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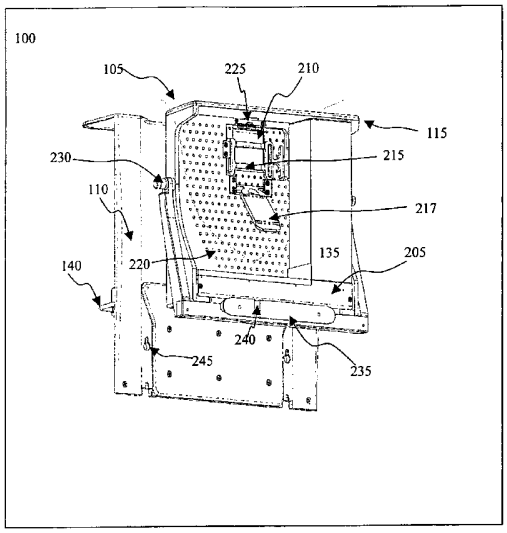
(54) Title: OPEN-ACCESS EMISSION TOMOGRAPHY SCANNER



(57) Abstract: An apparatus and a method for implementing emission tomography of a compressed and/or immobilized body part with open access for interventions, such as biopsy, hook-wire placement, or minimally invasive therapy, are provided. The apparatus includes one or more holders that compress and/or immobilize the body part on one or more sides of the body part. One or more of the holders contains an aperture through which an intervention can be carried out. Affixed to one or more holders are mechanical stages that carry and move a gamma-ray detector or detectors across the body part, so that the gamma-ray detector(s) can at times stay on the mechanical stages in a position that does not interfere with interventions through the aperture in the body part holder(s). A safety door mechanism is affixed to the aperture in the body part holder(s) in order to prevent the gamma-ray detector(s) from coming into physical contact with one or more portions of the body part that might otherwise protrude through the aperture.

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OPEN-ACCESS EMISSION TOMOGRAPHY SCANNER

BACKGROUND OF THE INVENTION

Cross-Reference to Related Applications

[0001] This application claims priority under 35 U.S.C. §119(e) to U.S. Provisional Application Serial No. 60/346,792, entitled "Design and Method for Full-Breast Positron Emission Mammography", filed January 8, 2002, the contents of which are incorporated by reference herein.

Field of the Invention

[0002] The present invention relates to an apparatus and a method for implementing emission tomography of a body part, and more particularly an apparatus and a method for implementing emission tomography of a body part with open access for medical or surgical interventions, such as a biopsy or minimally invasive therapy.

Description of the Related Art

[0003] Nuclear medicine imaging measures the distribution of injected radiotracers to describe biochemistry and/or physiology of a body part *in vivo*. The uses of compression and/or immobilization of a body part during the act of physiological image acquisition have been previously described in several patents, including U.S. Patent No. 5,252,830, U.S. Patent No. 5,323,006, and U.S. Patent No. 5,519,221, the contents of each of which are incorporated herein by reference. When the image acquisition is performed using a radiotracer emitting a single gamma-ray, and the body part is a breast that is compressed or immobilized by a body part holder or holders, and image acquisition is performed with one or more gamma-ray detector modules in close proximity to the breast, the procedure can be described as compression scintimammography. When the image acquisition is performed using a radiotracer emitting two coincident gamma-rays (i.e., as in positron annihilation), and the body part is a breast that is compressed or immobilized by a body part holder or holders,

and image acquisition is performed with one or more gamma-ray detector modules in close proximity to the breast, the procedure can be described as positron emission mammography.

[0004] It is preferable to sample the body part, or remove tissue from the body part, without releasing the body part from its compressed or immobilized position. This preference is due to the loss in spatial accuracy that may occur if the body part moves from the time that a target is selected on the basis of images, to the time that the target is sampled or removed. In order to perform an intervention, it is preferable to gain access to the body part through the body part holder, via one or more apertures in the body part holder.

[0005] Prior to the current invention, gamma-ray detector heads were generally stationary with respect to the body part holder during the process of gamma-ray detection, and it was necessary to remove the gamma-ray detector modules from the body part holders in order to provide access to the aperture when interventions were contemplated. For example, see R. Raylman et al., "Positron Emission Mammography-Guided Breast Biopsy", J. Nucl. Med. 2001, Vol. 42, pp. 960-966, the contents of which are incorporated herein by reference. Thus, the present inventors have observed that it would be advantageous to provide a capability to move the gamma ray detector heads during the detection process and thereby obviate the need to remove one or more of the detector modules from the body part holders during interventions.

[0006] Conventional body part holders on mammography equipment have large (e.g., 5 cm x 5 cm) open apertures that allow a portion of the breast to protrude during compression. This unrestrained portion of the breast may move during physical interventions such as needle insertions. Tissue movement can affect the ability to accurately target suspicious tissue for biopsy or treatment. Reducing the size of the aperture could better stabilize the tissue; however, interventions become more difficult since the accessible area is reduced. Accordingly, the present inventors have recognized a need for a means to stabilize the tissue which is being accessed through the aperture without substantially reducing access to the tissue.

SUMMARY OF THE INVENTION

[0007] In one aspect, the invention provides a diagnostic system for imaging a functional abnormality in a body part into which a radiotracer has been injected into the body part. The system includes at least one body part holder and at least one gamma ray detector module. Each body part holder immobilizes and compresses the body part. Each body part holder includes an aperture. The aperture provides access to the body part for performing a medical intervention. Each gamma ray detector module is movable with respect to the at least one body part holder. The gamma ray detector module obtains data by detecting gamma rays emitted by the injected radiotracer, and the system uses the obtained data to provide an image of the functional abnormality.

[0008] The body part holder may include at least one safety door which is hingedly affixed to the aperture of the body part holder. The safety door may prevent the body part from protruding through the aperture whenever the safety door is in a closed position. The safety door may prevent the gamma ray detector module from moving past the aperture whenever the safety door is in an open position. The safety door may be movable and removable with respect to the aperture. The safety door may include at least one open slot such that a portion of the body part to which access is provided by the aperture can be varied by movement or removal of the safety door, and such that the at least one safety door substantially stabilizes the portion of the body part to which access is provided by the aperture, and such that the access is not substantially reduced by the safety door. The safety door may also include a plurality of bars. The bars may displace the body part in order to prevent pinching of the body part during movement or removal of the safety door.

[0009] The body part holder may include a first safety door and a second safety door. The first safety door may be configured to open and close in a horizontal orientation with respect to the body part holder, and the second safety door may be configured to open and close in a vertical orientation with respect to the body part holder. The body part holder may also include a plurality of holes to allow the body part to be marked or to be accessed for sampling or for later identification. The body part holder may be fabricated using transparent material. The radiotracer may comprise a single-photon emitter or a positron emitter. The body part holder may include a fiduciary marker which is configured to facilitate the use of an additional medical device in conjunction with the system to improve the quality of the

imaging of the functional abnormality. The additional medical device may comprise a stereotactic x-ray mammography device.

[0010] The gamma ray detector module may include a printed circuit board. The printed circuit board may include scintillators, light guides, and position-sensitive photomultipliers. The printed circuit board may generate a signal, the signal including the obtained data, and the signal may be transmitted to a processor. The processor may use the transmitted signal to produce the image of the functional abnormality. The scintillators may comprise a plurality of arrays of lutetium-based crystals. The processor may be configured to receive x-ray data and to use the received x-ray data to improve the quality of the produced image of the functional abnormality. The processor may be configured to produce the image of the functional abnormality by using a maximum-likelihood iterative reconstruction algorithm. The processor may be configured to produce an anatomic image from the received x-ray data. The processor may include a graphical user interface configured to simultaneously display the anatomic image and the image of the functional abnormality. The anatomic image may be a projection of the x-ray, or a combination of projections. Typical x-ray projections used in mammography include a cranio-caudal projection, a medio-lateral projection, and +15 and –15 degree obliques to these projections. The image of the functional abnormality may be a typical x-ray mammography projection or a combination of projections, or oblique or orthogonal views to these projections, or a processed projection or combination of projections (e.g., maximal intensity projection image, in which the maximal value for each pixel along a projection is displayed). When a user indicates a specific location within the image of the functional abnormality, the graphical user interface may indicate a corresponding location within the anatomic image. When a user indicates a specific location within the anatomic image, the graphical user interface may indicate a corresponding location within the image of the functional abnormality. The system may include at least one optoelectronic element configured to determine a position of the gamma ray detector module.

[0011] In another aspect, the invention provides a method for imaging a functional abnormality in a body part. The method includes the steps of injecting a radiotracer into the body part; using an apparatus to immobilize and compress the body part; detecting gamma rays being emitted by the radiotracer by moving at least one gamma ray detector across the aperture; and using the detected gamma rays to produce an image of the functional

abnormality. The apparatus includes an aperture that provides access to a portion of the body part. The method may also include the step of implementing a safety mechanism to protect the body part from the moving gamma ray detector. The safety mechanism may be physically affixed to the apparatus at the aperture. The step of implementing a safety mechanism may include the step of closing at least one safety door that is hingedly affixed to the apparatus. The safety mechanism may be movable and removable with respect to the aperture. The method may also include the step of moving and/or removing the safety mechanism in order to allow access to a variety of portions of the body part. The safety mechanism may be configured to prevent pinching of the body part during movement or removal of the safety mechanism.

[0012] The method may also include the steps of obtaining an additional image of the body part by using an additional medical device and displaying data from the image of the functional abnormality in conjunction with a display of data from the obtained additional image. The additional medical device may comprise an x-ray device. The method may also include the step of using a fiduciary marker to facilitate the use of the x-ray device. When a user indicates a specific location within the image of the functional abnormality, the method may include the step of indicating a corresponding location within the obtained additional image. When the user indicates a specific location within the obtained additional image, the method may include the step of indicating a corresponding location within the image of the functional abnormality. The method may include the step of using at least one optoelectronic element to continuously determine a position of the gamma ray detector. The radiotracer may comprise a single-photon emitter or a positron emitter.

[0013] In yet another aspect, the invention provides an apparatus for imaging a functional abnormality in a body part into which a radiotracer has been injected into the body part. The apparatus includes at least one means for holding the body part, at least one means for detecting gamma rays, and a processor means for processing data and generating images. Each body part holding means is configured to immobilize and compress the body part. Each body part holding means includes an aperture which provides access to the body part for performing a medical intervention. Each gamma ray detection means is movable with respect to the body part holding means. The gamma ray detection means obtains data by detecting gamma rays emitted by the injected radiotracer. The processor means processes the obtained data to generate an image of the functional abnormality.

[0014] The body part holding means may include at least one safety means for protecting the body part. The safety means may be physically affixed to the aperture of the body part holding means. The safety means may be configured to prevent the body part from protruding through the aperture whenever the at least one safety means is in a closed position and to prevent the at least one gamma ray detection means from moving past the aperture whenever the at least one safety means is in an open position. The safety means may be movable and removable with respect to the aperture. The safety means may include at least one open slot, such that a portion of the body part to which access is provided by the aperture can be varied by movement or removal of the safety means, and such that the safety means substantially stabilizes the portion of the body part to which access is provided by the aperture, and such that the access is not substantially reduced by the at least one safety means. The safety means may also include a plurality of bars which are configured to displace the body part in order to prevent pinching of the body part during movement or removal of the safety means.

[0015] The body part holding means may include a first safety means for protecting the body part and a second safety means for protecting the body part. The first safety means may be configured to open and close in a horizontal orientation with respect to the body part holding means, and the second safety means may be configured to open and close in a vertical orientation with respect to the body part holding means. The body part holding means may include a plurality of holes configured to allow the body part to be marked. The body part holding means may be fabricated using transparent material. The radiotracer may comprise a single-photon emitter or a positron emitter. The body part holding means may include a means for providing a fiduciary marker to facilitate the use of an additional medical device in conjunction with the apparatus to improve the quality of the imaging of the functional abnormality. The additional medical device may comprise a stereotactic x-ray mammography device.

[0016] The gamma ray detection means may include a printed circuit board. The printed circuit board may include a plurality of scintillator means, a plurality of light guiding means, and a plurality of position-sensitive photomultiplier means. The printed circuit board may be configured to generate a signal that includes the obtained data and to transmit the signal to the processor means. The processor means may be configured to use the transmitted

signal to generate the image of the functional abnormality. The plurality of scintillator means may include a plurality of arrays of lutetium-based crystals. The processor means may be further configured to receive x-ray data and to use the received x-ray data to improve the quality of the generated image of the functional abnormality. The processor means may be further configured to generate the image of the functional abnormality by using a maximum-likelihood iterative reconstruction algorithm. The processor means may be configured to produce an anatomic image from the received x-ray data. The processor means may include a graphical user interface configured to simultaneously display the anatomic image and the image of the functional abnormality. When a user indicates a specific location within the image of the functional abnormality, the graphical user interface may be configured to indicate a corresponding location within the anatomic image. When a user indicates a specific location within the anatomic image, the graphical user interface may be configured to indicate a corresponding location within the image of the functional abnormality. The apparatus may include at least one optoelectronic means for optoelectronically determining a position of the gamma ray detection means.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Figure 1 shows a side view of an open-access emission tomography scanner apparatus according to a preferred embodiment of the present invention.

[0018] Figure 2 shows a first perspective view of the open-access emission tomography scanner apparatus of Figure 1.

[0019] Figure 3 shows a second perspective view of the open-access emission tomography scanner apparatus of Figure 1.

[0020] Figure 4 shows a series of four configurations of the safety doors of the scanner apparatus of Figure 1.

[0021] Figure 5 shows a flowchart illustrating a method of implementing the apparatus of Figure 1 according to a preferred embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0022] In a preferred embodiment of the present invention, the gamma-ray detector modules move within mechanical stages that are affixed to the holder or holders during the process of gamma-ray detection, so that access is provided to perform interventions on the body part without the need to remove the mechanical stages from the holder(s). Besides intervention, the aperture can also provide access to diagnostic tools that are dependent on close proximity or contact to the body part. Examples of such diagnostic tools include ultrasound, optical tomography, gamma or beta probes, and coils for magnetic resonance imaging. The use of moving gamma-ray detector modules affords economy and flexibility as compared to a stationary gamma-ray detector module, because a wider area can be surveyed with the moving gamma-ray detector modules than with the stationary modules, assuming that the gamma-ray acquisition process is efficient enough that a sufficient quantity of count statistics can be accumulated by the traveling gamma-ray detector modules. Fortunately, the gamma-ray collection efficiency of positron emission mammography is so high that very good quality images can be obtained under such conditions. For a further discussion of the gamma-ray collection efficiency of positron emission mammography, see C. Thompson et al., "Feasibility Study for Positron Emission Mammography", Med. Phys. 1994, Vol. 21, pp. 529-538, the contents of which are incorporated herein by reference.

[0023] In order to provide a user with feedback as to the nature and quality of the image of the body part during the process of gamma-ray acquisition, it is helpful to be able to perform image reconstruction in parts, so that as a new section of the body part is being surveyed, data from the body part which was previously surveyed is being backprojected, reconstructed, and/or displayed to the user. Because the gamma-ray detectors are moving with respect to the immobilized body part in a preferred embodiment of the invention, it is preferable to insure that no portion of the body part extends out of the aperture during travel of the detectors past the aperture, lest said portion be pinched or otherwise damaged by a gamma-ray detector module. Accordingly, in a preferred embodiment of the invention, a safety door or other body-part trapping apparatus is affixed to the aperture so that the body part does not extend past the body-part holder into the path of the traveling gamma-ray detector module(s).

[0024] In a preferred embodiment of the present invention, a fail-safe mechanism is provided in order that if the safety door or other body-part trapping apparatus does not effectively contain the body part out of the path of the traveling gamma-ray detector module(s), the gamma-ray detector module(s) are barred from traveling past the aperture. In a preferred embodiment, the fail-safe apparatus is implemented via mechanical means by having the door resist motion of the traveling gamma-ray detector module(s) when the safety door is not closed. In addition, a preferred embodiment of the present invention provides movable safety doors with open slots, which stabilize the tissue which is being accessed through the aperture, without substantially reducing access to the tissue.

[0025] Referring to Figure 1, a side view of an apparatus 100 according to one embodiment of the present invention is shown. In this embodiment, a patient lies above the apparatus 100, with the body part 105 to be examined (e.g., a breast) pendant through an aperture in a table (table not shown in Fig. 1). The body part 105 is immobilized and/or compressed by body part holders 110 and 115, said body part holders being relatively transparent to x-ray irradiation, and which are disposed on two sides of the body part 105. An x-ray emitter 120 is able to project x-rays through the body part 105, and through the body part holders 110 and 115 onto an x-ray sensor 125. In a preferred embodiment, the body part holders 110 and 115 are transparent to x-rays; however, the body part holders may be relatively transparent to other types of radiation or sources of signal providing anatomic information about the body part, such as, for example, MRI signals, ultrasound signals, infrared signals, or visible light signals. The tops of the body part holders 110 and 115 support the patient's body and keep the patient's body from directly contacting gamma-ray detector modules 130 and 135. In one embodiment, the modules 130 and 135 detect gamma rays emitted by the body part. However, the apparatus 100 may include detector modules that are sensitive to any signal (including gamma rays or any other signal) emitted by the body part which contains physiological information about the body part. The gamma-ray detector modules 130 and 135 are supported and moved by mechanical stages that are affixed to the body part holders 110 and 115. In Figure 1, one of the mechanical stages 140 is shown, while the other stage is obscured by body part holder 115. Referring also to Figure 2, the obscured mechanical stage 205 is shown in a perspective view of the apparatus 100. Body part holders 110 and 115 also have means of coupling to the table.

[0026] Referring again to Figure 2, body part 105 (again, typically a breast) is shown immobilized and/or compressed by body part holders 110 and 115. Body part holder 115 has an aperture 210 and safety doors 215 and 217, as well as multiple holes 220. The holes 220 in body part holder 115 can admit marking pen tips or other thin devices in order to mark the patient's skin if necessary. Preferably, body part holder 115 is fabricated from transparent material in order to better enable sight of the body part 105. Aperture 210 is shown with horizontal safety door 215 closed and with vertical safety door 217 open. Horizontal safety door 215 has holes that can admit needles or other interventional devices. Horizontal safety door 215 can swing open horizontally, and can also move up and down vertically, so that if the bars of the horizontal safety door 215 block the access of the needles, the bars can be repositioned. The bars of the horizontal safety door 215 displace the body part 105 away from the aperture 210 to keep the breast from being pinched as the horizontal safety door 215 is opened, swung on its hinge, or closed. The horizontal safety door 215 can be repositioned to cover different portions of the body part 105 by swinging the horizontal safety door 215 open on its hinge, or by replacing the horizontal safety door 215 in a different position, or by removing the horizontal safety door 215 entirely. This repositioning capability allows the body part 105 to be restrained and immobilized, while providing access to the area of the entire aperture 210. The open vertical safety door 217 does not permit travel of gamma-ray detector module 135. Thus, the safety doors 215 and 217 provide the following functions: (1) they restrain the body part 105 from protruding through the aperture; (2) they immobilize the body part 105 for improved accuracy during procedures; and (3) they act as safety measures by blocking travel of the detector modules 130 and 135 while safety door 217 is not closed.

[0027] Referring again to Figure 2, body part holder 115 includes a metal strip 225 which has a hole in its center. The x-ray projection of this hole can be used as a fiduciary marker in the following way: A compression paddle (body part holder) that is supplied by a manufacturer of a stereotactic x-ray mammography unit has a similar metal strip and hole. After the stereotactic x-ray mammography unit is calibrated with this native compression paddle, the user places a pin (said pin is also supplied by the manufacturer, and said pin is affixed to the table by the user during the calibration process) in the hole. The user then removes the native compression paddle and replaces the native compression paddle with body part holder 115, aligning the hole in metal strip 225 with the same pin, by making fine adjustments with screw 230 and other adjustment points. The hole in metal strip 225 can be

used by the stereotactic x-ray mammography unit to calibrate software needed to perform biopsies through aperture 210. In a preferred embodiment, gamma-ray detector module 135 includes scintillators, compact light guides, and compact position-sensitive photomultipliers on a printed circuit board that carries high voltage levels (which are needed to operate the photomultipliers) and a signal, wherein said signal is conveyed to a trigger and signal processing system, computer, and display system, such as that described in U.S. Patents Nos. 5,252,830; 5,323,006; and 5,519,221. Gamma-ray detector module 135 is conveyed by mechanical stage 205. Gamma-ray detector module 130 (not visible on Figure 2), which travels on body part holder 110, is conveyed by mechanical stage 140. Body part holder 110 fastens to the table of the stereotactic mammography unit via dovetail 235, which has a detent 240 to aid in alignment. Body part holder 110 attaches to the stereotactic mammography unit via screws through holes 245, and can have its position adjusted with respect to the stereotactic mammography unit by appropriate placement of screws through said holes 245.

[0028] Referring to Figure 3, a second perspective view of the system configuration of the apparatus 100 is shown. The x-ray sensor 125 is illuminated by an x-ray beam 305 from x-ray source 120. X-ray beam 305 traverses body part holders 110 and 115, as well as body part 105 and aperture 210. Gamma-ray detector module 135 is visible in Figure 3 while the other gamma-ray detector module 130 is not visible in this view. The gamma-ray detector modules 130 and 135 travel under computer control upon the mechanical stages 140 and 205 respectively. The purpose of this travel is to provide maximum flexibility so that the gamma-ray detector modules 130 and 135 can be swept across either the entire body part 105 (e.g., in order to acquire a full-breast image), or across the central portion of the body part 105 (e.g., in order to correlate with digital spot mammograms). When not acquiring gamma-ray data, the gamma-ray detector modules 130 and 135 are parked on one side of the mechanical stages 140 and 205 in order to provide access to the central field-of-view for biopsy or digital spot mammography x-rays. The gamma-ray detector modules 130 and 135 can be moved independently, so that they can move in the same direction across the body part 105, or they can be moved in opposite directions. Optoelectronic detector elements confirm location of the gamma-ray detector modules 130 and 135.

[0029] In a preferred embodiment of the apparatus 100 known as the "PEM-2400" (produced by PEM Technologies, Inc. of Rockville, Maryland, the assignee of the subject application), each of the gamma-ray detector modules 130 and 135 includes twelve arrays of

13x13 lutetium-based crystals. Each crystal measures 2 mm x 2 mm x 10 mm. The arrays are affixed to Hamamatsu R-8520-C12 position-sensitive photomultipliers ("PS-PMTs") with structured light guides to minimize gaps between arrays. In an exemplary process used for examining a breast, the PS-PMTs are read out with a multiplexing strategy in which events between PS-PMTs that are not adjacent to one another do not combine in the charge readout. External detector shielding is employed (i.e., 1 mm tungsten on five sides of each gamma-ray detector module, and 1.5 mm aluminum on the side facing the breast) such that the shielding minimally interferes with close access to the patient's chest wall. Last dynode signals that are ganged within each gamma-ray detector module are sent to a trigger board for coincidence testing. Triggering is accomplished with a two-step logic, in which a lower threshold is set to trigger on the first few electrons just above the noise level, and a higher threshold determines the desired energy threshold. The height of the gamma-ray detector modules is set so that the gamma-ray image's field-of-view overlaps the x-ray height by 2 mm. With this overlap, the entire x-ray field can be imaged with the PEM-2400. This is motivated by a desire to image as much of the posterior chest as possible. Considering that the degree of compression required for high sensitivity is not as demanding as for x-ray mammography, more of the posterior chest may be visible with the full-field PEM-2400 than with x-ray mammography, because of the ability to pull more of the breast into the table aperture and still maintain enough compression to get adequate gamma-ray images.

[0030] The use of moving gamma-ray detector modules that sweep past the breast imposes the need to address safety concerns, because without safeguards, the breast might protrude through an open biopsy aperture and be exposed to the moving detectors. As discussed above, this risk is mitigated by using hardware interlocks ("safety doors") that physically stop motion of the gamma-ray detector modules if the safety doors are not closed. Furthermore, the motor drive is set so that even minimal resistance will stop the gamma-ray detector modules. Referring to Figure 4, operation of the safety doors is shown as an interlock. Panel A shows body part holder 115 with horizontal gate 215 closed across aperture 210, and vertical gate 217 open, ready for biopsy or x-ray. The gamma-ray detector module 135 would not be able to move across aperture 210 because horizontal gate 215 would stop it. Panel B shows both gates 215 and 217 open, ready for biopsy or x-ray, with gamma-ray detector head 135 out of the way. Panel C shows both gates open, with biopsy gun 405 being used to place a needle through aperture 210. Panel D shows both gates open,

with device 410 in close proximity to breast 105. Device 410 could be an ultrasound transducer or a gamma probe.

[0031] Optoelectronic elements are set along the tracks in the mechanical stages 140 and 205 which hold the respective gamma-ray detector modules 130 and 135 so that the position of the gamma-ray detector modules is known at all times, even when the system 100 has lost power and recovered. Ribbon cables are looped within the mechanical stages 140 and 205 so that the gamma-ray detector modules 130 and 135 can move freely from one side of the mechanical stages 140 and 205 to the other without impediment. Each of the gamma-ray detector modules 130 and 135 is under separate software control, although in routine operation both gamma-ray detector modules move in the same direction. Note that because the gamma-ray detector modules 130 and 135 are very thin (approximately 6 cm in thickness), it is possible to obtain straight and ±15-degree x-ray images without removing the body part holders or x-ray sensors from the stereotactic x-ray mammography camera. This feature is important, because as a practical matter, the x-ray sensor is quite heavy and delicate, and thus it would be onerous to ask a technologist to remove the x-ray sensor in routine cases. The body part holders 110 and 115 have identical x-ray transmission specifications as compared to the native stereotactic unit paddle.

[0032] Files of detected gamma-ray signals are created in list-mode, with a separate list mode file created for delayed coincidences to accomplish later random subtractions. Images are backprojected during image acquisition, as the positron emission tomography ("PET") detector heads sweep across the breast, in order to provide feedback to the operator that the study is going well. Calibration is performed once a day using a sheet source for calculating matrices to correct for energy and spatial nonlinearity and efficiency correction. The history of deviations from initial factory settings is recorded for later analysis. A second calibration is performed every day to check the spatial correlation between the x-ray and the positron emission mammography ("PEM") image.

[0033] Images are captured from the x-ray mammography camera via a frame-grabber operating from a monitor video signal from the stereotactic mammography computer, as described in U.S. Provisional Patent Application No. 60/411,787, which is incorporated herein by reference. In this manner, there is no interference with any of the software functions in the native stereotactic x-ray mammography system.

[0034] Reconstruction is performed using a maximum-likelihood iterative reconstruction. In one embodiment, a graphical user interface (GUI) is implemented in Linux (RedHat 7.2 distribution) using C, C++, GTK+, and XML code which was inspired by the Amide package created by Andy Loening at UCLA. One software package in use with the PEM-2400 includes analysis tools such as region-of-interest calculation and electronic virtual calipers. Using the values established by the user in the x-ray correlation calibration, the user can click on the x-ray and find the corresponding location on the appropriate PET slice, and vice versa. It is noted that for the x-ray, image types may include a cranio-caudal projection, a mediolateral projection, or a 15-degree oblique projection, among other possible projections. For PET, image types may include, among others, a cranio-caudal projection, a projection that is orthogonal to the cranio-caudal, a mediolateral projection, a projection that is orthogonal to the mediolateral, and 15-degree oblique projections.

[0035] Referring to Figure 5, a flowchart illustrates an exemplary method according to a preferred embodiment of the invention. At step 505, a human subject is injected with 10 milliCuries of 2-fluorodeoxyglucose intravenously, and the subject is instructed to rest quietly prior to imaging with the PEM-2400 scanner. At step 510, the subject lies down in prone position upon a stereotactic mammography table, and inserts her breast into a wide table aperture as she would typically do for a stereotactic biopsy. At step 515, the safety doors are closed on the body part holder, so that portions of the breast will not protrude through the aperture when compression is applied. At step 520, the body part holders then apply compression to opposite sides of the breast. These body part holders have similar x-ray transmission and biopsy capability properties as the compression paddle or paddles that would normally be used with the stereotactic mammography table. At step 525, the user operates the PEM-2400 gamma-ray detector modules with computer control, and starts data acquisition, which is implemented by using the PEM-2400 gamma-ray detector modules to collect data as the modules sweep across the breast. At step 530, images of portions of the breast that have already been passed over are reconstructed and displayed during travel by the gamma-ray detector modules over other parts of the breast. When this full-breast image has been completed, at step 535, the PEM-2400 gamma-ray detector modules are parked on the side of the trays that is opposite from the human user (i.e., the operator of the PEM-2400). At step 540, the human user can inspect the PEM-2400 images and decide where a focal x-ray image or additional physiological image (e.g., an image obtained using positron emission

mammography) should be performed. Holes in the body part holder can accommodate marking pen tips to allow the user to draw markings on the surface of the breast to aid in repositioning, or to install locational wires for marking tumor locations. At step 545, x-rays can be obtained of the compressed breast by firing the x-ray source. Markings on the holders can be seen on the x-rays, enabling registration of the physiological images with the x-ray images. The x-rays form a digital image that is smaller than the aperture in the holder. At step 550, if necessary, the PEM-2400 gamma-ray detector modules can be moved under computer control to resurvey the area of the aperture. The PEM-2400 gamma-ray detector modules can be mounted on opposite (e.g., diagonally opposite) sides of the aperture in order to image radioactive needles during the intervention or to image remaining cancer tissue during an intervention. At step 555, the PEM-2400 digitizes the video monitor output of the digital spot x-ray mammography device and places this image on the PEM-2400 monitor, in order to facilitate cross-modality comparisons. At step 560, the user can click on a location in the functional image generated by the PEM-2400, and a corresponding marker is generated in the x-ray images (e.g., +15, -15, and straight views) to show the user where the functional abnormality is present on the anatomic image. Because the captured x-ray monitor images also show the location of the cursor that the user uses in order to specify locations for biopsy, the net effect is that the user can see how close the intended biopsy location (e.g., as suggested by the spot x-ray) is to the region of the functional abnormality. Finally, at step 565, the user performs an intervention, such as a biopsy of the abnormal area.

[0036] While the present invention has been described with respect to what is presently considered to be the preferred embodiment, it is to be understood that the invention is not limited to the disclosed embodiments. To the contrary, the invention is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the appended claims. For example, it is to be understood that the invention is applicable to body parts other than the breast, body parts from non-human animals and parts of inanimate objects, using detection means that are sensitive to signals other than gamma rays, whether or not the signals arrive at the detectors in coincidence. Furthermore, although in the preferred embodiments, the body part holders are mounted on an x-ray mammography camera, the body part holders can apply compression while mounted on a stand-alone platform that does not perform x-ray examination. The scope of the following claims is to be accorded the broadest interpretation so as to encompass all such modifications and equivalent structures and functions.

WHAT IS CLAIMED IS:

1. A diagnostic system for imaging a functional abnormality in a body part, a radiotracer having been injected into the body part, the system comprising:

at least one body part holder configured to immobilize and compress the body part, wherein the at least one body part holder includes an aperture, and wherein the aperture is configured to provide access to the body part for performing a medical intervention; and

at least one gamma ray detector module, the at least one gamma ray detector module being movable with respect to the at least one body part holder;

wherein the at least one gamma ray detector module is configured to obtain data by detecting gamma rays emitted by the injected radiotracer, and the system is configured to use the obtained data to provide an image of the functional abnormality.

2. The diagnostic system of claim 1, the at least one body part holder including at least one safety door, the at least one safety door being hingedly affixed to the aperture of the at least one body part holder, and

the at least one safety door being configured to prevent the body part from protruding through the aperture whenever the at least one safety door is in a closed position and/or to prevent the at least one gamma ray detector module from moving past the aperture whenever the at least one safety door is in an open position.

3. The diagnostic system of claim 2, the at least one safety door being configured to be movable and removable with respect to the aperture, and the at least one safety door including at least one open slot,

such that a portion of the body part to which access is provided by the aperture can be varied by movement or removal of the at least one safety door, and such that the at least one safety door is configured to substantially stabilize the portion of the body part to which access is provided by the aperture, and such that the access is not substantially reduced by the at least one safety door.

4. The diagnostic system of claim 3, the at least one safety door further including a plurality of bars, the bars being configured to displace the body part in order to prevent pinching of the body part during movement or removal of the at least one safety door.

5. The diagnostic system of claim 2, the at least one body part holder including a first safety door and a second safety door, the first safety door being configured to open and close in a horizontal orientation with respect to the at least one body part holder, and the second safety door being configured to open and close in a vertical orientation with respect to the at least one body part holder.

6. The diagnostic system of claim 1, the at least one body part holder including a plurality of holes configured to allow the body part to be marked.

7. The diagnostic system of claim 1, the at least one body part holder including a plurality of holes configured to allow a portion of the body part to be accessed for sampling or for later identification.

8. The diagnostic system of claim 1, the at least one body part holder being fabricated using transparent material.

9. The diagnostic system of claim 1, wherein the radiotracer comprises a single-photon emitter.

10. The diagnostic system of claim 1, wherein the radiotracer comprises a positron emitter.

11. The diagnostic system of claim 1, the at least one body part holder including a fiduciary marker, wherein the fiduciary marker is configured to facilitate the use of an additional medical device in conjunction with the system to improve the quality of the imaging of the functional abnormality.

12. The diagnostic system of claim 11, wherein the additional medical device comprises a stereotactic x-ray mammography device.

13. The diagnostic system of claim 1, the at least one gamma ray detector module including a printed circuit board, the printed circuit board comprising

a plurality of scintillators;

a plurality of light guides; and

a plurality of position-sensitive photomultipliers,

wherein the printed circuit board is configured to generate a signal, the signal including the obtained data, and to transmit the signal to a processor, and the processor is configured to use the transmitted signal to produce the image of the functional abnormality.

14. The diagnostic system of claim 13, the plurality of scintillators comprising a plurality of arrays of crystals, wherein the crystals include lutetium.

15. The diagnostic system of claim 13, wherein the processor is further configured to receive x-ray data and to use the received x-ray data to produce an anatomic image and to display the anatomic image in conjunction with a display of the image of the functional abnormality.

16. The diagnostic system of claim 15, wherein the anatomic image comprises a projection selected from the group consisting of a cranio-caudal projection, a medio-lateral projection, a +15-degree oblique projection, a -15-degree oblique projection, and a combination of two or more of said projections.

17. The diagnostic system of claim 15, wherein the image of the functional abnormality comprises a projection selected from the group consisting of a cranio-caudal projection, a projection that is orthogonal to the cranio-caudal projection, a medio-lateral projection, a projection that is orthogonal to the medio-lateral projection, a +15-degree oblique projection, a -15-degree oblique projection, and a combination or two or more of said projections.

18. The diagnostic system of claim 15, wherein the processor is further configured to produce the image of the functional abnormality by using a maximum-likelihood iterative reconstruction algorithm.

19. The diagnostic system of claim 15, wherein the processor includes a graphical user interface configured to simultaneously display the anatomic image and the image of the functional abnormality,

wherein, when a user indicates a specific location within the image of the functional abnormality, the graphical user interface is configured to indicate a corresponding location within the anatomic image, and when a user indicates a specific location within the anatomic image, the graphical user interface is configured to indicate a corresponding location within the image of the functional abnormality.

20. The diagnostic system of claim 15, wherein the processor includes a graphical user interface configured to simultaneously display the anatomic image and the image of the functional abnormality,

wherein, when a user indicates a specific location within the image of the functional abnormality, the graphical user interface is configured to indicate a corresponding location within the anatomic image.

21. The diagnostic system of claim 15, wherein the processor includes a graphical user interface configured to simultaneously display the anatomic image and the image of the functional abnormality,

wherein, when a user indicates a specific location within the anatomic image, the graphical user interface is configured to indicate a corresponding location within the image of the functional abnormality.

22. The diagnostic system of claim 1, the system further comprising at least one optoelectronic element configured to determine a position of the at least one gamma ray detector module.

23. A method for imaging a functional abnormality in a body part, the method comprising the steps of:

injecting a radiotracer into the body part;

using an apparatus to immobilize and compress the body part;

providing access to a portion of the body part through an aperture in the apparatus;

detecting gamma rays being emitted by the radiotracer by moving at least one gamma ray detector across the aperture; and

using the detected gamma rays to produce an image of the functional abnormality.

24. The method of claim 23, further comprising the step of providing a safety mechanism to protect the body part from the at least one moving gamma ray detector, wherein the safety mechanism is physically affixed to the apparatus at the aperture.

25. The method of claim 24, wherein the step of providing a safety mechanism comprises closing at least one safety door, wherein the at least one safety door is hingedly affixed to the apparatus.

26. The method of claim 24, wherein the safety mechanism is movable and removable with respect to the aperture, and the method further includes the step of moving and/or removing the safety mechanism in order to allow access to a variety of portions of the body part.

27. The method of claim 26, wherein the safety mechanism is configured to prevent pinching of the body part during movement or removal of the safety mechanism.

28. The method of claim 23, further comprising the steps of:

obtaining an additional image of the body part by using an additional medical device; and

displaying data from the image of the functional abnormality in conjunction with a display of data from the obtained additional image.

29. The method of claim 28, wherein the additional medical device comprises an x-ray device.

30. The method of claim 29, wherein the additional image comprises an x-ray image, and the x-ray image comprises a projection selected from the group consisting of a cranio-caudal projection, a medio-lateral projection, a +15-degree oblique projection, a -15-degree oblique projection, and a combination of two or more of said projections.

31. The method of claim 29, wherein the image of the functional abnormality comprises a projection selected from the group consisting of a cranio-caudal projection, a projection that is orthogonal to the cranio-caudal projection, a medio-lateral projection, a projection that is orthogonal to the medio-lateral projection, a +15-degree oblique projection, a -15-degree oblique projection, and a combination of two or more of said projections.

32. The method of claim 29, further comprising the step of using a fiduciary marker to facilitate the use of the x-ray device.

33. The method of claim 28, further comprising the steps of:

when a user indicates a specific location within the image of the functional abnormality, indicating a corresponding location within the obtained additional image; and

when the user indicates a specific location within the obtained additional image, indicating a corresponding location within the image of the functional abnormality.

34. The method of claim 28, further comprising the step of:

when a user indicates a specific location within the image of the functional abnormality, indicating a corresponding location within the obtained additional image.

35. The method of claim 28, further comprising the step of:

when the user indicates a specific location within the obtained additional image, indicating a corresponding location within the image of the functional abnormality.

36. The method of claim 23, further comprising the step of using at least one optoelectronic element to continuously determine a position of the at least one gamma ray detector.

37. The method of claim 23, wherein the radiotracer comprises a single-photon emitter.

38. The method of claim 23, wherein the radiotracer comprises a positron emitter.

39. An apparatus for imaging a functional abnormality in a body part, a radiotracer having been injected into the body part, the apparatus comprising:

at least one means for holding the body part, the at least one body part holding means being configured to immobilize and compress the body part, wherein the at least one body part holding means includes an aperture, and wherein the aperture is configured to provide access to the body part for performing a medical intervention;

at least one means for detecting gamma rays, the at least one gamma ray detection means being movable with respect to the at least one body part holding means; and

a processor means for processing data and generating images,

wherein the at least one gamma ray detection means is configured to obtain data by detecting gamma rays emitted by the injected radiotracer, and the processor means is configured to process the obtained data to generate an image of the functional abnormality.

40. The apparatus of claim 39, the at least one body part holding means including at least one safety means for protecting the body part, the at least one safety means being physically affixed to the aperture of the at least one body part holding means, and

the at least one safety means being configured to prevent the body part from protruding through the aperture whenever the at least one safety means is in a closed position and to prevent the at least one gamma ray detection means from moving past the aperture whenever the at least one safety means is in an open position.

41. The apparatus of claim 40, the at least one safety means being configured to be movable and removable with respect to the aperture, and the at least one safety means including at least one open slot,

such that a portion of the body part to which access is provided by the aperture can be varied by movement or removal of the at least one safety means, and such that the at least one safety means is configured to substantially stabilize the portion of the body part to which access is provided by the aperture, and such that the access is not substantially reduced by the at least one safety means.

42. The apparatus of claim 41, the at least one safety means further including a plurality of bars, the bars being configured to displace the body part in order to prevent pinching of the body part during movement or removal of the at least one safety means.

43. The apparatus of claim 40, the at least one body part holding means including a first safety means for protecting the body part and a second safety means for protecting the body part, the first safety means being configured to open and close in a horizontal orientation with respect to the at least one body part holding means, and the second safety means being configured to open and close in a vertical orientation with respect to the at least one body part holding means.

44. The apparatus of claim 39, the at least one body part holding means including a plurality of holes configured to allow the body part to be marked.

45. The apparatus of claim 39, the at least one body part holding means including a plurality of holes configured to allow a portion of the body part to be accessed for sampling or for later identification.

46. The apparatus of claim 39, the at least one body part holding means being fabricated using transparent material.

47. The apparatus of claim 39, wherein the radiotracer comprises a single-photon emitter.

48. The apparatus of claim 39, wherein the radiotracer comprises a positron emitter.

49. The apparatus of claim 39, the at least one body part holding means including a means for providing a fiduciary marker, wherein the fiduciary marking means is configured to facilitate the use of an additional medical device in conjunction with the apparatus to improve the quality of the imaging of the functional abnormality.

50. The apparatus of claim 49, wherein the additional medical device comprises a stereotactic x-ray mammography device.

51. The apparatus of claim 39, the at least one gamma ray detection means including a printed circuit board, the printed circuit board comprising

a plurality of scintillator means;

a plurality of light guiding means; and

a plurality of position-sensitive photomultiplier means,

wherein the printed circuit board is configured to generate a signal, the signal including the obtained data, and to transmit the signal to the processor means, and the processor means is configured to use the transmitted signal to generate the image of the functional abnormality.

52. The apparatus of claim 51, the plurality of scintillator means comprising a plurality of arrays of crystals, wherein the crystals include lutetium.

53. The apparatus of claim 51, wherein the processor means is further configured to receive x-ray data and to use the received x-ray data to produce an anatomic image and to display the anatomic image in conjunction with a display of the image of the functional abnormality.

54. The apparatus of claim 53, wherein the anatomic image comprises a projection selected from the group consisting of a cranio-caudal projection, a medio-lateral projection, a +15-degree oblique projection, a -15-degree oblique projection, and a combination of two or more of said projections.

55. The apparatus of claim 53, wherein the image of the functional abnormality comprises a projection selected from the group consisting of a cranio-caudal projection, a projection that is orthogonal to the cranio-caudal projection, a medio-lateral projection, a projection that is orthogonal to the medio-lateral projection, a +15-degree oblique projection, a -15-degree oblique projection, and a combination of two or more of said projections.

56. The apparatus of claim 53, wherein the processor means is further configured to generate the image of the functional abnormality by using a maximum-likelihood iterative reconstruction algorithm.

57. The apparatus of claim 53, the processor means including a graphical user interface configured to simultaneously display the anatomic image and the image of the functional abnormality,

wherein, when a user indicates a specific location within the image of the functional abnormality, the graphical user interface is configured to indicate a corresponding location within the anatomic image, and when a user indicates a specific location within the anatomic image, the graphical user interface is configured to indicate a corresponding location within the image of the functional abnormality.

58. The apparatus of claim 53, the processor means including a graphical user interface configured to simultaneously display the anatomic image and the image of the functional abnormality,

wherein, when a user indicates a specific location within the image of the functional abnormality, the graphical user interface is configured to indicate a corresponding location within the anatomic image.

59. The apparatus of claim 53, the processor means including a graphical user interface configured to simultaneously display the anatomic image and the image of the functional abnormality,

wherein, when a user indicates a specific location within the anatomic image, the graphical user interface is configured to indicate a corresponding location within the image of the functional abnormality.

60. The apparatus of claim 39, further comprising at least one optoelectronic means for optoelectronically determining a position of the at least one gamma ray detection means.

61. An apparatus for stabilizing a body part during emission tomography of the body part, the apparatus comprising:

a first emission-transparent structure configured to be disposed on a first side of the body part;

a second emission-transparent structure configured to be disposed on a second side of the body part;

an aperture disposed in the first emission-transparent structure and configured to provide access to the body part through the first emission-transparent structure; and

a movable safety door coupled to the first emission-transparent structure and configured to open and close at least a portion of the aperture, the movable door being further configured to prevent an emission tomography device from covering the at least a portion of the aperture.

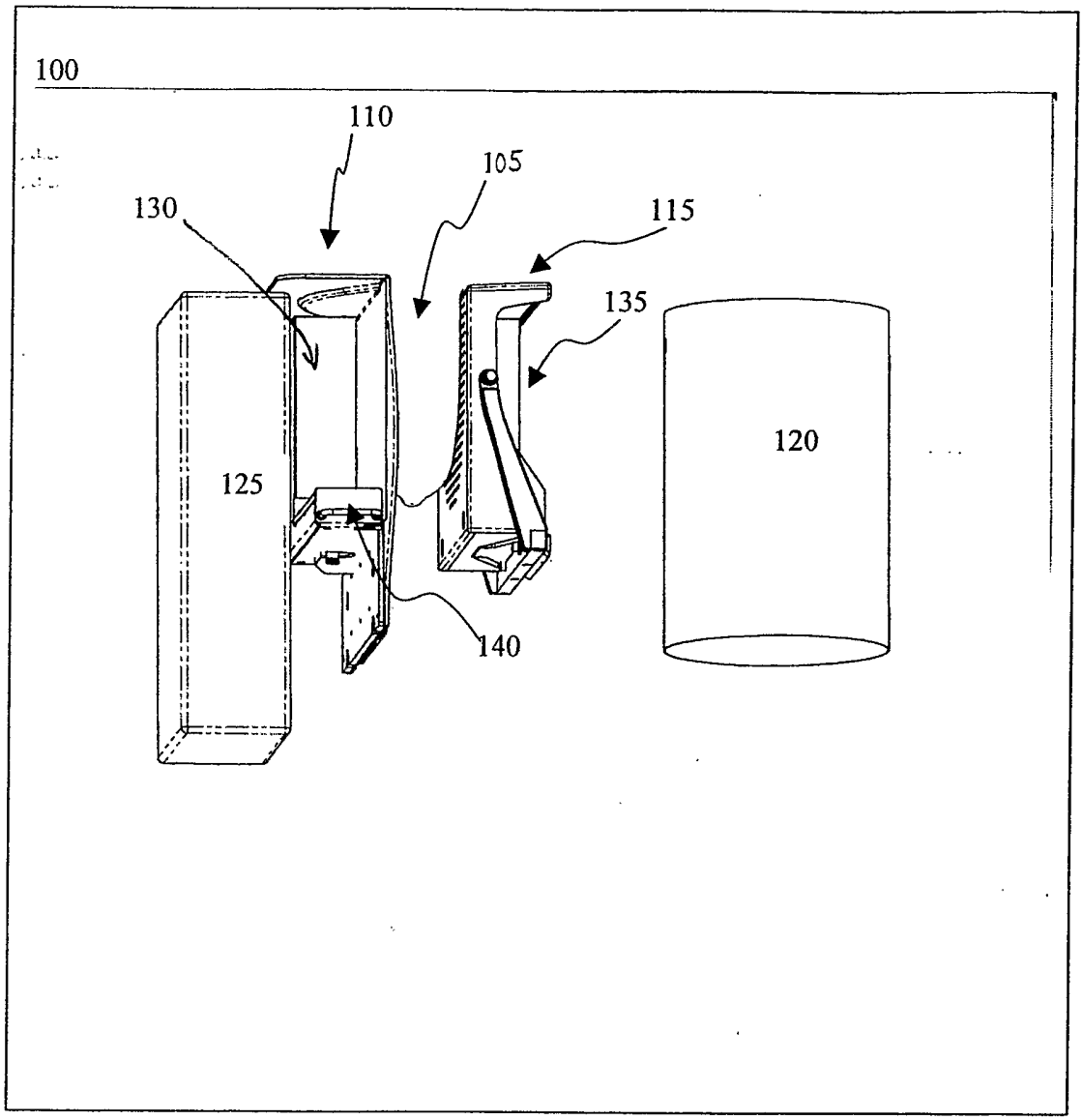

FIG. 1

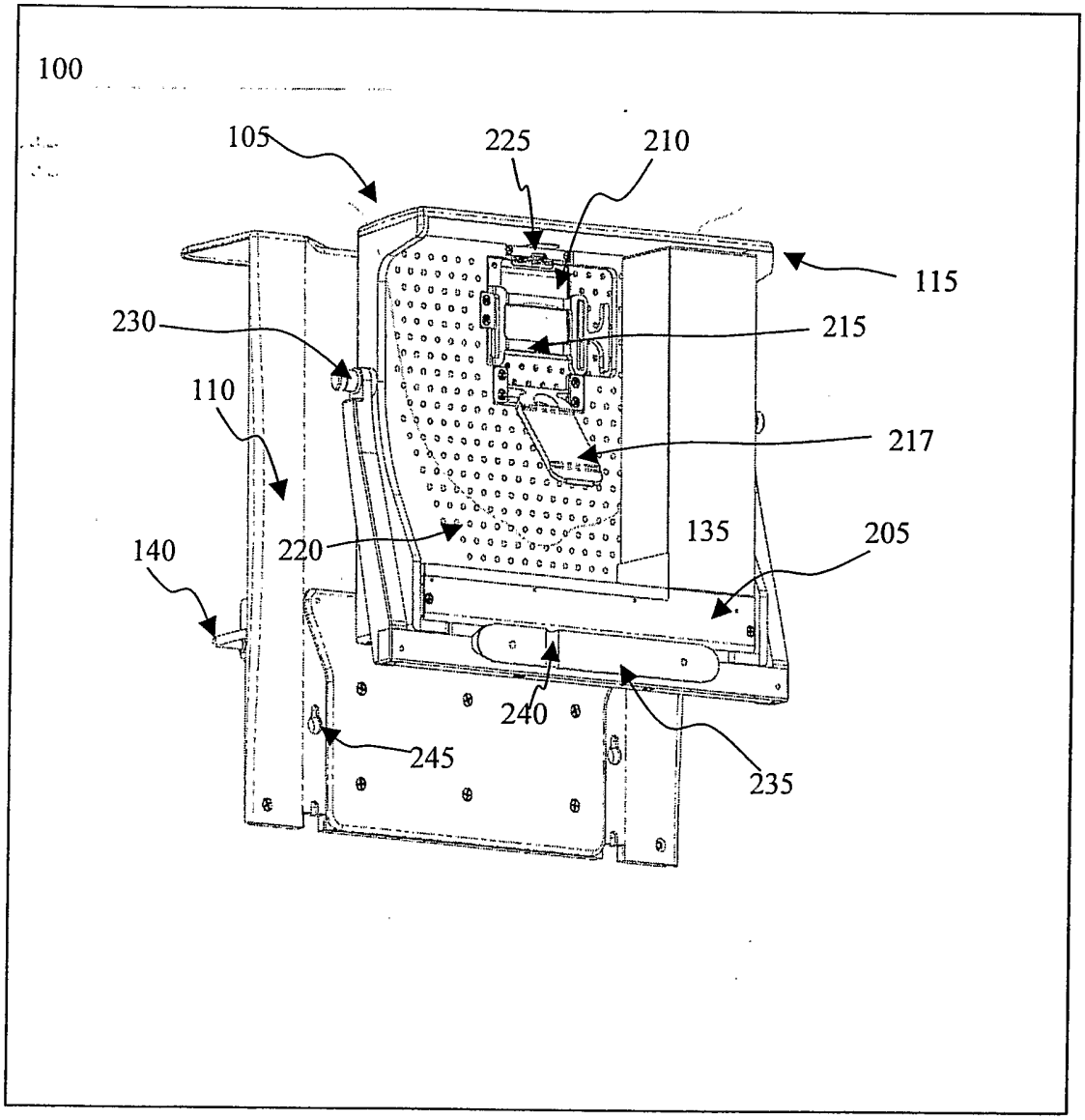

FIG. 2

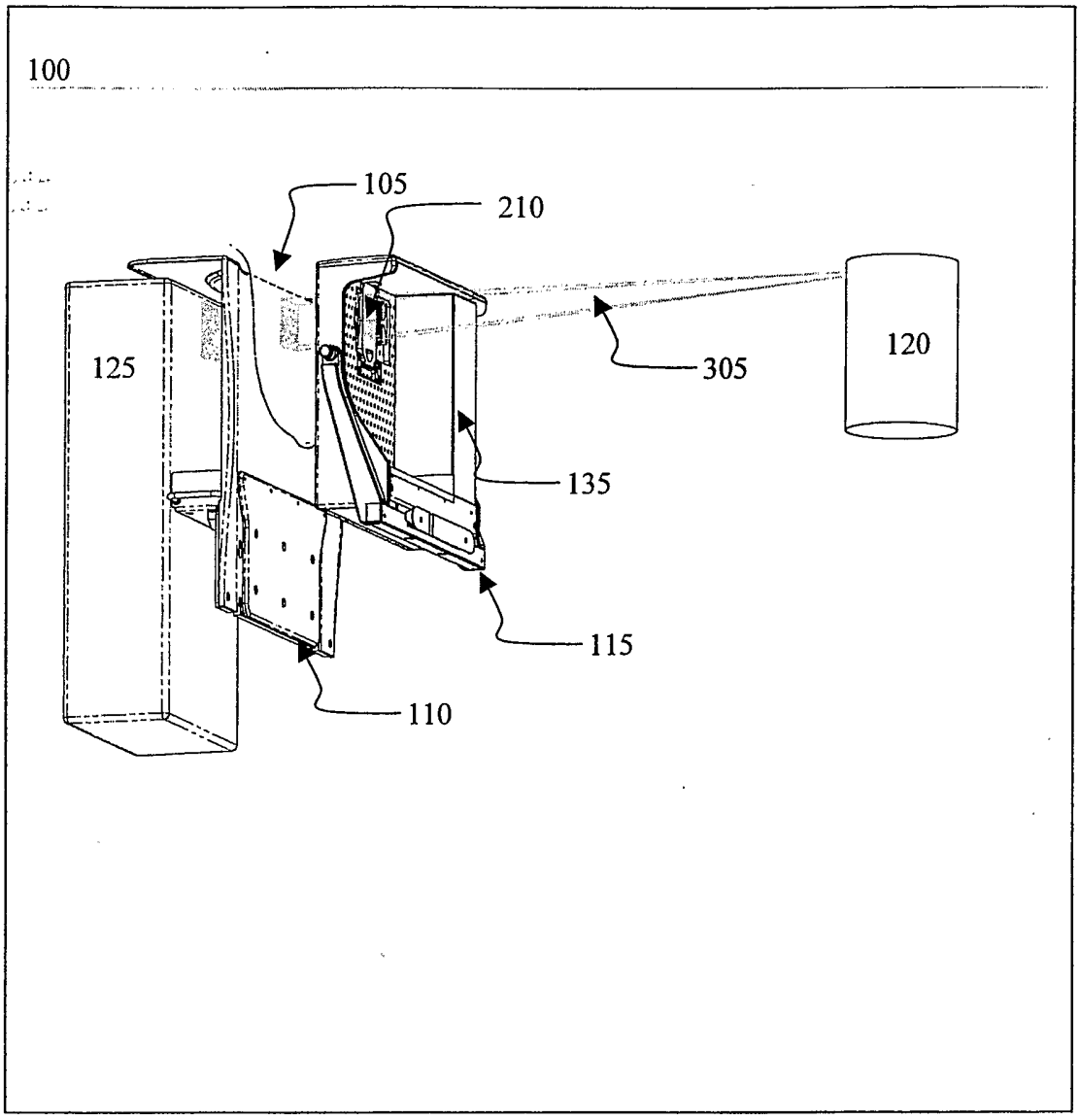

FIG. 3

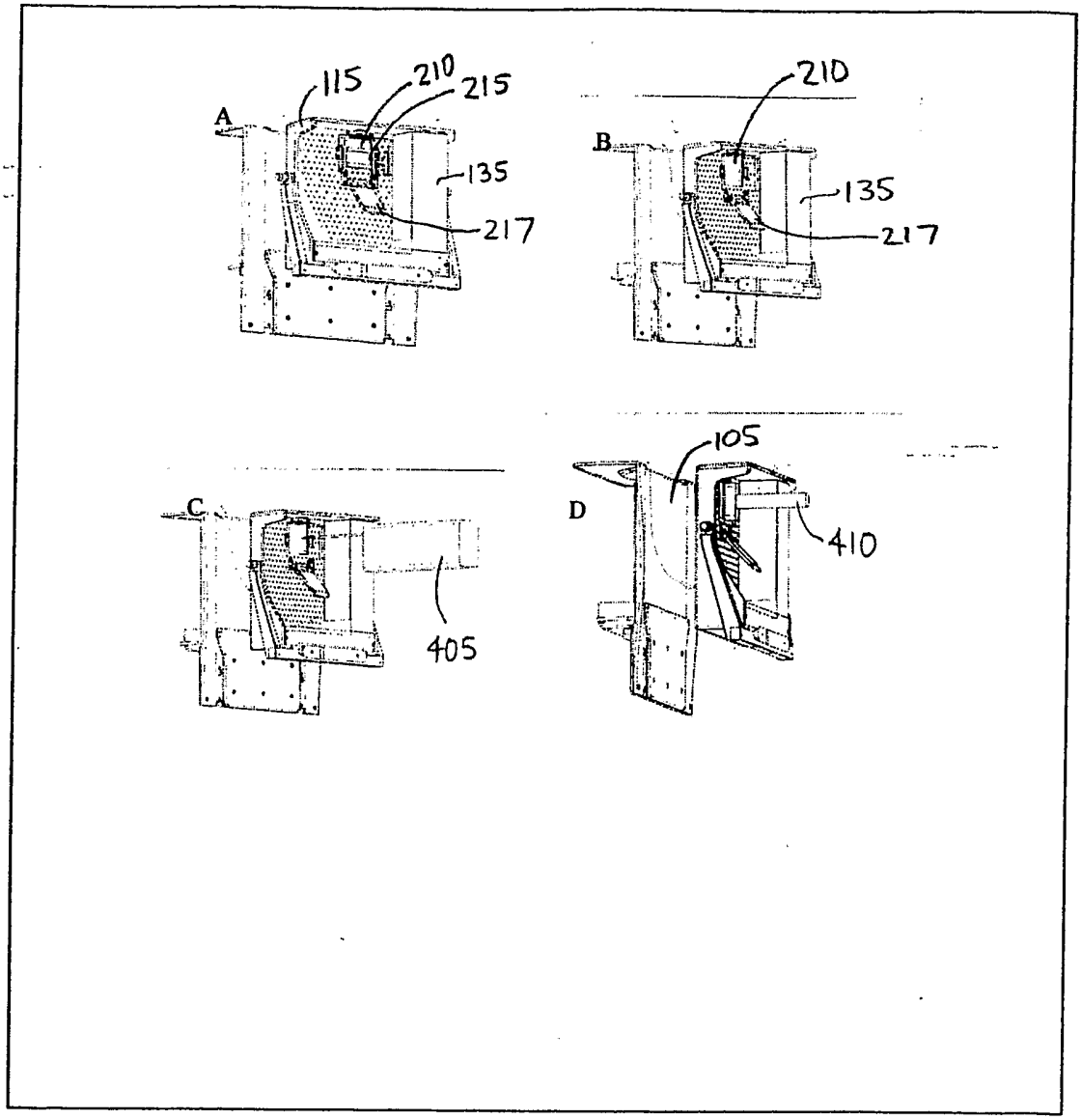

FIG. 4

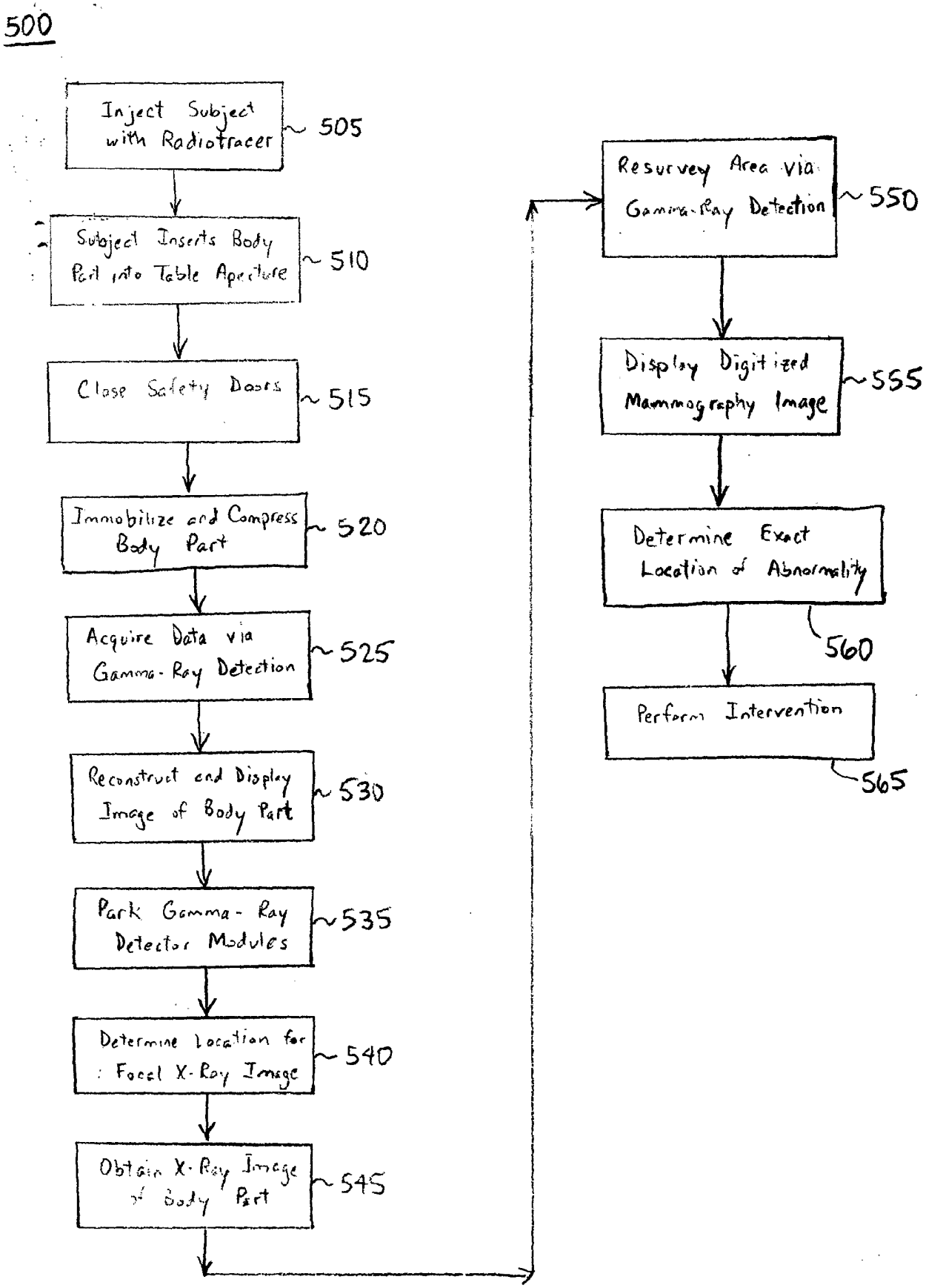
500
Inject Subject with Radiotracer
505
Subject Inserts Body Part into Table Aperture
510
Close Safety Doors
515
Immobilize and Compress Body Part
520
Acquire Data via Gamma-Ray Detection
525
Reconstruct and Display Image of Body Part
530
Park Gamma-Ray Detector Modules
535
Determine Location for Focal X-Ray Image
540
Obtain X-Ray Image of Body Part
545
Resurvey Area via Gamma-Ray Detection
550
Display Digitized Mammography Image
555
Determine Exact Location of Abnormality
560
Perform Intervention
565

Fig. 5

INTERNATIONAL SEARCH REPORT

Internati Application No
PCT/US 03/00368

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G01T1/161 A61B19/00 A61B6/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B G01T

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 21582 A (HUSSMAN KARL L) 17 August 1995 (1995-08-17) page 28, line 25 -page 32, line 5 figures 11A,C,F	1,39
X	US 5 519 221 A (WEINBERG IRVING) 21 May 1996 (1996-05-21) column 5, line 52 -column 6, line 35 column 12, line 6 - line 8 column 15, line 35 - line 55	1,39

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 May 2003	13/06/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Martelli, L

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/00368

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 23-38
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [X] Claims Nos.: 3-22,40-60
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 3-22,40-60

In view of the large number and also the wording of the claims presently on file, which render it difficult, if not impossible, to determine the matter for which protection is sought, the present application fails to comply with the clarity and conciseness requirements of Article 6 PCT (see also Rule 6.1(a) PCT) to such an extent that a meaningful search is impossible. Consequently, the search has been carried out for those parts of the application which do appear to be clear (and concise), namely:

A diagnostic system for imaging a functional abnormality in a body part, the system comprising:
- at least one body part holder configured to immobilise and compress the body part, wherein the at least one body part holder includes an aperture, and wherein the aperture is configured to provide access to the body part for performing a biopsy;
- mechanical stages affixed to the body part holders;
- at least one gamma ray detector module supported and moved by the mechanical stages;
- one safety door hingedly affixed to the aperture of the at least one body part holder;
wherein the at least one gamma ray detector module is configured to ontain data by detecting gamma rays emitted by an injected radiotracer and the system is configured to use the obtained data to provide an image of the functional abnormality.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internati[redacted] Application No
PCT/US 03/00368

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WO 9521582 A	17-08-1995	US 5590655 A	07-01-1997
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