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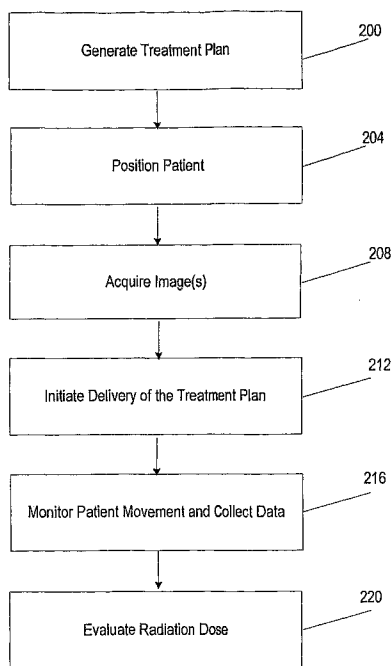
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[Continued on next page]

(54) Title: METHOD AND SYSTEM FOR EVALUATING DELIVERED DOSE



(57) Abstract: A system and method of evaluating a radiation dose delivered to a patient receiving radiation therapy. The method includes the acts of generating a time-based series of patient images, collecting a time-based series of data indicating patient motion, and evaluating a radiation dose delivered to the patient based upon the time-based series of patient images and the time-based series of data.

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## METHOD AND SYSTEM FOR EVALUATING DELIVERED DOSE

### RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Patent Application No. 60/701,580, filed on July 22, 2005, titled SYSTEM AND METHOD FOR FEEDBACK GUIDED QUALITY ASSURANCE AND ADAPTATIONS TO RADIATION THERAPY TREATMENT, the entire contents of which are incorporated herein by reference.

### BACKGROUND

[0002] Over the past decades improvements in computers and networking, radiation therapy treatment planning software, and medical imaging modalities (CT, MRI, US, and PET) have been incorporated into radiation therapy practice. These improvements have led to the development of image guided radiation therapy ("IGRT"). IGRT is radiation therapy that uses cross-sectional images of the patient's internal anatomy to better target the radiation dose in the tumor while reducing the radiation exposure to healthy organs. The radiation dose delivered to the tumor is controlled with intensity modulated radiation therapy ("IMRT"), which involves changing the size, shape, and intensity of the radiation beam to conform to the size, shape, and location of the patient's tumor. IGRT and IMRT lead to improved control of the tumor while simultaneously reducing the potential for acute side effects due to irradiation of healthy tissue surrounding the tumor.

[0003] IMRT is becoming the standard of care in several countries. However, in many situations, IMRT is not used to treat a patient due to time, resources, and billing constraints. Daily images of the patient can be used to guarantee that the high gradients generated by IMRT plans are located on the correct position for patient treatment. Also these images can provide necessary information to adapt the plan online or offline if needed.

[0004] It is commonly known in the field of radiation therapy that there are many sources of uncertainty and change that can occur during a course of a patient's treatment. Some of these sources represent random errors, such as small differences in a patient's setup position each day. Other sources are attributable to physiological changes, which might occur if a patient's tumor regresses or the patient loses weight during therapy. A third possible category regards motion. Motion can potentially overlap with either of the other categories,

as some motion might be more random and unpredictable, such as a patient coughing or passing gas, whereas other motion can be more regular, such as breathing motion, sometimes.

## SUMMARY

[0005] In radiation therapy, uncertainties can affect the quality of a patient's treatment. For example, when delivering a treatment dose to a target region, it is standard practice to also treat a high-dose "margin" region about the target. This helps ensure that the target receives the desired dose, even if its location changes during the course of the treatment, or even during a single fraction. The less definite a target's location, the larger the margins that typically need to be used.

[0006] Adaptive radiation therapy generally refers to the concept of using feedback during the course of radiation therapy treatment to improve future treatments. Feedback can be used in off-line adaptive therapy processes and on-line adaptive therapy processes. Off-line adaptive therapy processes occur while the patient is not being treated, such as in between treatment fractions. In one version of this, during each fraction, a new CT image of the patient is acquired before or after each of the fractions. After the images are acquired from the first few treatment fractions, the images are evaluated to determine an effective envelope of the multi-day locations of target structures. A new plan can then be developed to better reflect the range of motion of the target structure, rather than using canonical assumptions of motion. A more complex version of off-line adaptive therapy is to recalculate the delivered dose after each fraction and accumulate these doses, potentially utilizing deformation techniques, during this accumulation to account for internal motion. The accumulated dose can then be compared to the planned dose, and if any discrepancies are noted, subsequent fractions can be modified to account for the changes.

[0007] On-line adaptive therapy processes typically occur while the patient is in the treatment room, and potentially, but not necessarily, during a treatment delivery. For example, some radiation therapy treatment systems are equipped with imaging systems, such as on-line CT or x-ray systems. These systems can be used prior to treatment to validate or adjust the patient's setup for the treatment delivery. The imaging systems may also be used to adapt the treatment during the actual treatment delivery. For example, an imaging system potentially can be used concurrently with treatment to modify the treatment delivery to reflect changes in patient anatomy.

[0008] One aspect of the present invention is to disclose new opportunities for the application of adaptive therapy techniques, and additional aspects are to present novel methods for adaptive therapy. In particular, adaptive therapy has typically focused on feedback to modify a patient's treatment, but the present invention focuses on adaptive therapy processes being used in a quality assurance context. This is particularly true in the context of whole-system verification.

[0009] For example, a detector can be used to collect information indicating how much treatment beam has passed through the patient, from which the magnitude of the treatment output can be determined as well as any radiation pattern that was used for the delivery. The benefit of this delivery verification process is that it enables the operator to detect errors in the machine delivery, such as an incorrect leaf pattern or machine output.

[0010] However, validating that the machine is functioning properly does not itself ensure proper delivery of a treatment plan, as one also needs to validate that the external inputs used to program the machine are effective and consistent. Thus, one aspect of the invention includes the broader concept of an adaptive-type feedback loop for improved quality assurance of the entire treatment process. In this aspect, the invention includes the steps of positioning the patient for treatment and using a method for image-guidance to determine the patient's position, repositioning the patient as necessary for treatment based upon the image-guidance, and beginning treatment. Then, either during or after treatment, recalculating the patient dose and incorporating the patient image information that had been collected before or during treatment. After completion of these steps, quality assurance data is collected to analyze the extent to which the delivery was not only performed as planned, but to validate that the planned delivery is reasonable in the context of the newly available data. In this regard, the concept of feedback is no longer being used to indicate changes to the treatment based on changes in the patient or delivery, but to validate the original delivery itself.

[0011] As an example, it is possible that a treatment plan might be developed for a patient, but that the image used for planning became corrupted, such as by applying an incorrect density calibration. In this case, the treatment plan will be based upon incorrect information, and might not deliver the correct dose to the patient. Yet, many quality assurance techniques will not detect this error because they will verify that the machine is operating as instructed, rather than checking whether the instructions to the machine are

based on correct input information. Likewise, some adaptive therapy techniques could be applied to this delivery, but if the calibration problem of this example persisted, then the adapted treatments would suffer from similar flaws.

[0012] There are a number of processes that can be used to expand the use of feedback for quality assurance purposes. For example, in one embodiment, this process would include the delivery verification techniques described above. The validation of machine performance that these methods provide is a valuable component of a total-system quality assurance toolset. Moreover, the delivery verification processes can be expanded to analyze other system errors, such as deliveries based on images with a truncated field-of-view.

[0013] In one embodiment, the invention provides a method of evaluating a radiation dose delivered to a patient receiving radiation therapy. The method comprises the acts of generating a time-based series of patient images, collecting a time-based series of data indicating patient motion, and evaluating a radiation dose delivered to the patient based upon the time-based series of patient images and the time-based series of data.

[0014] In another embodiment, the invention provides a system for determining a radiation dose delivered to a patient. The system comprises a radiation therapy treatment device including a computer processor, the radiation therapy treatment device operable to deliver a treatment plan to a patient, and a software program stored in a computer readable medium accessible by the computer processor. The software program is operable to receive a time-based series of patient images, input a time-based series of data indicating patient motion, and evaluate a radiation dose delivered to the patient based upon the time-based series of patient images and the time-based series of data.

[0015] In yet another embodiment, the invention provides a method of evaluating a radiation dose delivered to a patient receiving radiation therapy. The method comprises the acts of generating a treatment plan for the patient, initiating radiation therapy treatment according to the treatment plan, generating 4DCT images of the patient during delivery of the radiation therapy treatment, and calculating a radiation dose on each of the 4DCT images.

[0016] In another embodiment, the invention provides a method of evaluating a radiation dose delivered to a patient receiving radiation therapy. The method comprises the acts of generating a treatment plan for the patient, the treatment plan including a reference image, acquiring a 4DCT image from an imaging device positioned on a radiation therapy treatment

system, relating the reference image to the 4DCT image using deformation, and calculating a radiation dose on the resulting 4DCT image.

[0017] In another embodiment, the invention provides a method of evaluating a radiation dose to be delivered to a patient. The method comprises the acts of generating a time-based series of patient images, retrieving a simulated time-based series of data indicating patient motion, and evaluating a radiation dose that would be delivered to the patient based upon the time-based series of patient images and the simulated time-based series of data.

[0018] Other aspects of the invention will become apparent by consideration of the detailed description and accompanying drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0019] FIG. 1 is a perspective view of a radiation therapy treatment system.

[0020] FIG. 2 is a perspective view of a multi-leaf collimator that can be used in the radiation therapy treatment system illustrated in FIG. 1.

[0021] FIG. 3 is a schematic illustration of the radiation therapy treatment system of FIG. 1.

[0022] FIG. 4 is a schematic diagram of a software program used in the radiation therapy treatment system.

[0023] FIG. 5 is a flow chart of a method of evaluating a radiation dose delivered to a patient according to one embodiment of the present invention.

[0024] FIG. 6 is a flow chart of a method of evaluating a radiation dose delivered to a patient according to one embodiment of the present invention.

[0025] FIG. 7 is a flow chart of a method of evaluating a radiation dose delivered to a patient according to one embodiment of the present invention.

[0026] FIG. 8 is a flow chart of a method of evaluating a radiation dose to be delivered to a patient according to one embodiment of the present invention.

#### DETAILED DESCRIPTION

[0027] Before any embodiments of the invention are explained in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of components set forth in the following description or illustrated in the following drawings. The invention is capable of other embodiments and of being practiced or of being carried out in various ways. Also, it is to be understood that the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The use of “including,” “comprising,” or “having” and variations thereof herein is meant to encompass the items listed thereafter and equivalents thereof as well as additional items. Unless specified or limited otherwise, the terms “mounted,” “connected,” “supported,” and “coupled” and variations thereof are used broadly and encompass both direct and indirect mountings, connections, supports, and couplings. Further, “connected” and “coupled” are not restricted to physical or mechanical connections or couplings.

[0028] Although directional references, such as upper, lower, downward, upward, rearward, bottom, front, rear, etc., may be made herein in describing the drawings, these references are made relative to the drawings (as normally viewed) for convenience. These directions are not intended to be taken literally or limit the present invention in any form. In addition, terms such as “first”, “second”, and “third” are used herein for purposes of description and are not intended to indicate or imply relative importance or significance.

[0029] In addition, it should be understood that embodiments of the invention include both hardware, software, and electronic components or modules that, for purposes of discussion, may be illustrated and described as if the majority of the components were implemented solely in hardware. However, one of ordinary skill in the art, and based on a reading of this detailed description, would recognize that, in at least one embodiment, the electronic based aspects of the invention may be implemented in software. As such, it should be noted that a plurality of hardware and software based devices, as well as a plurality of different structural components may be utilized to implement the invention. Furthermore, and as described in subsequent paragraphs, the specific mechanical configurations illustrated in the drawings are intended to exemplify embodiments of the invention and that other alternative mechanical configurations are possible.

[0030] FIG. 1 illustrates a radiation therapy treatment system 10 that can provide radiation therapy to a patient 14. The radiation therapy treatment can include photon-based radiation therapy, brachytherapy, electron beam therapy, proton, neutron, or particle therapy,



or other types of treatment therapy. The radiation therapy treatment system 10 includes a gantry 18. The gantry 18 can support a radiation module 22, which can include a radiation source 24 and a linear accelerator 26 operable to generate a beam 30 of radiation. Though the gantry 18 shown in the drawings is a ring gantry, i.e., it extends through a full 360° arc to create a complete ring or circle, other types of mounting arrangements may also be employed. For example, a C-type, partial ring gantry, or robotic arm could be used. Any other framework capable of positioning the radiation module 22 at various rotational and/or axial positions relative to the patient 14 may also be employed. In addition, the radiation source 24 may travel in path that does not follow the shape of the gantry 18. For example, the radiation source 24 may travel in a non-circular path even though the illustrated gantry 18 is generally circular-shaped.

[0031] The radiation module 22 can also include a modulation device 34 operable to modify or modulate the radiation beam 30. The modulation device 34 provides the modulation of the radiation beam 30 and directs the radiation beam 30 toward the patient 14. Specifically, the radiation beam 34 is directed toward a portion of the patient. Broadly speaking, the portion may include the entire body, but is generally smaller than the entire body and can be defined by a two-dimensional area and/or a three-dimensional volume. A portion desired to receive the radiation, which may be referred to as a target 38 or target region, is an example of a region of interest. Another type of region of interest is a region at risk. If a portion includes a region at risk, the radiation beam is preferably diverted from the region at risk. The patient 14 may have more than one target region that needs to receive radiation therapy. Such modulation is sometimes referred to as intensity modulated radiation therapy (“IMRT”).

[0032] The modulation device 34 can include a collimation device 42 as illustrated in FIG. 2. The collimation device 42 includes a set of jaws 46 that define and adjust the size of an aperture 50 through which the radiation beam 30 may pass. The jaws 46 include an upper jaw 54 and a lower jaw 58. The upper jaw 54 and the lower jaw 58 are moveable to adjust the size of the aperture 50.

[0033] In one embodiment, and illustrated in FIG. 2, the modulation device 34 can comprise a multi-leaf collimator 62, which includes a plurality of interlaced leaves 66 operable to move from position to position, to provide intensity modulation. It is also noted that the leaves 66 can be moved to a position anywhere between a minimally and maximally-

open position. The plurality of interlaced leaves 66 modulate the strength, size, and shape of the radiation beam 30 before the radiation beam 30 reaches the target 38 on the patient 14. Each of the leaves 66 is independently controlled by an actuator 70, such as a motor or an air valve so that the leaf 66 can open and close quickly to permit or block the passage of radiation. The actuators 70 can be controlled by a computer 74 and/or controller.

[0034] The radiation therapy treatment system 10 can also include a detector 78, e.g., a kilovoltage or a megavoltage detector, operable to receive the radiation beam 30. The linear accelerator 26 and the detector 78 can also operate as a computed tomography (CT) system to generate CT images of the patient 14. The linear accelerator 26 emits the radiation beam 30 toward the target 38 in the patient 14. The target 38 absorbs some of the radiation. The detector 78 detects or measures the amount of radiation absorbed by the target 38. The detector 78 collects the absorption data from different angles as the linear accelerator 26 rotates around and emits radiation toward the patient 14. The collected absorption data is transmitted to the computer 74 to process the absorption data and to generate images of the patient's body tissues and organs. The images can also illustrate bone, soft tissues, and blood vessels.

[0035] The CT images can be acquired with a radiation beam 30 that has a fan-shaped geometry, a multi-slice geometry or a cone-beam geometry. In addition, the CT images can be acquired with the linear accelerator 26 delivering megavoltage energies or kilovoltage energies. It is also noted that the acquired CT images can be registered with previously acquired CT images (from the radiation therapy treatment system 10 or other image acquisition devices, such as other CT scanners, MRI systems, and PET systems). For example, the previously acquired CT images for the patient 14 can include identified targets 38 made through a contouring process. The newly-acquired CT images for the patient 14 can be registered with the previously acquired CT images to assist in identifying the targets 38 in the new CT images. The registration process can use rigid or deformable registration tools.

[0036] In some embodiments, the radiation therapy treatment system 10 can include an x-ray source and a CT image detector. The x-ray source and the CT image detector operate in a similar manner as the linear accelerator 26 and the detector 78 as described above to acquire image data. The image data is transmitted to the computer 74 where it is processed to generate images of the patient's body tissues and organs.

[0037] The radiation therapy treatment system 10 can also include a patient support, such as a couch 82 (illustrated in FIG. 1), which supports the patient 14. The couch 82 moves along at least one axis 84 in the x, y, or z directions. In other embodiments of the invention, the patient support can be a device that is adapted to support any portion of the patient's body. The patient support is not limited to having to support the entire patient's body. The system 10 also can include a drive system 86 operable to manipulate the position of the couch 82. The drive system 86 can be controlled by the computer 74.

[0038] The computer 74, illustrated in FIGS. 2 and 3, includes an operating system for running various software programs and/or a communications application. In particular, the computer 74 can include a software program(s) 90 that operates to communicate with the radiation therapy treatment system 10. The software program(s) 90 is operable to receive data from external software programs and hardware and it is noted that data may be input to the software program(s) 90.

[0039] The computer 74 can include any suitable input/output device adapted to be accessed by medical personnel. The computer 74 can include typical hardware such as a processor, I/O interfaces, and storage devices or memory. The computer 74 can also include input devices such as a keyboard and a mouse. The computer 74 can further include standard output devices, such as a monitor. In addition, the computer 74 can include peripherals, such as a printer and a scanner.

[0040] The computer 74 can be networked with other computers 74 and radiation therapy treatment systems 10. The other computers 74 may include additional and/or different computer programs and software and are not required to be identical to the computer 74, described herein. The computers 74 and radiation therapy treatment system 10 can communicate with a network 94. The computers 74 and radiation therapy treatment systems 10 can also communicate with a database(s) 98 and a server(s) 102. It is noted that the software program(s) 90 could also reside on the server(s) 102.

[0041] The network 94 can be built according to any networking technology or topology or combinations of technologies and topologies and can include multiple sub-networks. Connections between the computers and systems shown in FIG. 3 can be made through local area networks ("LANs"), wide area networks ("WANs"), public switched telephone networks ("PSTNs"), wireless networks, Intranets, the Internet, or any other suitable networks. In a

hospital or medical care facility, communication between the computers and systems shown in FIG. 3 can be made through the Health Level Seven (“HL7”) protocol or other protocols with any version and/or other required protocol. HL7 is a standard protocol which specifies the implementation of interfaces between two computer applications (sender and receiver) from different vendors for electronic data exchange in health care environments. HL7 can allow health care institutions to exchange key sets of data from different application systems. Specifically, HL7 can define the data to be exchanged, the timing of the interchange, and the communication of errors to the application. The formats are generally generic in nature and can be configured to meet the needs of the applications involved.

[0042] Communication between the computers and systems shown in FIG. 3 can also occur through the Digital Imaging and Communications in Medicine (“DICOM”) protocol with any version and/or other required protocol. DICOM is an international communications standard developed by NEMA that defines the format used to transfer medical image-related data between different pieces of medical equipment. DICOM RT refers to the standards that are specific to radiation therapy data.

[0043] The two-way arrows in FIG. 3 generally represent two-way communication and information transfer between the network 94 and any one of the computers 74 and the systems 10 shown in FIG. 3. However, for some medical and computerized equipment, only one-way communication and information transfer may be necessary.

[0044] FIG. 4 is a schematic illustration of the software program 90. The software program 90 includes a plurality of modules that communicate with one another to perform functions of the radiation therapy treatment process.

[0045] The software program 90 includes a treatment plan module 106 operable to generate a treatment plan for the patient 14 based on data input to the system 10 by medical personnel. The data includes one or more images (e.g., planning images and/or pre-treatment images) of at least a portion of the patient 14. The treatment plan module 106 separates the treatment into a plurality of fractions and determines the radiation dose for each fraction or treatment based on the prescription input by medical personnel. The treatment plan module 106 also determines the radiation dose for the target 38 based on various contours drawn around the target 38. Multiple targets 38 may be present and included in the same treatment plan.

[0046] The software program 90 also includes a patient positioning module 110 operable to position and align the patient 14 with respect to the isocenter of the gantry 18 for a particular treatment fraction. While the patient is on the patient support 82, the patient positioning module 110 acquires an image of the patient 14 and compares the current position of the patient 14 to the position of the patient in a reference image. The reference image can be a planning image, any pre-treatment image, or a combination of a planning image and a pre-treatment image. If the patient's position needs to be adjusted, the patient positioning module 110 provides instructions to the drive system 86 to move the patient support 82 or the patient 14 can be manually moved to the new position. In one construction, the patient positioning module 110 can receive data from lasers positioned in the treatment room to provide patient position data with respect to the isocenter of the gantry 18. Based on the data from the lasers, the patient positioning module 110 provides instructions to the drive system 86, which moves the couch 82 to achieve proper alignment of the patient 14 with respect to the gantry 18. It is noted that devices and systems, other than lasers, can be used to provide data to the patient positioning module 110 to assist in the alignment process.

[0047] The patient positioning module 110 also is operable to detect and/or monitor patient motion during treatment. The patient positioning module 110 may communicate with and/or incorporate a motion detection system 114, such as x-ray, in-room CT, laser positioning devices, camera systems, spirometers, ultrasound, tensile measurements, chest bands, and the like. The patient motion can be irregular or unexpected, and does not need to follow a smooth or reproducible path.

[0048] The software program 90 can include an image module 118 operable to acquire images of at least a portion of the patient 14. The image module 118 can instruct the on-board image device, such as a CT imaging device to acquire images of the patient 14 before treatment commences, during treatment, and after treatment according to desired protocols. Other off-line imaging devices or systems may be used to acquire pre-treatment images of the patient 14, such as non-quantitative CT, MRI, PET, SPECT, ultrasound, transmission imaging, fluoroscopy, RF-based localization, and the like. The acquired pre-treatment image(s) can be used for registration of the patient 14 and/or to generate a deformation map to identify the differences between one or more of the planning images and one or more of the pre-treatment images.

[0049] The acquired images also can be used for registration of the patient 14 and/or to determine or predict a radiation dose to be delivered to the patient 14. The acquired images also can be used to determine a radiation dose that the patient 14 received during the prior treatments. The image module 118 also is operable to acquire images of at least a portion of the patient 14 while the patient is receiving treatment to determine a radiation dose that the patient 14 is receiving in real-time.

[0050] The software program 90 also includes a radiation dose calculation module 122 operable to calculate a radiation dose delivered to the patient 14. The dose calculation module 122 can determine the effect that the location and/or movement of the patient had on the delivery of the prescribed radiation dose. The dose calculation module 122 can calculate an amount of radiation dose delivered to the patient 14 or an amount of radiation that is going to be delivered to the patient 14 based on various types of plans. The dose calculation module 122 can calculate a radiation dose amount based on any plan at any instant of the plan. For example, the plan may be a prospective plan where medical personnel is reviewing dose options in order to determine which plan to use for delivery of treatment, or a retrospective plan where medical personnel is reviewing the dose amount delivered to the patient 14 and its effects in order to determine whether changes need to be made to the plan or a different plan(s) should be considered for future delivery of treatment. The types of plans can include, but are not limited to 4D, free-breathing, tracking, 3D, IMRT, gating, breathhold, and breathing synchronized delivery. "4D CT" images are a collection of 3D image volumes that each represent a "phase" of a motion pattern, such as breathing motion. The dose calculation module 122 can recalculate dose more accurately on one of these volumes.

[0051] The dose calculation module 122 is operable to receive patient data (real-time and historic), patient images (e.g., the planning images and/or the pre-treatment images), patient position data, anatomical position data, and system or machine data. The dose calculation module 122 can determine the amount of radiation dose that was delivered to the patient 14 by using data from the motion detection system 114 to identify the phase that the patient was in at any given time, and recalculating the radiation dose for each time in the phase of the 4D CT image that best matches the patient's instantaneous position. Stated differently, the dose calculation module 122 correlates the patient motion data with the image data and calculates a dose delivered. The dose delivered can be calculated phase-by-phase or can be calculated

as a cumulative dose delivered in all phases. Based on a better understanding of the amount of radiation dose that the patient is actually receiving, the medical personnel can make adjustments to the treatment plan, patient position/registration during treatment, dose amount, dose distribution, as well as other parameters and system settings. Dose calculations can also be performed on updated 4D CT images, as well as other types of 4D images, such as 4D PET or 4D MRI, that are acquired before or during treatment.

[0052] The dose calculation module 122 can provide information to the medical personnel related to the biological effect that the radiation dose has on the patient 14. The dose calculation module 122 can determine the biological effects of radiation on tissues, tumors, and organs based on the amount of radiation dose that the patient 14 has received and/or on the patient's registration. Based on the biological effects, the medical personnel can adjust the patient 14, the system settings, or make other adjustments in the treatment plan. The biological information can be incorporated in the patient registration process to identify a preferred position for the patient 14 that results in a delivered dose with a preferred biological effect.

[0053] The dose calculation module 122 can utilize data related to the radiation dose actually delivered and the biological effects of the radiation dose delivered and apply a biological model that relates the clinical radiation dose to the patient effect. The net radiation dose delivered (accumulation of radiation dose using deformation techniques) can be used to estimate the biological effect that would result from continuing the treatment, and likewise, possible alternatives for adapting the treatment can be evaluated for a preferred biological effect. The resulting fractionation schedule, dose distribution, and plans can be modified and/or updated to reflect this culmination of information.

[0054] The software program 90 also can include a deformation module 126 operable to receive data, such as image data from the image module 118 and the treatment planning module 106 and other patient and system data from the treatment plan module 106 to generate a deformation map of the images. The deformation module 126 can use deformation techniques to determine an accumulation of radiation dose for all of the delivered treatments.

[0055] A deformation map can be utilized to relate a plurality of images for dose calculation purposes. For example, a deformation map can relate a planning image that is

useful for dose calculation, and an on-line image, which has qualitative value but less direct utility for dose calculation. This relationship can then be used to “remap” the more quantitative image to the qualitative shape of the on-line or less quantitative image. The resulting remapped image would be more appropriate than either of the planning image or the on-line image for dose calculation or quantitative applications as it would have the quantitative benefits of the first image, but with the updated anatomical information as contained in the second image. This is useful in a variety of cases, such as where the first image (e.g., a planning image) is a CT image and where the second image lacks quantitative image values (e.g. MRI, PET, SPECT, ultrasound, or non-quantitative CT, etc. images). A deformation map also can relate a reference image, such as a 3D image (e.g., a planning image or a pre-treatment image), and a time-based series of images, such as a 4D CT image to determine an amount of radiation dose delivered to the patient 14.

[0056] The deformation module 126 can correct for geometrical distortion, imperfections, and/or incompleteness in lieu of, or in addition to, quantitative limitations. For example, a current MRI image that represents anatomy well but includes geometric distortion might be remapped to a CT image that is not distorted. Or, multiple images can be used to simultaneously correct for distortion while representing anatomical changes.

[0057] The deformation map can be used to calculate radiation dose on patient images acquired after the planning image. It is also useful to accumulate the doses for multiple delivered fractions. The doses can be added based upon the location of the doses in physical space, but another method is to incorporate deformation methods into the process so as to add doses based upon the structures that received the dose, even if the structures have changed location. The deformation module 126 can calculate the doses of radiation that the patient 14 has received from previously delivered fractions.

[0058] While the deformation process above was described in the context of registering one image to another image, it can also work with deformably registering a set of two or more images with another set of one or more images. For example, if there are two pairs of images, each pair comprising an MRI and a CT image, then the deformation map can register the two MRI images together in regions where the MRI has more information, and the CT images together where the CT has more information. These deformations could then be combined. Or deformation maps between the images could be used together, such as for using the CT deformation maps to correct for geometric distortion in the MRI images and



deformations, and then, having corrected that distortion, using the MRI deformation maps for better analysis of soft-tissue motion. In a general sense, this process enables imaging improvement via deformation, as poor images can be better understood, and therefore improved, by applying deformation techniques that indicate information like anatomical sizes, shapes, and content. It is also noted that a deformation map also can relate a reference image, such as a 3D image (e.g., a planning image or a pre-treatment image), and a time-based series of images, such as a 4D CT image to determine an amount of radiation dose delivered to the patient 14. This information can be incorporated into image reconstruction, modification, or enhancement processes.

[0059] The software program 90 also includes a treatment delivery module 130 operable to instruct the radiation therapy treatment system 10 to deliver the treatment plan to the patient 14 according to the treatment plan. The treatment delivery module 126 can generate and transmit instructions to the gantry 18, the linear accelerator 26, the modulation device 34, and the drive system 86 to deliver radiation to the patient 14. The instructions coordinate the necessary movements of the gantry 18, the modulation device 34, and the drive system 86 to deliver the radiation beam 30 to the proper target in the proper amount as specified in the treatment plan.

[0060] The treatment delivery module 130 also calculates the appropriate pattern, position, and intensity of the radiation beam 30 to be delivered, to match the prescription as specified by the treatment plan. The pattern of the radiation beam 30 is generated by the modulation device 34, and more particularly by movement of the plurality of leaves in the multi-leaf collimator. The treatment delivery module 130 can utilize canonical, predetermined or template leaf patterns to generate the appropriate pattern for the radiation beam 30 based on the treatment parameters.

[0061] FIG. 5 is a flow chart of a method of evaluating a radiation dose delivered to the patient 14. Medical personnel generate (at 200) a treatment plan for the patient 14 based on patient data, images, or other information. When the patient 14 is ready for a treatment, medical personnel position (at 204) the patient 14 on the couch 82 with the assistance of the patient positioning module 110 prior to delivery of treatment. An image of the patient 14 may be acquired to assist in the positioning. Additional positioning adjustments can be made as necessary. After the patient 14 is properly positioned, the image module 118 acquires (at 208) one or more images of the patient. The images can be a time-based series of images,

such as 4D CT images. The medical personnel initiates (at 212) delivery of the treatment plan. During delivery of the treatment plan, the motion detection system 114 monitors and collects (at 216) data relating to patient movement. The dose calculation module 126 evaluates (at 220) the radiation dose delivered to the patient 14 based on the images acquired prior to delivery of the radiation therapy treatment and the motion data.

[0062] FIG. 6 is a flow chart of another method of evaluating a radiation dose delivered to the patient 14. Medical personnel generate (at 250) a treatment plan for the patient 14 based on patient data, images, or other information. When the patient 14 is ready for a treatment, medical personnel position (at 254) the patient 14 on the patient support 82 with the assistance of the patient positioning module 110 prior to delivery of treatment. An image of the patient 14 may be acquired to assist in the positioning. Additional positioning adjustments can be made as necessary. The medical personnel initiates (at 258) delivery of the treatment plan. During treatment delivery, the image module 118 acquires (at 262) one or more images of the patient. The images can be a time-based series of images, such as 4D CT images. The dose calculation module 126 calculates (at 266) the radiation dose delivered to the patient 14 based on the images.

[0063] FIG. 7 is a flow chart of a method of evaluating a radiation dose delivered to the patient 14. Medical personnel generate (at 300) a treatment plan for the patient 14 based on patient data, images, or other information. The treatment plan includes a reference image, such as a planning image or a pre-treatment image. When the patient 14 is ready for a treatment, medical personnel position (at 304) the patient 14 on the patient support 82 with the assistance of the patient positioning module 110 prior to delivery of treatment. An image of the patient 14 may be acquired to assist in the positioning. Additional positioning adjustments can be made as necessary. After the patient 14 is properly positioned, the medical personnel initiates (at 308) delivery of the treatment plan. The image module 118 acquires (at 312) one or more images of the patient. The images can be a time-based series of images, such as 4D CT images. The deformation module 126 relates (at 316) the reference image to the newly-acquired image(s) using deformation. The dose calculation module 122 calculates (at 320) the radiation dose delivered to the patient 14 based on the image resulting from the deformation process.

[0064] FIG. 8 is a flow chart of a method of evaluating a radiation dose delivered to the patient 14. Medical personnel generate (at 350) a treatment plan for the patient 14 based on

patient data, images, or other information. The treatment plan can include an image, such as a time-based series of images or 4D CT images. Medical personnel retrieve (at 354) simulated or pre-existing motion data. The dose calculation module 126 evaluates (at 358) the radiation dose to be delivered to the patient 14 based on the time-based series of images and the motion data. When the patient 14 is ready for a treatment, medical personnel position (at 362) the patient 14 on the couch 82 with the assistance of the patient positioning module 110 prior to delivery of treatment. An image of the patient 14 may be acquired to assist in the positioning. Additional positioning adjustments can be made as necessary. After the patient 14 is properly positioned, the medical personnel initiates (at 366) delivery of the treatment plan.

[0065] One application of this invention is to correct for poor treatments that may result from poor planning or poor delivery of a treatment plan. The software program 90 can analyze the net dose delivered, and generate corrective plans to deliver the net desired radiation dose or a dose chosen to match the intended biological effect. The original treatments do not need to be limited to photon-based radiation therapy, but could be any form of treatment including brachytherapy, electron beam therapy, proton, neutron, or particle therapy, or other types of treatments.

[0066] Various features and advantages of the invention are set forth in the following claims.

## CLAIMS

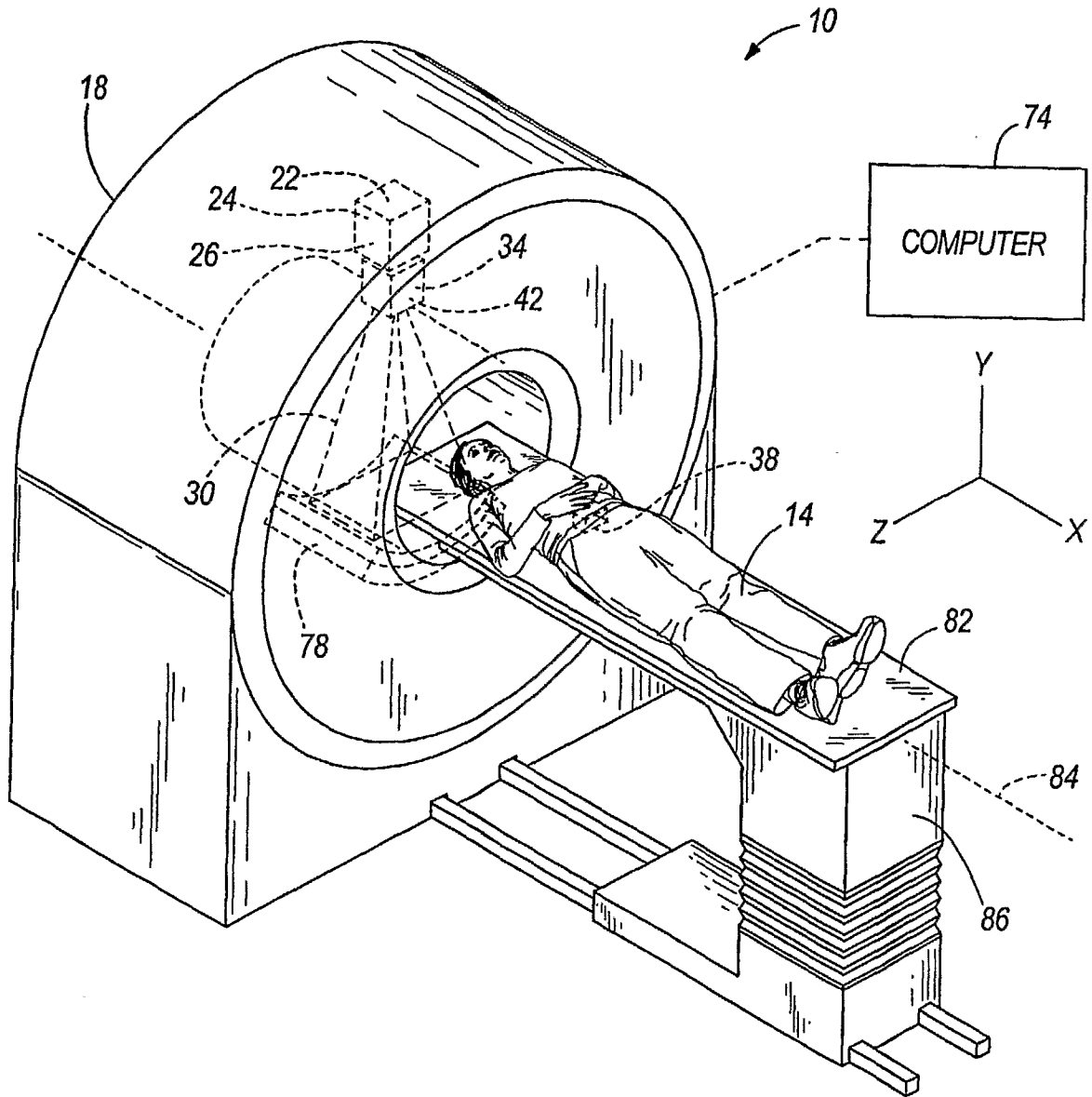
What is claimed is:

1. A method of evaluating a radiation dose delivered to a patient receiving radiation therapy, the method comprising:
  - generating a time-based series of patient images;
  - collecting a time-based series of data indicating patient motion; and
  - evaluating a radiation dose delivered to the patient based upon the time-based series of patient images and the time-based series of data.
2. A method as set forth in Claim 1 and further comprising correlating the patient motion data with the image data.
3. A method as set forth in Claim 1 wherein the series of patient images includes phases, and wherein the method further comprises the step of calculating the dose delivered in each phase.
4. A method as set forth in Claim 1 and further comprising calculating a cumulative dose delivered to the patient based on the series of images.
5. A method as set forth in Claim 4 and further comprising using deformable registration to relate the images.
6. A method as set forth in Claim 1 and further comprising acquiring data relating to clinical dose delivered and patient effects, and applying a biological model that relates the clinical dose to the patient effects.
7. A method as set forth in Claim 1 wherein the time-based series of the patient images is generated by one of 4D CT, 4D MRI, and 4D PET.
8. A method as set forth in Claim 1 wherein the time-based series of patient motion data originated from one of an on-board detector and an external device.

9. A method as set forth in Claim 8 wherein the external device is one of a camera, a spirometer, and a chest band.
10. A system for determining a radiation dose delivered to a patient, the system comprising:
  - a radiation therapy treatment device including a computer processor, the radiation therapy treatment device operable to deliver a treatment plan to a patient; and
  - a software program stored in a computer readable medium accessible by the computer processor, the software being operable to receive a time-based series of patient images, input a time-based series of data indicating patient motion, and evaluate a radiation dose delivered to the patient based upon the time-based series of patient images and the time-based series of data.
11. A system as set forth in Claim 10 further comprising a motion detection system, and wherein the motion detection system is operable to detect the motion of the patient and communicate with the computer processor.
12. A system as set forth in Claim 10 wherein the time-based series of images includes phases, and wherein the software program is further operable to evaluate the radiation dose delivered to the patient for each time in one or more phases of the image best representing the patient position.
13. A system as set forth in Claim 10 wherein the software program is operable to calculate a cumulative radiation dose delivered to the patient based on the series of images.
14. A system as set forth in Claim 13 wherein the software program is further operable to relate the series of images using deformable registration.

15. A method of evaluating a radiation dose delivered to a patient receiving radiation therapy, the method comprising:
  - generating a treatment plan for the patient;
  - initiating radiation therapy treatment according to the treatment plan;
  - generating 4D CT images of the patient during delivery of the radiation therapy treatment; and
  - calculating a radiation dose on each of the 4D CT images.
16. A method as set forth in Claim 15 wherein the 4D CT images includes phases, and wherein calculating the radiation dose of the 4D CT images includes calculating the radiation dose delivered in each phase.
17. A method as set forth in Claim 15 and further comprising calculating a cumulative dose delivered to the patient based on the 4D CT images.
18. A method as set forth in Claim 17 and further comprising using deformable registration to relate the 4D CT images.
19. A method of evaluating a radiation dose delivered to a patient receiving radiation therapy, the method comprising:
  - generating a treatment plan for the patient, the treatment plan including a reference image;
  - acquiring a 4D CT image from an imaging device positioned on a radiation therapy treatment system;
  - relating the reference image to the 4D CT image using deformation; and
  - calculating a radiation dose on the resulting 4D CT image.
20. A method as set forth in Claim 19 wherein the reference image is one of a planning image and a pre-treatment image.
21. A method as set forth in Claim 19 and further comprising acquiring patient motion data and correlating the patient motion data with the 4D CT image data.

22. A method as set forth in Claim 19 wherein the 4D CT images includes phases, and wherein calculating the radiation dose of the 4D CT images includes calculating the radiation dose delivered in each phase.
23. A method as set forth in Claim 19 and further comprising calculating a cumulative dose delivered to the patient based on the 4D CT image.
24. A method as set forth in Claim 23 and further comprising using deformable registration to relate the images.
25. A method as set forth in Claim 19 wherein the treatment plan can comprise a plurality of sub-plans.
26. A method as set forth in Claim 25 wherein the sub-plans are one of a prospective plan and a retrospective plan.
27. A method as set forth in Claim 25 wherein the sub-plans are one of a gating plan, a breathhold plan, a free-breathing plan, a three-dimensional plan, and a breathing synchronized delivery plan.
28. A method as set forth in Claim 19 and further comprising modifying the 4D CT image based at least in part on the combination of the deformation and the reference image.
29. A method as set forth in Claim 19 and further comprising modifying the reference image based upon the combination of the 4D CT image and the deformation.
30. A method of evaluating a radiation dose to be delivered to a patient, the method comprising:  
generating a time-based series of patient images;  
retrieving a simulated time-based series of data indicating patient motion; and  
evaluating a radiation dose that would be delivered to the patient based upon the time-based series of patient images and the simulated time-based series of data.



**FIG. 1**



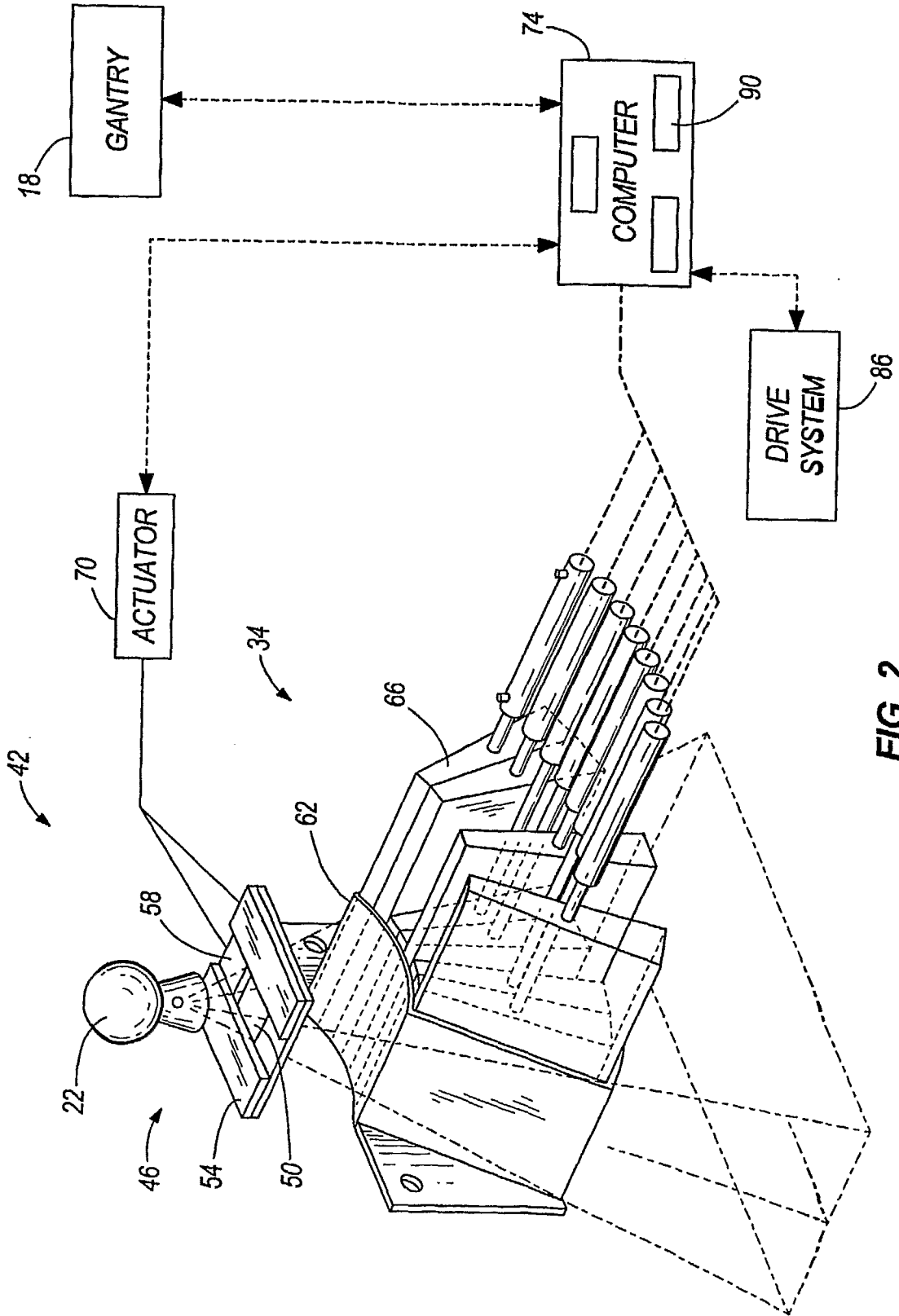


FIG. 2

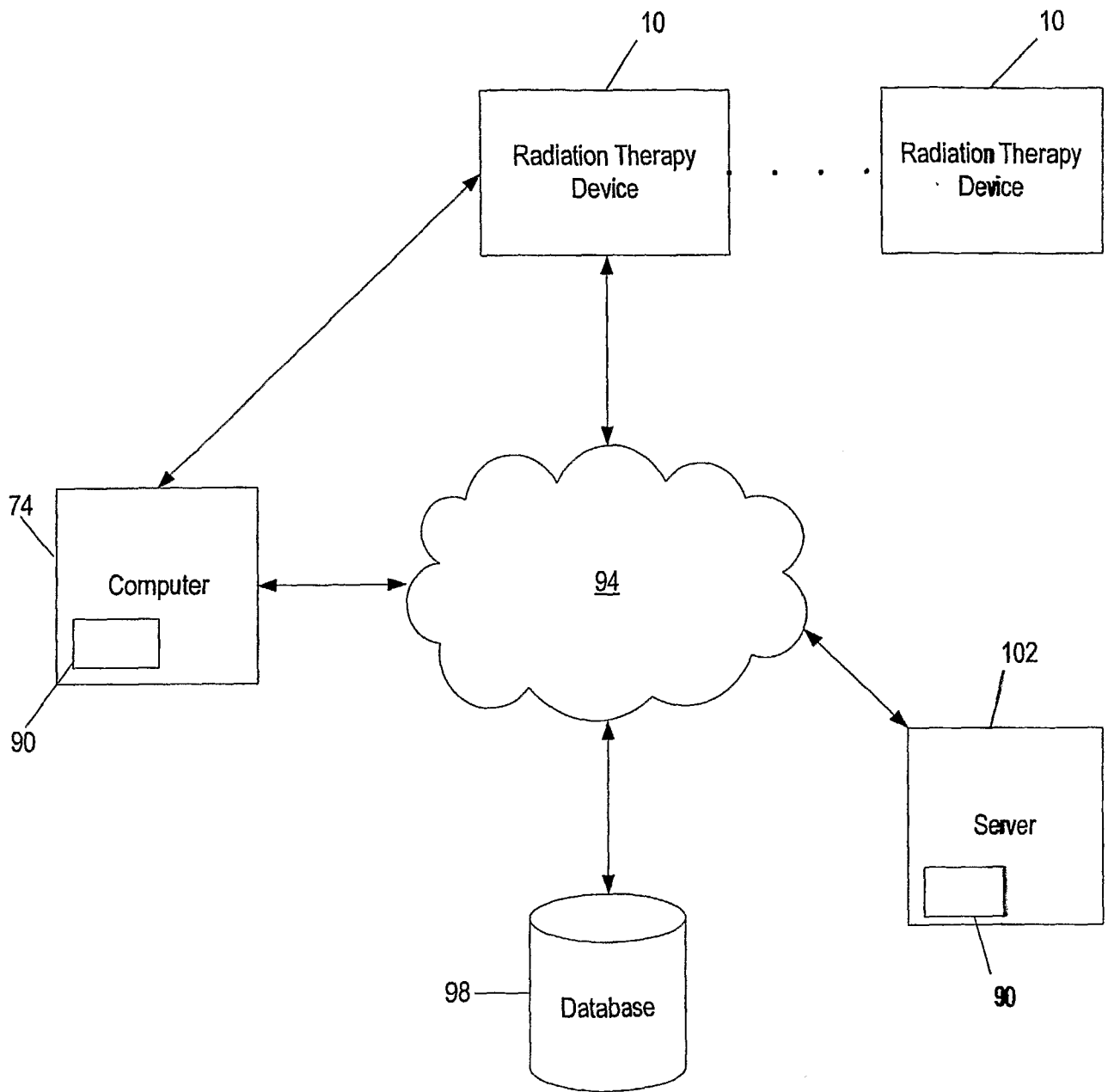


Fig. 3

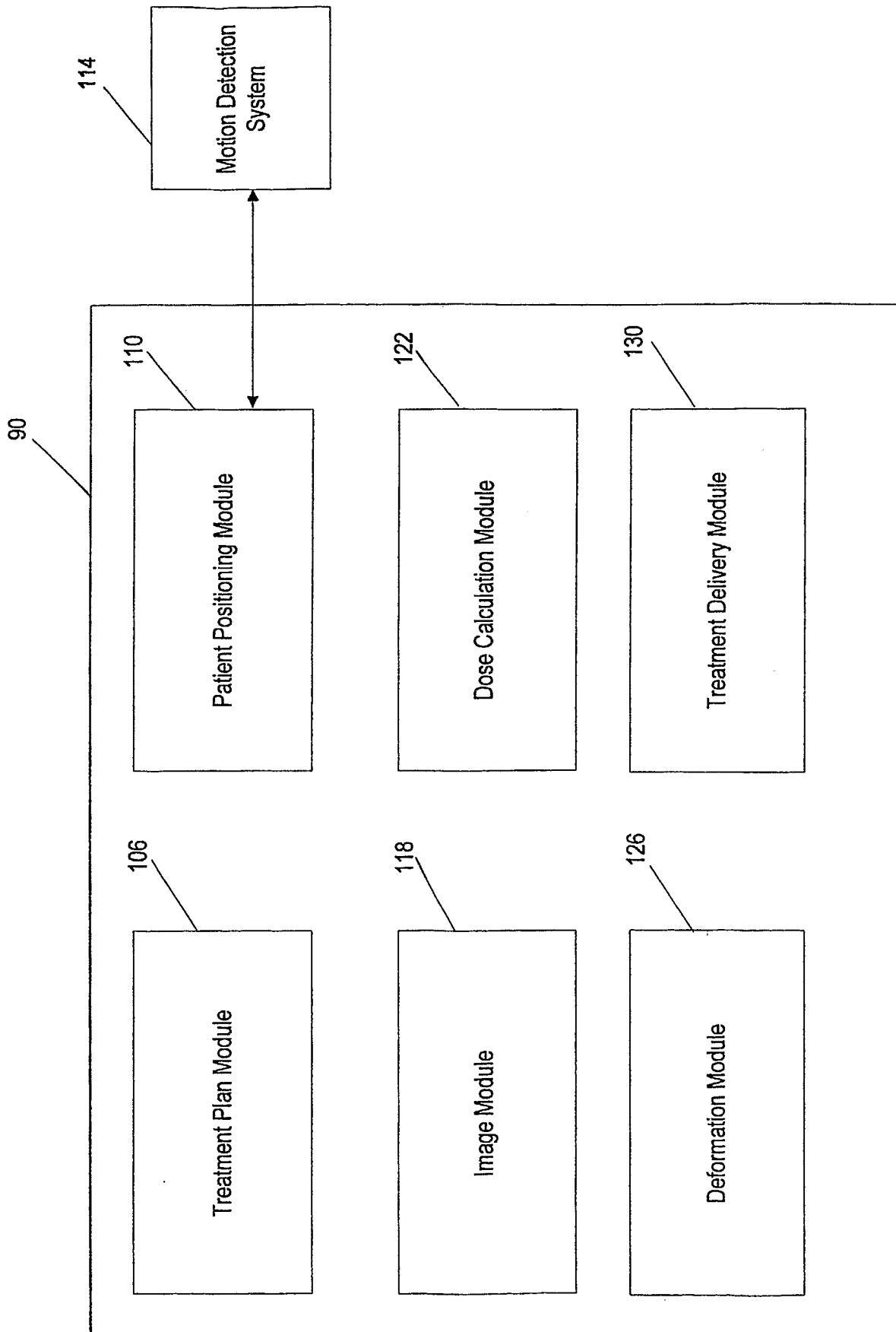


Fig. 4

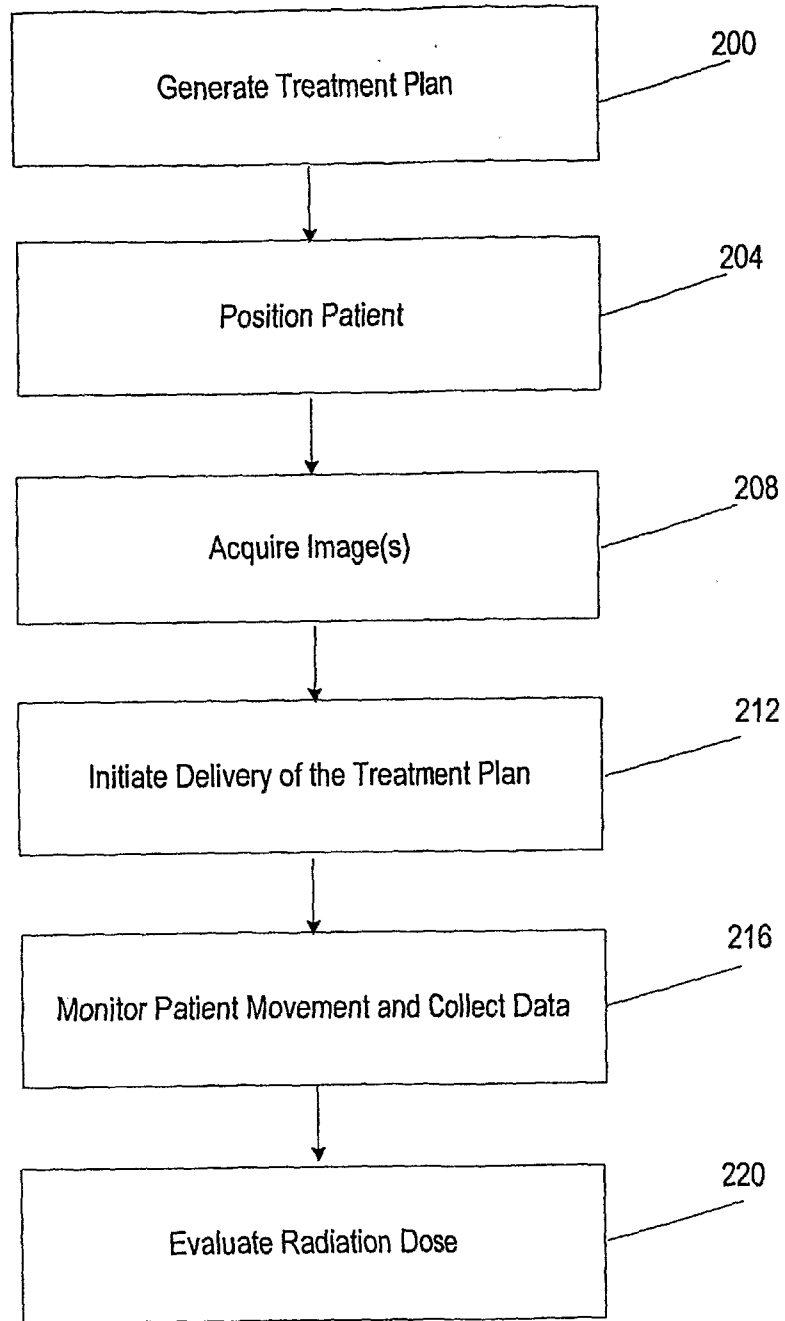
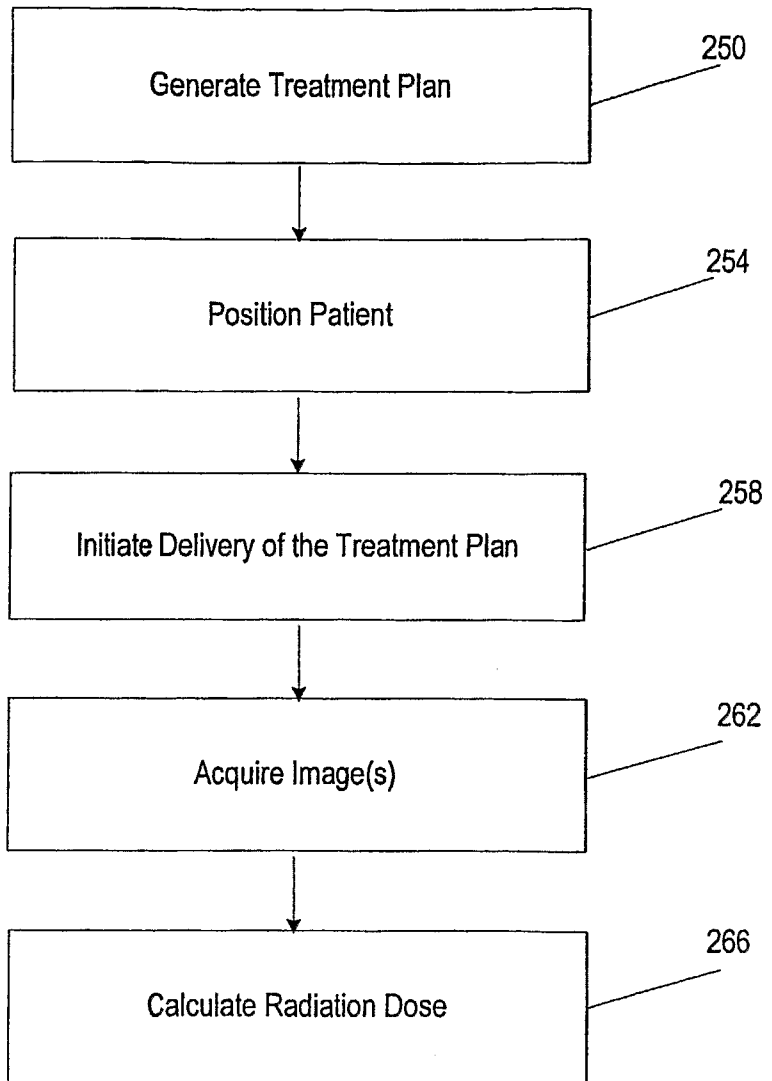


Fig. 5



**Fig. 6**

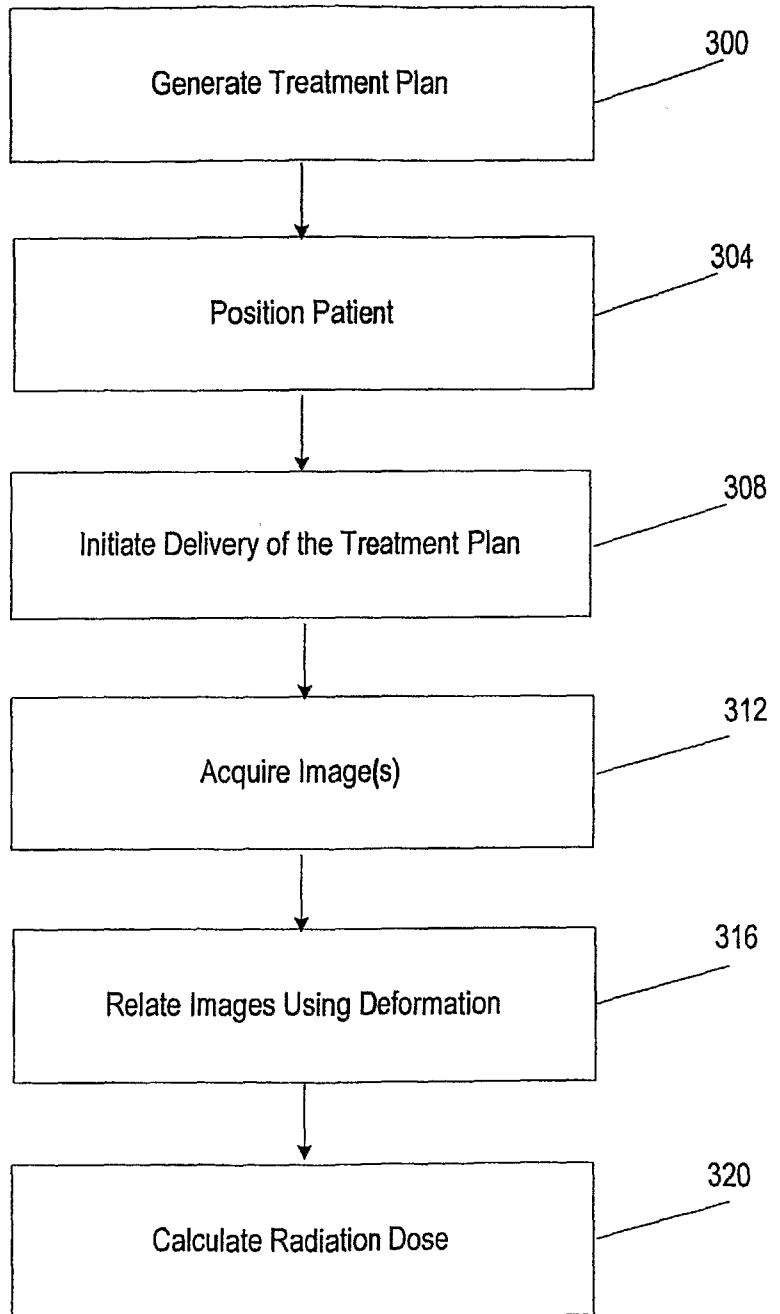
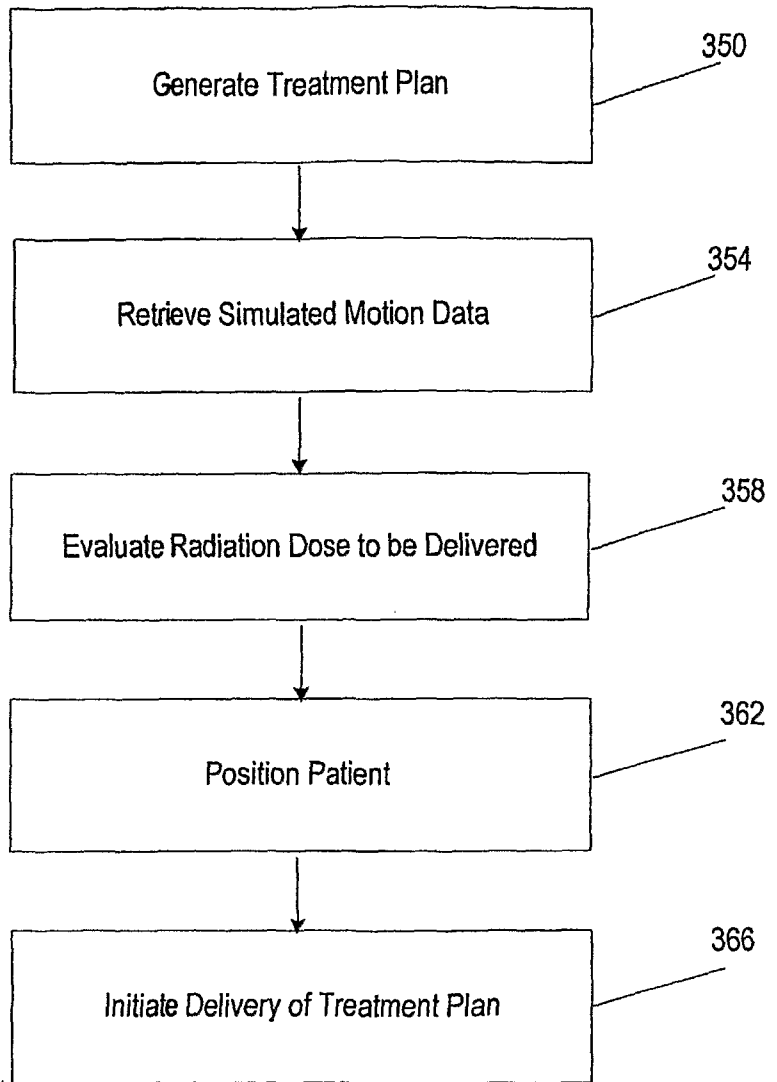


Fig. 7



**Fig. 8**