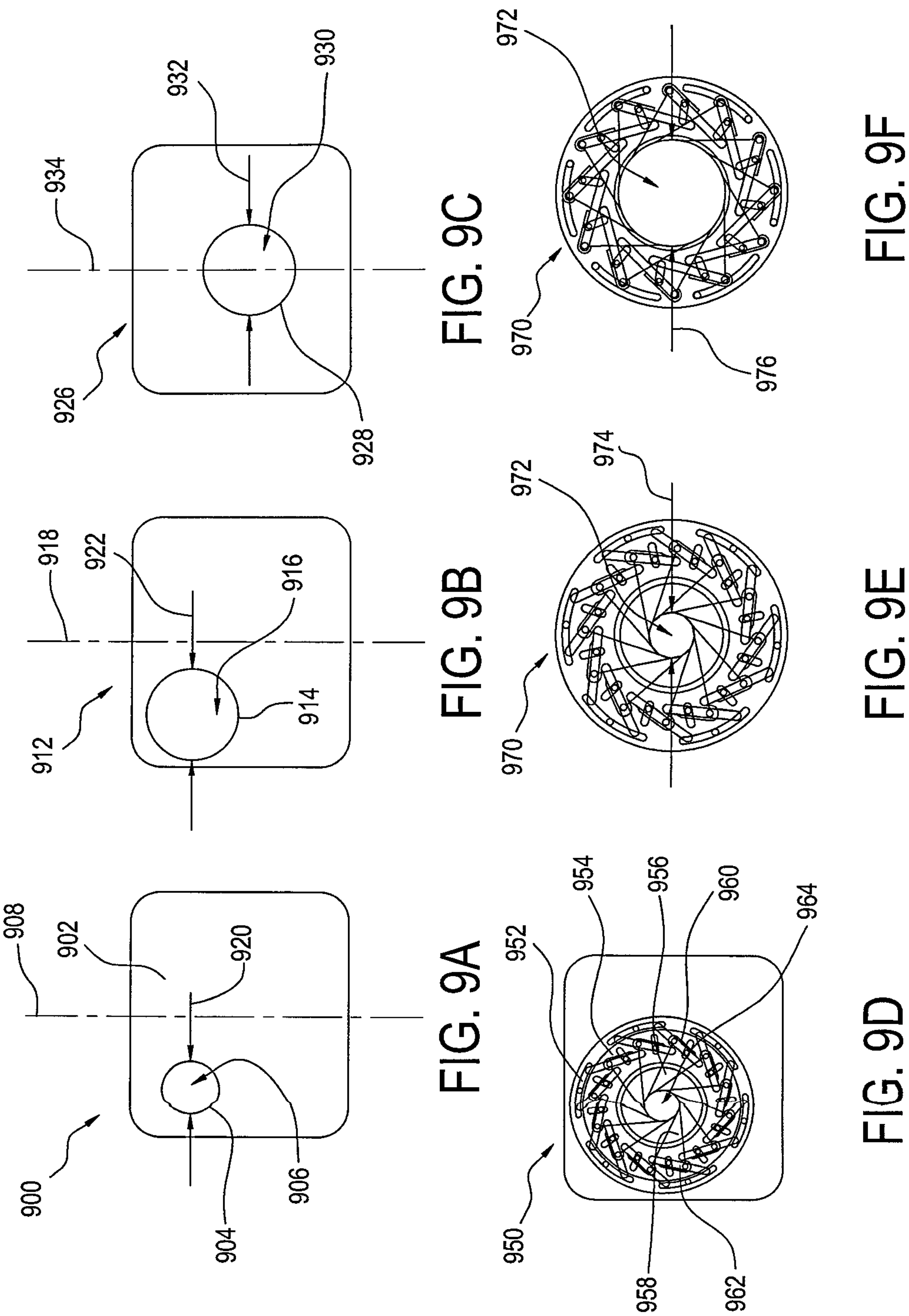

FIG. 9A
FIG. 9B
FIG. 9C
FIG. 9D
FIG. 9E
FIG. 9F

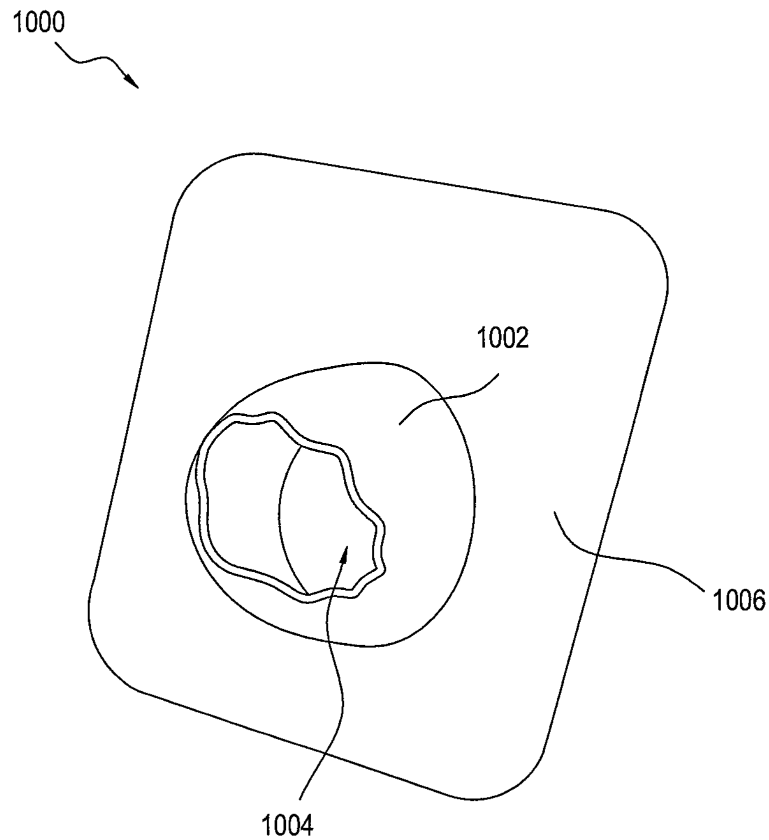

FIG. 10

CONE BEAM BREAST COMPUTED TOMOGRAPHY WITH PIVOTAL GANTRY SUBSYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation of PCT patent application PCT/US2023/018382 filed on Apr. 12, 2023, which claims the benefit of provisional patent applications OMNIBUS DISCLOSURE, set forth in an application for Letters Patent of the United States already filed on Apr. 14, 2022 as U.S. Provisional Application No. 63/331,153, and FIXTURING AND SUPPORT FOR MEDICAL IMAGING, set forth in an application for Letters Patent of the United States already filed on Aug. 26, 2022 as U.S. Provisional Application No. 63/401,475, and ERGONOMIC IMPROVEMENTS IN CONE BEAM BREAST COMPUTED TOMOGRAPHY, set forth in an application for Letters Patent of the United States already filed on Aug. 26, 2022 as U.S. Provisional Application No. 63/401,493, and STATIONARY DETAIL IMAGING IN CONE BEAM BREAST COMPUTED TOMOGRAPHY, set forth in an application for Letters Patent of the United States already filed on Aug. 26, 2022 as U.S. Provisional Application No. 63/401,513, and CONE BEAM BREAST COMPUTED TOMOGRAPHY WITH PATIENT SUPPORT SUBSYSTEM, set forth in an application for Letters Patent of the United States already filed on Aug. 26, 2022 as U.S. Provisional Application No. 63/401,546, and, CONE BEAM BREAST COMPUTED TOMOGRAPHY WITH PIVOTAL GANTRY SUBSYSTEM, set forth in an application for Letters Patent of the United States already filed on Aug. 26, 2022 as U.S. Provisional Application No. 63/401,548, and ULTRASONIC HYBRID IMAGING IN CONE BEAM BREAST COMPUTED TOMOGRAPHY, set forth in an application for Letters Patent of the United States already filed on Dec. 6, 2022 as U.S. Provisional Application No. 63/430,571, the disclosures of all of which are herewith incorporated by reference in their entireties.

FIELD OF THE INVENTION

The present invention relates to the field of cone beam tomographic imaging, and in particular to the field of patient ergonomics in cone beam breast tomographic imaging.

SUMMARY

According to the National Cancer Institute, one out of eight women will be diagnosed with breast cancer in her lifetime. And while a reduction in mortality from breast cancer is evident in published reports, each year 40,000 women will die of the disease.

The optimal breast imaging technique detects tumor masses when they are small, preferably less than 10 mm in diameter. It is reported that women with mammographically detected invasive breast carcinoma 1-10 mm in size have a 93% 16-year survival rate. In addition, as the diameter of the tumor at detection decreases, the probability of metastasis declines sharply. If a breast tumor is detected when it is 10 mm or less, the probability of metastasis will be equal to 7.31%. If a 4 mm carcinoma is detected, the metastatic probability will be decreased by more than a factor of 10, to 0.617%.

Although mammography, which on average can detect cancers about 12 mm in size, is the most effective tool for

the early detection of breast cancer currently available, mammography has relatively low sensitivity to small breast cancers (under several millimeters). Specificity and the positive predictive value of mammography remain limited owing to structure and tissue overlap. The limited sensitivity and specificity in breast cancer detection of mammography are due to its poor contrast detectability, which is common for all types of projection imaging techniques (projection imaging can only have up to 10% contrast detectability), and mammography initially detects only 65-70% of breast cancers. The sensitivity of mammography is further reduced to as low as 30% in the dense breast. Digital mammography (DM) was developed to try to overcome the limitations inherent in screen-film mammography (SFM) by providing improved contrast resolution and digital image processing; however, a large-scale clinical trial, the Digital Mammographic Imaging Screening Trial (DMIST), showed that the rates of false positives for DM and SFM were the same.

The relatively low specificity of mammography leads to biopsy for indeterminate cases, despite the disadvantages of added cost and the stress it imposes on patients. Nearly 80% of the over one million breast biopsies performed annually in the U.S. to evaluate suspicious mammographic findings are benign, burdening patients with excessive anxiety and the healthcare system with tremendous cost. There is a need for more accurate characterization of breast lesions in order to reduce the biopsy rate and the false-positive rate of pre-biopsy mammograms.

The results of phantom studies indicate that Cone Beam Breast Computed Tomography (CBBCT) can achieve a spatial resolution up to about 2.8 lp/mm, allowing detection of a 2 mm carcinoma and microcalcifications about 0.2 mm in size for an average size breast (about 13 cm in diameter at the chest wall) with a total dose of about 5 mGy. This dose is less than that of a single mammography exam, assuming two views are required for each breast. The image quality of CBBCT for visualizing breast tissues, breast tumors and calcifications is excellent, and coverage of the breast, including the chest wall region, is at least equivalent to mammography. Visualization of major blood vessels is very good without using a contrast agent. Accordingly, CBBCT offers significant improvement in detecting and biopsying suspected lesions in a patient.

While the imaging benefits of CBBCT are remarkable, in many ways, the ergonomic advantages of the technology are just as important. For example, in many CBBCT procedures, an image can be acquired without requiring the compression of the breast tissue generally associated with mammography.

It is characteristic of mammography, for example, that breast imaging is preceded by insertion of a patient's breast into a fixturing apparatus that significantly compresses breast tissue in a direction transverse to a breast longitudinal axis. Patients widely report physical and psychological discomfort related to the degree of compression required for conventional mammography, and studies have shown that this discomfort is a contributing factor to low rates of screening and diagnostic mammography among patients generally and, in particular, among some ethnic and cultural populations.

Moreover, the breast compression associated with mammography can result in a displacement of breast tissue that makes the later localization of features such as lesions and calcifications, for purposes of biopsy and lumpectomy procedures, more difficult.

Additional improvements in CBBCT imaging presented herewith offer the potential to expand on its imaging benefits and offer ergonomic improvements that are likewise highly beneficial. Among these improvements are technical improvements, and methods and apparatus that facilitate presentation of the patient to the CBBCT system. These include loading apparatus, patient seating facilities, and equipment arrangements and configurations that improve comfort and ease of presentation of the patient to the machine for both the patient, and for technical and medical personnel.

In current practice, a patient undergoing CBBCT lies prone on a table. A subject breast is disposed downward through an aperture in an upper surface of the table, depending from the chest wall into an imaging chamber disposed under the table. The position of the breast within the imaging chamber is maintained by the patient remaining stationary as the patient lies on the surface of the table.

An imaging apparatus is coupled to a mobile gantry which is supported on a bearing device for rotation about an axis of rotation. The axis of rotation is disposed in a generally vertical orientation and passes through the aperture of the table. Preferably, an approximate centroid of the breast to be imaged is arranged such that the axis of rotation passes through the approximate centroid.

During imaging, the mobile gantry rotates around the axis of rotation, bringing the imaging apparatus through at least a portion of a circular path. As it traverses this path, the imaging apparatus emits a series of x-ray pulses and captures corresponding image data which is processed to prepare a tomographic model of the breast.

Notwithstanding the many benefits and advantages of CBBCT, there are some patients who find it difficult or impossible to assume a prone position on a patient table. Such patients may be unable to locate themselves properly on the table, or to dispose the breast to be imaged through the aperture as necessary. Patients who are elderly, obese, pregnant, or disabled, as well as those suffering from paralysis or amputation, among other ailments, are among the many for whom the act of climbing onto a table and lying down in a specific prone position is prohibitively difficult.

The inventors of the present invention, having given long and careful consideration to the problems associated with breast imaging, with CBBCT imaging and, in particular, to questions of CBBCT ergonomics, have developed new and useful systems, apparatus and methods that represent a substantial improvement over previously known approaches. The present invention includes apparatus, and corresponding systems and methods, for the entry of the patient into the CBBCT system, and for support of the patient during the tomographic imaging process.

Accordingly, in certain embodiments of the present invention, a CBBCT system is provided that is arranged for upright patient positioning. In certain embodiments of the invention, a patient is provided with a saddle for support during scanning in an upright position. In certain embodiments of the invention, the saddle is arranged to pivot so as to facilitate patient entry. In certain embodiments of the invention, the gantry is adapted to move pivotally away from a vertical orientation once a patient is positioned for scanning. In certain embodiments of the invention, the patient stands on a patient step without employing a saddle.

The following description is provided to enable any person skilled in the art to make and use the disclosed inventions and sets forth the best modes presently contemplated by the inventors of carrying out their inventions. In the following description, for purposes of explanation, numerous specific details are set forth in order to provide a thorough understanding of the present invention. It will be apparent to one skilled in the art, however, that the present invention may be practiced without these specific details. In other instances, well-known structures and devices are shown in block diagram form in order to avoid unnecessarily obscuring the substance disclosed. These and other advantages and features of the invention will be more readily understood in relation to the following detailed description of the invention, which is provided in conjunction with the accompanying drawings.

It should be noted that, while the various figures show respective aspects of the invention, no one figure is intended to show the entire invention. Rather, the figures together illustrate the invention in its various aspects and principles. As such, it should not be presumed that any particular figure is exclusively related to a discrete aspect or species of the invention. To the contrary, one of skill in the art will appreciate that the figures taken together reflect various embodiments exemplifying the invention.

Correspondingly, references throughout the specification to “one embodiment” or “an embodiment” means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention. Thus, the appearance of the phrases “in one embodiment” or “in an embodiment” at various places throughout the specification are not necessarily all referring to the same embodiment. Furthermore, the particular features, structures, or characteristics will be combined in any suitable manner in one or more embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows, in cutaway perspective view, a portion of an exemplary CBBCT imaging system;

FIG. **2**A shows, in schematic side elevation, certain aspects of an exemplary CBBCT imaging system, including a pivotable gantry subsystem prepared according to principles of the invention;

FIG. **2**B shows, in schematic side elevation, additional aspects and configurations of an exemplary CBBCT imaging system, including a pivotable gantry subsystem prepared according to principles of the invention;

FIG. **3**A shows, in schematic perspective view, certain features of a CBBCT imaging system prepared according to principles of the invention, including a safety device;

FIG. **3**B shows, in schematic perspective view, additional features of a CBBCT imaging system prepared according to principles of the invention, including a further safety device;

FIG. **4**A shows, in schematic perspective view, certain features of a CBBCT imaging system prepared according to principles of the invention, including an exemplary handle;

FIG. **4**B shows, in schematic perspective view, additional features of a CBBCT imaging system prepared according to principles of the invention, including an exemplary handle;

FIG. **4**C shows, in schematic perspective view, still further features of a CBBCT imaging system prepared according to principles of the invention, including an exemplary handle;

FIG. **4**D shows, in schematic perspective view, yet other features of a CBBCT imaging system prepared according to principles of the invention, including an exemplary handle;

FIG. **4**E shows, in schematic perspective view, still more aspects and features of a CBBCT imaging system prepared according to principles of the invention, including an exemplary handle;

FIG. **5**A shows, in functional block diagram form, certain aspects of processes and methods for using a CBBCT imaging system prepared according to principles of the invention;

FIG. **5**B shows, in functional block diagram form, further aspects of processes and methods for using a CBBCT imaging system prepared according to principles of the invention;

FIG. **5**C shows, in functional block diagram form, additional aspects of processes and methods for using a CBBCT imaging system prepared according to principles of the invention;

FIG. **6** shows, in schematic side elevation, additional aspects and configurations of an exemplary CBBCT imaging system, including a patient support saddle feature prepared according to principles of the invention;

FIG. **7** shows, in schematic proximal elevation, certain features and of an exemplary CBBCT imaging system, including a patient interface panel, prepared according to principles of the invention;

FIG. **8** shows, in schematic proximal elevation, additional features and of an exemplary CBBCT imaging system, including a patient interface panel, prepared according to principles of the invention;

FIG. **9**A shows, in schematic proximal elevation, certain features of a CBBCT imaging system prepared according to principles of the invention, including exemplary subpanel elements;

FIG. **9**B shows, in schematic proximal elevation, additional aspects of a CBBCT imaging system prepared according to principles of the invention, including exemplary subpanel elements;

FIG. **9**C shows, in schematic proximal elevation, further exemplary aspects of a CBBCT imaging system prepared according to principles of the invention, including exemplary subpanel elements;

FIG. **9**D shows, in schematic proximal elevation, certain features of a CBBCT imaging system prepared according to principles of the invention, including exemplary adjustable subpanel elements;

FIG. **9**E shows, in schematic proximal elevation, further details of a CBBCT imaging system prepared according to principles of the invention, including exemplary adjustable subpanel elements;

FIG. **9**F shows, in schematic proximal elevation, additional configurations of a CBBCT imaging system prepared according to principles of the invention, including exemplary adjustable subpanel elements; and

FIG. **10** shows, in distal schematic perspective view, certain further features of a CBBCT imaging system prepared according to principles of the invention, including exemplary breast stabilization features.

DETAILED DESCRIPTION

The following description is provided to enable any person skilled in the art to make and use the disclosed inventions, and sets forth the best modes presently contemplated by the inventors of carrying out their inventions. In the following description, for purposes of explanation, numerous specific details are set forth in order to provide a thorough understanding of the present invention. It will be apparent, however, to one skilled in the art that the present invention may be practiced without these specific details. In other instances, well-known structures and devices are shown in block diagram form in order to avoid unnecessarily obscuring the substance disclosed.

It should be noted that while any of the embodiments described for exemplary purposes below will identify specific elements and combinations of elements, these examples are not intended to be determinative. Rather, discrete elements will, in appropriate circumstances, be combined into integral elements and/or assemblies. Further, the present disclosure of aspects and features of particular elements described herewith as integral, should be understood to convey also the disclosure of individual elements and assemblies providing the same characteristics and/or functionality.

FIG. **1** shows, in cutaway perspective view, a portion of an exemplary CBBCT imaging system **100**. The system **100** includes an x-ray source **102**. The x-ray source **102** is mounted on an upper surface **104** of a rotating gantry **106**. The rotating gantry **106** is supported by a bearing, and arranged for rotation about an axis of rotation **108**.

The x-ray source **102** is configured to emit a beam of x-rays **110**. The beam of x-rays **110** defines a beam longitudinal axis **112** that, in the illustrated embodiment, intersects (at **114**) the axis of rotation **108**.

In certain embodiments of the invention, beam **110** is configured as a cone beam. In certain configurations, a cross-section of the beam **110** taken transverse to the longitudinal axis **112** defines a disk of substantially uniform x-ray intensity with a substantially circular perimeter.

In other configurations within the scope of the invention, a cross-section of the beam **110** taken transverse to the longitudinal axis **112** defines a region of substantially uniform x-ray intensity with a substantially circular perimeter save for a portion of the disc outwardly of a chord of said circular perimeter. As will be appreciated on consideration of the further disclosure below, in certain embodiments, the chord will be disposed in generally parallel spaced relation to a lower surface of a patient table.

Accordingly, in certain configurations, a cross-section of the beam **110** taken transverse to the longitudinal axis **112** defines a truncated disk of substantially uniform x-ray intensity with a substantially truncated circular perimeter (i.e., a perimeter that is circular except for a horizontal chord of the circle at its upper periphery). This configuration optimizes imaging of the breast while minimizing irradiation of chest wall tissue above the breast. It is implemented, in certain embodiments, by the placement of an x-ray-opaque collimating plate across a portion of an otherwise circular-cross-section beam generated by the x-ray source.

In still further configurations within the scope of the invention, a cross-section of the beam **110** taken transverse to the longitudinal axis **112** defines a region of substantially uniform x-ray intensity with a polygonal perimeter, where the polygonal perimeter will, in respective embodiments and configurations, include any of a triangular perimeter, a rectangular perimeter, a pentagonal perimeter, hexagonal perimeter, a perimeter of any higher geometric shape, or a perimeter having any arbitrary curve or combination of line segments and curves according to the demands of a particular application. Moreover, it will be appreciated that any of the cross-sectional configurations described above may define a beam having a nonuniform intensity including, without limitation an intensity that falls to zero in a region, or certain regions, of the cross-section.

An x-ray detector **116** is also mounted on the upper surface **104** of the rotating gantry **106**. In one exemplary embodiment, the x-ray detector **116** includes a flat panel detector having a generally planar receiving surface **118**. Receiving surface **118** is disposed generally transverse to longitudinal axis **112** and on the opposite side of axis of rotation **108** from the x-ray source **102**. It will be appreciated by one of skill in the art that the configuration described is merely exemplary of many possible arrangements in which the x-ray source, the x-ray detector, and any other component of the system, may be supported from above, from a side, or in any other way appropriate to achieving the desired function, and that the shape and configuration of the gantry, and of the x-ray detector, will likewise assume any appropriate form in respective embodiments of the invention.

Rotation of the gantry **106** about axis of rotation **108** during operation of the imaging system **100** will result in the receiving surface **118** following a transit path about axis of rotation **108**. In a typical configuration, the transit path will include at least a portion of a circle disposed transverse to, and centered at, axis of rotation **108**. It should be noted, however, that other transit paths are considered to be within the scope of the invention, and to be disclosed herewith.

In certain embodiments of the invention, one or both of the x-ray source **102** and the x-ray detector **116** are arranged so that their respective positions on the upper surface **104** of gantry **106** are adjustable. For example, the x-ray source **102** and the x-ray detector **116** may be adjustable in a radial direction with respect to axis of rotation **108**, in a circumferential direction with respect to axis of rotation **108**, in a direction towards or away from gantry surface **104**, or in any other manner deemed beneficial by the designer or user of a particular apparatus embodying the invention.

A patient table **120** includes an upper surface **122** and a lower surface **124**. An aperture **126** communicates between the upper surface **122** and lower surface **124** of the table. The upper surface **122** is arranged to support a patient **128**, typically with the patient lying prone on the upper surface **122**, as illustrated. In this arrangement, a breast **130** of the patient is disposed pendant from the patient's chest wall downwardly through aperture **126**.

In operation, the gantry **106** rotates about axis of rotation **108**, carrying x-ray source **102** and x-ray detector **116** in transit in a path around the patient's breast. During this transit, x-ray image data is captured by operation of the x-ray detector **116** in conjunction with corresponding interface electronics and computer systems. The x-ray image data corresponds to a plurality of x-ray images taken at respective angular locations about axis of rotation **108**. Taken together, the x-ray image data, or a subset of the same, is processed to provide information about the internal state of the breast.

FIG. **2**A shows, in schematic side elevation, a portion of an exemplary CBBCT imaging system **200**, including a vertical plane gantry subsystem **202**. The vertical plane gantry subsystem **202** includes a vertical plane gantry **204** configured to rotate about a generally horizontal axis of rotation **206**.

Like system **100** described above, system **200** includes an x-ray source **208**. The exemplary x-ray source **208** is mounted on, and supported by, a mounting surface **210** of the vertical plane gantry **204**. The vertical plane gantry **204** is supported by a bearing **212**, and arranged for rotation about the axis of rotation **206**. The bearing **212** is, in turn, coupled to and supported by a structural member **214**, and the structural member **214** is pivotally coupled to, and supported by, a foundation element **216** of the of the vertical plane gantry subsystem **202** at a hinge element **217**.

The x-ray source **208** is configured to emit a beam of x-rays **218**. The beam of x-rays **218** defines a beam longitudinal axis **220** that, in the illustrated embodiment, intersects (at **222**) the axis of rotation **206**.

In certain embodiments of the invention, beam **218** is configured as a cone beam of any appropriate cross-sectional configuration. As discussed above, the configuration and characteristics of the x-ray beam will be selected according to the requirements of a particular application.

An x-ray detector **224** is also mounted on the mounting surface **210** of the rotating gantry **204**. In one exemplary embodiment, the exemplary x-ray detector **224** includes a flat panel detector having a generally planar receiving surface **226**. Receiving surface **226** is disposed generally transverse to longitudinal axis **220** and on the opposite side of axis of rotation **206** from the x-ray source **208**.

It will be appreciated by one of skill in the art that the configuration described is merely exemplary of many possible arrangements in which the x-ray source, the x-ray detector, and any other component of the system, may be supported from above, from a side, or in any other way appropriate to achieving the desired function, and that the shape and configuration of the gantry, and of the x-ray detector, will likewise assume any form in respective embodiments of the invention.

Rotation of the gantry **204** about axis of rotation **206** during operation of the imaging system **200** will result in the receiving surface **226** following a transit path **228** (as described above) about axis of rotation **206**. In a typical configuration, the transit path will include at least a portion of a circle disposed transverse to, and centered at, axis of rotation **206**. It should be noted, however, that other transit paths are considered to be within the scope of the invention, and to be disclosed herewith.

In certain embodiments of the invention, one or both of the x-ray source **208** and the x-ray detector **224** are arranged so that their respective positions on the mounting surface **210** of gantry **204** are adjustable. For example, the x-ray source **208** and the x-ray detector **224** may be adjustable in a radial direction with respect to axis of rotation **206**, in a circumferential direction with respect to axis of rotation **206**, in a direction towards or away from gantry surface **210**, in an angular orientation, or in any other manner deemed beneficial by the designer or user of a particular apparatus embodying the invention.

A base member **230** is coupled to the structural member **214**. A patient interface panel **238** is coupled through the base member **230** to the structural member **214** so that the structural member **214** and the base member **230** serve to support the patient interface panel **238**.

The patient interface panel **238** has a first patient interface surface region **240** and a second distal surface region **242**, where the distal surface region **242** is disposed in spaced relation to the patient interface surface region **240**. The exemplary patient interface panel functions to segregate the patient from the moving apparatus of the vertical plane gantry subsystem and provides an aperture for the breast.

Accordingly, referring to FIGS. **2**A and **2**B the patient interface panel includes an internal circumferential edge of the patient interface surface region. The internal circumferential edge circumscribes an aperture **246** through the patient interface panel **238** between patient interface surface region **240** and distal surface region **242**.

As will be further described below, the patient interface surface region **240** is arranged to segregate the patient from the balance of the vertical gantry subsystem **202** with a breast of the patient disposed through the aperture **246**. In various embodiments and aspects of the invention, a patient interface subsystem, as exemplified above, is disposed at the aperture **246**. In various aspects, the patient interface subsystem will provide one or more of an aperture sized and located according to the particular patient and breast being imaged, shielding for regions of the patient that might otherwise be exposed to scattered x-ray photons, and support and stabilization of the breast being imaged, among other features.

In operation, the gantry **204** rotates about axis of rotation **206**, carrying x-ray source **208** and x-ray detector **224** in a transit path **228** around the patient's breast. During this transit, x-ray image data is captured by operation of the x-ray detector **224** in conjunction with corresponding interface electronics and computer systems. The x-ray image data corresponds to a plurality of x-ray images taken at respective angular locations about axis of rotation **206**. Taken together, the x-ray image data, or a subset of the same, is processed to provide information about the internal state of the breast.

In certain embodiments of the invention, a patient step **250** is provided adjacent a lower surface region **252** of the patient interface panel **238**. The patient step **250** has an upper surface region **254**. The upper surface region **254** is configured and adapted to support a patient during imaging.

In certain embodiments of the invention, the patient step **250** is coupled to and supported by an adjustment mechanism **256**. Adjustment mechanism **256** is, in respective embodiments of the invention, coupled to base member **230**, or to patient interface panel **238**, or otherwise coupled to the CBBCT imaging system **200** for support.

In certain embodiments of the invention, adjustment mechanism **256** is arranged and configured to provide adjustable positioning, e.g., in direction **258**, with respect to the patient interface surface region **240** of patient interface surface panel **238**. Accordingly, the adjustment mechanism serves to optimize positioning of a patient, according to a patient's height and dimensions, with respect to aperture **246** for effective imaging of the subject breast.

According to certain aspects of the invention, patient parameters (such as e.g., breast height with respect to patient feet) are secured, either by manual measurement of the patient, by extraction from patient medical records, or by automatic measurement. The parameter values, once secured, are optionally used to set the position of the patient step, adjusting its elevation in direction **258** and its orientation. The patient then mounts the patient step **250** and leans into the patient interface surface **240** of the patient interface panel **238**.

Alternately, in certain embodiments of the invention, the patient steps onto the patient step. Thereafter, the height and orientation of the patient step are adjusted with the patient disposed in situ, and the necessary positioning (i.e., patient parameters) are ascertained from manual observation or automatic sensing of the patient body with respect to the system. In other words, the patient step is adjusted until the patient breast is properly situated within the table aperture.

In certain embodiments of the invention, the adjustment mechanism **256** will include one or more of a scissors link mechanism, or a linear bearing mechanism, along with any of the linear actuators identified below, or any other elevating mechanism consistent with the objectives of the invention, such as would become apparent to one of skill in the art in light of the requirements of a particular application and the present disclosure.

As will be appreciated by one of skill in the art, the herewith-described linear actuator (and any of the linear actuators referenced herewith) can be implemented with a wide variety of actuators available in the art. For example, in certain embodiments, the linear actuator will include one or more of a rack and pinion apparatus, an Acme screw and Acme nut; a ballscrew apparatus; a linear stepping motor; a transverse complementary ramps; a pneumatic cylinder; a pneumatic bladder; a pneumatic bellows; a hydraulic cylinder; a hydraulic bladder; a hydraulic bellows; a scissors linkage mechanism, including, for example, a scissors linkage mechanism linkage operated by a lead screw, a cylinder, or any of the other actuators discussed herewith, or any other appropriate actuator; a sarrus linkage mechanism; a thermoelectric actuator; a shape memory alloy actuator; a cable and pulley arrangement; as well as any of a wide variety of manual actuators such as, for example, a handcrank and/or a ratchet lever; a compressive spring; a tension spring; a torsion spring; an assembly of leaf springs; a spring including a plurality of Belleville washers; or any other linear actuator currently known, or that becomes known in the art, that is suited to the requirements of a particular application and to providing the requisite extension function.

Thus for example, in certain embodiments of the invention, the linear actuator will include one or more of an electrical solenoid, a pneumatic cylinder, hydraulic cylinder, a pneumatic bladder, a hydraulic bladder, a linear electric motor, linear stepping motor, a rotary actuator along with: an Acme screw and nut, a lead screw, a ballscrew, a cable, a pulley, a timing belt, a timing pulley, an appropriately sized worm gear reducer, a rack and pinion assembly, a rack and worm gear assembly, a piezoelectric actuator, a piezoelectric actuator combined with a ratchet and pawl driver, a spring loaded actuator, an actuator including a shape metal alloy, and any other appropriately functioning actuator component that is known or becomes known in the art.

Before or after adjustment, the patient is optionally secured to the patient interface panel **238** by employing one or more safety features, e.g., **260**. Safety feature **260** includes, for example, a strap or belt, a locking bar disposed behind the patient's back, a hook and loop (e.g., Velcro™) interface between the table and one or more straps or garments worn by the patient in advance and including corresponding hook and loop elements. It will be appreciated by one of skill in the art that, in certain embodiments one or more safety features are engaged as soon as the patient steps onto the step. In other embodiments, a safety feature will be engaged after positioning of the patient is complete.

FIGS. **3**A and **3**B show, in schematic perspective view, safety elements exemplary of safety feature **260** of CBBCT imaging system **200**.

FIG. **3**A shows a safety belt **300** for a CBBCT imaging system. Safety belt **300** includes a generally flexible member **302**. In the illustrated embodiment, flexible member **302** includes, for example, a textile material such as, for example, a woven textile material, a knitted textile material, a felted textile material, or a chain-linked textile material. In other embodiments of the invention, the flexible member **302** includes one or more of a molded elastomeric polymer, a spray-formed elastomeric polymer a rope or cable, a natural material such as a natural polymer, a leather, a vegetable material, or other material or combination of materials appropriate to the objectives and functions described herewith.

The illustrated safety belt **300** includes a coupling mechanism e.g., **304**, **306** adapted for detachably coupling the safety belt **300** to the patient support panel **238**. In various embodiments of the invention, the coupling mechanism **304**, **306** will include one or more of a buckle, a button, a hook and loop fastener, a mechanical snap fastener, a magnet fastener, an adhesive fastener, or any other fastener appropriate to the purposes in light of the present disclosure that is known or becomes known in the art, as well as combinations of the same.

In certain embodiments of the invention, the safety belt **300** will include a cushion element **308**. In certain embodiments, the cushion element will include a generally elastic element that serves to distribute forces across an inner surface of the flexible element **302**, operative to avoid excessive pressure at points of contact with the patient's back.

In certain embodiments of the invention, the cushion element **308** will include an expanding element such as for example, an air bladder, a liquid bladder, or a mechanical actuator. In certain embodiments of the invention, the expanding element is adapted to expand in a controlled fashion once the safety belt is coupled to the patient interface panel **238**, thereby urging the patient against the patient interface surface **240**.

FIG. **3**B shows an alternative safety belt **310** for a CBBCT imaging system. Like safety belt **300**, safety belt **310** includes a generally flexible member **312**. In the illustrated embodiment, flexible member **312** includes, for example, a textile material and/or any of the materials provided as examples above.

The flexible member **312** has a first end **314** and a second end **316** that are adapted to be coupled to respective regions of patient interface panel **238**. In certain embodiments of the invention, the respective ends **314** and **316** are substantially permanently coupled to the patient interface panel **238**. In other embodiments of the invention, ends **314** and **316** are removably and/or adjustably coupled to the patient interface panel **238**.

In the illustrated embodiment, the flexible member **312** has third **318** and fourth **320** internal ends that are adapted to be releasably coupled to each other. Accordingly, internal ends **318**, **320** will include respective complementary coupling features. Thus, for example, internal ends **318**, **320** will include respective complementary portions of a buckle, a button, a hook and loop fastener, a mechanical snap fastener, a magnet fastener, or any other fastener appropriate to the purposes in light of the present disclosure that is known or becomes known in the art, as well as combinations of the same.

In certain embodiments of the invention, the safety belt **300**, **310** will include, for example, a polymer material such as, for example, polyamide, or polyaramid.

In other embodiment of the invention, the safety belt **300**, **310**, including elements of its assembly, will include one or more of polyethylene, polypropylene, polybutylene, polystyrene, polyester, acrylic polymers, polyvinylchloride, polyamide, or polyetherimide like ULTEM.®; a polymeric alloy such as Xenoy.® resin, which is a composite of polycarbonate and polybutyleneterephthalate or Lexan.® plastic, which is a copolymer of polycarbonate and isophthalate terephthalate resorcinol resin (all available from GE Plastics), liquid crystal polymers, such as an aromatic polyester or an aromatic polyester amide containing, as a constituent, at least one compound selected from the group consisting of an aromatic hydroxycarboxylic acid (such as hydroxybenzoate (rigid monomer), hydroxynaphthoate (flexible monomer), an aromatic hydroxyamine and an aromatic diamine, polyesterimide anhydrides with terminal anhydride group or lateral anhydrides.

In addition, any polymeric composite such as engineering prepregs or composites, which are polymers filled with pigments, carbon particles, silica, glass fibers, conductive particles such as metal particles or conductive polymers, or mixtures thereof may also be used. For example, a blend of polycarbonate and ABS (Acrylonitrile Butadiene Styrene) may be used.

Referring again to FIG. **2**A, the exemplary patient interface panel **238** also includes one or more handles, e.g., **262**. The handles are positioned and configured such that a patient is able to grasp the handles during mounting and operation of the CBBCT imaging system **200**. This improves the ability of the patient to position their body on the patient interface panel, and provides stability to the patient during reorientation of the vertical plane gantry subsystem **202** as it pivots about hinge element **217**, as will be further described below. In addition, grasping the handles will allow the patient to maintain stasis during imaging, resulting in improved data/image quality.

In various embodiments of the invention, the handles **262** will be adjustable in one or more of the dimensions of a centerline of the patient interface panel **238**, and in a transverse dimension of that centerline, as well as in rotary fashion about a respective vertical axis disposed through the respective handle generally normal to surface **240** of the patient interface panel **238**. The reader will appreciate that the illustrated location and configuration of the exemplary handle presented here is only one of many possible locations and configurations. Further descriptions of exemplary handles are provided below in relation to FIG. **4**A-**4**E.

Accordingly, any of the handles described below in relation to FIGS. **4**A-**4**E should be understood to exemplify possible handles to be employed in relation to CBBCT imaging system such as imaging system **200**, along with other handles suitable to the application.

FIGS. **4**A-**4**E show, in schematic perspective view, exemplary handles that will be employed in respective embodiments of the invention. One of skill in the art will readily appreciate the advantages of the particular handle shown, and of others that are suggested by the present disclosure, and are deemed to be within its scope. For example, FIG. **4**A shows a handle **400** adapted to be grasped primarily about a transverse longitudinal axis **402** and to be substantially fixedly coupled to a patient support panel, directly or through an adjustment apparatus at first **404** and second **406** ends thereof. It will be noted that the handle of FIG. **4**A bear some similarity to the handles shown as elements **730**, **732** in FIG. **7**.

FIG. **4**B shows an alternative handle **410** adapted to be grasped primarily about a longitudinal axis **412** disposed generally normal to a surface of the patient support panel. A flange portion **414** of the handle **410** has a generally larger radius **416**, than a radius **418** of a grip portion **419**. This extended flange provides for effective coupling to the patient support panel, as well as improved stability and rigidity of the handle **410**.

FIG. **4**C shows a further alternative handle **420** adapted to be grasped primarily about a longitudinal axis **422** disposed generally normal to a surface of the patient support panel. A lower flange portion **424** of the handle **420** has a generally larger radius **426**, than a radius **428** of a grip portion **429**. An upper flange portion **430** is disposed in arcuate fashion away from the longitudinal axis **422**, and downward towards the table member to which it couples at a lower edge **432** thereof. The extended lower and upper flanges provide for effective coupling of the handle **420** to the patient support panel, as well as improved stability and rigidity of the handle.

FIG. **4**D shows a further alternative handle **434** adapted to be grasped primarily about a bulbous upper surface **436** disposed generally parallel to a surface of the patient support panel and transverse to a longitudinal axis **438** of the handle **434**. The longitudinal axis **438** is disposed generally normal to the surface of the patient support panel and, when in use, passes generally through the palm and/or the metacarpal phalangeal joints of the patient's hand. A circumferential recess **440** disposed below the bulbous upper surface **436** and generally transverse to longitudinal axis **438** is adapted to receive the tips of the patient's fingers therewithin, enhancing patient grip. A lower flange portion **442** of the handle **434** provides for effective coupling of the handle **434** to the patient support panel, as well as improved stability and rigidity of the handle.

FIG. **4**E shows a further alternative handle **444** adapted to be grasped primarily about a longitudinal axis **446** disposed generally normal to a surface of the patient support panel. A lower flange portion **448** of the handle **444** has a generally larger radius **450**, than a lateral dimension **452** of a grip portion **454**. One vertical surface region **456** of the handle **444** is generally convex and adapted to be placed in contact with a palm of a patient.

The opposing vertical surface region **458** includes a plurality of concave recesses, e.g., **460**, **462**, **464**, each adapted to receive a respective finger of the patient disposed therewithin. In certain embodiments, the handle **444** is substantially fixedly coupled a patient interface panel of the patient support panel. In other embodiments, the handle is coupled to the patient support panel through a rotary bearing and adapted to pivot circumferentially **466** substantially freely, or to be adjusted by pivoting circumferentially **466** and then releasably fixed in place, according to the requirements of a particular application of the invention. This pivotal motion allows adjustment of the position of surfaces **456** and **458** for optimum comfort of a patient grasping the handle.

Referring again to FIG. **2**A, an exemplary CBBCT imaging system **200** includes a pivotal adjustment subsystem **264**. In the exemplary embodiment of system **200**, the pivotal adjustment subsystem **264** includes a drive portion **266**, and a circumferential member **268**. A first end **270** of the circumferential member **268** is substantially fixedly coupled to the structural member **214**. A second end of the circumferential drive member **268** is disposed within, and operatively coupled to, a drive mechanism within the drive portion **266**.

In operation, the drive mechanism of the drive portion **266** serves to retract **272** and extend **274** the circumferential member **268**, thereby causing the structural member **214** (and the entire vertical plane gantry subsystem **202**) to pivot about the hinge element **217**.

Consequently, once a patient is properly positioned on the patient step **250**, and secured against the patient interface surface region **240** of the patient interface panel **238**, the vertical plane gantry subsystem **202** can be pivoted **276** about the hinge element **217**. This tends to improve breast positioning within the x-ray beam **218**, and to reduce patient fatigue that might otherwise result from standing during the imaging process.

Accordingly, FIG. **2**B shows CBBCT imaging system **200** in a pivoted configuration. The circumferential member **268** has been retracted in direction **272** so that the vertical plane gantry subsystem **202** is disposed at an angle **278** of approximately 60° with respect to a generally horizontal upper surface region **280** of the foundation element **216**.

It will be appreciated by one of skill in the art that, depending on the design details of a particular application or embodiment of the invention, it will be possible to pivot the vertical plane gantry subsystem **202** to an angle **278** of 45°, or anywhere down to and including zero. In addition, it will be evident that a negative angle positioning (i.e., patient head down) will also be available in corresponding embodiments of the invention. Accordingly, in respective embodiments of the invention, the vertical plane gantry subsystem will be positioned at an angle **278** within a range of from a least about 90° to at least about 80°; from at least about 80° to at least about 70°; from at least about 70° to at least about 60°; from at least about 60° to at least about 50°; from at least about 50° to at least about 40°; from least about 40° to at least about 30°; from at least about 30° to at least about 20°; at least about 20° to at least about 10°; from least about 10° to at least about 0°; from least about 0° to at least about −10°; release about −10° to at least about −20°.

In light of the foregoing, one of skill in the art will readily see that a wide variety of actuators will be employed in the drive mechanism of the drive portion **266**. For example, in certain embodiments of the invention, the circumferential member **268** will include a rack portion and the drive mechanism will include a pinion gear coupled directly or indirectly to an electric motor. In other embodiments of the invention, the circumferential member **268** will include a rack portion and the drive mechanism will include a worm gear coupled directly or indirectly to an electric motor.

In still other embodiments of the invention, the circumferential member **268** and drive portion **266** will be replaced by any of a wide variety of linear actuators, including any of those exemplified and listed above in relation to other aspects of the invention.

In still other embodiments of the invention, additional mechanisms will be provided that allow pivotal adjustment of the vertical plane gantry subsystem **202** about, for example, a longitudinal axis **282**, or about any other desired axis of rotation. The consequent additional degrees of freedom will permit the patient to be positioned in a spatial orientation that permits the subject breast to depend from the patient breast wall under the influence of gravity in a manner that optimizes imaging according to considerations of accommodating breast geometry, maintaining patient comfort and safety, improving image quality, limiting imaging duration and accommodating available imager dimensions and capacity, as well as imaging desirable chest wall features and managing direct and scattered x-ray exposure.

Thus, in certain embodiments of the invention, in addition to orienting the vertical plane gantry subsystem **202** about hinge **217**, other orientation adjustments will be made, either automatically, according to preprogrammed parameters, or under manual control of medical or technical personnel, so as to provide one or more desirable positioning's and orientations of the breast within the CBBCT imaging system **200**.

While the details of the additional mechanisms providing the additional degrees of freedom described above are omitted here for brevity, one of skill in the art will readily understand how such additional mechanisms would be provided and applied in light of the entirety of the present disclosure.

FIGS. **5**A-**5**C show, in functional block diagram form, processes and methods **500** for using a CBBCT imaging system according to principles of the invention. One of skill in the art will appreciate that the methods described herewith will be effectively employed along with any of the above-describe systems and with additional imaging systems and, in particular, with respect to CBBCT imaging system **200**.

Accordingly, FIG. **5**A illustrates the steps of arranging **502** a CBBCT imaging system in an initial (upright) state; capturing **504** patient measurements (i.e. body dimensions and characteristics); installing and configuring **506** a patient interface subpanel; adjusting **508** of patient step location; introducing **510** a patient to imaging system; attaching **512** or activating the patient safety device; further adjusting **514** patient positioning, including adjusting additional support system parameters (as further discussed below) to improve patient positioning for comfort and imaging; optionally inflating **516** the patient back bladder or otherwise activating the active cushion system towards the back of the patient so as to urge the patient against the patient interface panel and stabilize the patient against inadvertent movement; optionally installing **518** breast stabilization unit; further adjusting **520** patient interface subpanel configuration; releasing **522** safety interlock; rotating **524** vertical plane gantry subsystem about hinge element; activating **526** the x-ray source; rotating **528** the vertical plane gantry about the axis of rotation; and initiating **530** CBBCT scanning.

In addition to the steps indicated above, the methods and processes **500** will optionally include any one or more of the steps of: optionally initiating **532** secondary hybrid scanning such as, for example and without limitation, CBBCT/ultrasonic hybrid scanning, CBBCT/PET hybrid scanning, CBBCT/terahertz hybrid scanning, CBBCT/optical hybrid scanning; optionally configuring **534** a stationary scan subsystem and initiating **536** a stationary scan, as well as optionally de-configuring **538** the stationary scan subsystem; optionally configuring **540** a biopsy guidance subsystem, optionally conducting **542** a biopsy procedure, and optionally de-configuring **544** the biopsy guidance system. Of course one of skill in the art, having the benefit of the present disclosure will, in hindsight, appreciate that other optional steps combining available ancillary equipment and methods with the present method will be desirable and readily implemented. All of the foregoing, are therefore intended to be within the scope of the present disclosure.

The disclosed methods and processes further include the steps of rotating **546** the vertical scan gantry subsystem back to the initial (vertical) state; releasing **548** the safety device, including releasing relaxing any bladder or other active cushion system and releasing any safety belt; and dismounting **550** the patient from imaging system.

FIG. **6** shows, in schematic side elevation, a portion of an exemplary CBBCT imaging system **600**, similar to system **200**, including a vertical plane gantry subsystem **602**. The vertical plane gantry subsystem **602** includes a vertical plane gantry **604** configured to rotate about a generally horizontal axis of rotation **606**.

Like systems **100** and **200** described above, system **600** includes an x-ray source **608**. The exemplary x-ray source **608** is mounted on, and supported by, a mounting surface **610** of the vertical plane gantry **604**. The vertical plane gantry **604** is supported by a bearing **612**, and arranged for rotation about the axis of rotation **606**. The bearing **612** is, in turn, coupled to and supported by a structural member **614**, and the structural member **614** is pivotally coupled to, and supported by, a foundation element **616** of the vertical plane gantry subsystem **602** at a hinge element **617**.

A base member **630** is coupled to the structural member **614**. A patient interface panel **638** is coupled through the base member **630** to the structural member **614** so that the structural member **614** and the base member **630** serve to support the patient interface panel **638**.

The patient interface panel **638** has a first patient interface surface region **640** and a second distal surface region **642**, where the distal surface region **642** is disposed in spaced relation to the patient interface surface region **640**. The exemplary patient interface panel **638** is similar in form and function to the patient interface panel **238** of FIG. **2**.

Accordingly, referring to FIGS. **2** and **6** the patient interface panel includes an internal circumferential edge of the patient interface surface region. The internal circumferential edge circumscribes an aperture **646** through the patient interface panel **638** between patient interface surface region **640** and distal surface region **642**.

In a manner similar to that described above, the patient interface surface region **640** is arranged to segregate the patient from the balance of the vertical gantry subsystem **602** with a breast of the patient disposed through the aperture **646**. In various embodiments and aspects of the invention, a patient interface subsystem, as exemplified above, is disposed at the aperture **646**. In various aspects, the patient interface subsystem will provide one or more of an aperture sized and located according to the particular patient and breast being imaged, shielding for regions of the patient that might otherwise be exposed to scattered x-ray photons, and support and stabilization of the breast being imaged, among other features.

The CBBCT imaging system **600** also includes an exemplary seat apparatus **676**. In the illustrated embodiment, exemplary seat apparatus **676** is coupled to, and supported by, a corresponding portion **678** of the patient interface surface region **640**. In other embodiments of the invention, the exemplary seat apparatus **676** is coupled to and supported by base portion **630**, and/or patient step **650**, or to any other location, feature or aspect of the CBBCT imaging system, or combination of the same, appropriate to the requirements of a particular application and embodiment of the invention.

The seat apparatus **676** includes a saddle portion **680** with a structural body member **682** a saddle upper surface region **684**. Saddle upper surface region **684** is adapted to position and support a patient sitting astride the saddle portion **680** during imaging as well as during optional supplemental procedures.

In the illustrated embodiment, structural body member **682** is substantially fixedly coupled to an upper end of an exemplary seat column **686** which is coupled to the CBBCT imaging system **600** as described above, directly or through an appropriate positional adjustment apparatus. The seat column is optional, and in certain embodiments of the invention, the saddle structural body member is coupled directly to the CBBC to imaging system **600**.

Accordingly, in certain embodiments of the invention, a lower end of the exemplary seat column **686** is operatively coupled to a seat adjustment mechanism. The seat adjustment a mechanism is coupled, directly or indirectly, to the base member **630** for support. Consequently, the weight of a patient seated on the saddle upper surface region **684** is transferred through the structural body member **682** of the saddle to the seat column **686**, and from there through the seat adjustment mechanism to the base member **630**.

In a desirable aspect of certain embodiments of the invention, the seat adjustment mechanism permits positional adjustment of the saddle portion **680** vertically **688** i.e., transverse to an upper surface **690** of the base member **630**. In certain embodiments, the seat adjustment mechanism also permits pivotal rotations i.e., yaw of the saddle about a longitudinal axis of the seat column **686** and pitch about a transverse axis.

Beyond this, in certain embodiments of the invention, roll of the saddle portion **680** will also be adjustable to ensure comfort and optimal positioning of the patient with respect to the vertical plane gantry subsystem **602**.

In a still further aspect of the invention, in certain embodiments the saddle will be removable or foldable, or otherwise displaceable so that a patient being imaged will not sit on the saddle, but will stand on an upper surface **654** of the step portion **650**, for example. Accordingly, seating on the saddle will be available where desirable, but the saddle need not be employed where a standing mode of patient support is preferable.

As will be appreciated by one of skill in the art, the saddle portion **676** will be shaped and configured to promote optimal comfort and positioning of the patient with respect to the vertical plane gantry subsystem **602**. In certain embodiments, the saddle portion **676** will include materials that advantageously are biocompatible and exhibit desirable characteristics of rheology and elastic durometer.

Accordingly, in respective embodiments of the invention, the saddle portion **676** will include materials appropriate to achieve these ends. A variety of exemplary materials corresponding to respective embodiments of the invention are provided above in relation to the description accompanying FIG. **3**.

FIG. **7** shows, in schematic proximal elevation, certain aspects of an exemplary CBBCT imaging system **700**, including a vertical plane gantry subsystem **702**, prepared according to principles of the invention. It will be appreciated that vertical plane gantry subsystem **702** is similar in its features to the subsystems discussed above and shows further aspects and details of the same invention, as well as additional inventive features and aspects. Accordingly, vertical plane gantry subsystem **702** includes a patient interface panel **704**.

The patient interface panel **704** includes a patient interface surface region **706** adapted to support a patient during scanning. In various embodiments of the invention, the patient interface surface region **706** includes an inner circumferential edge **708** defining an aperture of the patient interface surface region through the patient interface panel **704**. In some embodiments of the invention, the aperture is adapted to receive a breast of the patient disposed therethrough. In other embodiments, including that illustrated in FIG. **7**, the aperture is adapted to receive a patient interface subpanel **710** that traverses circumferential edge **708**. The patient interface subpanel **710** is coupled to and/or supported by the patient interface panel **704**.

With respect to inner circumferential edge **708**, it will be apparent that the particular shape of the circumferential edge will be selected in a corresponding embodiment so as to optimize considerations such as functionality and ease of manufacture. Accordingly, the geometry shown is merely exemplary of a wide variety of configurations that will be immediately apparent to one of skill in the art in light of the entirety of the present disclosure.

The patient interface subpanel **710** includes a subpanel surface region **712**. A further inner circumferential edge **714** defines a subpanel aperture **716** through the subpanel. In the configuration illustrated, the subpanel aperture **716** is disposed to the right of a longitudinal centerline **718** of the patient interface panel **704**. Accordingly, in typical operation of the CBBCT imaging system, a right breast of the patient will be disposed through the subpanel aperture **716** during imaging.

One of skill in the art will appreciate that, in certain embodiments of the invention, a plurality of subpanels will be provided that include apertures of different respective dimensions. For example, a subpanel having an internal circumferential edge **724** defining an aperture with a smaller diameter (as compared with illustrated aperture **716** defined by inner circumferential edge **714**) will be available. Accordingly, technical or medical personnel will be able to select and install a subpanel having an aperture appropriate for the size of the breast of the particular patient to be imaged.

In other embodiments of the invention, the adjustment of aperture size will be effected by operation of an adjustment mechanism such as an iris leaf diaphragm aperture mechanism (see, e.g., FIGS. **9**D-**9**F below). In certain embodiments the adjustment mechanism will be substantially permanently coupled to the patient interface panel **704** of the vertical plane gantry subsystem **702**. In other embodiments of the invention, the adjustment mechanism will be coupled to a subpanel like subpanel **710** described above.

In certain embodiments of the invention, the aperture for receiving the breast to be imaged is disposed generally coincident with the centerline of the patient table. In such an embodiment, the patient will be positioned to align the breast to be imaged with the centerline of the table. Consequently, no additional transverse mechanism is required to align the breast with the axis of rotation of the gantry. It will be appreciated by one of skill in the art that this alignment of the breast aperture may be effected by providing the aperture directly in the patient table, or, alternately, in a subpanel configured for attachment or coupling to the patient table.

Accordingly, FIG. **8** shows, in schematic proximal elevation, certain aspects of an exemplary CBBCT imaging system **800** including, including a vertical plane gantry subsystem **802**, generally similar to vertical plane gantry subsystem **702** of FIG. **7**. Vertical plane gantry subsystem **802** includes a patient interface panel **804**.

The patient interface panel **804** includes a patient interface surface region **806** adapted to support a patient during scanning. In various embodiments of the invention, the patient interface surface region **806** includes an inner circumferential edge **808** defining an aperture of the patient interface surface region through **806** the patient interface panel **804**. In some embodiments of the invention, the aperture is adapted to receive a breast of the patient disposed therethrough. In other embodiments, including that illustrated in FIG. **8**, the aperture is adapted to receive a subpanel **810** that traverses circumferential edge **808**. The subpanel **810** is coupled to and/or supported by the patient interface panel **804**.

The subpanel **810** includes a subpanel surface region **812**. A further inner circumferential edge **814** defines a subpanel aperture **816** through the subpanel. In the configuration illustrated, the subpanel aperture **816** is disposed coincident with a longitudinal centerline **818** of the patient interface panel **804**. Accordingly, in typical operation of the CBBCT imaging system, either breast of the patient may be disposed through the subpanel aperture **816** during imaging, with the patient being arranged on the patient interface surface **806** of the patient interface panel **804** accordingly.

Although the inner circumferential edges **714**, **724**, **814** illustrated and discussed above are shown with substantially circular aspects, one of skill in the art will appreciate that the circumferential edge may be of any form considered advantageous according to the requirements of a particular application of the invention. Accordingly, in certain embodiments of the invention, circumferential edge will be generally elliptical, or may be generally triangular, or of any other regular or irregular polygonal form, or of any arcuate form or any combination of arcuate and linear segments, or any combination of the foregoing, all of which are considered to be within the scope of the present disclosure.

In the context of the foregoing discussions, FIGS. **9**A-**9**F show, in schematic fashion, a variety of exemplary subpanel configurations that fall within the scope of the present invention and are similar to subpanels **710** and **810** described above in relation to FIGS. **7** and **8**.

FIGS. **9**A-**9**C show respectively, in schematic elevation, exemplary subpanels having a variety of aperture locations and sizes.

Referring first to FIG. **9**A, subpanel **900** includes a subpanel surface region **902**. An inner circumferential edge **904** defines a subpanel aperture **906** through the subpanel. Consistent with the discussion above, the aperture **906** is adapted to receive a patient breast to be imaged therethrough. In the configuration illustrated, the subpanel aperture **906** is disposed to the left of a longitudinal centerline **908** of the subpanel **900**. Accordingly, in typical operation of the CBBCT imaging system, a left breast of the patient will be disposed through the subpanel aperture **906** during imaging.

FIG. **9**B shows a subpanel **912** similar to subpanel **900**. As with subpanel **900**, subpanel **912** has an inner circumferential edge **914** that defines a subpanel aperture **916** through the subpanel **912**. Like aperture **906**, aperture **916** is disposed to the left of a longitudinal centerline **918** of the subpanel **912**. However, aperture **906** has a diameter **920** that is relatively smaller than the corresponding diameter **922** of aperture **916**.

FIG. **9**C shows a subpanel **926** similar to subpanels **900** and **912**. As with subpanel **900**, subpanel **926** has an inner circumferential edge **928** that defines a subpanel aperture **930** through the subpanel **926**. Like aperture **906**, aperture **930** has a diameter **932** that is substantially equal to corresponding diameter **922** of aperture **916**. However, a centroid of aperture **930** is disposed substantially coincident with centerline **934** of the subpanel **926**. Accordingly, whereas apertures **906** and **916** are primarily configured for receiving a left breast of the patient for imaging, aperture **930** is well adapted to receiving either a left breast or a right breast.

It will also be appreciated by one of skill in the art that, where appropriate perimeter configurations and coupling features are provided, symmetries of the illustrated panels will be used in respective embodiments of the invention to image, for example, either a left breast or a right breast by symmetric rotation of subpanel **900** or **912** about centerlines **908** and **918** respectively.

Likewise, rotation of the panels about an axis transverse to the centerlines can be used to locate the illustrated apertures relatively higher or lower respectively, according to the needs of a taller or shorter patient.

In light of the foregoing discussion, it will be appreciated by the reader that, in certain embodiments of the invention, a plurality of subpanels will be provided along with an imaging system, such that the subpanel with the appropriate aperture will be selected according to the height, weight, breast size and other parameters of the patient.

In another aspect embodiment of the invention, individual reusable subpanels will be purchased so as to be available where required. In still other embodiments of the invention, disposable subpanels will be employed for single use with a respective patient, and thereafter discarded.

FIGS. **9**D-**9**F show schematic representations of a further subpanel **950** prepared according to principles of the invention. Subpanel **950** is shown in cutaway view, and illustrates an adjustment mechanism **952** included in subpanel **950**.

In the exemplary embodiment illustrated, adjustment mechanism **952** includes a mechanical iris mechanism **954**. The adjustable iris mechanism **954** includes a plurality of leaf elements, e.g., **956**, **958** respectively coupled to corresponding operative links **960**, **962**. One of skill in the art will recognize the adjustable iris mechanism **954** as similar in form and function to iris mechanisms employed in photographic cameras. Accordingly, by operation of the operative links **960**, **962**, the leaf elements **956**, **958** will be urged to pivot so as to adjust a diameter of an aperture **964** to a preferred value according to the requirements for imaging a particular patient breast.

By way of further illustration, in FIG. **9**E exemplary iris mechanism **970** is adjusted and configured to present an aperture **972** having a relatively small diameter **974**. In FIG. **9**F, exemplary iris mechanism **970** is adjusted and configured to present the same aperture **972** with a relatively large diameter **976**.

In a still further aspect of the invention FIG. **10** shows, in schematic distal cutaway perspective view, a subpanel **1000** including a breast stabilizer unit **1002** adapted and configured to support and stabilize a patient breast during imaging. As illustrated, the breast stabilizer unit **1002** is coupled to the subpanel **1000** at aperture **1004** of distal surface **1006**.

In certain applications, the stabilizer unit **1002** is configured and adjusted to maintain an approximate geometric centroid of the breast coincident with an axis of rotation (e.g., **206** of FIG. **2**A) and longitudinal axis **220** of the x-ray beam **218**. It will be appreciated by one of skill in the art, however, that any of a wide variety of placements and configurations of the breast will be desirable in respect to a particular patient, application, or imaging objective, and will be achieved by an appropriate configuration, shape, and placement of the stabilizer unit **1002**.

Accordingly, the stabilizer unit **1002** is arranged, adapted and configured to support, stabilize and hold in place, at least a portion of breast, with respect to the above-described transit path **228** of flat panel detector receiving surface **226**, during imaging of the breast by the imaging system.

One of skill in the art will readily appreciate the various benefits and modalities for employing a breast stabilizer unit like the exemplary stabilizer unit presented herewith upon review of the related applications listed above.

In certain embodiments of the invention, the CBBCT scanning system comprises a foundation element and a vertical plane gantry subsystem coupled to and supported by the foundation element. The vertical plane gantry subsystem includes a CBBCT gantry that is adapted and configured to rotate about a generally horizontal axis of rotation. The vertical plane gantry subsystem also includes a patient interface panel, the patient interface panel has a patient interface surface region with an aperture therethrough. A patient interface sub-panel may be disposed within the aperture of the patient interface panel.

Also included is a pivotal adjustment subsystem which includes a pivotal hinge mutually coupled between the foundation element and the vertical plane gantry subsystem. The pivotal hinge is adapted to rotate the patient interface panel from a first generally vertical orientation to a second generally non-vertical orientation.

In certain embodiments of the invention, the pivotal adjustment subsystem of the CBBCT scanning system further comprises an actuator, the actuator being adapted to control the rotation of the first patient interface panel.

In certain embodiments of the invention, the actuator comprises a linear actuator, the linear actuator having a first end operatively coupled to the foundation element and a second end operatively coupled to the vertical plane gantry subsystem.

In some embodiments of the invention, the patient interface panel of the CBBCT scanning system includes a patient support saddle portion.

In certain embodiments of the invention, the saddle portion is coupled to a seat adjustment mechanism.

In certain embodiments of the invention, the seat adjustment mechanism is adapted to adjust a saddle upper surface of the saddle portion in a vertical degree of freedom, while in some embodiments of the invention the seat adjustment mechanism is adapted to adjust a saddle upper surface of the saddle portion in a horizontal degree of freedom.

In certain embodiments of the invention, the seat adjustment mechanism is adapted to adjust a saddle upper surface of the saddle portion in at least one of a pitch degree of freedom, a roll degree of freedom, and a yaw degree of freedom.

In certain embodiments of the invention, the patient interface sub-panel of the CBBCT scanning system includes a breast aperture, the breast aperture being adapted to receive a patient breast therethrough for imaging.

In certain embodiments of the invention, the breast aperture includes an aperture adjustment mechanism, the aperture adjustment mechanism is adapted to change a diameter of the aperture, whereby the diameter will be adjusted according to a size of a patient breast.

In certain embodiments of the invention, the patient interface sub-panel of the CBBCT scanning system includes a breast stabilization unit to support a patient breast during imaging.

In certain embodiments of the invention a method of conducting a CBBCT scan comprises providing a foundation element with a generally horizontal upper surface region and a vertical plane gantry subsystem pivotally coupled to the foundation element. The vertical plane gantry subsystem has a patient step portion with a patient step upper surface region to support a patient during imaging.

The method also includes providing a pivotal adjustment subsystem mutually coupled between the foundation element and the vertical plane gantry subsystem, disposing the imaging system in a first substantially vertical configuration with respect to the generally horizontal upper surface region of the foundation element, adjusting the patient step portion for patient positioning, introducing the patient to the patient step upper surface in a standing posture, securing a safety feature to maintain patient positioning with respect to the vertical plane gantry subsystem, positioning a patient breast within an imaging aperture of the vertical plane gantry subsystem, activating the pivotal adjustment subsystem, rotating the imaging system from the first substantially vertical configuration into a second substantially non-vertical configuration with respect to the generally horizontal upper surface region of the foundation element and CBBCT scanning the patient breast with the vertical plane gantry subsystem.

The method further includes rotating the imaging system from the second substantially non-vertical configuration to the first substantially vertical configuration, releasing the safety feature and dismounting the patient from the patient step upper surface region of the patient step portion.

In certain embodiments of the invention the method of conducting a CBBCT scan further comprises the steps of installing a patient support subpanel at the subpanel aperture of the patient interface panel of the vertical plane gantry subsystem and disposing the patient breast through a breast aperture of the patient support subpanel.

In certain embodiments of the invention the method of conducting a CBBCT scan further comprises the steps of receiving a patient parameter value and selecting the patient support subpanel according to the patient parameter value.

In some embodiments of the invention selecting the patient support subpanel according to the patient parameter value of the patient further comprises the step of selecting a patient support subpanel having a breast aperture diameter corresponding to a breast diameter value of the patient, while in still further embodiments selecting the patient support subpanel further comprises selecting a patient support subpanel having a breast aperture beneficially disposed to one side of a centerline of the patient interface panel.

In certain embodiments of the invention the method of conducting a CBBCT scan comprises adjusting a diameter of the breast aperture of the patient support subpanel.

In certain embodiments of the invention the method of conducting a CBBCT scan comprises disposing a patient breast through the breast aperture of the patient support subpanel and further comprises positioning the patient breast within a breast stabilization unit of the patient interface panel.

In certain embodiments of the invention activating the pivotal adjustment subsystem during conduction of a CBBCT scan further comprises the step of manually motivating the pivotal adjustment subsystem while in still further embodiments activating the pivotal adjustment subsystem comprises energizing an electric motor within the pivotal adjustment subsystem and operating the electric motor to extend a linear actuator member of the pivotal adjustment subsystem.

In some embodiments of the invention activating the pivotal adjustment subsystem comprises energizing an electric motor within the pivotal adjustment subsystem and operating the electric motor to extend a linear actuator member of the pivotal adjustment subsystem.

In some embodiments of the invention activating the pivotal adjustment subsystem comprises activating a pneumatic cylinder of the pivotal adjustment subsystem while in still further embodiments of the invention activating the pivotal adjustment subsystem further comprises the step of releasing a safety interlock of the pivotal adjustment subsystem.

In certain embodiments of the invention the method of conducting a CBBCT scan further comprises adjusting a position of a saddle portion of the vertical plane gantry subsystem while in some embodiments of the invention the method of conducting a CBBCT scan further comprises seating a patient on a saddle portion of the vertical plane gantry subsystem.

In certain embodiments of the invention the method of conducting a CBBCT scan includes providing a foundation element with a generally horizontal upper surface region and a vertical plane gantry subsystem pivotally coupled to the foundation element. The vertical plane gantry subsystem has a patient step portion with a patient step upper surface region adapted to support a patient during imaging. The imaging system is disposed in a first substantially vertical configuration with respect to the generally horizontal upper surface region of the foundation element and the patient step portion is adjusted for patient positioning.

The method includes introducing the patient to the patient step upper surface in a standing posture, positioning a patient breast within an imaging aperture of the vertical plane gantry subsystem, rotating the imaging system from the first substantially vertical configuration into a second substantially non-vertical configuration with respect to the generally horizontal upper surface region of the foundation element and CBBCT scanning the patient breast with the vertical plane gantry subsystem. The imaging system is rotated from the second substantially non-vertical configuration to the first substantially vertical configuration so the patient can dismount from the patient step upper surface region of the patient step portion.

While the exemplary embodiments described above have been chosen primarily from the field of apparatus, and corresponding systems and methods in the operation of a CBBCT imaging system, including ergonomically improved systems and methods thereof, one of skill in the art will appreciate that the principles of the invention are equally well applied, and that the benefits of the present invention are equally well realized in a wide variety of other imaging technologies, for example, imaging of other body parts and imaging of other subjects such as industrial and technological products. Further, while the invention has been described in detail in connection with the presently preferred embodiments, it should be readily understood that the invention is not limited to such disclosed embodiments. Rather, the invention can be modified to incorporate any number of variations, alterations, substitutions, or equivalent arrangements not heretofore described, but which are commensurate with the spirit and scope of the invention. Accordingly, the invention is not to be seen as limited by the foregoing description, but is only limited by the scope of the appended claims.

The invention claimed is:

1. A method of conducting a Cone Beam Breast Computed Tomography (CBBCT) scan comprising:

providing a foundation element, said foundation element having a generally horizontal upper surface region;

providing a vertical plane gantry subsystem pivotally coupled to said foundation element, said vertical plane gantry subsystem having a patient step portion, said patient step portion having a patient step upper surface region, said patient step upper surface region being adapted to support a patient during imaging;

providing a pivotal adjustment subsystem mutually coupled between said foundation element and said vertical plane gantry subsystem;

disposing said imaging system in a first substantially vertical configuration with respect to said generally horizontal upper surface region of said foundation element;

adjusting said patient step portion for patient positioning;

introducing said patient to said patient step upper surface in a standing posture;

securing a safety feature to maintain patient positioning with respect to said vertical plane gantry subsystem;

positioning a patient breast within an imaging aperture of said vertical plane gantry subsystem;

activating said pivotal adjustment subsystem;

rotating said imaging system from said first substantially vertical configuration into a second substantially non-vertical configuration with respect to said generally horizontal upper surface region of said foundation element;

CBBCT scanning said patient breast with said vertical plane gantry subsystem;

rotating said imaging system from said second substantially non-vertical configuration to said first substantially vertical configuration;

releasing said safety feature; and

dismounting said patient from said patient step upper surface region of said patient step portion;

wherein said activating said pivotal adjustment subsystem further comprises the step of:

activating a pneumatic cylinder of said pivotal adjustment subsystem.

2. A method of conducting a Cone Beam Breast Computed Tomography (CBBCT) CBBCT scan as defined in claim **1**

wherein said activating said pivotal adjustment subsystem further comprises the step of:

releasing a safety interlock of said pivotal adjustment subsystem.

3. A method of conducting a Cone Beam Breast Computed Tomography (CBBCT) scan as defined in claim **1** further comprising the step of:

adjusting a position of a saddle portion of said vertical plane gantry subsystem.

4. A method of conducting a Cone Beam Breast Computed Tomography (CBBCT) scan as defined in claim **1** further comprising the step of:

seating a patient on a saddle portion of said vertical plane gantry subsystem.

5. A method of conducting a Cone Beam Breast Computed Tomography (CBBCT) scan as defined in claim **1** wherein said vertical plane gantry subsystem includes a patient interface panel, said patient interface panel having a subpanel aperture therethrough; and further comprising the steps of:

installing a patient support subpanel at said subpanel aperture of said patient interface panel; and

disposing said patient breast through a breast aperture of said patient support subpanel.

6. A method of conducting a Cone Beam Breast Computed Tomography (CBBCT) scan as defined in claim **5** further comprising the steps of:

receiving a patient parameter value; and

selecting said patient support subpanel according to said patient parameter value.

7. A method of conducting a Cone Beam Breast Computed Tomography (CBBCT) scan as defined in claim **6** wherein said selecting said patient support subpanel according to said patient parameter value of said patient further comprises the step of:

selecting a patient support subpanel having a breast aperture diameter corresponding to a breast diameter value of said patient.

8. A method of conducting a Cone Beam Breast Computed Tomography (CBBCT) scan as defined in claim **6** wherein said selecting said patient support subpanel according to said patient parameter value of said patient further comprises the step of:

selecting a patient support subpanel having a breast aperture beneficially disposed to one side of a centerline of said patient interface panel.

9. A method of conducting a Cone Beam Breast Computed Tomography (CBBCT) scan comprising:

providing a foundation element, said foundation element having a generally horizontal upper surface region;

providing a vertical plane gantry subsystem pivotally coupled to said foundation element said vertical plane gantry subsystem having a patient step portion, said patient step portion having a patient step upper surface region, said patient step upper surface region being adapted to support a patient during imaging;

disposing said imaging system in a first substantially vertical configuration with respect to said generally horizontal upper surface region of said foundation element;

adjusting said patient step portion for patient positioning;

introducing said patient to said patient step upper surface in a standing posture;

positioning a patient breast within an imaging aperture of said vertical plane gantry subsystem;

rotating said imaging system from said first substantially vertical configuration into a second substantially non-vertical configuration with respect to said generally horizontal upper surface region of said foundation element;

CBBCT scanning said patient breast with said vertical plane gantry subsystem;

rotating said imaging system from said second substantially non-vertical configuration to said first substantially vertical configuration;

dismounting said patient from said patient step upper surface region of said patient step portion.

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