US 20100080349A1

(19) **United States**

(12) **Patent Application Publication**

(10) **Pub. No.: US 2010/0080349 A1**

(43) **Pub. Date: Apr. 1, 2010**

Kalender et al.

(54) **MODULAR SYSTEM FOR DIAGNOSIS AND SURGICAL OPERATION ON A BREAST**

(75) Inventors: **Willi Kalender**, Moehrendorf (DE); **Harry Schilling**, Eichstaett (DE)

Correspondence Address:
DAFFER MCDANIEL LLP
P.O. BOX 684908
AUSTIN, TX 78768 (US)

(73) Assignee: **MIR MEDICAL IMAGING RESEARCH HOLDING GMBH**, Moehrendorf (DE)

(21) Appl. No.: **12/402,141**

(22) Filed: **Mar. 11, 2009**

(30) **Foreign Application Priority Data**

Sep. 29, 2008 (DE) 102008042430.7

Publication Classification

(51) **Int. Cl.**
A61B 6/04 (2006.01)

(52) **U.S. Cl.** **378/37**

(57) **ABSTRACT**

An X-ray machine for examining a breast of a female patient has a CT scanner attached to a patient's table. An instrument holder that is adapted to be moved to be located underneath a gantry of the CT scanner is provided with a positioning unit for positioning an instrument for examining or operating close to the breast. An exact position of the instrument holder relative to the gantry or the breast to be examined can be determined with a measuring system. Thereby, it is possible to position an examining or surgical intervention instrument extremely precisely.

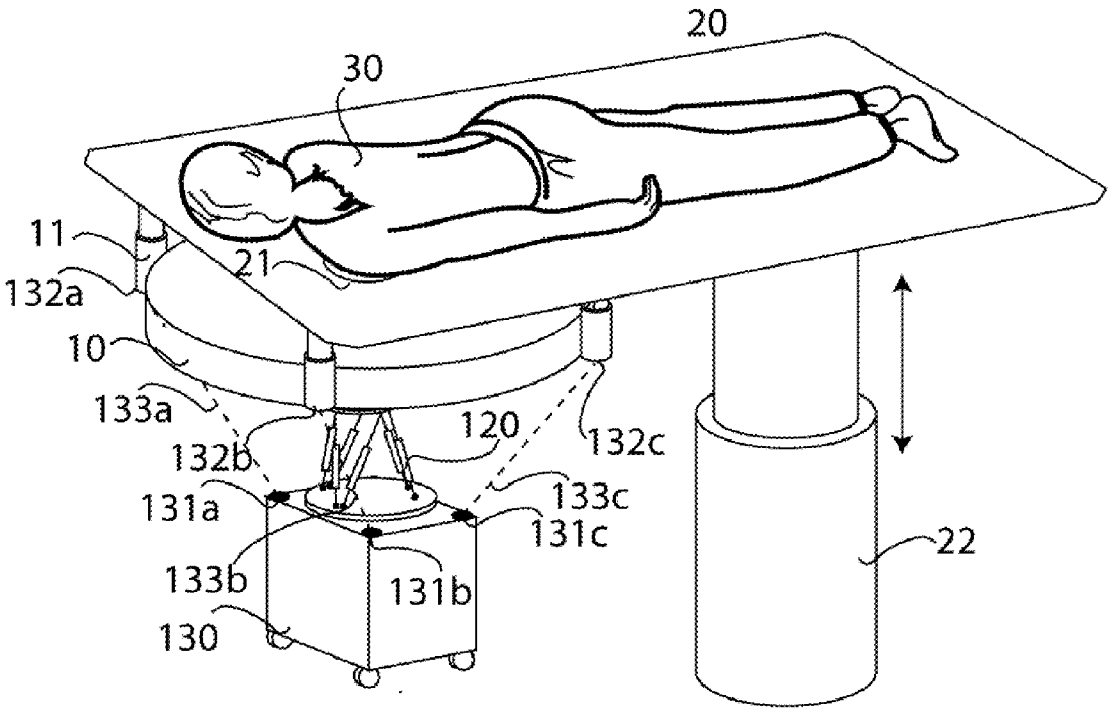


FIG. 1

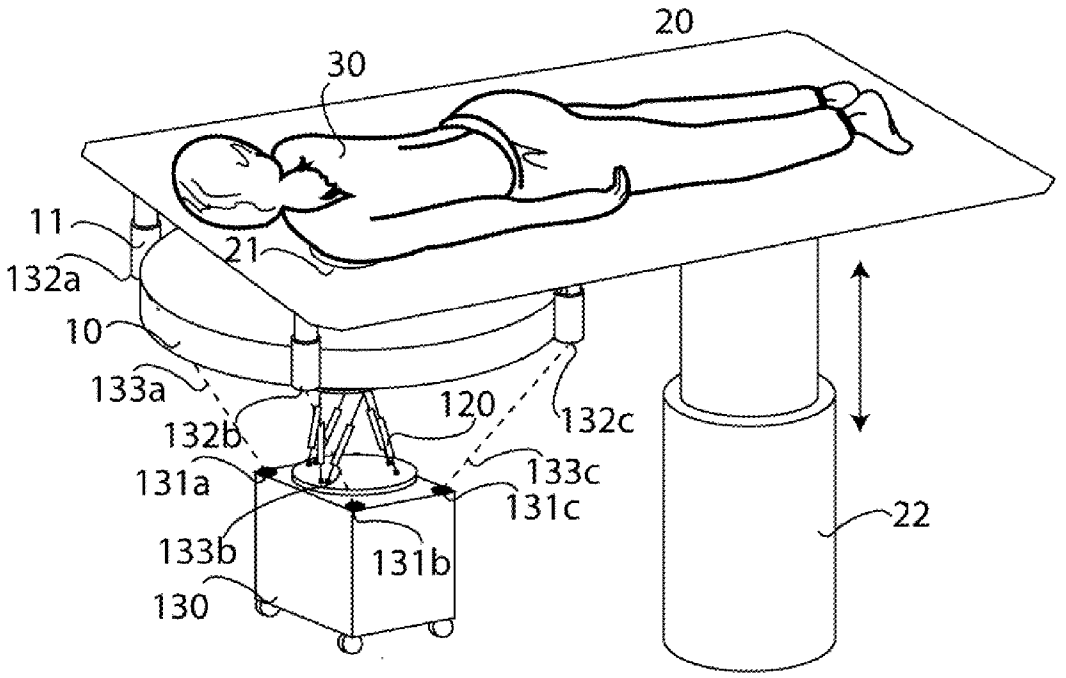

20
30
11
21
132a
10
133a
120
132c
132b
131a
133c
131c
133b
131b
130
22

FIG. 2

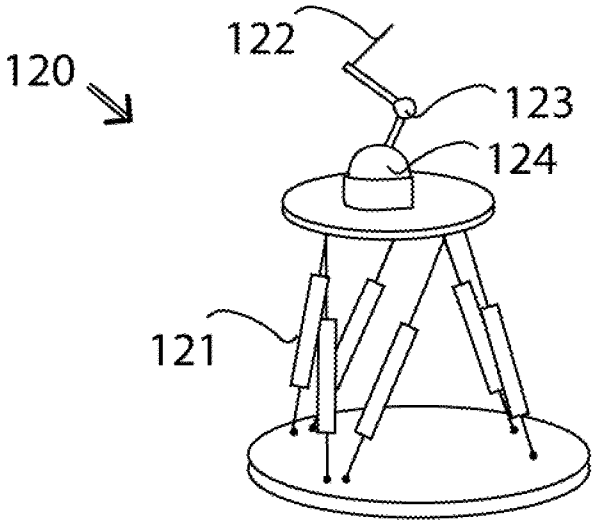

120
122
123
124
121

FIG. 3

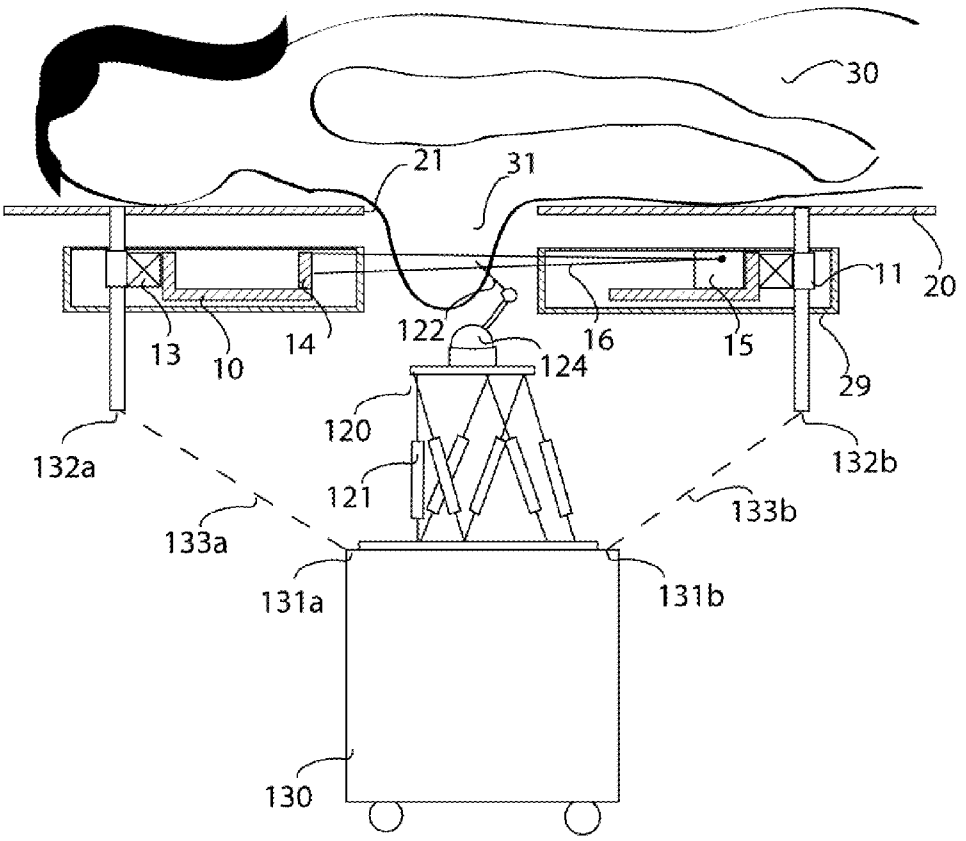
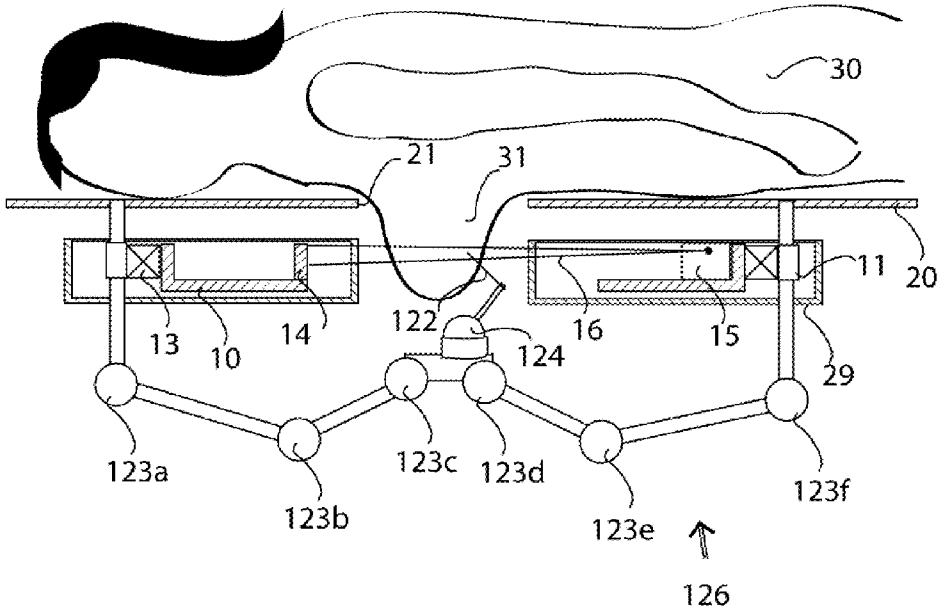

30
21
31
11
20
13
10
14
122
16
15
124
29
120
132a
132b
121
133b
133a
131a
131b
130

FIG. 4


30
21
31
11
20
13
10
14
122
124
16
15
29
123a
123b
123c
123d
123e
123f
126

MODULAR SYSTEM FOR DIAGNOSIS AND SURGICAL OPERATION ON A BREAST

PRIORITY CLAIM

[0001] This application claims priority to pending German Application No. 102008042430.7 filed on Sep. 29, 2008.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The invention relates to an X-ray machine for imaging a breast of a female patient. With this machine it is possible to perform a surgical operation on a breast.

[0004] 2. Description of Related Art

[0005] Various X-ray machines are known for performing an examination of a female breast. An X-ray facility having a rotating gantry with an X-ray tube and a detector is located below a patient's table on which a patient to be examined rests. A machine of this kind is disclosed for example in U.S. Pat. No. 4,015,836. A disadvantage of this prior art is the large requirement of space, and also the lack of access to a breast to be examined. Furthermore, the patient is put into a relatively uncomfortable position with her head lying low, in order that as large as possible a part of the breast can be covered by the X-ray machine. An improvement is represented by an arrangement described in U.S. Patent Application Publication No. 2006/0094950. Here, the patient is in a more comfortable position. However, the breast to be examined is accessible only with special instruments. A disadvantage of this arrangement is the large requirement of space resulting from the large structural shape of the gantry. An X-ray machine based on a spiral CT scanner is disclosed in U.S. Patent Application Publication No. 2007/0064867. Here, the resolution is limited by low stability of the mechanical design. In addition, here too the breast to be examined cannot be accessed from outside.

BRIEF SUMMARY OF THE INVENTION

[0006] The following description of the objective of the disclosure provided herein, the description of embodiment of an X-ray machine for imaging a breast of a female patient and performing surgical intervention of the breast, as well as the description of a method for operating such an X-ray machine is not to be construed in any way as limiting the subject matter of the appended claims.

[0007] The objective of the disclosure provided herein is to design an X-ray machine which images a female breast in a diagnostically correct manner, and also rapidly and at favorable cost, and at the same time makes it possible to perform a surgical operation or intervention on the breast. In addition, the machine is to provide a physician performing treatment with good and ergonomically advantageous access to the breast.

[0008] An embodiment of an X-ray machine for imaging a breast of a female patient and performing surgical intervention on the breast includes a gantry that is rotatable approximately about a vertical rotation axis and a gantry lift drive configured to move the gantry in a vertical direction, wherein a vertical movement of the gantry is dependent upon the rotational movement of the gantry. The X-ray machine further includes an X-ray tube and an X-ray detector mounted on the gantry and a horizontally disposed patient's table having a cutout portion for a breast, wherein the gantry is suspended from a lower side of the patient's table. In addition, the X-ray machine includes an instrument holder for accommodating at least one operating instrument in the vicinity of the breast through the gantry from below the patient's table so that surgical intervention can be effected with the operating instrument.

[0009] An embodiment of a method for operating an X-ray machine includes producing a three-dimensional X-ray exposure, detecting a position of a surgical intervention instrument relative to a gantry of the X-ray machine, and calculating a position of the surgical intervention instrument with respect to the three-dimensional X-ray exposure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] In the following the invention is described by way of example, without limitation of the general inventive concept, on examples of embodiments and with reference to the drawings.

[0011] FIG. **1** shows a perspective view of an example of an X-ray machine.

[0012] FIG. **2** shows a positioning unit with a hexapod.

[0013] FIG. **3** shows a partial side view of an example of an X-ray machine.

[0014] FIG. **4** shows a partial cross-sectional view of an example of an X-ray machine having an articulated arm to support an instrument holder.

[0015] While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof are shown by way of example in the drawings and will herein be described in detail. It should be understood, however, that the drawings and detailed description thereto are not intended to limit the invention to the particular form disclosed, but on the contrary, the intention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the present invention as defined by the appended claims.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0016] FIG. **1** shows perspective view of an example of an X-ray machine. A patient **30** is positioned on a patient's table **20**. A breast to be examined is suspended through a breast cutout portion **21** in the patient's table into an exposure range of a gantry **10**. The gantry **10** is a spiral computer tomography gantry with an X-ray tube and a detector which rotate about the breast to be examined. During the rotation, the breast is imaged, i.e. exposed to X-rays to obtain X-ray images. Simultaneously with the rotation, a displacement of the gantry in a vertical direction is performed via a gantry lift drive **11** so that the breast is scanned along a spiral trajectory. The height of the patient's table **20** can be adjusted by means of a patient's table lift drive **22**. In a case in which a patient's table is firmly installed, it can be optionally adapted to be rotated about an axis of the patient's table lift drive **22**.

[0017] A mobile platform **130** is located below the gantry **10**. During an examination, this mobile platform can be moved to or removed from below the gantry. It may be provided with wheels which advantageously can be locked in position. Optionally, it can roll or slide along the floor or on rails. Slide or air-bearings are of special advantage. The mobile platform may have a separate drive for exact positioning below the gantry or may be moved there manually. Guide rails or positioning aids embedded in the floor, such as induction loops, can simplify exact positioning. An instrument holder covered from view by the gantry is held in an operating

position close to a breast by means of a positioning unit **120**. The positioning unit may be, for example, a hexapod or also an articulated arm. For exact positioning, position measuring systems **131***a*, **131***b* and **131***c* are provided which determine the distance from measurement marks **132***a*, **132***b*, and **132***c* on the gantry suspension with measurement signals **133***a*, **133***b*, and **133***c*, which may be, for example, light signals. Optionally, on basis of the measurement made with the position measuring systems, an automatic or even manual correction of the position of the mobile platform may be effected. Alternatively and/or additionally, the position data obtained from the measuring system can be used for calculating the exact position of the instrument holder. Basically, the measuring system may operate according to any known principles for position or distance measurement. Preferably, it operates with optical sensors such as laser sensors or also ultrasound sensors or radio sensors.

[0018] FIG. **2** illustrates a positioning unit **120** for positioning the instrument holder **124** in a correct operating position with respect to a breast. Exact positioning is here effected by means of a hexapod **121**. In some embodiments, an articulated arm with at least one revolute or swivel joint **123** is provided between the instrument holder and a intervention instrument **122**. A plurality of joints may be provided. Because of the hexapod, however, this is usually not necessary in the illustrated embodiment.

[0019] FIG. **3** illustrates a partial side view of an example of an X-ray machine. For better illustration, the gantry is shown in cross-section. An X-ray tube **15** is located within the gantry housing **29** which generates an X-ray fan or X-ray beam **16** to be transmitted through the breast **31**. The radiation is received by a detector **14** connected to an evaluation unit (not shown). The gantry is supported to rotate around the breast by a gantry pivot bearing **13**, and its distance from the patient table **20** can be adjusted with a gantry lift drive **11**. With this, a scan of the breast **31** to be examined is possible along a spiral trajectory.

[0020] FIG. **4** illustrates an example of an X-ray machine having an articulated arm **126** for positioning the instrument holder **124** and the intervention instrument **122**. This articulated arm is shown attached to the supports of the gantry suspension. Advantageously, it can be removed from or re-attached to the gantry suspension during an examination or treatment. The articulated arm can be also attached to the patient's table **20** itself or to another structural component connected thereto, instead of to the gantry suspension. Preferably, an attachment of this kind can be released in a simple way and manner, for example with a quick acting closure, so that the entire structural component group including the articulated arm **126** can be rapidly assembled and again dismantled. In some embodiments, the arm may be also used on a mobile platform **130** as similarly described for the hexapod illustrated in FIG. **1**. The articulated arm shown in FIG. **4** has a plurality of pivot joints **123***a*, **123***b*, **123***c*, **123***d*, **123***e* and **123***f*. Preferably, rotary drives and/or angle sensors and/or position sensors are incorporated in the pivot joints. A measuring system may be present also on the instrument holder, so that an exact position of the instrument holder with respect to the gantry **10** and/or the patient's table can be determined.

[0021] An X-ray machine for imaging a breast of a female patient comprises a patient's table **20** from which a gantry **10** of a spiral computer tomograph is suspended. The patient's table **20** has a breast cutout portion **21** through which a breast **31** of a patient **30** is suspended preferably downwards in a direction towards the gantry **10**. The gantry **10** has a gantry lift drive **11** with which it can be moved relative to the patient's table. For taking an X-ray exposure, the gantry rotates around the breast **31** of a female patient. Simultaneously and/or at staggered time intervals, a displacement of the gantry **10** is effected along a longitudinal direction of the breast, i.e. preferably in a vertical direction. Optionally, the displacement can be made continuously at constant speed or proportional to the rotation of the gantry. Alternatively, the displacement can be also effected stepwise so that, for example, a displacement by an amount equal to one width of the detector **14** is made following each single revolution of the gantry.

[0022] For surgical intervention, in particular a biopsy, an instrument **122** is provided with which the intervention or operation is effected from below into the free opening of the gantry. With this, samples can be taken from, or contrast agents injected into, a breast without affecting the gantry. The instrument is preferably located on an instrument holder **124** which is optionally connected via an articulated arm **126** with the patient's table or the gantry suspension **125**. As an alternative to this, the instrument holder **124** can be disposed on a mobile platform **130**. In such cases, it is especially advantageous when the instrument holder, for being exactly positioned, is connected to the mobile platform via a hexapod **121**. Measuring facilities are provided for exactly positioning the instrument holder **124**. In the case of an articulated arm, its pivot joints are preferably provided with angle or position sensors. Furthermore, a measuring system can be provided which establishes optionally the position of the instrument holder or also that of the mobile platform with respect to the gantry, the patient's table or another component part firmly connected therewith. The measuring system transmits corresponding correcting information to the articulated arm or the hexapod.

[0023] With the X-ray machines described herein, X-ray exposures or examinations of a breast can be performed initially without the instrument holder or the instrument for surgical intervention. Owing to the design in which the gantry is suspended from the patient's table, a compact and space saving construction is achieved, in which also an examining or treating physician or other personnel have access to a breast to be examined. Thus, for example, a contrast agent can be injected into the breast prior to an exposure being made, or between two exposures. If a surgical intervention or operation such as a biopsy is to be made, then the instrument holder with an appropriate instrument is inserted from below the gantry. This is particularly simple when a mobile platform is available. In particular, a mobile platform may be moved from a lateral location to a location beneath the gantry, for example on wheels. In most cases, an exact adjustment will not be necessary, so that simple marks on the floor will be sufficient. An exact adjustment of the instrument holder with the instrument may then be effected with a positioning unit mounted to the mobile platform on a basis of position data that have been established by at least one measuring system. Following a surgical intervention, for example a biopsy, the mobile platform can be again removed from the region of the gantry, so that the breast is again accessible to an examining physician. With the devices and systems described herein, it is not necessary to re-locate the patient between an X-ray exposure and a biopsy. Furthermore, it is not necessary to mark the locations of punctures on the skin in accordance with an X-ray image and then perform a biopsy through these punctures. Instead, a biopsy now can be performed with exact control based on X-ray data.

[0024] In some cases, an exact positioning of an instrument can be monitored during a surgical intervention. For this, one or a plurality of X-ray exposures are made during the intervention to check the instrument or the position of the instrument. Advantageously, the gantry rotates continuously during the intervention and makes exposures which are displaced from each other by approximately 90°. Thereby, the intervention or operating instrument can be controlled in two planes. Thus, for example, it can be ascertained whether a biopsy needle is subject to bending.

[0025] A method for operating an X-ray machine includes producing a three-dimensional X-ray exposure, detecting a position of an intervention instrument relative to a gantry, and calculating a position of the intervention instrument with respect to the three-dimensional X-ray exposure. With this method the order of the first two steps can be interchanged. In either case, the calculation of the position of the intervention instrument **121** is by means of its position relative to the gantry or to a component connected to the gantry.

[0026] In the X-ray machines described herein, at least one measuring system for determining a position of the instrument holder or of a component connected thereto relative to the gantry or a component firmly connected thereto may be adapted to supply position information for positioning at least one of the instrument holder and the operating instrument relative to the breast.

[0027] It will be appreciated to those skilled in the art having the benefit of this disclosure that this invention is believed to provide an X-ray machine for imaging a breast of a female patient and performing surgical intervention of the breast as well as a method for operating such an X-ray machine. Further modifications and alternative embodiments of various aspects of the invention will be apparent to those skilled in the art in view of this description. Accordingly, this description is to be construed as illustrative only and is for the purpose of teaching those skilled in the art the general manner of carrying out the invention. It is to be understood that the forms of the invention shown and described herein are to be taken as the presently preferred embodiments. Elements and materials may be substituted for those illustrated and described herein, parts and processes may be reversed, and certain features of the invention may be utilized independently, all as would be apparent to one skilled in the art after having the benefit of this description of the invention. Changes may be made in the elements described herein without departing from the spirit and scope of the invention as described in the following claims.

1. An X-ray machine for imaging a breast of a female patient and performing surgical intervention on the breast, comprising:

a gantry that is rotatable approximately about a vertical rotation axis;

a gantry lift drive configured to move the gantry in a vertical direction, wherein a vertical movement of the gantry is dependent upon the rotational movement of the gantry;

an X-ray tube and an X-ray detector mounted on the gantry;

a horizontally disposed patient's table having a cutout portion for a breast, wherein the gantry is suspended from a lower side of the patient's table; and

an instrument holder for accommodating at least one operating instrument in the vicinity of the breast through the gantry from below the patient's table so that a surgical intervention can be effected with the operating instrument.

2. The X-ray machine according to claim **1**, further comprising a mobile platform for supporting the instrument holder via a positioning unit, wherein the mobile platform is adapted to be inserted underneath the gantry from a side of the X-ray machine.

3. The X-ray machine according to claim **2**, wherein the mobile platform comprises at least one measuring system for determining a position of the mobile platform relative to the gantry or another component firmly connected to the gantry, and wherein the mobile platform is configured to utilize position information determined with the measuring system for exact positioning of the instrument holder.

4. The X-ray machine according to claim **2**, wherein the positioning unit is a hexapod.

5. The X-ray machine according to claim **2**, wherein the mobile platform comprises wheels, slides or air bearings.

6. The X-ray machine according to claim **1**, further comprising an articulated arm for supporting the instrument holder, wherein the articulated arm is configured for attachment to a structural component of the X-ray machine.

7. The X-ray machine according to claim **6**, wherein the structural component is a gantry suspension for suspending the gantry below the patient's table or another component firmly connected to the gantry suspension.

8. The X-ray machine according to claim **6**, wherein the articulated arm is adapted to be unfastened from the structural component with a rapid closure means.

9. A method for operating an X-ray machine, comprising:

producing a three-dimensional X-ray exposure;

detecting a position of a surgical intervention instrument relative to a gantry of the X-ray machine; and

calculating a position of the surgical intervention instrument with respect to the three-dimensional X-ray exposure.

10. The method according to claim **9**, wherein the step of producing the three-dimensional X-ray exposure is performed prior to the step of detecting a position of the surgical intervention instrument.

11. The method according to claim **9**, wherein the step of producing the three-dimensional X-ray exposure is performed subsequent to the step of detecting a position of the surgical intervention instrument.

12. The method according to claim **9**, further comprising performing a surgical invention subsequent to calculating a position of the surgical intervention instrument.

13. The method according to claim **12**, further comprising producing additional X-ray exposures during the step of performing the surgical intervention to check a position of the surgical intervention instrument within the X-ray machine.

* * * * *