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(54) **DEDICATED BREAST RADIATION IMAGING/THERAPY SYSTEM**

(76) Inventors: **Kenneth Brooks**, Knoxville, TN (US); **Jay A. Stein**, Boston, MA (US); **Andrew P. Smith**, Lexington, MA (US)

Correspondence Address:
Cooper & Dunham, LLP
30 Rockefeller Plaza, 20th Floor
New York, NY 10112 (US)

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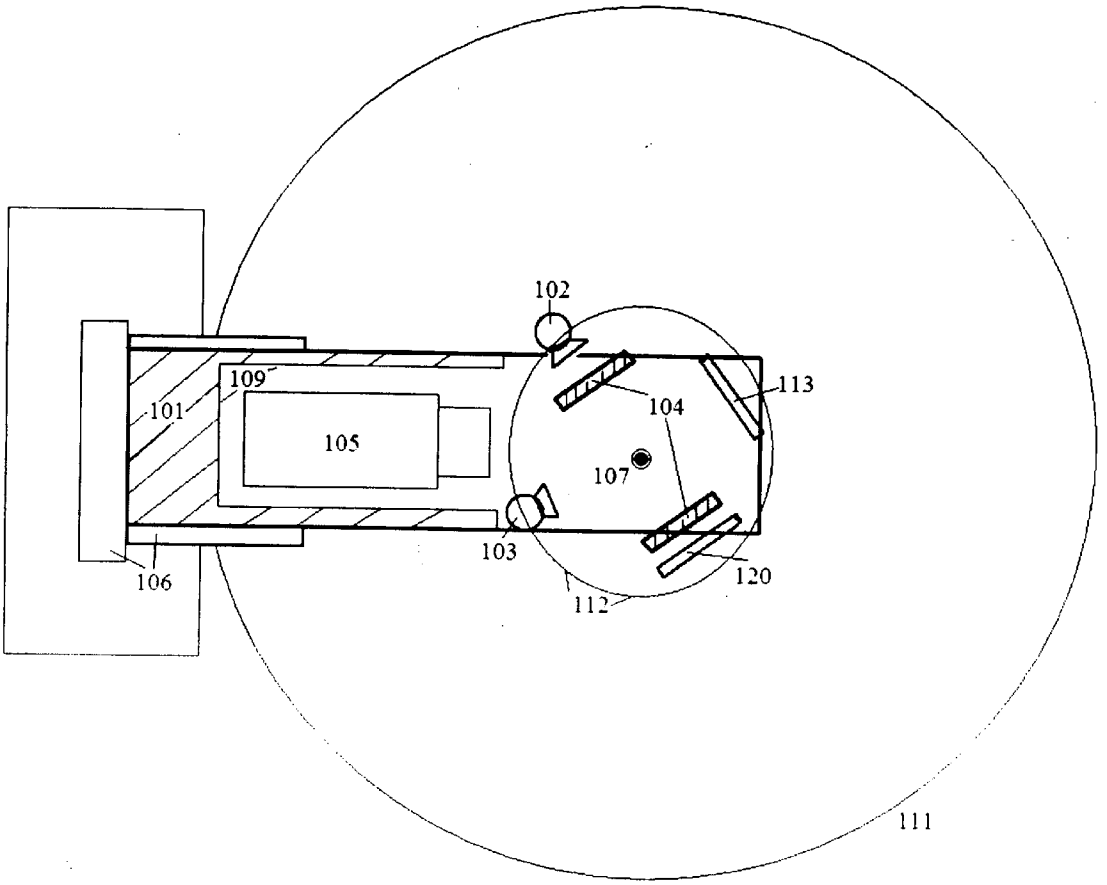
(57) **ABSTRACT**

System, apparatus and methods specialized for breast and related tissue radiation therapy and imaging of a prone patient but also usable for supine patient if desired or needed. A special treatment radiation source such as a LINAC unit generates radiation of types and energy ranges specifically matched to breast tissue. Any one or more of several imaging technologies may be used to localize the tissue to be irradiated and to generate information for therapy planning, adjustment, and verification.



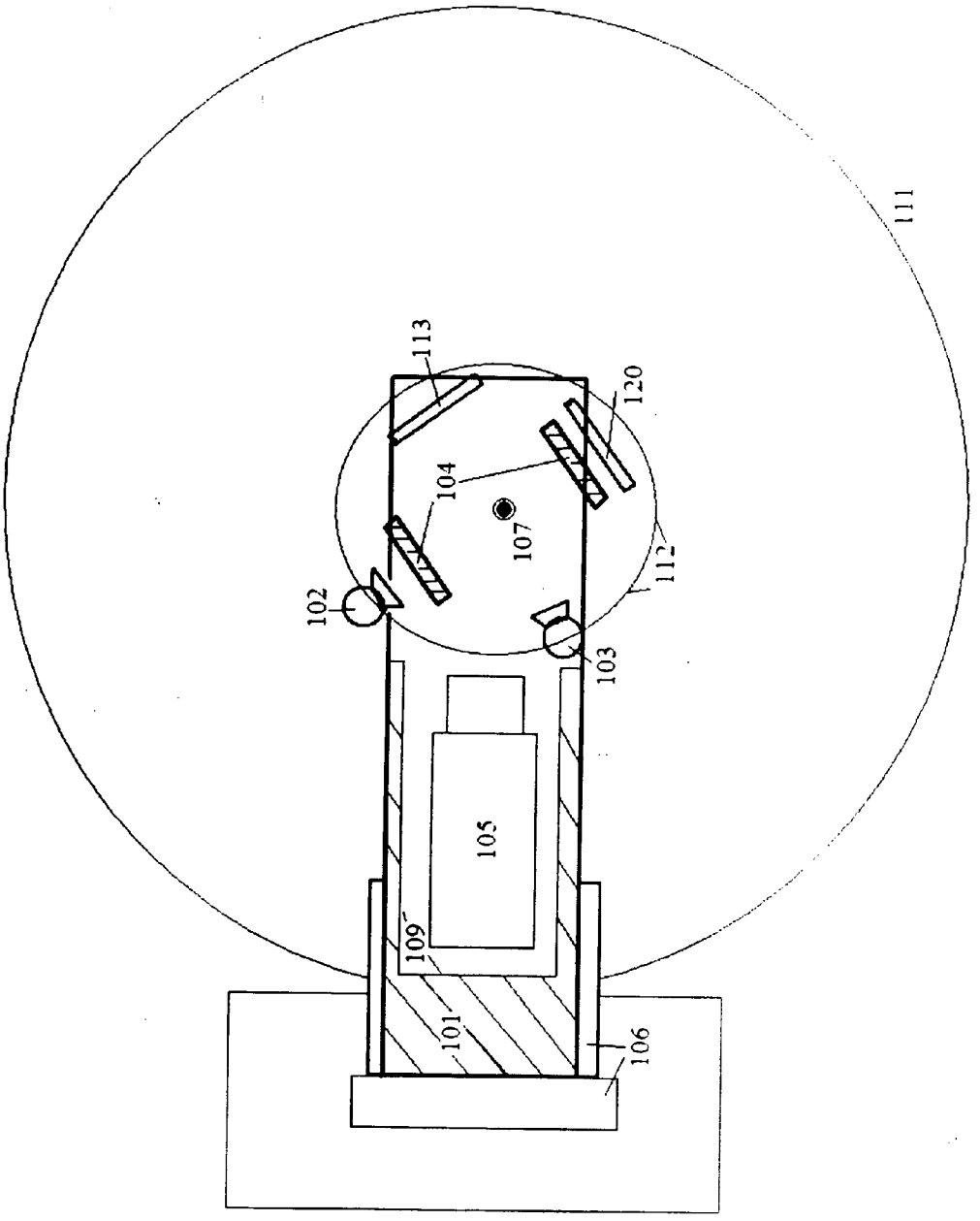


Figure 1

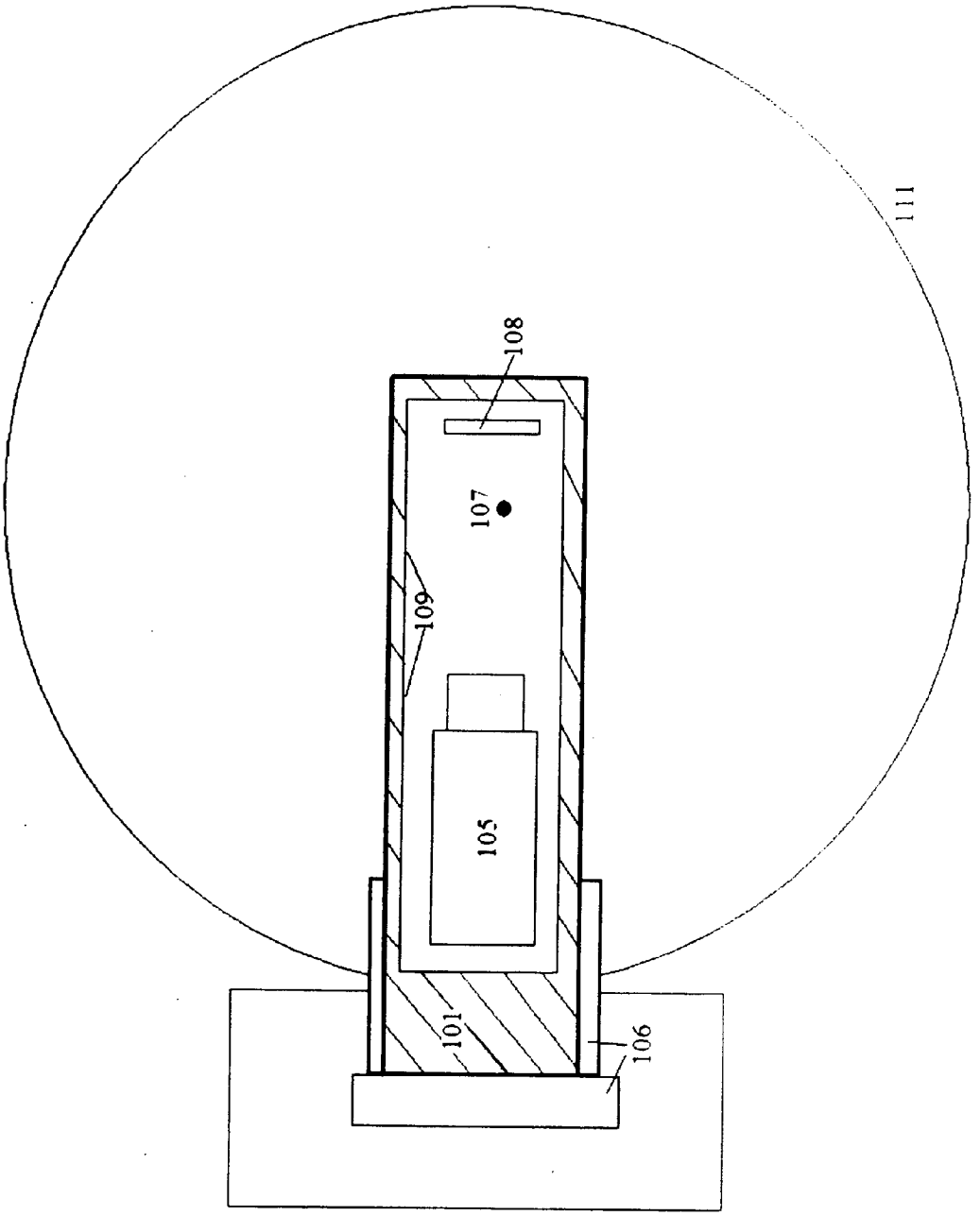


Figure 2a

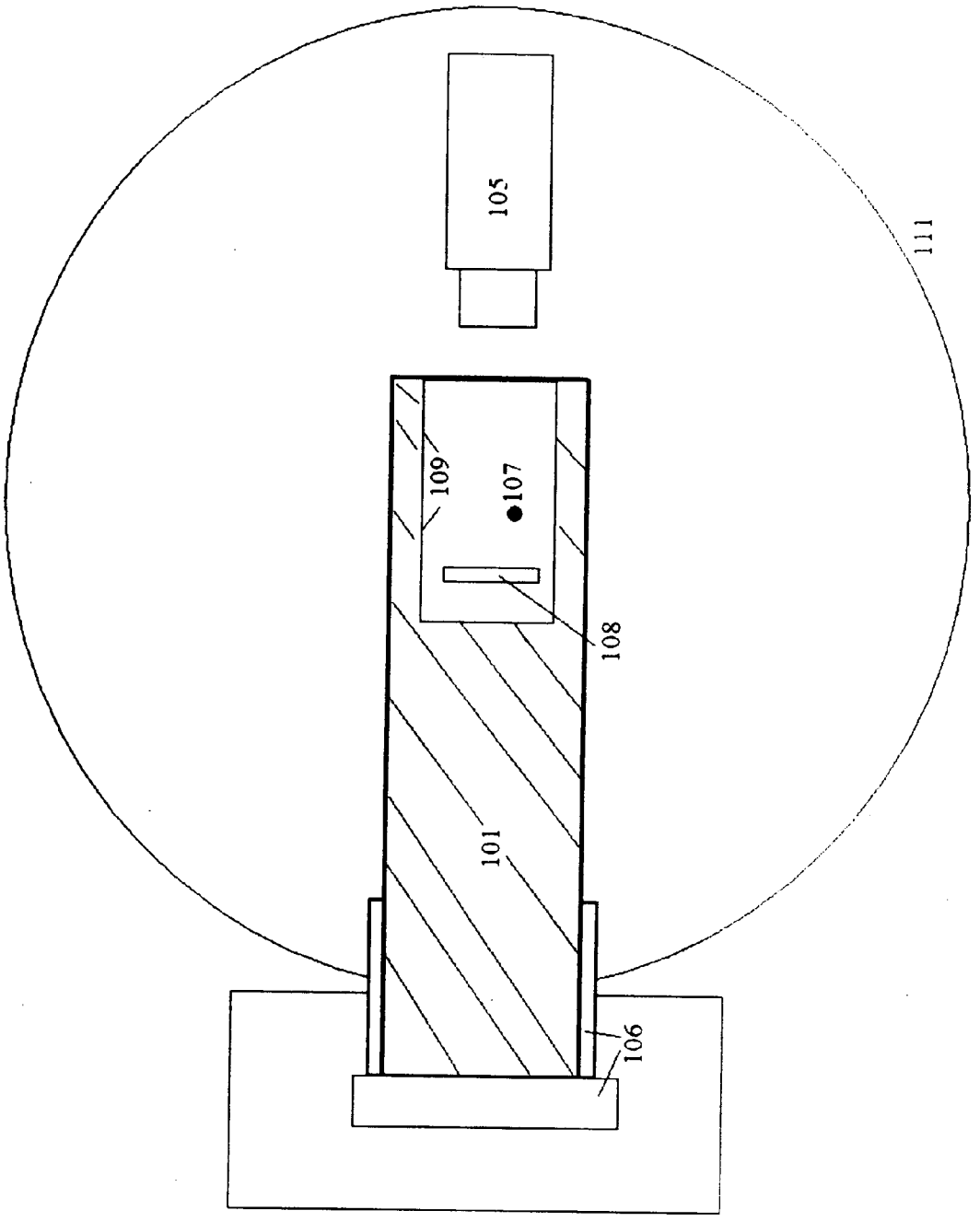


Figure 2b

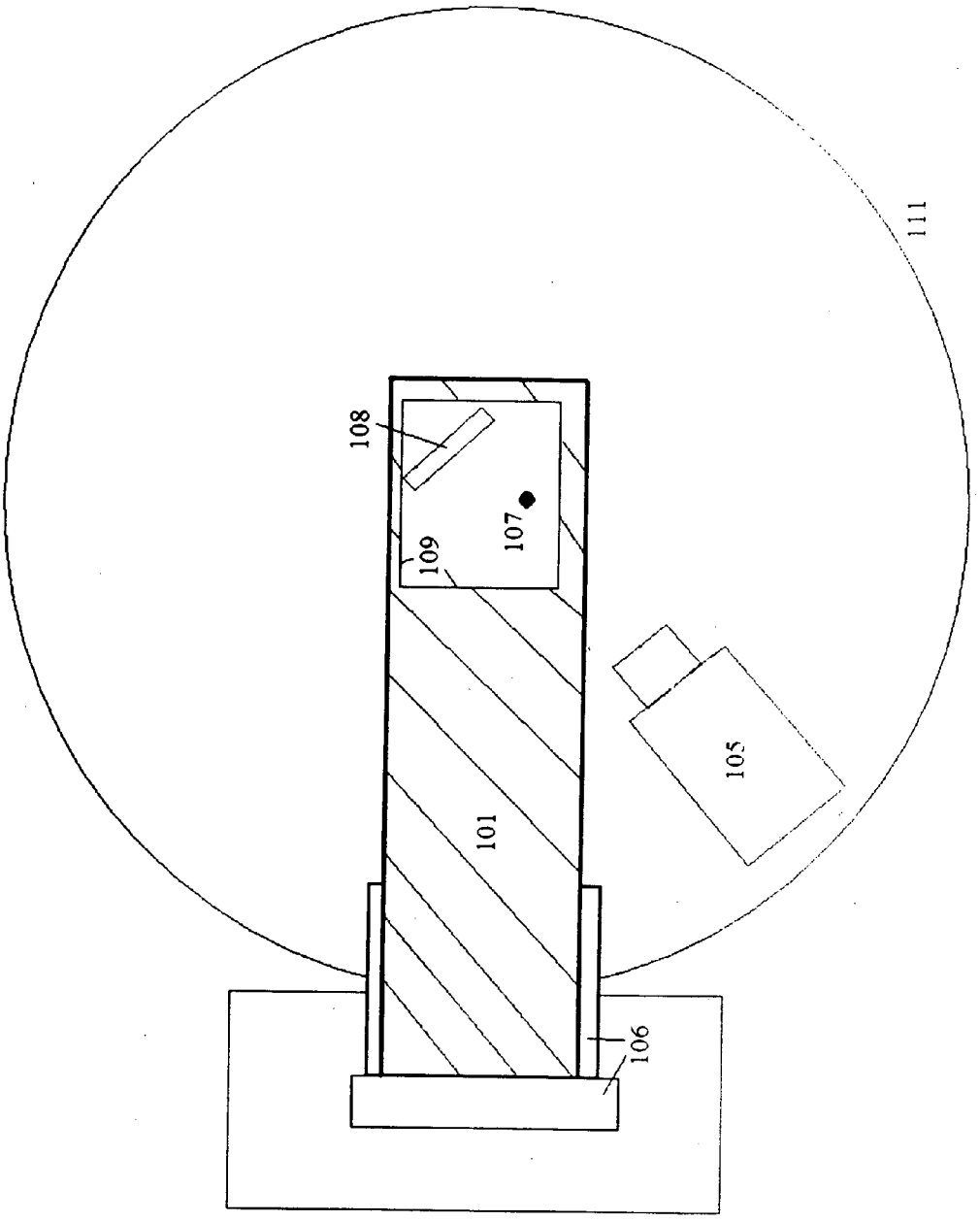


Figure 2c

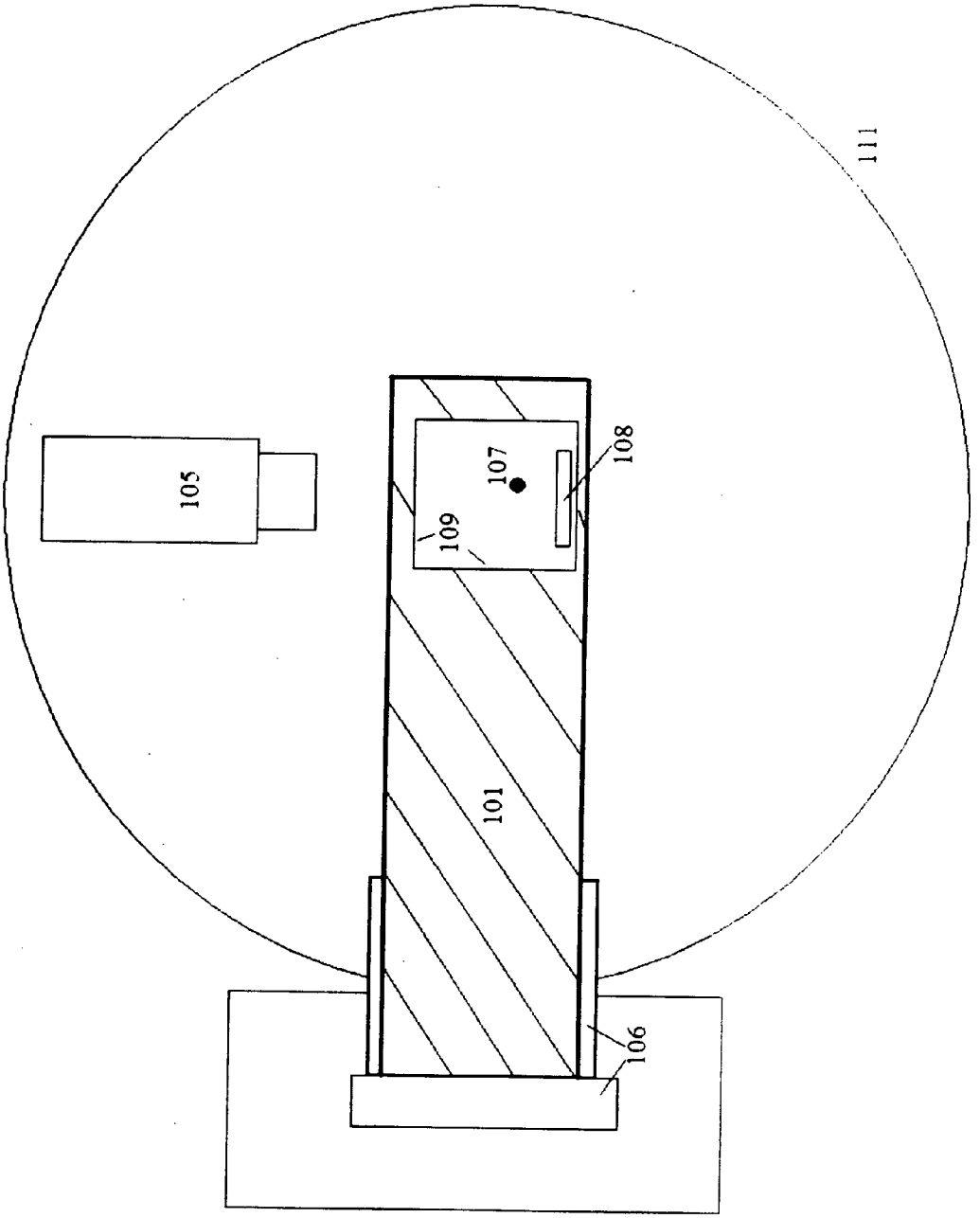


Figure 2d

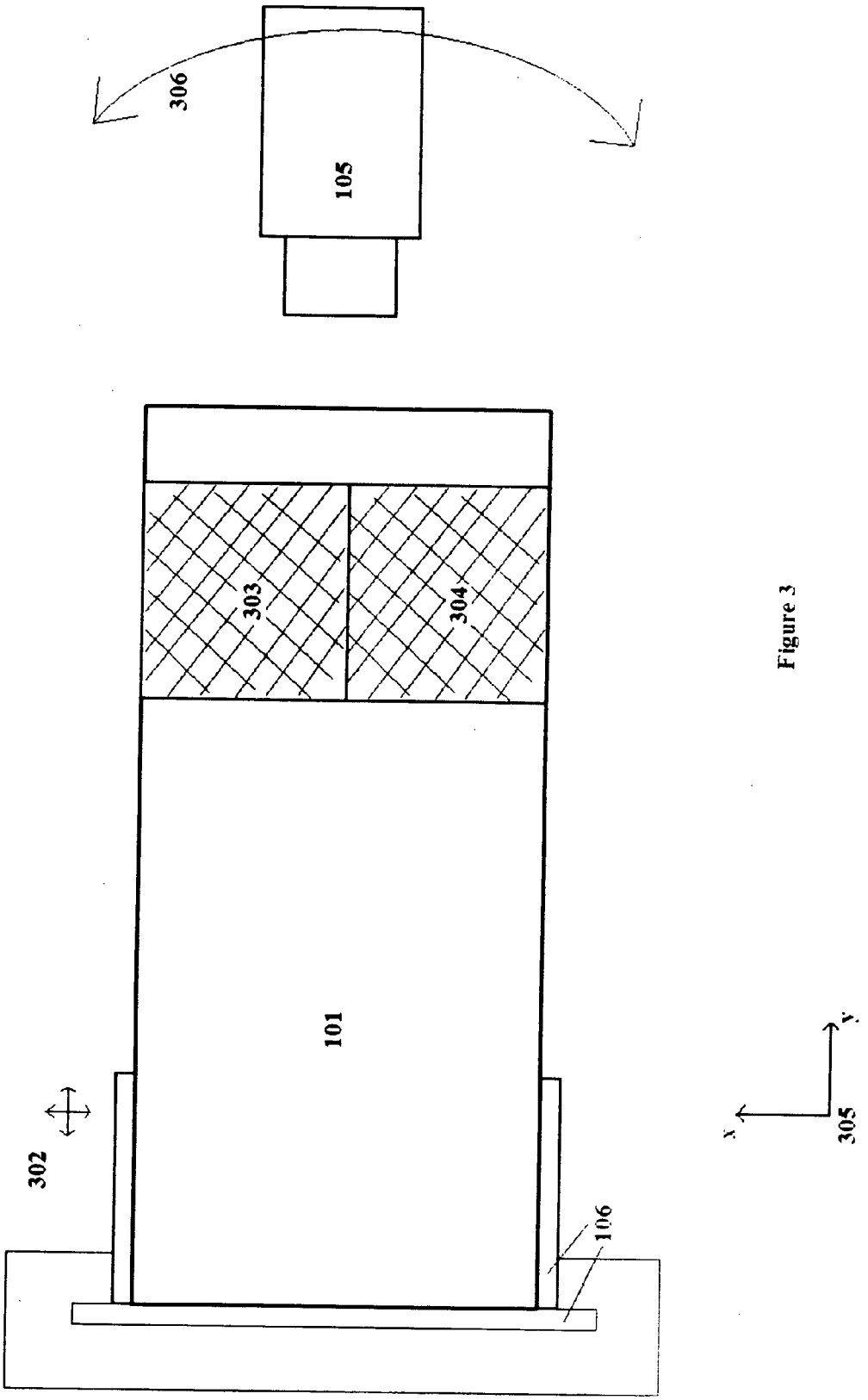
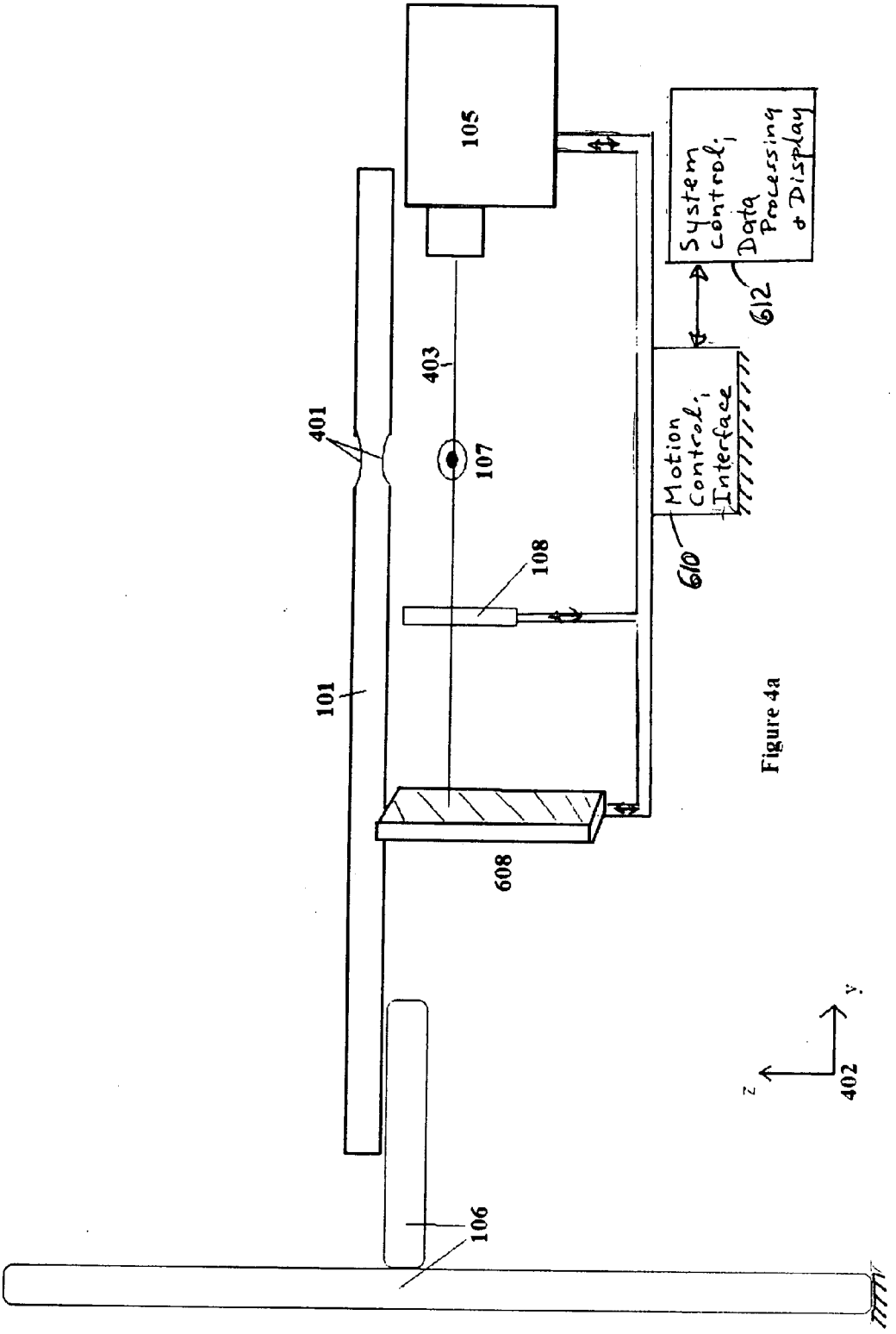


Figure 3


105
System Control, Data Processing & Display
612
403
401
107
Motion Control, Interface
610
108
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106
y
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402

Figure 4a

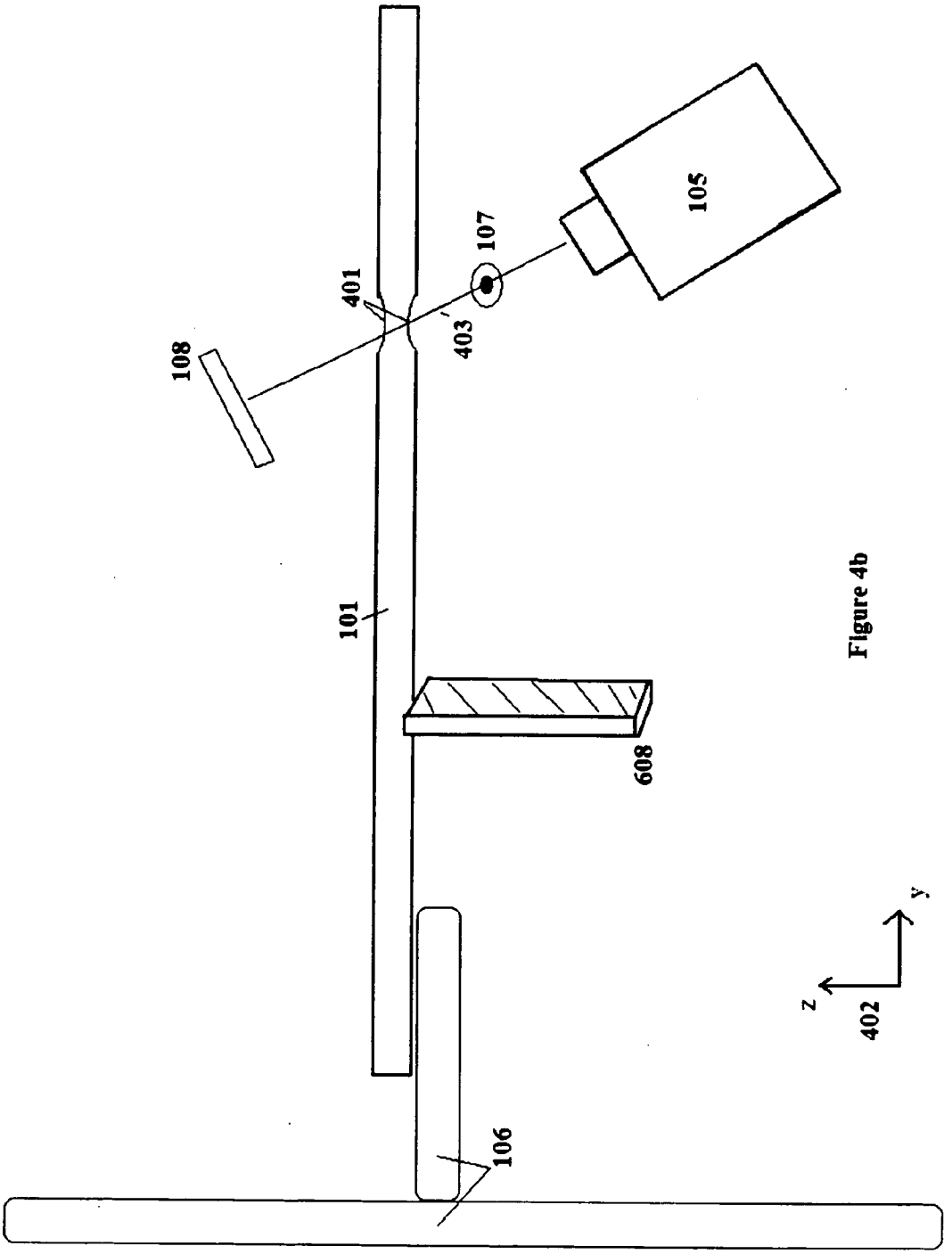

Figure 4b

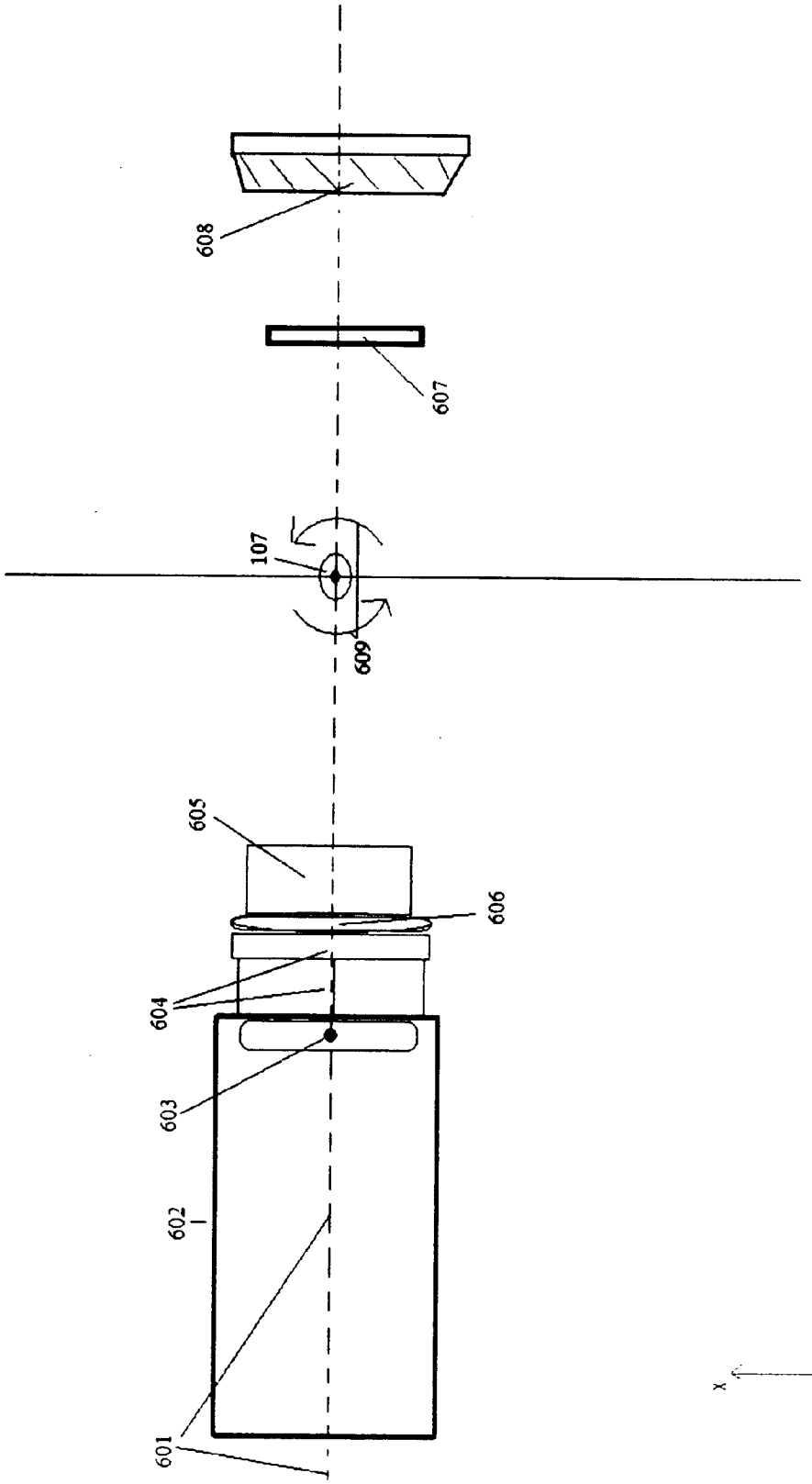

Figure 5a

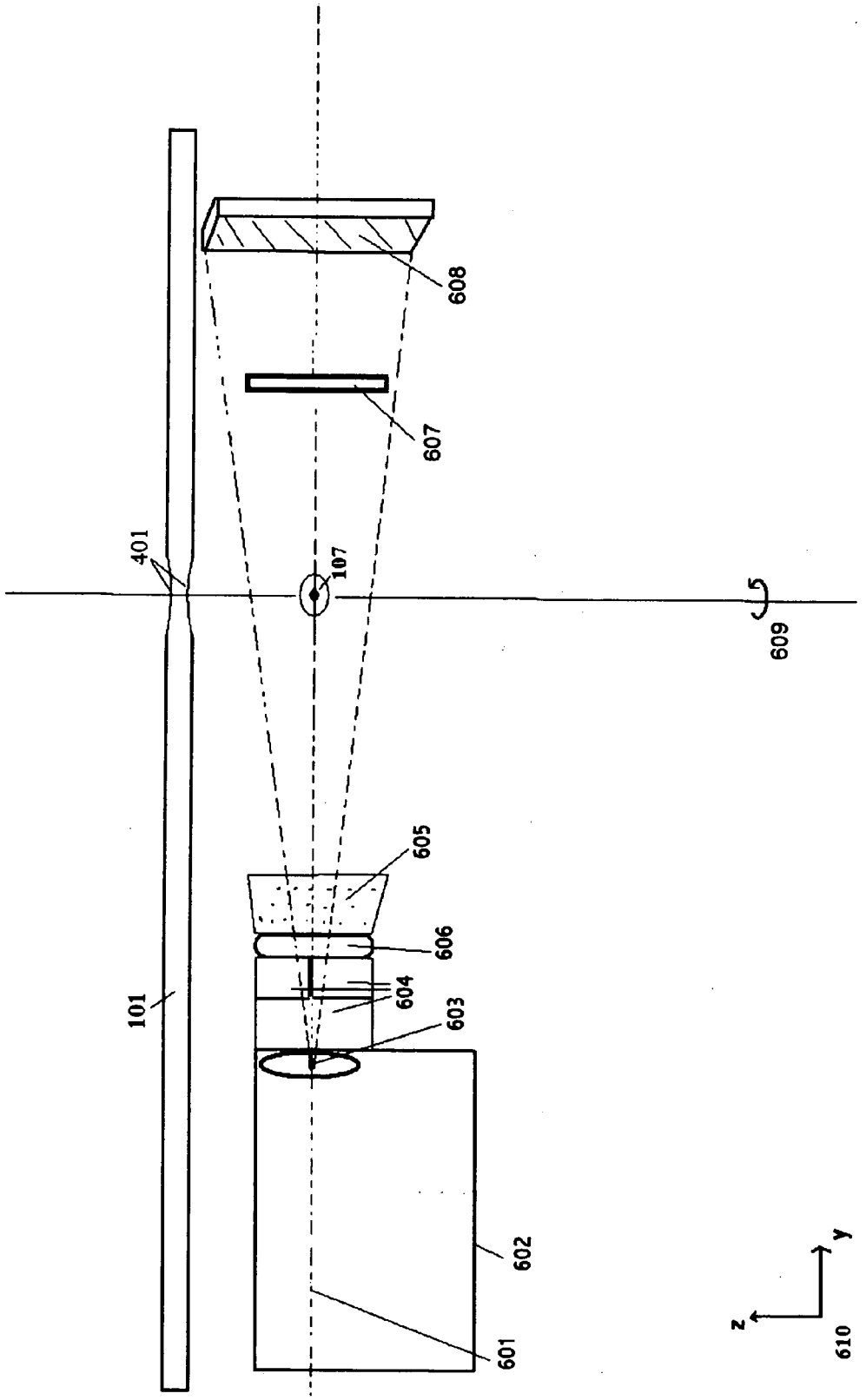

Figure 5b

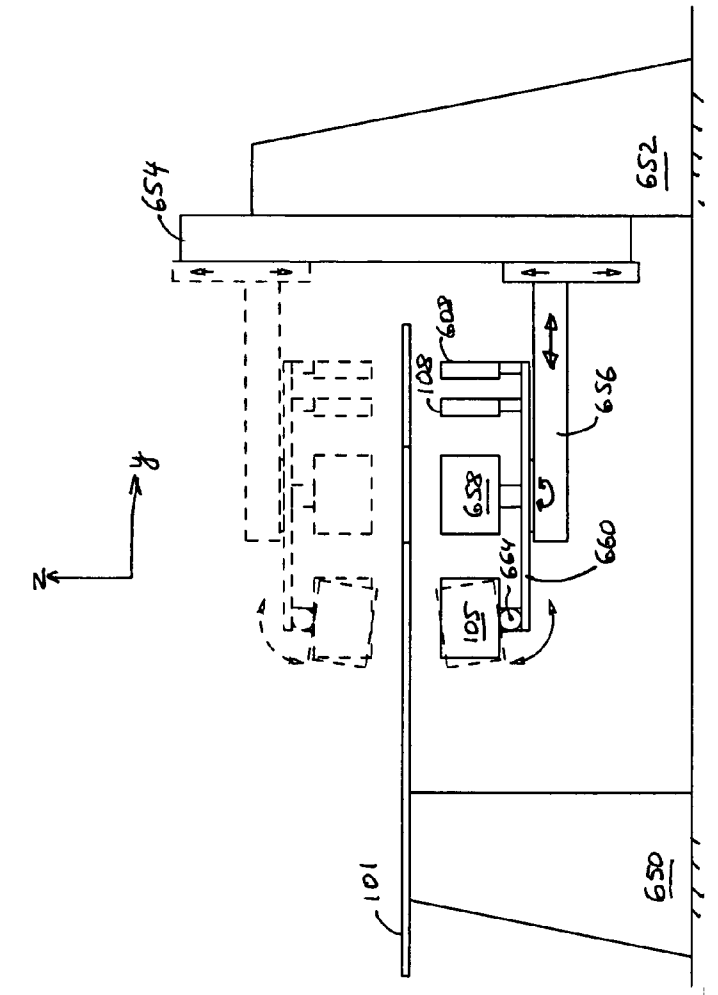
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Fig. 6a

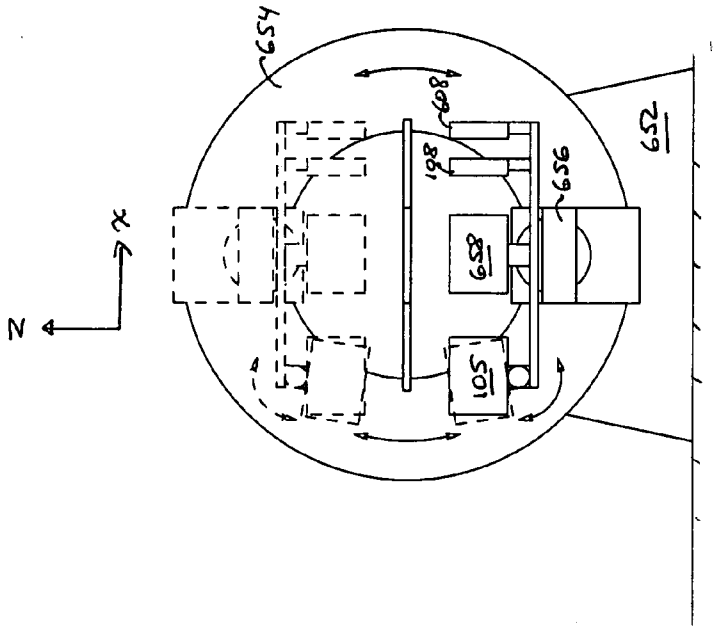
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Fig. 6b

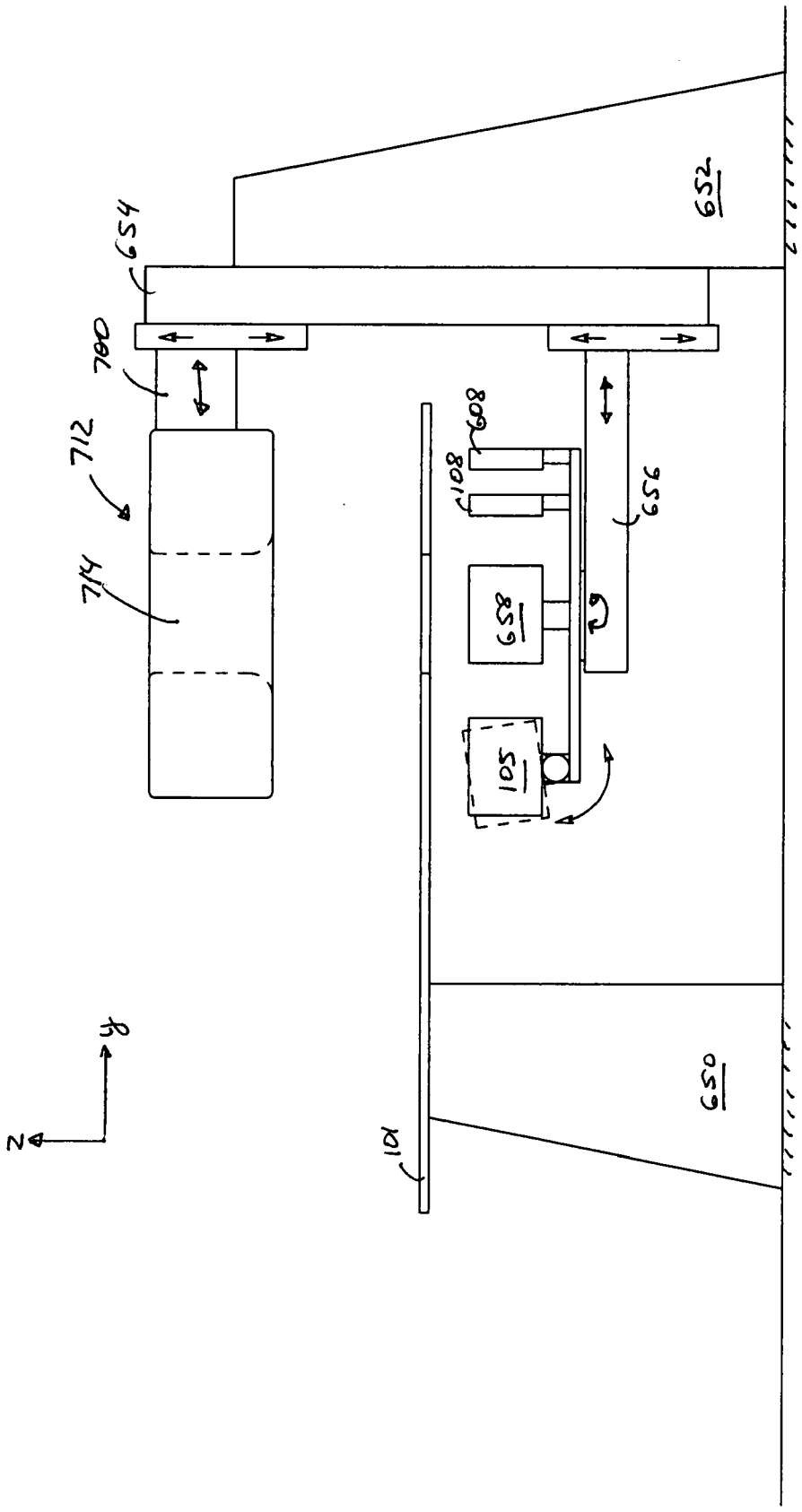

Fig. 7

DEDICATED BREAST RADIATION IMAGING/THERAPY SYSTEM

REFERENCE TO RELATED APPLICATIONS

[0001] This application is related to International application No. PCT/US07/017470 filed Aug. 3, 2007, claiming the benefit of provisional application Ser. No. 60/835,803 filed Aug. 3, 2006. This patent specification incorporates by reference the content of each of said earlier-filed applications.

FIELD

[0002] This patent specification is in the field of radiation therapy and associated imaging and therapy planning/adjustment/verification, and specifically pertains to dedicated, specialized radiation therapy of a patient's breast and associated imaging and planning procedures.

BACKGROUND

[0003] Radiation therapy has long been used in medicine. Typically, high energy radiation from sources such as linear accelerators and radioisotopes is used, especially in whole-body, external beam systems where the radiation may need to penetrate a significant amount of tissue in order to reach the target volume and attain within the target volume the prescribed therapeutic dose level and fractionation scheme. The irradiation of normal tissue is a necessary physical consequence of all modes of radiotherapy and typically becomes the limiting factor in any given patient's therapy regimen. In procedures that use radiation sources inside the patient's body, a similar challenge is the undesirable but unavoidable exposure of normal tissue. Conventional, whole-body, external beam systems can be used for breast therapy as well but their large, whole body geometry tends to lead to undesirable irradiation of significant amounts of healthy tissue. Also, whole body, external beam systems may be designed to irradiate at energy levels that are not optimized for breast tissue. In order to reduce normal tissue irradiation and achieve sufficient target volume dose, efforts have been made to find other approaches for breast radiation therapy, leading to methods that include, in addition to the orthovoltage radiation treatment disclosed in said earlier-filed patent applications, proposals by others such as (1) internal breast brachytherapy which involves inserting catheters or needles in the breast and placing radioactive substances in or through the catheters or needles or using radioactively coated needles, (2) surgically implanting a balloon in the breast and selectively delivering radioactive material to the balloon through a catheter, (3) surgically positioning a miniature x-ray tube inside the breast, (4) external stereotactic brachytherapy that involves compressing the breast between two sets of conforming channels through which a radioactive substance is placed in close proximity to the breast, (5) using orthovoltage radiation from an external kilovoltage x-ray source that irradiates the breast from the side or possibly through a purposely designed surgical opening in the tissue, (6) using a LINAC radiation source that rotates in a horizontal plane to irradiate a downwardly protruding breast of a patient on a table with an opening for the breast, and imaging the breast with that source or an adjunct source, and (7) combining a radioactive substance with a biologically active material designed to uptake selectively in the breast tissue where it decays and provides a therapeutic dose (such as monoclonal antibodies) or a substance which causes the tumor to be more radiosensitive during the treatment.

[0004] An external beam radiation therapy treatment typically involves therapy planning in which the location and perhaps other characteristics of a lesion or other target volume to be treated or avoided and monitored are identified by one or more imaging technologies such as ultrasound, X-ray computed tomography, static and dynamic planar imaging, nuclear medicine imaging, and magnetic resonance imaging. Information from these imaging modalities is used in computer processing to develop a treatment plan for the directions, energies, and durations of the therapy radiation beams and the number and frequency of the treatment sessions. In addition, before each radiation therapy session images of the lesion and/or other target volume may be taken to check the position of the target volume and other tissue relative to the geometry of the radiation therapy system, and various positioning aids may be used in the therapy system to verify and maintain a desired geometric relationship between the radiation treatment beam(s) and the target tissue.

[0005] See, for example, H. E. Johns & J. R. Cunningham. The Physics of Radiology, Ch. Thomas, 1983; S. C. Formenti, External-Beam Partial-Breast Irradiation, Seminars in Radiation Oncology, Elsevier 2005, 82-99; G. Jozsef, G. Luxton, S. C. Formenti, Application of radiosurgery principles to a target in the breast, A dosimetric study, Med. Phys. 27 (5). May 2000, 1005-1010; O. Gayou, D. S. Parda, M. Miften, Patient dose and image quality from mega-voltage cone beam computed tomography imaging, Med. Phys. 34 (2). February 2007, 499-506.

[0006] Despite such advances in radiation therapy systems, including for breast radiation, it is still desirable to improve breast radiation therapy by making it more effective and efficient.

SUMMARY OF THE DISCLOSURE

[0007] Disclosed is a dedicated system for radiotherapy of the breast and related tissue of a patient in the prone position, with radiation beams that can rotate below the patient about a vertical axis but in addition can rotate about an axis angled to the vertical to treat breast-related tissue such as axillary lymph nodes without turning the patient over. Maintaining the patient in the same prone, breast-pendulous position can ensure good registration between the treatment beams and target volume, and good consistency with treatment plans for both breast and related tissue. Further, the system can include a mode in which the patient can be treated in the supine position, if desired or if called for by special circumstances. The system also includes imaging functionalities that share a spatial frame of reference with the treatment functionalities, whether or not they also share components, and can verify and/or adjust a treatment plan or generate a treatment plan through two-dimensional (2D) or three-dimensional (3D) imaging/planning. The distance between the radiation source for treatment/imaging and the target volume can be varied if desired so the radiation source can move about the target volume or some other center rather than about a fixed isocenter. This can be done by one or both of source motion and patient table motion. The system can further include sensors/transmitters that can be implanted or otherwise secured in or to the patient, or can be otherwise fixed relative to a system frame of reference, to verify the position of a target volume or other tissue relative to the radiation beam(s) and/or to mea-

sure the radiation dose in two or three dimensions. The sensors/transmitters preferably include data storage and/or transmission functionalities to provide information to the system, preferably on an essentially real time basis. The patient can be on a patient table or couch that fits both the treatment/imaging system and conventional imaging modalities such as CD scanners so that the patient can remain in or conveniently and accurately resume the same position, such as the prone position with a breast protruding downwardly through an opening or into a depression of the patient table or couch, when imaged for treatment planning at one system and then when positioned for treatment/verification at another system. The patient can be positioned on the table and couch in the prone position with the protruding breast immobilized in an effort to maintain or accurately resume its position relative to the table or couch, and can be imaged in a CT scanner for radiation planning and then later positioned at the disclosed system for treatment in which the position of the breast or other target tissue relative to the system frame of reference is known from the information provided from treatment planning and the fact that the position of the table or couch relative to the treatment system also is known, e.g., from mechanical, optical, mechanical or other table mounting interlocks. The imaging functionalities of the disclosed system can include 2D and/or 3D imaging systems such as portal imaging using the treatment radiation source, an x-ray imaging using components mounted in known relationship to the system spatial frame of reference, nuclear medicine imaging (including metabolic activity imaging) using detectors also mounted in the same system as the radiation treatment source and in a known spatial relationship with the system frame of reference, ultrasound imaging with transducers maintained in known positions in the system frame of reference, and/or other imaging modalities. Suction or other devices can be used to pull breast tissue away from the chest wall as needed and/or to stabilize the breast for imaging/treatment. The system can be used for traditional treatment plans that use fractional doses over a longer period of time such as a number of weeks or for partial breast irradiation that typically treats only a part of the breast (e.g., a lumpectomy site) but over a shorter period of time such as once or twice a day for five days. Also disclosed are methods of using the system and methods of imaging, treatment planning/verification/adjustment and radiation treatment.

[0008] In one non-limiting embodiment the system comprises a table or couch for the patient to lie prone with at least one breast protruding downwardly through an opening or extending into a depression in the table or couch. Preferably a positioning device is used to maintain a reasonably consistent and stable position of the breast relative to the patient table or couch and the imaging and treatment system spatial frame of reference and, if desired, to help pull tissue away from the chest wall. In an imaging mode, the system provides information for identifying the position of the breast, the target volume in the breast and/or of some other tissue relative to both the system geometry and pre-treatment patient geometry by utilizing imaging technologies such as one or more of x-ray planar and computed tomography or tomosynthesis, nuclear medicine, ultrasound, other imaging modalities, and position-indicating and/or monitoring devices that can be implanted in or otherwise secured to or near the tissue of interest and are specifically designed to work within the confines of the system and patient geometry (and preferably can store and/or transmit information regarding position and dose). This pre-treatment imaging takes place before at least the first treatment session but may be repeated before additional treatment sessions, and can also be used to identify or estimate other characteristics such as shape and size of a lesion or other target volume parameters related to the tissue along intended therapy radiation paths and also to identify critical structure volumes whose unintended irradiation is to be minimized, characteristics of other portions of the breast and perhaps of other anatomy, and the like.

[0009] In a treatment planning/adjustment/verification mode, the system uses information obtained from other imaging modalities and/or information from the imaging mode of the system disclosed in this patent specification to plan treatment or at least to verify/adjust treatment plans and/or verify the position of the lesion or other target volume and/or of other body parts relative to system and patient geometry. In a radiation therapy mode of the system disclosed in this patent specification, a therapy radiation source below the patient table or couch moves about the downwardly extending breast of a patient in the prone position and emits radiation in energy ranges that are uniquely suited to breast-related radiation treatment. Importantly, the therapy radiation source can move not only in a horizontal plane (e.g., about a vertical axis) but also in other planes (e.g., about a non-vertical axis) to irradiate breast-related tissue such as the patient's axilla, target volumes that are very close to the chest wall, and other lymph nodes away from the breast. Also importantly, the therapy radiation source can rotate or otherwise move about the lesion or other target volume or about other loci to direct radiation along paths that maintain a low skin dose. The system directs and otherwise controls the radiation, preferably in accordance with current or updated treatment plans.

[0010] Preferably, the therapy radiation source is a special linear accelerator (Linac) that has two important characteristics—it emits treatment radiation that can be uniquely suited to breast-related tissue, and it is sufficiently compact to be mounted below the prone patient table for movement about a patient's breast such as in a horizontal plane and also for movement about the breast such as in a plane at an angle to the horizontal in order to direct primary radiation at other target tissue that may be associated with the breast.. Thus, the source can rotate about a vertical axis and/or about an axis that extends upwardly but at an angle to the vertical to enable therapy radiation to be directed to target volumes outside the prone patient's breast if desired, such as at or near the patient's chest wall or the patient's axilla. In addition, if desired the therapy radiation source can be moved above the patient or to other positions suitable for irradiation a supine patient. The linear accelerator produces a maximum energy that can be set at a value, or can vary, in the range of about 1-10 MeV Bremstrahlung photons, and preferably about 4-6 MeV. As an alternative example, the treatment radiation can be charged particles including but not limited to particles such as electrons, protons, and deuterons. Electrons for a treatment beam can come from the linear accelerator source when the conventional Bremstrahlung target is removed and appropriate bean shaping fields are provided. Other particles for a treatment beam can come from other accelerating sources known in high-energy physics.

[0011] The imaging system preferably uses penetrating radiation from an external source but may use, instead or in addition, radiation emitted from the breast and/or related tissue, such as from a radiation emitting substance injected or otherwise introduced into the patient's body, and can use

ultrasound imaging. In one example, portal imaging is used in which a Linac-based source also provides imaging radiation, and an imaging detector that is suitable for such high-energy radiation generates the image(s). Different energy levels of penetrating radiation from the source may be used for imaging versus therapy, if desired. Alternatively, a source different from that used for therapy can be used to provide imaging radiation. As a non-limiting example, imaging radiation can come from an x-ray source of the type typically used in x-ray mammography or for imaging the chest, and the imaging detector can also be of the type used in x-ray mammography or chest radiography, and preferably is a flat panel detector of the type commercially available from the common assignee, Hologic, Inc. If the source of the imaging radiation is internal, suitable imaging detectors are used, such as SPECT, PET, or nuclear medicine imaging detectors. Another imaging modality that can be used is ultrasound, preferably carried out in a manner that also provides information to positionally relate the imaged tissue with the geometry of the therapy radiation system and the patient's reference frame established before therapy and updated as needed during the course of therapy. A CT scanner suitable for breast imaging may be included in the system. Only one of the imaging modalities identified above may be used, or a combination of two or more imaging modalities can be used, to provide information for therapy planning, updating, and verification. Preferably, the imaging system also moves, e.g., rotates under the prone patient's table, about a vertical or non-vertical axis, and can be moved to the patient level or above the patient if desired to image a patient who is in the prone or other position, and preferably the rotation or other motion centers on the lesion or other target volume. Preferably, the imaging modality produces three-dimensional information, such as information based on tomosynthesis, CT scanning, stereotactic imaging, 3D ultrasound imaging, or other 3D imaging modalities.

[0012] The imaging information is used to generate both traditional, static, forward planned treatment plans as well as inverse planned, dynamic intensity modulated treatment plans using state-of-the-art integrated optimization methods that can be based on known treatment planning technology used for whole-body radiation therapy systems, such as those commercially available from Varian Medical Systems of Palo Alto, Calif., Philips Medical Systems of Andover, Mass., and CMS Inc. of St. Louis, Mo., but taking into account the unique geometry of the breast therapy/imaging system disclosed in this patent specification and its other unique parameters such as optimized multileaf collimator leaf sizes designed for targeting smaller breast lesions or other breast-related target volumes rather than the typically larger target volumes addressed by whole body systems, and the photon or particle energy levels which are also closely matched to breast-related tissue.

[0013] The patient's breast can be immobilized and maintained in position for pre-treatment planning in one or more imaging system and for treatment by devices that include but are not limited to thermoplastics, vacuum fixation bags, foam padding, appendage fixation devices, cones, vacuum and/or adhesives applied to such cones, or other means. Devices of this nature are proposed, e.g., by MedTec of Orange City, Iowa under the trade name Horizon Breastboard and by Varian Medical Systems.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The features of the subject matter of this disclosure can be more readily understood from the following detailed description with reference to the accompanying drawings wherein:

[0015] FIG. **1** illustrates a top view of an embodiment comprising an integration of a breast therapy system and multiple breast imaging systems.

[0016] FIGS. **2***a*-**2***d* illustrate a top view of the therapy system of FIG. **1** in several different positions of a therapy radiation source.

[0017] FIG. **3** illustrates a top view of a patient table for use in the system of FIG. **1**.

[0018] FIG. **4***a* illustrates a side view of a patient table and a center of rotation of the radiation source about an upwardly extending axis.

[0019] FIG. **4***b* illustrates a side view of a patient table and a center of rotation of the radiation source about a laterally extending axis.

[0020] FIG. **5***a* illustrates a perspective view of the imaging/therapy system in relation to a desired isocenter of rotation.

[0021] FIG. **5***b* illustrates a side view of the system.

[0022] FIG. **6***a* is a schematic illustration of an example of a radiation therapy and imaging system in side view, and FIG. **6***b* is a schematic illustration of the system in a front view.

[0023] FIG. **7** is is a schematic illustration of a system in side view that includes CT imaging provisions.

DETAILED DESCRIPTION

[0024] In describing preferred embodiments, specific terminology is employed for the sake of clarity. However, the disclosure of this patent specification is not intended to be limited to the specific terminology so selected and it is to be understood that each specific element includes all technical equivalents that operate in a similar manner. In addition, a detailed description of known functions and configurations will be omitted when it may obscure the subject matter of the present invention.

[0025] As illustrated in FIG. **1**, a non-limiting example of the system comprises a table or couch **101** that is especially adapted to support a patient in the prone position but may also be used to support a patient in other positions such as in the supine position. FIG. **1** also illustrates one or more imaging systems discussed below in more detail for localizing and identifying a lesion or abnormality or target volume, a radiation source such as a special Linear Accelerator (LINAC) **105** for producing therapy radiation, and a motorized cantilevered stand **106**. For clarity, the table is illustrated in FIG. **1** with a cutout **109** to allow visualizing the components that are below the table. Preferably the LINAC device **105** is a compact version capable of producing penetrating radiation uniquely suited to breast-related tissue rather than optimized for whole-body radiation therapy. Preferably, the imaging and therapy systems move about the patient's breast, preferably though not necessarily in rotation, and preferably the motion is centered on the lesion or target volume for therapy irradiation. However, as discussed below the system may include provisions for moving the therapy and/or imaging components in a manner suitable for patients in other patient positions, such as the supine patient position.

[0026] The imaging systems in FIG. **1** example may include: an x-ray system that uses an x-ray source **102** and x-ray digital imaging detector (flat panel) **120**, a stereotactic x-ray imaging system where two x-ray sources **102** and **103** are used with respective x-ray imaging panels **120** and **113** (or one set of a source such as **102** and a detector such as **120** is moved to one position for one x-ray image and another position for another image), PET or SPECT imaging panels or

ultrasound transducers **104**, combinations of two or more of the imaging systems identified above, or other imaging systems. If an x-ray imaging system is used, it can use only one, or both, of sources **102** and **103** and x-ray detector panels **113** and **120**, to image the patient's breast or other patient tissue. Imaging source **102** and x-ray panel **120** are mounted to move about the breast as a unit, to image the breast from different angles. If source **103** and panel **113** are used, they also rotate or otherwise move as a unit, and if both source/panel sets are used, the two sets can rotate as a unit or individually. In each case, the motion can be about a center **107** that can be at the lesion or target volume or some other center. The x-ray imaging system(s) may be used to derive projection tomosynthesis image data, for example by using motion and image reconstruction as disclosed in commonly assigned U.S. Pat. Nos. 7,245,694, 7,233,005, 7,123,684, 7,122,803, 6,851,851, and 6,282,264, or to derive stereotactic information, for example as discussed in U.S. Pat. No. 5,803,912 or U.S. Patent Publication 2004/0171933 A1.

[0027] FIGS. **2***a*-**2***d* are top views of the system that illustrate examples of the range of positions of the therapy system in relation to patient table **101** (that again is shown with cutout **109** to allow seeing components below the table). A motorized stand **106** supports table **101** for up-down motion and, if desirable, for motion along and across the length of the table, and also can support the imaging and therapy systems for rotation in a circle **111** representing a preferred 360 degree range of rotation of LINAC **105** and of the imaging system(s) around a selected center **107**. If portal imaging is used, a portal imaging detector **108** and the LINAC device **105** can move as a unit for imaging.

[0028] FIG. **2***a* illustrates the LINAC device at 0° relative to prone table **101** and isocenter **107**. Illustrative cutout **109** reveals the LINAC source **105**, center **107**, and a radiation detector **108**. FIG. **2***b* illustrates LINAC source **105** at 180° relative to patient table **101** and center **107**. Illustrative cutout **109** reveals center **107** and detector **108**. FIG. **2***c* illustrates LINAC source **105** at approximately 45° relative to table **101** and center **108**. Illustrative cutout **109** reveals center **107** and detector **108**. FIG. **2***d* illustrates LINAC source **105** at 270° relative to prone table **101** and center **107**. Illustrative cutout **109** reveals center **107** and detector **108**. In a non-limiting example, circle **111** representing the diameter and range of rotation of LINAC source **105** and imaging detector **108** preferably has a diameter of approximately three meters. Stand **106** preferably extends approximately 1 meter from a wall.

[0029] FIG. **3** illustrates additional features of patient table **101** as seen in top view. Table **101** comprises left and right removable mesh panels **303**, **304** that cover respective left and right openings in the table. When a mesh panel is removed from the table, the opening allows a patient's breast to extend downwardly for imaging and/or radiation therapy. The panels are designed to be replaced by a breast stabilizing aide, such as an aide made of an "Aquaplast" material or comparable material forming a semi-rigid thermoplastic surface around a breast. The system operating in an imaging mode with all of the associated modalities can be used to help establish the stabilizing aide and correlate what will become a semi-rigid surface of the thermoplastic material to the breast, the target volumes and the system reference frames. Additional or alternative stabilizing aides such as other thermoplastics, vacuum fixation, personal positioning cups, or variations of positioning boards and coaches may be employed in the radiotherapy apparatus disclosed herein.

[0030] The stabilizing aide(s) or combinations thereof preferably facilitate immobilizing a breast for imaging so that the target volume can be accurately located in relation to patient and system geometry and the lesion or other radiation target volume can then be given a planned radiotherapy dosage. The use of stabilizing aides described herein and variations thereof can assist the radiotherapy system in providing consistent and precise irradiation of a patient's anatomy on a daily basis. The stabilizing aides described herein are relatively inexpensive and can be re-fabricated as needed during the course of therapy for clinical (anatomy changes, adema, etc) or patient comfort requirements. As in the case of the stereotactic imaging and biopsy table available from the common assignee under the name MultiCare, the table surface can be shaped, originally or with the help of special pillows, to provide patient comfort and to extend the appropriate anatomy as much as possible below the patient table.

[0031] Additionally, implantable or otherwise attachable position and dose sensors for use within or near a patient's breast or other anatomy can be utilized to further increase the accuracy and effectiveness of an individualized patient radiotherapy treatment plan, optionally in combination with one or more breast stabilizing aides. There are implantable position sensors capable of communicating anatomical positioning information, an example of which is available from CALYPSO Medical. One or more implantable position sensors could be placed within a patient's breast and surrounding anatomy and using wireless technology communicate with an embodiment of the radiotherapy system. The combination of implantable position sensors in communication with an embodiment of the radiotherapy system using one or more imaging modalities can accurately determine patient geometry in relation to the radiotherapy system geometry thereby allowing accurate and daily irradiation of a patient concurrent with an individualized patient radiotherapy treatment plan.

[0032] Implantable or otherwise attachable dose monitoring sensors such as those available from Sicel Technologies, Inc. can be used within an embodiment of the disclosed radiotherapy system in addition to or optionally independent of implantable position monitors. Implantable monitoring sensors such as those from Sicel Technologies, Inc. can collect and store data related for example to tumor cell kinetics and physiology, pH or oxygen levels, temperature, uptake and retention of chemotherapeutic agents, as well as the radiation dose delivered to a region of a patient's anatomy. Said monitoring sensors then use wireless technology to communicate collected data to receivers located outside a patient's body. In a preferred embodiment of the radiotherapy system, one or more implantable monitors can be used in a non-limiting example as radiation dose monitors and can be implanted in a patient at or near the lesion to be treated with therapeutic radiation and optionally surrounding tissue as well. Implanted radiation dose monitors are able to communicate to the radiotherapy system precisely what radiation dose is striking a patient's anatomy. Precise internal radiation dose information from implanted dose monitors can accurately provide dose information to doctors, physicians, and embodiments of the radiotherapy system herein thereby limiting over- or under-irradiation of a patient's anatomy and aiding in accurate and consistent daily treatment according to a patient's radiotherapy treatment plan. Stray radiation possi-

bly striking other areas of a patient not intended to be irradiated can be monitored by properly implanted or otherwise secured dose monitors thereby increasing patient safety. Both position and dose monitors described herein are small devices capable of implantation using commercially available biopsy systems such as from the Suros Corporation and methods in current clinical use.

[0033] FIG. **3** further illustrates degrees of freedom of the motion of patient table **101**. The four directional arrows **302** represent the direction of motions along which motorized stand **106** can move prone table **101** (in addition to any up-down or tilting motion). In a preferred but non-limiting embodiment, table **101** can move approximately 10 centimeters in any direction from a resting position in the horizontal xy-plane parallel the floor. X and Y directions are shown by axis **305**. Stand **106** also can be configured to move the patient table in the vertical position, and/or to tilt table **101**, if desired. LINAC source **105** is shown in FIG. **3** at a 180° position relative to table **101**. Arc **306** is placed in FIG. **3** for illustrative purposes to exemplify a curved direction of motion of LINAC source **105** around table **101**, preferably about an isocenter of the system (not shown). In a non-limiting example, the rotational movement of LINAC source **105** can be combined with the vertical and horizontal movement of prone table **101** by motorized stand **106** allowing desired target volumes of patient's breast and surrounding tissue to be imaged and receive appropriate levels of therapeutic radiation in accordance with an individual patient's radiation therapy plan.

[0034] FIG. **4***a* is a side view of an example of the system, with LINAC source **105** at a 180° position around center **107**. A radiation beam centerline **403** is shown of a shaped beam, e.g. a conical beam, exiting LINAC source **105**, passing through center **107** and impinging on imaging detector **108**. An additional feature is an optional beam blocker **608** that substantially stops primary photon energy that passes through imaging detector **108**. Table **101**, which is not shown to scale in terms of thickness, further comprises rounded openings **401** for a patient's breast, directly above center **107**. Z-Y directional axis **402** is illustrated to show both the z-direction and y-direction of the system relative to the side view illustrated in FIG. **4***a*. A motion control **610** supports source **105**, imaging detector **108**, and beam blocker **608** and provides interface electrical and electronic connections between source **105**, detector **108**, and a sub-system **612** that serves as a system control and for processing and displaying data. Unit **610** and its connections to other units are shown schematically but it should be understood that the unit typically contains motors and associated components that impart the desired motions to source **105**, imaging detector **108**, and beam blocker **608**, including motion in the horizontal plane (flat or curved) about center **107**, tilting so that the motion about center **107** is in a plane (flat or curved) angled to the horizontal and such that at least source **105** can be at the level of or above patient table **101**, and translating motion that moves center **107** to the left or to the right or up or down as seen in FIG. **4***a*. The schematic connections shown between unit **610** and source **105** and imaging detector **108** represent both mechanical and electrical/electronic two-way communication. The two-directional arrows in the connections to units **105**, **108**, and **608** schematically illustrate telescoping mechanism that can be motor-driven, e.g., by fluidic or electrical motors, up and down along the lengths of the mechanical supports. Unit **612** need not be under table **101**; in fact, typically it is not in the same room as the therapy/imaging system. For clarity, the imaging systems illustrated in FIG. **1** are not shown in FIG. **4***a* but it should be understood that they can be mounted to and electrically/electronically connected to unit **610** in a manner in which their positions are known relative to the system frame of reference. Alternatively, they can be mounted and otherwise connected to a separate motion control and interface configured to move them in a way that does not interfere with the therapy radiation and portal imaging components. One of the motions of source **105** under patient table **105** about the patient's breast typically is in a horizontal plane; however, provisions can be made for deviations from a motion in a flat plane, such as for motion in which the vertical elevation of source **105** varies during its motion about the breast. In addition, as discussed in greater detail in connection with FIG. **4***b* below, source **105** can move to positions at the level of, or above, patient table **101**.

[0035] FIG. **4***b* is similar to FIG. **4***a* but illustrates an additional capability of a preferred embodiment of the disclosed radiotherapy system. For clarity, units **610** and **612** and the mechanical and electrical/electronic connections of FIG. **4***a* are not shown in FIG. **4***b* but it should be understood that they are a part of the system as it would be seen in this configuration as well. During radiotherapy treatment of a breast or related anatomy, it is occasionally desirable to irradiate lymphatic systems and anatomical tissue located outside of the breast tissue hanging pendulant through an opening or into a depression in table **101**. In these cases, an example being when breast cancer metastasizes, it is desirable to image and irradiate the lymphatic systems associated with a breast including axillary, parasternal, and pectoral nodes located in or near a patient's armpit area, collarbone area, or axillae. In these circumstances, the dislcosed imaging and therapy system can optionally tilt radiation source **105** such that a centerline of a therapy radiation it emits is at an angle to the horizontal, e.g. at 45°-55°. As illustrated in FIG. **4***b* (where the angle is greater for clarity of illustration), an emitted radiation beam centerline **403** can pass upwards through a patient's armpit area and therapeutically irradiate lymphatic tissue and surrounding anatomical structures as desired. For this purpose, source **105** is mounted for movement about center **107** about a non-vertical axis, in a non-horizontal plane that can be flat or curved, and one or both of source **105** and detector **108** can be mounted for movement toward and away from center **107**, along radiation centerline **403**, and thus toward or away from a target volume Radiation detector **108** can be moved into a position above patient table **101**, to remain perpendicular to the radiation beam centerline **403**. In this case it is not necessary for the radiation beam centerline **403** to pass through an isocenter of the system. The precise pathway of the therapeutic radiation emitted from LINAC device **105** is determined by the treatment plan for a particular patient. Although not shown in FIG. **4***b*, optional photon blocker **608** also can be moved from below prone table **101** and positioned behind radiation detector **108** to absorb primary radiation still passing through detector **108**.

[0036] FIG. **5***a* illustrates a top view of a portion of the radiotherapy system comprising an abstract depiction of a preferred center **107**, a LINAC device **105**, additionally a solid state flat panel detector **607**, and an optional beam blocker **608**. In the view of FIG. **5***a* the patient table normally located above the radiotherapy system as well as other components that are visible in other Figs. have been removed from the visual field so as to more easily illustrate features of a preferred embodiment of the radiotherapy system.

[0037] The radiotherapy system of FIG. **5***a* comprises a radiation beam centerline **601**, a compact LINAC **602**, a target assembly and carousel **603**, a primary dual independent collimator **604**, a tertiary multi leaf collimator **605**, a monitor chamber for beam streams **606**, a solid state panel detector **607** and optionally a beam blocker **608**. Also shown in FIG. **5***a* is center **107** of the system, arrows **609** representing the direction of rotation of the LINAC in tandem with detector **607** and beam blocker **608**, and x-y system **501** indicating the x-direction and y-direction of the machine in this illustration.

[0038] FIG. **5***b* illustrates a side view of a preferred embodiment of a portion of the radiotherapy and imaging device used in the system shown in FIG. **5***a*. Again, for ease of illustration components of the system that are visible in other Figs. have been omitted. As seen in FIG. **5***b*, the preferred embodiment comprises a linear accelerator (LINAC) **602**, a target assembly and carousel **603**, a primary collimator **604**, a tertiary collimator **605**, a flat panel detector **607**, and an optional beam blocker **608**.

[0039] The radiation source **602** (which can but need not be a Linac source) in this embodiment preferably operates to produce one or more of the following four therapeutic forms of radiation: (i) direct electron (e−) beams, (ii) direct proton (p+) beams, (iii) high energy Bremstrahlung photons from an accelerator source, (iv) high energy photons from a radioisotope (Cobalt-60). When high energy photons from a Bremstrahlung source are chosen as the therapeutic form of radiation then source **602** preferably operates to produce a stream of therapeutic photons having a maximum Bremstrahlung energy at or in the range 1 MeV to 10 MeV, preferably an average energy in the 4 MeV-6 MeV range, or in the 1 MeV-4 MeV range. In the most preferred configuration, a compact LINAC in the radiotherapy system produces a stream of therapeutic photons for irradiating breast tissue having an average energy in a specified range suitable for breast-related irradiation such as within the range of 1-2 MeV. As understood by applicants, a compact LINAC capable of producing therapeutic photons from a Bremstrahlung source wherein said photons have an average energy between 1-2 MeV, uses electrons with a peak energy preferably in the range of 1-6 MeV and more preferably within the energy range 4-6 MeV. Historically, as understood by applicants, LINAC manufacturers have attempted to reproduce the effective energy of Cobalt 60 decay photons (1.25 MeV) when making LINAC sources for treating breast tissue. Cobalt-60 itself could also be used in the radiotherapy device claimed herein and the need for an accelerator removed. When a direct electron beam is selected as the therapeutic form of radiation, the LINAC preferably produces a stream of electrons, wherein the electrons have an energy range from 1-10 MeV, preferably in the range of 4-6 MeV. When a direct beam of protons are used as the therapeutic form of radiation, the energy range is preferably between 1-15 MeV. Any of the forms of LINACs that are available from manufacturers such as Varian may also be made more compact and thus the machine size smaller by the utilization of superconductive wave guide materials and associated technologies such as currently being used to generate superconducting cyclotrons for treating other deep-seated lesions such as prostate cancer.

[0040] The radiation source **602** produces a radiation beam centerline that ideally passes from the exit of the source straight through a center of the system, which is usually the lesion of the breast being treated or is some line through another volume that should be subjected to radiation therapy.

[0041] The target assembly and carousel **603** included in the radiotherapy apparatus is used in an embodiment of the radiotherapy apparatus to switch the type of therapeutic radiation chosen for a particular volume in a patient's breast or surrounding tissue. In an electron mode, the radiotherapy apparatus can emit beta rays that are produced in a LINAC or comparable radiation source. While in a photon mode, the radiotherapy apparatus can be configured for the production of photons such as gamma or x-rays.

[0042] Following the target assembly and carousel is the primary dual independent collimator **604**. The primary collimator **604** is followed by the tertiary or multi leaf collimator **605** that can produce in a non-limiting example a 3 mm leaf width at radiation and rotational center **107** of the system for precision treatment of voxels located within the breast.

[0043] The radiotherapy apparatus additionally can house a monitor chamber **606** positioned before the multi leaf collimator to assist in determining the amount of radiation being emitted from the radiation source and subsequently delivered to a particular volume in a patient. Preferably, monitor chamber **606** would remain in dynamic communication with a concurrent radiation monitoring system so that the radiotherapy system as accurately as possible provides therapeutic radiation in accordance with an individualized radiotherapy patient treatment plan.

[0044] After passing through the center **107**, the radiation strikes a solid state flat panel detector **607** used for portal imaging. The flat panel detector **607** is moveable relative to the beam of radiation so that it can be placed in the path of the beam for imaging and taken out of the path of the beam for radiation treatment.

[0045] Optionally, a beam blocker **608** can be placed in the path of the beam to effectively stop radiation that has passed through the irradiated volume. As shown in FIGS. **5***a* and **5***b*, optional beam blocker **608** is placed within the path of the radiation emitted from source **602** illustrated by photon beam centerline **601** and positioned downstream of center **107** and flat panel detector **607**. The optional beam blocker **608** can cut down the cost of shielding the room thereby reducing the structural footprint of a room housing this system, and making the system as a whole easier and less expensive to install and operate in hospitals, clinics, and other such facilities.

[0046] FIGS. **6***a* and **6***b* illustrate a variation of the system in which patient table **101** is supported on a motorized pedestal **650** that can selectively move table **101** along some or all the x, y, and z axes illustrated in FIGS. **6***a* and **6***b*, and also can tilt table **101** about some or all of these the axes. Another motorized pedestal **652** supports a motorized plate **654** that in turn supports an arm **656** to which is mounted another arm **660** supporting therapy radiation source **105**, portal imaging detector **108**, and blocking plate **608** and any imaging system schematically illustrates at **658**. Pedestal **652** selectively rotates plate **654** to move arm **656** and the components it carries between the positions shown in solid and in dotted lines, including any intermediate position. Motorized plate **654** selectively moves arm **656** and the components attached to it up and down as illustrated by arrows in the z-direction and also telescopes or otherwise extends arm **656** and the components it carries in the y-direction as also illustrated by a bidirectional arrow. Arm **656** also can be motorized to selectively rotate arm **660** about the z-axis at point **662** as illustrated by a bidirectional curved arrow. In addition, arm **660** can be motorized to selectively rotate radiation source **105** about the x-axis at **664** as illustrated by another bidirec-

tional curved arrow. These translational and rotations motions are powered and controlled by units such as **610** and **612** (FIG. **4***a*) that are omitted from the illustration in FIGS. **6***a* and **6***b* for clarity. FIG. **6***b* illustrates the same arrangement as FIG. **6***a* but in a front elevation. Typically the patient would be prone on table **101**, with a breast extending downwardly through an opening or into a depression in table **101**, so that the breast and/or related tissue can be imaged and/or treated with radiation from below table **101**, through the motions referred to above patient tissue can also be treated with a radiation beam that extends from below table **101** through the patient at an angle to the horizontal, for example as illustrated in FIG. **4***b*, or at any other suitable angle to the horizontal. Alternatively, if desired the patient can be in another position, such as the supine position, to be imaged and/or treated with radiation from a source position above table **101**, such as illustrated in dotted lines in FIGS. **6***a* and **6***b*.

[0047] FIG. **7** illustrates in side elevation an alternative that includes, in addition to the arrangement of FIGS. **6***a* and **6***b*, an arm **700** that is at the other side of patient table **101** and is mounted to plate **654** in a manner similar to that used for arm **656**. Again, plate **654** can be motorized to selectively move arm **700** up and down as seen in FIG. **7** and illustrated by arrows, and to extend or contract arm **700** in the y-direction as illustrated with a bidirectional arrow. Arm **700** carries a specialized breast CT scanner **712** that is otherwise similar to commercially available CT scanners available from companies such as Giotto of Italy and distributed in this country primarily for imaging extremities by Hologic, Inc. of Bedford, Mass. but is smaller and lighter to serve as a dedicated breast CT scanner. When plate **654** rotates about the y-axis such that arm **700** is below patient table **101**, a patient breast extending downwardly from the upper surface of table **101** can be positioned in an opening **714** of CT scanner **712** and conventional CT scanning can be carried out to generate or adjust or verify treatment plans for treatment that can be carried out with the equipment mounted to arm **656**. The components and motions in FIG. **7** that are in addition to those associated with arm **700**, including ones not labeled or otherwise marked in FIG. **7**, can be the same as in FIGS. **6***a* and **6***b*.

[0048] All patents and other publications and patent application identified above are hereby incorporated by reference in this patent specification.

1. A method of treating breast-related tissue of a prone patient comprising:

placing the patient on a surface of a patient table in a prone position, with a patient's breast protruding downward from the table surface through an opening or into a depression in the table;

irradiating the breast-related tissue with treatment radiation from a source mounted for movement about an upwardly extending axis to emit a treatment radiation beam that originates below the table surface; and

selectively angling the beam to irradiate with primary radiation portions of the prone patient's breast-related tissue that are above the table surface.

2. A method as in claim **1** including imaging the patient placed on the table, before said irradiating step, with an imaging apparatus keyed to a spatial frame of reference to which said source also is keyed, to develop, adjust or verify a radiation treatment plan.

3. A method as in claim **2** in which said imaging comprises three-dimensional (3D) imaging.

4. A method as in claim **3** in which said 3D imaging comprises one or more of ultrasound, x-ray imaging, and imaging using radiation emitted from within the patient.

5. A method as in claim **1** including introducing into the patient one or more sensors for at least one of position and radiation dose and utilizing said sensors in at least one of developing, adjusting, and verifying a radiation treatment plan for the patient.

6. A method as in claim **1** including interacting with a prone patient's breast for imaging and radiation treatment with a device that both tends to pull the breast from the patient's chest wall and to secure the breast in a selected position.

7. A method as in claim **1** including imaging the patient's breast with CT scanning while the patient is in the position on the patient table in which said irradiating is carried out.

8. A method as in claim **1** including detecting treatment radiation delivered to a target volume in or at breast-related tissue of the patient and delivering information regarding said detecting to one or more utilizing stations associated with the treatment system.

9. A method as in claim **1** including moving the source of the radiation to selectively irradiate patient tissue from a number of selected directions and selectively varying the distance between the source of the radiation and target tissue.

10. A system for radiation treatment of breast-related tissue comprising:

a patient table having an upper surface for supporting a patient, said table having a selectively revealed opening or depression for a patient breast to extend downwardly from the patient table surface when the patient is in the prone position on said table;

a therapy radiation source selectively emitting therapy radiation and a mounting structure supporting the source and selectively moving the source in a first motion in which it irradiates a first target volume with a primary radiation beam that has a centerline below the table surface and in a second motion in which it irradiates a second target volume with a with primary radiation beam that has a centerline angled from the horizontal and intersecting the table surface.

11. A system as in claim **10** in which the first target volume is at a downwardly protruding breast of a patient in the prone position on the patient table and the second target volume is at the patient's axilla.

12. A system as in claim **10** further the mounting structure includes structure supporting the source for motion in which the source emits a therapy beam from a location above the table surface to directly irradiate breast-related tissue of a patient in the supine position on said table surface.

13. A system as in claim **10** including a table support and a an interlock mechanism configured to releasably secure the table at a selected position relative to a system frame of reference in which the source is at a known position, said interlock mechanism also configured to mate with a separate imaging device operative to generate imaging information for a radiation treatment plan for the patent, said treatment plan being spatially referenced to an interlocked position of the table to the imaging device.

14. A system as in claim **10** including a CT scanner mounted in the system and selectively brought in position for

CT imaging of a patient in the prone position on said patient table.

15. A system as in claim **10** including an imaging system mounted in a known frame of reference relative to the therapy radiation source for selectively imaging breast-related tissue.

16. A system as in claim **15** in which said imaging system selectively provides 2D images of said tissue.

17. A system as in claim **15** in which said imaging system selectively provides 3D imaging information of said tissue.

18. A system as in claim **10** in which said mounting structure includes a positioning mechanism selectively varying a distance between said source of therapy radiation and said target volume.

19. A system as in claim **10** including a control unit directing the radiation source in accordance with previously generated treatment plans.

20. A system as in claim **10** in which said mounting structure comprises a rotating plate support on which said therapy radiation source is mounted for rotation about an axis extending along a length of said patient table.

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