Office de la Propriété Intellectuelle du Canada
Un organisme d'Industrie Canada

Canadian Intellectual Property Office
An agency of Industry Canada

CA 2314794 A1 2002/02/01

(21) 2 314 794

(12) DEMANDE DE BREVET CANADIEN
CANADIAN PATENT APPLICATION

(13) A1

(22) Date de dépôt/Filing Date: 2000/08/01

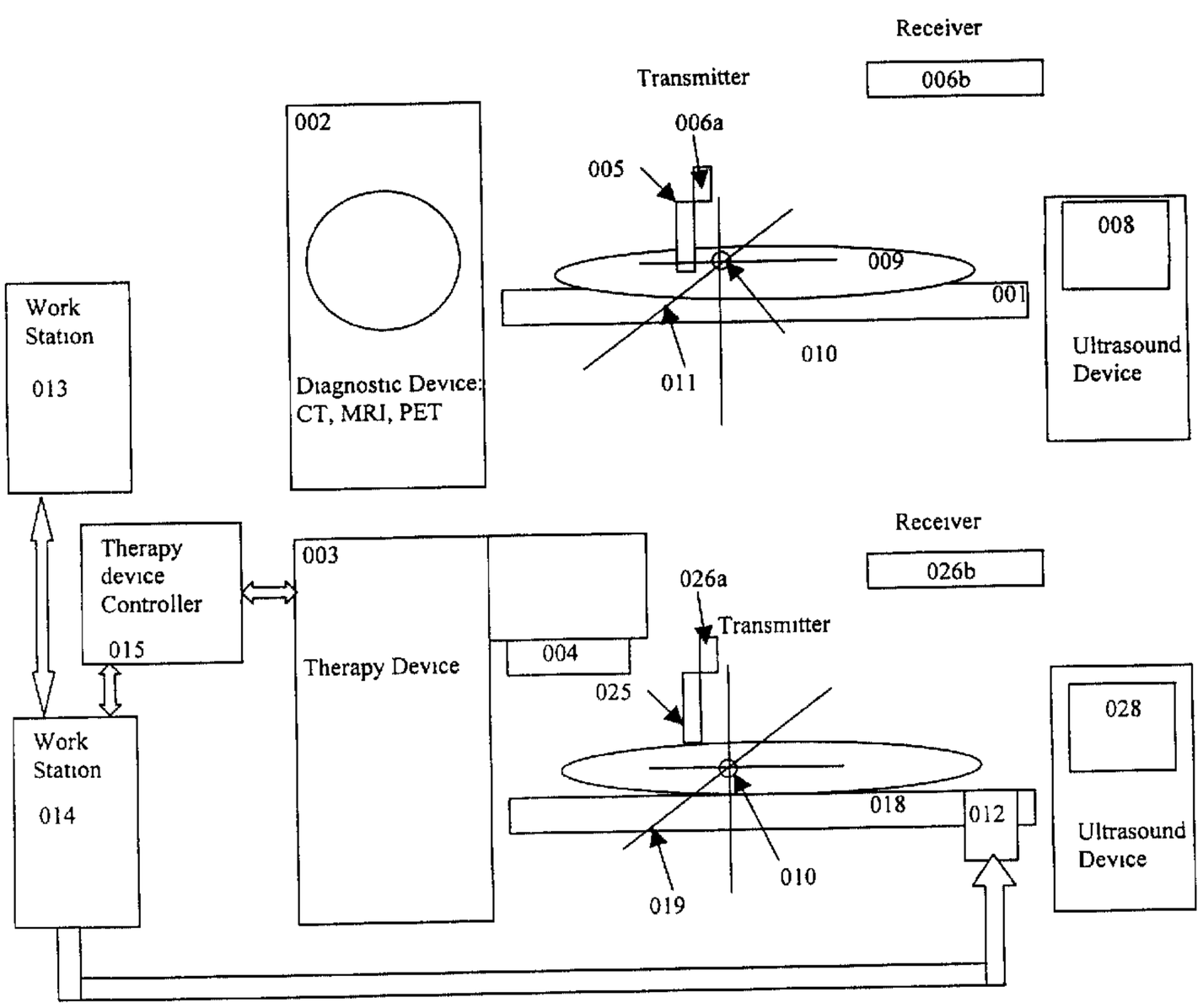
(41) Mise à la disp. pub./Open to Public Insp.: 2002/02/01

(51) Cl.Int.^{7}/Int.Cl.^{7} A61N 5/00

(71) Demandeurs/Applicants:
FALCO, TONY, CA;
HRISTOV, DIMITRE, CA

(72) Inventeurs/Inventors:
FALCO, TONY, CA;
HRISTOV, DIMITRE, CA

(54) Titre : APPAREIL DE LOCALISATION DE LESIONS OU D'ORGANES
(54) Title: APPARATUS FOR LESION OR ORGAN LOCALIZATION



(57) Abrégé/Abstract:
A method and apparatus for lesion or organ localization, definition and verification of treatment position. The system is a combination of a ultrasound imaging apparatus and a diagnostic imaging apparatus to acquire localization ultrasound images referenced in the coordinate space of the diagnostic modality through the use of a position sensing system. The system compares the location of the lesion in the localization ultrasound images with the position of the lesion in ultrasound images taken while the patient lies on the treatment table of a therapy treatment unit, suggests corrective measures to place the lesion in its intended treatment position and executes the correction upon confirmation from qualified personnel.

ABSTRACT

A method and apparatus for lesion or organ localization, definition and verification of treatment position. The system is a combination of a ultrasound imaging apparatus and a diagnostic imaging apparatus to acquire localization ultrasound images referenced in the coordinate space of the diagnostic modality through the use of a position sensing system.

The system compares the location of the lesion in the localization ultrasound images with the position of the lesion in ultrasound images taken while the patient lies on the treatment table of a therapy treatment unit, suggests corrective measures to place the lesion in its intended treatment position and executes the correction upon confirmation from qualified personnel.

ABSTRACT

A method and apparatus for lesion or organ localization, definition and verification of treatment position. The system is a combination of a ultrasound imaging apparatus and a diagnostic imaging apparatus to acquire localization ultrasound images referenced in the coordinate space of the diagnostic modality through the use of a position sensing system.

The system compares the location of the lesion in the localization ultrasound images with the position of the lesion in ultrasound images taken while the patient lies on the treatment table of a therapy treatment unit, suggests corrective measures to place the lesion in its intended treatment position and executes the correction upon confirmation from qualified personnel.

METHOD AND APPARATUS FOR LESION LOCALIZATION, DEFINITION AND VERIFICATION

BACKGROUND OF THE INVENTION

1. Field of the invention

The invention relates to a method and apparatus for localizing the position of a lesion to be treated by a radiation therapy device and verification of the position of the lesion with respect to the radiation beam or beams prior to the execution of a radiation treatment.

2. Description of Prior Art

The goal of modern day radiation therapy of cancerous tumors or lesions, is to eradicate the tumor while avoiding to the maximum possible extent damage to healthy tissue and organs in the vicinity of the tumor. Since the large majority of the tumors are radioresponsive, they can be controlled or eradicated completely if a sufficient radiation dose is delivered to the tumor volume. However, the delivery of the necessary tumorcidal dose may result in certain complications due to damage of healthy tissue that surround the tumor, or to other healthy body organs located in the proximity of the tumor. Conformal therapy is a radiation treatment approach which attempts to combine accurate target localization with focused radiation delivery in order to conform the high dose region closely to the region defined by the outer surface of the tumor while minimizing the dose to surrounding healthy tissue or adjacent healthy organs.

Conformal radiation therapy employs dedicated radiation units capable of producing highly energetic radiation beams of photons, electrons or other charged particles. The radiation unit typically has a radiation source, which is typically mounted on a rotatable gantry of the radiation treatment unit. Through gantry rotation, the radiation source is rotated about the patient who is typically placed on a treatment table and the radiation beam is directed towards the tumor or lesion to be treated. Various types of devices are used to conform the shape of the radiation treatment beam to encompass tightly the outline of the tumor as seen by the radiation treatment beam as it traverses the patient's body into the tumor. An example of such a device is a multileaf collimator, which consists of a set of computer-controlled movable leaves or fingers, which can be positioned individually in and out of the radiation beam in order to shape it to the tumor outline. Various types of radiation treatment planning systems can create a radiation treatment plan which, once implemented will deliver a specified dose to the tumor while sparing the surrounding healthy tissue or adjacent healthy organs.

Basic problem in conformal radiation therapy is knowing where the target, or lesion or tumor, or alternatively critical healthy organs are located with respect to the intended placement of the radiation beam or field (I) prior to the design of a radiation treatment plan and (II) at the time of the radiation treatment. Localization of the target volume within the patient prior to the design of a radiation treatment plan is performed by acquiring a three-dimensional image of the patient with a conventional diagnostic imaging device such as computerized tomographic imaging device ("CT"), a magnetic resonance ("MR") imaging device or a positron emission imaging device ("PET"), as they are known in the art. Both the patient's position and the position of the target within the patient at the time of the radiation treatment are assumed to be grossly the same at as they were at the time the treatment plan was created. If the position of the target volume is not correctly determined (I) prior to the treatment plan creation or (II) at the time of treatment, treatment failures can occur in a sense that the conformal dose of radiation may not be delivered to the correct location within the patient's body. Failures of type (I) can occur if the conventional imaging modality fails to reveal completely or partly the tumor or lesion or organ of interest. Failures of type (II) can occur as a result of organ displacement (motion) from day to day as well as from incorrect positioning of the patient on the treatment table of the radiation treatment unit. To avoid the above failures, the present day radiation treatment plans typically regard the target organ to occupy a space in the patient's body, which is larger than it really occupies, in order to ensure that the target organ, or tumor or lesion, regardless of the uncertainty of its location, falls within the volume of tissue which receives the desired radiation dose. Because some healthy tissue or healthy organs surround the target, a larger volume of

these will be irradiated with the maximum radiation dose intended for the tumor or target volume. Delivering the maximum radiation dose to a larger volume of healthy tissue or healthy organs may than increase the risk of damaging these. For this reason oncologists may decide to deliver a lower radiation dose to the intended treatment volume in order to spare the non-target tissue with the potential disadvantage of compromising the success of the treatment by underdosing some portion of the target organ.

In an attempt to improve the localization of the lesion for the treatment of prostate cancer and therefore rectify failures of type I, a method was claimed (Holupka et al., US patent #5810007) which utilizes a transrectal probe to generate a two-dimensional ultrasound image and also image registration to superimpose the above said ultrasound image on an image acquired with a conventional diagnostic imaging device. The image registration in the above said method requires the identification of at least 2 fiducials visible in both the ultrasiund image and the image acquired with the conventional diagnostic imaging device. However, the following shortcomings may limit the utility of the above said method.

1. The transrectal ultrasound probe may considerably displace the lesion or organ thus providing inaccurate information about the spatial location of the lesion at treatment time if at that time the transrectal probe is not inserted. On the other hand, inserting the transrectal probe for each treatment session can cause significant patient discomfort.

2. The above said method assumes that the ultrasound image and the image obtained with the conventional diagnostic imaging modality are acquired in the same plane. For this case two identifiable fiducials in both images would be sufficient to register and superimpose the images. However, the assumption of identical imaging planes cannot be asserted with the means of the above method and therefore a deviation from the above said assumption may compromise considerably the accuracy of the method.

3. The above said method registers and superimposes a two-dimensional ultrasound image onto a 2-dimensional image acquired with a conventional diagnostic imaging modality. Thus the ultrasound definition of the lesion is performed only in a single plane. For the purposes of three-dimensional conformal therapy a two-dimensional definition of the lesion is incomplete and therefore inadequate since in other imaging planes the extent of the lesion volume may be larger or smaller.

In attempt to rectify failures of type II, another system was proposed to verify the target or lesion position prior to a radiation treatment session (M. Carol, US patent #5411026). The system comprises a ultrasound imaging device to acquire at least one ultrasound image of the lesion in the patient's body and a device to indicate the position of the ultrasound image generating device or probe with respect to the radiation therapy device. The above said system verifies that the actual position of the lesion immediately before the treatment session conforms to the desired position of the lesion in the radiation treatment plan by comparing the outlines of the outer surface of the lesion as defined on the at least one ultrasound image to the outline of the outer surface of the lesion as defined on the at least one of the diagnostic images obtained by a computerized tomographic ("CT") or alternatively by magnetic resonance ("MR") device and used for the design of the radiation treatment plan However, the following shortcomings may limit the utility of the above said system to correct failures of type II.

1. The appearance of the tumor or lesion or organ in the ultrasound image or images can have an appearance different from the appearance of the tumor or lesion or organ in the images obtained with conventional diagnostic devices. Thus the process of comparing outlines of the outer surfaces of the tumor or lesion or organ as they appear in images obtained with different imaging devices may be inaccurate since these surfaces can be different both in appearance and extent.

2. The above said method does not address failures of type I whereby the diagnostic images obtained with computed tomography or magnetic resonance imaging devices do not reveal completely the location or the extent of the tumor or lesion or organ. Furthermore if the computed tomography or magnetic resonance diagnostic images do not reveal the tumor or organ or lesion the above said method will lack the means to outline an outer surface to serve as a reference for the comparison to the outer surface of the tumor or lesion or organ outlined on the one or more ultrasound images.

In view of the above description of the prior art it is therefore an object of the invention to provide an improved method and apparatus for radiation therapy treatments to decrease the rate of occurrence of the above defined failures of type I and type II.

It is another object of the invention to provide a novel method and apparatus for accurate localization and definition of tumor or lesion or other organ volume in preparation for radiation therapy.

It is further object of the invention to provide an improved method and apparatus for establishing an ultrasound image or plurality of ultrasound images for target definition and localization and correlating this image or plurality of ultrasound images to radiation therapy simulator images, obtained with conventional diagnostic imaging devices such as a computerized tomographic imaging device ("CT"), a magnetic

resonance ("MR") imaging device or a positron emission imaging device ("PET") .

It is also an object of the invention to provide a novel method for three-dimensional superposition of a three-dimensional ultrasound image of a lesion onto another three-dimensional lesion image, such as CT or MR or another ultrasound image.

It is yet another object of the invention to provide an improved method and apparatus for accurate positioning of the target relative to radiation therapy beams based on the registration of a ultrasound images or plurality of ultrasound images acquired immediately before or after the acquisition of conventional diagnostic images to a ultrasound image or plurality of images acquired immediately before a radiation treatment session.

The invention relates to a method and apparatus for (a) lesion localization and tumor or lesion or organ definition for radiotherapy treatment planning and (b) for verification and rectification of lesion position during radiotherapy treatment.

SUMMARY OF THE INVENTION

The present invention includes the following steps to improve the localization and the definition of the tumor or lesion or organ: disposing the patient on the table of the conventional diagnostic imaging device; acquiring a diagnostic image or plurality of diagnostic images with possibly fiducials placed on the patient surface so that the geometric orientation of the diagnostic image or images can be determined with respect to the diagnostic imaging device; acquiring a ultrasound image or plurality of ultrasound images immediately before or after the acquisition of the diagnostic images with the ultrasound image generating means being disposed in a known geometric orientation with respect to the diagnostic imaging device for each ultrasound image generated; superimposing (known in the art as fusing) or combining the ultrasound image or images with the diagnostic image or images with the previous knowledge about their geometric orientation: outlining the contours of the outer surface of the tumor or lesion or organ on the ultrasound image or images and simultaneously displaying the above said outer surface on the diagnostic image or images; employing the above said contours of the outer surface of the tumor or lesion or organ for the design of a radiation treatment plan.

With respect to the verification of the tumor or lesion or organ position with respect to the radiation therapy device the present invention includes the steps of: disposing the patient on the treatment table of a radiation therapy device; generating at least one US image of the lesion in the patient's body with the US image generating means, that is the probe, being disposed in a known geometric orientation for each US image generated; comparing the above said ultrasound image or images to the ultrasound image or images obtained at the time of the acquisition of the diagnostic images whereby the position of the tumor or lesion or organ with respect to the radiation therapy device may be verified to establish conformity with the desired position of the tumor or lesion or organ in the radiation treatment plan.

Another feature of the present invention may include the method of comparing or registering the ultrasound image or images acquired immediately before the radiation treatment session to the ultrasound image or images obtained immediately before or after the acquisition of the diagnostic images. This method may employ either gray-level image correlation without the need of contour outlines or alternatively the registration of geometric objects (as known in the art) composed of the outlines the outer surface of the tumor or lesion or organ as defined on the ultrasound image or images acquired in the diagnostic and the radiation therapy room.

As a result of the above said image comparison another feature of the present invention is the step of determining the necessary tumor or lesion or organ displacement in order to dispose the tumor or lesion or organ in the desired position prescribed by the radiation treatment plan. A further feature of the present invention may include the step of performing the above determined tumor or lesion or organ displacement by but not restricted to, moving the treatment table with respect to the radiation treatment device, rotating the treatment table with respect to the radiation treatment device, rotating the collimator of the radiation treatment device as well as rotating the gantry of the radiation therapy device.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a functional block diagram of an embodiment of the invention.

FIG. 2 is a perspective view of a conventional diagnostic imaging device with a patient schematically illustrated on the imaging table. The patient having a lesion disposed with in the patient body.

FIG. 3 is a perspective view of an image device of FIG. 2 with the patient passing through the imaging device.

FIG. 4 is an example of an image produced by the imaging device of FIG. 2 illustrating the position of the lesion within the patient body.

FIG. 5 is an example of an image produced by the imaging device of FIG. 2 illustrating fiducials with known position with respect to the diagnostic imaging device and visible on the diagnostic image or images.

FIG. 6 a representation of the three-dimensional diagnostic image data reconstructed from the multiple diagnostic images such as the one depicted in FIG. 5.

FIG. 7 is a perspective schematic view of the conventional diagnostic imaging device of FIG. 2,

including a means for generating an US image of the lesion with the patient's body.
FIG. 8 is a representation of a ultrasound image of the tumor or lesion or organ.
FIG. 9 is a perspective view indicating multiple ultrasound images being taken of a lesion with the US apparatus of FIG. 7
FIG. 10 is a representation of the three-dimensional ultrasound image data reconstructed from the multiple ultrasound images acquired in the room of the diagnostic imaging device and depicted in FIG. 9.
FIG. 11 is a representation of the three-dimensional ultrasound and diagnostic image data sets superimposed or combined.
FIG. 12 is a representation of a sequence of two-dimensional ultrasound pictures of the lesion within the three-dimensional ultrasound data with the lesion having its outer surface outlined.
FIG. 13 is a 3-D rendering of the outline of the image prepared from the lesion contours as illustrated in FIG. 12.
FIG. 14 is a perspective view of a conventional radiotherapy treatment device, or linear accelerator including a rotatable couch, collimator and gantry. The radiation treatment device can be any device capable of producing radiation for external beam therapy, e.g. tomotherapy unit, proton therapy unit, Cobalt-60 unit, etc.
FIG. 15 is a perspective schematic view of the linear accelerator of including a means for generating an ultrasound image of the lesion within the patient's body.
FIG. 16 is a perspective view indicating multiple US images being taken of a lesion with the ultrasound imaging device of FIG. 15.
FIG. 17 is a representation of the three-dimensional ultrasound image data reconstructed from the multiple ultrasound images acquired in the room of the therapy device and depicted in FIG. 16
FIG. 18 is a representation of several two-dimensional US images with the lesion of FIG. 17 having its outer surface outlined.
FIG. 19 is a 3-D rendering of the outline of the image prepared from the plurality of images from FIG. 18.
FIG. 20 is a representation of the process of determining the necessary corrections in the treatment setup (table position, collimator and gantry rotation) prior to a treatment session based on contour or surface registration.
FIG. 21 is a representation of the process of determining the necessary corrections in the treatment setup (table position, collimator and gantry rotation) prior to a treatment session based on image cross-correlation.

DETAILED DESCRIPTION OF THE INVENTION

An illustration of the method and apparatus of the invention is shown in the components of the apparatus and images derived therefrom in the figures. In the functional diagram of FIG. 1 the embodiment of the innovation is generally illustrated. With reference to FIG. 2, a conventional diagnostic image device **002** is schematically shown with a conventional imaging table **001**, upon which a patient **009** having a tumor or a lesion or an organ of interest **010** is disposed. Imaging device **002** can be a computed tomography scanner ("CT"), a magnetic resonance imaging scanner ("MR") or alternatively a positron emission tomography ("PET") scanner. The diagnostic device **002** is producing a cross-sectional image **023** or a "slice" of the body tissue, one such "slice" being illustrated in FIG. 4 with the tumor or lesion or organ of interest **010** shown. Several diagnostic images **023** are acquired by moving the table of the diagnostic device **001** and the patient **009** in the slice acquisition space **017** of the diagnostic imaging device **001** as shown in FIG. 3. FIG. 6 illustrates a three-dimensional picture **027** formed or reconstructed from the plurality of diagnostic images **023** of a part or a section of the patient anatomy **009.**

In FIG. 4, the tumor or lesion or organ **010** is shown at a location with coordinates (X_l, Y_l, Z_l) determined in a conventional manner by the CT or MR or other diagnostic imaging device with respect to the conventional coordinate system **011** of the diagnostic imaging device **002.** The determination of the coordinates (X, Y, Z) with respect to the conventional coordinate system **011** of the diagnostic imaging device **002** of any point within the three-dimensional picture **023** formed by the plurality of diagnostic images can be done by but not limited to the following standard method employed in radiation therapy. At least three fiducials **029** with known positions with respect to the diagnostic imaging device coordinate reference system **011** are placed on the patient body **009** in the vicinity of the lesion before the acquisition of the diagnostic images **023**. In FIG. 5, a diagnostic image of the at least three fiducials **029** is shown. Since the coordinates of the at least three fiducials are known in both the conventional coordinate system **011** of the diagnostic imaging device and in the image coordinate system **030** of FIG. 5, a conventional fitting algorithm known to those of ordinary skill in the art can be used to determine a transformation matrix, or coordinate transformation between the conventional coordinate system of the diagnostic device **011** and the image coordinate system **030**. This transformation matrix allows the localization of any image feature in the conventional coordinate system of the diagnostic imaging device **011** as illustrated in FIG. 6. It is to be noted that the tumor or organ or lesion **010** may not be

depicted, either partially or completely, in the plurality of diagnostic images **023**. In the case of such an event, the radiation treatment plan may fail to treat the lesion or tumor and thus it may compromise the success of the radiation treatment.

The definition and the localization of the lesion **010** may be improved in the following manner. A means **008** (FIG. 7) for generating at least one ultrasound image **016** of the lesion **010** (FIG. 8) is disposed in the diagnostic imaging room, as depicted in FIG. 7. Preferably the means **008** for generating an ultrasound image **016** utilizes a conventional, commercially available ultrasound probe **005** (FIG. 7). The ultrasound probe **005** is brought in contact with the patient body **009** (FIG. 7) in order to generate the ultrasound image or images **016** of the tumor or lesion or organ **010** (FIG. 8). By moving or rotating the ultrasound probe **005**, a plurality of ultrasound images **016** (FIG. 9) of the tumor or lesion or organ **010** may be acquired. In FIG. 9, the lesion **010** is shown disposed within the plurality of ultrasound images **016** with the plane of each ultrasound image representative of the orientation of the ultrasound probe **005** at the time of the ultrasound image acquisition. From the plurality of ultrasound images **016** a reconstruction of the three-dimensional volume or picture **031** (FIG. 10) of the ultrasound data is performed in the conventional coordinate system **011** of the diagnostic imaging device. It is to be noted that, depending of the size of the reconstructed volume **031** there may be location in the periphery of reconstructed volume **031** for which ultrasound data are not available. However, such an event is inconsequential to the invention as long as the tumor or organ or lesion is visible within the reconstructed volume.

In order to accurately reconstruct the three-dimensional volume **031** of the ultrasound data from the plurality of ultrasound images **016**, for each ultrasound image **016** acquired, the orientation and the position (hereafter referred to as the orientation) of the ultrasound probe **005** with respect to the conventional coordinate system **011** of the diagnostic imaging device **002** must be known. A means **006a-006b** for indicating the geometric orientation of the ultrasound probe **005** are disposed in the room of the diagnostic device **002** as shown in FIG. 7. Any conventional position sensing system can be used as means **006a-006b** to determine the position and the orientation of the ultrasound probe **005** with respect to the coordinate system **011** of the diagnostic imaging device **002.** These positioning systems can include: a camera system fixed in the room which looks at light emitting or reflective markers mounted on the ultrasound probe **005**; ultrasonic system with emitters mounted on the probe **005** with a detector measuring the distances to these emitters by time measurements and consequent geometric triangulation to determine the ultrasound probe **005** position and orientation; a positioning system based on mechanical arm with the ultrasound probe **005** attached to the arm. It is to be noted that neither the ultrasound probe **005** nor the means **006a-006b** for indicating the geometric orientation of the ultrasound probe **005** have to be fixed to the table **001** of the diagnostic imaging device **002**. The means **006a-006b** for indicating the geometric orientation of the ultrasound probe **005** are aligned with or as known in the art, calibrated to the conventional coordinate reference system **011** of the diagnostic device **002**. Because of this alignment or calibration, for any point or feature from the plurality of ultrasound images **016**, the coordinates (X, Y, Z) in the conventional coordinate reference system **011** of the diagnostic device **002** are known. With this knowledge the value of the ultrasound image data for each point within the reconstructed volume **031** (FIG. 10) can be determined by interpolating algorithms known to those of ordinary skill in the art. Furthermore, for any point or feature within the volume of ultrasound image **031** (FIG. 10), the coordinates (X, Y, Z) in the conventional coordinate reference system **011** of the diagnostic device **002** are known. The acquisition control and fusion software is executed on a dedicated computer or workstation **013** as illustrated in FIG. 1. Standard segmentation and other image enhancing tools are available to facilitate to process of lesion outlining and rendering. Since the acquisition of the plurality of ultrasound images **016** is done immediately before or after the acquisition of the plurality of diagnostic images **023**, the ultrasound three-dimensional image data **031** and the diagnostic three-dimensional image **027** represent pictures of spatially overlapping volumes or sections of the patient anatomy at two very close moments of time. For a large number of anatomical sites it can be assumed that, within the accuracy required for treatment planning, the patient anatomy at these two very close moments of time does not change and therefore both the ultrasound three-dimensional image data **031** and the diagnostic three-dimensional image data **027** represent temporally identical, spatially overlapping sections of the same patient anatomy. Given that the positions and the orientations of both the ultrasound three-dimensional image data **031** and the diagnostic three-dimensional image data **027** are known with respect the conventional coordinate reference system **011** of the diagnostic device **002** the ultrasound three-dimensional image data **031** and the diagnostic three-dimensional image data **027** can be superimposed as illustrated in FIG. 11. Since the ultrasound three-dimensional image data **031** and the diagnostic three-dimensional image data **027** are combined, contours **022** of the outer surface of the lesion **010** can be defined in arbitrary planes within ultrasound three-dimensional image data **031** (FIG. 12) and displayed at their correct location within the

diagnostic three-dimensional image data **027**. These contours **022** can be used to perform three-dimensional rendering **021** of the lesion within the diagnostic three-dimensional image data **027**. In this manner, the lesion **010** is (1) localized and defined with respect the conventional coordinate reference system **011** of the diagnostic device **002** and (2) localized, defined and visualized within the diagnostic three-dimensional image data **027**. Because of (1) and (2) above, a radiation treatment plan can be designed in conventional manner to deliver the necessary radiation to the lesion **010** even though the lesion may not be completely visualized by the image or images **023** acquired with the diagnostic imaging device **002.** Preferably the radiation treatment plan is a conformal plan whereby the shape of the radiation beam will conform to the spatial contour or outline **022** of the lesion. Alternatively, if a healthy organ **010** is localized and outlined with the above described procedure, the radiation treatment plan will preferably be designed to avoid excessive radiation damage to the organ **010**. The ultrasound three-dimensional image data **031**, the diagnostic three-dimensional image data **027**, the contours **022** of the outer surface of the lesion **010** and the three-dimensional rendering **021** of the lesion **010** are then transferred from the workstation **013** (FIG. 1) to a computer or a workstation **014** in the control area of the radiation therapy device **003** (FIG. 1) to serve as reference data for the verification of the treatment position of the tumor or lesion or organ **010** before the radiation treatment session.

Before the radiation treatment session, the verification of the tumor or lesion or organ **010** position proceeds in the following manner. With reference to FIG. 14, the patient **009** having a tumor or a lesion or an organ of interest **010** is disposed on the treatment table **018** of the conventional therapy device **003** hereafter referred to as linear accelerator. As depicted in FIG. 14, at the time of the treatment session, in the therapy room, the position (possibly including orientation and shape) of the tumor or lesion or organ **010** with respect to the conventional coordinate system **019** of the therapy device **003** will be generally different from the intended treatment position **032** (possibly including orientation and shape) of the lesion as prescribed by the radiation treatment plan. Since typically the conventional coordinate reference system **011** of the diagnostic device **002** and the conventional coordinate system **019** of the therapy device **003** are considered to be identical, the intended treatment position **032** (possibly including orientation) of the lesion **010** is calculated from the spatial coordinates and extent of the lesion **010** determined previously in the diagnostic imaging device **002** room with the localization and definition method described earlier and illustrated in FIG. 2 to FIG. 13. Typically, in the process of treatment planning a 4 x 4 transformation matrix T is determined which when applied to the patient by mechanical motions of the therapy device table **018**, of the treatment device collimator **004** as well as of the treatment device gantry **007** disposes the tumor or lesion or organ **010** in the desired treatment position. If the conventional coordinate reference system **011** of the diagnostic device **002** and the conventional coordinate system **019** of the therapy device **003** are not identical, a predefined transformation matrix or coordinate transformation is available between the conventional coordinate system **019** of the therapy device **003** and the conventional coordinate reference system **011** of the diagnostic device **002**.

As a first step towards the verification of the intended treatment position, localization and definition of the actual position of the tumor, or lesion or organ **010** is performed in the room of the conventional radiotherapy device **003** similarly to the localization and definition of the tumor, or lesion or organ **010** performed in the room of the diagnostic device **002.** A means **028** (FIG. 15) for generating at least one ultrasound image **020** of the lesion **010** (FIG. 15) is disposed in the therapy room, as depicted in FIG. 15. Preferably the means **028** for generating at least one ultrasound image **020** utilizes a conventional, commercially available ultrasound probe **025** (FIG. 15).

The ultrasound probe **025** is brought in contact with the patient body **009** (FIG. 15) in order to generate an ultrasound image or images **020** of the tumor or lesion or organ **010** (FIG. 16). By moving or rotating the ultrasound probe **025**, a plurality of ultrasound images **020** (FIG. 16) of the tumor or lesion or organ **010** may be acquired. In FIG. 16, the lesion **010** is shown disposed within the plurality of ultrasound images **020** with the plane of each ultrasound image representative of the orientation of the ultrasound probe **025** at the time of the ultrasound image acquisition. From the plurality of ultrasound images **020** a reconstruction of the three-dimensional volume or picture **033** (FIG. 17) of the ultrasound data is performed in the conventional coordinate system **019** of the therapy device **003**. It is to be noted that, depending of the size of the reconstructed volume **033** there may be location in the periphery of reconstructed volume **033** for which ultrasound data are not available.

In order to accurately reconstruct the three-dimensional volume **033** of the ultrasound data from the plurality of ultrasound images **020**, for each acquired ultrasound image **020**, the orientation and the position (hereafter referred to as the orientation) of the ultrasound probe **025** with respect to the conventional coordinate system **019** of the therapy device **003** must be known. A means **026a-026b** for indicating the geometric orientation of the ultrasound probe **025** are disposed in the room of the therapy device **003** as

shown in FIG. 15. Any conventional position sensing system can be used as means **026a-026b** to determine the position and the orientation of the ultrasound probe **025** with respect to the coordinate system **019** of the therapy device **003**. These positioning systems can include: a camera system fixed in the room which looks at light emitting or reflective markers mounted on the ultrasound probe **025**; ultrasonic system with emitters mounted on the probe **025** with a detector measuring the distances to these emitters by time measurements and consequent geometric triangulation to determine the ultrasound probe **025** position and orientation; a positioning system based on mechanical arm with the ultrasound probe **025** attached to the mechanical arm. It is to be noted that neither the ultrasound probe **025** nor the means **026a-026b** for indicating the geometric orientation of the ultrasound probe **025** have to be fixed to the table **018** of the therapy device **003**. The means **026a-026b** for indicating the geometric orientation of the ultrasound probe **025** are aligned with or as known in the art, calibrated to the conventional coordinate reference system **019** of the therapy device **003**. Because of this alignment or calibration, for any point or feature from the plurality of ultrasound images, the coordinates (X, Y, Z) in the conventional coordinate system **019** of the therapy device **003** are known. With this knowledge, the value of the ultrasound image data for each point within the reconstructed volume **033** (FIG. 17) can be determined by interpolating algorithms known to those of ordinary skill in the art. Furthermore, for any point or feature within the volume of ultrasound image data **033** (FIG. 17) the coordinates (X, Y, Z) in the conventional coordinate system **019** of the therapy device **003** are known. Thus the localization of the tumor or lesion or organ **010** as depicted by the three-dimensional ultrasound image data **033** (FIG. 17) is complete. Furthermore, contours **024** (FIG. 18) of the outer surface of the lesion **010** can be defined in arbitrary planes within the ultrasound three-dimensional image data **033** (FIG. 17). These contours **024** can be used to properly perform three-dimensional rendering **034** (FIG. 19) of the lesion in the coordinate system **019** of the therapy device **003**.

Once the tumor or lesion or organ **010** is localized in the room of the therapy device **003**, the necessary adjustments of the treatment table **018** position, of the treatment device collimator **004** rotation as well as of the treatment device gantry **007** rotation can be performed by either of the following two methods. With reference to FIG. 20, the first method establishes a coordinate transformation (4 x 4 transformation matrix) R between the coordinate system **011** of the diagnostic device **002** and the coordinate system **019** of the therapy device **003** by superimposing or matching of the three-dimensional surface **022** or contours **021**of the lesion **010** as outlined within the three-dimensional ultrasound localization data **031** acquired in the room of the diagnostic device **002** prior to the treatment plan to the three-dimensional surface **034** or contours **024** of the lesion **010** as outlined within the three-dimensional ultrasound localization data **033** acquired in the room of the therapy device **003** before the treatment session. Conventional methods for contour and surface matching include chamfer matching and "top-and-hat" least square distance matching. An alternative method for the establishment of the coordinate transformation R between the coordinate system **011** of the diagnostic device **002** and the coordinate system **019** of the therapy device **003**, which does not rely on predefined contours or surfaces is illustrated in FIG. 21, whereby image cross correlation is performed between the reconstructed three-dimensional ultrasound localization data **033** acquired in the room of the therapy device **003** before the treatment session and the three-dimensional ultrasound localization data **031** acquired in the room of the diagnostic device **002** prior to the design of the treatment plan. The coordinate transformation is selected to be the one which produces the highest peak of the correlation value between the two three-dimensional data sets **033** and **031**. The determination of the necessary adjustments of the treatment table **018** position, of the treatment device collimator **004** rotation as well as of the treatment device gantry **007** rotation is then performed by a decomposition of the 4 x 4 transformation matrix TR^{-1} by algorithms known to those of ordinary skill in the art. It is to be noted that after the establishment of the coordinate transformation R between the coordinate system **011** of the diagnostic device **002** and the coordinate system **019** of the therapy device **003** by either of the above said two methods, adjustments other than the above said adjustments of the treatment table **018** position, of the treatment device collimator **004** rotation as well as of the treatment device gantry **007** rotation can be undertaken. These may range from simple modifications of the initially intended radiation beam shapes to change in the beam intensities and even a completely new treatment plan with different beam arrangements. These adjustments are calculated with software running on the workstation **014** and executed by the therapy device controller **015** which is interfaced to the therapy device **003** and treatment table controller **012** as illustrated in FIG. 1.

While particular preferred embodiments of the invention have been shown and described, it will be obvious to those of skill in the art that changes and modifications can be made without departing from the spirit and the scope of the invention as set forth in the claims. Accordingly, the invention is limited only by the scope of the appended claims.

We claim:

1. A system for localizing a tumor or lesion or organ for the purpose of radiation treatment planning, for use with a conventional diagnostic imaging device, comprising:
   a) A means for generating at least one ultrasound image of the lesion; and
   b) A means for indicating the position and the orientation with respect to the diagnostic imaging of the means of generating at the at least one ultrasound image when the at least ultrasound image is generated.
2. The system of claim 2 wherein the means for generating the ultrasound image is an ultrasound probe.
3. The system of claim 2 wherein the means of indicating the position of the means for generating the at least one ultrasound image is a position sensing system which indicates the position and the orientation of the ultrasound generating means with respect to the diagnostic imaging device.
4. A method for localizing a tumor or lesion or organ for the purposes of radiation treatment planning comprising the steps of:
   a) Disposing the patient on the table of the diagnostic imaging device;
   b) Generating at least one diagnostic image of the tumor or lesion or organ with known orientation and position of the plane of the at least one diagnostic image with respect to the diagnostic imaging device for each diagnostic image generated;
   c) Generating at least one ultrasound image of the tumor or lesion or organ with the ultrasound generating means being disposed in a known position and orientation with respect to the diagnostic imaging device for each ultrasound image generated;
   d) Superimposing or fusing the at least one ultrasound image and the at least one diagnostic image whereby, with the knowledge about the position and the orientation with respect to the diagnostic device of the at least one ultrasound and of the at least on diagnostic image pixel data from said at least one ultrasound image is mapped to pixel data from said at least on diagnostic image. For these pixels of said at least one diagnostic image, for which ultrasound data are not acquired, ultrasound data are generated by interpolation and extrapolation of the data from the at least one ultrasound image;
5. The method of claim 4 further including the step of drawing contours of the outer surface of the lesion on the diagnostic images by drawing the contours of the outer surface of the lesion on the at least on ultrasound image;
6. A system for localizing a tumor or lesion or organ for the purpose of treatment verification, for use with a conventional therapy device, comprising:
   a) A means for generating at least one ultrasound image of the lesion; and
   b) A means for indicating the position and the orientation with respect to the conventional therapy device of the means of generating at the at least one ultrasound image when the at least one ultrasound image is generated.
7. The system of claim 6 wherein the means for generating the ultrasound image is an ultrasound probe.
8. The system of claim 6 wherein the means of for indicating the position of the means for generating the at least one ultrasound image is a position sensing system which indicates the position and the orientation of the ultrasound generating means with respect to the therapy device.
9. A method for localizing a lesion within a body of a patient prior to radiation treatment comprising the steps of:
   a) Disposing the patient on the table of the therapy device;
   b) Generating at least on ultrasound image of the tumor or lesion or organ with the ultrasound generating means being disposed in a known position and orientation with respect to the therapy device for each ultrasound image generated;
10. A method for verifying the position of the lesion prior to radiation treatment comprising the method in claim 9 and the further step of comparing the position and orientation of the lesion of the at least one localization ultrasound image acquired with the method of claim 9 with the position and the orientation of the lesion as depicted by the at least one ultrasound image acquired during the localization of the lesion with the method of claim 4.
11. The method of claim 10 wherein the said comparison is performed by comparing the outlines of the outer surface of the lesion as localized by the method of claim 9 to the outlines of the surface of the lesion drawn with the method of claim 5.
12. The method of claim 10 wherein the said comparison is performed by image cross-correlation between the at least one ultrasound image generated and localized with the method of claim 9 and the at least one ultrasound image generated and localized with the method of claim 4, without the need to compare lesion outlines.
13. The method of claim 10 further including the step of: determining the amount of movement of the lesion required to dispose the lesion in the desired

position of the lesion in the radiation treatment plan.

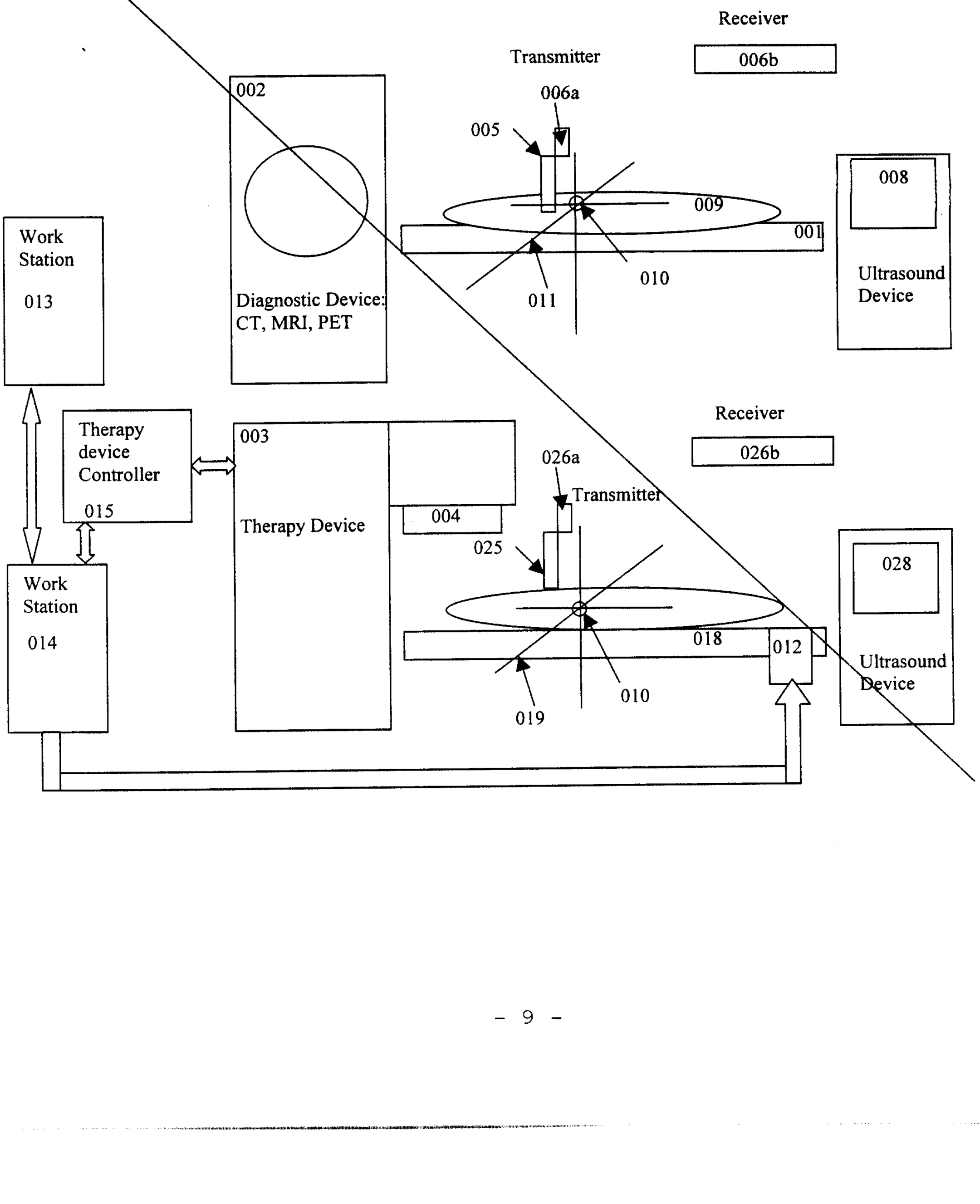
14. The method of claim 13 including the step of moving the lesion with respect to the therapy device to dispose the lesion in the desired treatment position.

15. A method comprising of repeating steps of claims 9 through 14.

16. The method of claim 14 wherein the step of moving the lesion is performed by rotating the treatment table with respect to the radiation therapy device, rotating the collimator of the radiation therapy device and rotating the gantry of the radiation therapy device.

FIGURES

FIG. 1 is a functional block diagram of an embodiment of the invention.



FIGURES

FIG. 1 is a functional block diagram of an embodiment of the invention.

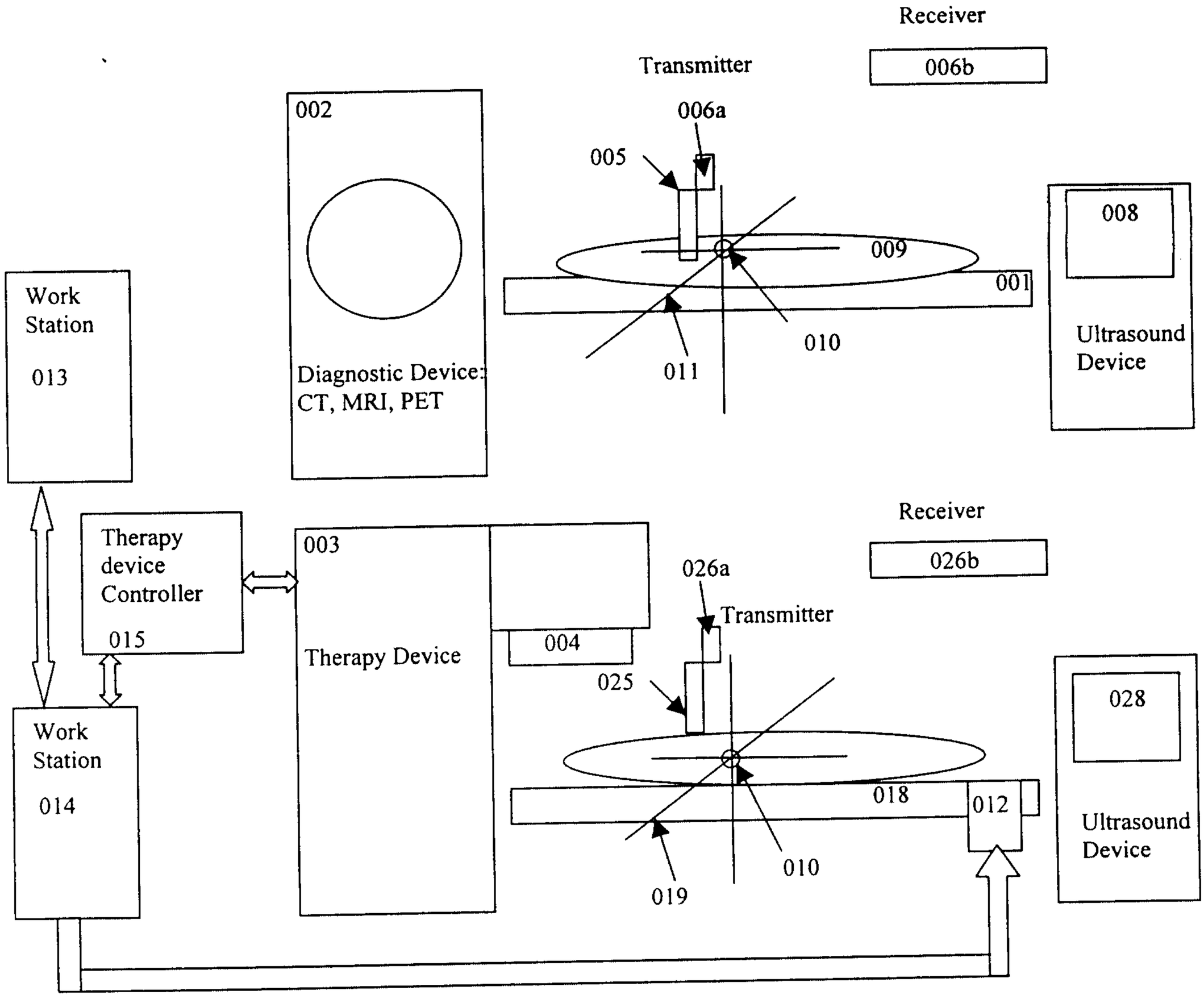


FIG. 2 is a perspective view of a conventional diagnostic imaging device with a patient schematically illustrated on the imaging table. The patient having a lesion disposed with in the patient body.

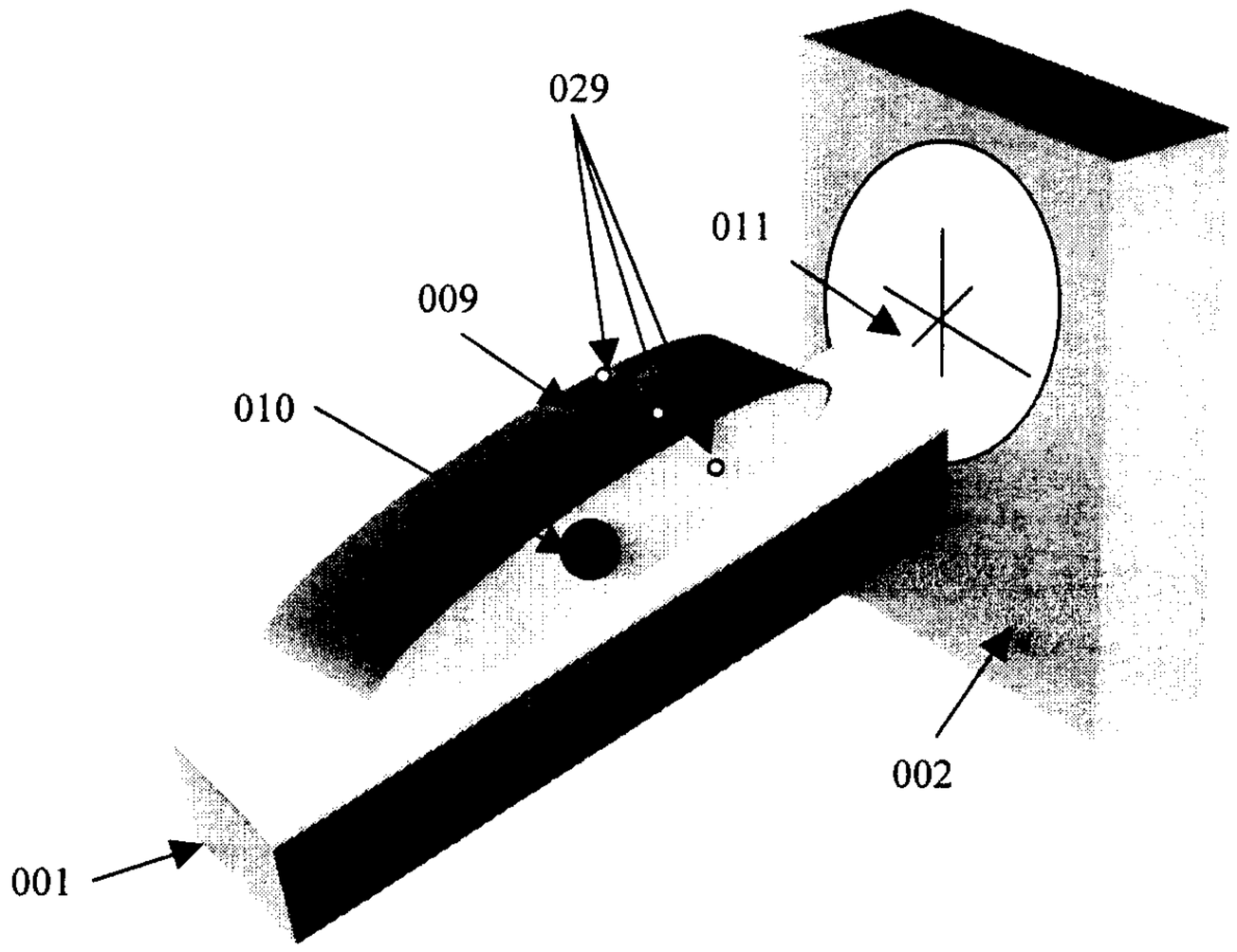


FIG. 3 is a perspective view of an image device of FIG. 2 with the patient passing through the imaging device.

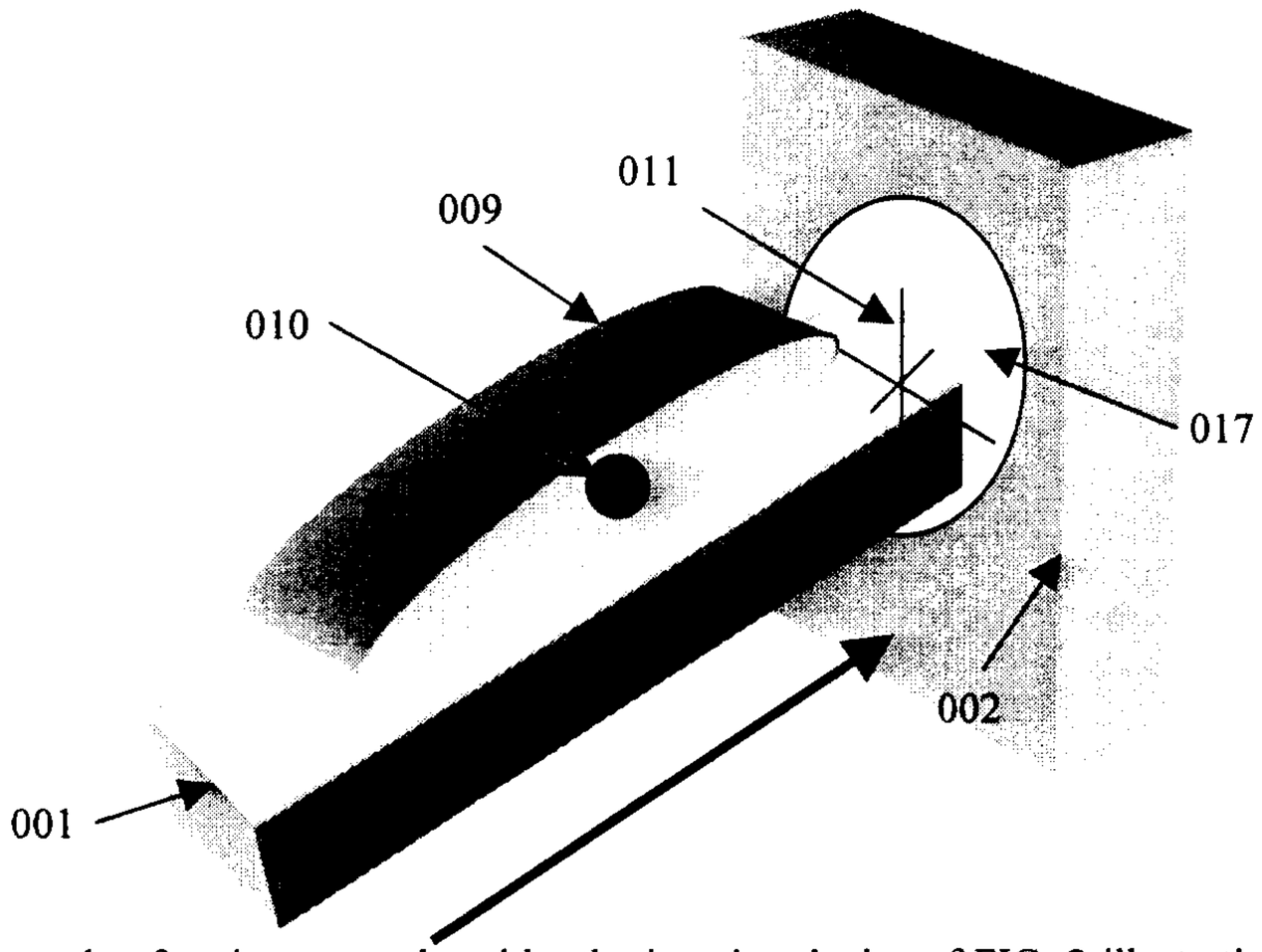


FIG. 4 is an example of an image produced by the imaging device of FIG. 2 illustrating the position of the lesion within the patient body.

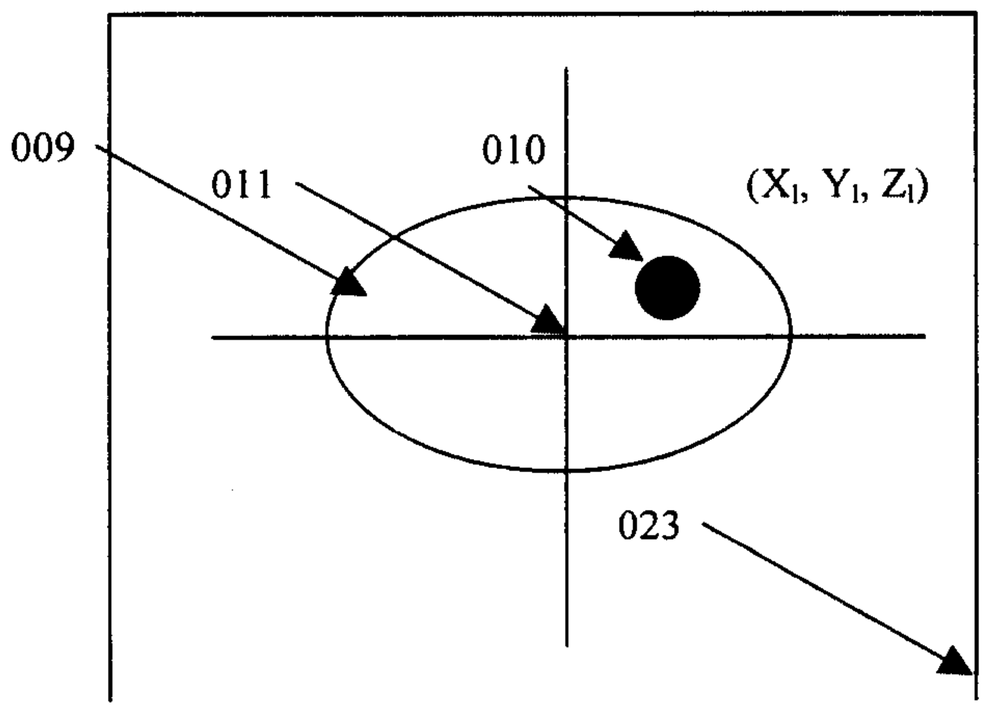


FIG. 5 is an example of an image produced by the imaging device of FIG. 2 illustrating fiducials with known position with respect to the diagnostic imaging device and visible on the diagnostic image or images.

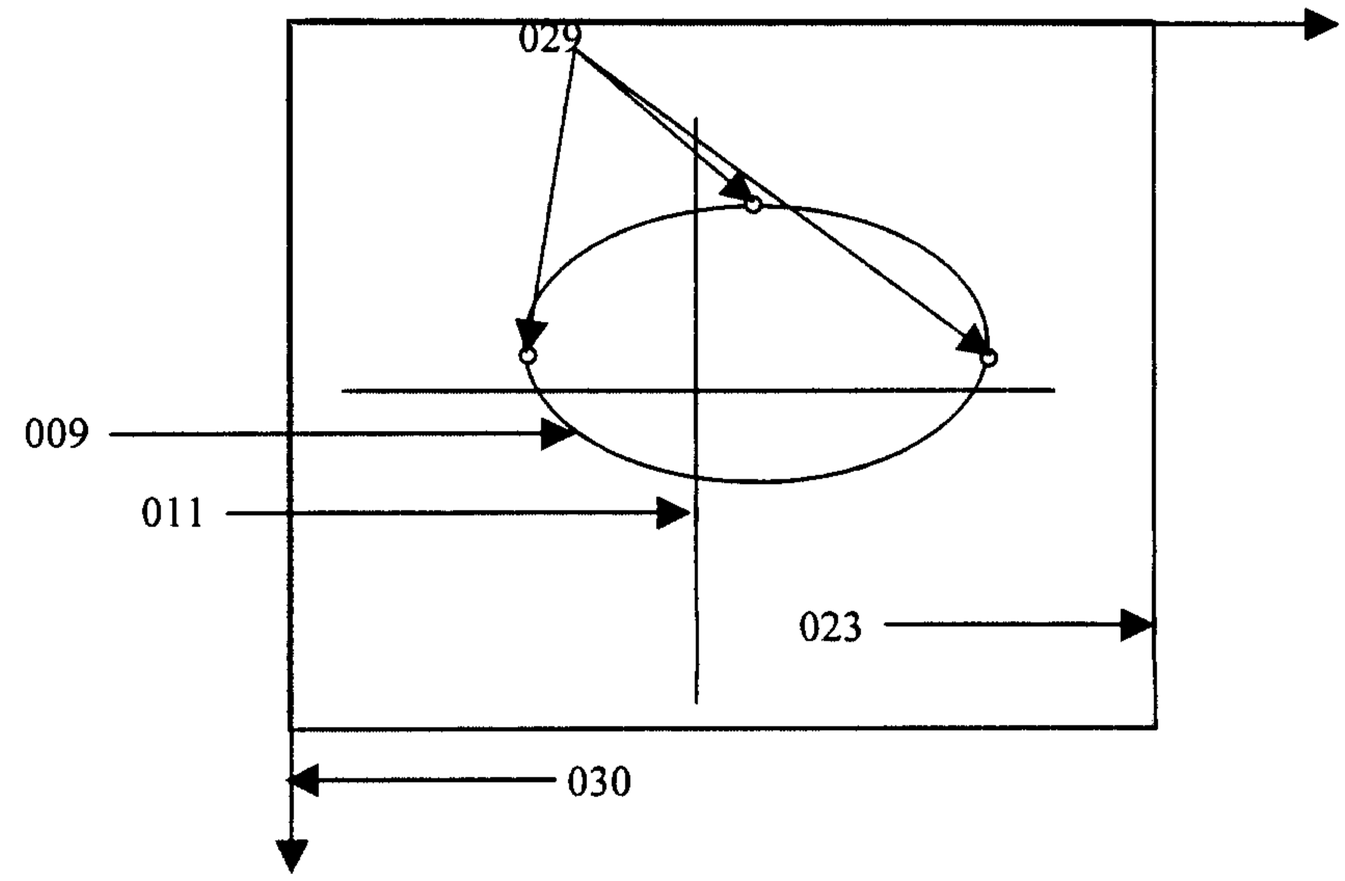


FIG. 6 a representation of the three-dimensional diagnostic image data reconstructed from the multiple diagnostic images such as the one depicted in FIG. 5.

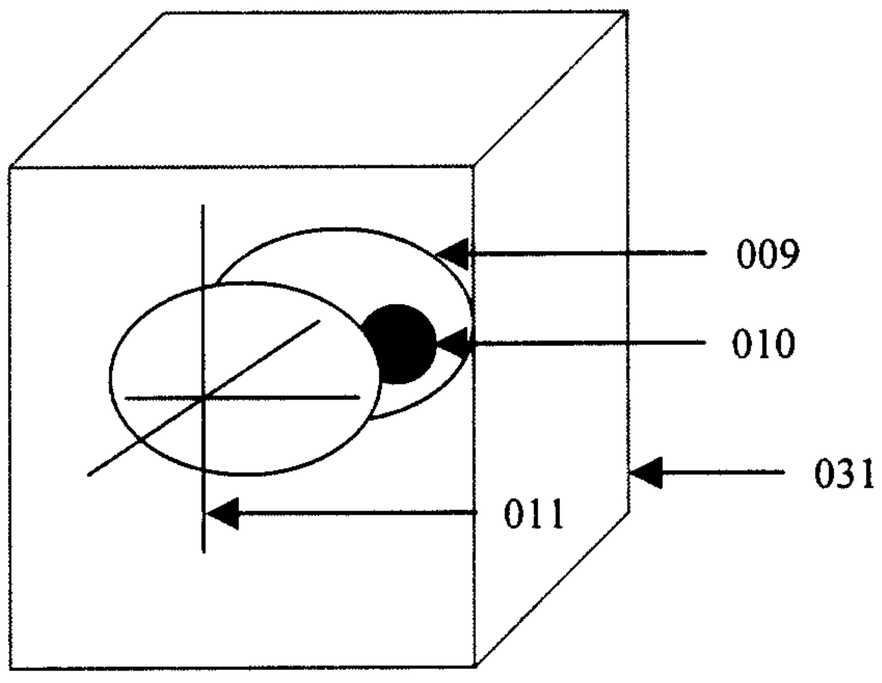


FIG. 7 is a perspective schematic view of the conventional diagnostic imaging device of FIG. 2, including a means for generating an US image of the lesion with the patient's body.

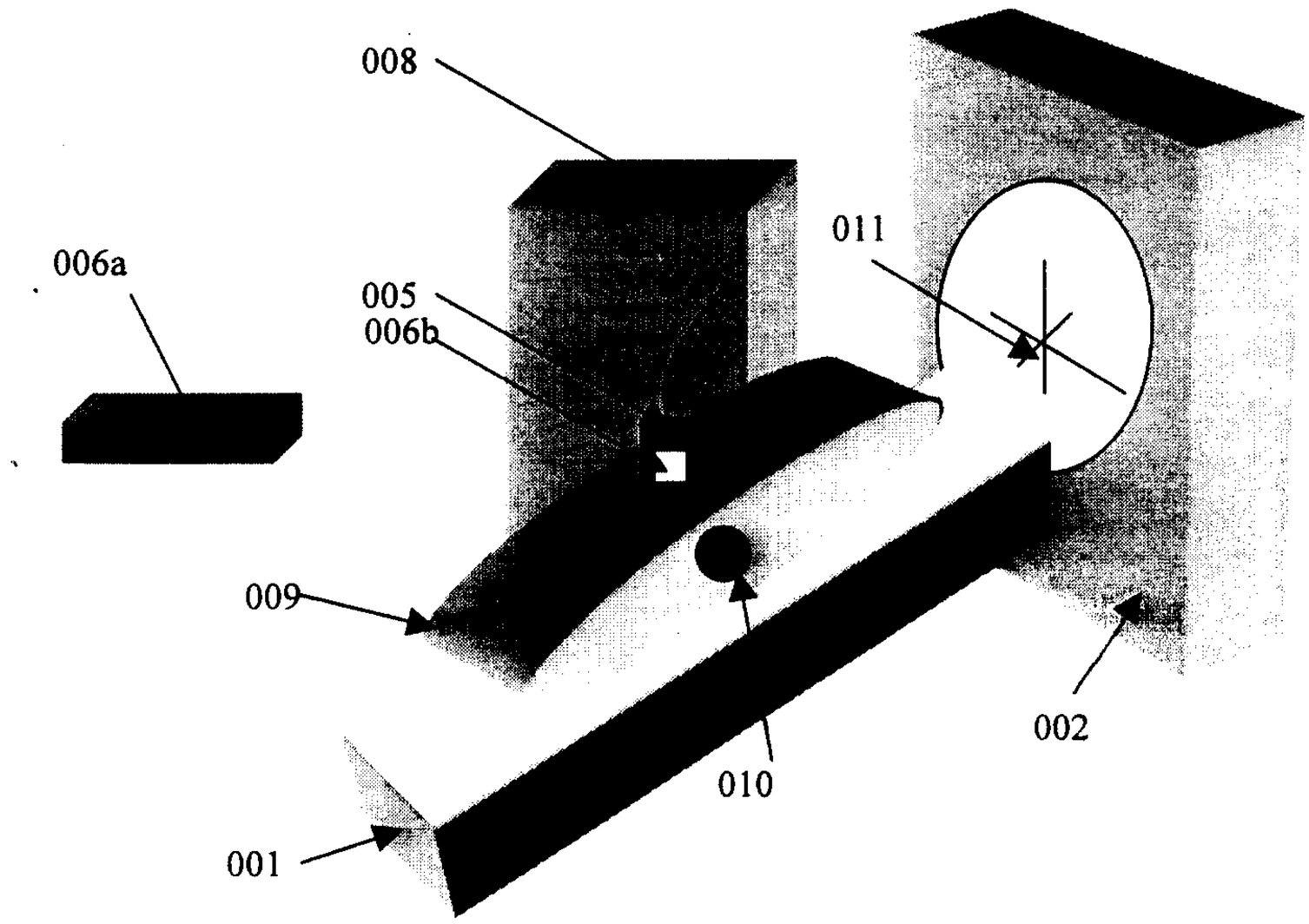


FIG. 8 is a representation of a ultrasound image of the tumor or lesion or organ.

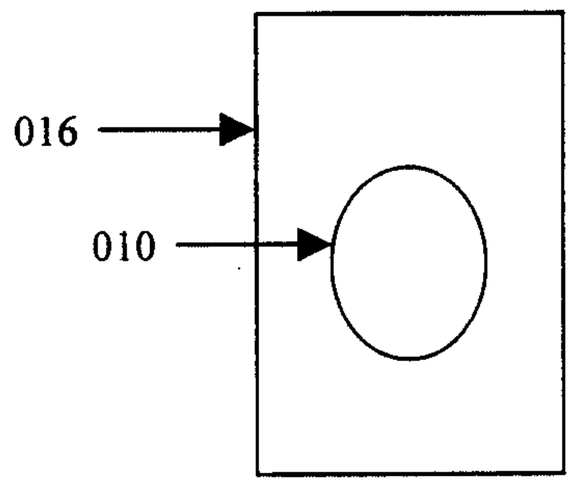


FIG. 9 is a perspective view indicating multiple ultrasound images being taken of a lesion with the US apparatus of FIG. 7

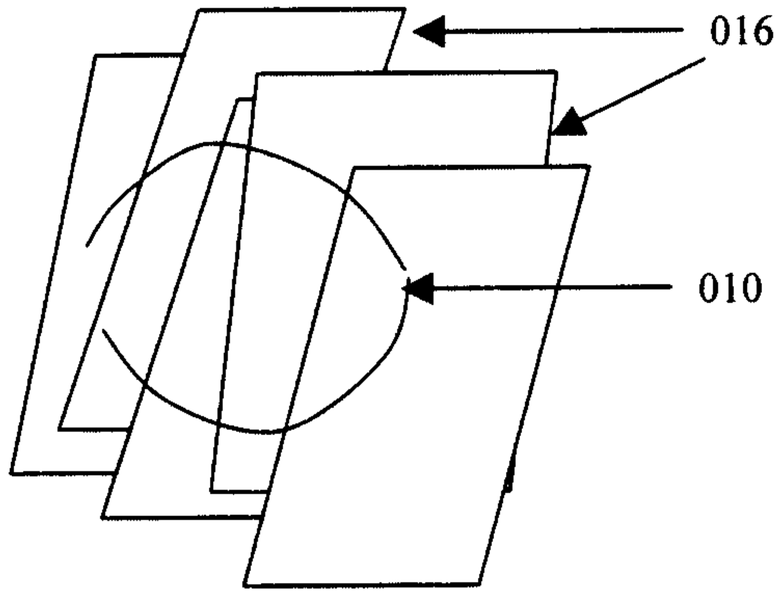


FIG. 10 is a representation of the three-dimensional ultrasound image data reconstructed from the multiple ultrasound images acquired in the room of the diagnostic imaging device and depicted in FIG. 9.

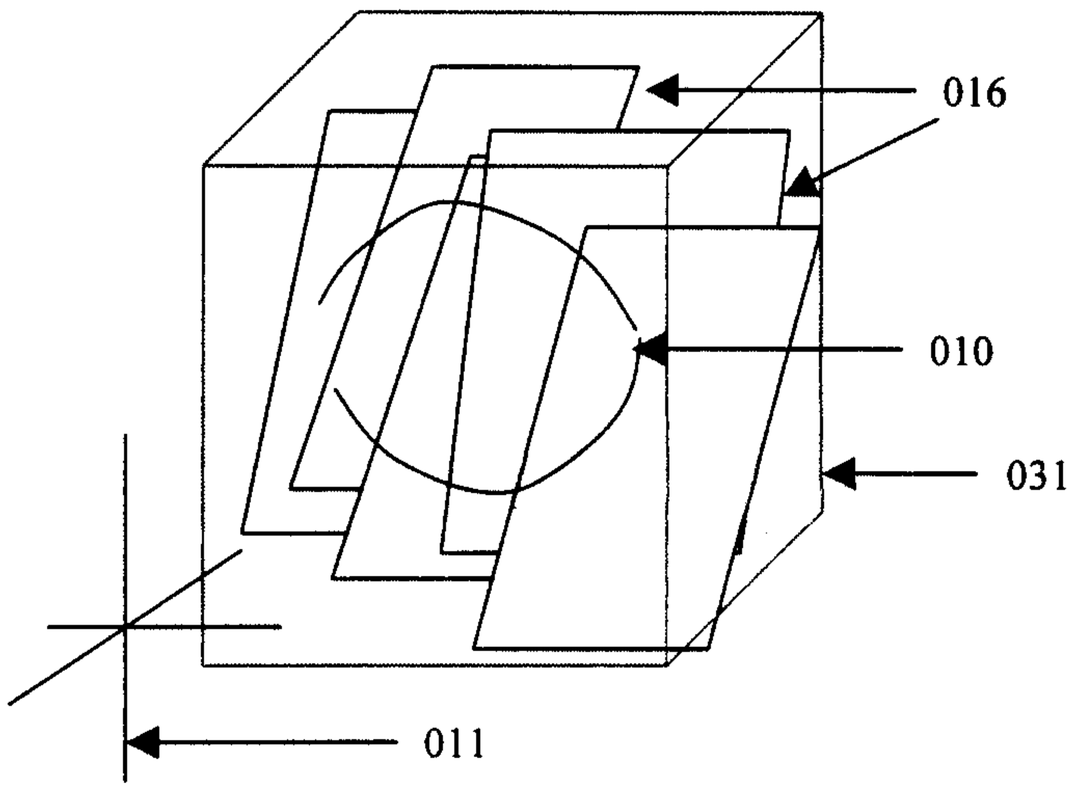


FIG. 11 is a representation of the three-dimensional ultrasound and diagnostic image data sets superimposed or combined.

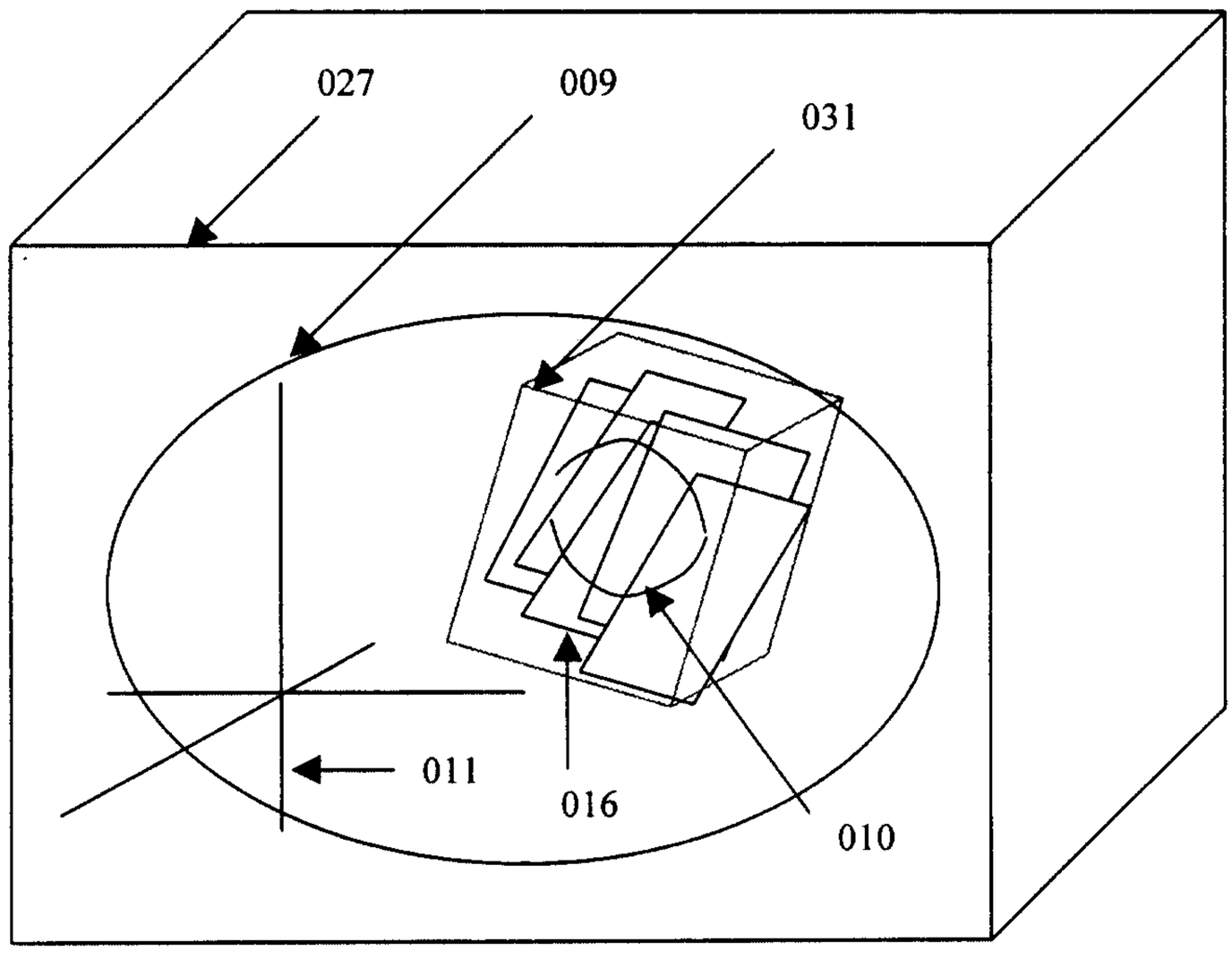


FIG. 12 is a representation of a sequence of two-dimensional ultrasound pictures of the lesion within the three-dimensional ultrasound data with the lesion having its outer surface outlined.

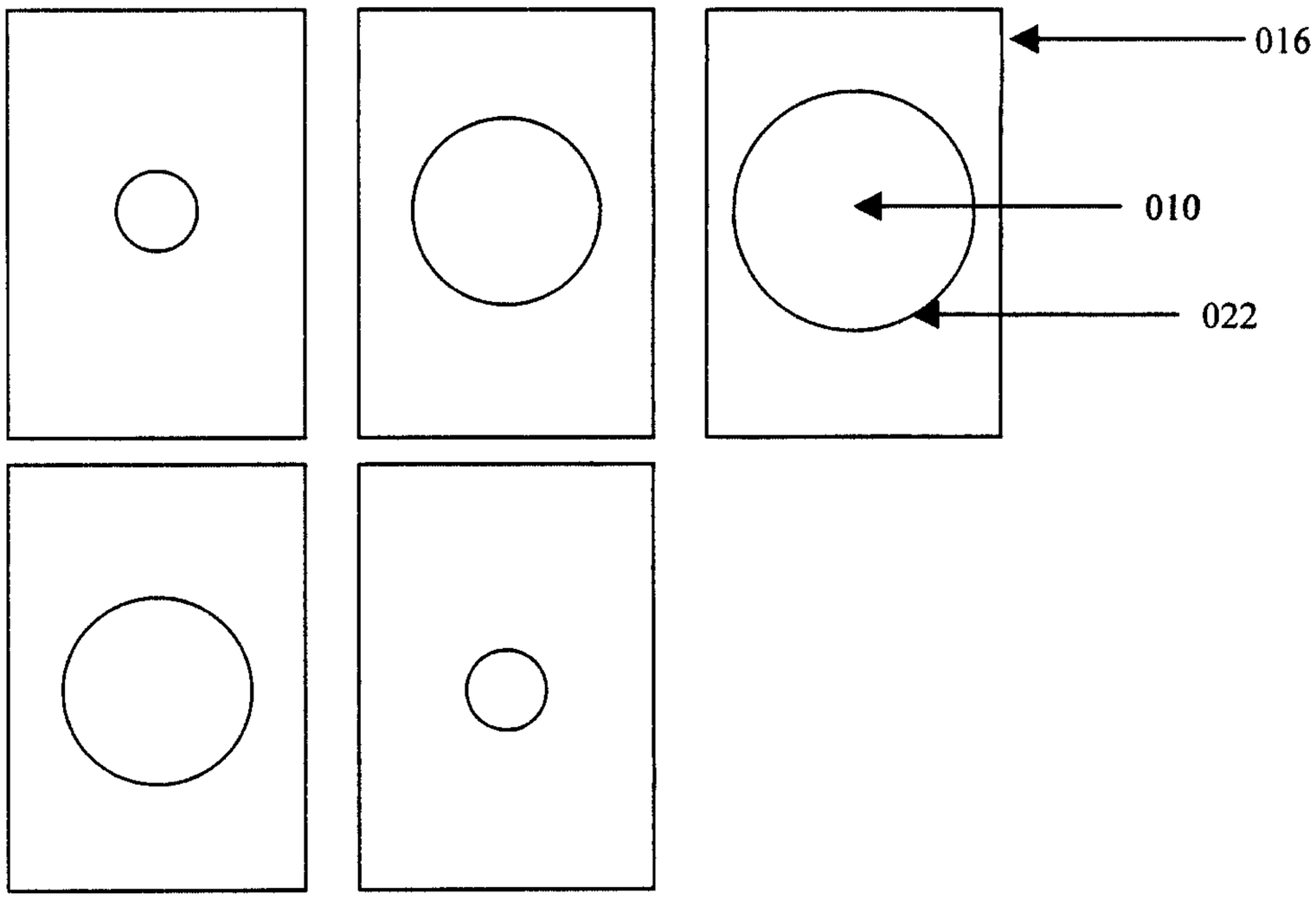


FIG. 13 is a 3-D rendering of the outline of the image prepared from the lesion contours as illustrated in FIG. 12.

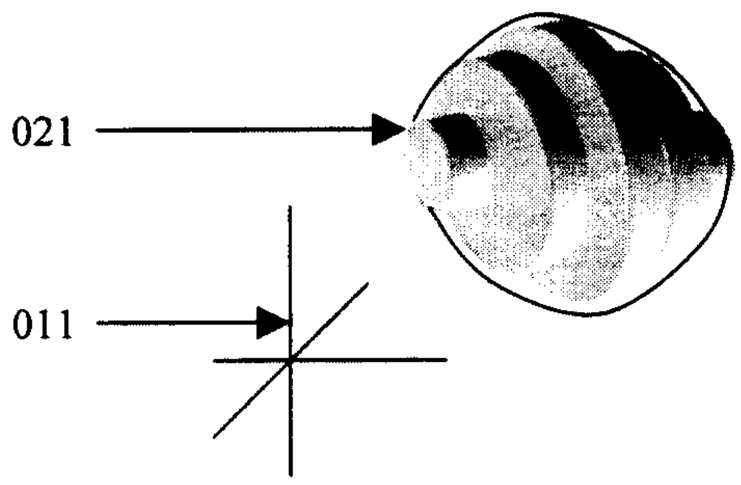


FIG. 14 is a perspective view of a conventional radiotherapy treatment device, or linear accelerator including a rotatable couch, collimator and gantry. The radiation treatment device can be any device capable of producing radiation for external beam therapy, e.g. tomotherapy unit, proton therapy unit, Cobalt-60 unit, etc.

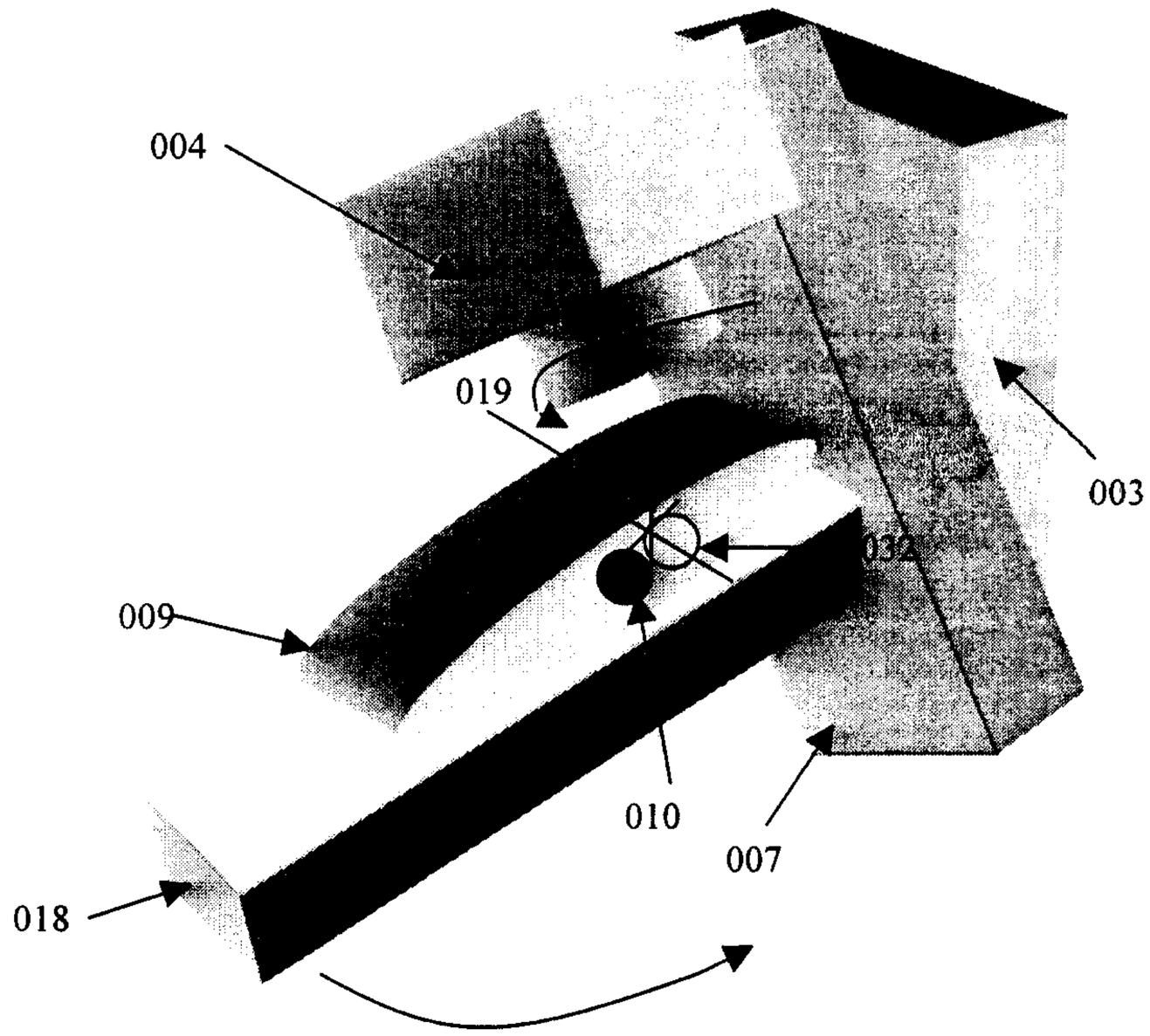


FIG. 15 is a perspective schematic view of the linear accelerator of including a means for generating an ultrasound image of the lesion within the patient's body.

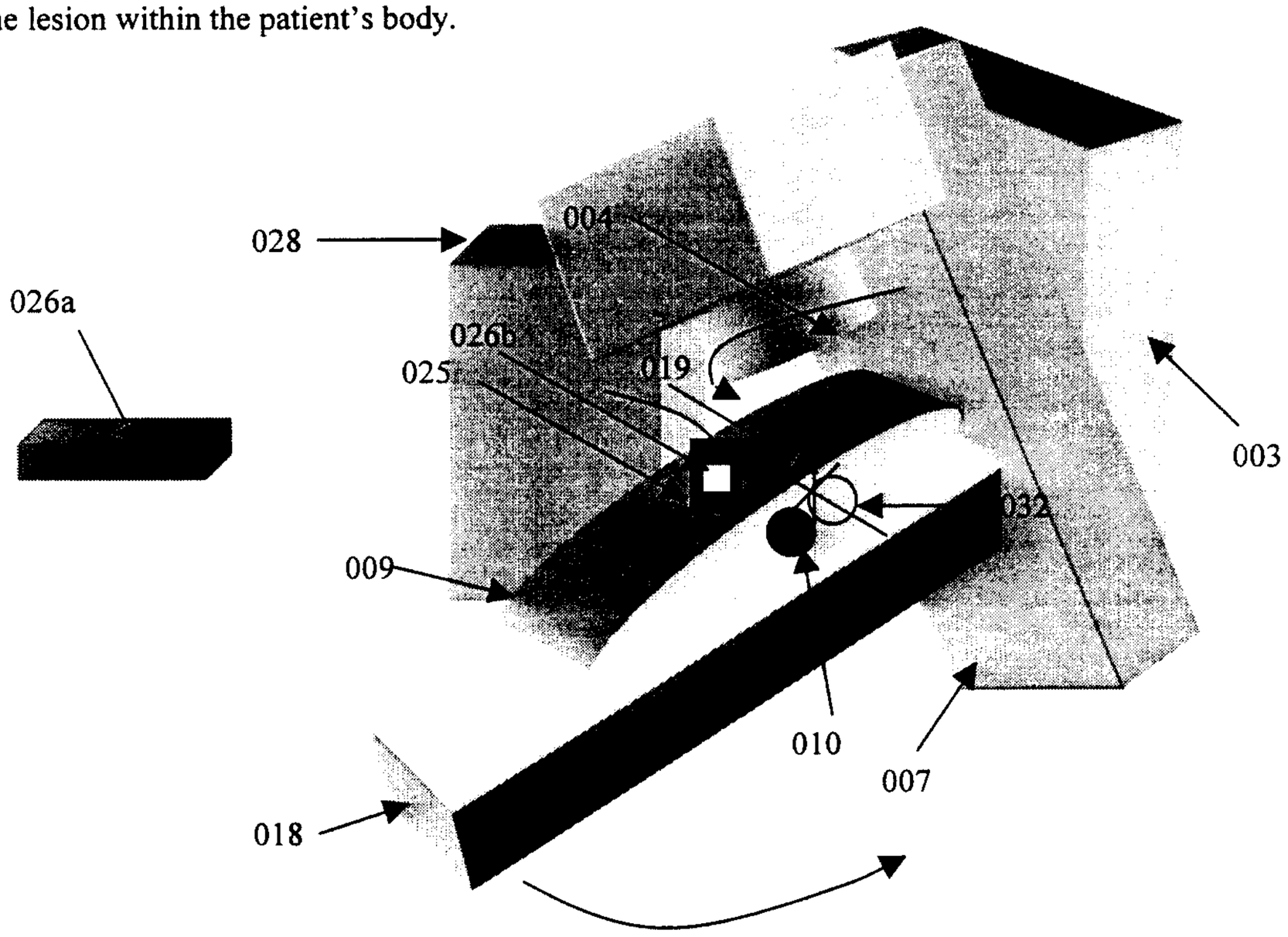


FIG. 16 is a perspective view indicating multiple US images being taken of a lesion with the ultrasound imaging device of FIG. 15.

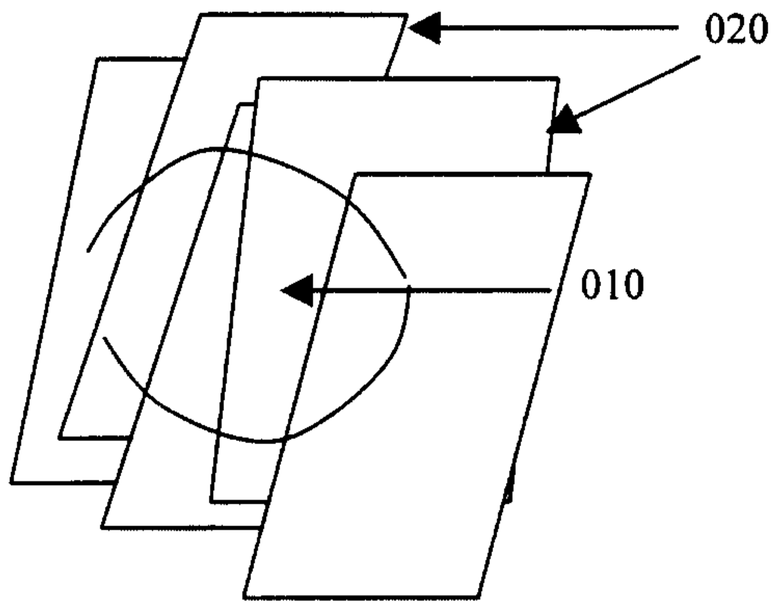


FIG. 17 is a representation of the three-dimensional ultrasound image data reconstructed from the multiple ultrasound images acquired in the room of the therapy device and depicted in FIG. 16

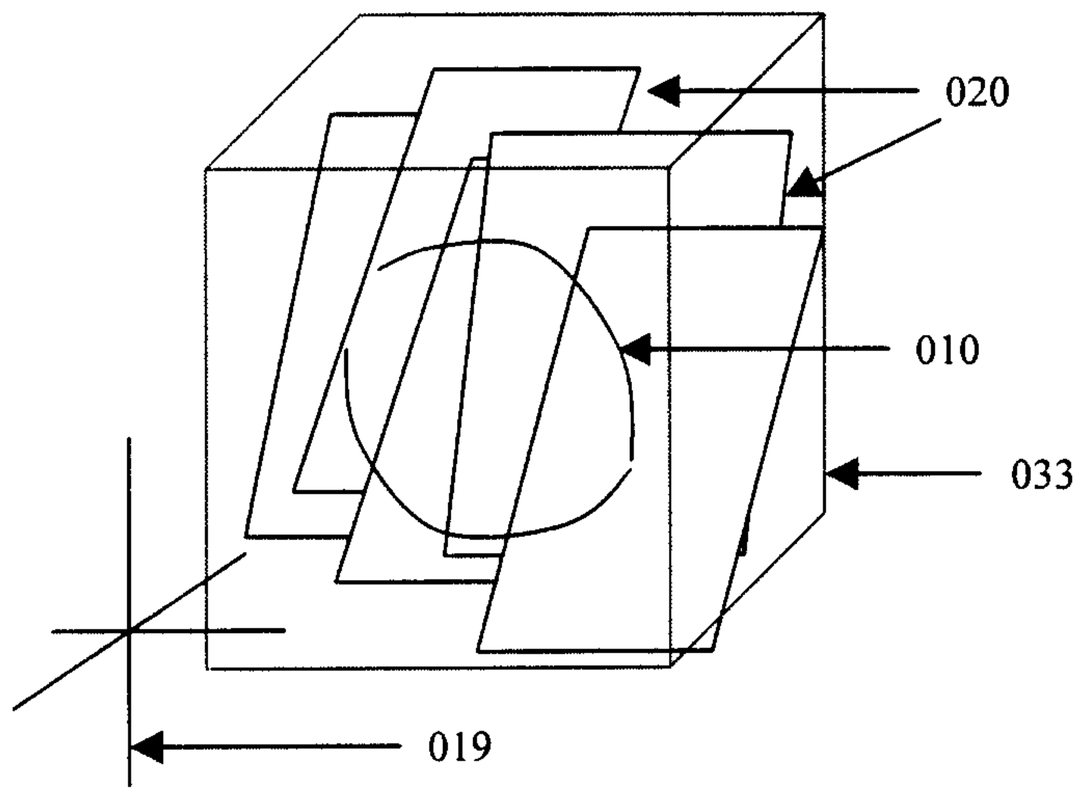


FIG. 18 is a representation of several two-dimensional US images with the lesion of FIG. 17 having its outer surface outlined.

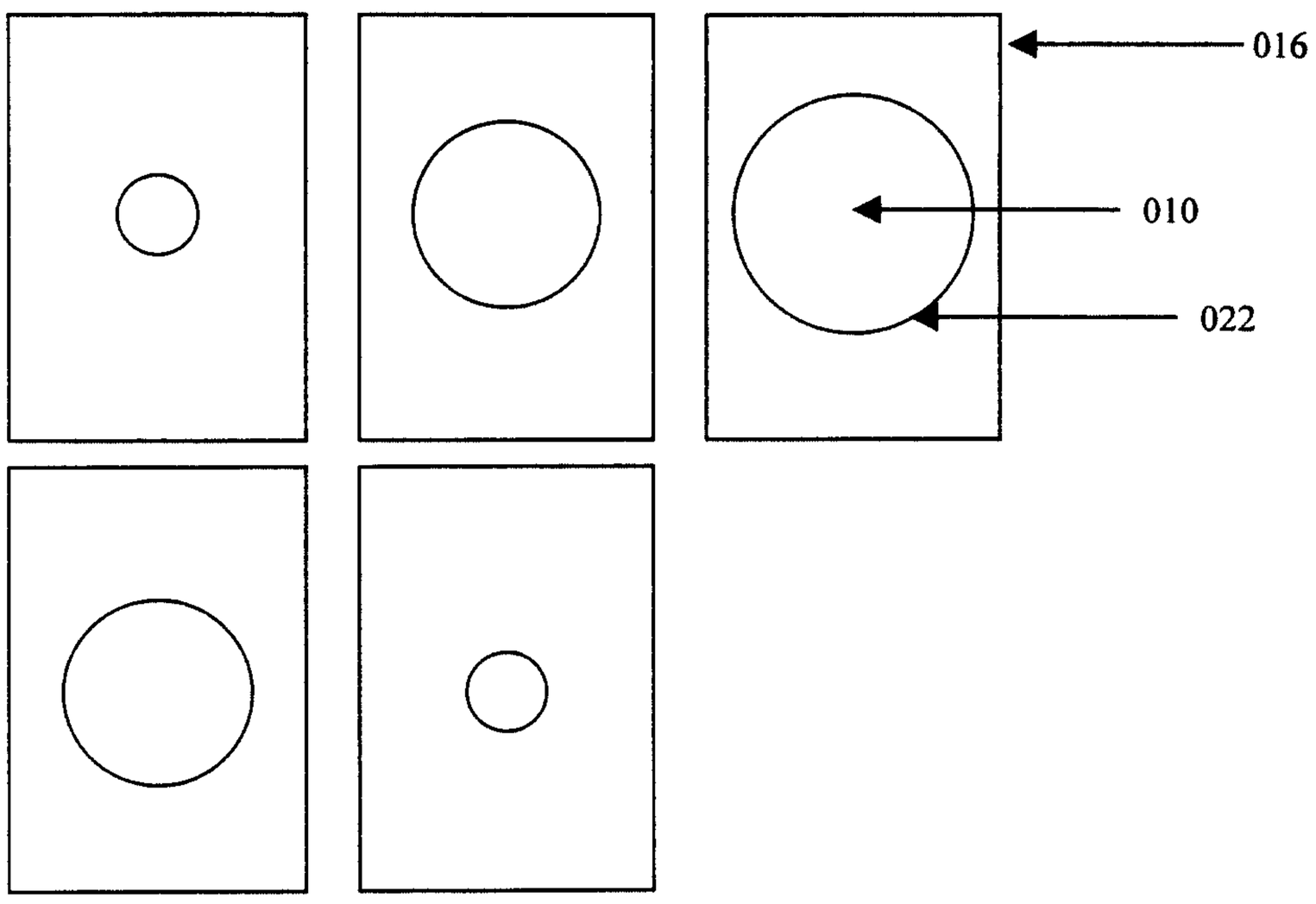


FIG. 19 is a 3-D rendering of the outline of the image prepared from the plurality of images from FIG. 18.

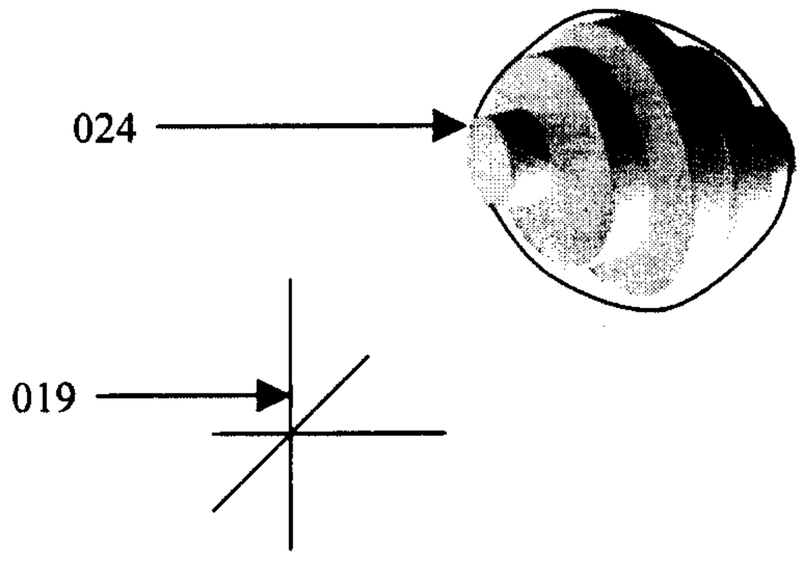


FIG. 20 is a representation of the process of determining the necessary corrections in the treatment setup (table position, collimator and gantry rotation) prior to a treatment session based on contour or surface registration.

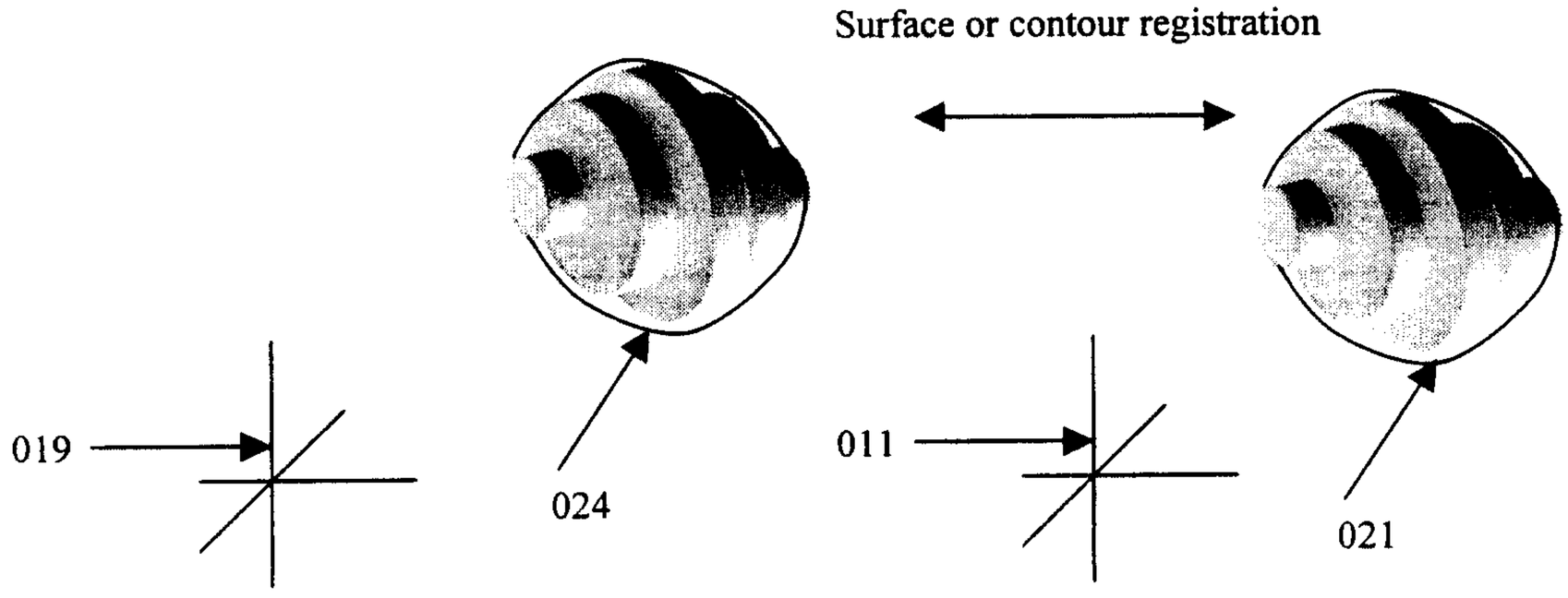


FIG. 21 is a representation of the process of determining the necessary corrections in the treatment setup (table position, collimator and gantry rotation) prior to a treatment session based on image cross-correlation.

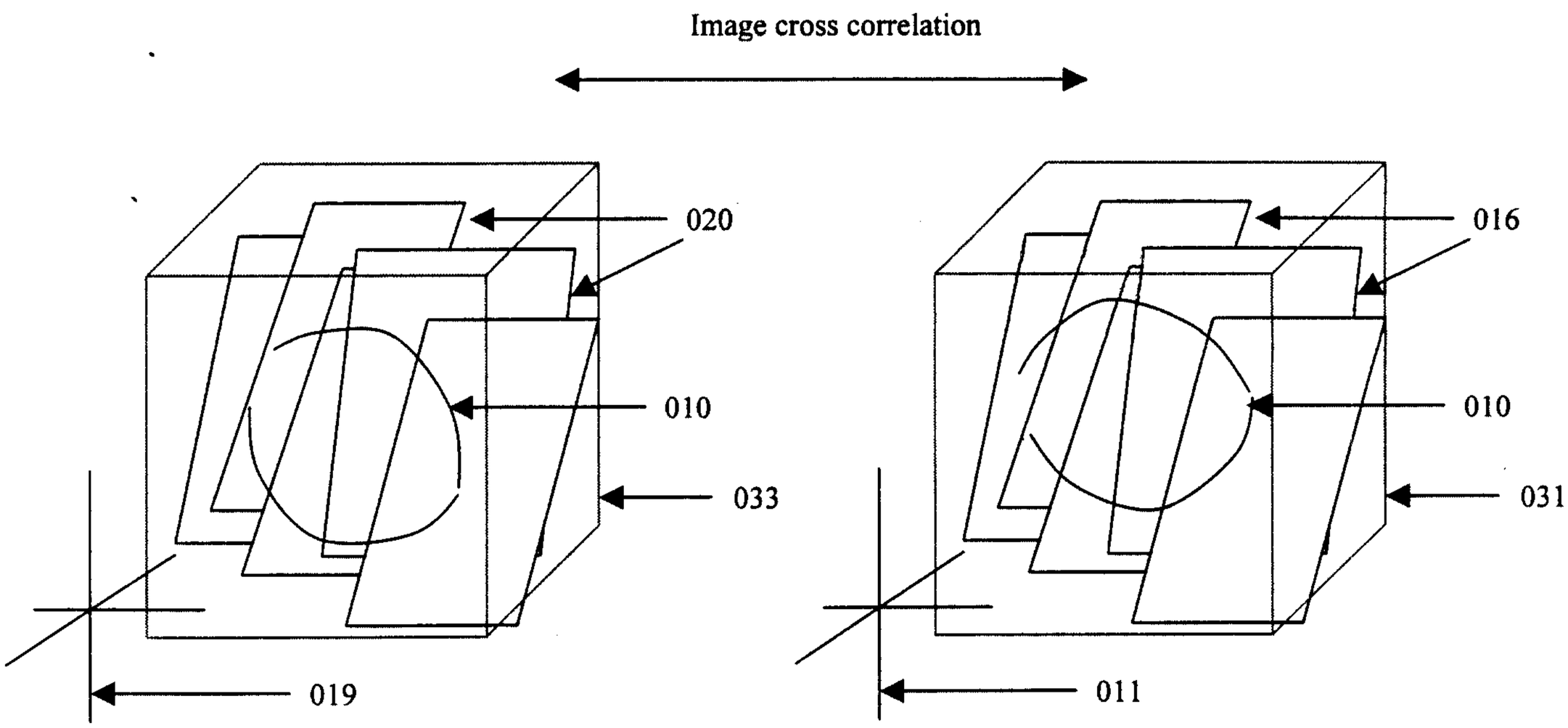


FIGURE LABELLING

001	CT-Simulator or MRI (or any other diagnostic imaging device) couch
002	Diagnostic imaging device (CT, MRI, PET or other)
003	Therapy treatment device (linear accelerator, Co-60 treatment unit, tomotherapy unit)
004	Therapy collimator (Jaws and/or Multi-leaf collimator)
005	Ultrasound probe used in the diagnostic imaging room
006a	Transmitter (localization device) attached to the ultrasound probe in the diagnostic imaging room
006b	Receiver (localization device) in the diagnostic imaging room
007	Therapy unit gantry
008	Ultrasound unit in the diagnostic imaging room
009	Patient
010	Tumor or organ or lesion
011	Diagnostic device reference coordinate system (usually defined room lasers aligned with the device mechanical axes)
012	Couch motion controller and/or couch motion tracking system
013	Diagnostic workstation for acquisition, viewing and analyzing three-dimensional ultrasound data. Segmentation and other image enhancing tools are available.
014	Therapy workstation for acquisition, viewing and analyzing three-dimensional ultrasound data. Segmentation and other image enhancing tools are available.
015	Therapy device controller. Used to modify treatments according to the adjustments necessary.
016	Image(s) from the ultrasound device in the diagnostic imaging (simulator) room
017	Slice acquisition space of the conventional diagnostic imaging device
018	Couch of the conventional radiation therapy device
019	Therapy device reference coordinate system (usually defined room lasers aligned with the device mechanical axes)
020	Ultrasound image or images obtained in the therapy room
021	Three-dimensional rendering of the lesion/organ from ultrasound images
022	Outer surface / contours of lesion defined on ultrasound images obtained in the simulator room
023	Image obtained with conventional diagnostic imaging modality (CT/MR)
024	Outer surface / contours of lesion defined on ultrasound images obtained in the therapy room
025	Ultrasound probe used in the therapy room
026a	Transmitter (localization device) attached to the ultrasound probe in the therapy room
026b	Receiver (localization device) in the therapy room
027	Three-dimensional reconstruction of diagnostic image data from the plurality of diagnostic images
028	Ultrasound unit in the therapy room
029	At least three fiducial markers identifiable on the diagnostic images and with known positions with respect to the diagnostic imaging device
030	Coordinate system of the three-dimensional picture reconstructed from conventional diagnostic (CT/MR) images
031	Three-dimensional reconstruction of the ultrasound data acquired in the diagnostic imaging room.
032	Lesion treatment location as prescribed by the radiation treatment plan.
033	Three-dimensional reconstruction of the ultrasound data acquired in the therapy room
034	Three-dimensional rendering of the lesion from ultrasound images obtained in therapy room

Work Station

013

002

Diagnostic Device:
CT, MRI, PET

Transmitter

Receiver

006b

006a

005

009

001

010

011

008

Ultrasound Device

Therapy device Controller

015

Work Station

014

003

Therapy Device

004

Receiver

026b

026a

Transmitter

025

018

012

019

010

028

Ultrasound Device