

Appendix T

Section 44: Anomaly Handling Procedure



ANOMALY HANDLING

SOP (b)(4)

REV (b)(4)

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APPROVAL

Business Process Owner: (b)(4)

Date: (b)(4)

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Section 20 Electromagnetic Compatibility and Electrical Safety

The Motion Tracking and Compensation Feature for use on the Radixact Treatment Delivery System does require EMC and electrical safety evaluation.

The performance of the device has been evaluated and tested for electrical safety and EMC compliance (b)(4) to the following standards:

- ANSI/AAMI ES60601-1: Electrical Safety of Medical Electrical Equipment
(Intertek Letter Report for Radixact with Motion Feature: (b)(4))
- IEC 60601-1-2: EMC for Medical Electrical Equipment
(60601-1-2 Radixact with Motion Feature EMC Report: (b)(4))

Note: The US National Differences from the IEC 60601-1 standard to the ANSI/AAMI ES60601-1 standard is covered on page 25 of the (b)(4) for Radixact Motion Feature (b)(4) included in Appendix V of this submission.

The performance of the device was self-evaluated for compliance to the following standards:

- IEC 60601-2-1: Particular Requirements for the Safety of Electron Accelerators
(60601-2-1 Compliance Memo for Radixact with Motion Feature: 30-Aug-2018)
- IEC 60601-1-3: Radiation Protection in Diagnostic X-ray Equipment
(60601-1-3 Radixact with Motion Feature Test Report: 08-23-2018)

A copy of the evidence documenting compliance with each of the above standards is provided in Appendix V. Additionally, a completed FDA Form 3654 for each of the standards identified above is located in Appendix U.



U.S. FOOD & DRUG
ADMINISTRATION

Accuray Incorporated
% Keith Picker
Senior Regulatory Affairs Specialist
1240 Deming Way
MADISON WI 53717

November 23, 2018

Re: K182687

Trade/Device Name: Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System

Regulation Number: 21 CFR 892.5050

Regulation Name: Medical charged-particle radiation therapy system

Regulatory Class: Class II

Product Code: IYE

Dated: September 25, 2018

Received: September 26, 2018

Dear Mr. Picker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in cursive script, appearing to read "Robert A. Ochs", is written over a large, faint, stylized "FDA" watermark.

Robert A. Ochs, Ph.D.

Director

Division of Radiological Health

Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

Enclosure

Appendix N

Section 38: Validation Test Plan

Accuray Incorporated

Part Number: (b)(4)

Revision: (b)(4)

Description: (b)(4)

(b)(4)



(b)(4)

Treatment Delivery System Motion Tracking and Compensation Feature Validation Test Plan

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K182687

Section 8 510(k) Summary

Submitter

Accuray Incorporated
1240 Deming Way
Madison, WI 53717
Phone: 608-824-3069
Fax: 608-830-3778

Contact: Keith Picker
Date Prepared: September 25, 2018

Device Identification

Device Name:	Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System
Trade & Brand Names:	Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System
Common Name:	Radiation Therapy System
Regulation Number:	21 CFR 892.5050
Regulation Name:	Medical charged-particle radiation therapy system
Regulatory Class:	Class II
Product Code:	IYE

Predicate Device

Radixact Treatment Delivery System (K161146)

Device Description

The Motion Tracking and Compensation Feature is designed for use with the predicate Radixact Treatment Delivery System last cleared on K161146. The Motion Tracking and Compensation Feature measures tumor location and motion using images provided by a kV imaging subsystem and predicts tumor location based upon a respiration amplitude measurement device. The Radixact Treatment Delivery System then compensates for tumor motion by making real-time adjustments.

The Radixact Treatment Delivery System is a radiation therapy delivery system that provides Image Guided Radiation Therapy (IGRT) using integral megavoltage CT imaging capabilities and delivers helical (rotational) and fixed-angle (non-rotational) radiation therapy to tumors and other targeted tissues.

Neither the Radixact Treatment Delivery System nor the Motion Tracking and Compensation Feature diagnose disease, recommend treatment regimens or quantify treatment effectiveness. Accordingly, they are not intended for diagnostic use.

Intended Use

The Motion Tracking and Compensation Feature is an option within the intended use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is intended to be used for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues. The megavoltage x-ray radiation is delivered using rotational, non-rotational, intensity modulated (IMRT), or non-modulated (non-IMRT/three dimensional conformal) treatment techniques and using image-guided (IGRT) or non-image-guided workflows in accordance with the physician approved plan.

Indications for Use

The Motion Tracking and Compensation Feature is an option within the indications for use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is indicated for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner.

The intended use and indications for use statements for the Motion Tracking and Compensation Feature (shown above) are the same as for the Radixact Treatment Delivery System (last cleared on K161146), except for the addition of the introductory sentence.

Technological Characteristics

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature has imaging and treatment capabilities equivalent to those of the predicate Radixact Treatment Delivery System. It also has a similar functionally-equivalent CT style gantry and patient couch.

The intended use and indications for use of the Motion Tracking and Compensation Feature fit within those of the predicate Radixact Treatment Delivery System. Additionally, the predicate and subject devices have substantially equivalent performance specifications and technological characteristics. Further, the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature and the predicate device employ the same fundamental scientific principles and have substantially equivalent principles of operation. The main difference between the predicate and the subject device is the use of the motion tracking and compensation feature. Where there are technological differences between the subject and predicate devices, those differences do not raise different questions of safety or effectiveness.

A substantial equivalence table comparing the similarities and differences between the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature and the predicate device is presented below. The minor differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

Device Comparison Table: Radixact Treatment Delivery System with Motion Tracking and Compensation Feature

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
System Description			
Intended Use	Omitted for brevity. Reference 510(k) Summary (Section 8 of 510(k) submission)	Same as predicate	Identical
Indications for Use	Omitted for brevity. Reference 510(k) Summary (Section 8 of 510(k) submission)	Same as predicate	Identical
System Configuration	Stand-alone radiation delivery system (does not include data management system or planning system)	Stand-alone radiation delivery system with kV imaging and motion tracking and compensation added (does not include data management system or planning system)	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not raise different issues of safety or effectiveness.
Vault (Treatment Room)			
Minimum Room Dimensions (H*W*L)	274 x 462 x 602 cm	274.3 x 463 x 602 cm	Substantially equivalent. Minor differences are negligible.
Device Dimensions (gantry and couch) (H*W*L)	255 x 280 x 473 cm	255 x 280 x 470.5 cm	Substantially equivalent. Minor differences are negligible.
Device Mass (kg)	6580 kg	6580 kg plus 235 kg for kV subsystem components	The weight added due to the kV subsystem does not result in different questions of safety or effectiveness.

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
Line Voltage	380 – 480 V _{ac} 3-Phase	Same as predicate	Identical
Ambient Room Temperature	20 – 24 °C	Same as predicate	Identical
Relative Humidity (non-condensing)	30 – 60 %	Same as predicate	Identical
Gantry Mechanical Features			
Bore Diameter	85 cm	Same as predicate	Identical
Degrees of Rotation	Continuous rotation around Y- axis (axes per IEC 61217)	Same as predicate	Identical
Direction of Rotation	Clockwise (as viewed from the foot of the couch)	Same as predicate	Identical
Rotational Speed (Treatment)	1 – 5 RPM	Same as predicate	Identical
Rotational Speed (Imaging)	10 RPM	Same as predicate	Identical
Couch Support in Bore	Provided	Same as predicate	Identical
Radiation Delivery Modes			
Description	Helical, Direct	Same as predicate	Identical
Photon Beam			
Accelerator Type	Standing wave	Same as predicate	Identical
RF Source	Magnetron	Same as predicate	Identical
Nominal Energy	6 MV	Same as predicate	Identical
Fixed Field Size	1.0 cm x 40 cm 2.5 cm x 40 cm 5.0 cm x 40 cm	Same as predicate	Identical
Dynamic Field Size	1.0 – 2.5 cm x 40 cm 1.0 – 5.0 cm x 40 cm	Same as predicate	Identical
Dose Rate	850 cGy/min standard 1000 cGy/min optional	Same as predicate	Identical
Collimation			
Description	Primary collimation, jaws and multi-leaf	Primary collimation, jaws and multi-leaf collimator	Substantially equivalent. Jaws have

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
	collimator		a new dynamic behavior for motion managed plans. Jaws will continually be adjusted to repoint the beam at the moving target (in IEC-Y) while maintaining the same field size.
MVCT Imaging			
Source	Megavoltage Computed Tomography (MVCT)	Same as predicate	Identical
Field of View (MVCT)	39 cm diameter	Same as predicate	Identical
Dose per MVCT Image (typical)	0.5 – 3.0 cGy	Same as predicate	Identical
Slice Spacing (MVCT)	1, 2, 3, 4 and 6 mm reconstruction intervals	Same as predicate	Identical
Spatial Resolution (MVCT)	1.6 mm	Same as predicate	Identical
kV Imaging			
Source	Feature not present	50-150 kV Radiography Class I (60601-2-28) X-ray tube assembly	The kV Imaging subsystem provides two-dimensional low-dose radiographic images used for patient alignment and measurement of tumor motion during treatment delivery. The functionality is provided by hardware and driver software. A kV radiograph can be performed at any arbitrary angle. A stable calibration from
Field of View	Feature not present	20 cm x 20 cm	
Spatial Resolution (kV)	Feature not present	< 1 mm	
Approximate Dose per kV x-ray image (range)	Feature not present	0.08 – 0.20 mGy	
Small Focal Spot Size	Feature not present	0.6 mm x 0.6 mm	
Large Focus Spot Size	Feature not present	1.0 mm x 1.0 mm	
Current Range (mA)	Feature not present	5 - 500 mA	

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
			the kV Imaging coordinate system to the machine coordinate system is made during configuration of the TDS. The new kV imaging components meet applicable safety requirements in the IEC 60601 series.
Motion Management			
Tracking Algorithm	Not present	Radixact Motion Tracking	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature is based on the core tracking algorithm introduced in K120233, Synchrony Respiratory Tracking System.
Compensation Algorithm	Not present	Radixact Motion Compensation	The compensation algorithm uses the jaws and MLC to effectively repoint the beam to accommodate for motion in a method substantially equivalent to K120233, Synchrony Respiratory Tracking System. Does not result in different questions of safety or effectiveness.
Synchrony Camera	Not present	Radixact Synchrony Motion Tracking	Substantially equivalent. The Synchrony camera has

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
			been in use for over ten years and was included most recently in K120233, Synchrony Respiratory Tracking System.
Laser System			
Stationary	Green lasers identify virtual and actual isocenter	Substantially equivalent	Minor differences are negligible and do not result in different questions of safety or effectiveness.
Moveable (for patient positioning and registration)	Red lasers identify offset from virtual isocenter	Substantially equivalent	Minor differences are negligible and do not result in different questions of safety or effectiveness.
Patient Couch			
Motion	Independent of each of the other axes	Independent of each of the other axes	Identical
Biocompatibility			
Couch Top	Carbon-fiber top	Carbon-fiber top	Identical
Synchrony Vest	Not Used	Same vest cleared under K120233, Synchrony Respiratory Tracking System	No new biocompatibility issues
Power Distribution			
Isolation	Transformer	Transformer	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature did not introduce changes to this subsystem.
UPS for Data Back-up	Provided	Provided	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
			did not introduce changes to this design
Operator Station (Treatment Delivery Console)			
Description	User interface to system functions (i.e., patient and procedure selection, and procedure delivery)	User interface to system functions (i.e., patient and procedure selection, and procedure delivery)	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not modify this architecture.
Machine Control Software			
Description	Controls radiation delivery and positioning systems (referred to as the ECS – Embedded Controls Subsystem)	Controls radiation delivery and positioning systems (referred to as the ECS – Embedded Controls Subsystem)	Substantially equivalent. The Motion Tracking and Compensation functionality was added to the existing design. No different issues of safety or effectiveness.
Data Interfaces Operator Station	Provides measurements and status during operation	Provides measurements and status during operation	Substantially equivalent. The Motion Tracking and Compensation functionality was added to the existing design. No different issues of safety or effectiveness.
Database			
Description	External database used for gathering operational data and storage of procedure data	External database used for gathering operational data and storage of procedure data	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not modify this design outside of accommodating for more data.

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
Safety Features			
Interlock Subsystems	Present	Present	Substantially equivalent. kV subsystem integrated into the Safety Interlocks. No different issues of safety or effectiveness.
Data integrity checking	Present	Present	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not modify this design.

Performance Data

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature was tested and shown to comply with the requirements of applicable FDA recognized consensus safety standards for radiation therapy equipment. Results of verification and validation testing confirm that the use of the Motion Tracking and Compensation Feature on the Radixact Treatment Delivery System conforms to design specifications and meets the needs of the intended users.

No animal or clinical tests were required to establish substantial equivalence with the predicate device. The performance data demonstrate that the Motion Tracking and Compensation Feature is compatible with the Radixact Treatment Delivery System, and the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is as safe and effective and performs as well as the predicate device. Further, these test results demonstrate that the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature has substantially equivalent safety and performance characteristics in comparison to the predicate device.

Conclusion

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is substantially equivalent to the predicate device. The intended use and indications for use of the Motion Tracking and Compensation Feature fit within those of the predicate Radixact Treatment Delivery System. Additionally, the major technological characteristics and the principles of operation of the Radixact Treatment

Delivery System with the use of the Motion Tracking and Compensation Feature are substantially equivalent to those of the predicate device. Minor differences do not raise different questions of safety and effectiveness of the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature in comparison to the predicate device. Further, the performance data demonstrate that the Motion Tracking and Compensation Feature is compatible with the Radixact Treatment Delivery System, and the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is as safe and effective and performs as well as the predicate device. Therefore, the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is substantially equivalent to the predicate device.

Indications for Use

510(k) Number (if known)
K182687

Device Name
Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System

Indications for Use (Describe)

The Motion Tracking and Compensation Feature is an option within the indications for use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is indicated for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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PRASStaff@fda.hhs.gov

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Precise, innovative tumor treatments™

September 25, 2018

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) -- WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

RE: Traditional 510(k) Premarket Notification Submission
Motion Tracking and Compensation for the Radixact Treatment Delivery System
Medical Device User Fee Payment Identification Number (b)(4)

Dear Sir or Madam:

Accuray Incorporated is submitting a Traditional 510(k) Premarket Notification for a Motion Tracking and Compensation Feature to be used on the Radixact Treatment Delivery System. Accuray Incorporated is submitting this 510(k) in accordance with 21 CFR Part 807, Subpart E -- Premarket Notification Procedures and FDA's guidance on "How To Market Your Device". There were no prior submissions for this new feature.

For your reference, the FDA Establishment Registration Number for our manufacturing facility is 3003873069.

A paper copy and an electronic copy (eCopy) are being provided with this submission in accordance with the instructions found in the FDA guidance document entitled "eCopy Program for Medical Device Submissions", issued on December 3, 2015. The eCopy is an exact duplicate of the paper copy.

Based upon device characteristics, indications for use and the predicate device, Accuray Incorporated suggests that the Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System be classified by the Radiology review panel as a Class II medical device under regulation number 21 CFR 892.5050 (medical charged-particle radiation therapy system) with a product code IYE.

The Motion Tracking and Compensation Feature is designed for use with the predicate Radixact Treatment Delivery System last cleared on K161146. The Motion Tracking and Compensation Feature measures tumor location and motion using images provided by a kV imaging subsystem and predicts tumor location based upon a respiration amplitude measurement device. The Radixact Treatment Delivery System then compensates for tumor motion by making real-time adjustments.

Neither the Radixact Treatment Delivery System nor the Motion Tracking and Compensation Feature diagnose disease, recommend treatment regimens or quantify treatment effectiveness. Accordingly, they are not intended for diagnostic use.

1209 Deming Way Madison WI 53717 Tel: 608.824.2800 Fax: 608.824.2996 www accuray.com

The Motion Tracking and Compensation Feature is an option within the intended use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is intended to be used for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues. The megavoltage x-ray radiation is delivered using rotational, non-rotational, intensity modulated (IMRT), or non-modulated (non-IMRT/three dimensional conformal) treatment techniques and using image-guided (IGRT) or non-image-guided workflows in accordance with the physician approved plan.

The Motion Tracking and Compensation Feature is an option within the indications for use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is indicated for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner.

The intended use and indications for use statements for the Motion Tracking and Compensation Feature (shown above) are the same as for the Radixact Treatment Delivery System (last cleared on K161146), except for the addition of the introductory sentence.

Some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61, and therefore not disclosable under the Freedom of Information Act even after the existence of this application becomes public. We ask that you consult with Accuray Incorporated as provided in 21 C.F.R. § 20.47 before making any part of this submission publicly available.

The principle factors concerning the design and use of the Motion Tracking and Compensation Feature are summarized in the following table:

Design and Use of the Device

Question	Yes	No
Intended for prescription use (21 CFR 801 Subpart D)	X	
Intended for over-the-counter use (21 CFR 807 Subpart C)		X
Contains components derived from a tissue or other biologic source		X
Provided sterile		X
Intended for single use		X
A reprocessed single use device		X
require reprocessed validation data		X
Contains a drug		X
Contains a biologic		X
Uses software	X	
Submission includes clinical information		X
Device is implanted		X

All other required cover letter information is included in the CDRH Premarket Review Submission Cover Sheet (FDA 3514) located in Section 4 of this premarket submission.

If you have questions regarding this 510(k) premarket submission or require additional information, please contact me using the following contact information:

Keith Picker
Senior Regulatory Affairs Specialist
Accuray Incorporated
1240 Deming Way
Madison, WI 53717
Phone: 608-824-3069
Fax: 608-830-3778
Email: kpicker@accuray.com

Sincerely,

(b)(6)

Keith Picker
Senior Regulatory Affairs Specialist

cc: Michael S. Preto, Regulatory Affairs Program Manager, Accuray Incorporated
Daniel Biank, Vice President Regulatory Affairs, Accuray Incorporated

Appendix J

Section 34: Medical Device Risk Management Procedure



MEDICAL DEVICE RISK MANAGEMENT

SOP (b)(4)

REV (b)(4)

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APPROVAL

Dept. Manager: (b)(4)

Date: (b)(4)

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Appendix P

Section 40: Unit Test Plan

ACCURAY INCORPORATED

Item Number:

Page 1 of 7

Revision: (b)(4)

(b)(4)

Description: (b)(4)



**(b)(4) TREATMENT DELIVERY SYSTEM
MOTION TRACKING AND COMPENSATION
FEATURE
EMBEDED CONTROL SYSTEM SOFTWARE
UNIT TEST PLAN**

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Section 15 Substantial Equivalence

15.1 Predicate Device

Trade Name: Radixact Treatment Delivery System

510(k) Number: K161146

510(k) Holder: Accuray Incorporated

15.2 General Discussion

The predicate device for the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is the Radixact Treatment Delivery System (last cleared on K161146). The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is substantially equivalent to the predicate device, in accordance with the FDA guidance document entitled “Evaluating Substantial Equivalence in Premarket Notifications [510(k)]”, issued on July 28, 2014.

As explained in more detail below, the intended use and indications for use of the Motion Tracking and Compensation Feature fit within those of the predicate Radixact Treatment Delivery System. Additionally, the devices have substantially equivalent performance specifications and technological characteristics. Further, the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature and the predicate device employ the same fundamental scientific principles and have substantially equivalent principles of operation. The main difference between the predicate and the subject device is the use of the motion tracking and compensation feature. Where there are technological differences between the subject and predicate devices, those differences do not raise different questions of safety or effectiveness. Further, performance testing demonstrates that the Motion Tracking and Compensation Feature is compatible with the Radixact Treatment Delivery System, and the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is as safe and effective and performs as well as the predicate device.

A substantial equivalence table comparing the similarities and differences between the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature and the predicate device is provided in the Technological Characteristics and Principles of Operation subsection below. The minor differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

15.3 Intended Use / Indications for Use

The intended use and indications for use of the Motion Tracking and Compensation Feature fit within those of the predicate Radixact Treatment Delivery System. Further, the intended use and indications for use of the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature are identical to those of the predicate device.

15.4 Technological Characteristics and Principles of Operation

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature has imaging and treatment capabilities equivalent to those of the predicate Radixact Treatment Delivery System. It also has a similar functionally-equivalent CT style gantry and patient couch. The subject device introduces the kV imaging with motion tracking and compensation.

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature and the predicate device employ the same fundamental scientific principles and have substantially equivalent technological characteristics and principles of operation. For further discussion, please see the Device Description in Section 14 of this 510(k) submission.

A table comparing the predicate cleared on K161146 and the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is presented below:

Device Comparison Table: Radixact Treatment Delivery System with Motion Tracking and Compensation Feature

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
System Description			
Intended Use	Omitted for brevity. Reference 510(k) Summary (Section 8 of 510(k) submission)	Same as predicate	Identical
Indications for Use	Omitted for brevity. Reference 510(k) Summary (Section 8 of 510(k) submission)	Same as predicate	Identical
System Configuration	Stand-alone radiation delivery system (does not include data management system or planning system)	Stand-alone radiation delivery system with kV imaging and motion tracking and compensation added (does not include data management system or planning system)	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not raise different issues of safety or effectiveness.
Vault (Treatment Room)			
Minimum Room Dimensions (H*W*L)	274 x 462 x 602 cm	274.3 x 463 x 602 cm	Substantially equivalent. Minor differences are negligible.

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
Device Dimensions (gantry and couch) (H*W*L)	255 x 280 x 473 cm	255 x 280 x 470.5 cm	Substantially equivalent. Minor differences are negligible.
Device Mass (kg)	6580 kg	6580 kg plus 235 kg for kV subsystem components	The weight added due to the kV subsystem does not result in different questions of safety or effectiveness.
Line Voltage	380 – 480 V _{ac} 3-Phase	Same as predicate	Identical
Ambient Room Temperature	20 – 24 °C	Same as predicate	Identical
Relative Humidity (non-condensing)	30 – 60 %	Same as predicate	Identical
Gantry Mechanical Features			
Bore Diameter	85 cm	Same as predicate	Identical
Degrees of Rotation	Continuous rotation around Y- axis (axes per IEC 61217)	Same as predicate	Identical
Direction of Rotation	Clockwise (as viewed from the foot of the couch)	Same as predicate	Identical
Rotational Speed (Treatment)	1 – 5 RPM	Same as predicate	Identical
Rotational Speed (Imaging)	10 RPM	Same as predicate	Identical
Couch Support in Bore	Provided	Same as predicate	Identical
Radiation Delivery Modes			
Description	Helical, Direct	Same as predicate	Identical
Photon Beam			
Accelerator Type	Standing wave	Same as predicate	Identical
RF Source	Magnetron	Same as predicate	Identical
Nominal Energy	6 MV	Same as predicate	Identical
Fixed Field Size	1.0 cm x 40 cm 2.5 cm x 40 cm 5.0 cm x 40 cm	Same as predicate	Identical
Dynamic Field Size	1.0 – 2.5 cm x 40 cm 1.0 – 5.0 cm x 40 cm	Same as predicate	Identical

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
Dose Rate	850 cGy/min standard 1000 cGy/min optional	Same as predicate	Identical
Collimation			
Description	Primary collimation, jaws and multi-leaf collimator	Primary collimation, jaws and multi-leaf collimator	Substantially equivalent. Jaws have a new dynamic behavior for motion managed plans. Jaws will continually be adjusted to repoint the beam at the moving target (in IEC-Y) while maintaining the same field size.
MVCT Imaging			
Source	Megavoltage Computed Tomography (MVCT)	Same as predicate	Identical
Field of View (MVCT)	39 cm diameter	Same as predicate	Identical
Dose per MVCT Image (typical)	0.5 – 3.0 cGy	Same as predicate	Identical
Slice Spacing (MVCT)	1, 2, 3, 4 and 6 mm reconstruction intervals	Same as predicate	Identical
Spatial Resolution (MVCT)	1.6 mm	Same as predicate	Identical
kV Imaging			
Source	Feature not present	50-150 kV Radiography Class I (60601-2-28) X-ray tube assembly	The kV Imaging subsystem provides two-dimensional low- dose radiographic images used for patient alignment and measurement of tumor motion during treatment delivery.
Field of View	Feature not present	20 cm x 20 cm	
Spatial Resolution (kV)	Feature not present	< 1 mm	
Approximate Dose per kV x-ray image (range)	Feature not present	0.08 – 0.20 mGy	
Small Focal Spot	Feature not present	0.6 mm x 0.6 mm	

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
Size			The functionality is provided by hardware and driver software. A kV radiograph can be performed at any arbitrary angle. A stable calibration from the kV Imaging coordinate system to the machine coordinate system is made during configuration of the TDS. The new kV imaging components meet applicable safety requirements in the IEC 60601 series.
Large Focus Spot Size	Feature not present	1.0 mm x 1.0 mm	
Current Range (mA)	Feature not present	5 - 500 mA	
Motion Management			
Tracking Algorithm	Not present	Radixact Motion Tracking	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature is based on the core tracking algorithm introduced in K120233, Synchrony Respiratory Tracking System.
Compensation Algorithm	Not present	Radixact Motion Compensation	The compensation algorithm uses the jaws and MLC to effectively repoint the beam to accommodate for motion in a method substantially equivalent to K120233, Synchrony Respiratory Tracking System.

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
			Does not result in different questions of safety or effectiveness.
Synchrony Camera	Not present	Radixact Synchrony Motion Tracking	Substantially equivalent. The Synchrony camera has been in use for over ten years and was included most recently in K120233, Synchrony Respiratory Tracking System.
Laser System			
Stationary	Green lasers identify virtual and actual isocenter	Substantially equivalent	Minor differences are negligible and do not result in different questions of safety or effectiveness.
Moveable (for patient positioning and registration)	Red lasers identify offset from virtual isocenter	Substantially equivalent	Minor differences are negligible and do not result in different questions of safety or effectiveness.
Patient Couch			
Motion	Independent of each of the other axes	Independent of each of the other axes	Identical
Biocompatibility			
Couch Top	Carbon-fiber top	Carbon-fiber top	Identical
Synchrony Vest	Not Used	Same vest cleared under K120233, Synchrony Respiratory Tracking System	No new biocompatibility issues
Power Distribution			
Isolation	Transformer	Transformer	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature did not introduce changes to this subsystem.

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
UPS for Data Back-up	Provided	Provided	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature did not introduce changes to this design
Operator Station (Treatment Delivery Console)			
Description	User interface to system functions (i.e., patient and procedure selection, and procedure delivery)	User interface to system functions (i.e., patient and procedure selection, and procedure delivery)	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not modify this architecture.
Machine Control Software			
Description	Controls radiation delivery and positioning systems (referred to as the ECS – Embedded Controls Subsystem)	Controls radiation delivery and positioning systems (referred to as the ECS – Embedded Controls Subsystem)	Substantially equivalent. The Motion Tracking and Compensation functionality was added to the existing design. No different issues of safety or effectiveness.
Data Interfaces Operator Station	Provides measurements and status during operation	Provides measurements and status during operation	Substantially equivalent. The Motion Tracking and Compensation functionality was added to the existing design. No different issues of safety or effectiveness.
Database			
Description	External database used for gathering operational data and storage of procedure data	External database used for gathering operational data and storage of procedure data	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not modify this design outside of

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
			accommodating for more data.
Safety Features			
Interlock Subsystems	Present	Present	Substantially equivalent. kV subsystem integrated into the Safety Interlocks. No different issues of safety or effectiveness.
Data integrity checking	Present	Present	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not modify this design.

15.5 Performance Data

Performance test data demonstrate that the Motion Tracking and Compensation Feature is compatible with the Radixact Treatment Delivery System, and the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is as safe and effective and performs as well as the predicate device. Supporting evidence is provided in Sections 19 and 21 of this 510(k) submission, as well as the following documents:

- Verification Test Plan (Appendix L)
- Verification Test Report (Appendix M)
- Validation Test Plan (Appendix N)
- Validation Test Report (Appendix O)

15.6 Conclusion

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is substantially equivalent to the predicate device. The intended use and indications for use of the Motion Tracking and Compensation Feature fit within those of the predicate Radixact Treatment Delivery System. Additionally, the major technological characteristics and the principles of operation of the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature are substantially equivalent to those of the predicate device. Minor differences do not raise different questions of safety and effectiveness of the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature in comparison to the predicate device. Further, the performance data demonstrate that the Motion Tracking and Compensation Feature is compatible with the

Radixact Treatment Delivery System, and the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is as safe and effective and performs as well as the predicate device. Therefore, the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is substantially equivalent to the predicate device.

October 2, 2018</br></br>

Acceptance Review Notification - Accepted

<p>An administrative acceptance review was conducted on your premarket notification (510(k)) K182687, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Nancy Wersto.</p>

<p>*** This is a system-generated email notification ***</p>

Section 13 Executive Summary

13.1 Device Description

The Motion Tracking and Compensation Feature is designed for use with the predicate Radixact Treatment Delivery System last cleared on K161146. The Motion Tracking and Compensation Feature measures tumor location and motion using images provided by a kV imaging subsystem and predicts tumor location based upon a respiration amplitude measurement device. The Radixact Treatment Delivery System then compensates for tumor motion by making real-time adjustments.

The Radixact Treatment Delivery System is a radiation therapy delivery system that provides Image Guided Radiation Therapy (IGRT) using integral megavoltage CT imaging capabilities and delivers helical (rotational) and fixed-angle (non-rotational) radiation therapy to tumors and other targeted tissues.

Neither the Radixact Treatment Delivery System nor the Motion Tracking and Compensation Feature diagnose disease, recommend treatment regimens or quantify treatment effectiveness. Accordingly, they are not intended for diagnostic use.

13.2 Intended Use

The Motion Tracking and Compensation Feature is an option within the intended use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is intended to be used for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues. The megavoltage x-ray radiation is delivered using rotational, non-rotational, intensity modulated (IMRT), or non-modulated (non-IMRT/three dimensional conformal) treatment techniques and using image-guided (IGRT) or non-image-guided workflows in accordance with the physician approved plan.

13.3 Indications for Use

The Motion Tracking and Compensation Feature is an option within the indications for use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is indicated for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner.

The intended use and indications for use statements for the Motion Tracking and Compensation Feature (shown above) are the same as for the Radixact Treatment Delivery System (last cleared on K161146), except for the addition of the introductory sentence.

13.4 Predicate Device Comparison

The predicate device for the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is the Radixact Treatment Delivery System (last cleared on K161146). The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is substantially equivalent to the predicate device, in accordance with the FDA guidance document entitled “Evaluating Substantial Equivalence in Premarket Notifications [510(k)]”.

The intended use and indications for use of the Motion Tracking and Compensation Feature fit within those of the predicate Radixact Treatment Delivery System. Additionally, the devices have substantially equivalent performance specifications and technological characteristics. Further, the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature and the predicate device employ the same fundamental scientific principles and have substantially equivalent principles of operation. The main difference between the predicate and the subject device is the use of the motion tracking and compensation feature. Where there are technological differences between the subject and predicate devices, those differences do not raise different questions of safety or effectiveness.

A substantial equivalence table comparing the similarities and differences between the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature and the predicate device is provided in the Substantial Equivalence discussion (Section 15) of this submission. The minor differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

13.5 Performance Testing

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature was tested and shown to comply with the requirements of applicable FDA recognized consensus safety standards for radiation therapy equipment. Results of verification and validation testing confirm that the use of the Motion Tracking and Compensation Feature on the Radixact Treatment Delivery System conforms to design specifications and meets the needs of the intended users.

No animal or clinical tests were required to establish substantial equivalence with the predicate device. The performance data demonstrate that the Motion Tracking and Compensation Feature is compatible with the Radixact Treatment Delivery System, and the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is as safe and effective and performs as well as the predicate device. Further, these test results demonstrate that the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature has substantially equivalent safety and performance characteristics in comparison to the predicate device.

13.6 Substantial Equivalence

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is substantially equivalent to the predicate device. The intended use and

indications for use of the Motion Tracking and Compensation Feature fit within those of the predicate Radixact Treatment Delivery System. Additionally, the major technological characteristics and the principles of operation of the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature are substantially equivalent to those of the predicate device. Minor differences do not raise different questions of safety and effectiveness of the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature in comparison to the predicate device. Further, the performance data demonstrate that the Motion Tracking and Compensation Feature is compatible with the Radixact Treatment Delivery System, and the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is as safe and effective and performs as well as the predicate device. Therefore, the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is substantially equivalent to the predicate device.

From: Keith Picker <kpicker@accuray.com>

Sent: Tuesday, November 20, 2018 4:59 PM

To: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov>

Cc: Michael Preto <mpreto@accuray.com>; Daniel Biank <dbiank@accuray.com>

Subject: RE: K182687 - Quick question

Hi Nancy,

(b)(4)

Please let me know if this satisfies the requirement.

Sincerely,

Keith

From: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov>

Sent: Tuesday, November 20, 2018 3:29 PM

To: Keith Picker <kpicker@accuray.com>

Cc: Michael Preto <mpreto@accuray.com>; Daniel Biank <dbiank@accuray.com>

Subject: RE: K182687 - Quick question

(b)(4)

(b)(4)

Kind regards,

Nancy

From: Keith Picker <kpicker@accuray.com<mailto:kpicker@accuray.com>>

Sent: Tuesday, November 20, 2018 3:50 PM

To: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov<mailto:Nancy.Wersto@fda.hhs.gov>>

Cc: Michael Preto <mpreto@accuray.com<mailto:mpreto@accuray.com>>; Daniel Biank <dbiank@accuray.com<mailto:dbiank@accuray.com>>

Subject: RE: K182687 - Quick question

Hi Nancy,

(b)(4)

Please let me know if this satisfies what you are looking for or if you need anything else.

Thank you for your patience.

Sincerely,

Keith

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Keith Picker
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kpicker@accuray.com<mailto:kpicker@accuray.com>

From: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov<mailto:Nancy.Wersto@fda.hhs.gov>>
Sent: Tuesday, November 20, 2018 11:55 AM
To: Keith Picker <kpicker@accuray.com<mailto:kpicker@accuray.com>>
Subject: FW: K182687 - Quick question

Hi Keith,

Sorry to bother you again. I am nearly done with the review of K182687.

(b)(4)

(b)(4)

Thank you so much,
Nancy

From: Keith Picker <kpicker@accuray.com<mailto:kpicker@accuray.com>>
Sent: Tuesday, November 06, 2018 3:55 PM
To: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov<mailto:Nancy.Wersto@fda.hhs.gov>>
Cc: Daniel Biank <dbiank@accuray.com<mailto:dbiank@accuray.com>>
Subject: RE: K182687 - Quick question

Hi Nancy,

Thank you for the update on the review of our 510(k) submission K182687.

(b)(4)

Please feel free to let me know if you have any other questions.

Best Regards,

Keith

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Keith Picker

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From: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov<mailto:Nancy.Wersto@fda.hhs.gov>>

Sent: Tuesday, November 6, 2018 2:09 PM

To: Keith Picker <kpicker@accuray.com<mailto:kpicker@accuray.com>>

Subject: K182687 - Quick question

Hi Keith,

Our review of K182687 is moving along, and several consultants are helping me on your submission. It does not appear that there are any major issues for which additional information will be needed:

(b)(4)

(b)(4)

Kind regards,

Nancy

Nancy Wersto, M.S., DABR

Scientific Reviewer/Senior Team Leader

Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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Section 8 510(k) Summary

Submitter

Accuray Incorporated
1240 Deming Way
Madison, WI 53717
Phone: 608-824-3069
Fax: 608-830-3778

Contact: Keith Picker
Date Prepared: September 25, 2018

Device Identification

Device Name:	Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System
Trade & Brand Names:	Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System
Common Name:	Radiation Therapy System
Regulation Number:	21 CFR 892.5050
Regulation Name:	Medical charged-particle radiation therapy system
Regulatory Class:	Class II
Product Code:	IYE

Predicate Device

Radixact Treatment Delivery System (K161146)

Device Description

The Motion Tracking and Compensation Feature is designed for use with the predicate Radixact Treatment Delivery System last cleared on K161146. The Motion Tracking and Compensation Feature measures tumor location and motion using images provided by a kV imaging subsystem and predicts tumor location based upon a respiration amplitude measurement device. The Radixact Treatment Delivery System then compensates for tumor motion by making real-time adjustments.

The Radixact Treatment Delivery System is a radiation therapy delivery system that provides Image Guided Radiation Therapy (IGRT) using integral megavoltage CT imaging capabilities and delivers helical (rotational) and fixed-angle (non-rotational) radiation therapy to tumors and other targeted tissues.

Neither the Radixact Treatment Delivery System nor the Motion Tracking and Compensation Feature diagnose disease, recommend treatment regimens or quantify treatment effectiveness. Accordingly, they are not intended for diagnostic use.

Intended Use

The Motion Tracking and Compensation Feature is an option within the intended use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is intended to be used for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues. The megavoltage x-ray radiation is delivered using rotational, non-rotational, intensity modulated (IMRT), or non-modulated (non-IMRT/three dimensional conformal) treatment techniques and using image-guided (IGRT) or non-image-guided workflows in accordance with the physician approved plan.

Indications for Use

The Motion Tracking and Compensation Feature is an option within the indications for use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is indicated for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner.

The intended use and indications for use statements for the Motion Tracking and Compensation Feature (shown above) are the same as for the Radixact Treatment Delivery System (last cleared on K161146), except for the addition of the introductory sentence.

Technological Characteristics

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature has imaging and treatment capabilities equivalent to those of the predicate Radixact Treatment Delivery System. It also has a similar functionally-equivalent CT style gantry and patient couch.

The intended use and indications for use of the Motion Tracking and Compensation Feature fit within those of the predicate Radixact Treatment Delivery System. Additionally, the predicate and subject devices have substantially equivalent performance specifications and technological characteristics. Further, the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature and the predicate device employ the same fundamental scientific principles and have substantially equivalent principles of operation. The main difference between the predicate and the subject device is the use of the motion tracking and compensation feature. Where there are technological differences between the subject and predicate devices, those differences do not raise different questions of safety or effectiveness.

A substantial equivalence table comparing the similarities and differences between the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature and the predicate device is presented below. The minor differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

Device Comparison Table: Radixact Treatment Delivery System with Motion Tracking and Compensation Feature

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
System Description			
Intended Use	Omitted for brevity. Reference 510(k) Summary (Section 8 of 510(k) submission)	Same as predicate	Identical
Indications for Use	Omitted for brevity. Reference 510(k) Summary (Section 8 of 510(k) submission)	Same as predicate	Identical
System Configuration	Stand-alone radiation delivery system (does not include data management system or planning system)	Stand-alone radiation delivery system with kV imaging and motion tracking and compensation added (does not include data management system or planning system)	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not raise different issues of safety or effectiveness.
Vault (Treatment Room)			
Minimum Room Dimensions (H*W*L)	274 x 462 x 602 cm	274.3 x 463 x 602 cm	Substantially equivalent. Minor differences are negligible.
Device Dimensions (gantry and couch) (H*W*L)	255 x 280 x 473 cm	255 x 280 x 470.5 cm	Substantially equivalent. Minor differences are negligible.
Device Mass (kg)	6580 kg	6580 kg plus 235 kg for kV subsystem components	The weight added due to the kV subsystem does not result in different questions of safety or effectiveness.

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
Line Voltage	380 – 480 V _{ac} 3-Phase	Same as predicate	Identical
Ambient Room Temperature	20 – 24 °C	Same as predicate	Identical
Relative Humidity (non-condensing)	30 – 60 %	Same as predicate	Identical
Gantry Mechanical Features			
Bore Diameter	85 cm	Same as predicate	Identical
Degrees of Rotation	Continuous rotation around Y- axis (axes per IEC 61217)	Same as predicate	Identical
Direction of Rotation	Clockwise (as viewed from the foot of the couch)	Same as predicate	Identical
Rotational Speed (Treatment)	1 – 5 RPM	Same as predicate	Identical
Rotational Speed (Imaging)	10 RPM	Same as predicate	Identical
Couch Support in Bore	Provided	Same as predicate	Identical
Radiation Delivery Modes			
Description	Helical, Direct	Same as predicate	Identical
Photon Beam			
Accelerator Type	Standing wave	Same as predicate	Identical
RF Source	Magnetron	Same as predicate	Identical
Nominal Energy	6 MV	Same as predicate	Identical
Fixed Field Size	1.0 cm x 40 cm 2.5 cm x 40 cm 5.0 cm x 40 cm	Same as predicate	Identical
Dynamic Field Size	1.0 – 2.5 cm x 40 cm 1.0 – 5.0 cm x 40 cm	Same as predicate	Identical
Dose Rate	850 cGy/min standard 1000 cGy/min optional	Same as predicate	Identical
Collimation			
Description	Primary collimation, jaws and multi-leaf	Primary collimation, jaws and multi-leaf collimator	Substantially equivalent. Jaws have

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
	collimator		a new dynamic behavior for motion managed plans. Jaws will continually be adjusted to repoint the beam at the moving target (in IEC-Y) while maintaining the same field size.
MVCT Imaging			
Source	Megavoltage Computed Tomography (MVCT)	Same as predicate	Identical
Field of View (MVCT)	39 cm diameter	Same as predicate	Identical
Dose per MVCT Image (typical)	0.5 – 3.0 cGy	Same as predicate	Identical
Slice Spacing (MVCT)	1, 2, 3, 4 and 6 mm reconstruction intervals	Same as predicate	Identical
Spatial Resolution (MVCT)	1.6 mm	Same as predicate	Identical
kV Imaging			
Source	Feature not present	50-150 kV Radiography Class I (60601-2-28) X-ray tube assembly	The kV Imaging subsystem provides two-dimensional low-dose radiographic images used for patient alignment and measurement of tumor motion during treatment delivery. The functionality is provided by hardware and driver software. A kV radiograph can be performed at any arbitrary angle. A stable calibration from
Field of View	Feature not present	20 cm x 20 cm	
Spatial Resolution (kV)	Feature not present	< 1 mm	
Approximate Dose per kV x-ray image (range)	Feature not present	0.08 – 0.20 mGy	
Small Focal Spot Size	Feature not present	0.6 mm x 0.6 mm	
Large Focus Spot Size	Feature not present	1.0 mm x 1.0 mm	
Current Range (mA)	Feature not present	5 - 500 mA	

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
			the kV Imaging coordinate system to the machine coordinate system is made during configuration of the TDS. The new kV imaging components meet applicable safety requirements in the IEC 60601 series.
Motion Management			
Tracking Algorithm	Not present	Radixact Motion Tracking	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature is based on the core tracking algorithm introduced in K120233, Synchrony Respiratory Tracking System.
Compensation Algorithm	Not present	Radixact Motion Compensation	The compensation algorithm uses the jaws and MLC to effectively repoint the beam to accommodate for motion in a method substantially equivalent to K120233, Synchrony Respiratory Tracking System. Does not result in different questions of safety or effectiveness.
Synchrony Camera	Not present	Radixact Synchrony Motion Tracking	Substantially equivalent. The Synchrony camera has

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
			been in use for over ten years and was included most recently in K120233, Synchrony Respiratory Tracking System.
Laser System			
Stationary	Green lasers identify virtual and actual isocenter	Substantially equivalent	Minor differences are negligible and do not result in different questions of safety or effectiveness.
Moveable (for patient positioning and registration)	Red lasers identify offset from virtual isocenter	Substantially equivalent	Minor differences are negligible and do not result in different questions of safety or effectiveness.
Patient Couch			
Motion	Independent of each of the other axes	Independent of each of the other axes	Identical
Biocompatibility			
Couch Top	Carbon-fiber top	Carbon-fiber top	Identical
Synchrony Vest	Not Used	Same vest cleared under K120233, Synchrony Respiratory Tracking System	No new biocompatibility issues
Power Distribution			
Isolation	Transformer	Transformer	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature did not introduce changes to this subsystem.
UPS for Data Back-up	Provided	Provided	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
			did not introduce changes to this design
Operator Station (Treatment Delivery Console)			
Description	User interface to system functions (i.e., patient and procedure selection, and procedure delivery)	User interface to system functions (i.e., patient and procedure selection, and procedure delivery)	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not modify this architecture.
Machine Control Software			
Description	Controls radiation delivery and positioning systems (referred to as the ECS – Embedded Controls Subsystem)	Controls radiation delivery and positioning systems (referred to as the ECS – Embedded Controls Subsystem)	Substantially equivalent. The Motion Tracking and Compensation functionality was added to the existing design. No different issues of safety or effectiveness.
Data Interfaces Operator Station	Provides measurements and status during operation	Provides measurements and status during operation	Substantially equivalent. The Motion Tracking and Compensation functionality was added to the existing design. No different issues of safety or effectiveness.
Database			
Description	External database used for gathering operational data and storage of procedure data	External database used for gathering operational data and storage of procedure data	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not modify this design outside of accommodating for more data.

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
Safety Features			
Interlock Subsystems	Present	Present	Substantially equivalent. kV subsystem integrated into the Safety Interlocks. No different issues of safety or effectiveness.
Data integrity checking	Present	Present	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not modify this design.

Performance Data

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature was tested and shown to comply with the requirements of applicable FDA recognized consensus safety standards for radiation therapy equipment. Results of verification and validation testing confirm that the use of the Motion Tracking and Compensation Feature on the Radixact Treatment Delivery System conforms to design specifications and meets the needs of the intended users.

No animal or clinical tests were required to establish substantial equivalence with the predicate device. The performance data demonstrate that the Motion Tracking and Compensation Feature is compatible with the Radixact Treatment Delivery System, and the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is as safe and effective and performs as well as the predicate device. Further, these test results demonstrate that the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature has substantially equivalent safety and performance characteristics in comparison to the predicate device.

Conclusion

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is substantially equivalent to the predicate device. The intended use and indications for use of the Motion Tracking and Compensation Feature fit within those of the predicate Radixact Treatment Delivery System. Additionally, the major technological characteristics and the principles of operation of the Radixact Treatment

Delivery System with the use of the Motion Tracking and Compensation Feature are substantially equivalent to those of the predicate device. Minor differences do not raise different questions of safety and effectiveness of the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature in comparison to the predicate device. Further, the performance data demonstrate that the Motion Tracking and Compensation Feature is compatible with the Radixact Treatment Delivery System, and the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is as safe and effective and performs as well as the predicate device. Therefore, the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is substantially equivalent to the predicate device.

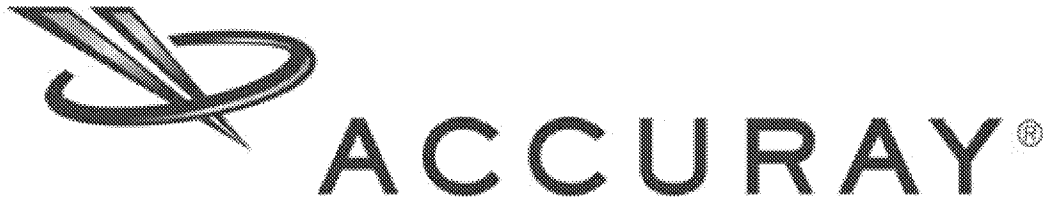
Appendix M

Section 37: Verification Test Report

Accuray Incorporated

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Treatment Delivery System Motion Tracking and Compensation Feature Verification Test Summary Report

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Appendix G

Section 31: Version Description Document



(b)(4) Treatment Delivery System (TT)

Version Description Document (VDD) and Software Build Instructions (SBI)

Release: (b)(4)

(b)(4)

Revision: (b)(4)

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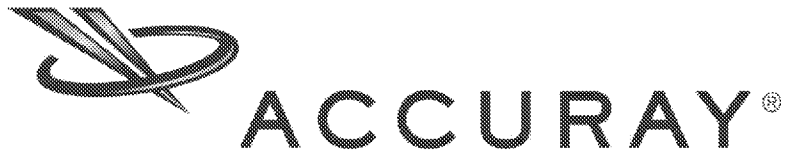
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Appendix S

Section 43: Design Control Procedure



PRODUCT DEVELOPMENT PROCESS

SOP (b)(4)

REV (b)(4)

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APPROVAL

Dept. Manager: (b)(4)

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Section 17 Sterilization and Shelf Life

This section is not applicable.

Sterilization

Neither the Motion Tracking and Compensation Feature for use on the Radixact Treatment Delivery System nor any components or accessories are provided to the customer in a sterile state. Additionally, neither the device nor any components or accessories are intended to be sterilized prior to use.

Shelf Life

Neither the Motion Tracking and Compensation Feature for use on the Radixact Treatment Delivery System nor any components or accessories have a shelf life limitation. Storage conditions could not affect device safety or effectiveness. Accuray trained and qualified personnel install and verify the proper functioning of the Motion Tracking and Compensation Feature for use on the Radixact Treatment Delivery System before it is placed in service for clinical use.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) ACCURAY INC Keith Picker Accuray Incorporated 1302 Deming Way Madison WI 53717 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****8932	2. CONTACT NAME Keith Picker 2.1 E-MAIL ADDRESS kpicker@accuray.com 2.2 TELEPHONE NUMBER (include Area code) 608-824-3069 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 408-716-4601
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm) <u>Select an application type:</u> ☒ Premarket notification(510(k)); except for third party ☐ 513(g) Request for Information ☐ Biologics License Application (BLA) ☐ Premarket Approval Application (PMA) ☐ Modular PMA ☐ Product Development Protocol (PDP) ☐ Premarket Report (PMR) ☐ 30-Day Notice ☐ De Novo Request 3.1 Select a center ☒ CDRH ☐ CBER <u>3.2 Select one of the types below</u> ☒ Original Application <u>Supplement Types:</u> ☐ Efficacy (BLA) ☐ Panel Track (PMA, PMR, PDP) ☐ Real-Time (PMA, PMR, PDP) ☐ 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) ☐ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA ☒ NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:	
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? ☒ YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.) ☐ NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)	
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. ☐ This application is the first PMA submitted by a qualified small business, including any affiliates ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only ☐ The sole purpose of the application is to support conditions of use for a pediatric population ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). ☐ YES ☒ NO	
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118	

the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

11-Jul-2018

Form FDA 3601 (08/16)

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Section 12 Declarations of Conformity and Summary Reports

This section is not applicable as this premarket notification is not an Abbreviated 510(k).

From: Smith, Alysia * [Alysia.Smith@fda.hhs.gov]
Sent: 9/26/2018 8:26:58 PM
To: kpicker@accuray.com
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K182687 Acknowledgment Notification
Attachments: K182687 Acknowledgment Notification.pdf



Acknowledgment Letter

9/26/2018

Keith Picker, Senior Regulatory Affairs Specialist
Accuracy Incorporated
1240 Deming Way
Madison, WI 53717
UNITED STATES

Dear Keith Picker:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K182687
Received: 9/26/2018
Applicant: Accuracy Incorporated
Device: Motion Tracking and Compensation Feature for the Radixact Treatment
Delivery System

We will notify you when the review of this submission has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>.

Sincerely yours,

Center for Devices and Radiological Health

Section 11 Financial Certification or Disclosure Statement

This section is not applicable. No data from clinical studies is submitted with this 510(k) premarket notification.

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Appendix H

Section 32: Off-The-Shelf Software

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Embedded Control System SOUP Software Requirements Specification

Version: **(b)(4)**

Printed by: **(b)(4)**

Printed on:

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From: Keith Picker <kpicker@accuray.com>
Sent: Tuesday, November 20, 2018 3:50 PM
To: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov>
Cc: Michael Preto <mpreto@accuray.com>; Daniel Biank <dbiank@accuray.com>
Subject: RE: K182687 - Quick question

Hi Nancy,

(b)(4)

Please let me know if this satisfies what you are looking for or if you need anything else.

Thank you for your patience.

Sincerely,
Keith

 	Keith Picker Senior Regulatory Affairs Specialist One Erdman Place Madison, WI 53717 USA Phone: 608-824-3069 kpicker@accuray.com

From: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov>
Sent: Tuesday, November 20, 2018 11:55 AM
To: Keith Picker <kpicker@accuray.com>
Subject: FW: K182687 - Quick question

Hi Keith,

Sorry to bother you again. I am nearly done with the review of K182687.

(b)(4)

(b)(4)

Thank you so much,
Nancy

From: Keith Picker <kpicker@accuray.com>
Sent: Tuesday, November 06, 2018 3:55 PM
To: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov>
Cc: Daniel Biank <dbiank@accuray.com>
Subject: RE: K182687 - Quick question

Hi Nancy,

Thank you for the update on the review of our 510(k) submission K182687.

(b)(4)

Please feel free to let me know if you have any other questions.

Best Regards,
Keith

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Keith Picker
Senior Regulatory Affairs Specialist
One Erdman Place
Madison, WI 53717
USA
Phone: 608-824-3069
kpicker@accuray.com

 [facebook.com]

 [twitter.com]

 [fr.linkedin.com]  [youtube.com]

From: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov>

Sent: Tuesday, November 6, 2018 2:09 PM

To: Keith Picker <kpicker@accuray.com>

Subject: K182687 - Quick question

Hi Keith,

Our review of K182687 is moving along, and several consultants are helping me on your submission. It does not appear that there are any major issues for which additional information will be needed. (b)(4)

(b)(4)

Kind regards,
Nancy

Nancy Wersto, M.S., DABR
Scientific Reviewer/Senior Team Leader
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-6548
e-mail: nancy.wersto@fda.hhs.gov

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Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/slcdhrcustomerservice?ID=1974&S=E> [research.net].

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From: Keith Picker <kpicker@accuray.com>
Sent: Tuesday, November 20, 2018 4:59 PM
To: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov>
Cc: Michael Preto <mpreto@accuray.com>; Daniel Biank <dbiank@accuray.com>
Subject: RE: K182687 - Quick question

Hi Nancy,

(b)(4)

Please let me know if this satisfies the requirement.

Sincerely,
Keith

From: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov>
Sent: Tuesday, November 20, 2018 3:29 PM
To: Keith Picker <kpicker@accuray.com>
Cc: Michael Preto <mpreto@accuray.com>; Daniel Biank <dbiank@accuray.com>
Subject: RE: K182687 - Quick question

(b)(4)

Kind regards,
Nancy

From: Keith Picker <kpicker@accuray.com>
Sent: Tuesday, November 20, 2018 3:50 PM
To: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov>
Cc: Michael Preto <mpreto@accuray.com>; Daniel Biank <dbiank@accuray.com>
Subject: RE: K182687 - Quick question

Hi Nancy,

(b)(4)

Please let me know if this satisfies what you are looking for or if you need anything else.

Thank you for your patience.

Sincerely,
Keith



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From: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov>
Sent: Tuesday, November 20, 2018 11:55 AM
To: Keith Picker <kpicker@accuray.com>
Subject: FW: K182687 - Quick question

Hi Keith,

Sorry to bother you again. I am nearly done with the review of K182687.

(b)(4)

(b)(4)

Thank you so much,
Nancy

From: Keith Picker <kpicker@accuray.com>
Sent: Tuesday, November 06, 2018 3:55 PM
To: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov>
Cc: Daniel Biank <dbiank@accuray.com>
Subject: RE: K182687 - Quick question

Hi Nancy,

Thank you for the update on the review of our 510(k) submission K182687.

(b)(4)

Please feel free to let me know if you have any other questions.

Best Regards,
Keith

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From: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov>
Sent: Tuesday, November 6, 2018 2:09 PM
To: Keith Picker <kpicker@accuray.com>
Subject: K182687 - Quick question

Hi Keith,

Our review of K182687 is moving along, and several consultants are helping me on your submission. It does not appear that there are any major issues for which additional information will be needed.

(b)(4)

(b)(4)

Kind regards,
Nancy

Nancy Wersto, M.S., DABR
Scientific Reviewer/Senior Team Leader
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

U.S. Food and Drug Administration
Tel: 301-796-6548
e-mail: nancy.wersto@fda.hhs.gov

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Appendix D

Section 28: System Requirements Specification

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ID

Treatment Delivery System - System Requirements Specification

Object
Type

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(b)(4)

Accuray Incorporated

Item Number (b)(4)

Revision (b)(4)

Description (b)(4)



ACCURAY®

(b)(4)

Treatment Delivery System Motion Tracking and Compensation Feature System Requirements Specification

Release: (b)(4)

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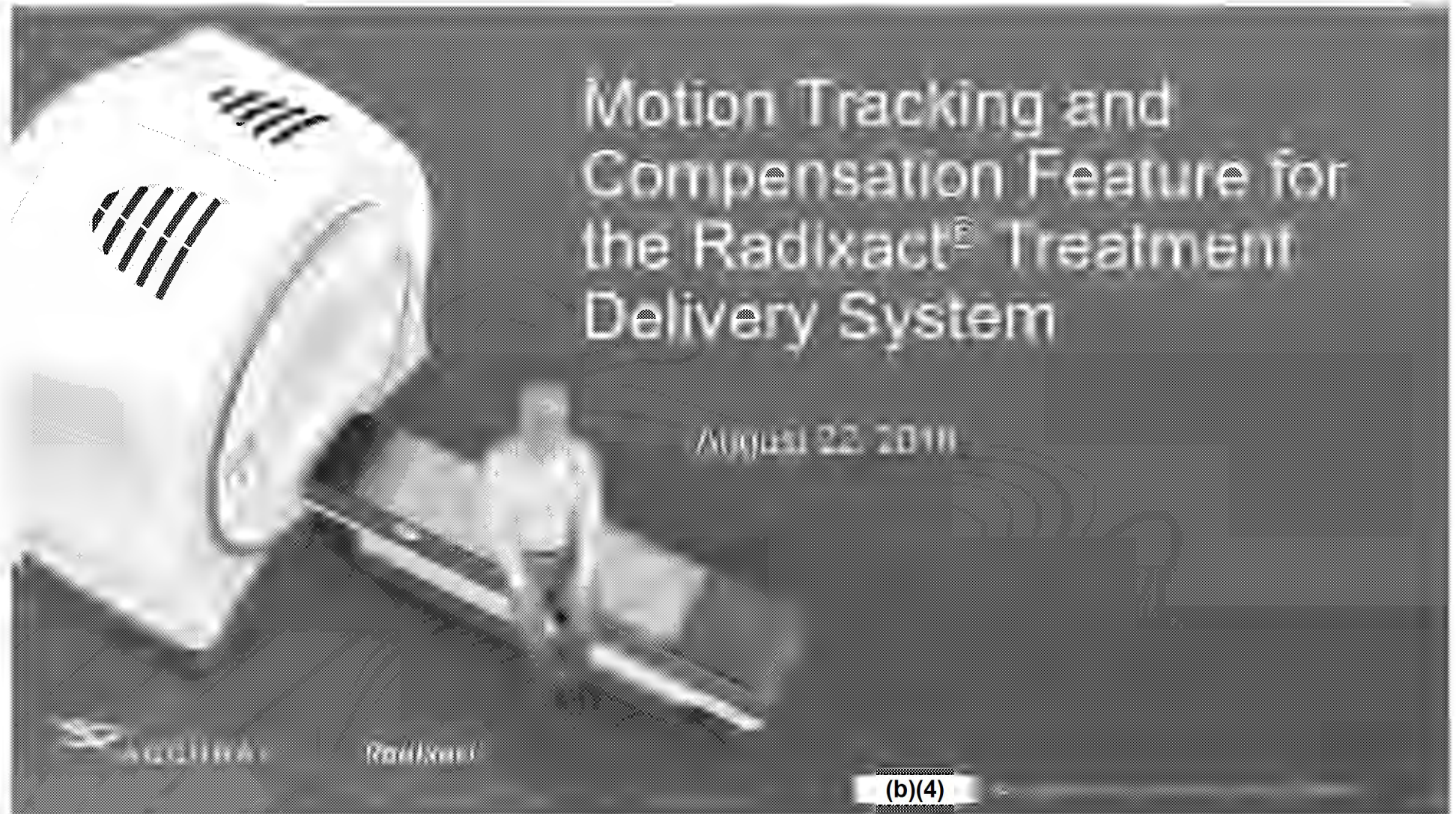
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Appendix A

Section 25: Labeling



Radixact Treatment Delivery System Overview

The Radixact Treatment Delivery System, Accuray Precision[®] Treatment Planning System and iDMS[™] Data Management System are designed to provide clinicians with the imaging capabilities, treatment flexibility and precise dose delivery they've come to expect with the TomoTherapy[®] System. To further enhance patient treatment delivery, the Radixact System now offers real-time motion tracking and compensation.



Radixact

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2

Real-time Motion Tracking and Compensation

Treatment deliveries can be enhanced on the Radixact® System with the addition of a kV imaging system for real-time motion tracking and compensation. The x-ray system is mounted 90 degrees ahead of the MV treatment beam and works in conjunction with an optical camera system.



Radixact

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3

Real-time Motion Tracking and Compensation

Radixact Fiducial Tracking with Synchrony® and Radixact Xsight® Lung Tracking with Synchrony use x-ray images that are acquired every few seconds during gantry rotation. Respiratory motion is addressed by correlating internal target positions visible in the x-ray images with marker positions continuously detected by the camera. The result of this correlation is a model that is constantly updated to determine target position in three-dimensions. Motion correction is performed by continuously updating jaw positions and MLC leaf patterns to reshape the treatment beam and follow the target's motion. Radixact Fiducial Tracking addresses non-respiratory motion by tracking targets with periodically acquired x-ray images and does not require a correlation model or camera signal.



Radixact

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4

Real-time Motion Tracking and Compensation

Treatment Modalities

- Radixact Fiducial Tracking
- Radixact Fiducial Tracking with Synchrony®
- Radixact Xsight® Lung Tracking with Synchrony (without fiducials)



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5

Real-time Motion Tracking and Compensation

Jaw collimation and response

- Jaw positions projected to isocenter: -1.5cm (across mid-line) to 2.5cm in dynamic mode
- Axis of travel: IEC-Yf
- Field size mode: The jaws are always in dynamic mode when real-time motion tracking and compensation is being used
- Jaws response to motion: less than 100 msec
- MLC response to motion: less than 30 msec



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6

Radixact Fiducial Tracking and Lung Tracking

	Overall Accuracy	Residual Accuracy
Radixact Fiducial Tracking	5%, 4 mm	1.5 mm
Radixact Fiducial Tracking with Synchrony® Radixact Xsight® Lung Tracking with Synchrony (without fiducials)	3%, 3 mm	1.5 mm



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X-Ray system

- Min/max kV: 50-150
- Min/max mA: 5-500
- Typical mAs for static shot: 0.5 to 2.5
- Focal spot size: 0.6 mm and 1.0 mm



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8

Photor Beam to Target Feeding

Panel

- Size (cm): 40.9 x 40.9 (40.0 x 40.0 usable)
- Pixel size / matrix size: 400 μ m, 1024 x 1024
- Dynamic range: >87 dB
- Gain: 0.25 to 8 pF
- DQE IEC RQA5: >67% (at 0 cycle/mm)
- MTF IEC RQA5: >63% (at 0.5 cycle/mm)



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Photon Beam Target Feeding

System

- Typical clinical protocol: 100-140 kV, 100-200 mA, 10ms, 4-8 pF (anatomy-specific protocols)
- Typical image non-uniformity (air scan): < 3%
- Motion tracking: between 2 and 6 views per rotation
- kV imaging field of view: 20 x 20 cm (centered at isocenter)
- Weight of additional components: approx. 235 kg (517 lbs)

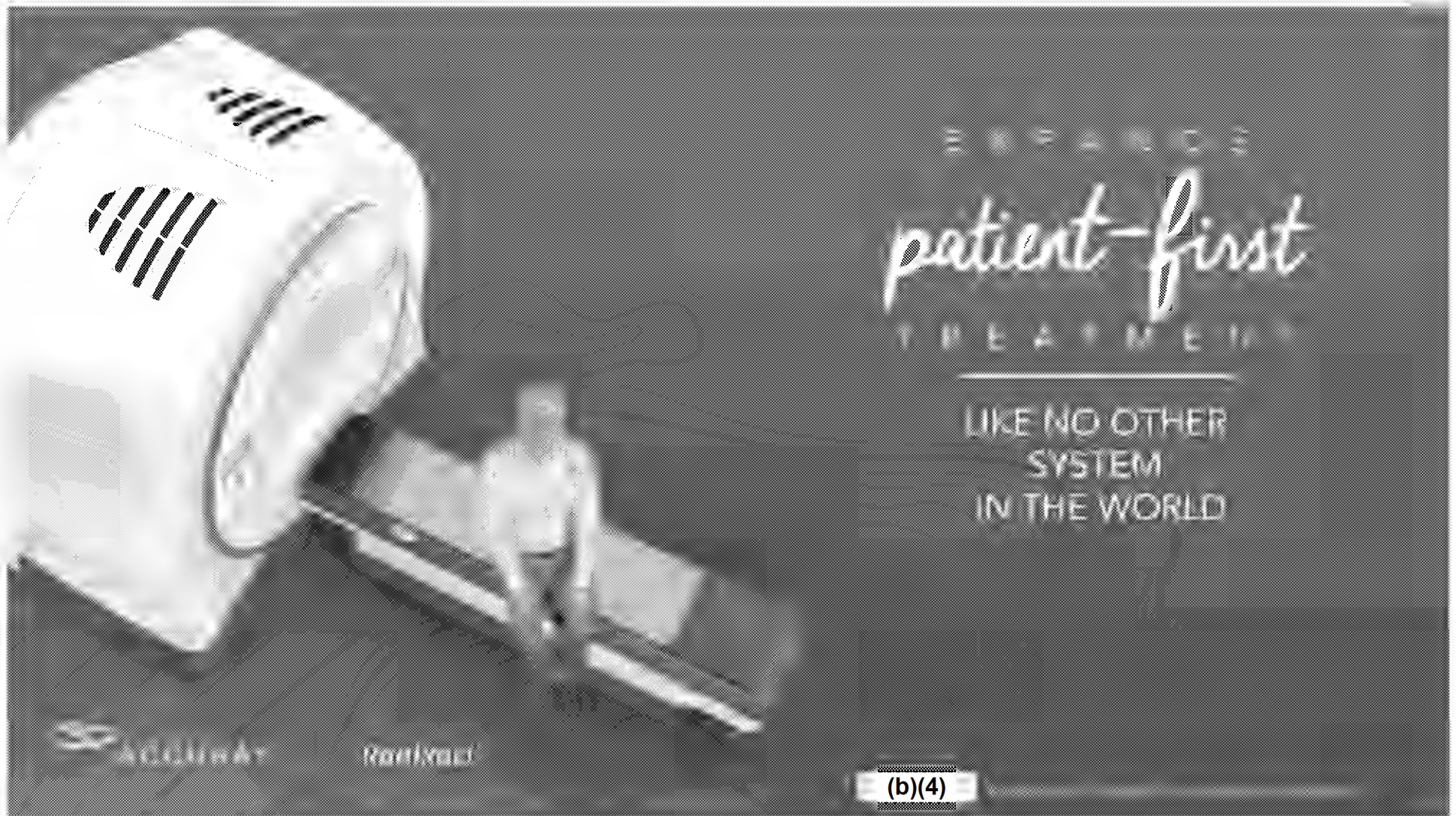


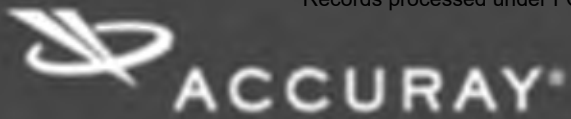
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10





Radixact[™]

Treatment Delivery Manual

Date of Revision: 2018-08
1064003-ENG A
Version 2.0.0.0



Radixact[™] Treatment Delivery System

Treatment Delivery Manual

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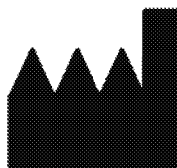
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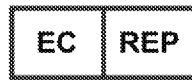
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Australia

Customer Support

For more information, to request documentation, or if you have a service issue, please contact Accuray Customer Support (North America) at +1-866-368-4807, contact your Distributor, or visit the Accuray Technical Solution Center at:

www.accuray.com/services/service-support/



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With proper care and maintenance, the expected service life of the system is 10 years.

The Accuray System, including each computer workstation and associated system software, has been validated to demonstrate that the system will perform as expected. The installation of additional software not released by Accuray Incorporated (e.g. third party, off-the-shelf, etc.) on these computer workstations is not permitted. This includes any Microsoft® Windows® updates. Any effect on the safe and intended operation of the Accuray System caused by the introduction of additional software is unknown and Accuray cannot be responsible for any impact caused by adding such software.

Hardware and Software Maintenance

Only qualified service personnel should service or maintain system hardware components. If you feel that Accuray System hardware components or associated features or functions do not perform as expected, or they provide results that are inconsistent with your established clinical and research protocols, call Accuray Customer Support (North America) at 1-866-368-4807, contact your Distributor, or visit the Accuray Technical Solution Center located at:

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is available upon written request. Automatic image registration is based on routines in Numerical Recipes: The Art of Scientific Computing, published by Cambridge University Press, which are used with permission.

Instructions for Use of the Accuray System

Safe operation of the Accuray System requires careful attention to the serious hazards associated with the use of linear accelerators and complex radiation therapy equipment and ways to avoid or minimize the hazards, and familiarity with emergency procedures. Untrained or careless operation of the Accuray System can damage the system, its components or other property; cause poor performance; or lead to serious bodily injury and possibly death. Anyone who operates, services, maintains, or is otherwise associated with the Accuray System must read, understand, and be thoroughly familiar with the information in this manual, and take precautions to protect themselves, their associates, patients, and the equipment. At each step in the installation, specific warnings and cautions are given for specific actions.

Personnel must be trained by Accuray Incorporated before the Accuray System is used for research or clinical purposes. Accuray System documentation was originally drafted, approved, and supplied in English (US).

The following statements are intended to alert the user to potential conditions that could result in injury to the patient (warning) or conditions that could affect system components (caution).



Warning Warning statements describe possible conditions that can result in serious or fatal injury to the patient or facility personnel. Each warning gives the possible condition and how to avoid it.



Caution Caution statements describe possible conditions that can affect system performance or cause damage to system components. Each caution gives the possible condition and how to avoid it.

Prescription Device Statement



Caution: Federal law restricts this device to sale by or on the order of a physician.



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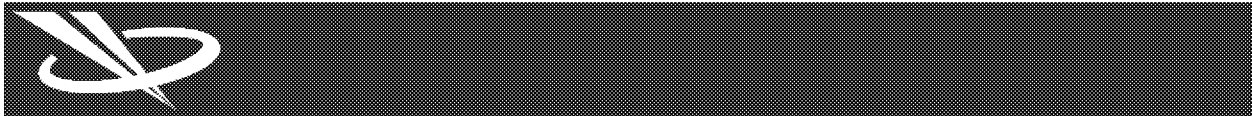
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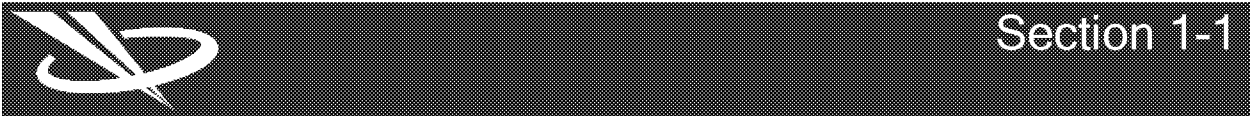
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Delivery System Safety

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General System Safety

This section outlines fundamental safety information related to use of the treatment delivery system. Operators should observe this guidance at all times when using the treatment delivery system.

- ◆ Undesirable Side Effects. 2
- ◆ Use of the Treatment System 3
- ◆ Laser System Safety 7
- ◆ Electrical Safety 7
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- ◆ Labels 8
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WARNING: The treatment system is a radiation device. Improper use can result in serious injury or death.

- Only properly trained personnel should operate the treatment system.
- Refer to this manual and the *Treatment Planning Manual* provided by Accuray Incorporated for instructions, safety information, and recommendations.
- Make sure all signs required by local codes for the operation of a radiation device are posted.
- When operating the treatment system, follow the procedures and requirements established by your facility’s Radiation Safety Officer.
- Make sure all gantry enclosures are in place before you operate the treatment system.
- Make sure all safety mechanisms are functioning correctly, as specified in the *Physics Essentials Guide*.



WARNING: Independent devices may not be safe, compatible, or acceptable for use with Accuray products. Prior to using any independent product with any Accuray product, contact Accuray Customer Support.

◆ Undesirable Side Effects

The treatment system delivers ionizing radiation that can have undesirable side effects such as nausea, burns, nerve damage, and even death. To help prevent these side effects, all personnel who operate the treatment system should be appropriately educated and trained.

◆ Use of the Treatment System

Intended Use

The Radixact Treatment Delivery System is intended to be used for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues. The megavoltage x-ray radiation is delivered using rotational, non-rotational, intensity modulated (IMRT), or non-modulated (non-IMRT/three dimensional conformal) treatment techniques and using image-guided (IGRT) or non-image-guided workflows in accordance with the physician approved plan.

Indications for Use

The Radixact Treatment Delivery System is indicated for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner.

Training



WARNING: The treatment system is a radiation emitting device and incorrect use can result in serious injury or death. Only properly educated and trained personnel are qualified to create a treatment plan and deliver a treatment procedure using the treatment system.

Product Licensing

Accuray Systems contain features that require licensing. These features are referenced throughout this document. The availability of certain features depends on your system configuration. For information about licensing options, contact your sales representative or Accuray Customer Support.

Treatment Room Protocol



WARNING: The treatment system generates radiation for CTrue™ image guidance scans, treatment procedures, and quality assurance procedures. To avoid unnecessary radiation exposure during non-patient procedures, ensure the treatment room is unoccupied and the entrance is secured. Before a scan or treatment procedure is started, ensure that the patient is the only person in the treatment room and the entrance to the treatment room is secure.



WARNING: Excessive kV image acquisition may cause or contribute to a higher dose deposited in patient skin, resulting in radiation burns. To prevent or reduce this side effect, use the minimum quantity of kV images needed, and the lowest dose X-ray technique, that meets all other tracking requirements according to the standard protocols and practices of your clinic.



WARNING: Patient data or confidentiality may be compromised if a workstation is left unattended. To prevent this, lock or exit your workstation before leaving. In addition, you can clear patient information from the workstation display if you are no longer working with a patient.



WARNING: Serious injury may occur if any body parts obstruct the path of mechanical components that move the treatment couch or tabletop. Always verify that operators, patients, and any bystanders are positioned in safe locations and that the area is free of obstructing objects before moving the couch.



WARNING: To prevent unintended displacement of the patient during couch movement, do not allow any items (e.g. bed linens, fixation devices, cabling, or patient gowns, limbs, hair, etc.) to overhang the end of the couch tabletop. Unintended displacement of the patient can result in displacement of the radiation delivery, and possible injury to the patient. As directed in this manual, always check that the patient movement path is clear of obstructions, including items overhanging the end of the couch tabletop.



CAUTION: Damage to treatment couch, gantry covers, or other property may occur if any objects obstruct the path of the treatment couch or tabletop. Always verify that the area is free of obstructing objects, and that the couch is free to move through the entire range required for irradiation before moving the couch or initiating a procedure.

Facility Requirements



WARNING: To operate a radiation emitting device, obey procedures and requirements enforced by your facility. Failure to do so could result in patient injury, patient mistreatment, or equipment damage.

- Make sure signs required by local codes are posted. These signs alert personnel to the operation of a radiation device and the presence of radiation.
- Obey all procedures and monitoring requirements established by your facility's Radiation Safety Officer (RSO).

Electromagnetic Compatibility Considerations



WARNING: Special precautions regarding electromagnetic compatibility should be employed when using all medical electrical equipment. The treatment system should be installed and operated in agreement with the electromagnetic information supplied in the *Technical Descriptions* manual.

Portable and mobile radio frequency communications equipment can affect medical electrical equipment. Accuray Incorporated recommends that you observe and verify normal operation if you operate the treatment system with portable or mobile radio frequency communications equipment within the treatment room.

Implanted Fiducials



WARNING: The use of unapproved implanted fiducials could result in patient mistreatment. Use only fiducials that have been approved by Accuray Incorporated for use with the system. Implanted fiducial tracking has been validated using approved fiducials only.

Stop System Operation



WARNING: If the patient requires assistance or the system operates in an unexpected manner, interrupt or terminate system operation to prevent injury to the patient or facility personnel. See “Use of Safety Mechanisms” (page 20) for more information.

Patient and Plan Selection



WARNING: Patient mistreatment may occur if you do not select the correct patient and plan. Before you start a *CTrue* image scan or treatment procedure, make sure you select the correct patient and plan using any available verification means, such as the patient photo, to identify the patient.

Patient Weight Restriction



WARNING: Couch sag can cause inaccurate radiation delivery for a treatment procedure. The couch is not designed to support a weight heavier than 200 kg (440 lbs). Make sure the distributed weight of the patient on the couch is not more than 200 kg (440 lbs).

Pinch Points



WARNING: As the couch moves, pinch points can cause serious injury. Avoid contact with moving parts and instruct the patient to stay clear of moving parts. If required, press a **Stop** button to stop couch movement.

Electronic Implanted and Body-Worn Devices



WARNING: Radiation and electromagnetic interference (EMI) may affect the operation of electronic implanted and body-worn devices (e.g., a pacemaker) in patients. Radiation and EMI from the treatment system is expected to be similar to that of other linear accelerator-based systems. Before you scan or treat a patient who is wearing an electronic implanted or body-worn device, you may wish to do the following:

- Contact the manufacturer of the device regarding its susceptibility to radiation and EMI.
- Devices should be checked for correct operation after exposure to radiation.
- Refer to appropriate professional organizations' recommendations, for example, American Association of Physicists in Medicine Report Number 45: *Management of Radiation Oncology Patients with Implanted Cardiac Pacemakers* (Report of Task Group 34).

Virus Protection Software and Firewalls

Accuray Incorporated employs an off-the-shelf whitelist anti-virus malware solution that is installed on the Treatment Delivery Console computer, Gateway, and Registration Review Nodes. Periodic updates are not necessary because the software only allows previously authorized applications per the whitelist to run.

The iLinkSM system employs a single Security Appliance as its main point of connection to the hospital's network, and additional Security Appliances per connection to each system or vault. All Security Appliances come standard as part of your Accuray System, and are required for complete *iLink* functionality.

Each of the Security Appliances has its configuration tuned to the exact needs of each deployment location and its users. These configurations include providing product and location-specific access control rules and network address translation to each of the devices behind the Security Appliances. The access control rules and network address translations restrict incoming and outgoing traffic to a few select applications and programs approved by Accuray Incorporated.

Use of Unapproved Equipment

Use of equipment or accessories not approved by Accuray Incorporated for use with the treatment system may result in damage to equipment or personal injury. Accuray Incorporated will not be held liable for damages or injuries resulting from the use of unapproved equipment or accessories. Consult accompanying documents provided by the accessory manufacturer for safety precautions, maintenance requirements, conditions, and limits of use.

◆ Laser System Safety



WARNING: Laser beams can cause permanent retinal damage. Never look directly into the laser beams. Instruct the patient to not look directly into the laser beams.



WARNING: If the Class II lasers designed for use with the treatment system are not used, the patient may not be correctly positioned before treatment. Do not use any other laser equipment with the treatment system.

◆ Electrical Safety



WARNING: Do not connect non-compliant peripherals to the treatment system. Non-compliant peripherals can damage components or injure the patient during system operation. Only peripherals that comply with the applicable standard for that component and have been approved by Accuray Incorporated should be connected to the treatment system.

◆ Quality Assurance (QA)

Required QA Procedures



WARNING: Do not treat a patient if scheduled or required QA procedures have not been performed. Scheduled QA procedures must be performed by qualified clinical personnel in accordance with accepted practices and protocols, relevant to specific machine applications and usage.

Accuray System Service



WARNING: Only qualified service personnel should service and maintain Accuray treatment systems. Incorrect service can result in personal injury and damage to system components. If you determine that the treatment system requires service, contact the Accuray Technical Solution Center.

Use of QA Procedures



WARNING: Treating a patient with a QA procedure can cause serious injury to the patient. Do not treat a patient with a QA procedure. Verify that patients and personnel are outside the treatment room before performing QA procedures. QA procedures are intended to be performed only by qualified clinical personnel for quality assurance purposes.

Optimized Plans



CAUTION: The quality of optimized plans created on the treatment system depends on the quality of the data entered by users. Any irregularities or uncertainties about input data units, identification, or quality of any other nature must be thoroughly investigated before use.

Calibration and Commissioning Files



WARNING: Treatments based on incorrect calibration or commissioning data may result in serious injury or death to the patient. After the machine has been commissioned, do not modify any calibration or commissioning data files. If there has been a significant change to the dosimetric properties of the machine, contact Accuray Incorporated for assistance.

◆ Labels

This section describes symbols that are used to identify controls and indicators on equipment. It also describes labels that provide equipment information. Some treatment systems may carry labels that vary slightly from, but are substantially equivalent in content to, the representative versions shown here. Depending on the age of your system, the labels specified below may vary from the labels you currently have. Previous labels were the correct production version at the time the respective manual was printed.

Electrical Testing Laboratories (ETL) Label

This label indicates the compliance of the treatment system couch, gantry, and status console with AAMI ES 60601-1 and CAN/CSA C22.2 No. 60601-1 standards.



System Compliance

System certification labels are issued by independent testing organizations. The system is compliant with the following standards:

- EN/IEC 60601-1
- EN/IEC 60601-1-2
- EN/IEC 60601-1-4
- EN/IEC 60601-1-6
- EN/IEC 60601-2-1
- CAN/CSA C22.2 No. 60601-1
- AAMI ES 60601-1

In addition to the above standards, the couch is also compliant with:

- Associated equipment-Treatment Couch
- EN/IEC 60601-2-44

Status Console Label

This label is on the **Status Console**. It advises users to observe safe exposure factors and operating instructions in order to avoid safety hazards.

WARNING: THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS AND OPERATING INSTRUCTIONS ARE OBSERVED

Couch Obstruction

At the head end of the couch tabletop, the following labels appear. These symbols advise the user to review the accompanying documents for couch safety information.



WARNING: To prevent unintended displacement of the patient during couch movement, do not allow any items (e.g. bed linens, fixation devices, cabling, or patient gowns, limbs, hair, etc.) to overhang the end of the couch tabletop. Unintended displacement of the patient can result in displacement of the radiation delivery, and possible injury to the patient. As directed in this manual, always check that the patient movement path is clear of obstructions, including items overhanging the end of the couch tabletop.

Subsystem Component Label (Standard)

This standard subsystem label is used to identify those components specific to the treatment system.

Subsystem Component Label (CE Mark)

This label is fixed to the Power Distribution Unit (PDU), gantry, Treatment Delivery Console (TDC), Optimizer Server, **Status Console**, and the workstation for the Accuray Precision™ Treatment Planning System to identify them as major treatment system subcomponents that have complied with the Medical Device Directive (MDD) 93/42/EEC.

Couch Subsystem Label

This label is fixed to the couch and indicates its compliance with the Medical Device Directive (MDD) 93/42/EEC.

System Label

This label is fixed to the Power Distribution Unit and gives the “indication of origin”, “model or type reference”, and electrical supply requirements. It also indicates compliance with the Medical Device Directive (MDD) 93/42/EEC.

◆ Symbols

This section describes symbols that are used to identify controls and indicators on equipment. It also describes labels that provide equipment information.

Caution

Symbol	Description
	“Attention, proceed with caution.” This label is used to identify the location on pinch points that can be created by movement of the couch. It is also fixed to the system label (on the Power Distribution Unit) and subsystem labels to indicate that accompanying documents include related safety information. Symbol source: IEC 60417; 0434B.

CE Marking

Symbol	Description
	Located on the system and subsystem labels to signify that Accuray Incorporated declares that the equipment complies with the requirement of the European Union Medical Device Directive. Symbol source: 93/42/EEC, Annex II.

Data Matrix Barcode

Symbol	Description
	Located on the system label, this barcode contains encoded information about the Accuray System.

Date of Manufacture

Symbol	Description
	Located on the system and subsystem labels to identify the date that the Accuray System was manufactured. Symbol source: ISO 7000; 2497.

Door

Symbol	Description
	Identifies the location of the entrance interlock status LED on the Power Control Panel . Symbol source: IEC 60878; 5624 and 5623.

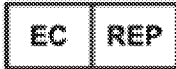
Electric Energy

Symbol	Description
	Identifies the location of the Power Distribution Unit power status LED on the Power Control Panel . Symbol source: IEC 60878; 0232.

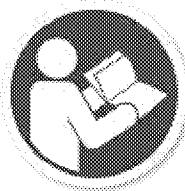
Emergency Stop

Symbol	Description
	Identifies the location of the Emergency Stop button on the Status Console , and the emergency stop status LED on the Power Control Panel . Symbol source: IEC 60878; 5638.

European Authorized Representative

Symbol	Description
	Located on the system and subsystem labels to identify the location and contact information of the European Authorized Representative for Accuray Incorporated. Symbol source: EN ISO 15223-1; 5.1.2.

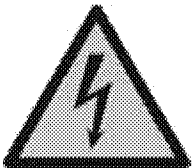
Follow Instructions for Use

Symbol	Description
	“Attention, follow instructions for use.” This symbol indicates that you should consult the accompanying documents for information related to the labeled item. The symbol also indicates that the item is mandatory and safety related. Symbol source: IEC 60878; ISO 7010-M002.

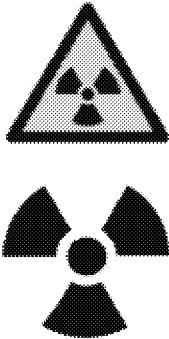
General Warning Sign

Symbol	Description
	“Attention, follow instructions to prevent risk of harm.” This label is used to identify the location on pinch points that can be created by movement of the couch. It is also fixed to the system label (on the Power Distribution Unit) and subsystem labels to indicate that accompanying documents include related safety information. The label also indicates that a failure to follow instructions could place the patient or operator at risk of harm. Symbol source: IEC 60878; ISO 7010-W003.

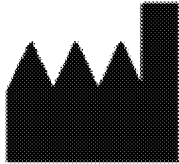
High Voltage

Symbol	Description
	Located on the Power Distribution Unit and accompanied by warning text to indicate the presence of high voltage. Symbol source: IEC 60878; ISO 7010-W012.

Ionizing Radiation

Symbol	Description
	Located on the system label to identify the capability of creating ionizing radiation. Symbol source: IEC 60878; 7010-W003 and ISO 361.

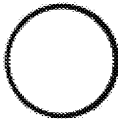
Manufacturing Facility

Symbol	Description
	Located on the system and subsystem labels to identify the facility where the Accuray System was manufactured. Symbol source: ISO 7000; 3082.

Model Reference Number

Symbol	Description
	Located on the system and subsystem labels to identify the model reference number associated with the Accuray System. Symbol source: ISO 7000; 2493.

OFF Power

Symbol	Description
	Identifies the location of the power OFF button on the Power Control Panel. Symbol source: IEC 60878; 5008.

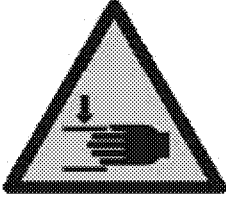
ON Power

Symbol	Description
	Identifies the location of the power ON button on the Power Control Panel. Symbol source: IEC 60878; 5007.

Operating Instructions

Symbol	Description
	“Attention, consult accompanying documents.” This symbol indicates that you should consult the accompanying documents for information related to the labeled item. Symbol source: ISO 7000; 1641.

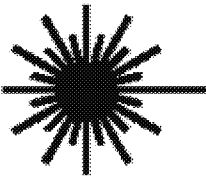
Pinch Point Warning

Symbol	Description
	These symbols identify the location of pinch points that can be created when the longitudinal manual release handle is used to retract the couch and patient from the bore during emergency situations. Symbol source: ISO 7010; 0149 and 3864-2.
	
	

By Prescription Only

Symbol	Description
	(United States) Caution: Federal law restricts this device to sale by or on the order of a physician. Symbol source: 21 CFR 801.109.

Radiation Laser Apparatus

Symbol	Description
	Identifies the lasers used with the treatment system as Class II products. Use of any lasers or laser systems not approved by Accuray Incorporated is prohibited. Symbol source: IEC 60878; 5152.

Restriction of Hazardous Substances (RoHS) 15

Symbol	Description
	This label is located on the gantry frame under the covers. It indicates that the treatment system contains hazardous substances that are safe for use for 15 years, as declared by Accuray Incorporated. Symbol source: SJ/T11364-2006, section 5.4.

Serial Number

Symbol	Description
	Located on the system and subsystem labels to identify the serial number associated with the Accuray System. Symbol source: ISO 7000; 2498.

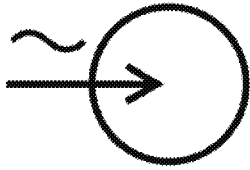
Start of Action

Symbol	Description
	Identifies the location of the Start button on the Status Console . Symbol source: IEC 60878; 5104.

Stop of Action

Symbol	Description
	Identifies the location of the Stop button on the Status Console and Positioning Control Panel . Symbol source: IEC 60878; 5110A.

Rated Power Input

Symbol	Description
	Located on certain system labels to identify the acceptable range of voltage and current supplied to the Accuray System. Symbol source: IEC 60417; 6045.

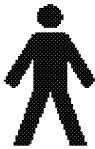
Three Phase Alternating Current

Symbol	Description
	Located on the system/subsystem to identify the equipment is suitable for three-phase alternating current electrical power with no neutral input. Symbol source: IEC 60878; 5032-1.

Three Phase Alternating Current with Neutral Conductor

Symbol	Description
	Located on the system/subsystem to identify the equipment is suitable for three-phase alternating current electrical power with neutral conductor input. Symbol source: IEC 60878; 5032-2.

Type B Equipment

Symbol	Description
	Located on system labeling to indicate that the patient contact surface (couch top) is classified as a Type B Applied Part according to IEC 60601-1. Symbol source: IEC 60878; 5840.

Warning, Laser Beam

Symbol	Description
	Fixed to each laser housing inside the treatment room, and is accompanied by the following text: "Laser light, do not stare into beam." Symbol source: IEC 60878; ISO 7010-W004.

Weight Restriction

Symbol	Description
	Fixed to the end plate at the foot of the couch, and is accompanied by the text: 200 kg (440 lbs). The total distributed load on the couch is not to exceed this value. Symbol source: ISO 7010; P012.
	

X-Ray Source (emitting)

Symbol	Description
	Identifies the location of the Radiation ON light on the Status Console . Symbol source: IEC 60878; 5339.

Use of Safety Mechanisms

- ◆ Open and Closed Interlocks 20
- ◆ Entrance Interlock 21
- ◆ Stop Button 22
- ◆ Emergency Stop Buttons 23
- ◆ Facility Emergency Off Buttons 24



WARNING: The potential for serious injury to the patient or facility personnel exists during an emergency situation or other unexpected system operation. Terminate irradiation and stop movement of all components as recommended in this guide.

◆ Open and Closed Interlocks

Open Interlocks

When the interlocks are in an **Open** state, irradiation cannot start or irradiation is interrupted. There are two **Open** interlock states: System Up and System Interrupt.

Closed Interlocks

When the interlocks are in an a **Closed** state, the system is preparing for irradiation or irradiation is in progress. There are two **Closed** interlock states: System Ready and Beam On.

System and Interlock States

The current state of the system determines whether the interlocks are **Closed** or **Open**.

State	Interlock	Description
System Up	Open	The system has been initialized and is idle, or the patient is being setup on the couch.
System Ready	Closed	• The patient is in the Ready position (inside the bore of the gantry). • The entrance interlock is closed. • The dedicated key has been used to turn the mode switch on the Status Console to the appropriate setting (Image or Treat).

State	Interlock	Description
Beam On	Closed	- The System Ready state has been achieved. - The Start button on the Status Console has been pressed. - The system is producing radiation.
System Interrupt	Open	Once the System Up state has been achieved, a System Interrupt can occur at any time. There are 3 types of system interruptions. Intentional: Acceptable methods to initiate an intentional interruption include the use of the Entrance Interlock, Stop button, and Emergency Stop button. See also “Facility Emergency Off Buttons” (page 24). Unintentional: Unintentional interruptions include, but are not limited to, the following: - The Start button on the Status Console is not pressed within 60 seconds after the Ready light turns on. - The mode switch on the Status Console is turned to Program during a Beam On state. System Initiated: Typically, a system-initiated interruption is caused by a treatment system hardware or software component that may require service. System-initiated interruptions do not include interruptions caused by facility-supplied power.

◆ Entrance Interlock

The entrance interlock is intended to provide a safety measure against unintentional exposure to radiation. Before irradiation is started, the operator ensures that the patient is the only individual in the treatment room, and then sets the entrance interlock to “closed”. The treatment system requires that the entrance interlock remain closed immediately prior to, and during, irradiation. If the entrance interlock is “opened” during beam-on, the safety interlocks are set to a system-interrupt state, couch movement stops, and irradiation stops.

System Responses

If the entrance interlock is opened, the system responses are the same as those described for the **Stop** button.

◆ Stop Button

Use

The **Stop** button is intended to be used in non-emergency situations. For example, press the **Stop** button if the patient moves out of position during setup or a beam-on procedure.

Location

There is a yellow mechanical **Stop** button located on the **Status Console**, and electronic stop buttons on either **Positioning Control Panel**.

System Response

Based on the current state of the system, the following table describes the system response after the **Stop** button is pressed.

State	Response
Idle	• The couch stops if it is moving to the Setup or Ready position. • The manual couch controls on the Positioning Control Panel or the Couch Control Keypad can be used to move the couch, or the tabletop can be released and moved by hand. • The safety interlocks cannot be set to Closed, and the procedure cannot be started.
Procedure Ready	• The safety interlocks are set to an Open, system-interrupt state, and radiation cannot be started. • The couch stops moving. • The manual couch controls on the Positioning Control Panel or the Couch Control Keypad can be used to move the couch, or the tabletop can be released and moved by hand. • The safety interlocks cannot be set to Closed, and the procedure must be started over.
Beam On	• The safety interlocks are set to an Open, system-interrupt state. • The linear accelerator stops generating radiation. • The multi-leaf collimator leaves close. • The collimator jaws close. • The rotating gantry slows to a stop. • The couch stops moving. • The aural signal at the Status Console stops sounding. Any aural signals that are facility supplied stop sounding. • The Radiation On light on the Status Console turns off. Any visual indicators that are facility supplied turn off.

◆ Emergency Stop Buttons



CAUTION: Using an Emergency Off button or an **Emergency Stop** button to regularly shut down the system can cause unnecessary stress and damage to system components. Always properly shut down the system as instructed in this guide.

Use

An **Emergency Stop** button is intended to be used in situations that require power be shut down to the gantry subsystem. For example, the **Emergency Stop** button can be used in the following situations:

- The **Stop** button fails to interrupt a beam-on procedure.
- The patient requires immediate attention.
- The patient moves during treatment.
- During treatment, the dose delivered begins to exceed or is lower than the expected dose.
- Radiation does not terminate after a *CTrue* image scan or treatment procedure has completed.
- The couch does not move, or does not move as expected, during a *CTrue* image scan or treatment procedure.

Emergency Stop Buttons

The treatment system is equipped with three **Emergency Stop** buttons. There are two **Emergency Stop** buttons on the front of the gantry enclosure (left and right) and there is one **Emergency Stop** button on the **Status Console**.

Facility Emergency Stop Buttons

At the discretion of each facility, **Emergency Stop** buttons can be installed inside or outside the treatment room. Accuray Incorporated provides a connection for **Emergency Stop** buttons. See “Emergency Stop Buttons” (page 23) and “Facility Emergency Off Buttons” (page 24).

System Response

Based on the current state of the system, the following table gives the system response when an **Emergency Stop** button is pressed.

State	Response
System Up	• Power to the rotating side of the gantry subsystem is shut down. • The couch stops if it is moving to the Setup or Ready position. • The couch tabletop can be moved manually by hand. • The safety interlocks cannot be set to Closed, and the procedure cannot be started.
System Ready	• The safety interlocks are set to an Open, system-interrupt state, and power to the rotating side of the gantry subsystem is shut down (irradiation cannot be produced). • The couch tabletop can be moved manually by hand to quickly retract the patient from the bore of the gantry. • The safety interlocks cannot be set to Closed, and the procedure must be started over.
Beam On	• The safety interlocks are set to an Open, system-interrupt state. • Power to the rotating side of the gantry subsystem is shut down. • The linear accelerator stops generating radiation. • The multi-leaf collimator leaves close. • The collimator jaws close. • The rotating gantry slows to a stop. • The couch stops moving. • The couch tabletop can be moved manually by hand to quickly retract the patient from the bore of the gantry. • The aural signal at the Status Console stops sounding. Any aural signals that are facility supplied stop sounding. • The Radiation On light on the Status Console turns off. Any visual indicators that are facility supplied turn off.

◆ Facility Emergency Off Buttons



CAUTION: Using an Emergency Off button or an **Emergency Stop** button to regularly shut down the system can cause unnecessary stress and damage to system components. Always properly shut down the system as instructed in this guide.

Use

An Emergency Off button is intended to be used in situations which require that the patient be quickly removed from the treatment room or facility. These types of situations may include natural or environmental hazards that occur in the vicinity of the facility. An Emergency Off button may also be used if there is smoke or fire visible in the treatment room or areas adjacent to the treatment room.

Installation and Location

While the treatment system is equipped with **Emergency Stop** buttons, the installation of additional Emergency Off buttons is left to the discretion of your facility. Accuray Incorporated provides a connection for Emergency Off connections. See “Emergency Stop Buttons” (page 23) and “Facility Emergency Off Buttons” (page 24).

Emergency Off buttons can be installed inside or outside the treatment room. If installed outside the treatment room, Accuray Incorporated recommends that an Emergency Off button be located near the Treatment Delivery Console.

System Response

When a facility installed Emergency Off button is pressed, power to the entire treatment system is shut down. This includes the Power Distribution Unit which supplies power to the couch and gantry subsystems, the Treatment Delivery Console computer, and the moveable lasers. As a result, an Emergency Off button will terminate irradiation and stop the movement of all treatment system components.

Operator Responsibilities

This section outlines fundamental responsibilities for all operators of the treatment delivery system. Operators should observe this guidance at all times when using the treatment delivery system.

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- ◆ Check the Patient Monitoring System 26
- ◆ Treatment Room Protocol..... 26
- ◆ Clean Components 27
- ◆ Planned Maintenance and Service..... 28

◆ Radiation Safety

For more information on radiation safety, see the *Physics Essentials Guide*.



WARNING: The treatment system generates radiation for CTrue™ image guidance scans, treatment procedures, and quality assurance procedures. To avoid unnecessary radiation exposure during non-patient procedures, ensure the treatment room is unoccupied and the entrance is secured. Before a scan or treatment procedure is started, ensure that the patient is the only person in the treatment room and the entrance to the treatment room is secure.



CAUTION: Low dose outputs can occur if a warmup procedure is not performed. If you intend to analyze dose data, you must perform a warmup procedure to ensure the integrity of the resulting data is not affected.

◆ Check the Patient Monitoring System

Make sure you have a clear view of the patient from the Treatment Delivery Console. If cameras are used, they should give a clear view of the patient at all times. Verify that the audio and visual monitoring devices located outside the treatment room function correctly.

◆ Treatment Room Protocol

Accuray Incorporated provides interlock connections to make sure irradiation can not be started until the entrance to the treatment room is closed. Before you can start a CTrue image scan or treatment procedure, the entrance to the treatment room must be closed. Only the patient should be in the treatment room during irradiation.



WARNING: Placing unauthorized materials in the beam path can affect imaging or treatment accuracy. Always check that there are no unauthorized materials on the couch tabletop before starting a *CTrue* image scan or treatment procedure.



WARNING: Patient data or confidentiality may be compromised if a workstation is left unattended. To prevent this, lock or exit your workstation before leaving. You may also clear patient information from the workstation display if you are no longer working with a patient.

◆ Clean Components

Couch Top

To clean the couch top, if required, use a non-abrasive solution with a pH value of 7. Decontaminate the couch top using facility decontamination protocols. According to your facility protocols, it is recommended that you place a clean linen or sheet on the couch tabletop before a patient is positioned on the couch.

Couch Drainage System



WARNING: The treatment room floor may become slippery when wet. If the couch drainage system diverts fluid to the foot of the couch, proceed with caution in this area to avoid injury.

If fluid seeps into the couch, it is diverted onto the floor at the foot of the couch. Clean the floor at the foot of the couch according to your facility procedures. Decontaminate the floor using facility decontamination protocols. Contact a Service Representative to have the internal drainage system made accessible for a clinical representative to decontaminate.



NOTE: An Accuray Incorporated Service Representative will replace the parts of the drainage system that cannot be decontaminated. Replaced parts should be disposed of according to your facility procedures. All other parts will be made available for a clinical representative to decontaminate according to facility protocols.

Clean the Positioning Control Panel (PCP)

Before you clean the PCP, shut down the system. To clean the PCP, use a microfiber cloth to remove visible dust or dirt. Then, use a proper cleaning kit (anti-static and alcohol- and ammonia-free).

- Always spray cleaner into the cleaning cloth, rather than directly onto the LCD display.
- Gently wipe the screen in a circular motion.
- Remove all moisture from the screen to prevent damage.
- Allow the LCD display to dry completely before power is restored to the system.

Repeat this process several times if any markings remain after an initial cleaning. Do not use excessive pressure or scrubbing pads.

Clean Synchrony® Respiratory Tracking Components

To clean the Synchrony® Respiratory Tracking components, disconnect the couch connector on the Light Box from the couch tabletop, and then disconnect the Tracking Marker cables from the Light Box. Clean the cables, Light Box, and Tracking Markers with a damp cloth, avoiding the electrical and optical connectors and the Velcro patches. As needed, you may also use a non-abrasive solution with a pH value of 7. Decontaminate the components using facility decontamination protocols.

Additional Information

Accuray Incorporated cannot advise specific decontamination methods, as these can vary by disease. If additional direction is required, consult your national center for disease control.

◆ Planned Maintenance and Service



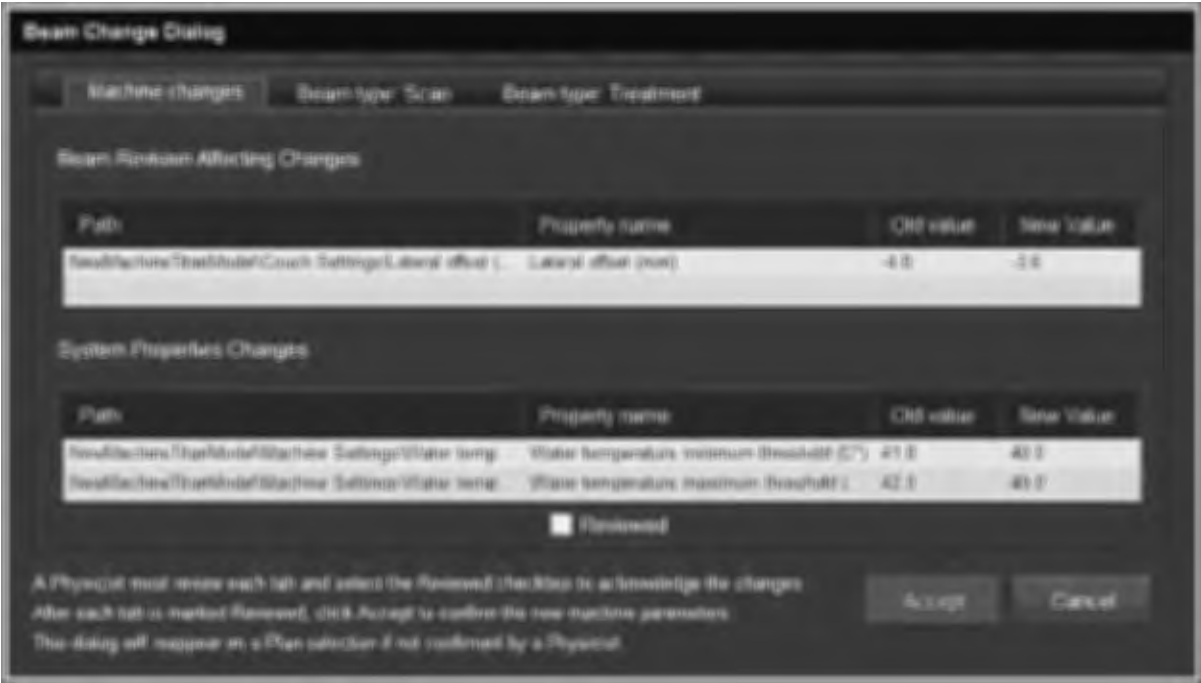
WARNING: Only qualified service personnel should service and maintain Accuray treatment systems. Incorrect service can result in personal injury and damage to system components. If you determine that the treatment system requires service, contact the Accuray Technical Solution Center.

Planned maintenance procedures are scheduled to be performed by a qualified service technician on a regular basis. If you determine that the treatment system requires maintenance or service, always contact the Accuray Technical Solution Center.

◆ Beam Change Dialog Box

Resolve the Beam Change Dialog Box

The **Beam Change Dialog** box may appear when you attempt to load a plan. A physicist must select the **Reviewed** check box and click **Accept** for each tab in the dialog box before you can finish loading the plan.





Coordinates and Movements

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Axes, Planes, and Lasers 34

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Couch Positions and Adjustments 42

Coordinates and Isocenters

◆ Fixed Coordinate System (IEC f)	32
◆ Machine and Virtual Isocenters	32

◆ Fixed Coordinate System (IEC f)

The patient alignment coordinate system used by the treatment system is based on the stationary coordinate system and fixed in space (IEC f). It is defined by three coordinate axes, all of which originate from the treatment system machine isocenter.

The fixed coordinate system is in accordance with IEC 61217, Radiotherapy equipment-coordinates, movements, and scales. See the illustration “Machine and Virtual Isocenters” (page 32).

Lateral Axis (X)

The lateral axis (X_f) originates at the machine isocenter and is directed toward ($+X_f$) the right side of the gantry when viewed from the foot of the couch.

Longitudinal Axis (Y)

The longitudinal axis (Y_f) originates at the machine isocenter and is directed away ($+Y_f$) from the foot of the couch toward the gantry. The treatment system gantry rotates about the Y_f axis.

Vertical Axis (Z)

The vertical axis (Z_f) originates at the machine isocenter and is directed upward ($+Z_f$) when viewed from the foot of the couch.

◆ Machine and Virtual Isocenters

Machine Isocenter

The machine isocenter is commissioned by Accuray Incorporated at a specific point beneath the beam path (linac) in the gantry bore. In accordance with the IEC f coordinate system, the machine isocenter is fixed in space.

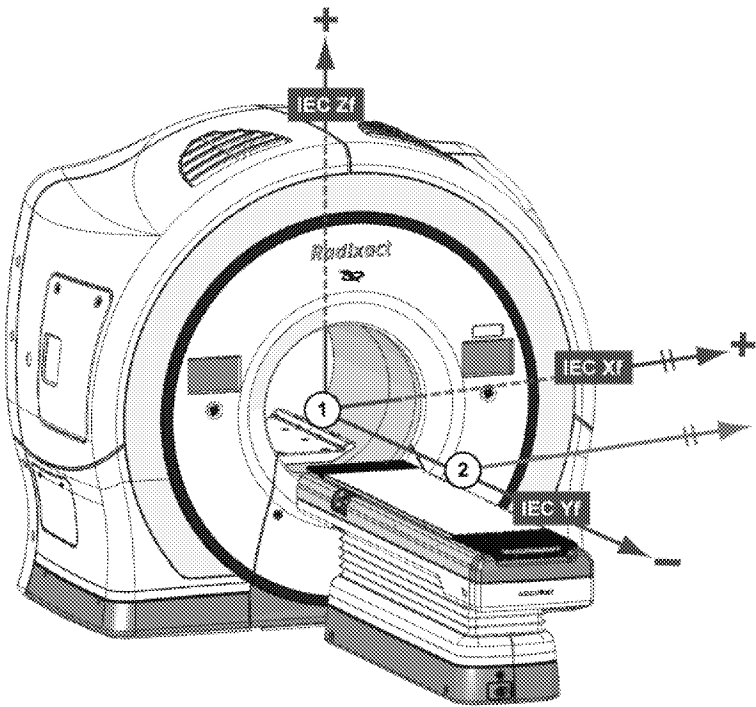
Virtual Isocenter



NOTE: For nearly all treatment systems, the distance from the machine to the virtual isocenter is -700.0 mm (IEC Y). To identify the true distance for your system, contact the Accuray Technical Solution Center.

The virtual isocenter is -700.0 mm IEC Yf from the machine isocenter. It is fixed in space at the same height as the machine isocenter along the IEC Yf axis of rotation and coincident with the IEC Xf axis. See also, “Virtual Isocenter Laser” (page 35).

In the following figure, blue lines depict the IEC Yf, Zf, and Xf axes, and the green line depicts the coincident IEC Xf relationship between the machine and virtual isocenter.

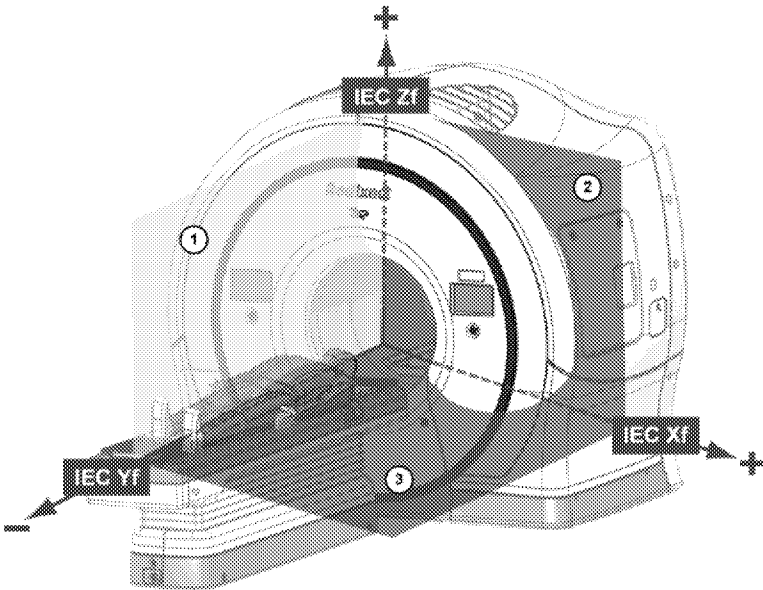


Item	Isocenter	IEC f Coordinates
①	Machine Isocenter	• 0.0 IEC Xf (lateral) • 0.0 IEC Yf (longitudinal) • 0.0 IEC Zf (vertical)
②	Virtual Isocenter	• 0.0 IEC Xf (lateral) • -700.0 mm IEC Yf (longitudinal) • 0.0 IEC Zf (vertical)

Axes, Planes, and Lasers

- ◆ Axes and Planes 34
- ◆ Green, Stationary Lasers 35
- ◆ Red, Moveable Lasers 36

◆ Axes and Planes



Item	Plane	Description
①	Sagittal Plane	The IEC Y and IEC Z axes define a sagittal plane.
②	Axial Plane	The IEC Z and IEC X axes define an axial plane.
③	Coronal Plane	The IEC X and IEC Y axes define a coronal plane.



NOTE: Oblique axial planes are not supported by the system and cannot be used for treatment planning.

◆ Green, Stationary Lasers

The planes projected by the green, stationary lasers are fixed and relative to the machine isocenter coordinate axes.

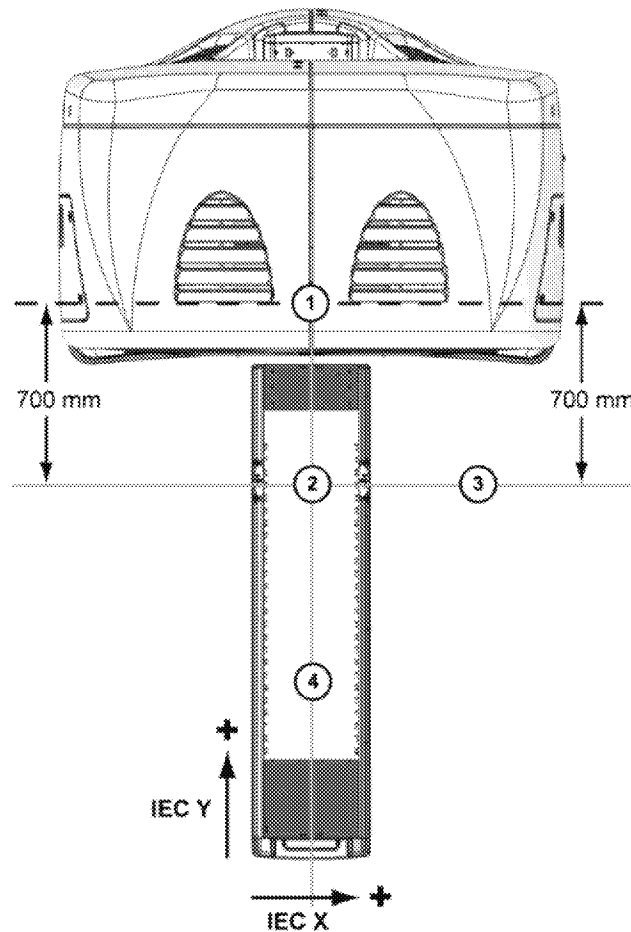
Gantry Isocenter Laser

One gantry isocenter laser is mounted to the wall behind the bore of the gantry. This laser projects a green cross hair that defines a coronal plane and a sagittal plane through the gantry bore. This laser is typically used by physicists for quality assurance and research procedures.

- The sagittal plane (laser line) is centered laterally, with respect to the machine isocenter.
- The coronal plane (laser line) is coincident with the height of the machine isocenter.

Virtual Isocenter Laser

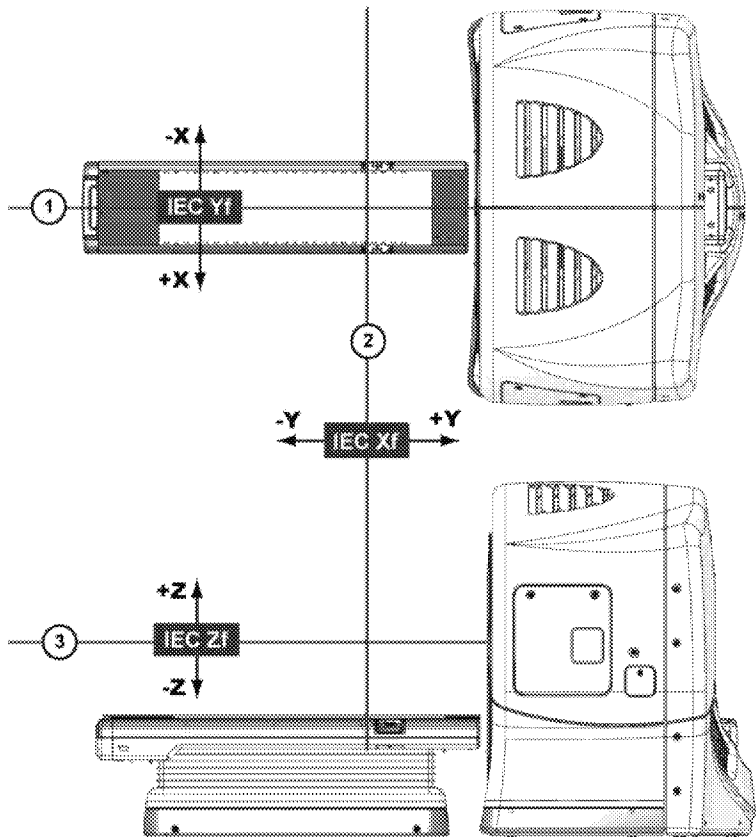
One virtual isocenter laser is mounted to the ceiling of the treatment room, above the couch. This laser projects a green cross-hair that defines an axial plane and a sagittal plane.



Item	Name	Description
①	Machine Isocenter	Coordinates: 0.0 IEC Xf, Yf, and Zf
②	Virtual Isocenter	Coordinates: 0.0 IEC Xf and Zf, -700.0 mm IEC Yf
③	Axial Plane	The axial plane (laser line) is -700.0 mm IEC Y from the machine isocenter.
④	Sagittal Plane	The sagittal plane (laser line) is centered laterally with respect to the machine isocenter.

◆ Red, Moveable Lasers

The planes projected by the red, moveable lasers are offset from the IEC f coordinate axes. The positions of the red lasers are determined by parameters in the patient's plan or by registered offset adjustments.



Item	Laser	Description
①	Sagittal Laser	One overhead laser is mounted to the ceiling of the treatment room. This laser projects a red line to define a variable sagittal plane and moves in a lateral (IEC X) direction.
②	Axial Lasers	Two vertical side lasers are mounted below ceiling height on the left and right upper side walls of the treatment room. Each laser projects a red line to define the same variable axial plane, and moves in a longitudinal (IEC Y) direction.
③	Coronal Lasers	Two vertical side lasers are mounted to the left and right side walls of the treatment room. Each laser projects a red line to define the same variable coronal plane, and moves in a vertical (IEC Z) direction.

Translation and Rotation Movements

◆ Couch Translations	38
◆ Patient Rotations	39

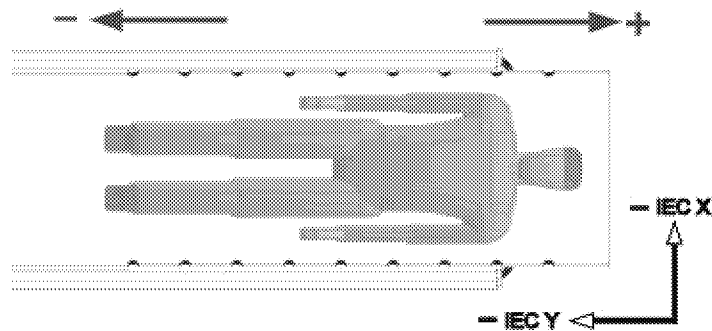
◆ Couch Translations

The following patient images are shown in a head first supine orientation.

Longitudinal Couch Movement

When viewed from above the couch:

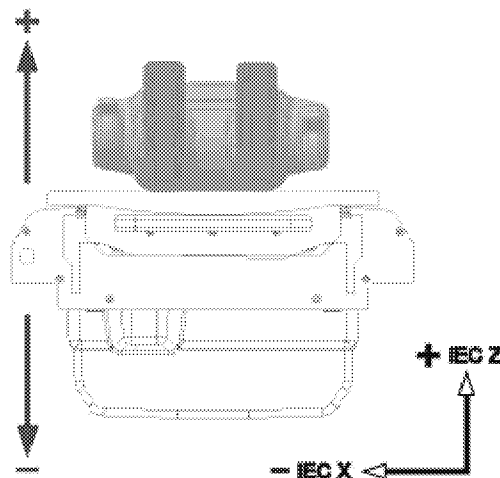
- Positive (+) longitudinal movement is in toward the gantry.
- Negative (-) longitudinal movement is away from the gantry.



Vertical Couch Movement

When viewed from the foot of the couch:

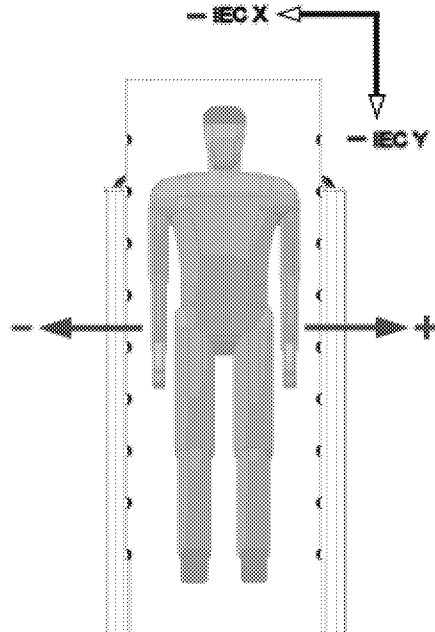
- Positive (+) vertical movement is up.
- Negative (-) vertical movement is down.



Lateral Movement

When viewed from above the couch:

- Positive (+) lateral movement is right.
- Negative (-) lateral movement is left.



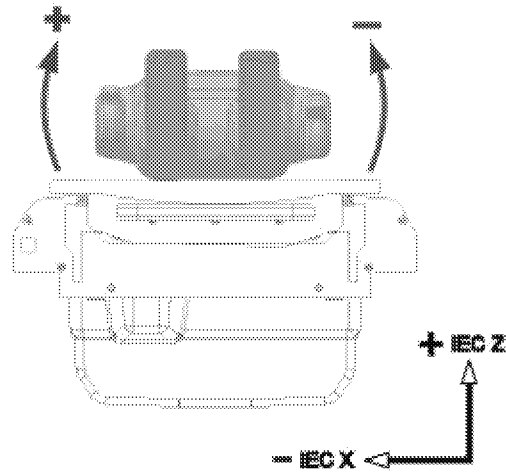
◆ Patient Rotations

The following images illustrate how a patient's position relates to the coordinate system. The couch cannot make roll, pitch, or yaw movements. Roll is compensated automatically. See "Automatic Roll Correction" (page 128). Pitch and yaw must be manually compensated.

Roll

When viewed from the foot of the couch:

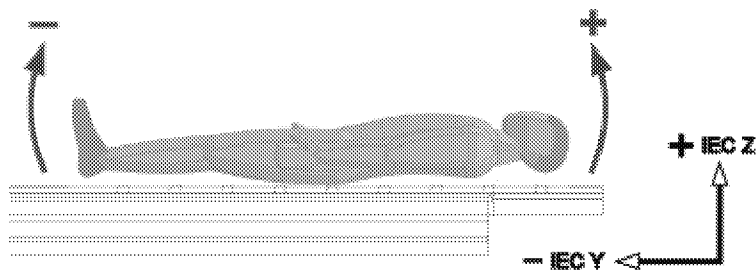
- Positive (+) roll is clockwise.
- Negative (-) roll is counterclockwise.



Pitch

When viewed from the right side of the couch:

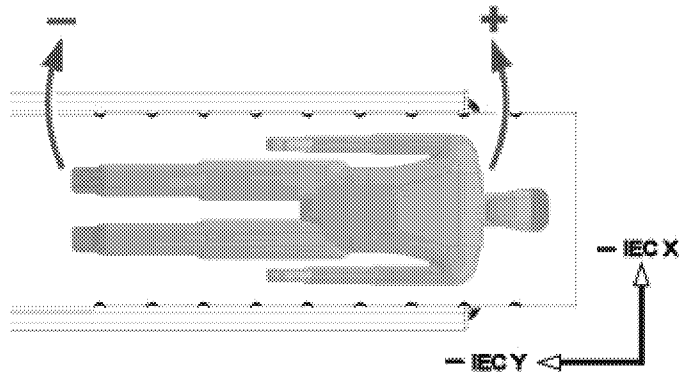
- Positive (+) pitch is counterclockwise.
- Negative (-) pitch is clockwise.



Yaw

When viewed from above the couch:

- Positive (+) yaw is counterclockwise.
- Negative (-) yaw is clockwise.



Couch Positions and Adjustments

◆ Preprogrammed Couch Positions	42
◆ Translation and Rotation Adjustments	42

◆ Preprogrammed Couch Positions

The following positions are controlled by preprogrammed couch parameters. When each position is initiated as described below, the preprogrammed parameters are used to move the couch.

Step Move

Step Move on the **Positioning Control Panel** is used to enter preprogrammed movements. Enter a distance and press a Move button to initiate the specified movement.

Planned Setup Position

Planned Setup is the position of the couch (and lasers) based on parameters saved in the patient's Plan. When **Setup** on the **Positioning Control Panel** is pressed, the couch moves the patient into general alignment with the lasers.

Ready Position

Immediately before radiation is started, the Ready position is the position of the couch inside the bore of the gantry. Once the patient is in the correct Initial Setup or Registered Setup position, press the **Ready** button on the **Positioning Control Panel** to move the couch to the Ready position.

◆ Translation and Rotation Adjustments

Initial Setup Position

Initial Setup is the position of a patient before a *CTrue* image scan is performed. Once the couch and lasers are in the Planned Setup position, the patient is adjusted manually and physically to achieve Initial Setup.

Registered Setup Position



WARNING: Patient mistreatment can occur if the patient is not positioned correctly. If you are not confident that the patient is in the correct Registered Setup position, Accuray Incorporated recommends that you perform a new *CTrue* image scan and image registration to verify the position of the patient. You can then apply the new registration results.

The couch moves into the Registered Setup position when the therapist presses **Setup** on the **Positioning Control Panel**. The couch moves the patient based on *CTrue* image registration adjustments.

Final Couch Position



WARNING: Patient mistreatment can occur if the patient is not positioned correctly. If you are not confident that the patient is in the correct Registered Setup position, Accuray Incorporated recommends that you perform a new *CTrue* image scan and image registration to verify the position of the patient. You can then apply the new registration results.

If you position a patient for treatment without a *CTrue* image scan, the Final Couch position is the manually aligned position of the couch before the therapist moves it to the Ready position. See “Treatment Without a CTrue Image Scan” (page 205) for additional information.

Manual Translation Adjustments

Use the couch movement controls to adjust the position of the couch during initial setup.

Physical Lateral Adjustments



WARNING: Patient mistreatment can occur if the patient is not positioned correctly. If you are not confident that the patient is in the correct Registered Setup position, Accuray Incorporated recommends that you perform a new *CTrue* image scan and image registration to verify the position of the patient. You can then apply the new registration results.

If the intended lateral position of the patient is not achievable, physical adjustment may be required. Based on your clinical objectives, you may physically adjust the patient to achieve the correct setup position. If the physical adjustment occurs after a *CTrue* image scan, Accuray Incorporated recommends that you perform a new *CTrue* image scan and image registration to verify the adjusted position of the patient.

Physical Rotation Adjustments

Based on registration adjustments, you can manually adjust the pitch and yaw position of the patient. Roll is compensated automatically. See “Automatic Roll Correction” (page 128). Rotational adjustments should be made only after all translational adjustments are complete. See “Patient Rotations” (page 39).



WARNING: If a roll correction was accepted during image registration, the gantry will automatically correct for roll when you click **Prepare Treatment**. To prevent incorrect patient setup, do not adjust the roll position of the patient if an automatic roll correction was accepted during image registration.



WARNING: Patient mistreatment can occur if the patient is not positioned correctly. If you are not confident that the patient is in the correct Registered Setup position, Accuray Incorporated recommends that you perform a new *CTrue* image scan and image registration to verify the position of the patient. You can then apply the new registration results.



System Controls

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Control Status Indicators 64

Motion Tracking Components 65

Power Control Panel and Power Distribution Unit

The **Power Control Panel** is installed on the side of the gantry enclosure. Use it to turn power to the treatment system **On** and **Off**. The Power Distribution Unit delivers power to the radiation delivery subsystem.

- ◆ Power Control Panel 46
- ◆ Power Distribution Unit 47

◆ Power Control Panel



System Power Switch and Key

A mechanical key (power key) is required to set the **System Power** switch to the **Enabled** and **Disabled** positions. The power key must be set to **Disabled** before it can be removed from **System Power** switch. The **System Power** switch must be turned to **Enabled** to turn on power to the system. To turn off power, do one of the following:

- Press **Stop** on the **Status Console** while the **System Power** switch is turned to **Enabled**.
- Shut down *Microsoft Windows* to turn off the TDC computer. Wait for the computer to shut down.
- Enter the treatment room and turn the **System Power** switch to **Disabled**.

System Status Indicators

Indicators (LEDs) on the **Power Control Panel** give the current status of the Power Distribution Unit (PDU), Entrance Interlock, and **Emergency Stop**.

Status	Indicators
PDU Power	OK indicates power from the Power Distribution Unit to the system is sufficient. Fail indicates there is a problem with power supplied to the system.
Entrance Interlock	Closed indicates the barrier to the treatment room is secure. Open indicates the barrier to the treatment room is not secure.
Emergency Stop	Ready indicates power has not been interrupted and the system is ready for use. Interrupt indicates power for the system has been interrupted. In this case, an Emergency Stop button was used or another type of power interruption has occurred.

◆ Power Distribution Unit

Facility power is supplied to the Power Distribution Unit (PDU), which delivers power to the Treatment Delivery Console computer, moveable lasers, couch, and gantry. The main circuit breaker on the Power Distribution Unit is also used when you start up the system.



AC Mains Circuit Breaker



Uninterruptible Power Supply (UPS)

Status Console

Use the **Status Console** to start and stop a *CTrue* image scan or treatment procedure. The **Status Console** is located near the Treatment Delivery Console computer.

- ◆ Mode Switch and Key 48
- ◆ Procedure Indicators and Controls 49
- ◆ Stop a Scan or Treatment 49



◆ Mode Switch and Key

A mechanical key (mode key) is required to set the mode switch to the **Program**, **Image**, and **Treat** positions. The mode key must be set to **Program** before it can be removed from the mode switch.

Program Mode

The mode switch is set to **Program** when a scan or treatment procedure is not in progress.

Image Mode

The mode switch must be set to **Image** before you can start a *CTrue* image scan.

Treat Mode

The mode switch must be set to **Treat** mode before you can start a treatment procedure. While in **Treat** mode, you may also acquire kV radiograph images, which are used for motion tracking treatments.

◆ Procedure Indicators and Controls

Ready Light

When the system is ready to start a *CTrue* image scan or treatment procedure, the green **Ready** light turns on. This light stays on for 60 seconds. If you do not press the **Start** button within 60 seconds, you must start the *CTrue* image scan or treatment procedure over.

Start Button

When the **Ready** light is on, press the green **Start** button to start the *CTrue* image scan or treatment procedure.

Radiation On Light

The yellow **Radiation On** light turns on as radiation is generated by the system. Once the scan or treatment is complete, the **Radiation On** light turns off. It also turns off if irradiation is interrupted.

◆ Stop a Scan or Treatment

Stop Button

At the **Status Console**, press the yellow **Stop** button to stop movement of the couch and terminate irradiation.

Emergency Stop Button

At the **Status Console**, press the red **Emergency Stop** button to stop movement of the couch and shut down power to the rotating side of the gantry.

Positioning Control Panel

A **Positioning Control Panel (PCP)** is located on the front left and right side of the gantry enclosure.

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◆ Step Move Tab	53
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◆ Couch and Laser Positions

Current Couch Positions

The current longitudinal, vertical, and lateral couch positions display the absolute position of the couch. **Current Couch Position** fields appear on **Main**, **Ref Position**, and **Step Move** tabs.

Current Laser Positions

The laser positions are based on fixed coordinates (IEC “f”) relative to the treatment room.

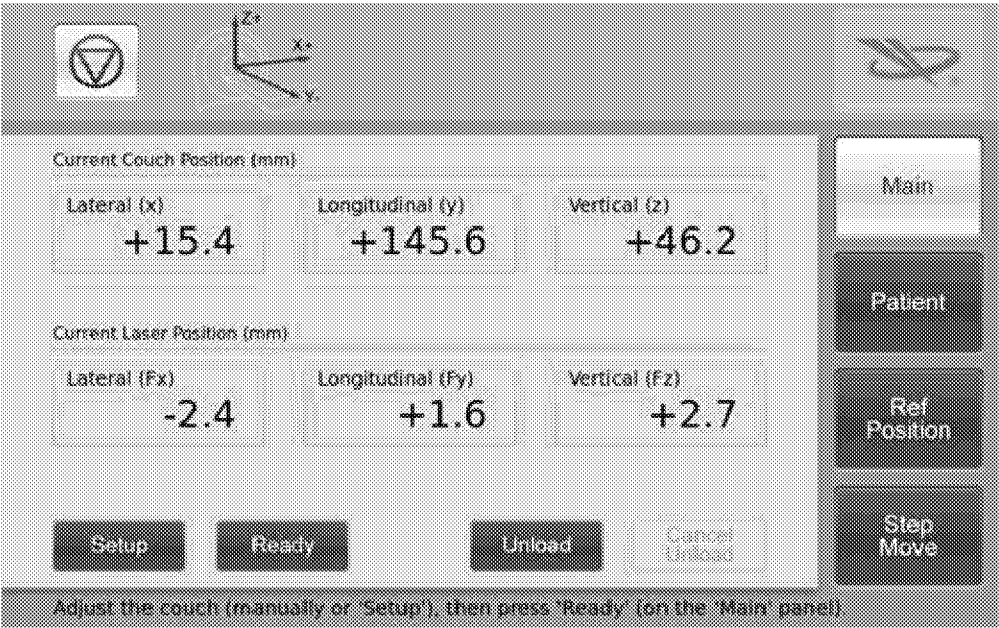
- **Lateral (x)** is the lateral position of the red, overhead sagittal laser.
- **Longitudinal (y)** is the longitudinal position of the red, overhead axial lasers.
- **Vertical (z)** is the vertical position of the red, left- and right-side coronal lasers.

◆ Use the Main Tab

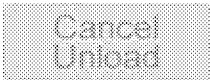
The **Main** tab is the primary tab on the **Positioning Control Panel**. The current lateral (X), longitudinal (Y), and vertical (Z) positions of the couch are displayed. Use the **Main** tab controls to move the couch to the Setup and Ready positions.



WARNING: As the couch moves, pinch points can cause serious injury. Avoid contact with moving parts and instruct the patient to stay clear of moving parts. If required, press a **Stop** button to stop couch movement.



Main Tab

Button	Description
	Press the Setup button to move the couch to the planned setup or registered setup position.
	Press the Ready button to move the couch to the Ready position before the start of a <i>CTrue</i> image Scan or treatment procedure.
	Press the Unload button to move the couch to a position that is convenient for assisting a patient onto and off of the couch.
	Press the Cancel Unload button to stop couch movement to the unload position. A dialog box appears. Press OK to confirm that movement was stopped. Cancel Unload does not cancel the procedure.
	Press the yellow stop button to stop any preprogrammed movement. The stop button also cancels the current procedure.

Unload Position

Press the **Unload** button to move the couch from its current position to the lowest vertical (-Z) and farthest longitudinal (-Y) position away from the gantry. When the couch descends to the Unload position, a pinch point may exist between the tabletop and the gantry covers. The unload function also moves the lateral position of the couch tabletop to 0.0 mm IEC X.



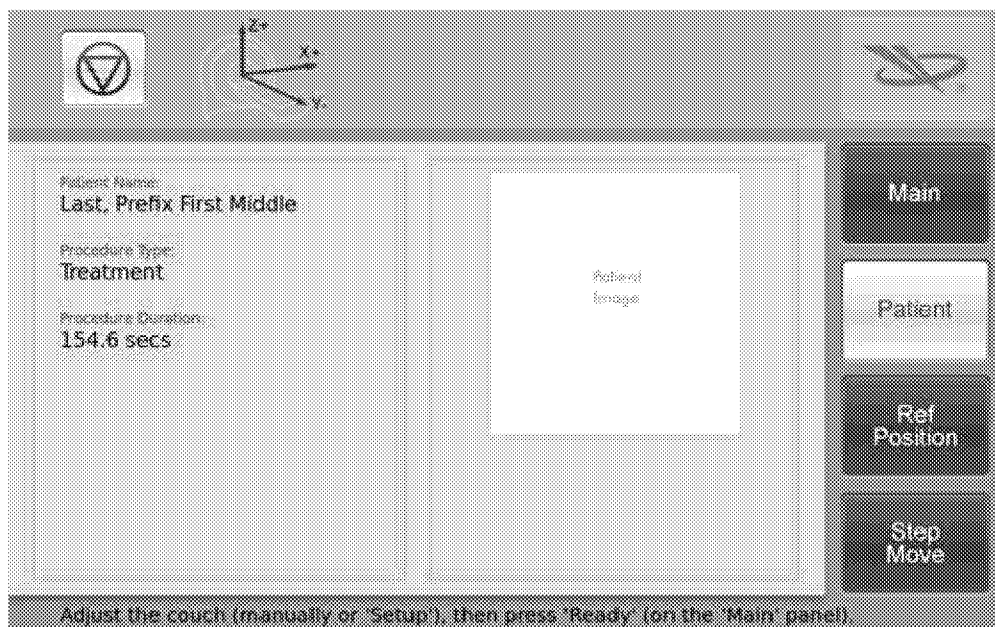
WARNING: As the couch moves, pinch points can cause serious injury. Avoid contact with moving parts and instruct the patient to stay clear of moving parts. If required, press a **Stop** button to stop couch movement.



TIP: Move the couch to the unload position before assisting each patient onto the tabletop. This returns the lateral position of the couch tabletop to the zero position (no lateral offset).

◆ Display Patient Information

On the **Positioning Control Panel**, press **Patient** to display the **Patient** tab. If a patient image is displayed on the Common Frame, the same photo is displayed on the **Patient** tab. The patient's name, procedure type, and procedure duration are given. If patient data exceeds the space available on the display, use the scroll bar.



Patient Tab

◆ Verify Couch Adjustments

On the **Positioning Control Panel**, press **Ref Position** (referenced couch position) to display the **Ref Position** tab. This screen can be used to verify adjustments that have been applied to the couch.

Reset Origin

Press the **Reset Origin** button to set the **Referenced Couch Position** to zero (0). Once couch movement is complete, use the **Referenced Couch Position** to verify that the couch is in the correct position before treatment. The system resets the couch origin when a move to the Ready position is accepted.

◆ Step Move Tab



WARNING: As the couch moves, pinch points can cause serious injury. Avoid contact with moving parts and instruct the patient to stay clear of moving parts. If required, press a **Stop** button to stop couch movement.

Press **Step Move** to display the **Step Move** tab. This screen is used to specify lateral, longitudinal, and vertical couch movement. By default, the current position of the couch is displayed.

Current Couch Position (mm)

Lateral (x)	Longitudinal (y)	Vertical (z)
+15.4	+145.6	+46.2

Units (mm): 0.1, 1.0, 10.0

Move Amount (mm): - +52.3 +

Buttons: Clear, Cancel Move, Move X, Move Y, Move Z, Step Move

Right Panel: Main, Patient, Ref Position, Step Move

Adjust the couch (manually or 'Setup'), then press 'Ready' (on the 'Main' panel).

Step Move Tab

Use Step Move

To perform a step move, use the plus and minus buttons to enter a value in the **Move Amount** field, and then press a **Move X**, **Move Y**, or **Move Z** button.

- If a step move exceeds the couch's range of motion, a dialog box appears and informs you that your request is not valid. Press **OK** to acknowledge the message, and then verify your positioning intentions before attempting another step move.
- To switch between large and small step moves, press the **Units (mm)** button.

Cancel Move

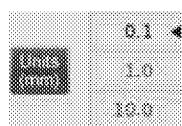
Press the **Cancel Move** button to stop a step move. A dialog message appears. Press **OK** to confirm that movement was stopped and acknowledge the current position of the couch.

Units (mm)



NOTE: The couch has a positional accuracy of 0.35 mm, so if you choose an increment of 0.1 mm, the couch may not move. If you have any questions or concerns, please contact the Accuray Technical Solution Center.

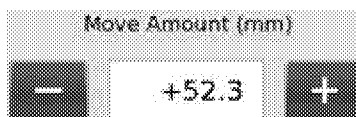
Press the **Units (mm)** button to specify 10 mm, 1 mm, 0.1 mm increments used to enter values into the **Move Amount** field. Each time the **Units (mm)** button is pressed, the blue arrow toggles to the next increment.



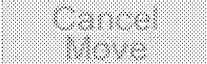
Units (mm)

Move Amount

Press plus (+) or minus (-) buttons to specify the amount of couch movement. The total step move distance appears in the **Move Amount** field. The **Move Amount** value determines the amount of movement for the **Move X**, **Move Y**, and **Move Z** controls.



Move Amount (mm)

Button	Description
	Press the Move X button to move the couch in a lateral direction.
	Press the Move Y button to move the couch in a longitudinal direction.
	Press the Move Z button to move the couch in a vertical direction.
	Press the Clear button to set the Move Amount (mm) value to zero.
	Press the Cancel Move button to stop a couch step move. Cancel Move does not cancel the procedure.

◆ Couch Status Indicators

Couch Status alerts may appear on any **Positioning Control Panel** tab that displays the **Current Couch Position**. Status alerts inform users of conditions that may affect couch positioning, and can be displayed prior to or during couch movement.

Alert Descriptions

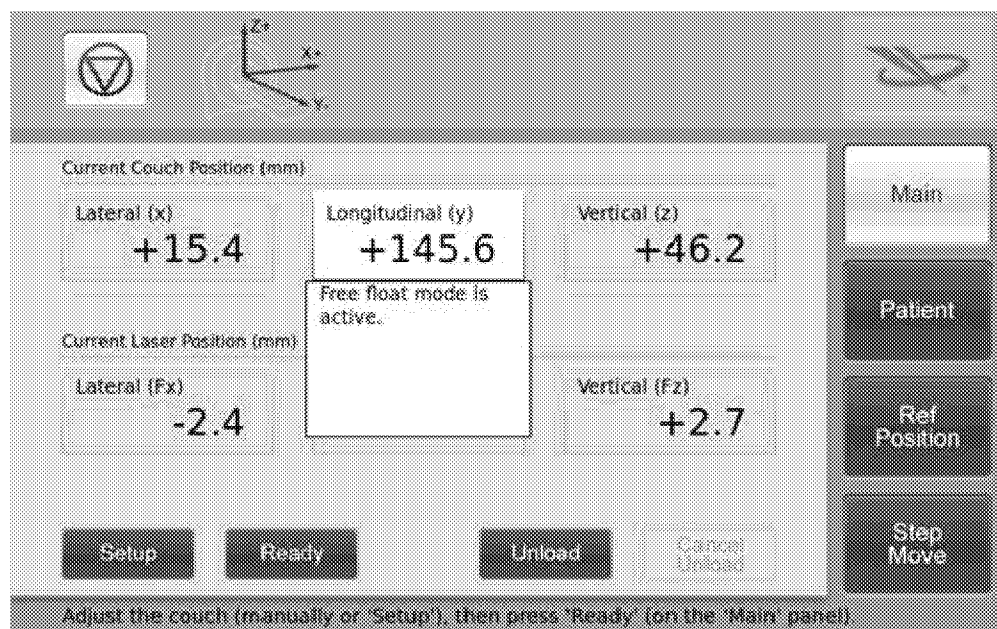
The lateral (X), longitudinal (Y) or vertical (Z) field changes to white or yellow to indicate a condition that may prevent or interrupt couch movement. The field changes to green when the **Current Couch Position** field matches the **Expected Couch Position**.

- Press a white or yellow field to view the cause of the alert.
- Once it appears, the message remains open for five seconds. Press the field again to display the message.
- Touch the alert message to remove it immediately.

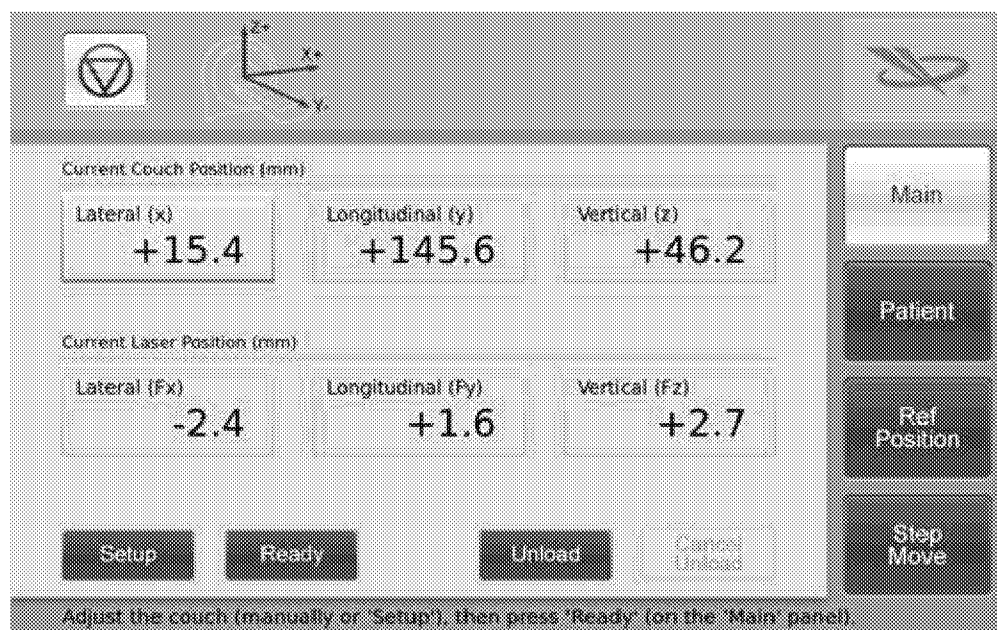
Alert Messages

The following messages may appear during system operation:

- Couch is at an end stop.
- Free float mode is active.
- Couch did not reach the unload position.
- Unable to complete movement request.
- Bore Avoidance.



Longitudinal Alert Message



Lateral Alert

Ready Position Verification

When the **Ready** button on the **Main** tab is pressed before a registered treatment, the current position of the couch is compared to the intended setup position. If the positions are inconsistent ($\pm 0.5\text{mm}$), a **Confirmation** dialog appears.

The dialog displays the **Current** and **Expected** couch position. If an axis is out of position, the coordinate will be red.

You may not move the couch while the **Confirmation** dialog is displayed. Click **Cancel** to return to the **Main** tab, and then click **Setup** to move the couch into the **Expected** position.

Warning

The Couch is not at the expected position. Adjust the couch manually or use the Setup button before clicking the Ready button.

	Couch Position (mm) [IEC X/Y/Z]		
Current	+0.0	+245.0	+350.0
Expected	+0.0	+250.0	+350.0

Cancel

◆ Treatment Delivery Console Couch Controls

The Treatment Delivery Console Couch Controls is a licensable feature that allows you to move the couch to the Registered Setup and Ready positions from outside the treatment room. The **Couch Controls** dialog displays after you prepare a treatment or calibration procedure. This control is synchronized with each **Positioning Control Panel** inside the treatment room. When the **Couch Controls** dialog appears, you may still choose to use couch movement controls inside the treatment room.



IMPORTANT: If the Treatment Delivery Console Couch Controls are unable to connect to the system, or if you close the **Couch Controls** dialog, you must use the couch movement controls inside the treatment room.



CAUTION: Before moving the couch with the **Setup** or **Ready** buttons, verify that there is sufficient vertical clearance between the bore and any large objects or phantoms on the couch. Failure to do so could result in equipment damage.

Couch Control Main Panel

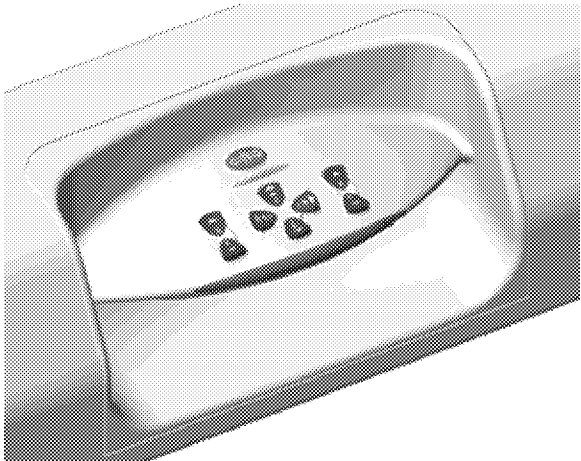
The **Couch Controls** dialog box has several of the same functions as the **Main** tab of the **Positioning Control Panel**. The **Current Couch Position** fields are green when they match the **Expected Couch Position**.



Couch Control Keypad

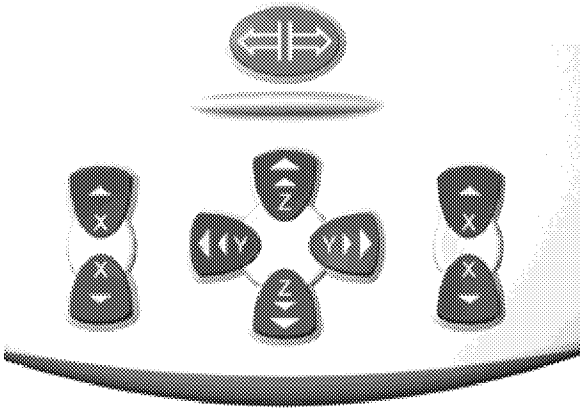
A Couch Control Keypad (CCK) is located on both sides of the couch. The Couch Control Keypad provides couch movement in longitudinal, vertical, and lateral directions. Longitudinal release buttons are available on the Couch Control Keypad.

- ◆ Couch Control Keypad Interface..... 59
- ◆ Free Float Mode 61



Couch Control Keypad

- ◆ Couch Control Keypad Interface

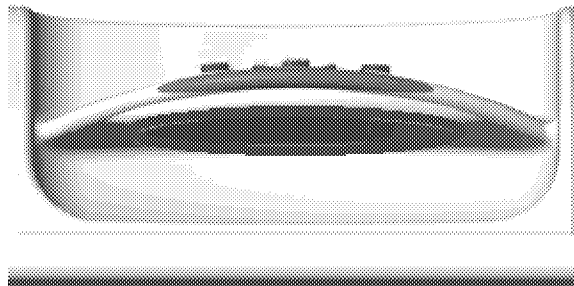


Couch Control Interface

Enable Button

Press the enable button located on the bottom side of the Couch Control Keypad to activate the keypad before pressing move buttons or the longitudinal release button. While an enable button is pressed, both Positioning Control Panels and the other Couch Control Keypad are disabled.

- Press and hold the enable button, and then press a Move button to move the couch. To stop movement, release the enable button or Move button.
- Press and hold the enable button, and then press the longitudinal release button to enter free float mode.



Enable Button (outlined in red)

Keypad Buttons

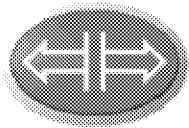
Press and hold the enable button and then press and hold the X, Y or Z button to move the couch. To move faster, push down on a Y or Z button until it clicks. To stop couch movement, release pressure on the Move or Enable button. Longitudinal (Y) and vertical (Z) movement has slow (small arrow) and fast (large arrow) speeds. The lateral (X) axis only moves at slow speed due to the small adjustments normally made in this direction.



CAUTION: Press only one directional button on the Couch Control Keypad at a time. Ensure only one user presses the directional buttons on the Couch Control Keypad at any given time. Activating more than one directional button or Couch Control Keypad simultaneously may cause the following to occur:

- The couch interprets multiple activated directional buttons or a button stuck in the depressed state as a keypad malfunction.
- The lights for the directional buttons turn off.
- The functionality of the couch is disabled.

If this issue occurs, restart the system. A full system restart restores functionality to the couch.

	Press the lateral X up or X down buttons to move the couch $\pm$ IEC X. Lateral movement controls are located on the left and right side of each keypad.
	Press the longitudinal Y out or Y in buttons to move the couch $\pm$ IEC Y.
	Press the vertical Z up or Z down buttons to move the couch $\pm$ IEC Z.
	A longitudinal release button is located on each Couch Control Keypad. Press any longitudinal release button to release the tabletop and enter free float mode.



WARNING: Registration and treatment accuracy can be affected if the patient does not remain in the correct setup position. Do not activate free float mode when the patient is in the Registered Setup Position or Ready Position.

◆ Free Float Mode

Press and hold the enable button and then press a longitudinal release button to enter free float mode. This allows you to physically move the tabletop along the longitudinal axis. When in free float mode, you cannot use the movement controls on the **Positioning Control Panel** and Couch Control Keypad. Press a longitudinal release button to exit free float mode and lock the tabletop into place.

Couch Motion

- ◆ Vertical Movement 62
- ◆ Longitudinal Movement. 63



WARNING: Patients should remain still while the couch is in motion. It is also recommended that while the couch is in motion, therapists should avoid physically adjusting the patient. Patient movement during a scan or treatment may result in reduced treatment accuracy. Patient movement during other couch movements may result in system interruptions or minor injury.

- ◆ **Vertical Movement**

Preprogrammed Movement

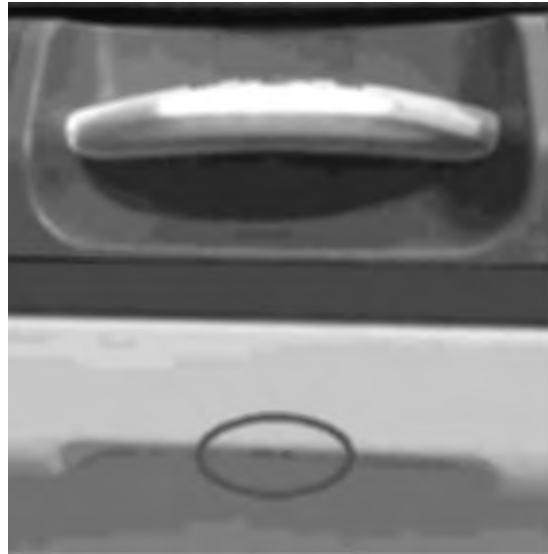
If the tabletop is extended into the bore, the couch will prevent any point-to-point movement that would cause the tabletop to descend into the gantry. If the couch is at a low position and the tabletop is extended, the couch will also prevent any point-to-point movement that would cause the tabletop to rise into the gantry.

Manual Movement

Manual movements are initiated from the Couch Control Keypad. When a keypad button is pressed, the couch moves until the button is released, or until it reaches the end of a movement axis. If the couch is at a low position and the tabletop is extended, the couch will also prevent any point-to-point movement that would cause the tabletop to rise into the gantry.

Emergency Stop Override

The Emergency Stop Override button is located under the bottom edge of the couch under the Couch Control Keypad. Use it to retract and lower the couch when an **Emergency Stop** button has been pressed.



◆ Longitudinal Movement

Preprogrammed Movement

Preprogrammed longitudinal movements are initiated from the **Positioning Control Panel**. When the **Setup** button is pressed, or if a movement is initiated from the **Step Move** tab, the couch automatically moves from the current position to the specified position.

The couch tabletop cannot move longitudinally when it is below the gantry bore. When the tabletop is extended into the gantry bore, its vertical movement is limited to the bore height and maximum height.

Manual Movement

Manual movements are initiated from the Couch Control Keypad. When a keypad button is pressed, the couch moves until the button is released, or until it reaches the end of a movement axis. When longitudinal movements are initiated from the Couch Control Keypad, the tabletop will continue to move until it reaches the end of the axis, or approaches the gantry.

Control Status Indicators

- ◆ PCP Status Indicators 64
- ◆ CCK Status Indicators 64

◆ PCP Status Indicators

Preprogrammed Move Buttons

Shaded buttons indicate that a function is inactive. Some buttons, such as **Cancel Unload** and **Cancel Move**, are only active when an unload or **Step Move** motion is in progress. Buttons are also inactive if they are concealed by a dialog box or couch status alert. To re-enable these buttons:

- Dismiss a dialog box by pressing **Yes**, **No**, **OK** or **Cancel**.
- Dismiss a status alert message by pressing anywhere on the screen.

Status Bar

The status bar is the grey area located at the bottom of the **Positioning Control Panel** screen. Information relevant to current system activity is displayed on the status bar.

◆ CCK Status Indicators

Move Buttons

Move buttons illuminate to indicate that the control is enabled and ready for use. If the buttons are not illuminated, they are not active. If the buttons are flashing, a couch fault has occurred. For example, there may have been a collision, or the couch may be outside the range of motion defined by the system.



IMPORTANT: If the buttons on the Couch Control Keypad are flashing, retract the tabletop and restart the system. If this does not restore normal couch function, contact the Accuray Technical Solution Center.

Longitudinal Release Buttons

When the couch tabletop is in free float mode, the longitudinal release buttons illuminate.

Motion Tracking Components

Synchrony® Respiratory Tracking is a licensable feature and its availability is dependent on your system configuration. *Synchrony* tracks and compensates for the motion of targets in areas affected by respiration. These may include targets in the lung, liver, pancreas, and kidneys, among others. *Synchrony* compensates for the respiratory motion of the target by correlating target motion with the respiratory motion of the patient and synchronizing beam delivery with target motion. *Synchrony* procedures require a set of hardware components, including the *Synchrony* camera, LED Tracking Markers, Light Box, *Synchrony* vest, Reference Post, and the associated cabling.

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- ◆ Synchrony Camera 69
- ◆ Synchrony Vest 70
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◆ Tracking Markers

The Motion Tracking LEDs (light emitting diodes) provide signals to the *Synchrony* camera to monitor the respiratory patterns of the patient. These LEDs are generally referred to as Tracking Markers. Tracking Marker cables are labeled with identifying tags (1, 2, 3, 4) near the ends of the cables. These numbers match the LED number labels listed in the Treatment Delivery Console software.

Markers 1, 2, and 3 attach to the Velcro strips on the *Synchrony* vest, and marker 4 is placed at the top of the Reference Post. Marker 4 allows the system to adjust the tracking results for couch motion. The tracking marker cables connect to the Light Box through a single large connector.

Tracking Marker cables contain optical fibers that transmit light. Although fiber optic material is degraded by radiation exposure over time, it has much less dosimetric impact than a typical metal cable. The light that is emitted at the end of the cable through the LEDs is actually created by the Light Box, and the light travels through the cables and out through the LED.

Placing Tracking Markers

Correct placement of the Tracking Markers on the *Synchrony* Tracking Vest is important for the accuracy of the entire *Synchrony* system. Place the three Tracking Markers close together on separate Velcro strips and at the patient's maximum respiration area, e.g. where the patient's belly or chest is moving the most during breathing.



IMPORTANT: The Accuray System supports treatment for supine and prone treatments in all motion tracking modes. The system does not support scans or treatments of patients positioned on their sides.

Attach the Tracking Markers labeled 1, 2, and 3 to the *Synchrony* Tracking Vest and connect them to the Light Box as described below:

1. Observe the patient's breathing to identify the location of maximum motion due to respiration.
 - In the supine position, this location is typically in the diaphragm area, but could be the lower thoracic area (for "chest breathers") or in the abdominal area (for "stomach breathers").
 - In the prone position, this location is typically in the thoracic area on the back of the patient, but can also be in the lumbar area.



CAUTION:: Do not place Tracking Markers over the tumor location unless this is the location of maximum body motion during respiration. Direct radiation exposure will significantly decrease the life span of Tracking Markers.

2. Attach Tracking Markers 1, 2, and 3 to the white Velcro strips on the *Synchrony* Tracking Vest at the location of maximum body motion due to respiration.



Tracking Markers on *Synchrony* Vest

3. Secure the cables of the Tracking Marker harness using the cable management Velcro tabs on the vest. Make final adjustments to the Tracking Markers so that they are pointed at the camera.
4. Route the Tracking Marker harness cables along the left edge of the couch tabletop and insert the connector into the Light Box module.
5. Verify that Tracking Marker cables running along the side of the couch to the Light Box are secure, and that they will not become entangled in the patient or couch during couch movement.



TIP: Perform a visual check of the Tracking Markers to ensure camera visibility. If the LEDs are solid, they are visible. If LEDs are blinking, the Tracking Markers are not visible.



WARNING: To prevent unintended displacement of the patient during couch movement, do not allow any items (e.g. bed linens, fixation devices, cabling, or patient gowns, limbs, hair, etc.) to overhang the end of the couch tabletop. Unintended displacement of the patient can result in displacement of the radiation delivery, and possible injury to the patient. As directed in this manual, always check that the patient movement path is clear of obstructions, including items overhanging the end of the couch tabletop.

Light Box

The Light Box produces the light that travels through the cables to the Tracking Markers. The light in each Tracking Marker is activated in a sequence that is not detectable by the human eye, but is interpreted by *Synchrony* camera to uniquely identify each Tracking Marker. The Light Box connects to the cable port at the foot end of the couch, as illustrated in the following image. The Tracking Marker cables connect at the opposite end of the Light Box. The Light Box has a magnetic surface to ensure that it remains in a stable position on the couch.



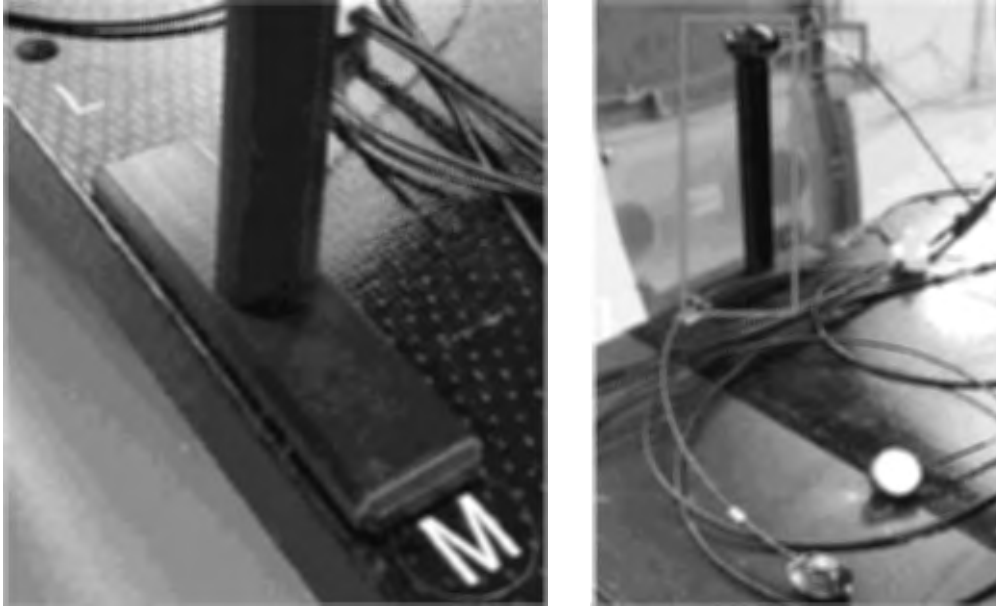
Light Box with Tracking Marker Cable and Couch Cable Connected

Reference Post

The Reference Post is a small plastic tower that connects to the indexing holes on the left side of the couch tabletop. It holds the motion Tracking Marker labeled number 4, which is a reference for the *Synchrony* camera. This reference allows the motion tracking system to remove couch motion from the Tracking Marker data.

Although the Reference Post can be placed in any position along the side of the couch where it is visible to the *Synchrony* camera, certain positions tend to give the camera a clearer line of sight than others. For example, if the Reference Post is located closer to the head end of the couch behind the patient's shoulders, patient anatomy may partially block the line of sight to the camera after the couch moves into the gantry bore. Generally, the Reference Post should be positioned next to the pelvis or hips, closer to the foot end of the couch.

For typical use, Accuray Incorporated recommends that the Reference Post is connected near the foot end of the couch tabletop near the 12 position.



◆ *Synchrony* Camera

The *Synchrony* camera is mounted near the foot end of the couch. Depending on your site configuration, it is either mounted to the wall or to the ceiling. The *Synchrony* camera array consists of three sensors that detect the motion of the patient by monitoring the position of the Tracking Markers. Tracking Markers move with patient breathing, and these signals from the *Synchrony* camera array are used to track and display patient breathing patterns on the Treatment Delivery Console.

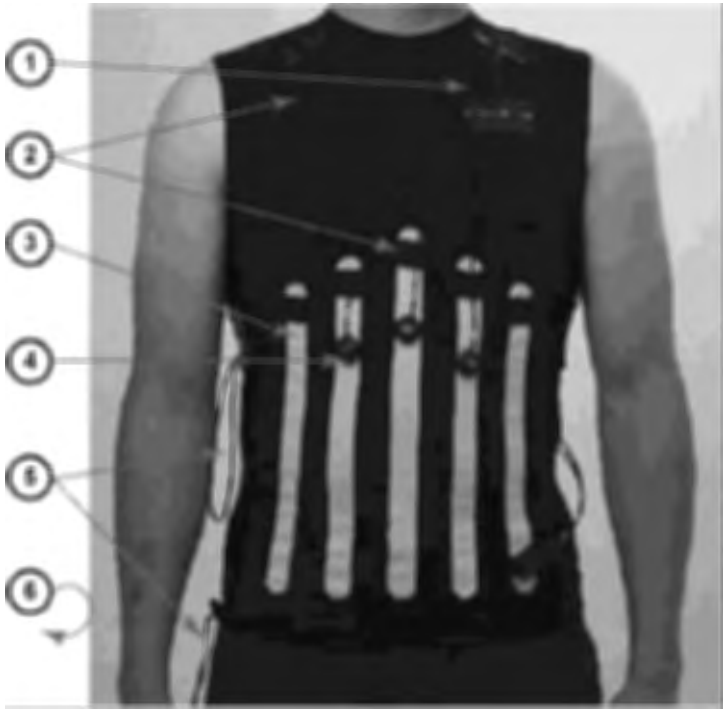


***Synchrony* Camera**

For the *Synchrony*® Respiratory Tracking feature to work effectively, the Tracking Markers must be visible to the *Synchrony* camera. The camera is positioned to maximize the visibility of Tracking Markers during patient setup and during treatment. However, accessories or patient anatomy may block the line of sight from the camera to the Tracking Markers. If the camera can see the Tracking Markers, the LEDs glow steadily. If the camera cannot see the Tracking Markers, the LEDs blink.

◆ *Synchrony* Vest

The patient wears the *Synchrony* Tracking Vest during pre-treatment scanning and during *Synchrony* treatment. The *Synchrony* Tracking Vest is shown in the figures below. The three tracking marker LEDs attach to the Velcro on the vest.



Synchrony Tracking Vest

Item	Description
①	Fiber Optic Tracking Marker Cables
②	Cable Management Velcro Tabs
③	Velcro Strips (Supine and Prone)
④	Tracking Markers
⑤	Drawstrings
⑥	Full Length Zipper and Personalized Name Tag (on back of vest)

***Synchrony* Tracking Vest Sizes**

The *Synchrony* Tracking Vest is available in three sizes with the following general size guidelines:

Vest Size	Height	Weight
Small	<5'5" (1.68 m)	<130 lb (59 kg)
Medium	5'5" - 6'0" (1.68 - 1.83 m)	130 - 180 lb (59 - 81.6 kg)
Large	>6'0" (1.83 m)	>180 lb (81.6 kg)



NOTE: Patient body shape may affect vest size selection. It may be necessary to select a vest that is one size larger or one size smaller.

Putting on and Taking off the *Synchrony* Vest

Follow the guidelines below to put the *Synchrony* Tracking Vest on the patient and remove the vest after treatment:

1. Select the appropriate size of *Synchrony* Tracking Vest for the patient.
2. Take the vest out of the pouch. If the name tag is blank, write the patient name on the name tag located on the back of the vest.
3. Instruct the patient to put on the *Synchrony* Tracking Vest. If necessary, assist the patient.
4. Unzip the back of the vest. Detach the Velcro tab on the bottom back of the vest. Ensure the two drawstrings on the vest are in their loosest position.
5. All patient undergarments should be removed from the waist up. A sport or jogging bra with no metal inserts or fasteners is permissible if necessary for large-breasted patients.
6. Slip the vest over the patient's head. Slip the patient's arms into the arm holes of the vest.
7. Fasten the Velcro tab at the bottom back of the vest.
8. Pull the zipper down to the bottom of the vest. You may also pull on the string attached to the zipper.
9. Detach the Velcro tab at the bottom of the vest to ensure that the zipper has been pulled all the way to the bottom of the vest. Then refasten the Velcro tab.

10. Pull the whole vest down toward the waist as far as possible, and cinch the bottom drawstring for a snug fit. This helps prevent the *Synchrony* Tracking Vest from moving up.
11. To remove the *Synchrony* Tracking Vest from the patient, remove the Tracking Markers and cables. Then unzip the back of the vest, and slip the vest over the patient's head. Do not adjust the drawstrings.



TIP: Do not readjust the drawstrings on the *Synchrony* Tracking Vest. The drawstrings help maintain body shape consistently between pretreatment scanning and treatment delivery.



IMPORTANT: *Synchrony* LED vests are disposable, and should not be worn by more than one patient. Follow the appropriate sterilization and biohazard procedures when storing or disposing of *Synchrony* vests.



IMPORTANT: After treatment, sanitize the *Synchrony* motion tracking components according to your clinical protocols.

◆ Storing *Synchrony* Components

If the next patient in your clinical schedule does not require the *Synchrony* motion tracking components, disconnect and store the light box, fiber optic cables and Tracking Markers, and the Reference Post.

- Remove the Tracking Markers from the *Synchrony* vest. Store or appropriately dispose of the *Synchrony* vest.
- Disconnect the Tracking Markers cable from the Light Box, and remove Tracking Marker 4 from the Reference Post.
- Disconnect the Light Box cable from the couch, but leave the cable attached to the Light Box.
- Remove the Reference Post from the couch indexing holes.
- Loosely wind the Tracking Marker cables. To prevent damage to the fiber optic material inside the cables, do not wind or bend the cables at an angle less than 30°.
- Store the *Synchrony* components in a cool dry location. To improve the life of components, store the items outside of the treatment room to minimize exposure to scatter radiation.



IMPORTANT: *Synchrony* tracking vests are disposable, and should not be worn by more than one patient. Follow the appropriate sterilization and biohazard procedures when storing or disposing of *Synchrony* vests.



IMPORTANT: After treatment, sanitize the *Synchrony* motion tracking components according to your clinical protocols.

Identifying Synchrony Components

Each *Synchrony* component can be uniquely identified by a part number.

Item	Part Number	Identifier Location
Small Vest	1005522	Vest packaging only
Medium Vest	1005523	Vest packaging only
Large Vest	1005524	Vest packaging only
Tracking Marker LED cables	1061035	Cable packaging only
Light Box	1060562	Bottom of Light Box
Reference Post	1061036	Bottom of post
Light Box to Couch cable	1061034 and 202355-2	1061034 on cable packaging 202355-2 on cable label

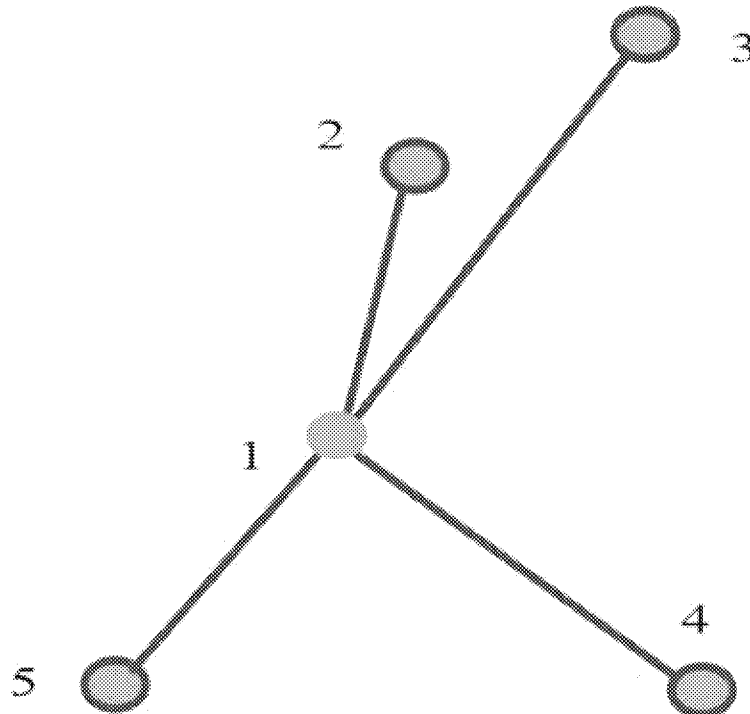
◆ Implanted Fiducials

Fiducial Tracking requires implanted fiducials. Synchrony® Respiratory Tracking can be performed with or without implanted fiducials. XSight® Lung Tracking is performed without implanted fiducials.

Fiducial Placement Principles

The fiducial tracking system enables tracking of extracranial tumors by tracking implanted fiducials. Fiducial tracking correlates fiducial locations in reference images with live X-ray images. Tracking the target relies on the fixed relationship between the target volume and the configuration of fiducials.

In order to treat the patient with ease and accuracy, a few key principles need to be taken into consideration when fiducials are implanted for patient treatments with the Accuray System. Using three or more fiducials significantly improves targeting accuracy. The recommended number of fiducials is 4 to 6. A sample fiducial configuration is shown in the following image.



Example Configuration of 5 Fiducials

Fiducial placements should meet the following requirements:

- Minimum distance of 0.5 cm (5 mm) between fiducials.
- Within ± 2.5 cm of the superior/inferior center (longitudinal, IEC Y) of the tumor volume.
- Maximum distance of 5 - 6 cm from lesion in IEC X (lateral) or IEC Z (vertical).



IMPORTANT: Fiducial placements that meet the requirements listed above are recommended so that the Accuray System can track and treat tumors with submillimeter accuracy. Fiducial placement errors adversely affect tumor localization and treatment accuracy.

You may find that some of the implanted fiducials are unusable. For example, implanted fiducials may be unusable for any of the following reasons:

- Migration
- Close placement of fiducials (closer than 0.5 cm). For example, the fiducials labeled 1 and 2 in the prior image.

Fiducials Approved for Soft Tissue Tracking

Information on approved fiducial supplies for soft tissue is given below. The fiducials supplied by the following manufacturers have been validated for use with the Accuray System for the purposes of soft tissue tracking.



WARNING: Use only fiducials approved by Accuray Incorporated for treatment with the Accuray System. Fiducial tracking has been validated using approved fiducials only. Use of unapproved fiducials is not supported and could result in patient mistreatment.

CIVCO

Type	CIVCO Part Number	Dimensions (Diameter x Length)	Description
Gold Seed	MT-NW-887-808	0.8 x 3.0 mm	3 sterile soft tissue goldmarkers.
	MT-NW-887-809	0.9 x 3.0 mm	3 sterile soft tissue goldmarkers.
	MT-NW-887-812	1.2 x 3.0 mm	3 sterile soft tissue goldmarkers.
CyberMark™ Gold Seed	MT-NW-887-851 (-853)	1.0 x 5.0 mm	Sterile placement needles (single or 3-pack) with 1.0 x 5.0 mm soft tissue marker.
Coupled™ Marker	MT-NW-887-710	1.0 x 3.0 mm	Sterile placement needle with two 3 mm gold soft tissue markers attached at a fixed distance.
	MT-NW-887-709	0.8 x 3.0 mm	

RadioMed

Type	RadioMed Part Number	Dimensions (Diameter x Length)	Description
Visicoil™ Coiled Gold Markers	FP-0755	0.75 x 5.0 mm	Coiled gold soft tissue marker on a carrier for transport, easy to deploy into most needle hubs.
	VC-075-005-PL	0.75 x 5.0 mm	Coiled gold soft tissue marker in a preloaded needle with bone wax at the tip.
	VC-010-005-PL	1.1 x 5.0 mm	Coiled gold soft tissue marker in a preloaded needle with bone wax at the tip.

Olympus

Type	Olympus Part Number	Dimensions (Diameter x Length)	Description
Gold Sphere	N/A	Diameter 1.5 mm	Individual gold spheres.

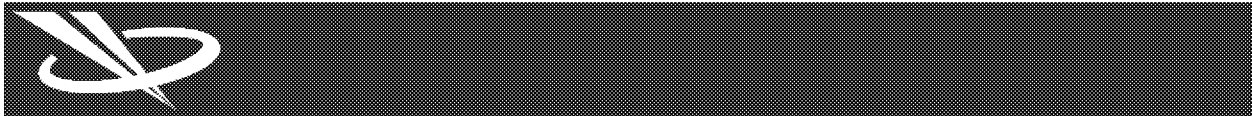
Alpha Omega

Type	Alpha Omega Part Number	Dimensions (Diameter x Length)	Description
Gold Seed	SMG0242-025	0.8 x 5.0 mm	25 gold seeds per vial, packaged non-sterile. 19G thin walled biopsy needle 10 - 11 cm or 15 cm length.

Fiducial Placement Methodology

Accuray Incorporated does not recommend or require any particular fiducial placement procedure. Accuray Incorporated cannot recommend a specific waiting period between fiducial implantation and planning image acquisition, as this depends on the progress of patient recovery and your

clinical protocols. You can generally expect to wait 10-14 days after fiducial implantation in the lung, or 7-10 days for other soft tissues, but this is a clinical decision.



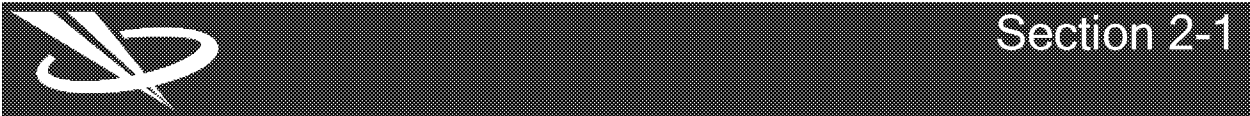
Chapter 2

Treatment Delivery Console Software

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Treatment Delivery Console Overview

Home Screen 82

Home Screen

The Home Screen is the display that appears when you start the system software. It consists of the top frame, at the top of the page, and the dashboard below the top frame.

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- ◆ Dashboard..... 86



◆ Top Frame

The top frame is located at the top of the display. It contains tools and information, including the Data Display, Water Temperature Indicator, and What's Next box.



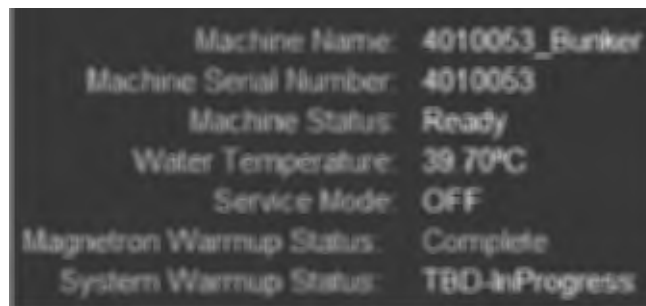
Item	Name
1	Data Display information
2	What's Next box

Item	Name
③	Top Frame tools
④	Product and Version

Data Display

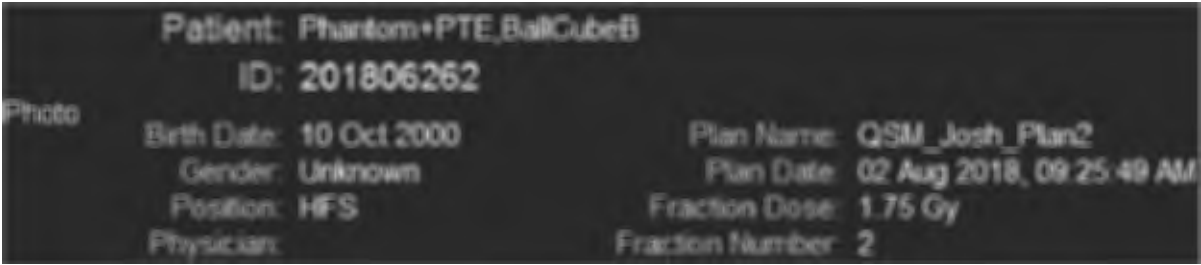
The Data Display is on the left side of the top frame. It shows the following information when the Home Screen is open:

- Machine Name
- Machine Serial Number
- Machine Status
- Water Temperature
- Service Mode
- Magnetron Warmup Status
- System Warmup Status



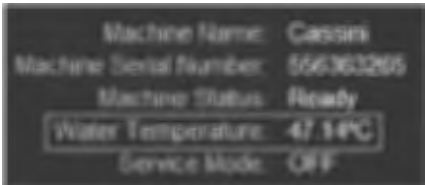
The Data Display shows the following patient information when you are performing a **Treat Patient** workflow:

- Photo
- Patient
- ID
- Birth Date
- Gender
- Position
- Physician
- Plan Name
- Plan Date
- Fraction Dose
- Fraction Number



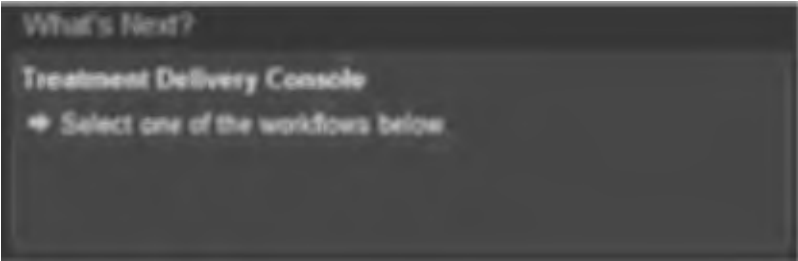
Water Temperature Indicator

The Water Temperature Indicator is in the Data Display on the left side of the top frame. It shows the current temperature of the water supplied to the temperature control system.



What's Next

The What's Next box is in the middle of the top frame. It displays brief instructions for the next step in the process you are performing.



Top Frame Tools

The following tools may be displayed in the top frame depending on the workflow you are performing.

Click...	To...
	Go to the Home Screen.

Click...	To...
	Open the Patients List dialog box.
	Print the current screen.
	Open the list of tools available: • Service Message allows you to send a message to Accuray service. • Export Machine QA Scans allows you to DICOM export an MVCT image volume acquired during machine QA. • Change Language allows you to change the language displayed on the TDC. The selected language appears after system restart. • Acquire Planning Image allows you to obtain an MVCT planning image. • Review Machine QA Registration allows you to review the registration adjustments of machine QA procedures. • Edit Scan Default Settings allows you to edit the default settings for the Scan tab. For more information on these settings, ssee “Window/Level” (page 95) and “CTrue Reconstruction Settings” (page 105). • Log Off logs you off from the system software. • Exit System Software closes the system software. • Load Patient Photo from File allows you to load a patient photo into their record. Acceptable file formats include .jpg or .jpeg, .png, and .gif. • Remove Patient Photo allows you to remove a patient photo from their record. • DICOM Administration, Patient Administration, Plan Administration, and Report Administration are iDMS™ Data Management System tools. Please refer to the <i>iDMS Manual</i> for more information. • Disable Dose Control Servo, Edit Machine, Reset Users Settings, Edit Machine, Review Machine QA Registration, and Upload Logs are used by Accuray service.
	Lock the system software so that a password is required to unlock it.

◆ Dashboard



The dashboard is below the top frame. When the Home Screen is open, it displays the following workflow buttons:

- Air Scan
- Create Machine QA
- CT Number Calibration
- Machine QA
- Patient QA
- Review Registration
- Static Couch Patient QA
- Treat Patient
- Treatment Phantom Plan
- Warmup

When a workflow is open, it displays the appropriate tabs such as **Run**, **Scan**, **Register**, and **Treat**.

Air Scan

An **Air Scan** is a daily procedure that verifies the *CT_{True}* image quality of the system for the most accurate registration results prior to performing a *CT_{True}* image scan. The **Air Scan** button opens the workflow for an Air Scan procedure.



Create Machine QA

The **Create Machine QA** workflow is used to create custom machine quality assurance procedures. The **Create Machine QA** button opens the workflow to create a Machine QA procedure, which defaults to the **Procedure** tab. Options on the **Procedure** tab include:

- **View:** See machine parameters on the data server or open a procedure **XML** file located from the data server or from a local file.
- **Basic Create:** Make a new procedure **XML** file by selecting options and specifying parameters in a simplified data-entry form.
- **Create:** Make a new procedure **XML** file based on an existing procedure on the data server or a local **XML** file.
- **Create From Patient Plan:** Make a new procedure **XML** file based on the parameters of an existing patient plan.
- **Delete:** Select a procedure to remove.

For more information on creating Machine QA procedures, refer to the *Physics Essentials Guide*.



CT Number Calibration

CT Number Calibration is a weekly procedure that improves the stability of CT numbers produced by the *CT_{True}* image reconstruction software. The **CT Number Calibration** button opens the workflow for a CT Number Calibration procedure.



Machine QA

A **Machine QA** procedure is a custom quality assurance procedure to be delivered on the treatment system. The **Machine QA** button opens the **Procedures** list. Selecting a procedure opens its workflow, which defaults to the **Scan** tab. For more information on performing Machine QA procedures, refer to the *Physics Essentials Guide*.



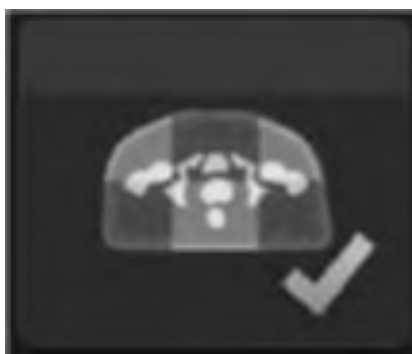
Patient QA

A **Patient QA** plan applies the delivery instructions (couch, jaws, gantry, and MLC) from the patient treatment plan to a phantom. Plan dose is re-calculated with the phantom geometry and density, and the expected treatment dose can be verified in the phantom with one or more calibrated ion chambers. The **Patient QA** button opens the workflow for a Patient QA procedure. For more information on Patient QA plans, refer to the *Physics Essentials Guide*.



Review Registration

Review Registration is used to review previously acquired *CTrue* images. This may include reviewing offsets that were applied to the image or comparing the selected image to the planning image for the patient. The **Review Registration** button opens the **Patients** list. Selecting a patient and then a stored *CTrue* image for the patient opens the **Register** tab.



Static Couch Patient QA

A **Static Couch Patient QA** procedure is delivered to the detector array without the couch in the gantry bore so there is no couch attenuation. The collected detector data can then be compared against the fraction's planned dose using third-party analysis software. The **Static Couch Patient QA** button opens the **Patients** list. Selecting a patient opens their plan, which defaults to the **Treat** tab. For more information on Static Couch Patient QA procedures, refer to the *Physics Essentials Guide*.



Treat Patient

Treatment procedures are performed to deliver a specific dose of radiation to a selected patient, according to their patient plan. The **Treat Patient** button opens the **Patients** list. Selecting a patient opens the workflow for a patient treatment procedure.



Treat Phantom Plan

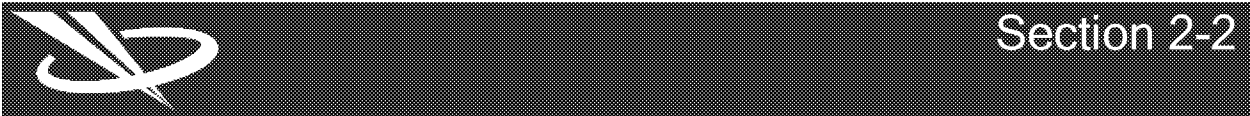
A phantom plan is a treatment plan optimized and calculated on a phantom image volume. The **Treat Phantom Plan** button opens the **Data Selection** list. Selecting a procedure opens the workflow for the selected phantom plan. For more information on phantom plans, refer to the *Physics Essentials Guide*.



Warmup

A **Warmup** is a daily procedure that prepares the radiation delivery subsystem to generate and deliver radiation for a procedure. The **Warmup** button opens the workflow for a Warmup procedure.





Tools

View and Position Patient Images 94

View and Position Patient Images

This section describes the tools and features available on the Image Viewer, which is used to display images on several different panes.

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- ◆ Image Viewer Tools 94
- ◆ Image Viewer Options. 97
- ◆ Position a Patient Image. 97

◆ Image Viewer Coordinates

The Image Viewer uses a coordinate system that is based on the IEC f coordinate system. However, there is no set zero position on the Image Viewer, since the zero position will be different for each set of images. The Image Viewer coordinate system is stationary relative to the tabletop of the couch.

- The positive Z axis runs vertically upward from the tabletop, perpendicular to the medial axis of the couch.
- The positive Y axis runs longitudinally toward the bore of the gantry, parallel to the medial axis of the tabletop.
- The positive X axis, when viewed from the foot of the couch, runs laterally toward the right side of the couch, perpendicular to the medial axis of the tabletop.

◆ Image Viewer Tools

The Image Viewer includes several tools you can use to manipulate the image for better viewing.

Measure

The Image Viewer measurement tools allow you to draw a line or circle to measure distance (cm) within a window. Double-click in the Image Viewer before you draw to retain lines or circles.

Icon	Description
	Click the Measure tool to use the Line or Circle tool.
	Use the Line tool to click and drag a line on the Image Viewer. The length of the line is displayed.
	Use the Circle tool to click and drag a circle on the Image Viewer. The diameter of the circle is displayed.

Zoom

Icon	Description
	Zoom changes the magnification of the image. Click and drag the icon toward the top of the screen to make the image larger, or click and drag the mouse toward the bottom of the screen to make it smaller. The magnification percent is displayed when using this tool. Press Shift and then click the icon to restore the image to its original size.

Window/Level

This grayscale bar, which is located along the right side of the Image Viewer, changes the window and level of the image. When you hover over the tool, the cursor changes to a pointing hand and two numbers appear, indicating the current values for window and level:

- The number to the left of the short green horizontal line indicates the window, that is, the range of values (in Hounsfield Units) as mapped onto a grayscale image. Drag the mouse to the right to increase the window. Drag the mouse to the left to decrease the window.
- The number to the left of the short red horizontal line indicates the level, that is, the center value (in Hounsfield Units) of the current window range. Drag the mouse toward the top of the screen to increase the level. Drag the mouse toward the bottom of the screen to decrease the level. Lower levels result in lighter images and higher levels result in darker images.
- The range of values for window and level are:
 - Level: from -1,024 through 3,072
 - Window: from 1 through 4,097
- Move the mouse in a diagonal direction to change both values.
- Press **Shift** and then click the tool to restore the image to its original window and level.
- When you complete a scan, your selections are saved with the plan as the default settings.
- Initial default values can be defined in **Edit Scan Default Settings** under the **Tools** menu.

Window/Level Presets

To select a preset value, right-click the Window/Level tool, and select the preset from the shortcut menu. By default, the values are displayed in HU.

Mode	HU	Density (g/cc)
General	Window = 1,100 Level = -200	Window = 1.100 Level = 0.824
Soft Tissue	Window = 500 Level = -25	Window = 0.500 Level = 0.999
Bone	Window = 450 Level = 225	Window = 0.450 Level = 1.249
Low Density	Window = 700 Level = -600	Window = 0.700 Level = 0.424

Slice



TIP: Use the Slice tool in the Coronal and Sagittal views to verify the resolution of the image. Drag the mouse until you are at the last slice. The number of the last slice indicates the image resolution.

Icon	Description
	Slice indicates the slice number currently displayed. When you activate the tool, you can do one of the following: • Drag the mouse to the left or right to page through the available slices. • Click left or right arrows to move through image slices one at a time. • Use the PageUp and PageDown buttons on your keyboard to scroll through slices. • Use the mouse wheel to scroll through slices.

Pan

Icon	Description
	Pan moves the image in the direction of the mouse movement. The center coordinate of the image volume is displayed when you are using this tool. Click and drag the icon to move the image. Press Shift and click the icon to restore the image to its original position. If you have zoomed the image, it returns to its original size.

◆ Image Viewer Options

The Image Viewer options appear when you right-click in the Image Viewer. Select a check box to use an option.

Show Readout

Select the **Show Readout** check box to display CT details in the upper-left corner of the Image Viewer, including:

- X, Y, and Z coordinates of the cursor position in mm.
- CT values (in HU) for the image at the cursor position.

When dose data is available, this feature also displays the dose (in Gy or cGy) for the cursor position.

Gang TCS Views

Select the **Gang TCS Views** check box to link the Axial, Coronal, and Sagittal views. Crosshairs appear in each view to mark the same voxel in each view. If you move the crosshair in one view or use the Slice tool to view a different plane of the image, the positions of the crosshairs and slices in the other two views move accordingly.

Gang TCS Window-Level

Select the **Gang TCS Window-Level** check box to link the Window/Level tool for the Axial, Coronal, and Sagittal views. Any changes to the window or level in one window are reflected in the others. Gang TCS Window-Level is selected by default.

Show Image Border

Select the **Show Image Border** check box to display a yellow rectangle that outlines the extent of the image.

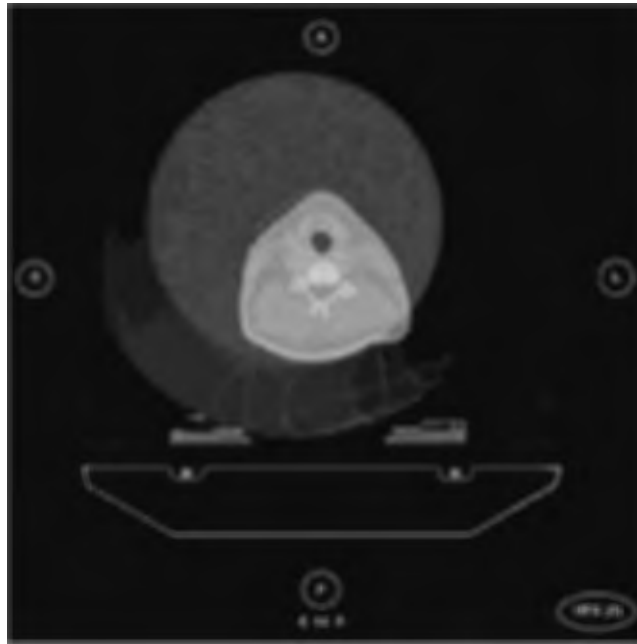
◆ Position a Patient Image

Machine Geometry Indicators

When you use the **Lasers** option, the machine geometry indicators are the green lines that indicate the position of the gantry relative to the patient image and correspond to the green lasers on the treatment system. The larger circle indicates the gantry bore, the smaller circle represents the multileaf collimator and MVCT fields of view, and the central crosshairs indicate the axis of rotation.

Orientation Indicator

These labels in the Image Viewer provide information about the orientation of the current image.



Possible labels include:

- A = anterior
- P = posterior
- L = left
- R = right
- G = gantry
- H = head
- F = feet
- HFS(A) = head first, supine (axial)
- HFS(S) = head first, supine (sagittal)
- HFS(C) = head first, supine (coronal)
- HFP(A) = head first, prone (axial)
- HFP(S) = head first, prone (sagittal)
- HFP(C) = head first, prone (coronal)
- FFS(A) = feet first, supine (axial)
- FFS(S) = feet first, supine (sagittal)
- FFS(C) = feet first, supine (coronal)
- FFP(A) = feet first, prone (axial)
- FFP(S) = feet first, prone (sagittal)
- FFP(C) = feet first, prone (coronal)



Treatment Delivery Console Tabs

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Common Features

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◆ Procedures List

The **Procedures** list is on the **Scan**, **Treat**, and **Run** tabs. It lists *CTrue* image scans, treatment procedures, and quality assurance (QA) procedures for the selected Patient and Plan. The following are all possible columns in the **Procedures** list, depending on the workflow context:

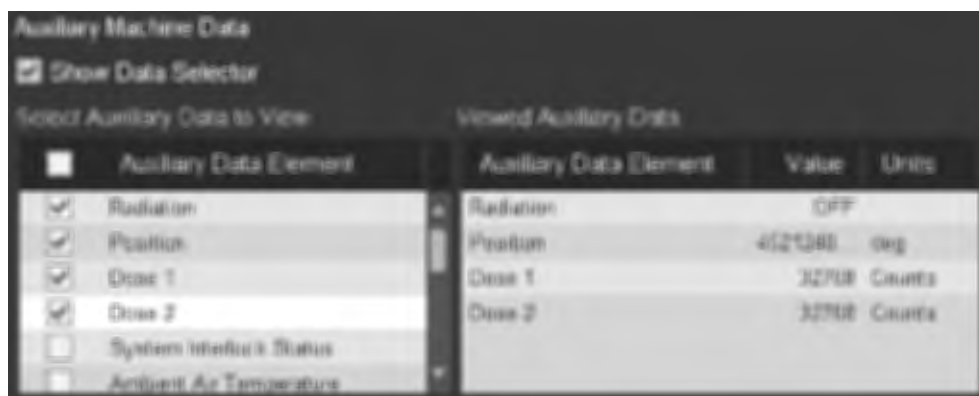
Column	Description
Fx	The plan fraction number for treatment workflows. A number with a decimal indicates a makeup fraction.
Status	• Deliverable indicates a procedure that is available to performed. • In Progress indicates the procedure loaded in the current workflow. • Completed indicates a scheduled procedure has been performed. • Interrupted indicates that a procedure was interrupted during irradiation. • After a makeup fraction has been generated for an interrupted procedure, it is listed as Deliverable. • Inconsistent indicates the status is unknown for the system.
Delivery	The expected procedure duration when performing a treatment, or the actual procedure duration when performing a warmup or air scan.
Elapsed	The duration of a previously performed procedure. If the procedure is Deliverable , this field is blank by default. If the procedure is Interrupted , this is the time elapsed up to the interruption.
MU (C1/C2)	The number of monitor chamber units (MU) delivered in the procedure. The C1 value represents monitor chamber one, and C2 represents monitor chamber two.
Date and Time	The day, month, year, and time the procedure was performed. If the procedure is Deliverable , this field is blank by default.

Column	Description
Procedure Details	A description of the procedure and current status.
Slices	The number of slices selected for the procedure.
Number	The number of each machine QA procedure.

◆ Auxiliary Machine Data

Auxiliary Machine Data is used by service technicians to identify components that may need to be serviced. Your service representative may request the machine data to determine if an on-site visit is required. To view **Auxiliary Machine Data**:

1. Look at the lower-right corner of the **Scan**, **Run**, or **Treat** tab in the system software and click the **Auxiliary Data** tab. Data is shown in the **Viewed Auxiliary Data** table.
2. Select the **Show Data Selector** check box to open the **Select Auxiliary Data to View** list.
3. Select the check boxes for the data elements you want to view, or select the **Auxiliary Data Element** check box to select all of the data elements. Data for each element you select is displayed in the **Viewed Auxiliary Data** table.



◆ System Status Bar

The system status bar is at the bottom of each Treatment Delivery Console tab. It provides the current status of the system.

◆ Couch Position (millimeters)

Couch Position (millimeters) is on the **Scan**, **Treat**, and **Run** tabs. It provides the following information:

- The current lateral position of the couch (IEC X).
- The current longitudinal position of the couch (IEC Y).
- The current vertical position of the couch (IEC Z).

◆ Monitor Chamber Information

Monitor Chamber (Dose Monitor Units) C1 and C2 display the **Cumulative (mu)** dose monitor units for both monitor chambers in real time. **Expected (mu)** displays the expected dose monitor units for both chambers as specified in the treatment plan. The **Rate** is also given in monitor units per minute.



NOTE: The cumulative dose monitor unit will not begin incrementing until the beam warmup period is complete.



IMPORTANT: For TomoDirect™ Treatment Delivery plans, the **Cumulative (mu)** field displays the cumulative monitor units of the last beam that was delivered. The **Procedure Total** fields display the sum of the cumulative (mu) for all of the beams delivered.

◆ Gantry Angle (degrees)

Gantry Angle (degrees) shows the current angle of the gantry with **Roll Correction** and **Gantry Correction**. It appears on the **Run** tab and the **Treat** tab.

◆ Procedure Details

Procedure Details appears on the **Run** tab at all times and the **Treat** tab when running a *TomoDirect* plan.

Column	Description
Beam Name	The beam name specified in the procedure.
Planned Angle	The beam angle (in degrees) specified in the procedure.

Column	Description
Beam On time	The length of time (in seconds) the beam was on during the procedure.
Progress	The status of the procedure.



NOTE: After a beam has been delivered, you may pause on an entry in the **Beam Name** column to display a tool tip that contains the cumulative monitor units for the individual beam. This tool tip is available after treatment is complete, all system interruptions are resolved, and the **Status Console** mode switch is turned to **Program**.

◆ Time (seconds)

The **Time (seconds)** display appears on the **Run**, **Scan**, and **Treat** tabs under the following names:

- **Treatment Progress Time (seconds)**
- **Fixed-angle Beam Time (seconds)**
- **Scan Progress Time (seconds)**

The following are part of the procedure progress display on the tab:

- **Elapsed** shows the amount of time since the procedure was started.
- **Remaining** shows the amount of time left to complete the procedure.
- A progress indicator below the **Time (seconds)** display gives a visual representation of the time remaining to complete the procedure and indicates when the procedure is finished. For treatment procedures, an indicator for beam **Warmup** progress is also provided.

Run Tab

Use the **Run** tab to perform a warmup or air scan.

- ◆ Prepare Calibration 104
- ◆ Calibration Status 104
- ◆ Procedure Total 104



- ◆ **Prepare Calibration**

Click **Prepare Calibration** after you have selected a procedure from the **Procedures** list. This initiates the calibration procedure. Brief instructions appear in **What's Next** to guide you through the procedure.

- ◆ **Calibration Status**

Calibration Status shows the progress of the calibration procedure.

- ◆ **Procedure Total**

Procedure Total shows the total dose (in monitor units) recorded in **Monitor Chamber C1** and **Monitor Chamber C2** during a warmup or air scan.

Scan Tab

Use the **Scan** tab to create a *CTrue* image procedure and scan the patient.

- ◆ CTrue Reconstruction Settings..... 105
- ◆ Slice Selector 106
- ◆ VOIs Tab 108
- ◆ Setup Notes..... 108
- ◆ Prepare Scan 109
- ◆ CTrue Image 110



◆ CTrue Reconstruction Settings

Use the settings above the Image Viewer to select the **Orientation**, **Pitch**, **Reconstruction Interval**, and **Algorithm** used for the *CTrue* image scan.



NOTE: The most recently selected **CTrue Reconstruction** settings will be saved if you complete a scan and then return to the same plan later.

Orientation

The **Orientation** radio buttons specify which anatomical plane (**Sagittal** or **Coronal**) is used to select slices for the *CTrue* image scan.

Acquisition Pitch and Reconstruction Interval

Acquisition Pitch and **Reconstruction Interval** specify the quality and slice spacing of a *CTrue* image scan. For a more detailed scan, use a smaller slice interval (Pitch). A smaller or tighter Pitch will require more time to deliver, and expose patients to a higher dose.

Use the **Acquisition Pitch** drop-down list to select the slice interval used to scan the image.

- Select **Fine** for the smallest slice interval and the most detailed *CTrue* image.
- Select **Normal** for standard *CTrue* image quality.
- Select **Coarse** for the largest slice interval and a less detailed *CTrue* image.

Use the **Reconstruction Interval** drop-down list to select a smaller or larger slice interval. These settings achieve smaller or larger slice intervals through image reconstruction and detector interpolation, with no additional dose or imaging time.

Algorithm

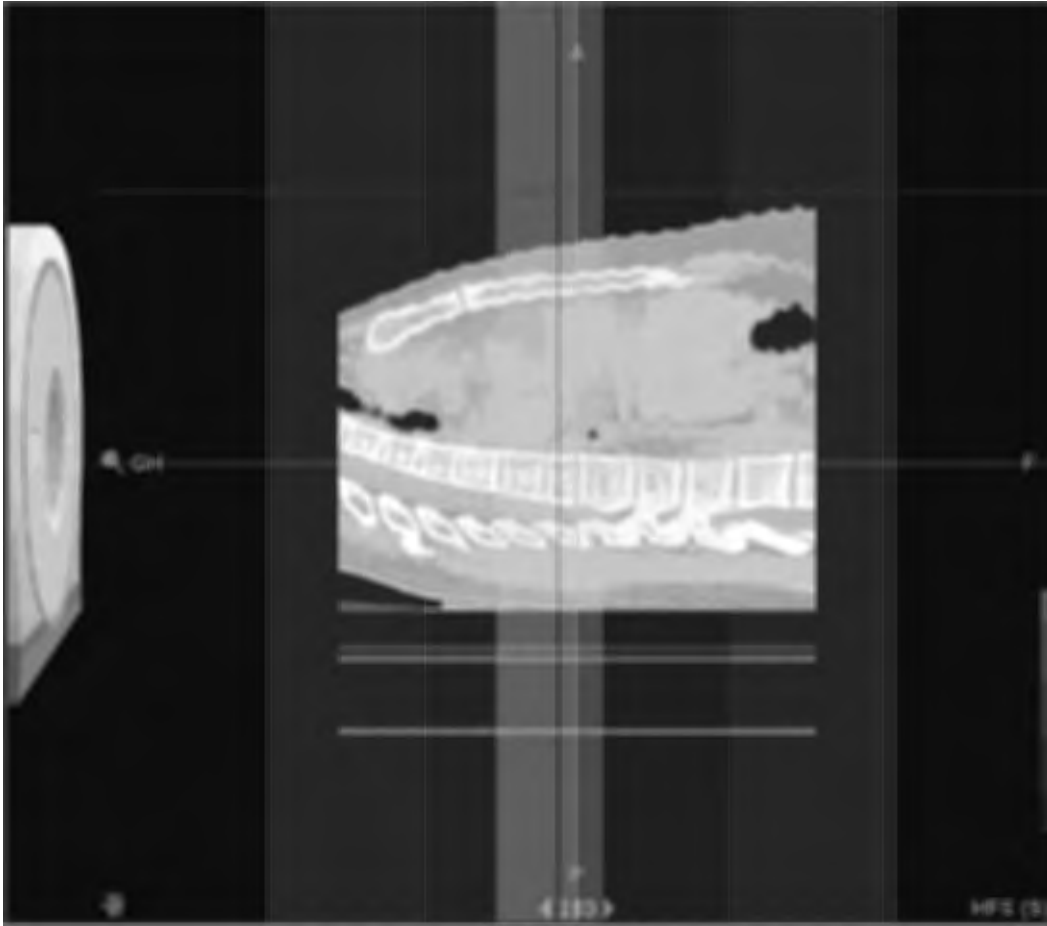
Algorithm specifies which reconstruction option is used for the *CTrue* image scan.

- Select **Standard** for a standard reconstruction.
- If licensed, select **IR General** for the iterative reconstruction that lowers image noise relative to a **Standard** image.
- If licensed, select **IR Soft Tissue** for the iterative reconstruction that smooths image noise relative to **IR General** to improve soft tissue visibility.

◆ Slice Selector

The **Slice Selector** is used to select the anatomical region of the patient (target) that you want to include in the *CTrue* image scan. Click and drag on the image to select slices.

- A maximum of 300 slices can be selected.
- The transverse pixel size for a *CTrue* image is 0.76 mm (512 x 512 pixels in the field of view).
- The **Pitch** determines image dose, acquisition speed, and superior/inferior resolution.
- The **Reconstruction Interval** determines slice spacing.
- The number of slices determines the volume receiving the imaging dose.



Offset Distance and Selected Slices

Hold the cursor over a slice to display the offset distance from the red, moveable, axial laser. The number of slices also appears.

Accept Slices

Click **Accept Slices** below the **Slice Selector** after you select the necessary slices for the *CTrue* image scan. The system uses your slice selection to calculate scan parameters. The system also adds a scheduled *CTrue* image scan in the **Procedures** list.

Clear Selected Slices

If you want to reselect the slices, click **Clear Selected Slices** below the **Slice Selector** to remove the current slices from the plan image.



TIP: To add slices, move the pointer to the desired location in the **Slice Selector**, hold down **CTRL**, and click the left mouse button. To trim a section of slices, hold down **CTRL** and click the left mouse button at the point you want to remove.

◆ VOIs Tab

Use the **VOIs** tab to choose the volumes of interest (VOIs) that appear in the **Slice Selector** and the **CTrue Image** pane and adjust their colors. Select the check box to the left of a VOI name to display that VOI, or select the top check box to select all of the VOIs.



◆ Setup Notes

Setup Notes is a licensable feature and its availability depends on your system configuration. Any clinician with patient data permissions is allowed to store setup information for patient treatment. The **Setup Notes** button is located at the bottom of the **Scan** tab in the **Treat Patient** workflow. For information about licensing options, contact your sales representative or Accuray Customer Support.

Click **Setup Notes** to open a window where you can do the following:

- Enter any useful details about patient setup.
- Insert photos of patient setup.
- Save your notes for later use.
- Print your setup notes for use in the treatment room.

Print

Click **Print** to print the **Setup Notes** content.



NOTE: Only the content that is currently viewable in the window will be included in the print.

Revert

Use the following instructions to revert the latest edits you made to the **Setup Notes** content:

1. Click **Revert**. A confirmation appears.
2. Click **Yes** to successfully revert the edits, or click **No** to cancel the revert.

Save

Use the following instructions to save the edits you made to the **Setup Notes** content:

1. Click **Save**. A dialog box appears prompting you to enter your username and password.
2. Click **OK** to successfully save the edits, or click **Cancel** to cancel the save of the edits.



NOTE: You do not have to be the current user to enter your credentials and successfully save the edits.

3. If desired, click **Shutdown** to power down the system. A confirmation appears.
4. Click **Yes** to power down the system, or click **No** to cancel.



NOTE: Your edits will not be saved if you power down the system.

Close

Click **Close** to close the **Setup Notes** window.

If you have made edits without saving or reverting, a confirmation will appear. Click **Yes** to save the edits and then close. Click **No** to close without saving. Click **Cancel** to leave the window open.

◆ Prepare Scan

The **Prepare Scan** button is available only after you have accepted slices. When you are ready to position the patient, click **Prepare Scan**. This initiates the scan procedure. Brief instructions appear in **What's Next** to guide you through the patient setup process.

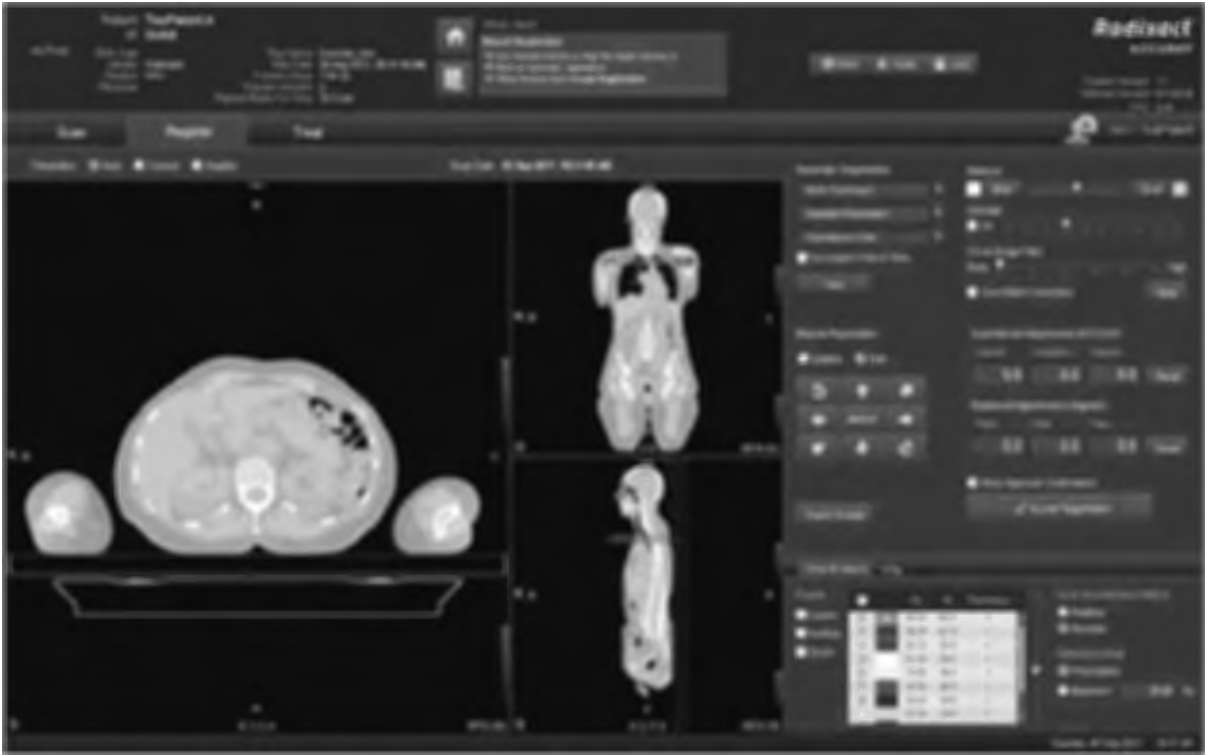
◆ CTrue Image

As a patient is scanned, the scan image appears in the **CTrue Image** pane.

Register Tab

Use the **Register** tab to align a *CTrue* image data set with the planning image. The amount and direction of movement required to align the images is used to reposition the patient before treatment.

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- ◆ Scan Date 112



◆ Registration Images

The *CTrue* image overlays the planning image in each of the three views on the **Register** tab (axial, coronal, and sagittal). Each of the images can be modified using **Image Viewer** tools.

You can use the automatic or manual registration controls to align the *CTrue* image with the plan image. Each of the three views is updated based on the adjustments.

You can also click and drag in each of the three views to move the entire *CTrue* image and align it with the plan image. Moving the entire *CTrue* image in one view also moves the *CTrue* image in the other two views. The *CTrue* image does not move in this way when the **Checker** check box is selected.

Scan Date

The **Scan Date** appears above the registration image pane. It displays the date and time of the most recently completed *CTrue* image scan for the current patient or phantom. The **Scan Date** only appears on the **Register** tab for the **Treat Patient**, **Treat Phantom Plan**, and **Patient QA** workflows.

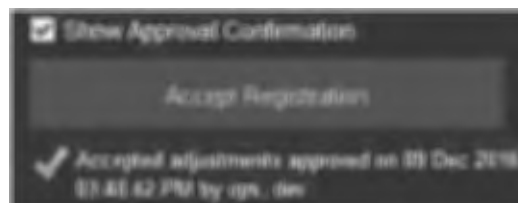
Scan Date: 17 Oct 2017, 03:06:58 PM

◆ Orientation

Select **Axial**, **Coronal**, or **Sagittal** above the main Image Viewer pane to display your chosen view. The other two images appear in the smaller panes.

◆ Accept Registration

Once you have aligned the *CTrue* image and plan image, you must verify the results and accept the registration. Click **Accept Registration** to confirm the registration adjustments. The **Registration Adjustments** dialog appears



Accept Registration Button



Registration Adjustments Dialog

Show Approval Confirmation

Use the **Show Approval Confirmation** to record the user that approved the registration.

1. Select the **Show Approval Confirmation** check box and then click **Accept Registration**. The **Approve Registration** dialog box appears.
2. Enter your username and password, and then click **OK**. A message appears below the **Accept Registration** button stating that the current user approved the accepted adjustments at a specific date and time.



NOTE: If you subsequently clear the check box and then click the **Accept Registration** button, a different message appears below the button stating that the adjustments were accepted but not approved.

After the registration adjustments are accepted and approved, the following information is stored in the iDMS™ Data Management System:

- Approval of the registration adjustments
- Name of the approver
- Date and time of the approval

Acquire Registered Couch Position

Select the **Longitudinal**, **IEC Y** or **Vertical**, **IEC Z** check box in the **Acquire Registered Couch Position** area to save the current registration adjustments with the patient plan. Future treatments will use the adjusted couch position for patient setup.

Print

If the Treatment Delivery Console is connected to a printer, click **Print** to print the patient adjustments. You can use the printed adjustments as a guide to reposition the patient.

Apply

Click **Apply** to apply the registration adjustments to the current procedure. The red lasers move to the new position, but the couch will not move to the new position until **Setup** is pressed on the **Positioning Control Panel**.

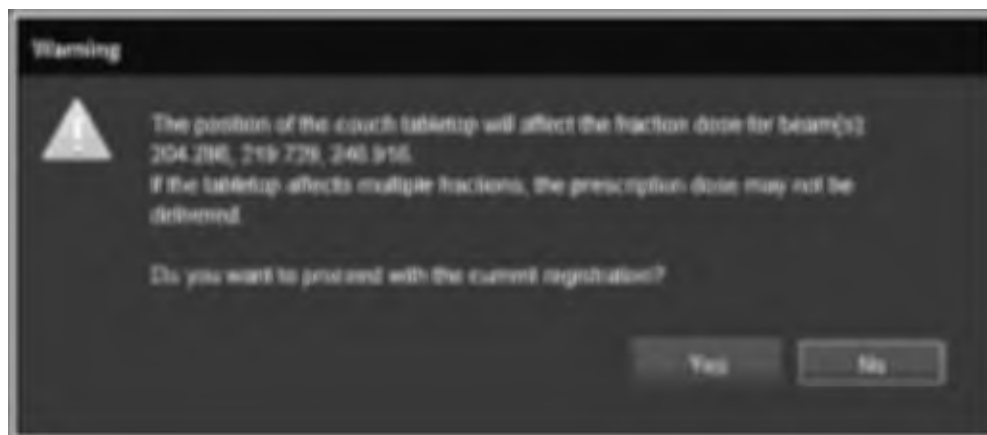
View Prior Registrations

You can access **Review Registration** locally or remotely to verify that the accepted adjustment values are stored in the *iDMS* System. For more information, see “Review Registration” (page 202).

1. From the TDC dashboard, click **Review Registration** and then click **OK**.
2. Select the patient, plan, and scan to view the registration approval details.

TomoDirect and Couch Alignment

For *TomoDirect* plans, couch position is verified after **Accept Registration** is clicked. Depending on beam angle settings, registration adjustments may cause the couch tabletop to change the attenuation of the treatment beam. If the tabletop position affects one or more treatment beams, a **Warning** appears.



WARNING: For a *TomoDirect* treatment, if beam and couch positions are not consistent between plan calculation and treatment delivery, overdose or underdose may occur. To prevent changes in beam attenuation at the time of treatment, the patient must be positioned on the couch so that the tabletop is in the correct position after image registration.

This warning message appears when registration offsets change the relative position of the couch such that the attenuation of the beam (by the couch) is expected to be different from what was planned at the Accuray Precision™ Treatment Planning System. This warning will appear under only the following circumstances:

- The plan type is *TomoDirect*.
- After registration adjustments are applied, more beams will pass through the couch before they reach the target than beams which will not pass through the couch before they reach the target.

Over many treatment fractions, this difference in beam attenuation may have an effect on the actual dose delivered to the patient. To avoid this, consider the following:

- During plan creation, the *Accuray Precision* System notifies the user if couch position may cause the beam attenuation to change due to image registration adjustments.
- If the couch position warning appears prior to treatment, you may choose to physically adjust the patient on the tabletop. If you physically adjust the patient, perform a new scan and image registration to realign the patient for treatment and verify couch and patient position.
- On the **Beam Angles** tab, display beams to review the couch and beam intersection. Based on your clinical protocols, you may choose to treat or not to treat the patient.



WARNING: If the couch position affects attenuation over many fractions, the prescription dose may not be delivered. Accuray Incorporated recommends that you perform **Patient QA** to assess the effect on fraction dose. If the effect is significant, you may compensate using dose monitoring and replanning tools.

◆ Export Screen

Some oncology information system protocols require images of patient registration. To export a registration image from the current procedure, click **Export Screen**. A screen capture of the registration image is saved to:

C:\accuray\exports



WARNING: Incorrect use of image comparison tools can lead to patient positioning errors, resulting in mistreatment. As the **Balance** bar is moved away from the **Scan** setting, the **Plan** image is increasingly displayed over itself, which can result in a false-positive alignment confirmation. To determine the correct image registration adjustments, set the **Balance** bar to **Scan** so that both the **Plan** and **Scan** images are visible in the Image Viewer.

◆ Balance

Move the **Balance** slider to the right and left to change the level of transparency for the correlated images. If the **Checker** check box is selected, both images are 100% opaque by default and do not overlap. Otherwise, both images are 50% opaque by default.

Plan and Scan Buttons

By default, the *CTrue* image is displayed on top of the planning image. Click **Plan** to make only the planning image visible, or click **Scan** to make only the *CTrue* image visible. You can also move the slider between the **Plan** and **Scan** buttons to make the *CTrue* or planning image more opaque.

Image Colors

To change an image's color, click the colored box for the **Plan** image or **Scan** image to display the **Choose Image Color** tools. Cyan is the default color for the *CTrue* image, but you may change the color of both the **Plan** and **Scan** images as desired.

◆ Checker

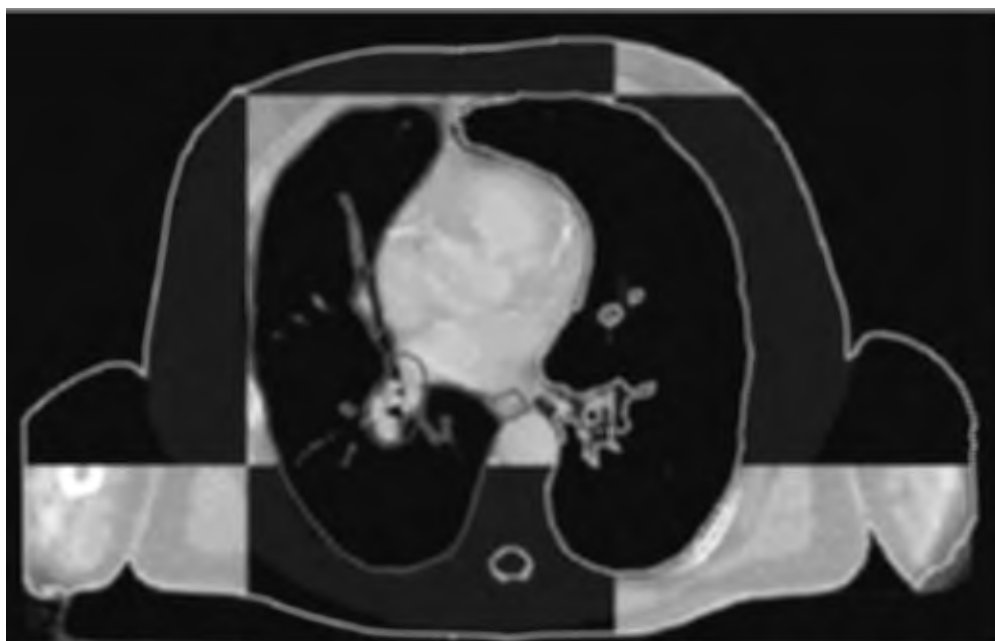
Select the **Checker** check box, and then use the slider to display a pattern of squares on the *CTrue* image and plan image. To evaluate registration, click and drag the image to move the pattern. Compare the checker pattern for the *CTrue* image against the plan image to verify alignment. The checker setting you select is retained until it is changed or until the Treatment Delivery Console is shut down.



NOTE: The **Balance** slider on the **Register** tab is used to view both plan and scan images. The sliding bar defaults to one extreme (**Plan** or **Scan**) when the **Checker** is selected for the first time for a given patient. When the sliding bar is in the middle of **Plan** and **Scan**, the two images appear overlaid, but are not blended or fused together.



WARNING: Patient mistreatment can occur if the patient is not in the correct position. Do not approve registration adjustments after reviewing images with the **Balance** sliding bar at only one of the extremes (**Plan** or **Scan**). Image registration is intended to align plan and scan images. If only the plan or scan image is displayed, it is likely to result in incorrect registration.



◆ CTrue Image Filter

The **CTrue Image Filter** applies an edge-preserving smooth filter to the image volume. Use the **CTrue Image Filter** option to smooth rough edges of the *CTrue* image, and reduce the effect of image artifacts. The **CTrue Image Filter** may take up to several minutes to apply, so this option should be used on an as-needed basis. Click and drag the slider to select the filter level and click **Apply**. Depending on the size of the image volume, and the selected filter level, the time required to apply the filter may vary.

CTrue Image Artifact Correction

CTrue image artifact correction can be applied to the registration image. This filter removes artifacts from the center of the image, commonly referred to as “zipper” or “button” artifacts. Select the **Use artifact correction** check box to turn on artifact correction.

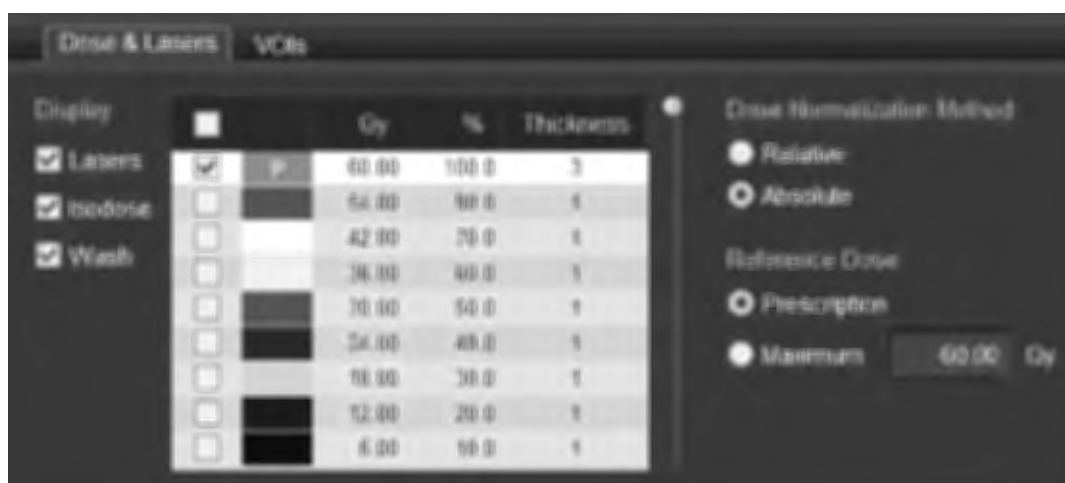
◆ Dose & Lasers, VOIs, and Beam Angles Tabs

The **Dose & Lasers**, **VOIs**, and **Beam Angles** tabs are in the lower-right corner of the **Register** tab.



NOTE: The **Beam Angles** tab is available only with *TomoDirect* plans.

Dose & Lasers Tab



Use the **Dose & Lasers** tab to choose the isodose contours and color washes displayed in the Image Viewer.

- Select the **Lasers** and **Isodose** check boxes under **Display** to show the lasers and isodoses in the Image Viewer.

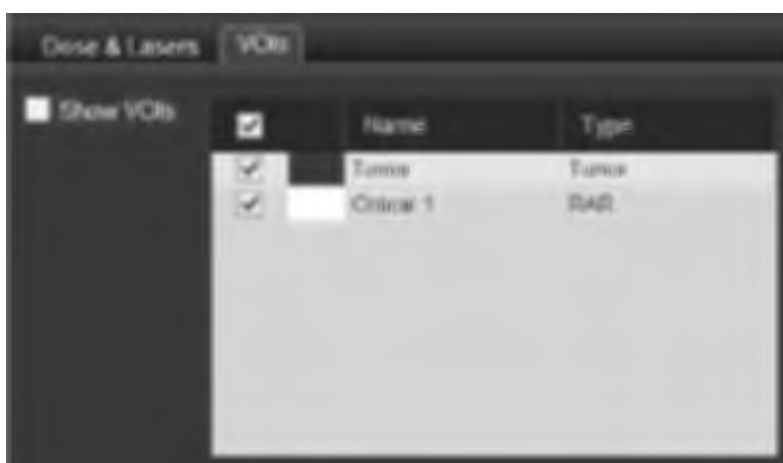
Wash is automatically selected when you select **Isodose**. This applies the color wash assigned in the isodose table to the isodose contours on the Image Viewer. Use the slider to the right of the isodose table to control the transparency of the colors.

- Select the check boxes on the left side of the isodose table to choose the isodose contours that are shown on the Image Viewer. Select the check box at the top of the table to select all of the contours.
- Click the color box to the right of the check boxes in the isodose table to open a palette of colors. Click to choose a color for an isodose. The prescription dose is always at the top of the list and is marked by a **P**.

- Enter a dose in the **cGy** or **Gy** column and a percentage of the reference dose in the **%** column for any non-prescription isodose. The prescription dose is set in the plan and cannot be altered.
- Enter the desired thickness for isodose lines in the **Thickness** column. Line thickness can range from 1 to 5 and must be a whole number.
- Select either **Relative** or **Absolute** under **Dose Normalization Method**.
- Select either **Prescription** or **Maximum** under **Reference Dose**. If you select **Maximum**, you must also enter a value in the **cGy** or **Gy** box.

VOIs Tab

Use the **VOIs** tab to choose the volumes of interest (VOIs) that appear in the Image Viewer and their colors. Select the check box to the left of a VOI name to display that VOI, or select the top check box or **Show VOIs** check box to select all of the VOIs.



NOTE: VOIs are only visible in the registration image if the **Show VOIs** check box is selected. In addition, the check boxes to the left of the VOI names and column header are only active if the **Show VOIs** check box is selected.

Beam Angles Tab

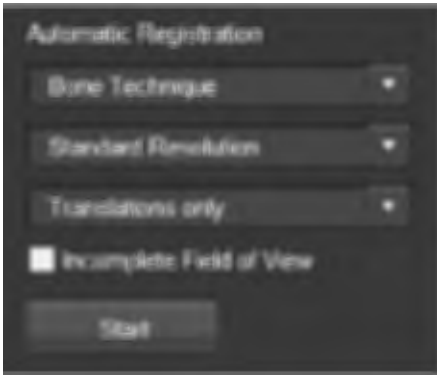
The **Beam Angles** tab is available only with *TomoDirect* plans. Select a check box to the left of a beam name to display that beam in the Image Viewer. Select the **Beam Name** check box to select all beams. The beam is displayed at the angle shown in the **Angle in degrees** column.



NOTE: When selecting beam angles, verify that they do not intersect the couch in the Image Viewer.

Dose & Lasers VOIs Beam Angles		
☒	Beam Name	Angle in degrees
☒	Ang1	0.0
☒	Ang2	45.0
☒	Ang3	315.0

◆ Automatic Registration



NOTE: The **Automatic Registration** options are used to perform automatic registration only. Additional manual registration changes may be performed after automatic registration.

Techniques

Each technique specifies the data points used by the automatic registration process to align the *CTrue* image and plan image. Click the drop-down list to select a technique.

- The **Bone Technique** (default) uses only bone (high density) data points from the images.
- The **Bone and Tissue Technique** uses bone and tissue (high and low density) data points from the images.
- The **Full Image Technique** uses bone, tissue, and air data points from the images.

Resolution

Each resolution specifies the number of data points used by the automatic registration process to align the correlated images. Click the drop-down list to select a resolution.

- The **Standard Resolution** (default) uses the least amount of data points.
- The **Fine Resolution** uses a greater amount of data points than **Standard Resolution**.
- The **Super Fine Resolution** uses the greatest amount of data points.

Translation and Rotations

Specify translations and rotations that are used by the system to perform automatic registration. If a roll adjustment is required, you can instruct the system to use the gantry angle to perform the roll correction automatically. See “Automatic Roll Correction” (page 128). Click the drop-down list to display the translations and rotations.

- **Translations Only** performs only translational adjustments to the image.
- **Translations+Roll** performs translational and roll adjustments to the image.
- **Translations+Yaw** performs translational and yaw adjustments to the image.
- **Translations+Yaw+Roll** performs translational, yaw, and roll adjustments to the image.
- **Translations+Pitch+Yaw+Roll** performs translational, pitch, yaw, and roll adjustments to the image.



IMPORTANT: If rotations are selected, the system does not correct for pitch or yaw. The image registration will be performed, but the registration adjustments will not be applied to the treatment.



IMPORTANT: If automatic registration is run multiple times with different options selected, alignment results may vary.

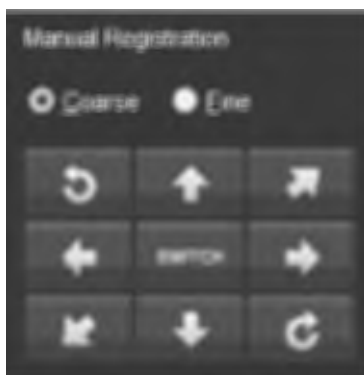
Incomplete Field of View

If a portion of the patient is outside the *CTrue* image field of view, the automatic registration process may be affected by anatomical structures at the edge of the field of view. To reduce these effects, select the **Incomplete Field of View** check box.

Start and Stop Button

Click **Start** to align the *CTrue* image with the plan image. During automatic registration, this button is displayed as **Stop**. Click **Stop** to cancel automatic registration. Manual registration controls are not available during automatic registration.

Manual Registration Controls



Switch

Click **Switch** to change the image displayed in the large viewing area of the Register tab.

Coarse and Fine Controls

The **Coarse** and **Fine** controls determine the amount of movement used for the manual move controls.

- The **Fine** control can be used for precise movement. This control provides 1 mm or 1 degree incremental movement.
- The **Coarse** control can be used to position the *CTrue* image into general alignment with the plan image. This control provides 10 mm or 10 degree incremental movement.

Move In and Move Out

Use the move in and move out buttons to move the axial, sagittal, and coronal planes of the plan image. The amount of movement is determined by the **Coarse** or **Fine** option.



Based on IEC coordinates, the direction of movement for each plane is listed in the following table. The plane that appears in the large pane of the Image Viewer dictates the direction of movement for the two, smaller panes. For example, if the axial plane appears in the large pane, then the slices for all planes (Image Viewer panes) will scroll + Y (move in) and -Y (move out).

Button	Axial	Coronal	Sagittal
Move In	+Y	-Z	+X
Move Out	-Y	+Z	-X

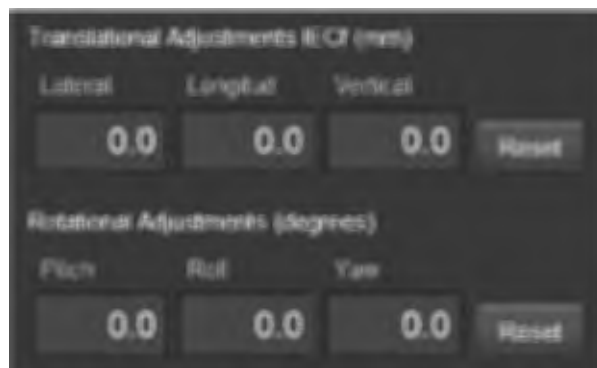
Manual Move Controls

Use the move controls to manually align the *CTrue* image with the plan image. The direction for each manual control depends on the image’s view orientation.

- Movement in the sagittal plane is viewed from the left side of the couch.
- Movement in the coronal plane is viewed from above the couch.
- Movement in the axial plane is viewed from the foot of the couch.

View Orientation	Move Up	Move Down	Move Left	Move Right	Rotate Left	Rotate Right
Axial	+Z	-Z	-X	+X	- roll	+ roll
Coronal	+ Y	- Y	- X	+ X	+ yaw	- yaw
Sagittal	+ Y	- Y	+ Z	- Z	+ pitch	- pitch

◆ Translational Adjustments and Rotational Adjustments



The translational and rotational adjustment values are calculated as you align the *CTrue* image with the plan image. You can also type adjustment values to move the *CTrue* image. Adjustments are applied to the procedure before treatment.

The minimum and maximum values for the translational and rotational adjustment fields are:

Field Name	Minimum Value (mm)	Maximum Value (mm)
Lateral	-50.0	+50.0
Longitudinal	-999.9	+999.9
Vertical	-200.0	+200.0
Pitch	-90.0	+90.0
Roll	-180.0	+180.0
Yaw	-90.0	+90.0



NOTE: If you enter a value greater than +25.0 mm or less than -25.0 mm in the **Lateral** field, a dialog appears to inform you that the entered value exceeds the movement limits of the couch. The software will not allow you to prepare and perform a treatment procedure with an unachievable lateral adjustment.



NOTE: The ranges of enterable values listed in the above table may extend beyond clinical relevance for use of the treatment system. During clinical use, ensure that you only enter values into these fields that are relevant to your clinical objectives.

1. After image registration is complete, click **Accept Registration**. The accepted adjustment values are stored in the *iDMS* System.
2. You can access **Review Registration** locally or remotely to verify that the accepted adjustment values are stored in the *iDMS* System. For more information, see “Review Registration” (page 202).
3. From the TDC dashboard, click **Review Registration** and then click **OK**.
4. Select the patient, plan, and scan and then click **OK**.
5. Verify that the accepted adjustment values are displayed on the **Register** tab.
6. Proceed to the **Treat** tab to apply the patient adjustments.

Reset

Click **Reset** to reset the adjustment parameters to zero and the *CTrue* image to its original position. You can also type zero (0) for one or more parameters.

Registration Quick Keys

Use the combination of keystrokes listed below to quickly perform many of the basic registration functions.

Manual Registration

Command	Quick Keys
View the next slice	Page Up or Page Down
Move <i>CTrue</i> image in	Shift + Right arrow
Move <i>CTrue</i> image out	Shift + Left arrow
Move <i>CTrue</i> image up	Up arrow
Move <i>CTrue</i> image down	Down arrow
Move <i>CTrue</i> image left	Left arrow
Move <i>CTrue</i> image right	Right arrow
Move <i>CTrue</i> image clockwise	Shift + Down arrow
Move <i>CTrue</i> image counterclockwise	Shift + Up arrow
Switch to Coarse registration	Alt + C

Command	Quick Keys
Switch to Fine registration	Alt + F



NOTE: If the image volume is rotated clockwise or counterclockwise (roll correction), lateral and vertical adjustments become linked. Future lateral (left or right) or vertical (up or down) adjustments will proportionally affect each other. For example, after a rotation value is entered, an increase in vertical adjustment +1.0 mm may cause the lateral adjustment field to be reduced by 0.1 mm.

Composition

Command	Quick Keys
Increase checker size	Alt + Page Up
Decrease checker size	Alt + Page Down
Move checkerboard up	Alt + Up arrow
Move checkerboard down	Alt + Down arrow
Move checkerboard left	Alt + Left arrow
Move checkerboard right	Alt + Right arrow
Switch to Plan view	Alt + P
Switch to Scan view	Alt + S
Select or clear the Checker check box	Alt + K

Orientation

Command	Quick Keys
Change orientation on Image Viewer	Alt + Enter

Treat Tab

Use the **Treat** tab to select and start a scheduled treatment procedure. TomoHelical™, TomoDirect™, TomoEDGE™ Dynamic Jaws, Pause and Resume, Fiducial Tracking, Synchrony® Respiratory Tracking, and XSight® Lung Tracking are licensable options and their availability depends on your system configuration. The **Treat** tab interface contains different items depending on the plan type and available licenses.

- ◆ Prepare Treatment 128
- ◆ Automatic Roll Correction 128
- ◆ Registration Adjustment Instructions 128
- ◆ IEC Y Field (mm)..... 130
- ◆ Load Fraction 128
- ◆ Delivery Report and Summary Report 130
- ◆ Pause and Resume Treatment..... 130
- ◆ TomoDirect Features 132
- ◆ Common Motion Tracking Features 134
- ◆ Fiducial Tracking 141
- ◆ Synchrony® Respiratory Tracking 144
- ◆ XSight® Lung Tracking 146



TomoHelical/Treat Tab with *TomoEDGE* Dynamic Jaws

◆ Load Fraction

The first undelivered fraction will be automatically selected in the **Procedures** list. You can also select a different fraction or a makeup fraction from the list. Select the fraction from the **Procedures** list and then click **Load Fraction** to load your selection.

◆ Prepare Treatment

When you are ready to start the treatment, select the loaded **Deliverable** fraction, and click **Prepare Treatment**. This initiates the treatment procedure, and moves the couch to the Registered Setup Position, based on the adjustments approved on the **Register** tab. Brief instructions appear on the Treatment Delivery Console to guide you through the patient setup process. The loaded fraction will be bold in the **Procedures** list.

◆ Registration Adjustment Instructions

After you click **Prepare Treatment** on the **Treat** tab, the **Registration Adjustments** dialog box opens. This shows the adjustments required to reposition the patient, based on registration results.

◆ Automatic Roll Correction



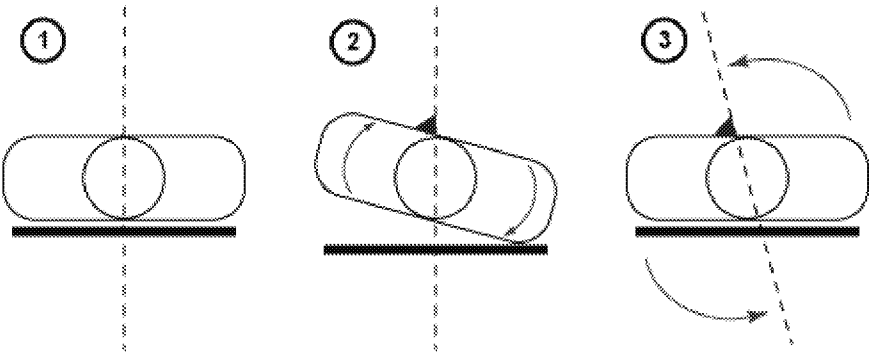
WARNING: If a roll correction was accepted during image registration, the gantry will automatically correct for roll when you click **Apply** in the **Registration Adjustments** dialog. To prevent incorrect patient setup, do not adjust the roll position of the patient if an automatic roll correction was accepted during image registration.

If an automatic roll correction adjustment was made during image registration, it will be applied to the treatment fraction when you click **Apply** in the **Registration Adjustments** dialog. The treatment system will use the gantry angle to correct for the roll adjustment. Refer to the following figures for an explanation of how automatic roll correction is applied by changing the gantry angle.

The software allows a roll correction of any angle prior to treatment. However, a roll correction greater than $\pm 10^\circ$ should not be performed. In these cases, Accuray Incorporated recommends repositioning and rescanning the patient.

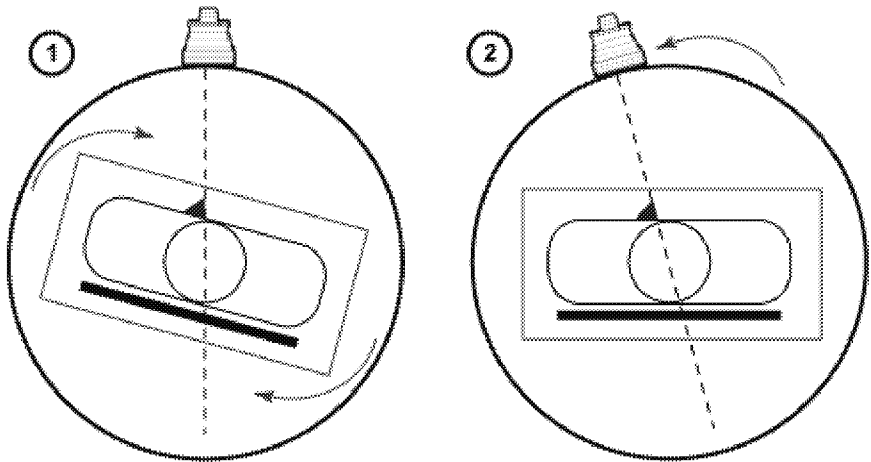


WARNING: If roll corrections greater than $\pm 10^\circ$ are performed, dose accuracy may be affected. Reposition the patient and perform a new *CTrue* image scan.



Patient and Gantry Rotations

Item	Description
1	The solid dark rectangle represents the patient couch, and the dashed line represents the radiation source. The beveled rectangle and circle represent a patient or image volume.
2	During the image registration process, rotational adjustments may be required to acquire the correct angular relationship between the radiation source and the patient. This angular relationship is represented by the blue triangle at the intersection of the radiation source path and the patient. On the Register tab of the Treatment Delivery Console, rotational adjustments are applied to the image volume (as in this image). In the physical world, rotating the patient would create a gap between the patient and couch, so it is not possible to automatically adjust for roll correction in this way.
3	Instead of moving the patient or couch, the gantry adjusts the position of the radiation source to acquire the necessary angular relationship. Notice that the clockwise rotation in the previous image results in a counter-clockwise rotation of the gantry.



Patient Rotation Applied to Gantry Angle

Item	Description
①	On the Register tab, the image volume is rotated because it is easier to visualize patient rotation than gantry angle adjustments. In application, the couch and patient do not move.
②	From the previous image, rotational adjustment in one direction results in gantry rotation in the opposite direction to achieve the correct angular relationship between the radiation source and patient. To verify that the roll correction is correctly applied to a treatment, see “Verify Planned Angle Roll Correction” (page 133).

◆ IEC Y Field (mm)

IEC Y Field (mm) displays the current position of the front and back jaws, and the current treatment beam field width.

- **Mode** displays **Fixed** or **Dynamic**. Fixed jaws do not move during the procedure, and the field width is constant. If licensed, Dynamic jaws move during the procedure, and the field width is variable.
- **Front** is the current position of the front jaw field edge in millimeters.
- **Back** is the current position of the back jaw field edge in millimeters.
- **Width** is the current IEC Y treatment beam width in millimeters.

◆ Delivery Report and Summary Report

Click **Delivery Report** or **Summary Report** to open the iDMS™ Data Management System software where you can run the delivery or summary reports. See the *iDMS Manual* for more information.

◆ Pause and Resume Treatment

Pause and **Resume** is a licensable feature and its availability is dependent on your system configuration. Unlike the **Stop** or **Emergency Stop** buttons that stop radiation almost immediately (within 100 milliseconds), the **Pause** button stops treatment more slowly due to software and communications latency.



IMPORTANT: The **Pause** button should only be used for non-emergency situations. It is not intended to replace the **Stop** or **Emergency Stop** buttons for emergency situations.

After the **Pause** button is clicked, the treatment system stops the delivery of radiation and transitions to a waiting state. From a treatment system perspective, the waiting state is still part of the patient treatment. In this waiting state, the **Status Console** key remains in the **Treat** position, and you may not enter the treatment room or navigate away from the **Treat** tab on the Treatment Delivery Console or you will trigger a system interruption. Click the **Resume** button to restart the delivery of radiation. To ensure treatment accuracy, make sure the patient does not move out of the correct setup position.



WARNING: Registration and treatment accuracy can be affected if the patient does not remain in the correct setup position. Make sure the patient does not move during a *CTrue* image scan, image registration, or a treatment procedure. Use the audio and visual system to monitor the patient from the Treatment Delivery Console.

When a treatment is paused, the system requires time to transition many moving components to the waiting state. When a treatment is resumed, the system also requires time to synchronize the gantry speed, gantry angle, couch speed, couch position, treatment beam, and collimators. Pause and resume delays may vary from procedure to procedure, depending on a variety of factors. While the system transitions between states, controls on the **Treat** tab are disabled.

For non-motion tracking treatment procedures, you may pause treatment to reduce background noise to better communicate with a patient through the intercom system. For motion tracking treatment procedures, you or the system may initiate a treatment pause. You might pause a motion-tracking treatment to make changes to the motion model, or to rebuild the model. The system will automatically initiate a treatment pause if the parameter limits defined in the motion tracking model are exceeded.



IMPORTANT: Pausing a treatment will increase the duration of the treatment session, which may affect your clinical schedule. It may be necessary to budget extra time in the schedule to accommodate delays in treatment due to the use of the **Pause** and **Resume** feature, especially for motion tracking treatments.

System Initiated Pause

During motion tracking treatments, the system will pause treatment if any parameter in the motion model exceeds its threshold value. When this happens, you may consider one or more of the following clinical decisions before resuming treatment.

- Make no changes to the motion tracking model, but take time to talk to the patient through the intercom and get them to relax, remain still, and breathe normally before resuming treatment.
- Acquire another set of kV radiograph images. If there was a sudden movement, any images that captured the shift will eventually be replaced by new images in the motion tracking model.

- If there is a troublesome or migrated fiducial, clear the fiducial's check box to turn it off. This tells the algorithm to stop using the fiducial in the motion model, and to stop looking for it in the kV radiograph images.
- If there is an incorrect fiducial or target location, in the image viewer you may click and drag the fiducial or tumor VOI to the correct location to retrain the algorithm to look in the indicated position.
- Adjust the couch back to isocenter using the **Move Couch to Apply Longitudinal Offset** button. By re-centering the couch, thresholds may no longer be exceeded.
- For a respiratory motion tracking treatment, you may reset the motion tracking model and build a new one. If the Tracking Marker LEDs are not visible, you may also interrupt the procedure to enter the treatment room and reposition the tracking markers. If the treatment is interrupted, you will need to load the makeup fraction to resume treatment.

◆ *TomoDirect* Features

The following features appear on the **Treat** tab when you have a *TomoDirect* plan.

Estimated Procedure Time Remaining (sec)

Estimated Procedure Time Remaining (sec) displays the approximate time required to move the gantry to each beam angle and treat. For each beam in the treatment, time is allotted for the gantry to reach the next beam angle, but gantry positioning may require more or less time.



IMPORTANT: The **Estimated Procedure Time Remaining (sec)** value should not be used as a means to verify correct treatment duration. Refer to the **Beam On Time** for each beam in the plan to verify treatment time.

Procedure Details

Procedure Details				
Status: Beam Angl was interrupted.				
218.5 seconds remain in the procedure.				
30.2 seconds remain in beam Angl.				
12.9 seconds of warmup in beam Angl.				
1.2 seconds per projection in beam Angl.				
Procedure Beam Details				
Beam Name	Planned Angle	Delivery Time	Elapsed Time	Status
Ang1	208.3	43.6 sec	43.6 sec	Completed
Ang2	215.7	41.4 sec	41.4 sec	Completed
Ang3	248.9	59.2 sec	40.0 sec	Interrupted
Ang4	12.0	44.8 sec	0.0 sec	
Ang5	47.5	43.4 sec	0.0 sec	

The contents of the **Procedure Details** may vary depending on the procedure you select from the **Procedures** list:

- **Status** is the delivery status of beams in the selected fraction including **seconds that remain in the procedure**, **seconds of warmup**, and **seconds per projection**.
- **Procedure Beam Details** shows additional information including **Beam Name**, **Planned Angle**, **Delivery Time**, **Elapsed Time**, **MU (C1/C2)**, and **Status**.

Verify Planned Angle Roll Correction

After automatic roll correction is applied, you can use the following values on the **Treat** tab to validate the angle of the gantry (at the radiation source):

- **Planned Angle** is the angle of the gantry at the start of the beam procedure.
- **Gantry Angle (degrees)** is the current gantry angle.
- **Roll Correction** is any automatic roll correction applied from image registration adjustments.
- **Gantry Correction** is the same number as **Roll Correction** with the opposite sign (- or +).

Calculate Gantry Start Angle

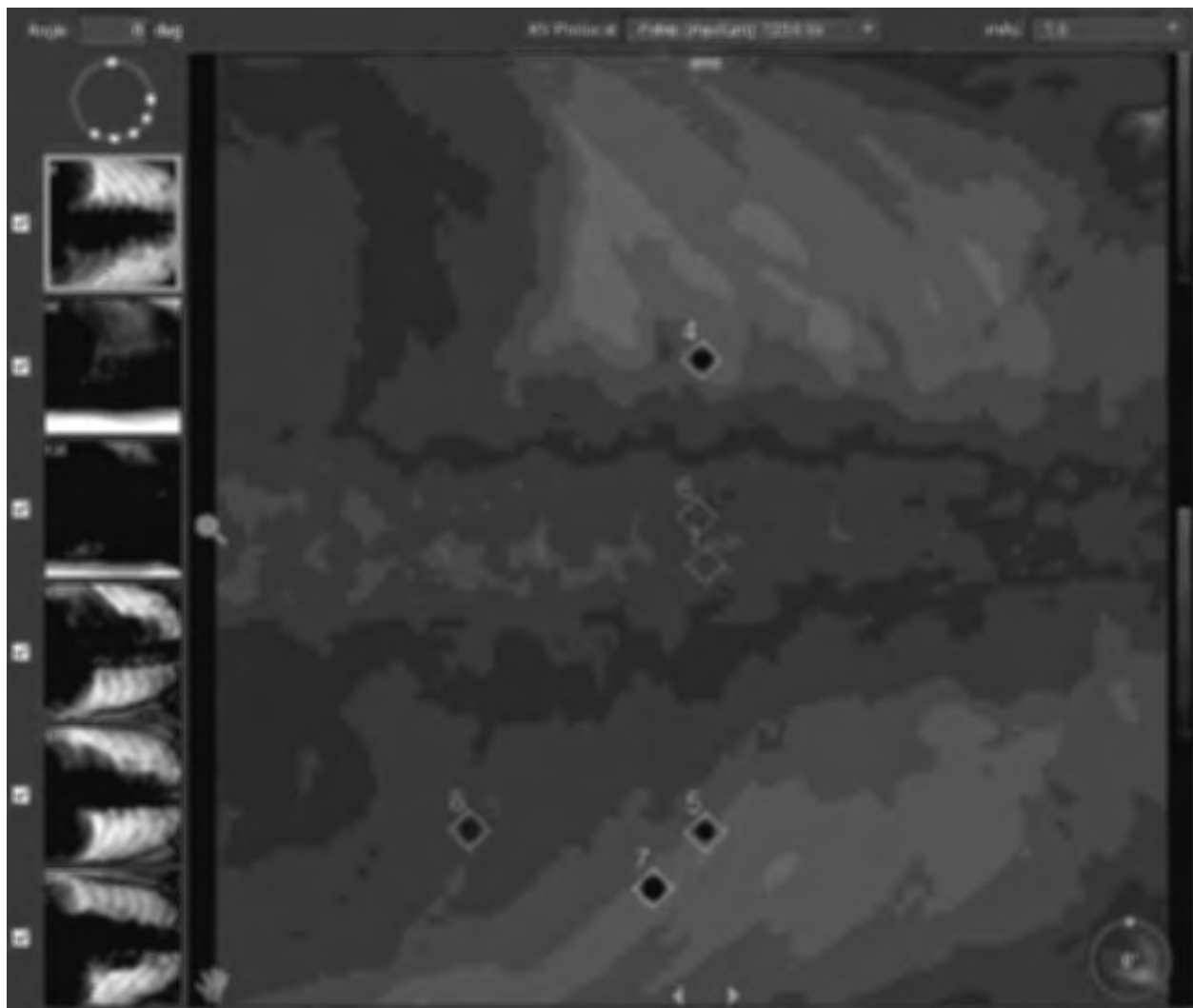
To determine if the gantry angle is correct, subtract the **Roll Correction** from the **Planned Angle**. The current **Gantry Angle** should reach the adjusted angle position before each beam is delivered. A positive **Roll Correction** normally results in a smaller gantry angle, and a negative **Roll Correction** normally results in a larger gantry angle. The exception occurs when the **Planned Angle** is near 0 or 360 degrees. If the result of your calculation is less than zero, add 360. If the result of your calculation is greater than 360, subtract 360.

◆ Common Motion Tracking Features

Many motion tracking controls on the Treatment Delivery Console are shared by the Fiducial Tracking, Synchrony® Respiratory Tracking, and XSight® Lung Tracking treatment modalities. Controls that are unique to each modality are also explained later in this chapter.

kV Radiograph Images

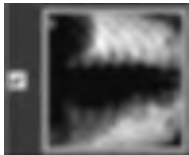
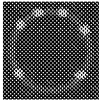
For all motion tracking treatments, kV image information and controls appear on the left side of the **Treat** tab. Initial kV radiograph beam angles are defined in the patient plan, but can be modified during a treatment session. You may define up to six kV radiograph beam angles to use during a treatment session. However, you cannot edit angles or add angles when the system is acquiring radiographs, model building, or delivering treatment.



kV Image Controls and Information



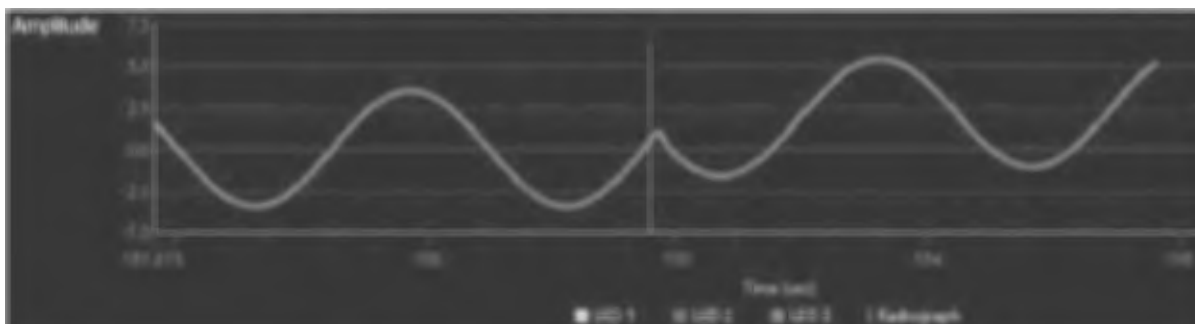
WARNING: Excessive kV image acquisition may cause or contribute to a higher dose deposited in patient skin, resulting in radiation burns. To prevent or reduce this side effect, use the minimum quantity of kV images needed, and the lowest dose X-ray technique, that meets all other tracking requirements according to the standard protocols and practices of your clinic.

Item	Description
kV radiograph beam angles 	Each kV radiograph angle defined for the treatment session is represented in a miniature display to the left of the primary kV image viewer. The beam angle number in degrees is displayed over the last acquired radiograph. The radiograph angles with a check box selected will be used to acquire images at each rotation of the gantry. You may clear a check box to stop using a radiograph angle, but the settings for that radiograph angle are retained for later use. Click on the desired miniature kV image display to highlight a previously defined radiograph angle. Once a radiograph angle is highlighted, you may change the degree value. Select an empty kV beam angle check box to define an additional beam angle.
Angle  	This field indicates the gantry angle of the kV radiograph that is currently selected (highlighted). You may enter a new value from 0 to 360 to change the angle of the selected kV radiograph. Accuray Incorporated requires that Kv beam angles are spaced at least 30 degrees apart. Below the Angle field is a visual representation of the enabled beam angles. Target volumes or implanted fiducials should be visible in each radiograph angle used to build motion tracking models or monitor patient movement.
kV Protocol	This drop-down menus contain preset protocol options with defined mAs ranges. The menu contains areas of the body and sizing options.
mAs	Each technique is a combination of a kV (kilovolt) value and mAs (mille amp-seconds) value. You can adjust the mAs value of the technique defined by your protocol selections to improve image clarity.
kv image viewer	The kV image viewer displays the last acquired image from the highlighted kV beam angle. In the lower-right corner of the image viewer, position and value of the angle appears. The kV image viewer contains the same common functions as the image viewer on the Scan and Register tabs, except that target volumes or implanted fiducials within the kV radiographs are automatically identified.

Amplitude Graph

The **Amplitude** graph provides a real-time illustration of the range of patient respiratory motion, and the times that **Radiographs** (vertical blue lines) are acquired. The vertical axis represents the distance in millimeters, and the horizontal axis represents time in seconds.

Each LED Tracking Marker appears as a separate respiratory pattern line in the **Amplitude** graph. The three tracking curves will typically be close to each other in the graph, depending on where the Tracking Markers are placed on the patient anatomy.



Amplitude Graph

Removing kV Radiograph Images from the Model

As noted in the Model Building and Tracking Parameters section, you can right click in the **X** column to remove a radiograph data row from the motion tracking model. Examples of reasons why you might remove a kV radiograph image from the model are:

- Cannot find all fiducials in the image.
- Found fiducials, but **Confidence** is low.
- **Rigid Body Error** exceeds threshold tolerance
- Image is too old. For example, after a pause.

kV Dose Table

The following table provides an approximate kV radiograph dose for each available combination of **kV Protocol** and **mAs** setting.

Item	Thorax			Pelvic		
Size	Small	Normal	Large	Small	Normal	Large
kV	120	120	120	120	120	120
mAs	0.80	1.00	1.60	1.00	1.25	2.00
mGy	0.08	0.10	0.16	0.10	0.13	0.20

Model Building and Tracking Parameters

Different model and threshold parameters are available depending on the methods used to track patient motion. The following section describes all of the available parameters and controls. The default settings for algorithm parameter thresholds are likely to be adequate for most patient cases and are recommended by Accuray Incorporated as a starting point for building a motion tracking model.

If any parameter of the motion tracking model exceeds its threshold value, the value will be highlighted with an orange outline. For example, in the following image, the **Instability** value is highlighted in orange. The range of threshold values that can be entered is 0 to 50, where 0 is the most restrictive value, and 50 is the most permissive value.

In rare cases (<5% of patients), you may discover that a patient is not a good candidate for a motion tracking treatment. If you are unable to determine settings to build a motion tracking model with a sufficient confidence threshold, the treatment may not be achievable by the motion tracking treatment modality. In such a case, the patient plan needs to be recreated for a non-motion treatment modality.



Example of the Model Building Controls for a Synchrony® Respiratory Tracking Treatment

Button	Description
Prepare and Treat	For all motion tracking plans, the Prepare and Treat buttons function the same as non-motion tracking plans. However, after treatment has started, the Treat button text will change to Pause , and if a pause is initiated by you or the system, the button text will change to Resume .
Acquire Images	For respiratory motion tracking plans, click Acquire Images to obtain initial radiographs before building a motion model. Review the initial radiographs to confirm that the tumor VOI or fiducials are visible. Initial radiographs will be used in model building if they do not cause model parameters to exceed defined thresholds.

Button	Description
Build Model and Cancel Model	For all motion tracking plans, click Build Model to begin creating a motion tracking model. When model building begins, the button text changes to Cancel Model . Click Cancel Model if you want to modify model parameters or radiograph settings. As the gantry rotates, radiographs are acquired at the specified gantry angles, and the data for each new radiograph in the model are added to the data table. When the model acquires a suitable number of data points and achieves the desired Confidence % , model building will stop.

Item	Description
X	Right click in the X column to remove a radiograph data row from the model.
Angle	The gantry angle of the radiograph.
2D Error	The difference between the predicted target location and the location detected in radiographs. When multiple fiducials are being tracked, a single number is calculated by averaging the 2D Error for each fiducial used in the model.
Rigid Body	The difference between the position of any pair of implanted fiducials from the plan compared to the position of fiducials detected in radiographs. The distance between each pair of fiducials in the kV radiograph images is calculated and compared with the respective distances as determined in the planning image volume.
Confidence %	The current motion tracking model confidence value in %. This value is a measure of how well the data points in the motion tracking model fit together.
Threshold %	The lowest Confidence % value that the motion tracking model will accept before the system initiates a treatment pause.
Threshold	The lowest value that the motion tracking model will accept for a parameter before the system initiates a treatment pause. Treatment cannot begin until all parameters are within their thresholds.
Calculated	The current parameter value calculated from the model data. Calculated values change in real-time as new radiographs are acquired.
Instability	The variance of the motion tracking model in the current breathing phase compared across all breathing phases.

Item	Description
Max IEC-XZ Offset	The distance between the current tumor position and the planned tumor position in the IEC XZ plane. This parameter is related to the number of leaves required to shift the multileaf collimator (MLC) leaf pattern to compensate for motion.
Max IEC-Y Offset	The distance between the current tumor position and the planned tumor position in the IEC Y direction. This parameter is related to the distance that the jaws travel to compensate for motion.

Image History

The **Image History** tab contains a record of each kV radiograph. This record includes the acquisition **Angle**, **kV Protocol**, **kV Technique**, and the **Time** that the radiograph was acquired.

Confidence Graphs	Position Graphs	Image History	Procedures	Auxiliary Data
Angle	kV	mAs	Time	
257.4	120.0	10	11:14:39 AM	
290.2	120.0	10	11:14:39 AM	
57.7	120.0	10	11:14:41 AM	
152.3	120.0	10	11:14:43 AM	
257.4	120.0	10	11:15:15 AM	
290.2	120.0	10	11:15:16 AM	
57.7	120.0	10	11:15:17 AM	
152.3	120.0	10	11:15:18 AM	

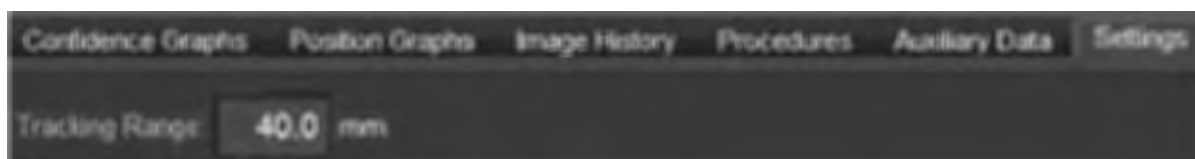
Confidence Graphs

The **Confidence Graphs** tab displays the **Confidence** graph and the **2D Error** graph. These graphs provide ongoing real-time illustrations of the **Confidence %** and **2D Error** data. You may view these graphs to see the variance of these values in time.

Settings Tab

The **Settings** tab contains the fiducial **Tracking Range** setting.

Tracking Range defines the size of the area where the system expects to find implanted fiducials or the target VOI in radiographs.

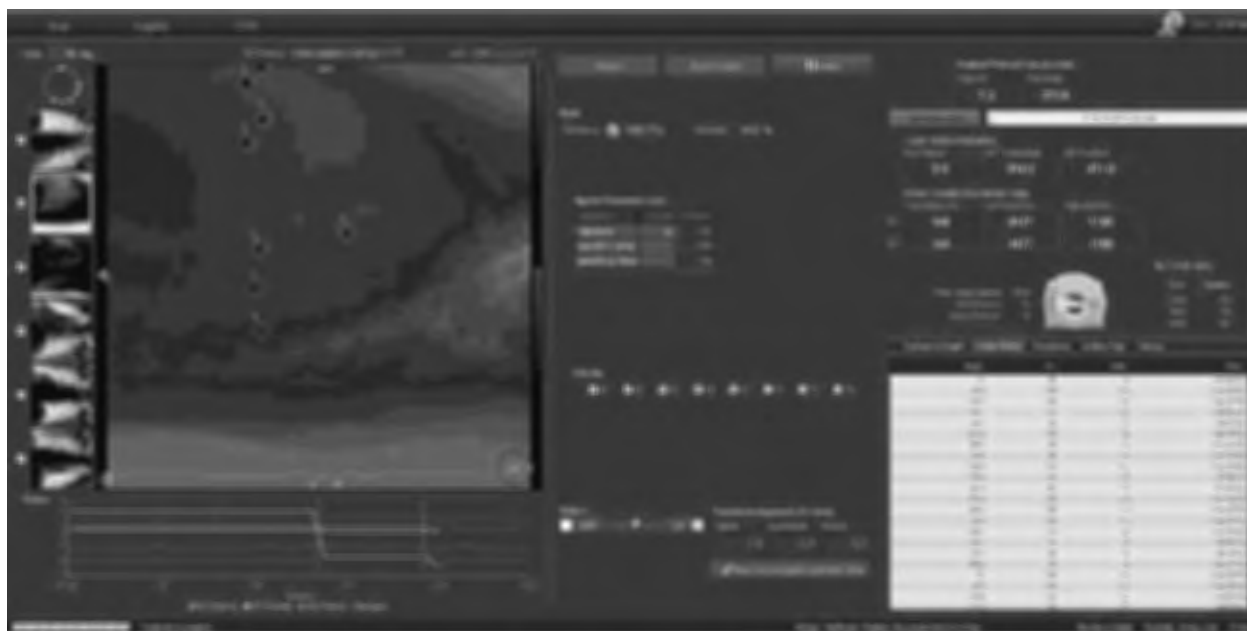


Settings Tab

◆ Fiducial Tracking

Fiducial Tracking is a licensable feature and its availability is dependent on your system configuration. The Fiducial Tracking feature requires that you also have the **Pause** and **Resume** feature.

You may have up to eight implanted fiducials defined. A minimum of two usable fiducials are required to perform a motion tracking treatment, but all available fiducials should be considered to improve the motion tracking model.



Fiducial Tracking Treat Tab without Respiratory Tracking

Implanted fiducial indicators appear in the center of the **Treat** tab. Each fiducial has a status box, usage check box, and each is labeled F1, F2, F3, and so on. These fiducial number labels also appear on the fiducials that appear in the kV image viewer. All fiducials with check boxes selected are used by the motion tracking model.



Implanted Fiducial Indicators

Fiducial status boxes change color to indicate fiducials that have exceeded the **Rigid Body Error** threshold. A red status indicates the largest difference, and a yellow status indicates the second largest difference. If a fiducial exceeds the parameter thresholds and causes frequent treatment pauses (initiated by the system), you may clear the fiducial check box to remove it from the motion tracking model. The red and yellow fiducial status boxes indicate the two fiducials with the largest **Rigid Body Error** difference. After

clearing the check box of a red or yellow fiducial, the fiducial with the next largest difference will be indicated, if there are more than two fiducials that exceed the **Rigid Body Error** threshold.



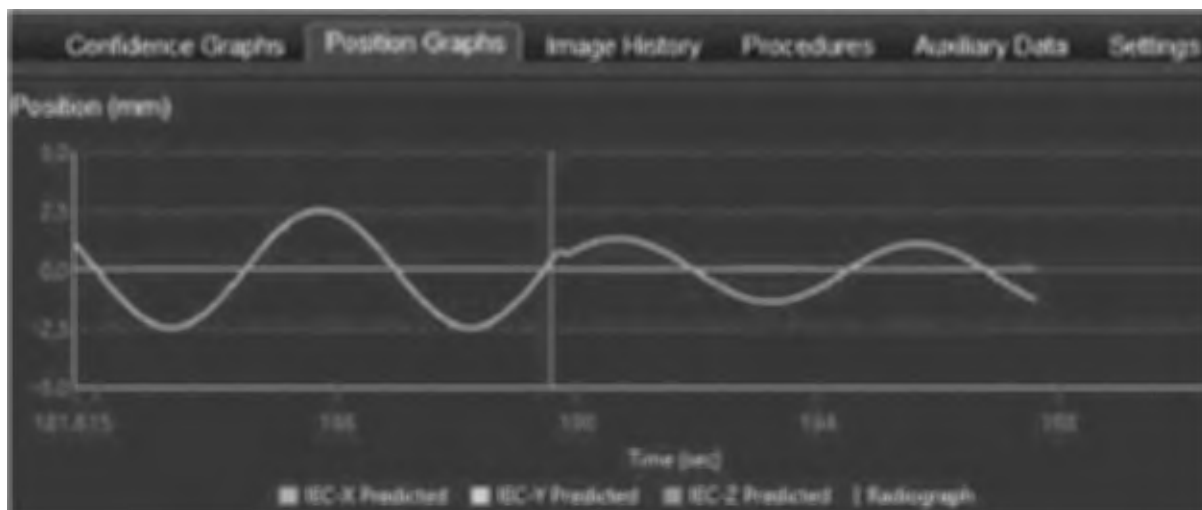
IMPORTANT: If you observe a large **Rigid Body Error** value, confirm that the patient has not moved out of position.

A non-respiratory motion tracking plan (also known as quasi-static) will have a **Treat** tab that is similar to a respiratory motion tracking plan, except the following items will be absent:

- LED Tracking Markers
- Synchrony® respiratory tracking model parameters **Instability** and **2D Error**
- **Amplitude** Graph (replaced by **Position** Graphs)
- **Comet** Graphs

Position Graphs

The **Position** graph provides a real-time illustration of the detected and predicted range of patient motion. The **Predicted** IEC X, Y, and Z positions of the implanted fiducials or the target volume are indicated with square data points. Each **Radiograph** appears as a vertical blue line. The vertical axis represents the distance in millimeters, and the horizontal axis represents time in seconds.

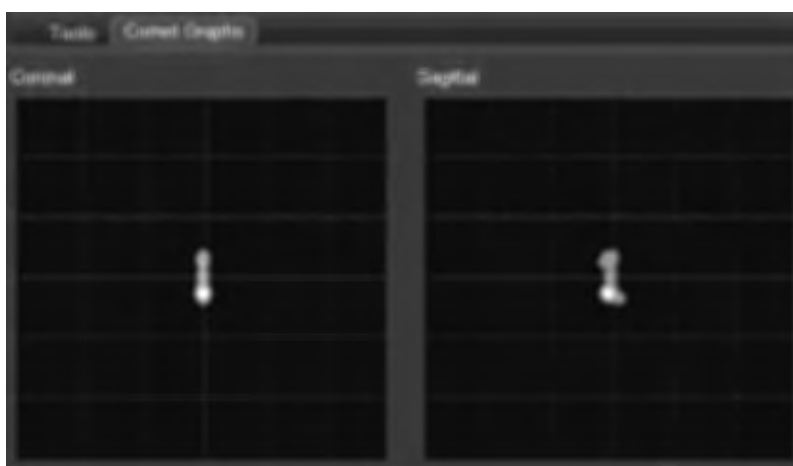


Comet Graphs

If at least two kV radiographs have been acquired, the **Comet Graphs** tab provides a virtual see-through view of the patient from the **Coronal** and **Sagittal** perspectives. These views provide a qualitative picture of how well

the model points fit the current *Synchrony* model. Comet graphs consider both the Tracking Marker position on the chest wall as well as internal images of the target location.

The vertical axis represents the Inferior/Superior direction in the patient coordinate system. The large moving point or “comet” represents the average movement of the Tracking Markers in real-time and shows where the *Synchrony* model indicates the tumor is currently located and where the treatment system is delivering radiation in the current model. Static points represent radiographs in the *Synchrony* model, and the tail of the comet illustrates the shape of the *Synchrony* model. To examine data associated with a static point, click on a static point to select it. The corresponding rows in the model table and **Image History** tab are automatically selected.



Coronal and Sagittal Comet Graphs

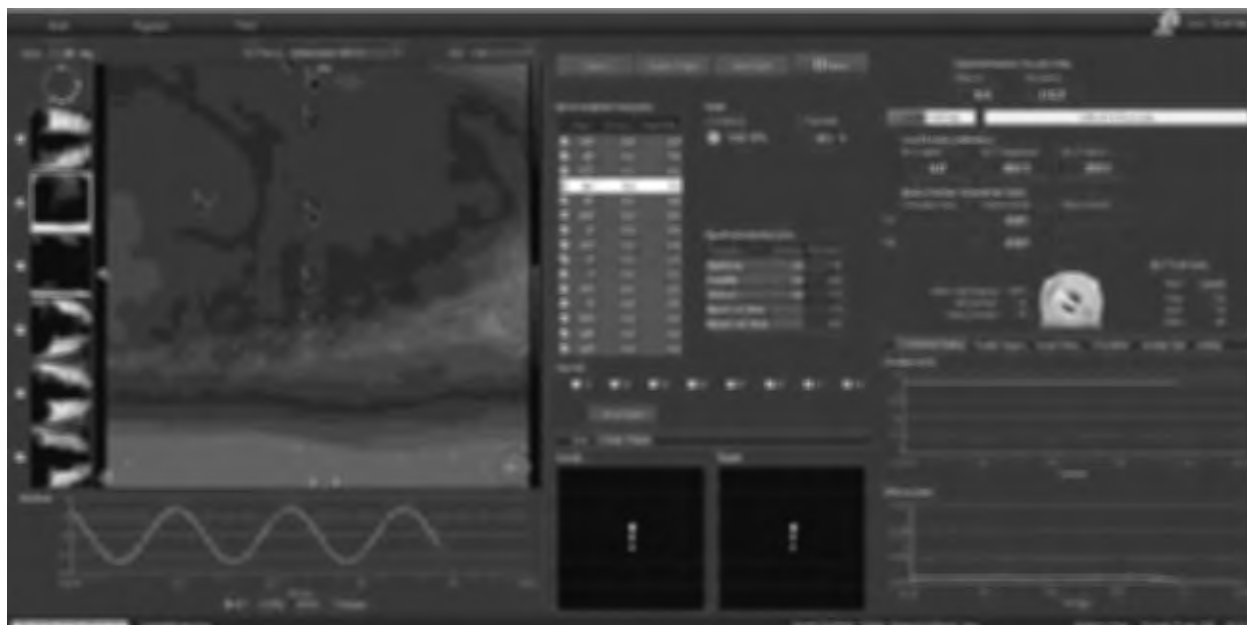
Removing Fiducials from the Model

You can remove a fiducial from the motion tracking model. The following are examples of why you might clear a fiducial check box to remove the fiducial so that it is no longer used for tracking:

- The fiducial has migrated, resulting in **Rigid Body** values that exceed the threshold.
- The fiducial is incorrectly identified.
- The fiducial has a low confidence threshold due to poor image quality in the kV radiograph images. This can also be caused by fiducial migration, obstruction by an object, or close proximity to another fiducial.

◆ Synchrony® Respiratory Tracking

Synchrony® Respiratory Tracking is a licensable feature and its availability is dependent on your system configuration. The Synchrony® Respiratory Tracking feature requires that you also have the **Pause** and **Resume** feature, and the Fiducial Tracking or Xsight® Lung Tracking features.



Synchrony Treat tab with Fiducials

Synchrony® Respiratory Tracking is used in combination with the LED (light emitting diode) Tracking Markers attached to the patient vest and positioned over the chest wall. The motion of the Tracking Markers due to respiration is continually monitored by the *Synchrony* camera. This motion is used to monitor patient movement between radiographs, and also predict future motion according to patterns in the patient breathing cycle.

The *Synchrony* motion model contains 15 radiograph points in the model table. These points are updated as new radiographs are acquired. The positions of implanted fiducials or the target volume detected in the radiographs are used to confirm the movement predicted by the model, and to continuously refine the model to synchronize with patient breathing patterns.

You may also perform a Synchrony® Respiratory Tracking treatment without fiducials using the Xsight® Lung Tracking feature. A fiducial-free respiratory motion tracking plan will have a **Treat** tab that is similar to a respiratory plan with fiducials, except the following items will be absent:

- Fiducial controls, status indicators, and fiducial markers in the kV image viewer
- Rigid Body

Tracking Marker Status

The Tracking Marker status area appears at the top of the **Register** and **Treat** tabs of the Treatment Delivery Console for *Synchrony* procedures. The *Synchrony* camera monitors LED (light emitting diode) Tracking Markers to observe patient breathing patterns.



Tracking Markers Status

LED Tracking Marker cables are labeled 1, 2, 3, and 4, which correspond with the LED number labels on the Treatment Delivery Console. Tracking Markers 1, 2, and 3 monitor patient respiratory motion. Check boxes next to LEDs 1, 2, and 3, indicate which LEDs are used by the motion model. You may clear a check box to remove one Tracking Marker from the motion model, or select an empty check box to begin using it again. At least two LEDs are required to monitor patient respiratory motion.

Tracking Marker 4 is labeled **Couch LED** in the status area. The **Couch LED** is attached to a reference post that is inserted into indexing holes on the couch. The **Couch LED** is required for the camera to adjust for couch motion.



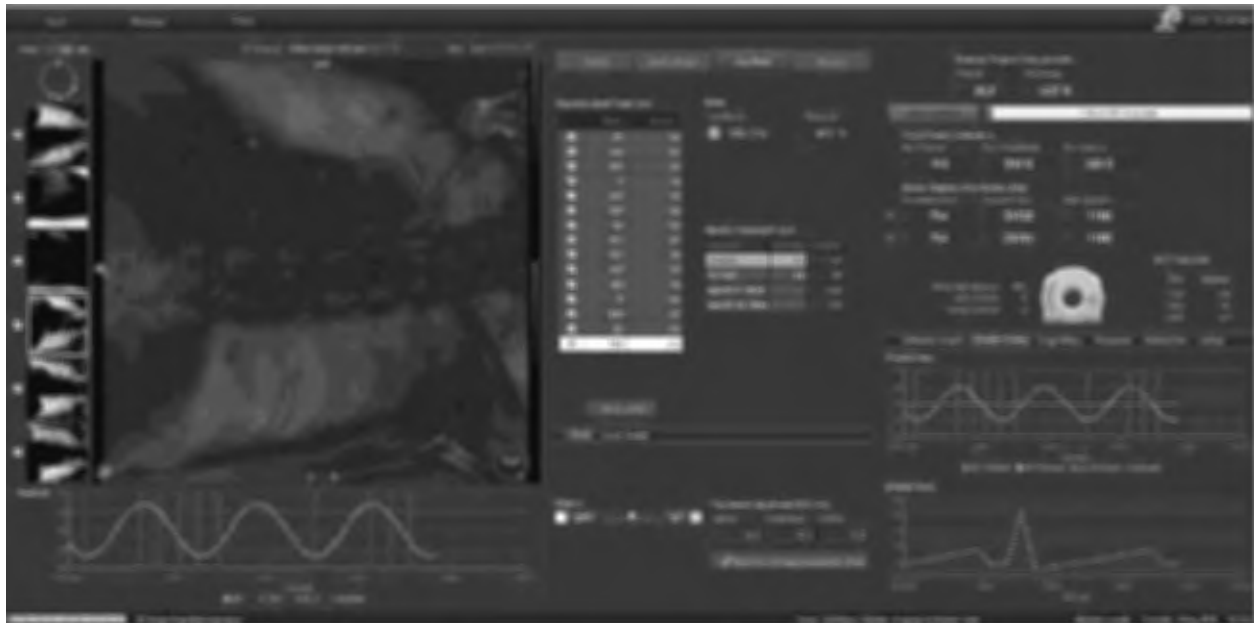
Status Color Bars

The status box to the left of the Tracking Marker label indicates whether the marker is currently visible from the perspective of the *Synchrony* camera. A green status indicates that the Tracking Marker is visible, and a gray status indicates that the marker is not visible. The status bar to the right of the Tracking Marker label records the visibility history of each marker for the last 120 seconds. History data continuously fills in from right-to-left, with the newest data on the left side of the bar.

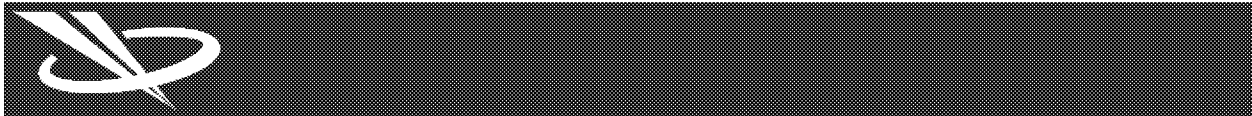
◆ Xsight® Lung Tracking

Xsight® Lung Tracking is a licensable feature and its availability is dependent on your system configuration. The Xsight® Lung Tracking feature requires that you also have the **Pause** and **Resume** feature, and the Synchrony® Respiratory Tracking feature.

Xsight® Lung Tracking detects tumor volumes within kV radiographs without the use of implanted fiducials. The *Xsight* algorithm identifies the tumor VOI within each kV radiograph. Tumor movement is tracked with a combination of the tumor VOI detected in radiographs and the LED Tracking Markers used in Synchrony® Respiratory Tracking.



Xsight Lung Tracking Treat Tab



Chapter 3

System Procedures

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Basic Tasks and Information

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Start Up and Shut Down the System

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◆ Start Up the System



IMPORTANT: If the treatment system was just shut down, wait at least one minute before it is restarted.

1. At the **Status Console**, set the mode switch to **Program**.
2. Make sure all **Emergency Stop** buttons are reset (ready).
3. Go to the next step if the Power Distribution Unit (PDU) is already turned on. Otherwise, enter the treatment room, and switch circuit breaker 1 (CB1, AC mains) on the Power Distribution Unit to the **On** position.
4. At the **Power Control Panel**:
 - Use the power key to turn the **System Power** switch to **Enabled**.
 - Press the green **ON** button.
5. Wait until the lights on the Couch Control Keypad turn on.
6. At the Treatment Delivery Console (TDC), log on to *Microsoft Windows*.
7. Click **Start > All Programs > Accuray > Start System Software** to start the software application.
8. Log on to the TDC application.
9. Wait for the system to finish the initialization process. When finished, the **Positioning Control Panel** displays the couch and laser positions.



IMPORTANT: If the system is restarted immediately after an unrecoverable interruption, a few minutes will be required for the system to prepare internal components, even though normal startup procedures are not required.

10. If necessary, continue to “Daily Warmup” (page 153).

◆ Shut Down the System

1. At the **Status Console**, set the mode switch to **Program**.
2. Make sure all **Emergency Stop** buttons have been reset.
3. As needed, exit the current workflow in the TDC software and return to the Home Screen.
4. On the top frame, click **Tools**, and then click **Exit System Software**.
5. Shut down *Microsoft Windows*, and wait for the computer to shut down.
6. Enter the treatment room.
7. At the **Power Control Panel**, turn the **System Power** switch to **Disabled**, and then remove the power key.

◆ Restart the System After an Interruption

Perform the following steps to restart the system after an unrecoverable interruption. Recoverable interruptions do not require system restart.

1. Click **Details** on the Treatment Delivery Console (TDC) interruption message and check the **Severity Code** to see if the interruption is recoverable or unrecoverable.



NOTE: If the TDC shuts down immediately after the system interruption, the interruption is unrecoverable. If the TDC was shut down in this way, steps 4 through 6 are not required.

2. At the **Status Console**, set the mode switch to **Program**.
3. Make sure any activated **Emergency Stop** buttons have been reset.
4. As needed, exit the current workflow in the TDC software and return to the Home Screen.
5. On the top frame, click the **Tools** button, and then click **Exit System Software** to close the system software.
6. Shut down Microsoft® Windows® to turn off the TDC computer. Wait for the computer to shut down.
7. Enter the treatment room.
8. At the **Power Control Panel**, turn the **System Power** switch to **Disabled**.
9. Wait for the lights on the Couch Control Keypad to turn off.
10. Wait at least one minute before the system is restarted.
11. At the **Power Control Panel**:

- Use the power key to turn the **System Power** switch to **Enabled**.
 - Press the green **On** button.
12. At the TDC, log on to *Microsoft Windows*.
 13. Click **Start > All Programs > Accuray > Start System Software** to start all software applications.
 14. Log on to the TDC application.
 15. Wait for the system to finish the initialization process. When finished, the **Positioning Control Panel** displays the couch and laser positions.

◆ Restore the System After a Power Interruption

If an Emergency Off button is used to interrupt system operation or a power failure occurs, complete the instructions that follow to restore the system.

1. At the **Status Console**, set the mode switch to **Program**.
2. Make sure all Emergency Off buttons are reset.
3. Enter the treatment room.
4. At the **Power Control Panel**, turn the **System Power** switch to **Disabled**.
5. Wait for the lights on the Couch Control Keypad to turn off.
6. On the Power Distribution Unit, switch circuit breaker 1 (**CB1, AC Mains**) to Off.



IMPORTANT: Start up and shut down procedures do not normally require you to turn off or turn on the Uninterruptible Power Supply (UPS). However, during a power failure, the Uninterruptible Power Supply will rely on battery power.

If the power outage lasts several hours, this may drain the backup battery. You may choose to turn off the Uninterruptible Power Supply by pressing the UPS button on the Power Distribution Unit until the indicator light is off to preserve the backup battery. If you decide to turn the Uninterruptible Power Supply off, you will need to turn it on again before performing the standard steps in the system start up procedure.

7. Once the cause of the power failure or Emergency Off interruption has been resolved, properly start up the system as instructed in this guide.

Daily Warmup

- ◆ Purpose of a Warmup 153
- ◆ Perform a Warmup 153

◆ Purpose of a Warmup

Each day, a warmup procedure must be delivered before the first Air Scan, *CTrue* image, treatment, or machine QA procedure is performed. A warmup procedure prepares the radiation delivery subsystem to generate and deliver radiation for a procedure.

If the system has been idle for an hour or more, it is the responsibility of qualified clinical personnel to ensure that a warmup procedure is delivered before any *CTrue* image scans or treatment procedures are performed. This is done to avoid:

- Less than optimal *CTrue* image quality.
- System interruptions during irradiation for a scheduled treatment procedure.



WARNING: Treating a patient with non-treatment procedures such as Air Scan, Warmup, CT Number Calibration, or other Machine QA can cause serious injury to the patient. Do not treat a patient with a QA procedure. Verify that patients and personnel are outside the treatment room before performing QA procedures. QA procedures are intended to be performed only by qualified clinical personnel for quality assurance purposes.

◆ Perform a Warmup



CAUTION: Low dose output for a scheduled treatment fraction can occur if a warmup procedure is not performed. This can cause system interruptions during treatment. Perform a warmup procedure before the first treatment of the day is delivered, and if the system has been idle for 60 minutes or more.

1. Start up the system, and wait for it to reach a water temperature greater than 39° C.



IMPORTANT: If the water temperature is not greater than 39° C within 30 minutes, contact the Accuray Technical Solution Center.

2. Go to the dashboard and click **Warmup**.
3. Select a scheduled procedure from the **Procedures** list on the **Run** tab, and click **Prepare Calibration**.

4. Click **OK** when the **Informational** dialog box appears.



CAUTION: To prevent unnecessary wear on the Lateral Drive Assembly (LDA), make sure the couch tabletop is retracted from the gantry bore before an air scan or warmup procedure.

5. Verify the position of the couch tabletop. If it is not in the gantry bore, proceed to the next step. If it is in the gantry bore, enter the treatment room, and do one of the following:
 - Press **Setup** on the **Positioning Control Panel** or the **Couch Control** dialog box (if available). This moves the tabletop out of the gantry bore automatically.
 - Move the tabletop out of the gantry bore manually. See “Manually Retract the Couch Tabletop” (page 173).
6. Press **Ready** on the **Positioning Control Panel**.
7. Exit and secure the entrance to the treatment room.



IMPORTANT: To avoid a recoverable interruption, do not turn the mode switch to **Treat** until **What's Next** in the top frame prompts you to do so.

8. At the **Status Console**:
 - Turn the mode switch to **Treat**.
 - When the **Ready** light turns on, press the **Start** button.

A notice appears in the Calibration Status field when the warmup is finished.
9. When the warmup procedure is complete, turn the mode switch on the **Status Console** to **Program**.

Daily Air Scan

- ◆ Purpose of an Air Scan 155
- ◆ Perform an Air Scan 155

◆ Purpose of an Air Scan



CAUTION: Low dose outputs during an air scan may result in less than optimal *CTrue* images. To ensure quality *CTrue* images during image registration, a warmup procedure must be performed before the first air scan or *CTrue* image scan of the day.

CTrue image quality can affect registration results. For the most accurate registration results, Accuray Incorporated recommends that you perform an air scan every day before the first *CTrue* image scan. An air scan dialog message will instruct you to perform a scan at the beginning of the day. Do not use Air Scan procedures to warm up the system.



CAUTION: To ensure the quality of Air Scan calibration data, do not perform an air scan as a means to warm up the treatment system. The system must be started and initialized, and then a warmup procedure must be delivered before the first air scan or scheduled treatment procedure is performed.

◆ Perform an Air Scan

1. Do the following in the order given:
 - Start up the system. Refer to “Start Up the System” (page 150) for more information.
 - Perform a warmup. Refer to “Perform a Warmup” (page 153) for more information.
2. Go to the dashboard and click **Air Scan**.
3. Select a scheduled procedure from the **Procedures** list on the **Run** tab, and click **Prepare Calibration**.
4. Click **OK** when the **Informational** dialog box appears.



CAUTION: To prevent unnecessary wear on the Lateral Drive Assembly, make sure the couch tabletop is retracted from the gantry bore before an air scan or warmup procedure.

5. Verify the position of the couch tabletop. If it is not in the gantry bore, proceed to the next step. If it is in the gantry bore, enter the treatment room, and do one of the following:
 - Press **Setup** on the **Positioning Control Panel** or the **Couch Control** dialog box (if available). This moves the tabletop out of the gantry bore automatically.
 - Move the tabletop out of the gantry bore manually. See “Manually Retract the Couch Tabletop” (page 173).
6. Press **Ready** on the **Positioning Control Panel**.



IMPORTANT: The patient couch must not obstruct the beam during this procedure.

7. Make sure the couch is not in the bore of the gantry. The couch does not move into the bore of the gantry for an Air Scan.
8. Press **Ready** on the **Positioning Control Panel**.
9. Exit and secure the entrance to the treatment room.
10. At the **Status Console**:
 - Turn the mode switch to **Treat**.
 - When the **Ready** light turns ON, press the **Start** button.
11. When the air scan is complete, turn the mode switch on the **Status Console** to **Program**.

CT Number Calibration

The CT number calibration procedure should be performed once a week to improve the stability of CT numbers produced by the *CTrue* image reconstruction software. This is especially important if you calculate dose based on *CTrue* images. The most recent calibration values will be used for the reconstruction of new CT images. Adjustments to the calibration do not affect images that were previously reconstructed.

- ◆ Prepare a CT Number Calibration Scan 157
- ◆ Position the Tomo Phantom 158
- ◆ Perform the CT Number Calibration Procedure 159
- ◆ CT Number Calibration Results 160



WARNING: If CT Number Calibration procedures are not performed regularly, the accuracy of dose calculations that are based on *CTrue* images may be affected. This includes any software application that uses *CTrue* images to perform dose calculations.



WARNING: If *CTrue* images are used to calculate dose, the MVCT Image Value to Density Table should be verified regularly. The CT Number Calibration helps to improve the stability of CT numbers in *CTrue* images, but it is not a substitute for regular verifications of the MVCT Image Value to Density Table.



NOTE: The Treatment Delivery Console will inform the user if the **CT Number Calibration** procedure has not been performed in the last seven days.

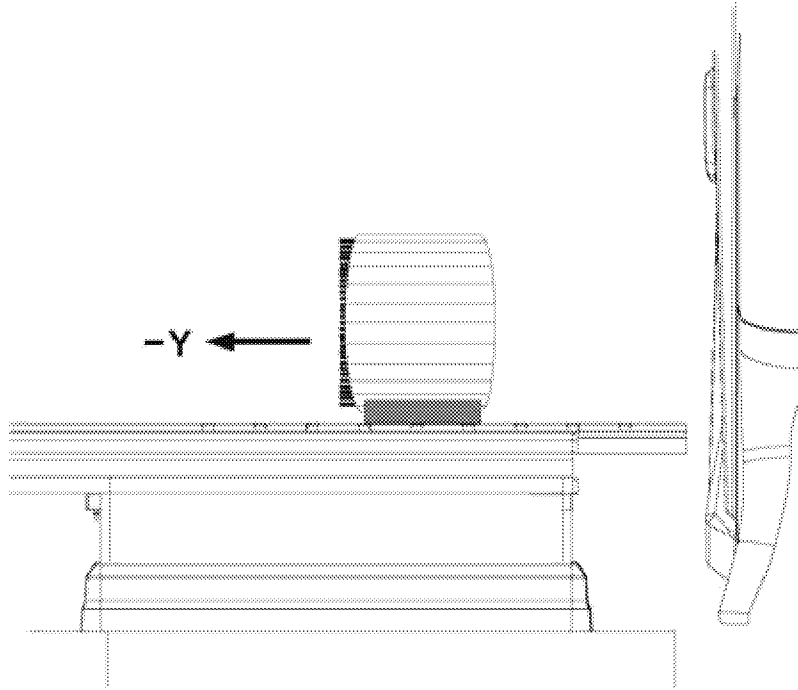
◆ Prepare a CT Number Calibration Scan

1. Verify that the system is ready for calibration. If the system is not ready for use, do the following in the order given:
 - Start up the system. Refer to “Start Up the System” (page 150) for more information.
 - Perform a warmup procedure. Refer to “Perform a Warmup” (page 153) for more information.
 - Perform an air scan procedure. Refer to “Perform an Air Scan” (page 155) for more information.
2. At the dashboard, click **CT Number Calibration**.
3. Click **Accept Slices**.
4. Click **Prepare Scan**. An **Informational** dialog box appears.

5. Click **OK** and continue to “Position the Tomo Phantom” (page 158).

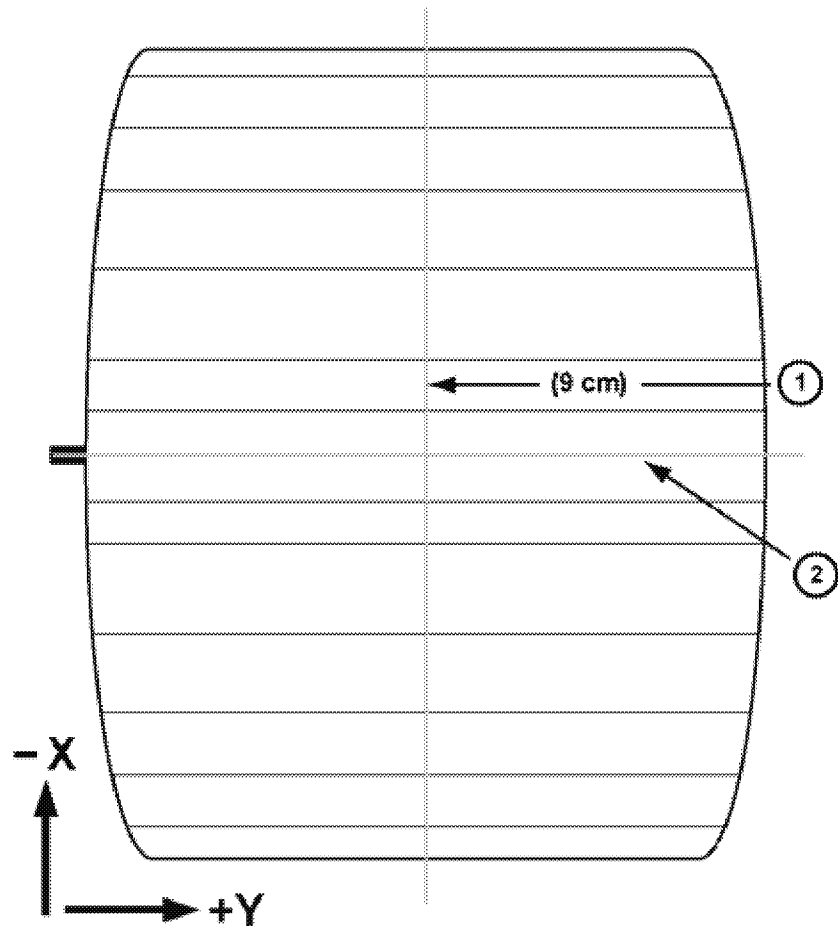
◆ Position the *Tomo* Phantom

1. Position the *Tomo* Phantom on the couch with the front side facing away from the gantry, as in the following image:



TIP: The CT Number Calibration procedure does not require density plugs.

2. Align the *Tomo* Phantom center with the green lasers:



Item	Description
①	The <i>Tomo</i> Phantom is 18 cm wide. The green laser should be centered on the <i>Tomo</i> Phantom, 9 cm from either side.
②	The overhead laser should bisect the <i>Tomo</i> Phantom. The gantry bore laser should also bisect the <i>Tomo</i> Phantom.

- 3. Press **Ready** on the **Positioning Control Panel**.
- 4. Exit and secure the entrance to the treatment room. Continue to “Perform the CT Number Calibration Procedure” (page 159).

◆ **Perform the CT Number Calibration Procedure**

- 1. At the **Status Console**:
 - When the system prompts you, set the mode switch to **Image**.

- Press **Start** when the **Ready** light turns on.
- 2. When the *CT_{True}* image scan is complete, set the mode switch to **Program**.
- 3. After the mode switch is turned back to **Program**, the **CT Number Calibration Results** dialog box appears. Continue to “CT Number Calibration Results” (page 160).

◆ CT Number Calibration Results

The **CT Number Calibration Results** dialog displays a comparison of the expected and measured hounsfield units for **Air** and **Phantom** virtual water.

- **Expected HU** is the value the system expects based on existing CT parameters.
- **Average Measured HU** is the value the system measured in the calibration procedure.

Successful Calibration

If the difference between the **Expected HU** and **Average Measured HU** is within an acceptable tolerance, the calibration is successful. CT number calibration parameters are updated with the new measurements.

Accuray Incorporated recommends that you scroll through the scanned slices to verify that the green VOIs within the phantom are located in solid water, and the blue VOIs outside the phantom are located in air. If any VOIs appear to include undesired pixels, Accuray Incorporated recommends that you adjust the phantom position and perform another CT Number Calibration procedure.



Correct Phantom Image

Unsuccessful Calibration

If the difference between the **Expected HU** and **Average Measured HU** is outside the accepted tolerance, the calibration is unsuccessful. CT number calibration parameters are not updated.

If the *Tomo* Phantom was not positioned correctly, as in the following image, the calibration procedure will be unsuccessful. Check the *Tomo* Phantom position and perform another calibration procedure.



Incorrect *Tomo* Phantom Image



IMPORTANT: If the calibration procedure is unsuccessful after several attempts, notify your Service Representative for further investigation.

Prevent LDA Irradiation

A Lateral Drive Assembly (LDA) is internally located at each end of the couch tabletop to provide mechanized lateral motion. The LDAs are sensitive to radiation, and the LDA located closest to the gantry is susceptible to exposure during air scan, warmup, quality assurance procedures, and some patient procedures.

- ◆ Prevention Information 162
- ◆ Dosimetric Considerations 164



WARNING: If patient target regions are positioned over the LDA, treatment accuracy will be affected. LDA density is not accounted for in dose optimization. To prevent under dose to the patient, target regions should not be positioned over the LDA.



CAUTION: To prevent unnecessary wear on the LDA, DO NOT irradiate patient target regions, phantoms, dosimetry devices or films within the LDA region of the couch tabletop.

◆ Prevention Information



CAUTION: Failure to retract the couch from the bore before procedures such as air scan or warmup may result in unnecessary wear on the LDA.

Facility personnel must verify that the LDA region of the couch (highlighted in red in the images that follow) is outside the radiation beam path when the following procedures are performed:

- Air scans.
- Warmups.
- Patient QA.
- Machine QA.
- Film analysis.
- Dosimetry analysis.
- Patient image scans and treatments.
- Rotational variance.
- Other quality assurance or research procedures.

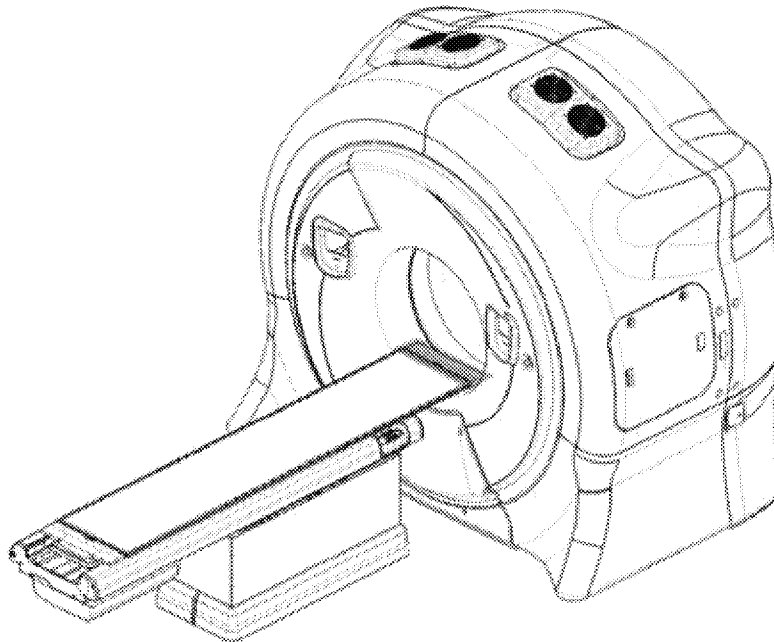


CAUTION: Failure to separate the target area from the region of the couch that contains the LDA may result in unnecessary wear on the LDA.

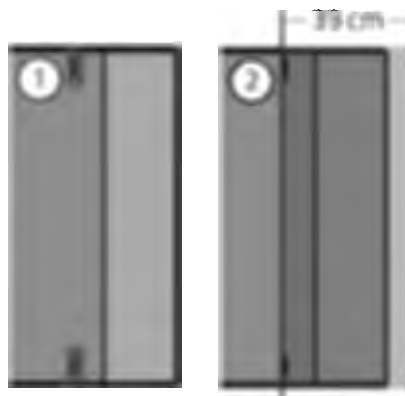
When procedures are created in the **Create Machine QA** workflow, if the **Setup To Ready Longitudinal Distance (cm)** parameter does not match the distance from the virtual isocenter to the machine isocenter (nominally 70 cm), verify that the LDA will not be in the intended target area after pressing the **Ready** button.

Setup To Ready Longitudinal Distance (cm): 70.0

Create Machine QA > Basic Create



Couch and Gantry View



Couch LDA Top View

Item	Description
①	The couch tabletop includes two dashes. These dashes indicate one side of the region of the couch that should not be irradiated.
②	The area highlighted in red should not be irradiated. It is 39 cm wide and extends from the dashes to an area past the end of the couch (air).

◆ Dosimetric Considerations

The density of the Lateral Drive Assembly and of the structure near the Lateral Drive Assembly is not included in the couch image used for dose optimization. High density components in this region may result in significant attenuation and lower than expected dose. If the primary radiation beam passes through the Lateral Drive Assembly region, this will also cause the accelerated deterioration of radiation-sensitive parts inside the Lateral Drive Assembly.



CAUTION: Due to the high density of the Lateral Drive Assembly, and Lateral Drive Assembly radiation sensitivity, Accuray Incorporated requires that no target volumes are positioned over the Lateral Drive Assembly region of the couch. Failure to do so could result in equipment damage.



Safety Procedures

Resolve System Interruptions 166

Manually Retract the Couch and Remove a Patient 173

Shut Down and Start Up the Data Server and Server Rack . . 176

Resolve System Interruptions

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◆ Emergency Off Interruptions	168
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◆ Initial Setup Interruptions	170
◆ Resolve an Interruption Prior to Treatment	171

◆ Ensure Patient Safety

If an interruption occurs during patient setup or irradiation, attend to the patient immediately. This guide provides general protocols, but specific considerations depend on the type of interruption and the needs of the patient. Facility personnel are responsible for ensuring patient safety, correct patient setup, and accurate treatment. See “Use of Safety Mechanisms” (page 20) for information about the following safety mechanisms:

- Entrance interlock.
- **Stop** button.
- **Emergency Stop** buttons.
- Facility emergency off buttons.

Pause and Resume Treatment

The ability to **Pause** and **Resume** treatments (if licensed) is a special type of system interruption that may be initiated by a user or by the system. If a treatment procedure enters a paused state, you may continue treatment if the following conditions are all true:

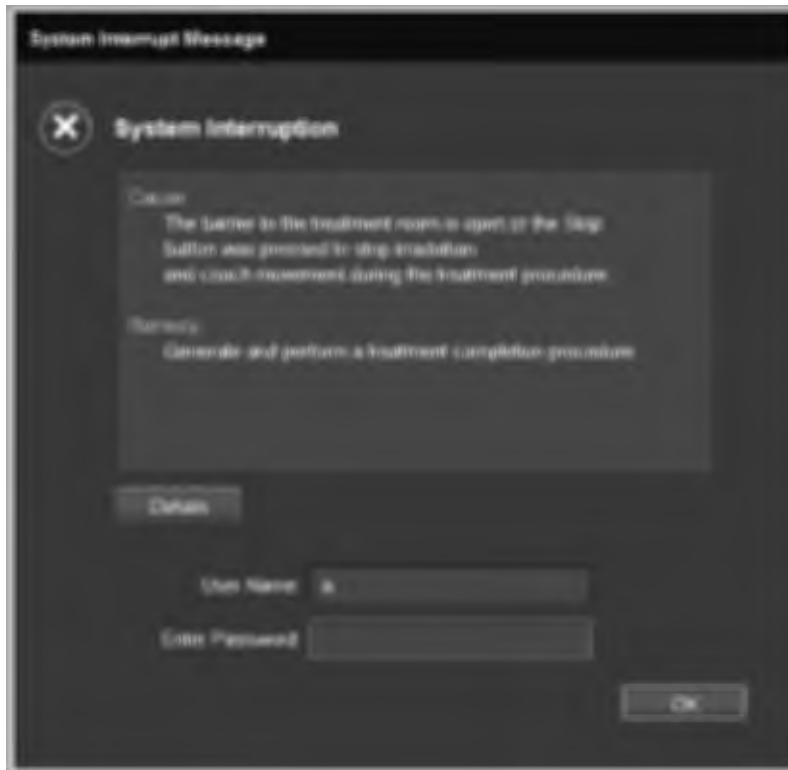
- The patient is able to continue the treatment
- You are confident that the patient is still in the correct position
- The system is functioning normally and the **Resume** button is available

Remove the Patient (if required)

It may be necessary to remove the patient from the couch in emergency situations, or if power is shut down to the system for other reasons. Retract the patient from the bore of the gantry and then assist the patient off of the couch. Follow your facility's protocols to make sure the patient does not fall. If necessary, escort the patient from the treatment room.

◆ System Interrupt Message

After a system interruption, the Treatment Delivery Console displays a **System Interrupt Message** when the mode switch on the **Status Console** is turned to **Program**.



1. After an interruption has occurred, attend to the patient and then turn the mode switch on the **Status Console** to **Program**. The **System Interrupt Message** appears and provides the **Cause** and **Remedy** for the interruption.
2. Click **Details** to see information about the severity of the interruption.
3. Type your password, and click **OK** to clear the message.
4. If necessary, shut down the system.
5. Resolve the system interruption. If you cannot resolve the system interruption, continue to “Contact Service” (page 167).

◆ Contact Service



WARNING: Only qualified service personnel should service and maintain Accuray treatment systems. Incorrect service can result in personal injury and damage to system components. If you determine that the treatment system requires service, contact the Accuray Technical Solution Center.

Contact the Accuray Technical Solution Center to resolve the following:

- A **System Interrupt Message** instructs you to call the Accuray Technical Solution Center. Be prepared to give a description of the problem.
- After an interrupt condition has been resolved, you are not confident that the system can perform as expected.
- After being resolved, the same interruption occurs repeatedly.

◆ Emergency Off Interruptions



WARNING: If a power failure occurs, an Emergency Off button is pressed, or an **Emergency Stop** button is pressed, the tabletop enters free float mode. To avoid patient injury, ensure the tabletop does not move as you remove the patient from the tabletop.

If a facility installed Emergency Off button is pressed, power to the couch, gantry, moveable lasers, and Treatment Delivery Console is completely shut down. The instructions that follow apply to a system interruption that turned off power to the system.

1. Attend to the patient.
2. Manually retract the couch tabletop from the bore of the gantry. See “Manually Retract the Couch and Remove a Patient” (page 173) for more information.
3. If necessary, assist the patient off of the couch and escort the patient from the treatment room.
4. After the interruption has been resolved, properly shut down and then start up the system as instructed in this manual.
5. Was a *CTrue* image scan or treatment procedure interrupted?
 - If a *CTrue* image scan was interrupted, you can create a new *CTrue* image scan to start the procedure over, or you can use the stored, partial image scan according to your clinic’s protocols.
 - If a treatment procedure was interrupted during irradiation, perform a makeup fraction. If the patient moved, or was assisted off the couch, you must reposition the patient. Accuray Incorporated recommends you perform a *CTrue* image scan and registration, and then apply the registration adjustments to the procedure.
 - If a treatment procedure was interrupted before irradiation began, you may need to perform a new *CTrue* image scan and registration, and then reapply the registration adjustments to the procedure. Continue to “Resolve an Interruption Prior to Treatment” (page 171).

◆ Power Failure Interruptions



WARNING: If a power failure occurs, an Emergency Off button is pressed, or an Emergency Stop button is pressed, the tabletop enters free float mode. To avoid patient injury, ensure the tabletop does not move as you remove the patient from the tabletop.

If facility power to the treatment system fails, power to the couch, gantry, moveable lasers, and Treatment Delivery Console is completely shut down.

1. Attend to the patient.
2. Manually retract the couch tabletop from the bore of the gantry. See “Manually Retract the Couch and Remove a Patient” (page 173) for more information.
3. If necessary, assist the patient off of the couch and escort the patient from the treatment room.
4. Contact facility personnel to identify and resolve the cause of the power failure. Do not contact the Accuray Technical Solution Center unless you are certain the treatment system requires service.
5. After the cause of the power failure has been resolved, continue to “Restore the System After a Power Interruption” (page 152).
6. Was a *CTrue* image scan or treatment procedure interrupted?
 - If a *CTrue* image scan was interrupted, you can create a new *CTrue* image scan to start the procedure over, or you can use the stored, partial image scan according to your clinic's protocols.
 - If a treatment procedure was interrupted during beam on, perform a makeup fraction to deliver the remaining dose for the fraction. If the patient does not remain in position, you must perform a new *CTrue* image scan and registration, and then reapply the registration adjustments to the procedure.
 - If a treatment procedure was interrupted before irradiation began, you must perform a new *CTrue* image scan and registration, and then reapply the registration adjustments to the procedure.

◆ Beam On Interruptions

***CTrue* Image Scan**

Do the following when radiation for a *CTrue* image is interrupted:

1. Attend to the patient.
2. If a power failure or Emergency Off button has caused the interruption, see:

- “Emergency Off Interruptions” (page 168), or
 - “Power Failure Interruptions” (page 169).
3. At the Treatment Delivery Console, turn the mode switch to **Program**. The **System Interrupt Message** appears.
 4. Enter your password, and then shut down the system if necessary. See “System Interrupt Message” (page 167) for more information.
 5. Create a new *CTrue* image scan and start the procedure over, or use the stored, partial image scan according to your clinic’s protocols.

Treatment Procedure

Do the following when radiation for a treatment procedure is interrupted:

1. Attend to the patient.
2. If a power failure or Emergency Off button has caused the interruption, see:
 - “Emergency Off Interruptions” (page 168), or
 - “Power Failure Interruptions” (page 169).
3. At the Treatment Delivery Console, turn the mode switch to **Program**. The **System Interrupt Message** appears.
4. Enter your password, and then shut down the system if necessary. See “System Interrupt Message” (page 167) for more information.
5. A makeup fraction is automatically generated. Perform the makeup fraction to deliver the remaining fraction dose.

◆ Initial Setup Interruptions

Initial Setup is the position of the patient for a *CTrue* image scan. The patient is not in the Ready position and the beam is off. Follow these instructions if an interruption occurs during Initial Setup of the patient.

1. Attend to the patient.
2. At the Treatment Delivery Console, turn the mode switch to **Program**. The **System Interrupt Message** appears.
3. Enter your password, and then shut down the gantry software if necessary. See “System Interrupt Message” (page 167) for more information.
4. Was the **Stop** or **Emergency Stop** button used to interrupt initial setup for the *CTrue* image scan?
 - If the **Stop** button was pressed, continue to the next step.
 - If the **Emergency Stop** button was pressed, restart the system. See “Restart the System After an Interruption” (page 151) for more information.

5. Once the interruption has been resolved, start the procedure over and prepare a new *CTrue* image scan.

◆ Resolve an Interruption Prior to Treatment

System interruptions prior to treatment may occur when the **Ready** button is pressed, as the couch moves to the Ready position, or as the system prepares to begin delivering radiation. A system interruption also happens when the **Stop** or **Emergency Stop** button is pressed.



WARNING: To prevent overdose or underdose to the patient, perform a makeup fraction if the scheduled fraction was interrupted during irradiation.

Before you continue with these instructions, confirm the following:

- In the **Procedures** list, the treatment procedure is listed as **Scheduled**. If the procedure is listed as **Interrupted**, see “Resolve System Interruptions” (page 166) for more information.
 - The patient is in the Registered Setup position or Ready position, or the couch is moving to the Ready position. The patient must remain still until the procedure is resumed and the treatment is complete.
1. Attend to the patient.
 2. At the Treatment Delivery Console, turn the mode switch to **Program**. The **System Interrupt Message** appears.
 3. Enter your password, and then shut down the gantry software if necessary. See “System Interrupt Message” (page 167) for more information.
 4. At the Treatment Delivery Console, select the scheduled treatment procedure.
 5. Click **Prepare Treatment**. Click **OK** in the dialog box that appears. This confirms there are no new registration adjustments for the procedure.
 6. At the **Positioning Control Panel**, press **Ref Position** to view the **Current Couch Position**.
 7. Compare the **Current Couch Position** with the registered coordinates from the original treatment. (Refer to the values from the previous step.) If the couch is still in the final Registered Setup position, continue to the next step. If not, continue to step 10.



WARNING: If the patient is not in the correct Registered Setup position, treatment accuracy can be affected. Accuray Incorporated recommends that you perform a *CTrue* image scan and image registration. You can then apply the registration results to the treatment procedure.

8. On the **Main** tab of the **Positioning Control Panel**, press the **Setup** button to return the couch to the Registered Setup position.
9. Press **Ref Position** to view the **Current Couch Position** and verify the couch is now in the correct position. If the couch is not in the correct position, use the couch movement controls to move the couch to the registered coordinates.
10. Verify that the patient has not moved out of the Registered Setup position. If the patient has moved, you must reposition the patient, perform a new *CTrue* image scan and image registration, and then apply the new registration results to the treatment procedure.
11. Instruct the patient not to move, and then press **Ready** on the **Positioning Control Panel**. A confirmation message appears.
12. On the confirmation message, do one of the following:
 - Press **Yes** to move the couch to the Ready position. Observe the patient until the couch has reached the Ready position inside the bore of the gantry (couch movement stops).
 - If the patient has moved out of position, press **No** and create a new *CTrue* image scan to start the procedure over. Accuray Incorporated recommends you perform image registration to reapply adjustments to the treatment procedure.
13. Once the patient is in the Ready position, treat the patient as instructed in this guide.

Manually Retract the Couch and Remove a Patient

- ◆ Remove a Patient from the Couch Tabletop 173
- ◆ Manually Retract the Couch Tabletop 173
- ◆ Retract and Lower the Couch During an Emergency Stop 174

◆ Remove a Patient from the Couch Tabletop



WARNING: If a power failure occurs, an Emergency Off button is pressed, or an **Emergency Stop** button is pressed, the tabletop enters free float mode. To avoid patient injury, ensure the tabletop does not move as you remove the patient from the tabletop.

1. Retract the couch tabletop to remove the patient from the bore of the gantry. See “Manually Retract the Couch Tabletop” (page 173) for more information.
2. Follow your facility's protocols to assist the patient from the couch and make sure the patient does not fall.
3. When power is restored to the system, retract the tabletop to the foot of the couch until it locks into place.

◆ Manually Retract the Couch Tabletop

Use the following instructions to retract the couch tabletop with or without power to the system.

1. Does the system have power?
 - If yes, press the Enable button and the longitudinal release button on a Couch Control Keypad. The lights inside the longitudinal release buttons turn on when the tabletop enters free float mode.
 - If no, proceed to step 2.



CAUTION: Couch sensors may be damaged if the tabletop forcefully collides with an end stop. Retract the couch tabletop carefully to avoid collisions.

2. Pull the couch handle to retract the tabletop away from the bore of the gantry.
3. If there is power to the system, lock the tabletop in place by pressing the Enable button and the longitudinal release button. The lights inside the longitudinal release buttons turn off when the tabletop is locked.



WARNING: If there is no power to the system, the tabletop cannot be locked and may move when the patient leaves the couch. An unlocked tabletop may shift unexpectedly, potentially resulting in injury. Use caution assisting the patient from the couch when there is no power to the system.

4. Assist the patient from the couch. Follow your facility's protocols to make sure the patient does not fall. If there is power to the system, you can use a Couch Control Keypad to lower the couch.

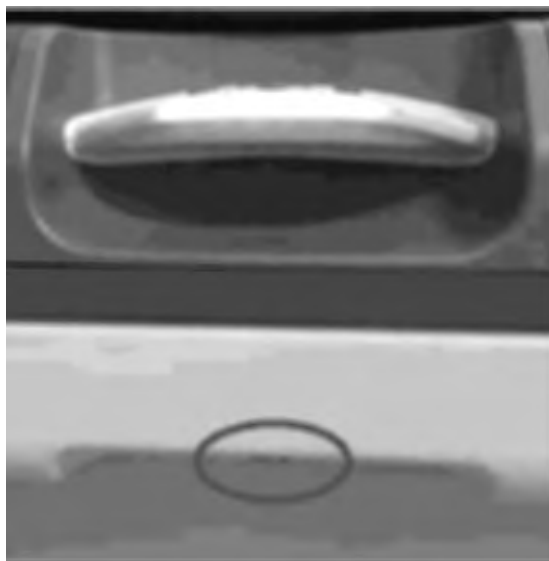
◆ Retract and Lower the Couch During an Emergency Stop

Complete the instructions that follow to retract and lower the couch when an **Emergency Stop** button has been pressed.



NOTE: If an **Emergency Stop** button is pressed, the tabletop automatically unlocks from the couch.

1. Use one hand to press and hold the Emergency Stop Override button on the bottom edge of the couch under the Couch Control Keypad.



2. Use your other hand to press the Enable button and the longitudinal release button on the Couch Control Keypad. The lamps housed inside the longitudinal release buttons turn off when the tabletop is locked.



CAUTION: Couch sensors may be damaged if the tabletop forcefully collides with an end stop. Retract the couch tabletop carefully to avoid collisions.

3. Use the Couch Control Keypad to retract and lower the couch.



WARNING: If a power failure occurs, an Emergency Off button is pressed, or an Emergency Stop button is pressed, the tabletop enters free float mode. To avoid patient injury, ensure the tabletop does not move as you remove the patient from the tabletop.

4. Release the Emergency Stop Override button when you can safely assist the patient from the couch. As needed, position a patient bed next to the couch and secure the wheels. There should be enough clearance for the bed, and the range of couch heights is similar to hospital beds. Assist the patient off the couch according to your facility protocols to make sure the patient does not fall.

Shut Down and Start Up the Data Server and Server Rack

- Restart the Data Server 176
- Shut Down the Server Rack 177
- Start Up the Server Rack 180

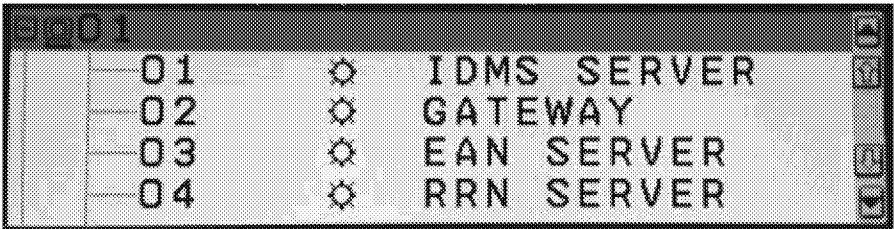
Restart the Data Server

The Data Server is the iDMS™ Data Management System computer in the server rack. Under certain circumstances, you may need to restart the *iDMS* System computer. (For example, the connection may be lost, or the computer may become very slow).

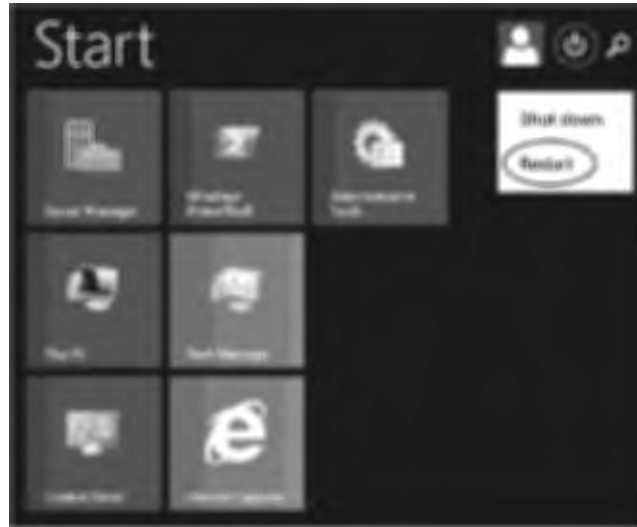
1. Close all Accuray applications.
2. Go to the KVM (Keyboard Video Mouse) in the server rack, slide the release latches toward each other, and pull the KVM out.



3. Lift the top of the KVM, hold down Fn, and press Scr Lk twice. A menu of computers in the rack appears.



4. Use the arrow keys to select IDMS SERVER, and press Enter.
5. Enter the appropriate credentials to log on to the *iDMS* System computer. If you do not have the credentials, contact Accuray Customer Support.
6. Select **Power Options** from the **Start** menu, and then select **Restart** from the drop-down list to restart the *iDMS* System computer.



7. Click **Continue** in the dialog box that asks for a reason for the restart. The restart begins.
8. Wait five minutes for the *iDMS* System computer to establish the correct time for the other computers in the rack.
9. Start up the Accuray Precision™ Treatment Planning System and Treatment Delivery Console applications.
10. Do one of the following:
 - Start up the treatment system if it was shut down when you restarted the *iDMS* System computer.
 - Shut down and start up the treatment system if it was not shut down when you restarted the *iDMS* System computer.

◆ Shut Down the Server Rack

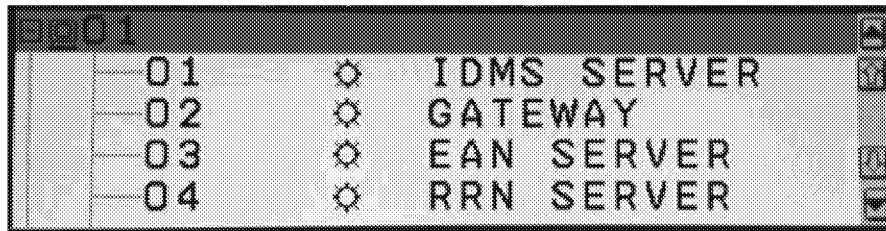


IMPORTANT: Please contact Accuray Customer Support if you have any questions or concerns about performing this procedure.

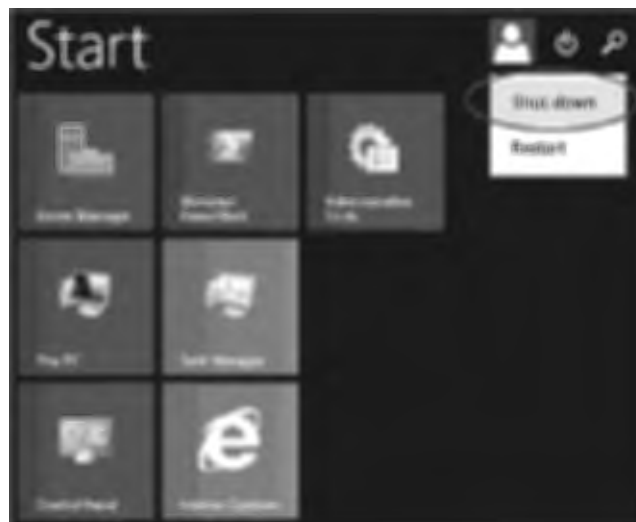
1. In the following order, shut down the Treatment Delivery Console, *Accuray Precision* System, and *MD Suite* workstations.
2. Go to the KVM (Keyboard Video Mouse) in the server rack, slide the release latches toward each other, and pull the KVM out.



3. Lift the top of the KVM, hold down Fn, and press Scr Lk twice. A menu of computers in the rack appears.



4. Use the arrow keys to select **IDMS SERVER** from the menu, and then press **Enter**.
5. Enter the appropriate credentials to log on to the *iDMS* System computer. If you do not have the appropriate credentials, contact Accuray Customer Support.
6. Select **Power Options** from the **Start** menu, and then select **Shut down** from the drop-down list to shut down the *iDMS* System computer.



7. Click **OK**, and wait for the computer to turn off completely before continuing. (The power light turns off when the computer is completely turned off.)
8. If a Storage Vault is installed, remove the magnetic faceplate, press the power button, and then reinstall the faceplate.



9. Go to the KVM, hold down **Fn**, and press **Scr Lk** twice. Use the arrow keys to select **GATEWAY** from the menu of rack computers.
10. Press **Enter**, and then select **Shut Down** from the **Start** menu to shut down the Gateway computer.
11. If a PreciseART™ adaptive computer is installed, go to the KVM, hold down **Fn**, and press **Scr Lk** twice. Use the arrow keys to select **EAN SERVER** from the menu of rack computers.
12. Press **Enter**, and then select **Shut Down** from the **Start** menu.
13. If a Remote Registration Node (RRN) is installed, go to the KVM, hold down **Fn**, and press **Scr Lk** twice. Use the arrow keys to select **RRN SERVER**.
14. Use the arrow keys to select **Shutdown**, and then press **Enter**.
15. Select **Shutdown Server**.
16. Enter the appropriate logon credentials when prompted. If you do not have the appropriate credentials, contact Accuray Customer Support.
17. Press **F8** to select **Yes**.
18. Wait five minutes until the node has turned off completely.
19. Press and hold the power button on each UPS (Uninterruptible Power Supply) until you hear a beep. This turns off the UPS.



◆ Start Up the Server Rack



IMPORTANT: Please contact Accuray Customer Support if you have any questions or concerns about performing this procedure.

1. Press the power button on each UPS (Uninterruptible Power Supply) to turn them on.



2. If a Storage Vault is installed, remove the magnetic faceplate, press the power button, and then reinstall the faceplate.



3. Press the Power button on the front of the *iDMS* System computer, and wait five minutes for the *iDMS* System computer to establish the correct time for the other computers in the rack.
4. Press the power button on the front of the following components:
 - Gateway Node
 - PreciseART™ adaptive Node (optional)
 - Remote Registration Node (optional)
5. In the following order, turn on the *Accuray Precision System*, *MD Suite*, and Treatment Delivery Console workstations.



Scan, Position, and Treat

Prepare Patient and Equipment. 182

Scan the Patient. 183

Register the CTrue Image 187

Position the Patient for Treatment. 191

Treat the Patient. 195

Perform a Motion Tracking Treatment. 197

Review Registration 202

Treatment Without a CTrue Image Scan. 205

Acquire MVCT Planning Image 207

Perform a Makeup Fraction 209



WARNING: Patient mistreatment may occur if you do not select the correct patient and plan. Before you start a *CTrue* image scan or treatment procedure, make sure you select the correct patient and plan using any available verification means, such as the patient photo, to identify the patient.

Prepare Patient and Equipment

Depending on the treatment modality and immobilization strategy, you may need to set up some equipment prior to positioning the patient on the treatment couch.

- ◆ Immobilization Devices 182
- ◆ Setup Synchrony Components 182

◆ Immobilization Devices

As needed, setup any immobilization devices on the treatment couch. If the immobilization device is compatible with the indexing holes on the couch, ensure that the device is secure in the holes.

◆ Setup *Synchrony* Components

If the prior patient in your clinical schedule did not receive a Synchrony® Respiratory Tracking treatment, you may need to set up the *Synchrony* components.

1. Retrieve Synchrony components from their storage location. This should be located outside the treatment room.
2. Insert the Reference Post into the indexing holes of the couch. For most procedures, Accuray Incorporated recommends that the Reference Post is positioned near couch indexing hole 12.
3. Place the Light Box on the couch tabletop at the foot of the couch, near the left edge. The Light Box should be positioned so that the magnetic side of the Light Box is touching the couch tabletop.
4. Connect the Light Box cable to the couch port.
5. Carefully unwind the Tracking Marker cables. Ensure that you do not bend the fiber optic cables at angles less than 30°.
6. Connect the Tracking Markers cable to the Light Box.
7. Position Tracking Marker 4 on top of the Reference Post so that the LED faces the Synchrony camera.
8. Set the remaining Tracking Markers to the side or foot of the couch tabletop so that they do not obstruct the patient when they lay on the couch.

Scan the Patient

◆ Prepare a CTrue Image Scan	183
◆ Set Up the Patient	184
◆ Perform the CTrue Image Scan	185



IMPORTANT: Before scanning a patient, review the warnings and cautions in “General System Safety” (page 2) and “Operator Responsibilities” (page 26).

◆ Prepare a *CTrue* Image Scan

1. At the **Status Console**, set the mode switch to **Program**.
2. At the Treatment Delivery Console, click the **Treat Patient** button.



IMPORTANT: If **MITA Policies** are enabled in the iDMS™ Data Management System, a Physicist must approve plan QA before the plan can be delivered. Unapproved patient plans will not appear in the patient list. For more information on **MITA Policies**, see the *iDMS™ Data Management Manual*.

3. Select the correct patient, plan, and fraction for the patient from the **Patient List** dialog box, and then click **OK**.
4. On the **Scan** tab, wait for the reference image to display in the **Slice Selector**.
5. If desired, change the default settings for:
 - **Orientation**
 - **Pitch**
 - **Reconstruction Interval**
 - **Algorithm**
6. Select the slices in the **Slice Selector** for the region you want to scan.
7. Click **Accept Slices** to add a *CTrue* image scan to the **Procedures** list.
8. Click **Prepare Scan** to position the red lasers based on the Planned Setup position. The **Prepare Patient and Room** dialog box appears.
9. Continue to “Set Up the Patient” (page 184).

◆ Set Up the Patient

Prior to the arrival of the patient, you may click **Setup Notes** to review a summary of the treatment setup. If this will be the first fraction, or if no prior notes have been entered, you may want to spend extra time to acquire photos or record details on the patient setup.



WARNING: As the couch moves, pinch points can cause serious injury. Avoid contact with moving parts and instruct the patient to stay clear of moving parts. If required, press the **Stop** button to stop couch movement.



WARNING: Couch sag can cause inaccurate radiation delivery for a treatment procedure. The couch is not designed to support a weight heavier than 200 kg (440 lbs). Make sure the distributed weight of the patient on the couch is not more than 200 kg (440 lbs).



WARNING: To prevent unintended displacement of the patient during couch movement, do not allow any items (e.g. bed linens, fixation devices, cabling, or patient gowns, limbs, hair, etc.) to overhang the end of the couch tabletop. Unintended displacement of the patient can result in displacement of the radiation delivery, and possible injury to the patient. As directed in this manual, always check that the patient movement path is clear of obstructions, including items overhanging the end of the couch tabletop.



IMPORTANT: When adjusting the position of a patient on the couch, or when directing a patient to adjust their position, avoid abrupt, forceful movements to prevent the couch from entering free float mode.

1. On the **Positioning Control Panel**, press the **Unload** button to move the couch to the unload position and ensure the lateral position of the tabletop is reset.
2. For a Synchrony® Respiratory Tracking treatment, help the patient to remove clothing above the waist, and put on the *Synchrony* vest. Then attach Tracking Markers to the vest. Secure the Tracking Marker cables to ensure that they do not become tangled in patient anatomy or the couch. For more information, see:
 - “Putting on and Taking off the Synchrony Vest” (page 71)
 - “Placing Tracking Markers” (page 65)
3. Assist the patient onto the couch. Make sure the patient is in the correct orientation for the planned treatment position.
4. Set up the patient for the *CTrue* image scan. Press **Setup** on the **Positioning Control Panel** to move the couch to the Planned Setup position.

5. Align the patient with the red lasers to achieve the Initial Setup position. As needed, do the following:
 - Physically adjust the pitch, yaw, or roll position of the patient.
 - Use manual couch controls to adjust the vertical, longitudinal, and lateral position of the patient.
6. Verify the patient is positioned correctly and then press **Ready** on the **Positioning Control Panel**. A confirmation message appears.
7. At the confirmation message:
 - Press **Yes** to move the couch to the Ready position.
This will also reset the **Referenced Couch Position** origin to the **Current Couch Position** before the couch moves into the bore.
 - If the patient has moved out of position, press **No** and reposition the patient. When you have confirmed the patient is positioned correctly, press **Ready**.
8. Continue to “Perform the CTrue Image Scan” (page 185).

◆ Perform the *CTrue* Image Scan

1. Make sure the patient does not move until you give them further instructions. Instruct the patient to avoid heavy breathing during the *CTrue* image scan.



WARNING: The treatment system generates radiation for CTrue™ image guidance scans, treatment procedures, and quality assurance procedures. To avoid unnecessary radiation exposure during non-patient procedures, ensure the treatment room is unoccupied and the entrance is secured. Before a scan or treatment procedure is started, ensure that the patient is the only person in the treatment room and the entrance to the treatment room is secure.

2. Make sure the patient is the only person in the treatment room.
3. Exit and secure the entrance to the treatment room.
4. Verify that the patient is setup in the correct orientation, and click **OK**.



WARNING: Serious injury to the patient can result if the patient does not remain in the correct setup position. Make sure the patient does not move during a *CTrue* image scan, image registration, or treatment procedure. Use the audio and visual system to monitor the patient from the Treatment Delivery Console.

5. At the **Status Console**:
 - When the system prompts you, set the mode switch to **Image**.
 - Press **Start** when the **Ready** light turns on.



IMPORTANT: If the *CTrue* image scan is interrupted and you have determined there is enough anatomy to register the image, you can proceed with the partial *CTrue* image scan. Otherwise, perform a new *CTrue* image scan.

6. When the *CTrue* image scan is complete, the system will prompt you to set the mode switch to **Program**.
7. Continue to “Register the CTrue Image” (page 187).



NOTE: You can register a *CTrue* image with a partial scan.

Register the *CTrue* Image

Align the *CTrue* image with the reference image. After registration adjustments are applied to the patient, you may verify the patient position with another *CTrue* image scan.

- ◆ Perform Image Registration 187
- ◆ Position the Patient and Verify Adjustments (Optional) 189



WARNING: Abnormal MVCT image quality can reduce image registration accuracy. Compare the MVCT image to the corresponding kVCT image to assess any suspected abnormalities. If you determine that the imaging system is producing inaccurate or abnormal results, contact Accuray Customer Support.

◆ Perform Image Registration

Align the *CTrue* image with the reference image.



WARNING: Registration and treatment accuracy can be affected if the patient does not remain in the correct setup position. Make sure the patient does not move during a *CTrue* image scan, image registration, or a treatment procedure. Use the audio and visual system to monitor the patient from the Treatment Delivery Console.

1. On the Treatment Delivery Console, click the **Register** tab to view the planning and *CTrue* image volumes. If needed, change the appearance and orientation of the images.



NOTE: The decision to use manual registration, automatic registration, or both is left to the discretion of the operator.

2. Determine the methods you want to use to align the *CTrue* image with the reference image (manual, automatic, or both). Do one or both of the following:
 - Perform manual registration.
 - To perform automatic registration, select one or more options using the **Automatic Registration Control** and then click **Start**.



WARNING: Incorrect patient setup can affect treatment accuracy. If you are not confident that the *CTrue* image registration results can be used to achieve the desired registered setup position of the patient, Accuray Incorporated recommends that you “Position the Patient and Verify Adjustments (Optional)” (page 189).

3. Verify the **Translational Adjustments IECf (mm)** and **Rotational Adjustments (degrees)** displayed on the **Register** tab:

- If you are not confident that the desired registered setup position of the patient can be achieved using the current registration results, perform image registration again or continue to “Position the Patient and Verify Adjustments (Optional)” (page 189).
- If you are confident that the registration results can be used to achieve the desired registered setup position of the patient, continue to the next step.



IMPORTANT: If you determine that a lateral adjustment of greater than ± 25 mm is required, it will not be applied when you press the **Setup** button. In order to achieve lateral couch adjustments greater than ± 25 mm, Accuray Incorporated recommends that you manually adjust the patient on the couch and perform and register another *CTrue* image scan.



IMPORTANT: For *TomoDirect* plans, select the **Beam Angles** tab in the lower-right corner of the **Register** tab. See “Beam Angles Tab” (page 119). If one or more beams pass through the couch, proceed according to the protocols of your facility.

4. Does the lateral adjustment exceed ± 25 mm?

- If yes, the **Lateral Adjustment Range Check** dialog will appear if you accept registration adjustments. In order to achieve lateral couch adjustments greater than ± 25 mm, Accuray Incorporated recommends that you manually adjust the patient on the couch and perform and register another *CTrue* image scan. Continue to “Prepare a CTrue Image Scan” (page 183).
 - If no, continue to step 5.
5. When satisfied with the registration adjustments, click **Accept Registration**. The **Registration Adjustments** dialog appears. Click **Apply** to move the red lasers to the adjusted position. Continue to “Position the Patient for Treatment” (page 191).
- If needed, click **Export Screen** to save an image of the current registration settings.



WARNING: Using an exported registration image screen capture as part of the patient positioning process could result in patient mistreatment. Do not use the exported registration image screen capture to confirm patient setup or apply the results intended for future treatments.

- The screen capture is intended to support billing processes and record keeping only.
- The screen capture does not indicate user acceptance of the offsets.

◆ Position the Patient and Verify Adjustments (Optional)

Before you start the treatment procedure, you can position the patient based on registration adjustments and then perform another *CTrue* image scan and image registration. This method may be used to confirm the desired registration adjustments or to verify significant patient rotations or other adjustments that are required.

Apply Adjustments to a New Scan



IMPORTANT: The instructions below must be performed immediately after you have performed image registration and have accepted the results.

1. Immediately after you have performed image registration, click **Accept Registration** and then click the **Scan** tab.
2. Select a **Pitch** for the region you want to scan and select slices.
3. Click **Accept Slices** and then click **Prepare Scan**. The initial registration adjustments for the patient appear.



NOTE: If roll correction is required for a *CTrue* image scan, it must be applied physically. Automatic roll correction is not available for scans.

4. Verify the registration adjustments. If desired, select the **Acquire Registered Couch Position** check box.
5. Click **Apply**. The red lasers move based on the registration adjustments.



NOTE: Select **Acquire Registered Couch Position** the first time a patient receives image registration, or any time you would like to update the couch position saved with the patient plan.

6. Continue to “Adjust and Scan the Patient” (page 189).

Adjust and Scan the Patient

1. In the treatment room, press **Main** on the **Positioning Control Panel**.



WARNING: As the couch moves, pinch points can cause serious injury. Avoid contact with moving parts and instruct the patient to stay clear of moving parts. If required, press the **Stop** button to stop couch movement.

2. Press **Setup** to move the couch based on the registration adjustments. A confirmation message appears.

3. Press **Yes** to move the couch longitudinally, laterally, and vertically based on the registration adjustments. Monitor the patient for movement until the couch has completed all preprogrammed movements.
4. Press **Ready** on the **Positioning Control Panel**. A confirmation message appears.
5. Press **Yes** to reset the **Referenced Couch Position** origin and move the couch to the Ready position. Observe the patient until the couch has reached the Ready position inside the bore of the gantry (couch movement stops).
6. Proceed to “Perform the CTrue Image Scan” (page 185) and “Register the CTrue Image” (page 187) to verify the registration adjustments (patient position) from the previous *CTrue* image scan.

Position the Patient for Treatment

Use registration adjustments to reposition the patient for a scheduled treatment procedure.

- ◆ Apply Adjustments to the Procedure 191
- ◆ Adjust Patient Translations 191
- ◆ Adjust Patient Rotations 193



IMPORTANT: Before positioning a patient for treatment, review the warnings and cautions in “General System Safety” (page 2) and “Operator Responsibilities” (page 26).

◆ Apply Adjustments to the Procedure

Apply registration adjustments to a treatment procedure.

1. From the **Procedures** list on the **Treat** tab, select a **Scheduled** procedure.
2. Click the **Prepare Treatment** or **Prepare** button. If longitudinal (Y), lateral (X), or vertical (Z) patient adjustments were accepted on the **Register** tab, they will be applied when the **Setup** button on the **Positioning Control Panel** is pressed.

◆ Adjust Patient Translations

Translational adjustments are preprogrammed by the system based on registration parameters. Use the **Positioning Control Panel** to move the couch vertically, laterally, and longitudinally based on the registration adjustments.

Translational Adjustments



WARNING: As the couch moves, pinch points can cause serious injury. Avoid contact with moving parts and instruct the patient to stay clear of moving parts. If required, press a **Stop** button to stop couch movement.

1. Enter the treatment room.
2. At the **Positioning Control Panel**, press **Main**.



WARNING: Patient mistreatment may occur if the red lasers are used for repositioning after image registration results have been applied. After registration adjustments are applied to a treatment procedure, do not use the red lasers to determine the exact location of the treatment region. The image registration process may apply shifts that cause the lasers not to align with external fiducial marks. Use the lasers only as a reference to verify that laser adjustments are consistent with registration results.

3. Make sure the position of the moveable lasers are consistent with the amount and direction of the registration adjustments. Check all directions (lateral, longitudinal, and vertical).
4. Press **Setup** to move the couch based on the registration adjustments. A confirmation message appears.



WARNING: If the couch is moved, or the patient moves, before or after registration adjustments are applied, treatment accuracy can be affected.

- Do not adjust the vertical, lateral, or longitudinal position of the couch after registration adjustments have been applied and verified.
 - Instruct the patient not to move during or after an imaging procedure.
5. At the confirmation message, do one of the following:
 - Press **Yes** to move the couch longitudinally, laterally, and vertically based on the registration adjustments. As the couch moves, make sure the patient does not move out of position.
 - If the patient moves, or if you are not confident the patient is positioned correctly, press **No**. Perform another *CTrue* image scan and image registration to verify patient setup. Continue to “Position the Patient and Verify Adjustments (Optional)” (page 189) to reposition the patient.



WARNING: Patient mistreatment can occur if the patient is not positioned correctly. If you are not confident that the patient is in the correct Registered Setup position, Accuray Incorporated recommends that you perform a new *CTrue* image scan and image registration to verify the position of the patient. You can then apply the new registration results.

6. Press **Ref Position** to view the **Referenced Couch Position (mm)** values.
 - Verify that the longitudinal, lateral, and vertical couch values are consistent with the registration adjustments.
 - If the required registration offsets exceed the distance available on the lateral axis, you must physically adjust the patient.
7. If physical rotation adjustments are required (pitch, yaw, or manual roll), continue to “Adjust Patient Rotations” (page 193).

8. Do one of the following:

- If any physical adjustments were required, continue to “Position the Patient and Verify Adjustments (Optional)” (page 189) to verify that the position of the patient is consistent with registration adjustments.
- If physical adjustments were not required, continue to the next step.



IMPORTANT: If the patient is enrolled in PreciseART™ adaptive monitoring, you must perform a new *CTrue* scan and image registration after any physical adjustments to ensure accurate adaptive monitoring for that treatment fraction. If the physical position of the patient in the *CTrue* image volume used for registration is different from that in the planning image volume, it may reduce the accuracy of adaptive monitoring statistics.

9. Instruct the patient not to move, and then press **Ready** on the **Positioning Control Panel**. A confirmation message appears.

10. On the confirmation message, do one of the following:

- Press **Yes** to move the couch to the Ready position. Observe the patient until the couch has reached the Ready position inside the bore of the gantry (couch movement stops).
- If the patient has moved out of position, press **Cancel** and then continue to “Prepare a CTrue Image Scan” (page 183). You must perform image registration to reapply adjustments to the treatment procedure.

11. Once the patient is in the Ready position, continue to “Treat the Patient” (page 195).

◆ Adjust Patient Rotations

If needed, apply physical rotational adjustments. Do not adjust the roll position of the patient if automatic roll correction adjustments were applied during image registration. After you perform physical patient adjustments, Accuray Incorporated recommends that you perform a new *CTrue* image scan and image registration.

1. All translational adjustments must be complete. As needed, physically adjust the pitch and yaw position of the patient.



WARNING: If a roll correction was accepted during image registration, the gantry will automatically correct for roll when you click **Prepare Treatment**. To prevent incorrect patient setup, do not adjust the roll position of the patient if an automatic roll correction was accepted during image registration.

2. Physically adjust the roll position of the patient if you did not apply the automatic roll correction to the procedure. If you applied the roll correction option, do not adjust the roll position of the patient.



WARNING: Patient mistreatment can occur if the patient is not positioned correctly. If you are not confident that the patient is in the correct Registered Setup position, Accuray Incorporated recommends that you perform a new *CTrue* image scan and image registration to verify the position of the patient. You can then apply the new registration results.

3. Continue to "Position the Patient and Verify Adjustments (Optional)" (page 189).

Treat the Patient

The following procedure applies to all patient plans created without motion tracking enabled.



IMPORTANT: Before treating a patient, review the warnings and cautions in “General System Safety” (page 2) and “Operator Responsibilities” (page 26).

1. Make sure the patient does not move until you give them further instructions.



WARNING: The treatment system generates radiation for image guidance scans, treatment procedures, and quality assurance procedures. To avoid unnecessary radiation exposure during non-patient procedures, ensure the treatment room is unoccupied and the entrance is secured. Before a scan or treatment procedure is started, ensure that the patient is the only person in the treatment room and the entrance to the treatment room is secure.

2. Make sure the patient is the only person in the treatment room.
3. Exit and secure the entrance to the treatment room.
4. At the **Status Console**, set the mode switch to **Treat**.



IMPORTANT: If a treatment procedure includes a long gantry period, the system may require additional time before the **Ready** light on the **Status Console** turns on.

5. When the **Ready** light turns on, press the **Start** button to begin the treatment.



WARNING: Registration and treatment accuracy can be affected if the patient does not remain in the correct setup position. Make sure the patient does not move during a *CTrue* image scan, image registration, or a treatment procedure. Use the audio and visual system to monitor the patient from the Treatment Delivery Console.



WARNING: If a treatment procedure is interrupted during irradiation (beam on), the complete dose for the fraction is not delivered. If this happens:

- Perform the makeup fraction to make sure the remaining dose for the interrupted fraction is delivered. Go to “Perform a Makeup Fraction” (page 209).
 - Never perform an additional treatment fraction in place of an interrupted fraction.
6. After the treatment has been delivered, the **Procedures** list displays the completed procedure as **Performed**.
 7. When the system prompts you, set the mode switch to **Program**.

8. Enter the treatment room.



WARNING: As the couch moves, pinch points can cause serious injury. Avoid contact with moving parts and instruct the patient to stay clear of moving parts. If needed, press the **Stop** button to stop couch movement.

9. On the **Positioning Control Panel**, press the **Unload** button to move the couch to the Unload position.
10. Assist the patient off of the couch.

Perform a Motion Tracking Treatment

The following procedure applies to Fiducial Tracking, Synchrony® Respiratory Tracking, and XSight® Lung Tracking treatment modalities.



IMPORTANT: Before treating a patient, review the warnings and cautions in “General System Safety” (page 2) and “Operator Responsibilities” (page 26).



WARNING: Motion tracking treatment workflows contain time-sensitive clinical decisions that may affect patient treatment outcomes. To prevent mistreatment, excessive imaging, inferior treatment outcomes, or scheduling delays, clinicians must understand the additional risks, display information, data inputs, and controls used to deliver motion tracking treatments that are described throughout this manual.

1. Make sure the patient does not move until you give them further instructions.



WARNING: Registration and treatment accuracy can be affected if the patient does not remain in the correct setup position. Make sure the patient does not move during an image scan, image registration, or a treatment procedure. Use the audio and visual system to monitor the patient from the Treatment Delivery Console.



WARNING: The treatment system generates radiation for image guidance scans, motion tracking, treatment procedures, and quality assurance procedures. To avoid unnecessary radiation exposure during non-patient procedures, ensure the treatment room is unoccupied and the entrance is secured. Before a scan or treatment procedure is started, ensure that the patient is the only person in the treatment room and the entrance to the treatment room is secure.

2. Make sure the patient is the only person in the treatment room.
3. Exit and secure the entrance to the treatment room.
4. At the **Status Console**, set the mode switch to **Treat**.



IMPORTANT: If a treatment procedure includes a long gantry period, the system may require additional time before the **Ready** light on the **Status Console** turns on.

5. When the **Ready** light turns on, press the **Start** button to begin the treatment.



WARNING: If a treatment procedure is interrupted during irradiation (beam on), the complete dose for the fraction is not delivered. If this happens:

- Perform the makeup fraction to make sure the remaining dose for the interrupted fraction is delivered. Go to “Perform a Makeup Fraction” (page 209).
- Never perform an additional treatment fraction in place of an interrupted fraction.

6. If desired, adjust the default values in the **Confidence Tolerance** and **Algorithm Parameters and Tolerances** fields.



WARNING: Excessive kV image acquisition may cause or contribute to a higher dose deposited in patient skin, resulting in radiation burns. To prevent or reduce this side effect, use the minimum quantity of kV images needed, and the lowest dose X-ray technique, that meets all other tracking requirements according to the standard protocols and practices of your clinic.

7. Click the **Acquire Images** button to acquire radiographs at the enabled angles. Do one of the following:
 - For a respiratory motion treatment, continue to the next step (step 8).
 - For a non-respiratory motion treatment (also known as quasi-static), proceed to step 11.
8. For a respiratory motion treatment, review each radiograph in the kV image viewer prior to building a motion model:
 - Adjust the **Plan/Scan** slider balance of the kV image viewer, or adjust the **Window/Level** gradient. The tumor VOI or implanted fiducials should be visible in each radiograph.
 - If needed, you may change the angle of a radiograph to improve tumor VOI or fiducial visibility. You may also create new radiograph angles, or turn off unneeded radiograph angles. After you have finished reviewing and making changes to all of the defined radiographs, repeat this step (step 8) from the beginning to acquire new radiographs and review the results.
 - If needed, remove individual radiographs from the motion tracking model table. If undesired radiographs are not removed, the system will attempt to use them in the model building step, which may result in a failed model.



NOTE: The frequency of kV radiograph acquisition is determined by gantry period, and the number of radiograph angles enabled. For example, a gantry period of 18 seconds per rotation with 6 radiograph angles enabled would result in a radiograph acquired approximately every 3 seconds, if the angles were evenly distributed.



IMPORTANT: If the tumor VOI or implanted fiducials are not visible in the defined radiographs angles, you will not be able to create a motion tracking model with a sufficient confidence threshold.

9. Verify that the status of Tracking Markers is green. This indicates that the Tracking Markers are within the field of view of the *Synchrony* camera with the couch and patient extended into the gantry bore.

If Tracking Marker adjustments are needed, cancel the procedure (resulting in a system interruption and makeup fraction) to enter the treatment room. Adjust the position of any Tracking Marker attached to the patient. You may also adjust the position of the reference marker attached to the couch. After adjustments are complete, proceed with delivering the makeup. Proceed to “Perform a Makeup Fraction” (page 209).

10. Click **Build Model**. The system continuously acquires and displays kV radiographs until the required confidence threshold is reached, or until values in the motion tracking model parameters exceed the defined thresholds. If any parameters exceed thresholds, those parameters are highlighted orange.

11. Did the model achieve the confidence threshold?

- If yes, continue to the next step (step 12) to begin treatment.
- If no, and you want to change the current threshold parameters, you may adjust the values in the **Confidence Tolerance** and **Algorithm Parameters and Tolerances** fields.
- If no, and you are satisfied with the current threshold parameters, you may remove individual kV radiographs from the model, disable radiograph angles, change radiograph angles, or disable fiducials.

After making changes to model usage and threshold settings, you can either return to the prior step (step 10 for a respiratory treatment; step 7 for non-respiratory treatment) to rebuild the model. For respiratory treatments, you can also click **Reset Model** to remove all of the radiographs from the model table.



IMPORTANT: If you are unable to create a motion tracking model with an acceptable confidence threshold, the patient indication may not be suitable for the motion tracking treatment modality. In such a case, the patient treatment will need to be rescheduled, and the patient plan will need to be recreated for a non-motion treatment modality.

12. Click the **Treat** button to start radiation treatment. Understand the following:

- The system continuously displays information about the plan as it is delivered. You are responsible for monitoring this information along with audio and visual indicators to determine if any intervention or adjustments are needed.

- The system also monitors the treatment information, and will pause the treatment if any parameter exceeds the specified thresholds, or if the position indicators are no longer visible.
 - You may enable or disable any kV radiograph angle and observe how the change impacts the motion model. You may also remove individual kV radiographs from the motion model. However, you may only establish new radiograph angles or modify the angle of existing radiographs when treatment is paused.
 - If you navigate outside of the TDC **Treat** tab, or push the **Stop** or **Emergency Stop** buttons on the **Status Console**, a system interruption will occur and a makeup fraction will be created.
 - At any time during treatment, you may press the **Pause** button to temporarily stop treatment. If you or the system pause treatment, proceed to the next step.
13. If the treatment fraction was completely delivered, proceed to the next step (step 14). If you or the system paused the treatment, understand the following:
- If the tumor VOI or fiducials have shifted partially out of the field of view, click the **Move Couch to Apply Longitudinal Offset** button to adjust the position of the couch.
 - If desired, you may enable or disable position indicators (LED Tracking Markers or implanted fiducials) used by the model.
 - If desired, you may modify the parameters of the motion model (and then reset and rebuild the model).
 - When you are ready to resume treatment, click the **Resume** button and return to the previous step (step 12) until the treatment is complete or paused again.



WARNING: If the treatment is paused for too long, the current motion tracking model may become inaccurate. To ensure the best possible treatment outcomes, Accuray Incorporated recommends that you reset and rebuild the motion tracking model if treatment is paused for longer than three minutes.

14. After the treatment has been delivered, the **Procedures** list displays the completed procedure as **Performed**.
15. When the system prompts you, set the mode switch to **Program**.
16. Enter the treatment room.



WARNING: As the couch moves, pinch points can cause serious injury. Avoid contact with moving parts and instruct the patient to stay clear of moving parts. If needed, press the **Stop** button to stop couch movement.

17. On the **Positioning Control Panel**, press the **Unload** button to move the couch to the Unload position.

18. Assist the patient off of the couch. If the patient is wearing a *Synchrony* vest, help them remove the vest and tracking markers.
19. If the next patient in your clinical schedule does not require the *Synchrony* motion tracking components, disconnect and store the light box, fiber optic cables and Tracking Markers, and the Reference Post.

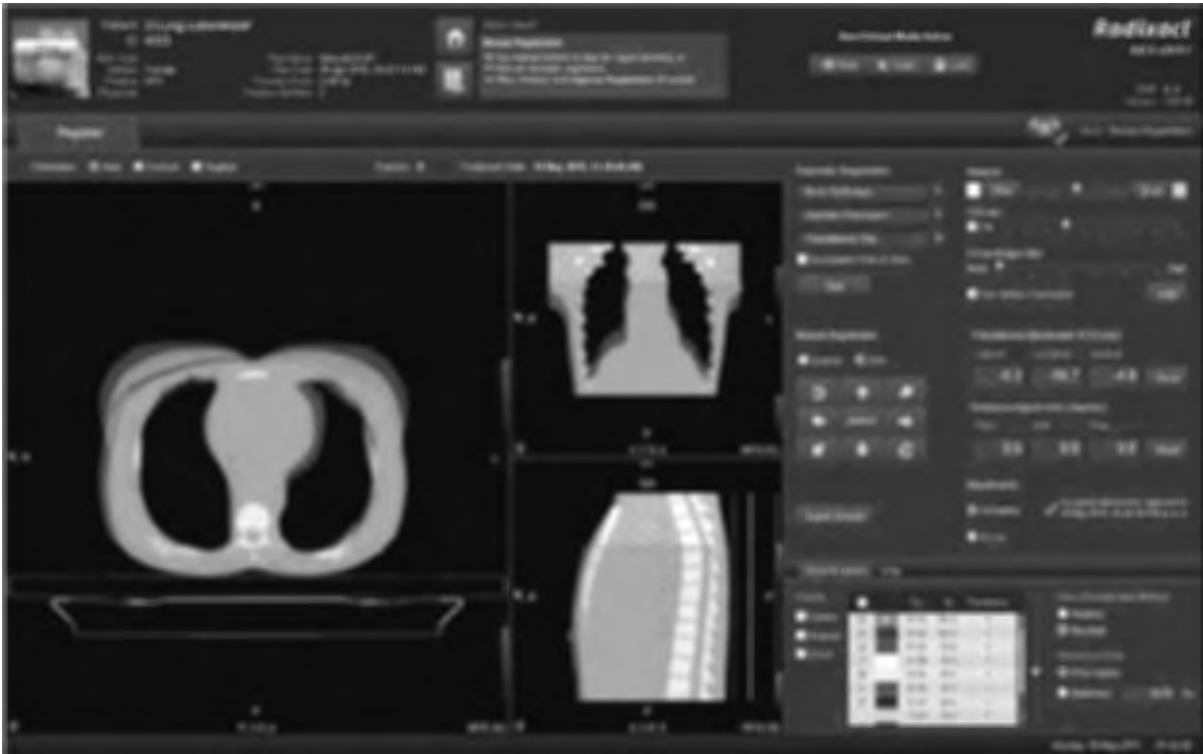


IMPORTANT: *Synchrony* vests are disposable, and should not be worn by more than one patient. Follow the appropriate sterilization and biohazard procedures when storing or disposing of *Synchrony* vests.

Review Registration

Review Registration is used to review previously acquired *CTrue* images. This may include reviewing offsets that were applied to the image or comparing the selected image to the planning image for the patient. For more information on reviewing image registrations, see “Register Tab” (page 111).

- ◆ Review Registration 202
- ◆ Review Registration 202



WARNING: Previously reconstructed images are for review only. They must not be used to reposition or treat a patient, as mistreatment could occur.

◆ Review *CTrue* Images Locally

Use the following instructions to view previously acquired *CTrue* images on your local machine:

1. At the Treatment Delivery Console, go to the dashboard and click **Review Registration**.
2. Choose a patient and fraction from the **Patients List**.

3. Select either **Accepted** or **Actual** under **Adjustments** on right side of the **Register** tab.

Accepted shows the image with the offsets that were accepted in registration. **Actual** shows the offsets accepted in registration and the offsets that were actually used in treatment.

4. Click **Approve Registration** or leave the workflow.



NOTE: You may be required to enter your credentials when you click **Approve Registration**.

◆ Review *CTrue* Images Remotely

The **Remote Registration** application is a licensable feature and its availability depends on your system configuration. Through the application, you can review previously acquired *CTrue* images remotely. Access **Remote Registration** with GoToMyPC® or with **Remote Desktop Connection**.

Connect with GoToMyPC®

To access **Remote Registration** through *GoToMyPC*, do the following:

1. In your web browser, type **www.gotomypc.com**.
2. Enter the email address and account password that you used to create your *GoToMyPC* account.
3. Click **Log In**.
4. If prompted, choose the account you want to access and click **Go**. The **My Computers** page appears.
5. On the right side of the screen, find the nickname of the Remote Registration Node (RRN) you want to access and click **Connect**.
6. Depending on your browser, click one of the following to download the **GoToMyPC Viewer**:
 - **Run**
 - **Always**
 - **Allow**
 - **Trust**
7. When prompted, enter your access code for the host and click **OK**.
8. Click the **Remote Registration** desktop shortcut and log on using your *Windows* username and password.

Connect with Remote Desktop Connection

To access **Remote Registration** through **Remote Desktop Connection**, do the following:

1. On your computer, open **Remote Desktop Connection** and enter one of the following settings, where **X.X.X.X** is the IP address:
 - **X.X.X.X:3389**
 - **X.X.X.X:3390**
 - **X.X.X.X:3391**
 - **X.X.X.X:3392**



NOTE: **X.X.X.X:3389** connects to the first virtual machine, **X.X.X.X:3390** connects to the second virtual machine, and so on. If you fail to connect to **Remote Desktop Connection** with any of the four available settings, connect with a different setting until you are allowed access. Note that inactive sessions are automatically logged out after 10 minutes.



2. When prompted, enter your *Windows* username and password.
3. Click the **Remote Registration** desktop shortcut and log on using your *Windows* username and password.

Treatment Without a *CTrue* Image Scan

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◆ Use of Existing Fiducials



WARNING: Use of inaccurate fiducial marks can affect the position of the patient and can also affect treatment accuracy.

- Perform *CTrue* image registration to verify the accuracy of fiducial marks.
- Use of existing fiducials to position a patient should be approved by a qualified radiation oncologist in accordance with accepted facility practices and protocols.

It is not the intent of Accuray Incorporated to suggest or recommend the use of existing planning fiducials to position a patient for treatment. Rather, you should understand the potential hazards before a patient is treated without *CTrue* image registration adjustments.

- Use of existing fiducials to position a patient is left to the discretion of the patient's responsible physician.
- Changes in patient anatomy can affect the accuracy of laser alignment with existing fiducials.
- If you are not confident that existing fiducials accurately mark the intended target (tumor), perform a *CTrue* image scan and image registration to verify the fiducials.
- If you are not certain the patient has been positioned correctly, perform a *CTrue* image scan and image registration to verify that the patient is positioned correctly.
- If you are confident that fiducial marks on the patient are accurate, *CTrue* image registration is still required to correct for couch sag and possible anatomical changes, including weight loss or gain, or changes in tumor size.

◆ Use of Re-marked Planning Fiducials

After *CTrue* image registration is performed, you may re-mark the registered fiducials in place of the existing CT fiducials. Re-marked fiducials may be used to position the patient before a *CTrue* image scan or to position the patient for treatment without a *CTrue* image scan.



WARNING: Use of inaccurate fiducial marks can affect the position of the patient and can also affect treatment accuracy.

- Perform *CTrue* image registration to verify the accuracy of fiducial marks.
 - Use of existing fiducials to position a patient should be approved by a qualified radiation oncologist in accordance with accepted facility practices and protocols.
1. After *CTrue* image registration is performed (all adjustments applied to the patient), mark the registered fiducials using the overhead and horizontal green lasers. If the green laser located behind the gantry bore is not visible on the anatomy of the patient, the couch table top height can be used as an alternative method for marking the vertical position of the patient.
 2. On the next treatment day, position the patient using the green laser marks from the previous day (step 1) before performing a *CTrue* image scan.



NOTE: If you want to mark the red lasers on the same day that you marked the green lasers, open a **Warmup** procedure, click **Prepare Procedure**, and then press the **Stop** button on the **Status Console**. This will reset the patient's red lasers to the original position. Once this has been completed, return to preparing the scan or treatment procedure.

3. After the new fiducials are in alignment with the green lasers, re-mark the red laser position on the patient. These will be the final patient fiducials.
4. Perform a *CTrue* image scan to verify the accuracy of the final fiducial marks.
5. If the final fiducials are accurate, you may use the red lasers with the final registered fiducials to position the patient.
6. On a subsequent day, click the **Prepare Treatment** button on the **Treat** tab and process any dialog messages to position the lasers. Once the treatment procedure is prepared, align the patient to the lasers.



WARNING: Patient mistreatment can occur if the patient is not in the correct position. If you use the lasers as the sole method to position the patient for treatment, you must ensure that the lasers are in the correct position before aligning the patient. The lasers do not move into the correct position for the patient plan until a procedure is prepared. To prevent mistreatment, you must click the **Prepare Treatment** button on the **Treat** tab and process any dialog messages before aligning the patient to the lasers.

Acquire MVCT Planning Image

The patient must already exist in the data server to acquire an MVCT planning image and associate the image with the patient. Refer to the iDMS™ Data Management System manual for instructions to create a new patient. You must scan the patient to acquire an MVCT image set that will be used for planning. Because a planning image does not exist, it is not displayed in the **Slice Selector** on the **Scan** tab. Consequently, the anatomical location of the target must be known relative to the stationary, green transverse laser (virtual isocenter) to achieve the correct patient setup and slice selection for the image set.



WARNING: Do not use a *CTrue* image set to diagnose a patient for treatment. A diagnostic imaging device must be used to prescribe patient treatment by a qualified physician according to established protocols and clinical objectives enforced by your facility. The **Acquire Planning Image** feature is intended to be used to create lower fidelity plans, such as those used to ease the discomfort of palliative patients. It may also be used to reduce planning image artifacts for patients with metal implants or other attenuating objects.



WARNING: If an outdated MVCT density model is used for plan optimization, it may affect the accuracy of dose calculations. CT Number Calibration procedures do not eliminate the need for dosimetric checks and updates of your MVCT density model, if you are using MVCT images to calculate dose.

1. If the **CT Number Calibration** has not been run today, perform this procedure before acquiring an MVCT planning image.
2. At the **Status Console**, set the mode switch to **Program**.
3. At the Treatment Delivery Console, select **Tools > Acquire Planning Image**.
4. Select the correct patient from the **Patient List** dialog box and click **OK**.
5. On the **Scan** tab, an **Informational** dialog appears. Select the desired setup orientation from the **Patient position** drop-down and click **OK**.
6. Enter the treatment room and assist the patient onto the couch. Make sure the patient is in the correct orientation for the intended treatment position.
7. You cannot use the **Setup** button on the **Positioning Control Panel** to move the patient to a Planned Setup position. Instead, use the manual couch control buttons to adjust the position of couch and patient.



IMPORTANT: Because you are creating a new *CTrue* image set for planning, the **Setup** button on the **Positioning Control Panel** cannot be used to move the couch to a Planned Setup position. An approved patient plan, which includes the couch parameters, does not yet exist for the patient.

8. Identify the approximate location of the target region within the patient.
9. Position the patient so that the anatomical location of the treatment target is approximately centered on the green transverse laser.
10. Instruct the patient not to move out of position and return to the Treatment Delivery Console.
11. At the **Scan** tab, make a selection for the following settings:
 - **Orientation**
 - **Pitch**
 - **Reconstruction Interval**
 - **Algorithm**
12. Select the slices in the **Slice Selector** for the region you want to scan.
13. Use the green virtual isocenter laser to select the relevant number of slices for the scan. Include enough slices to surround the intended target by at least 5 cm. This will help ensure the target is acquired in the image set. If you do not select enough slices inferior and superior to the target region, the dose calculation may not be as accurate for slices in close proximity to the end slices.
14. Click **Accept Slices** to add a new scan to the **Procedures** list.
15. Click **Prepare Scan**. The **Prepare Patient and Room** dialog box appears.
16. Ensure the patient is in the correct orientation, and click **OK**.
17. Enter the treatment room. Verify that the patient has not moved out of position.
18. At the **Positioning Control Panel**, press **Main > Ready > Yes** to move the couch to the Ready position.
19. Continue to "Perform the CTrue Image Scan" (page 185). After you perform the scan, the image will be available for plan creation in the Accuray Precision™ Treatment Planning System.



WARNING: Mistreatment may result from patient anatomy outside the MVCT image that is not considered in plan dose calculation. The MVCT field of view is approximately 390 mm, which is smaller than most CT scanners used for planning. Depending on the area of patient anatomy scanned (such as the hips or shoulders), portions of the patient anatomy may not be included in the planning image. This may result in underdose to the target, and unintended dose deposited outside of the target region. To ensure accurate delivery, and to prevent beams from passing through areas of the patient not considered in dose calculation, any treatment angles that include anatomy outside of the field of view should be blocked in the patient plan.

Perform a Makeup Fraction

If a treatment procedure is interrupted during irradiation, you must perform a makeup fraction to deliver the remaining dose.

- ◆ Verify Makeup Fraction Duration 209
- ◆ Verify TomoDirect Makeup Fraction Beam Duration 210
- ◆ Perform a Makeup Fraction 212

◆ Verify Makeup Fraction Duration

Before you deliver a TomoHelical™ Treatment Delivery or a TomoDirect™ Treatment Delivery makeup fraction, verify its duration.



NOTE: If the interruption occurred when the fraction was within the warmup period or before irradiation started, the **Delivery Time** should be the same as the original procedure. If not, contact Accuray Customer Support.



NOTE: For *TomoHelical* procedures, a makeup fraction is not needed if the interruption occurred at the end of a treatment (there is no remaining treatment time), or the completion would not have any MLC leaf open time. For *TomoDirect* procedures, a makeup fraction is not needed only if the interrupted beam was the last beam of the procedure.

- 1. Select the **Interrupted** procedure from the **Procedures** list on the **Treat** tab.
- 2. Subtract the **Elapsed Time** from the **Delivery Time**, and add the **seconds of warmup** in **Status**.

Procedures

Pt	Status	Delivery Time	Elapsed Time	Date and Time
1	Performed	112.6 sec	112.6 sec	19 Aug 2015, 11:27:04 AM
2	Performed	112.6 sec	112.6 sec	19 Aug 2015, 11:27:27 AM
3	Performed	112.6 sec	112.6 sec	19 Aug 2015, 12:30:39 PM
4	Performed	112.6 sec	112.6 sec	24 Aug 2015, 11:45:12 AM
5	Performed	112.6 sec	112.6 sec	24 Aug 2015, 11:45:45 AM
6	Interrupted	112.6 sec	30.0 sec	25 Aug 2015, 03:57:30 PM
6.1	Scheduled	92.6 sec		

Load Fraction

Delivery Report

Summary Report

Procedure Details

Status: Procedure was interrupted.
92.6 seconds remain in the procedure.
35.0 seconds of warmup.
0.3 seconds per projection.



NOTE: In the following step, 0.2 seconds is added to the **seconds per projection** because the software rounds displayed values.

3. Go to the **Procedures** list, and compare the **Delivery Time** for the **Scheduled** makeup fraction with the result from the previous step:
 - If the absolute value of the difference between these numbers is less than or equal to the **seconds per projection** in **Status** plus 0.2 seconds, continue to the next step.
 - If the absolute value of the difference between these numbers is greater than the **seconds per projection** plus 0.2 seconds, do not deliver the makeup fraction. Contact Accuray Customer Support for assistance.
4. Compare how many **seconds remain in the procedure** in **Status** with the **Delivery Time** for the **Scheduled** makeup fraction in the **Procedures** list.
 - If these numbers are equal, continue to “Perform a Makeup Fraction” (page 212).
 - If these numbers are not equal, do not deliver the makeup fraction. Contact Accuray Customer Support for assistance.

◆ Verify *TomoDirect* Makeup Fraction Beam Duration

When an interruption occurs for a specific beam angle, you must calculate the interrupted angle's completion duration. The **Delivery Time** for all remaining angles does not change.



NOTE: If the system interruption occurred when the fraction was within the warmup period or before irradiation started, the **Delivery Time** should be the same as the original procedure. If not, contact the Accuray Technical Solution Center.

1. Select the **Interrupted** procedure from the **Procedures** list on the **Treat** tab.
2. Go to **Procedure Beam Details**. Subtract the **Elapsed Time** from the **Delivery Time** for the interrupted angle, and add the **seconds of warmup in beam**.

Procedures

Fr	*	Status	Delivery Time	Elapsed Time	Date and Time
1		Performed	154.2 sec	154.2 sec	30 Sep 2015, 12:44:34 PM
2		Interrupted	154.2 sec	103.9 sec	30 Sep 2015, 12:45:52 PM
2.8		Scheduled	185.4 sec		

Load Fraction

Delivery Report

Summary Report

Procedure Details

Status: Beam Ang1 was interrupted.
103.4 seconds remain in the procedure.
18.5 seconds remain in beam Ang1.
10.7 seconds of warmup in beam Ang1.
0.7 seconds per projection in beam Ang1.

Procedure Beam Details

Beam Name	Planned Angle	Delivery Time	Elapsed Time	Status
Ang3	235.6	25.3 sec	25.3 sec	Completed
Ang2	258.3	45.2 sec	45.2 sec	Completed
Ang1	26.7	34.9 sec	27.4 sec	Interrupted



NOTE: In the following step, 0.2 seconds is added to the **seconds per projection in beam** because the software rounds displayed values.

- Go to **Status**. Compare how many **seconds remain in beam** with the result from the previous step:
 - If the absolute value of the difference between these numbers is less than or equal to the **seconds per projection in beam** plus 0.2 seconds, continue to the next step.
 - If the absolute value of the difference between these numbers is greater than the **seconds per projection in beam** plus 0.2 seconds, do not deliver the makeup fraction. Contact the Accuray Technical Solution Center for assistance.
- Select the **Interrupted** procedure in the **Procedures** list. Go to **Status**, and note how many **seconds remain in beam**.



IMPORTANT: When you select a **Scheduled** makeup fraction in the **Procedures** list, the first beam in the **Procedure Beam Details** should be the **Interrupted** beam. If it is not, contact the Accuray Technical Solution Center for assistance.

- Select the **Scheduled** makeup fraction in the **Procedures** list. Go to **Status**, and compare the **Delivery Time** of the completion beam with the value noted in the previous step:
 - If these numbers are equal, continue to "Perform a Makeup Fraction" (page 212).

- If these numbers are not equal, do not deliver the makeup fraction. Contact the Accuray Technical Solution Center for assistance.

◆ Perform a Makeup Fraction

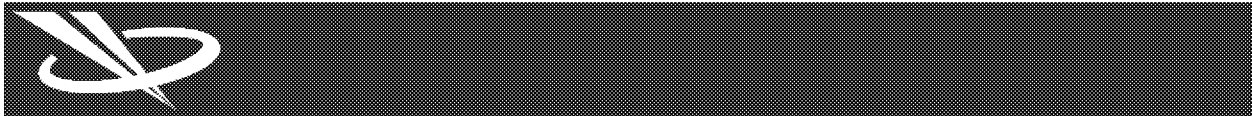
1. At the Treatment Delivery Console, select the makeup fraction from the **Procedures** list.
2. Click **Load Fraction**.
3. Click **Prepare Treatment**. The **Patient Adjustment Instructions** dialog appears if new registration adjustments were applied.
4. Verify the registration adjustments. If desired, select the **Acquire Registered Couch Position** check box.
5. Click **Print** to print adjustments or record the registration parameters for the couch and patient.
6. Click **Apply**. The red lasers move based on the registration adjustments.
7. At the **Positioning Control Panel**, press the **Setup** button. Understand the following:
 - If the patient did not need to be reloaded at the Treatment Delivery Console following a recoverable interruption, the **Setup** button may be used to restore the registered coordinates.
 - If the patient was reloaded at the Treatment Delivery Console immediately after an unrecoverable system interruption, the **Setup** button may be used to restore the registered coordinates.
 - Be aware that if any other plan was loaded at the Treatment Delivery Console before the interrupted procedure was reloaded, the **Setup** button will not restore the registered coordinates.
8. At the **Positioning Control Panel**, press **Ref Position**. Compare the **Current Couch Position** with the registered values you recorded from the original treatment. (See “Adjust Patient Translations” (page 191) for more information.) Is the couch in the correct Registered Setup position?
 - If no, use the couch movement controls to move the couch to the correct Registered Setup position.
 - If yes, continue to the next step.



WARNING: Patient mistreatment can occur if the patient is not positioned correctly. If you are not confident that the patient is in the correct Registered Setup position, Accuray Incorporated recommends that you perform a new *CT_{True}* image scan and image registration to verify the position of the patient. You can then apply the new registration results.

9. Verify that the patient has not moved out of position.

- If the patient has moved out of position, proceed to “Prepare a CTrue Image Scan” (page 183).
 - If you are confident that the patient has not moved out of the correct setup position, continue to the next step.
10. Instruct the patient not to move, and then press **Ready** on the **Positioning Control Panel**. A confirmation message appears.
11. On the confirmation message, do one of the following:
- Press **Yes** to move the couch to the Ready position. Observe the patient until the couch has reached the Ready position inside the bore of the gantry (couch movement stops).
 - If the patient has moved out of position, press **Cancel** and then continue to “Prepare a CTrue Image Scan” (page 183). You must perform image registration to reapply adjustments to the treatment procedure.
12. Once the patient is in the Ready position, continue to “Treat the Patient” (page 195).



Appendix A

Error & Warning Messages

What To Do About Error & Warning Messages 216

TDC Error & Warning Messages 217

PCP Error & Warning Messages 236

What To Do About Error & Warning Messages



WARNING: Any hardware or software related problems should be recorded in the appropriate log and reported to Accuray as soon as possible. Failure to do so may result in injury or death to users or the patient.

The treatment system displays error and warning messages at two locations:

- Treatment Delivery Console (TDC)
- Positioning Control Panel (PCP)

All error and warning messages that appear on the TDC and PCP are listed in the following sections.

Some of the messages listed in the following sections contain variables that serve as placeholders for text or numbers that are unique to an individual message. The table below lists and defines all variables within the TDC and PCP error and warning messages.

Variable	Meaning
{v}	Placeholder for a specific hardware/software version.
<x>, <y>, <z>	Placeholder for a number that represents the couch position (in mm) in the specified x, y, or z axis.

Contact Accuray Customer Support if you have any concerns or questions about the function of your system.

TDC Error & Warning Messages

- ◆ System Interruptions 217
- ◆ General Application Errors 230

Two types of error and warning messages are displayed on the Treatment Delivery Console (TDC):

- **System Interruptions** are errors that originated from the treatment system.
- **General Application Errors** are any errors that did not originate from the treatment system (communication errors, logic errors, data loading errors, and so on).

The tables in this section list all error and warning messages displayed on the TDC. If you encounter a message described in these tables, perform the recommended action shown.



IMPORTANT: When encountering or resolving an error message, check whether the error is recoverable or unrecoverable. Unrecoverable errors require you to shut down the system. If unrecoverable system errors persist, contact Accuray Customer Support.

Contact Accuray Customer Support if an error persists, or if you have any concerns or questions about the function of your system.

◆ System Interruptions

Text	Recommended Action
Unknown problem.	Contact Accuray Customer Support.
No fault detected.	Contact Accuray Customer Support.
Task was not completed because another task interrupted it.	No action required.
Internal communication problem.	Restart the system.
Internal software problem.	Contact Accuray Customer Support.
The software installation is not correct.	Contact Accuray Customer Support.
The software is not ready.	Restart the system.
The barrier to the treatment room is open or the Stop button was pressed.	If course of action is not clear, contact Accuray Customer Support.

Text	Recommended Action
The Emergency Stop button is pressed.	Reset the Emergency Stop button. Restart the system.
User action is not correct.	If course of action is not clear, contact Accuray Customer Support.
User shutdown system.	If course of action is not clear, contact Accuray Customer Support.
The treatment machine is not initialized.	Restart the system.
Partial detector data is saved to the TDC.	Contact Accuray Customer Support.
Internal communication error.	Restart the system. If this issue persists, contact Accuray Customer Support.
The system is not commissioned correctly.	Contact Accuray Customer Support.
The system is not able to get the procedure from the TDC.	Contact Accuray Customer Support.
The system is not able to get important data from the TDC.	Restart the system.
The system is not able to get setup data from the TDC.	Restart the system.
Procedure return data is not saved to the TDC.	Restart the system.
Detector data is not saved to the TDC.	Contact Accuray Customer Support.
User does not have permission to access the TDC.	Contact Accuray Customer Support.
Unknown user.	Contact Accuray Customer Support.
The system is not able to get patient data from the TDC.	Contact Accuray Customer Support.
Procedure is not created.	Contact Accuray Customer Support.
Selected plan is not loaded.	Contact Accuray Customer Support.
The system encountered an error in the data loaded from the TDC.	Contact Accuray Customer Support.
Detector data is not saved to the TDC.	Contact Accuray Customer Support.
Linac hardware error.	Contact Accuray Customer Support.

Text	Recommended Action
MLC hardware error.	Contact Accuray Customer Support.
MLC leaf is in wrong position.	Contact Accuray Customer Support.
Safety interlock hardware error.	Contact Accuray Customer Support.
The system requires service.	Contact Accuray Customer Support.
The safety interlock is open. Possible causes include: the stop button, the treatment room barrier is open, the key is turned to Program, or other unsafe condition.	Close the safety interlock. Verify that the patient is the only person in the treatment room before resuming treatment.
Radiation is not stopped in time.	Contact Accuray Customer Support.
Status Console hardware error.	Contact Accuray Customer Support.
The Status Console key is in the wrong position.	Turn the key to the correct position.
The Start button is not pressed in time.	If course of action is not clear, contact Accuray Customer Support.
PCP communication error.	Contact Accuray Customer Support.
Invalid PCP data.	Contact Accuray Customer Support.
Laser is not ready.	Check that the lasers have power.
Laser error.	Check that the lasers have power. If not, restart the system. If this issue persists, contact Accuray Customer Support.
The gantry is not ready.	Check that the gantry has power.
The gantry position is not correct.	Contact Accuray Customer Support.
The gantry motion is not correct.	Contact Accuray Customer Support.
Gantry error.	Check that the gantry has power. If not, restart the system. If this issue persists, contact Accuray Customer Support.
Couch error.	Contact Accuray Customer Support.

Text	Recommended Action
The couch is not ready.	Check that the couch has power. If not, restart the system. If this issue persists, contact Accuray Customer Support.
The couch is too far from the gantry.	Move the couch into the bore at least 2.0 cm.
The couch horizontal release button is active.	Press the yellow manual release button on the couch.
The couch is too close to the gantry.	Manually position the couch further away from the gantry.
The couch cannot communicate with the PCP.	Restart the system.
The couch is too low.	Manually raise the couch to pass through the bore.
The couch motion is not correct.	Contact Accuray Customer Support.
The couch setup position is not correct.	Manually position the couch to the desired setup position.
The couch failed to retract to the correct setup position.	Press the Setup button.
The couch caused a system interrupt.	Check that the couch has power.
Jaw error.	Contact Accuray Customer Support.
The jaws are not ready.	Contact Accuray Customer Support.
The system requires service.	Contact Accuray Customer Support.
Low water temperature.	Contact Accuray Customer Support.
High water temperature.	Contact Accuray Customer Support.
Low water pressure.	Contact Accuray Customer Support.
High water pressure.	Contact Accuray Customer Support.
Low air temperature.	Contact Accuray Customer Support.
High air temperature.	Contact Accuray Customer Support.
Low air pressure.	Contact Accuray Customer Support.
High air pressure.	Contact Accuray Customer Support.

Text	Recommended Action
Low water flow rate.	Contact Accuray Customer Support.
High water flow rate.	Contact Accuray Customer Support.
Machine did not warmup in time.	Contact Accuray Customer Support.
Data acquisition error.	Contact Accuray Customer Support.
Power phase is not correct.	Facility personnel should check the main power supply.
Monitor dose value is not correct.	Contact Accuray Customer Support.
Dose is too high when radiation is off.	Contact Accuray Customer Support.
Dose during radiation is too low.	Contact Accuray Customer Support.
Dose during radiation is too high.	Contact Accuray Customer Support.
Detector temperature is too low.	Contact Accuray Customer Support.
Detector temperature is too high.	Contact Accuray Customer Support.
The safety interlock is open.	Contact Accuray Customer Support.
The outside of the beam is too strong.	Contact Accuray Customer Support.
The inside of the beam is too strong.	Contact Accuray Customer Support.
SF6 is out of pressure tolerance	Contact Accuray Customer Support.
The magnetron is too hot.	Contact Accuray Customer Support.
The gun board is not ready.	Contact Accuray Customer Support.
Water flow error.	Contact Accuray Customer Support.
The Ring Data Receiver is not ready.	Contact Accuray Customer Support.
Machine timing software is not correct.	Contact Accuray Customer Support.
Machine timing or detector hardware is not correct.	Contact Accuray Customer Support.
Machine fault caused timing error.	Contact Accuray Customer Support.
The Dose Control System has encountered an interrupt. You will not be able to proceed with treating patients without service interaction.	Contact Accuray Customer Support.

Text	Recommended Action
The Dose Control System has encountered an interrupt. The hardware may require service.	Contact Accuray Customer Support.
The Dose Control System has encountered an interrupt. The electron gun current was detected to be operating outside the range limits.	If this issue persists, contact Accuray Customer Support.
An error has occurred in the Machine Software. A service call may be required.	If this issue persists, contact Accuray Customer Support.
An error has occurred during Machine initialization. A service call may be required.	If this issue persists, contact Accuray Customer Support.
An error has occurred in retrieving data from the OS. A service call may be required.	If this issue persists, contact Accuray Customer Support.
An error has occurred in the data from the OS. A service call may be required.	If this issue persists, contact Accuray Customer Support.
An error has occurred in part of the Machine Hardware. A service call may be required.	If this issue persists, contact Accuray Customer Support.
A Machine Software operation has timed out. A service call may be required.	If this issue persists, contact Accuray Customer Support.
The Machine Software has detected an error in the control of Machine. A service call may be required.	If this issue persists, contact Accuray Customer Support.
An error has occurred in a Machine network feature. A service call may be required.	If this issue persists, contact Accuray Customer Support.
An error has occurred in the allocation of memory for the Machine Software. A service call may be required.	If this issue persists, contact Accuray Customer Support.
An error has occurred during communication with the OS. A service call may be required.	If this issue persists, contact Accuray Customer Support.
The Machine Software did not receive data from the OS. A service call may be required.	If this issue persists, contact Accuray Customer Support.
The system encountered an error.	Contact Accuray Customer Support.
The System Beam Line Monitor Timed-out waiting for procedure.	If this issue persists, contact Accuray Customer Support.
Dose outside of allowed range. Beam parameters may require adjustment.	If this issue persists, contact Accuray Customer Support.

Text	Recommended Action
Automatic frequency controller error.	If this issue persists, contact Accuray Customer Support.
Injector control assembly command error.	If this issue persists, contact Accuray Customer Support.
Ion pump power supply command error.	If this issue persists, contact Accuray Customer Support.
Ion pump pressure or power supply high-voltage error.	If this issue persists, contact Accuray Customer Support.
Magnetron magnet power supply error.	If this issue persists, contact Accuray Customer Support.
Magnetron magnet power supply out-of-range error.	If this issue persists, contact Accuray Customer Support.
Solid state modulator error.	If this issue persists, contact Accuray Customer Support.
Dose Chamber 1 offset is out-of-range.	If this issue persists, contact Accuray Customer Support.
Dose Control System hardware detection error.	Contact Accuray Customer Support.
An operating system exception occurred.	Restart the system. If this issue persists, contact Accuray Customer Support.
A safety watchdog timer expired.	Restart the system. If this issue persists, contact Accuray Customer Support.
The entrance door was opened during a procedure.	Close the entrance door. Verify that the patient is the only person in the treatment room before resuming treatment.
The power distribution unit OK signal is outside of an acceptable range.	Restart the system. If this issue persists, contact Accuray Customer Support.
The power distribution unit off button has been pressed or the power distribution unit key has been moved to the disabled switch position.	Restart the system. If this issue persists, contact Accuray Customer Support.

Text	Recommended Action
The power distribution unit voltage is lower than acceptable range.	Restart the system. If this issue persists, contact Accuray Customer Support.
Gantry failed to home, or homed status is unavailable.	Contact Accuray Customer Support.
An error has occurred while starting or stopping gantry motion.	If this issue persists, contact Accuray Customer Support.
Failure to reset gantry drive.	Contact Accuray Customer Support.
An error in Detector Data has been discovered. A service call may be required.	If this issue persists, contact Accuray Customer Support.
The Beam Trigger Monitor subsystem has encountered an error while processing timing data. The hardware may require service.	If this issue persists, contact Accuray Customer Support.
The Beam Trigger Monitor subsystem has encountered a fault condition. The hardware may require service.	If this issue persists, contact Accuray Customer Support.
Internal data mismatch detected.	If this issue persists, contact Accuray Customer Support.
An error occurred in the control of the Machine. A service call may be required.	If this issue persists, contact Accuray Customer Support.
Gain exclusive control of subsystem.	Contact Accuray Customer Support.
Error in getting the error code.	Contact Accuray Customer Support.
Failed to get gantry's position from encoder.	Contact Accuray Customer Support.
Failed to get gantry's position from drive controller.	Contact Accuray Customer Support.
Position verification failed, gantry out of position.	Contact Accuray Customer Support.
Velocity verification failed; invalid velocity.	Contact Accuray Customer Support.
Velocity verification failed; invalid velocity via RPM calculation.	Contact Accuray Customer Support.
Gantry electrical current is out of tolerance.	Contact Accuray Customer Support.
No Gantry Error as reported by the gantry.	Contact Accuray Customer Support.

Text	Recommended Action
Exclusive or shared control pointer; used in gantry shutdown.	Contact Accuray Customer Support.
Gantry monitoring software has exited.	Contact Accuray Customer Support.
Error updating system settings	Contact Accuray Customer Support.
Unable to read user settings	Contact Accuray Customer Support.
Error reading radiograph instructions file	Contact Accuray Customer Support.
Internal error displaying What's Next Help	Contact Accuray Customer Support.
Error in file.	Contact Accuray Customer Support.
Error in saving changes to file.	Contact Accuray Customer Support.
Error in updating approved machine revision.	Contact Accuray Customer Support.
Unable to open delivery report.	Contact Accuray Customer Support.
Unable to open summary report.	Contact Accuray Customer Support.
Unable to load fraction.	Contact Accuray Customer Support.
Error processing Air Scan data	Contact Accuray Customer Support.
The current system configuration requires service.	Contact Accuray Customer Support.
Image registration and treatment delivery activities have been disabled.	Contact Accuray Customer Support.
An error occurred while retrieving the plan image.	Contact Accuray Customer Support.
An error occurred while retrieving the scanned image.	Contact Accuray Customer Support.
Serious problem occurred accepting the registration.	Contact Accuray Customer Support.
Error accepting registration	Contact Accuray Customer Support.
Error printing registration adjustments	Contact Accuray Customer Support.
Unable to import machine.	Contact Accuray Customer Support.
Unable to export machine.	Contact Accuray Customer Support.

Text	Recommended Action
Unable to export system model.	Contact Accuray Customer Support.
Unable to export beam model:	Contact Accuray Customer Support.
Unable to write machine archive.	Contact Accuray Customer Support.
Unable to import commissioning data. No treatment beam found.	Contact Accuray Customer Support.
Unable to import commissioning data.	Contact Accuray Customer Support.
Unable to create system model.	Contact Accuray Customer Support.
Error importing couch image.	Contact Accuray Customer Support.
The system failed to prepare the image reconstruction process.	Contact Accuray Customer Support.
Air Scan calibration is not available.	Contact Accuray Customer Support.
Invalid result retrieving Air Scan procedure	Contact Accuray Customer Support.
Invalid result retrieving CT number calibration procedure	Contact Accuray Customer Support.
Invalid result retrieving warmup procedure	Contact Accuray Customer Support.
Machine data is not available to perform safety checks.	Contact Accuray Customer Support.
Unable to load the selected TomoDirect	Contact Accuray Customer Support.
Unable to check couch travel for plan license	Contact Accuray Customer Support.
Machine capabilities are not valid - mis-match between OS and DRS	Contact Accuray Customer Support.
Unable to load the selected TomoDirect™ plan	Contact Accuray Customer Support.
The system capabilities could not be confirmed.	Contact Accuray Customer Support.
The current system configuration requires service.	Contact Accuray Customer Support.
Machine connected, but capabilities can not be confirmed	Contact Accuray Customer Support.
Unable to load the selected Dynamic Jaw Mode plan.	Contact Accuray Customer Support.

Text	Recommended Action
This Patient QA Plan is invalid due to changes in Delivery System parameters.	Contact Accuray Customer Support.
Error uploading results to DMS. Return to the workflow to try again, or exit the application.	Attempt to upload the results to the DMS again, or exit the system software. If the error persists, contact Accuray Customer Support.
Error storing the parameters.	Contact Accuray Customer Support.
Error in claiming machine. Please try again.	Contact Accuray Customer Support.
Error loading fraction	Contact Accuray Customer Support.
Error resetting user settings:	Contact Accuray Customer Support.
Error loading photo file.	Contact Accuray Customer Support.
Error removing photo.	Contact Accuray Customer Support.
Error reading the service message.	Contact Accuray Customer Support.
Delete failed: {v} could not be deleted.	Contact Accuray Customer Support.
Delete failed: Service Message is read-only.	Contact Accuray Customer Support.
Error saving the Service Message.	Contact Accuray Customer Support.
Error writing to output file.	Contact Accuray Customer Support.
Error processing procedure return data.	Contact Accuray Customer Support.
Error saving procedure results to DMS.	Contact Accuray Customer Support.
An error has been detected in the procedure results. The procedure will be reset to Scheduled.	Contact Accuray Customer Support.
An error has been detected in the procedure results. The data has been packaged for support. Please contact Accuray Customer Support.	Contact Accuray Customer Support.
Illegal or unknown procedure status:	Contact Accuray Customer Support.
Error calculating CT scan parameters.	Contact Accuray Customer Support.
Serious problem occurred in the image server.	Contact Accuray Customer Support.
Error reconstructing data.	Contact Accuray Customer Support.

Text	Recommended Action
Unable to process CT Number Calibration without a complete image	Contact Accuray Customer Support.
Error retrieving delivery plan	Contact Accuray Customer Support.
Error persisting positioning instruction set.	Contact Accuray Customer Support.
Registration can not be accepted with a lateral adjustment if a scan was not performed prior to registration.	Contact Accuray Customer Support.
Error printing offsets	Contact Accuray Customer Support.
Error: unknown jawMode:	Contact Accuray Customer Support.
Unable to load plan.	Contact Accuray Customer Support.
Error creating new sinogram:	Contact Accuray Customer Support.
Error loading file:	Contact Accuray Customer Support.
Error saving file:	Contact Accuray Customer Support.
The leaf sinogram could not be loaded. The selected file, endian type, and data type do not reference a valid leaf sinogram.	Contact Accuray Customer Support.
The selected file is not a valid image for import:	Contact Accuray Customer Support.
There was an error with the DDT. An unexpected or invalid value was specified. The invalid value was for the field {v}	Contact Accuray Customer Support.
Machine Not Found	Contact Accuray Customer Support.
Unable to connect to MachineState server.	Contact Accuray Customer Support.
Error adding file:	Contact Accuray Customer Support.
Error creating archive:	Contact Accuray Customer Support.
Error sending email. Please try resending	Contact Accuray Customer Support.
Automatic registration failed due to an error	Contact Accuray Customer Support.
Automated registration failed. An error occurred during the automatic registration calculation. Please report this problem to Accuray Customer Support.	Contact Accuray Customer Support.

Text	Recommended Action
Error Loading Data Definition	Contact Accuray Customer Support.
Error loading Machine QA file:	Contact Accuray Customer Support.
Load Error	Contact Accuray Customer Support.
Error writing Machine QA to file:	Contact Accuray Customer Support.
Error Loading From Data Server:	Contact Accuray Customer Support.
Unexpected error validating parameters:	Contact Accuray Customer Support.
Unexpected error during validation	Contact Accuray Customer Support.
Error exporting delivery plan	Contact Accuray Customer Support.
Critical Error	Contact Accuray Customer Support.
Error acknowledging system interruption	Contact Accuray Customer Support.
Error initializing network connections, exiting	Contact Accuray Customer Support.
Error checking for prior instance	Contact Accuray Customer Support.
System Interruption	Contact Accuray Customer Support.
This system is not configured for Running Start-Stop delivery.	Verify that your system is configured to run Start-Stop delivery. If it is and you are seeing this error message, contact Accuray Customer Support.
The system is not configured for fixed-angle delivery.	Verify that your system is configured to run fixed-angle delivery. If it is and you are seeing this error message, contact Accuray Customer Support.
2D Error	Contact Accuray Customer Support.
Rigid Body Error	Contact Accuray Customer Support.
An error occurred in the encounter.	Contact Accuray Customer Support.

◆ General Application Errors

ID	Text	Recommended Action
1	Error retrieving Beam changes to review.	Contact Accuray Customer Support.
2	Error retrieving Hardware Failure alerts.	Contact Accuray Customer Support.
3	Error loading workflow: {v}	Restart the system. If error persists, contact Accuray Customer Support.
4	Error loading workflow: {v}	Restart the system. If error persists, contact Accuray Customer Support.
5	Error retrieving beam changes to review	Restart the system. If error persists, contact Accuray Customer Support.
7	Procedure was sent to machine before cancel was received.	Stop the procedure, and then attempt to re-scan.
8	Internal error preparing procedure for delivery	Contact Accuray Customer Support.
9	Invalid startup order or failed startup	Restart the system. If error persists, contact Accuray Customer Support.
10	Version {v} is not compatible with DMS version {v}	Contact Accuray Customer Support.
11	Version {v} is not compatible with ECS version {v}	Contact Accuray Customer Support.
12	Recovery missing prerequisites	Restart the system. If error persists, contact Accuray Customer Support.
13	An unrecoverable restart has been detected. The data can not be collected and requires support intervention. Please contact Accuray Customer Support. The system will now exit.	Contact Accuray Customer Support.
14	Recovery requires a machine connection.	Restart the system. If error persists, contact Accuray Customer Support.
15	A recoverable restart has been detected.	Click OK.

ID	Text	Recommended Action
16	The plan required for recovery is locked.	Ensure the plan is not loaded on a separate workstation.
17	A recoverable restart has been detected.	Click OK.
18	Internal Error	Contact Accuray Customer Support.
19	Serious problem occurred printing machine changes.	Restart the system. If error persists, contact Accuray Customer Support.
20	Error loading main workflow	Contact Accuray Customer Support.
21	User unlock failed, closing application	Restart the system.
22	Change user failed, closing application	Restart the system.
23	Service Message was not accepted.	Contact Accuray Customer Support.
25	User did not enter a password on the System Interruption dialog.	Enter your username and password.
27	Missing procedure data for procedure list.	Restart the system. If error persists, contact Accuray Customer Support.
28	The {v} UI has stopped responding. The system will shut down. If the problem persists please contact service.	Restart the system. If error persists, contact Accuray Customer Support.
32	Unable to initialize network connections	Restart the system. If error persists, contact Accuray Customer Support.
33	Unable to retrieve plan information for registration adjustments dialog.	Contact Accuray Customer Support.
34	Failed to connect to the mail server.	Contact Accuray Customer Support.
35	Failed to validate install.	Contact Accuray Customer Support.
36	Failed to validate	Contact Accuray Customer Support.
37	Failed to auto login	Contact Accuray Customer Support.
38	Serious problem occurred changing user.	Restart the system. If error persists, contact Accuray Customer Support.
39	Serious problem occurred preparing procedure for delivery.	Contact Accuray Customer Support.

ID	Text	Recommended Action
40	Error clearing current procedure.	Restart the system. If error persists, contact Accuray Customer Support.
41	Illogical condition: machine state: {v}	Contact Accuray Customer Support.
42	Illogical condition: undefined machine state	Contact Accuray Customer Support.
43	Logic Error: Impossible panel state.	Contact Accuray Customer Support.
44	Error responding to machine state	Restart the system. If error persists, contact Accuray Customer Support.
45	Fault occurred processing transition to machine state {v}	Restart the system. If error persists, contact Accuray Customer Support.
46	Logic Error: Impossible panel state on Procedure Panel	Contact Accuray Customer Support.
47	Unexpected return data handling type: {v}	Restart the system. If error persists, contact Accuray Customer Support.
48	Post processing could not access the current procedure.	Restart the system and follow the system prompts. Contact Accuray Customer Support when instructed to do so.
50	Post processing detected invalid procedure in data model	Restart the system and follow the system prompts. Contact Accuray Customer Support when instructed to do so.
51	Serious problem occurred clearing slice selection.	Contact Accuray Customer Support.
52	Serious problem occurred creating the {v}	Restart the system. If error persists, contact Accuray Customer Support.
53	Fault occurred processing transition to machine state {v}	Restart the system. If error persists, contact Accuray Customer Support.
54	Logic Error: Impossible panel state on ScanPanel	Contact Accuray Customer Support.
57	Serious problem occurred reconstructing the {v}.	Contact Accuray Customer Support.
58	Fault occurred processing transition to machine state {v}	Restart the system. If error persists, contact Accuray Customer Support.

ID	Text	Recommended Action
59	Logic Error: Impossible panel state on Treatment Panel	Contact Accuray Customer Support.
60	Unable to build a new machine QA procedure for delivery	Contact Accuray Customer Support.
62	Serious problem occurred acknowledging the system interruption.	Restart the system. If error persists, contact Accuray Customer Support.
63	Error Loading TomoDirect Procedure to the MachineStatusPanel.	Contact Accuray Customer Support.
64	Not enough data found for beam angles to match the delivery plan.	Contact Accuray Customer Support.
65	Unable to show jaw positions: no procedure or beam	Contact Accuray Customer Support.
66	Error finding plan to update couch setup position: {v}	Contact Accuray Customer Support.
67	Error uploading settings file to server: {v}	Restart the system. If error persists, contact Accuray Customer Support.
68	Error writing settings file: {v}	Contact Accuray Customer Support.
69	Error retrieving settings from server: {v}	Restart the system. If error persists, contact Accuray Customer Support.
70	The {v} cannot communication with the machine. The system will shut down. If the problem persists please contact service.	Restart the system. If error persists, contact Accuray Customer Support.
71	The {v} encountered an error processing real time machine data. The system will shut down. If the problem persists please contact service.	Restart the system. If error persists, contact Accuray Customer Support.
75	Error displaying machine fault dialog	Contact Accuray Customer Support.
76	Error starting real time data connection	Restart the system. If error persists, contact Accuray Customer Support.
77	Serious problem occurred loading data for registration.	Restart the system. If error persists, contact Accuray Customer Support.

ID	Text	Recommended Action
78	Serious problem occurred approving the registration.	Contact Accuray Customer Support.
79	Error initializing network connections	Restart the system. If error persists, contact Accuray Customer Support.
80	Unexpected IOException thrown when manipulating prior instance socket ports.	Restart the system. If error persists, contact Accuray Customer Support.
81	Serious problem occurred initializing {v}.	Restart the system. If error persists, contact Accuray Customer Support.
82	Serious problem occurred printing registration adjustments.	Contact Accuray Customer Support.
83	Unexpected error handling activity action.	Restart the system. If error persists, contact Accuray Customer Support.
84	A serious error occurred painting the sinogram	Contact Accuray Customer Support.
85	Unexpected error creating calibration definition panels.	Contact Accuray Customer Support.
86	Fatal error mapping procedure values to underlying model: {v}	Contact Accuray Customer Support.
87	Fatal error mapping procedure values to underlying model:	Contact Accuray Customer Support.
88	Fatal error mapping procedure values to underlying model:	Contact Accuray Customer Support.
89	Unexpected error configuring context menu.	Contact Accuray Customer Support.
90	Unexpected error handling context menu action.	Contact Accuray Customer Support.
91	Unexpected error validating data.	Contact Accuray Customer Support.
92	An error has been detected.	Contact Accuray Customer Support.
93	Unable to process the selected image.	Contact Accuray Customer Support.
94	Error in printing setup notes.	Contact Accuray Customer Support.
95	Error accessing previous setup notes.	Contact Accuray Customer Support.

ID	Text	Recommended Action
96	Error saving setup notes file.	Contact Accuray Customer Support.
N/A	A fraction (%s) has already been delivered today. You have selected to deliver fraction %s. Would you like to continue with this fraction?	Confirm whether or not you intend to deliver two fractions of treatment to the same patient on the same day before proceeding.
N/A	A fraction has already been delivered today. The last treatment delivered today (%s) was interrupted, and the next expected treatment is the makeup fraction (%s). You have selected %s. Would you like to continue with this fraction?	Confirm whether or not you intend to deliver two fractions of treatment to the same patient on the same day before proceeding.
N/A	A patient fraction has already been delivered today under plan %s. Would you like to continue with this fraction?	Confirm whether or not you intend to deliver two fractions of treatment to the same patient on the same day before proceeding.
N/A	A fraction has already been delivered today. Would you like to continue with this %s?	Confirm whether or not you intend to deliver two fractions of treatment to the same patient on the same day before proceeding.

PCP Error & Warning Messages

The following table lists all error and warning messages displayed on the Positioning Control Panel (PCP). If you encounter a message described in this table, perform the recommended action shown.

Contact Accuray Customer Support if an error persists, or if you have any concerns or questions about the function of your system.

Text	Recommended Action
Procedure interrupted. Please return to the Operator Station to continue.	Return to the workstation and follow the system prompts.
The system is shutting down...	Restart the system.
Connection with main server interrupted. Waiting to retry...	Restart the system.
COMM FAILURE: STC protocol version incompatible	Contact Accuray Customer Support.
Could not establish connection with main server.	Restart the system. If error persists, contact Accuray Customer Support.
Linux sockets initialization failed.	Contact Accuray Customer Support.
The couch is not at the expected Setup position. Approval may result in serious misadministration. Approve the current treatment position? WARNING: Continuing this procedure may result in mistreatment.	If you do not want the couch at the current position, move the couch back to the Setup position. If you do want the couch at the current position and the Approve check box is present, select the Approve check box and continue. If you do want the couch at the current position and the Approve check box is not present, restart the procedure.
The couch is not at the expected position. Adjust the couch manually or use the Setup button before clicking the Ready button.	Click Cancel to return to the Main tab. Click Setup to move the couch into the Expected position.
The couch is not at the expected Setup position. Adjust the couch manually or use the Setup button before clicking the Ready button.	Adjust the couch manually or use the Setup button before clicking the Ready button.
The couch is currently below the bore. Raise the couch <z> mm for clearance.	Raise the couch <z> mm for clearance.
The requested Y ready position is not reachable.	Adjust the couch manually in the Y direction.

Text	Recommended Action
There is not enough room in the Y axis to complete the procedure.	Use position of the couch.
There is yaw present between the W and X axis. Correct via jog or step move.	Adjust the couch using the Couch Control Keypad or the Step Move buttons on the PCP.
The Y axis must be past <y> mm in order to proceed.	Adjust the couch in the Y direction.
The X axis missed the requested position <x> mm.	Look for any objects that are obstructing the movement of the couch. If the error persists, Contact Accuray Customer Support.
The Y axis missed the requested position <y> mm.	Look for any objects that are obstructing the movement of the couch. If the error persists, Contact Accuray Customer Support.
The Z axis missed the requested position <z> mm.	Look for any objects that are obstructing the movement of the couch. If the error persists, Contact Accuray Customer Support.
The requested step move to <x> mm, on the X axis, is not reachable.	Adjust the couch in the X direction.
The requested step move to <y> mm, on the Y axis, is not reachable.	Adjust the couch in the Y direction.
The requested step move to <z> mm, on the Z axis, is not reachable. There is no room to correct the Y axis.	Adjust the couch in the Z direction.
The requested step move to <z> mm, on the Z axis, is not reachable. The Y correction would collide with the bore.	Adjust the couch in the Z direction.
WARNING: Please verify the current couch position (shown above) before continuing. It has changed since this dialog appeared.	Verify the current couch position matches the expected position. If it does not, move the couch to the expected position.

Radixact[™]





DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

eConsult Cover Sheet

Consult Number: CON1823947 and CON1823948

Document Number: K182687

Applicant: Accuracy Incorporated

Trade Name: Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System

Consult Type: Electromagnetic Compatibility

Requestor: Nancy Wersto [NGW]

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Requestor Home: CDRH\ OIR\ DRH\ NMRT

Requested Consultant: Amarjeet Bhullar [AMARJEET.BHULLAR]

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Gatekeeper / Consultant: Amarjeet Bhullar [AMARJEET.BHULLAR]

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Consultant Home: CDRH\ OIR\ DRH\ NMRT

Date Requested: October 2, 2018

Due Date: November 1, 2018

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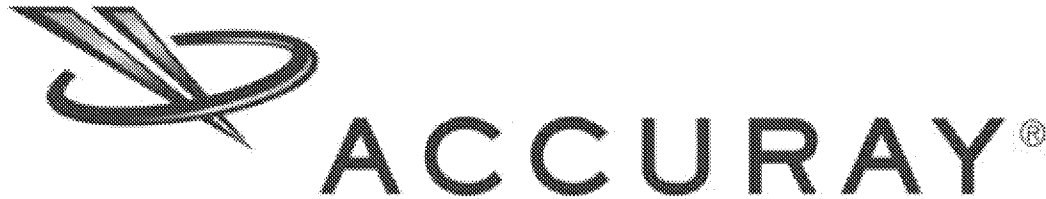
Appendix K

Section 35: Requirements Traceability Matrices

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**Treatment Delivery System
Motion Tracking and Compensation Feature SyRS
Verification As Run Traceability Matrix**

Release: (b)(4)

Doc Revision: (b)(4)

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Treatment Delivery System Motion Tracking and Compensation Feature URS Validation As Run Traceability Matrix

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Indications for Use

510(k) Number (if known)

Device Name

Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System

Indications for Use (Describe)

The Motion Tracking and Compensation Feature is an option within the indications for use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is indicated for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 23 Performance Testing - Clinical

Clinical testing of the Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System is not required for the following reasons:

(b)(4)

Publication References (A copy of the following publications are provided in Appendix W):

1. Q. Wen et al., "The Value of CBCT-based Tumor Density and Volume Variations in Prediction of Early Response to Chemoradiation Therapy in Advanced NSCLC," Scientific Reports 7: 14650, 1-10
2. A. Suryanto, et al., "Comparison of Tumor Density by CT Scan Based on Histologic Type in Lung Cancer Patients," Acta Medica Indonesiana – Indonesian Journal of Internal Medicine 37 (2005) 195-8
3. J. Peterson et al., "Stereotactic Body Radiotherapy for Large (> 5 cm) Non-Small-Cell Lung Cancer," Clinical Lung Cancer 18 (2017) 396
4. Z. Alibhai et al., "The Impact of Tumor Size on Outcomes After Stereotactic Body Radiation Therapy for Medically Inoperable Early-Stage Non-Small Cell Lung Cancer," International Journal of Radiation Oncology – Biology || Physics 87 (2013) 1064
5. Seppenwoolde et al., "Precise And Real-Time Measurement Of 3d Tumor Motion In Lung Due To Breathing And Heartbeat, Measured During Radiotherapy," International Journal of Radiation Oncology – Biology || Physics 53 (2002) 822
6. T. Zhao, et al., "Characterization of free breathing patterns with 5D lung motion model," Medical Physics: The International Journal of Medical Physics Research and Practice 36 (2009) 5183
7. K. Kitamura et al., "Three-Dimensional Intrafractional Movement Of Prostate Measured During Real-Time Tumor-Tracking Radiotherapy In Supine And Prone Treatment Positions," International Journal of Radiation Oncology – Biology || Physics 53 (2002) 1117

Publication References [continued]:

8. T.R. Willoughby et al., “Target Localization And Real-Time Tracking Using The Calypso 4D Localization System In Patients With Localized Prostate Cancer,” International Journal of Radiation Oncology – Biology || Physics 65 (2006) 528
9. C-Y Huang et al., “Six Degrees-of-Freedom Prostate and Lung Tumor Motion Measurements Using Kilovoltage Intrafraction Monitoring,” International Journal of Radiation Oncology – Biology || Physics 91 (2015) 368-75
10. Q Shang et al., “Prostate rotation detected from implanted markers can affect dose coverage and cannot be simply dismissed,” Journal of Applied Clinical Medical Physics, Volume 14 (2013) 177-91



U.S. FOOD & DRUG
ADMINISTRATION

Build Correspondence

Convert to PDF

Accuray Incorporated
% Keith Picker
Senior Regulatory Affairs Specialist
1240 Deming Way
MADISON WI 53717

Re: K182687

Trade/Device Name: Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System

Regulation Number: 21 CFR 892.5050

Regulation Name: Medical charged-particle radiation therapy system

Regulatory Class: Class II

Product Code: IYE

Dated: September 25, 2018

Received: September 26, 2018

Dear Mr. Picker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Appendix F

Section 30: Software Design Description

Accuray Incorporated

Item Number: (b)(4)

Revision: (b)(4)

Description: ECS Delivery Interface Software Unit



(b)(4)

Embedded Control Subsystem Delivery Interface Software Unit Software Design Document

Release (b)(4)

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Accuray Incorporated

File Name: (b)(4)

Page 1 of 21

(b)(4)



(b)(4)

Embedded Control Subsystem

(b)(4)

Software Design Document

Release: (b)(4)

Doc Revision: (b)(4)

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Release: (b)(4)

Page 1 of 20

(b)(4) Rev (b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Accuray Incorporated

Item Number: (b)(4)

Revision: (b)(4)

Description: (b)(4)



(b)(4)

Embedded Control Subsystem Multi-Leaf Collimator Software Unit Software Design Document

Release: (b)(4)

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Section 24 Cybersecurity for the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature

The Motion Tracking and Compensation Feature was reviewed for any new cybersecurity risks introduced to the predicate Radixact Treatment Delivery System in accordance with the FDA guidance document entitled “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”, issued on October 2, 2014.

It was concluded that there are no new Cybersecurity risks introduced with the addition of the Motion Tracking and Compensation Feature as this new feature does not present any new external interfaces to the predicate Radixact Treatment Delivery System cleared on K161146. Therefore, no new cybersecurity controls are required for the addition of the Motion Tracking and Compensation Feature to the Radixact Treatment Delivery System.



Food and Drug Administration
CDRH/OIR/DRH/NMRT
WO66 RM4216
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6548

Premarket Notification 510(k) Review

Date: November 20, 2018			
Reviewer: Nancy Wersto			
Subject: Traditional 510(k)# K182687			
Applicant: Accuray Incorporated		Device Trade Name: Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System	
Contact Name: Keith Picker		Contact Title: Senior Regulatory Affairs Specialist	
Correspondent Firm: Accuray Incorporated		Phone: (608) 824-3069 Email: kpicker@accuray.com	
Received Date: September 26, 2018		Due Date: December 25, 2018	
Pro Code(s): IYE Class: II Reg #: 892.5050		Reg Name: Medical Charged-Particle Radiation Therapy System	
Predicate Devices:			
Submission #	Pro Code	Device Trade Name	Applicant
K161146	IYE	Radixact Treatment Delivery System	Accuray Incorporated

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter Accuray Incorporated		2. Date of the Application/Submission Which This Certification Accompanies 09/25/2018	
3. Address Address 1 (Street address, P.O. box, company name c/o) 1240 Deming Way Address 2 (Apartment, suite, unit, building, floor, etc.) City Madison State/Province/Region Wisconsin Country USA ZIP or Postal Code 53717		4. Telephone and Fax Numbers (Include country code if applicable and area code) (Tel): 608-824-3069 (Fax): 608-830-3778	

PRODUCT INFORMATION

5. For Drugs/Biologics: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

Common or Classification Name Radiation Therapy System
Trade or Proprietary Name Motion Compensation and Tracking Feature for the Radixact Treatment Delivery System

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number
(If number previously assigned)

If BLA was selected in Item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes (See instructions for additional information and explanation)

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

CERTIFICATION STATEMENT / INFORMATION (Continued)

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(j)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. (Add continuation page as necessary.)

NCT Number(s): _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Keith Picker	Senior Regulatory Affairs Specialist

12. Address

Address 1 (Street address, P.O. box, company name c/o)
1248 Deming Way

Address 2 (Apartment, suite, unit, building, floor, etc.)

City	State/Province/Region
Madison	Wisconsin

Country	ZIP or Postal Code
USA	53717

13. Telephone and Fax Numbers

(Include country code if applicable and area code)

(Tel): 608-824-3069

(Fax): 608-830-3778

14. Date of Certification

09/25/2018

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative (Sign)

Sign

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

*****DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*****

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

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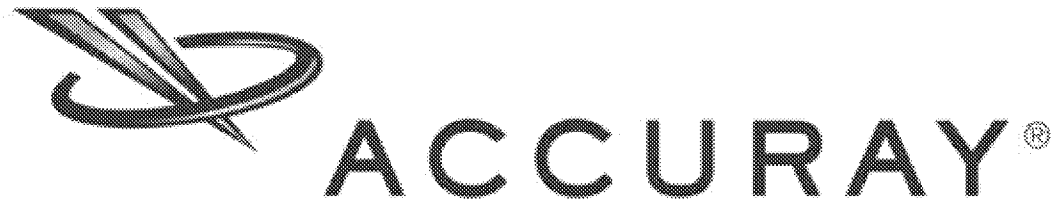
Appendix L

Section 36: Verification Test Plan

Accuray Incorporated

(b)(4) Rev (b)(4)

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Treatment Delivery System Motion Tracking and Compensation Feature Verification Test Plan

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Appendix R

Section 42: Unit Test Cases

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Unit test cases for the MLC portion of the **(b)(4)**

Version: **(b)(4)**

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Unit test cases for the MLC portion of the (b)(4)

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Unit test cases for SOUP third party requirements

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Section 9 Truthful and Accuracy Statement

I certify that, in my capacity as Vice President of Regulatory Affairs for Accuray Incorporated, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)

Daniel Biank
September 25, 2018



Food and Drug Administration
CDRH/OIR/DRH/NMRT
WO66 RM4216
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6548

Premarket Notification 510(k) Review

Date: November 20, 2018

Reviewer: Nancy Wersto

Subject: Traditional 510(k)# K182687

Applicant: Accuray Incorporated

Contact Name: Keith Picker

Correspondent Firm: Accuray Incorporated

Received Date: September 26, 2018

Pro Code(s): IYE **Class:** II **Reg #:** 892.5050

Device Trade Name: Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System

Contact Title: Senior Regulatory Affairs Specialist

Phone: (608) 824-3069 **Email:** kpicker@accuray.com

Due Date: December 25, 2018

Reg Name: Medical Charged-Particle Radiation Therapy System

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K161146	IYE	Radixact Treatment Delivery System	Accuray Incorporated

Recommendation

I recommend that the Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System is/are **Substantially Equivalent (SESE)**

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Digital Signature Concurrence Table (Doc ID: 04500.12.19)

This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.

Reviewer Sign-Off

November 20, 2018

Nancy G. Wersto -S

2018.11.20

19:23:16 -05'00'

Appendix Q

Section 41: Unit Test Report

ACCURAY INC.

Item Number: (b)(4)

Page 1 of 13

Revision: (b)(4)

(b)(4)

Description: (b)(4)



(b)(4)

MOTION TRACKING COMPENSATION EMBEDDED CONTROL SOFTWARE UNIT TEST REPORT

VERSION (b)(4)

Accuray Confidential

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APPROVALS

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

CONSULT REVIEW

Date: November 5, 2018

To: Nancy Wersto
Division of Radiological Health (DRH)
Office of *In Vitro* Diagnostics and Radiological Health (OIR)

From: Jin Zhang, Ph.D.
Division of Radiological Health (DRH)
Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Subject: K182687 – Motion Tracking and Compensation Feature for Radixact Treatment Delivery System (Tomotherapy)

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November 23, 2018</br></br><p>We have completed our review. Please refer to the attached letter for details.</p>

<p>If you have any questions, please contact the lead reviewer assigned to your submission, Nancy Wersto.</p>

<p>*** This is a system-generated email notification ***</p>

Appendix B

Section 26: System Architecture Description

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Section 22 Performance Testing - Animal

This section is not applicable. No performance testing utilizing animals were required or conducted to support this 510(k) premarket notification.

Section 16 Proposed Labeling

The proposed user manual and product labeling for the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature are provided in Appendix A. The documents included in this Appendix are:

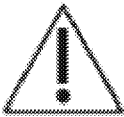
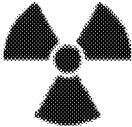
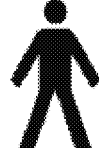
- Radixact Treatment Delivery Manual (1064003)
The instructions for use of the Motion Tracking and Compensation Feature are found in the following sections of the Radixact Treatment Delivery Manual:
 - Section 1-3: reference the subheading entitled “Motion Tracking Components”
 - Section 2-3: reference the content under the following bullet points
 - Pause and Resume Treatment
 - Common Motion Tracking Features
 - Fiducial Tracking
 - Synchrony® Respiratory Tracking
 - Xsight® Lung Tracking
 - Section 3-3: reference the subheadings entitled:
 - Setup Synchrony Components
 - Perform a Motion Tracking Treatment
- Motion Tracking and Compensation Feature Brochure (b)(4)

There are no user serviceable parts in the Radixact Treatment Delivery System.

The Radixact Treatment Delivery System qualifies for exemption per 21 CFR 801 Subpart D.

The Motion Tracking and Compensation Feature does not carry a separate label, but is an option for use on the Radixact Treatment Delivery System. For reference, an example of the Radixact Treatment Delivery System label is shown below:

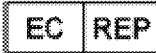
Radixact™ Treatment Delivery System

REF	1080200	  
SN	XXXX	
	YYYY-MM-DD	

Manufactured: MONTH YEAR

 380 /400 /415 /440 /460 /480 VAC, 3~, 60Hz
76.3/72.5/69.9/65.9/63.0/60.4 A

 Accuray Incorporated
1310 Chesapeake Terrace
Sunnyvale, California 94089
USA

 Accuray International Sarl
Route de la Longeraie, 9
1110 Morges Switzerland

Manufacturing Facility:
Accuray Incorporated
1209 Deming Way
Madison, Wisconsin 53717
USA



(01)00811376030009(11)
180711(21)4010063

Protected by U.S. and International patents, and patents pending. Label PN 2-540-00005

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
 OMB No. 0910-0120
 Expiration Date: June 30, 2020
 See PRA Statement on page 5.

Date of Submission September 25, 2018	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)

SECTION A TYPE OF SUBMISSION

PMA ☐ Original Submission ☐ Premarket Report ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment ☐ Licensing Agreement	PMA & HDE Supplement ☐ Regular (180 day) ☐ Special ☐ Panel Track (PMA Only) ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA & HDE Supplement ☐ Other	PDP ☐ Original PDP ☐ Notice of Completion ☐ Amendment to PDP	510(k) ☒ Original Submission: ☒ Traditional ☐ Special ☐ Abbreviated (Complete section I, Page 5) ☐ Additional Information ☐ Third Party	Request for Feedback ☐ Pre-Submission ☐ Informational Meeting ☐ Submission Issue Meeting ☐ Day 100 Meeting ☐ Agreement Meeting ☐ Determination Meeting ☐ Study Risk Determination ☐ Other (specify):
IDE ☐ Original Submission ☐ Amendment ☐ Supplement	Humanitarian Device Exemption (HDE) ☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment	Class II Exemption Petition ☐ Original Submission ☐ Additional Information	Evaluation of Automatic Class III Designation (De Novo) ☐ Original Submission ☐ Additional Information	Other Submission ☐ 513(g) ☐ Other (describe submission):

Have you used or cited Standards in your submission? ☐ Yes ☐ No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Accuray Incorporated		Establishment Registration Number (if known) 3009813196	
Division Name (if applicable)		Phone Number (including area code) 608-824-3069	
Street Address 1240 Deming Way		FAX Number (including area code) 608-830-3778	
City Madison	State / Province Wisconsin	ZIP/Postal Code 53717	Country USA
Contact Name Keith Picker			
Contact Title Senior Regulatory Affairs Specialist		Contact E-mail Address kpicker@accuray.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1	REASON FOR APPLICATION - PMA, PDP, OR HDE

☐ New Device ☐ Withdrawal ☐ Additional or Expanded Indications ☐ Request for Extension ☐ Post-approval Study Protocol ☐ Request for Applicant Hold ☐ Request for Removal of Applicant Hold ☐ Request to Remove or Add Manufacturing Site	☐ Change in design, component, or specification: ☐ Software / Hardware ☐ Color Additive ☐ Material ☐ Specifications ☐ Other (specify below)	☐ Location change: ☐ Manufacturer ☐ Sterilizer ☐ Packager
☐ Process change: ☐ Manufacturing ☐ Packaging ☐ Sterilization ☐ Other (specify below)	☐ Labeling change: ☐ Indications ☐ Instructions ☐ Performance Characteristics ☐ Shelf Life ☐ Trade Name ☐ Other (specify below)	☐ Report Submission: ☐ Annual or Periodic ☐ Post-approval Study ☐ Adverse Reaction ☐ Device Defect ☐ Amendment
☐ Response to FDA correspondence:	☐ Change in Ownership ☐ Change in Correspondent ☐ Change of Applicant Address	

☐ Other Reason (specify):

SECTION D2	REASON FOR APPLICATION - IDE

☐ New Device ☐ New Indication ☐ Addition of Institution ☐ Expansion / Extension of Study ☐ IRB Certification ☐ Termination of Study ☐ Withdrawal of Application ☐ Unanticipated Adverse Effect ☐ Notification of Emergency Use ☐ Compassionate Use Request ☐ Treatment IDE ☐ Continued Access	☐ Change in: ☐ Correspondent / Applicant ☐ Design / Device ☐ Informed Consent ☐ Manufacturer ☐ Manufacturing Process ☐ Protocol - Feasibility ☐ Protocol - Other ☐ Sponsor	☐ Response to FDA Letter Concerning: ☐ Conditional Approval ☐ Deemed Approved ☐ Deficient Final Report ☐ Deficient Progress Report ☐ Deficient Investigator Report ☐ Disapproval ☐ Request Extension of Time to Respond to FDA ☐ Request Meeting ☐ Request Hearing
☐ Report submission: ☐ Current Investigator ☐ Annual Progress Report ☐ Site Waiver Report ☐ Final		

☐ Other Reason (specify):

SECTION D3	REASON FOR SUBMISSION - 510(k)

☐ New Device	☐ Additional or Expanded Indications	☒ Change in Technology
☐ Other Reason (specify):		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	IYE	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- ☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K161146	1	Radixact Treatment Delivery System	1	Accuray Incorporated
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Radiation Therapy

	Trade or Proprietary or Model Name for This Device		Model Number
1	Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System	1	1080200 (Radixact with Motion Tracking Feature)
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing☐ Animal Trials☐ Human Trials**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code IYE	C.F.R. Section (if applicable) 892.5050	Device Class ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification Panel Radiology		

Indications (from labeling)

The Radixact Treatment Delivery System is indicated for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner.

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number 3003873069	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name Accuray Incorporated		Establishment Registration Number 3003873069	
Division Name (if applicable)		Phone Number (including area code) 608-824-3609	
Street Address 1209 Deming Way		FAX Number (including area code) 608-830-3778	
City Madison		State / Province Wisconsin	ZIP Code 53717
		Country USA	
Contact Name Keith Picker	Contact Title Senior Regulatory Affairs Specialist	Contact E-mail Address kpicker@accuray.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City		State / Province	ZIP Code
		Country	
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City		State / Province	ZIP Code
		Country	
Contact Name	Contact Title	Contact E-mail Address	

SECTION I**UTILIZATION OF STANDARDS**

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

1	Standards No. ES60601-1	Standards Organization ANSI/AAMI	Standards Title Medical Electrical Equipment - Part 1: General Requirements For Basic Safety and Essential Performance (IEC 60601-1:2005 MOD)	Version 2005/(R)2012	Date 2005/(R)2012
2	Standards No. 60601-1-2	Standards Organization IEC	Standards Title Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	Version Edition 3	Date 03/01/2007
3	Standards No. 60601-2-1	Standards Organization IEC	Standards Title Medical Electrical Equipment - Part 2-1: Particular Requirements For The Basic Safety and Essential Performance of Electron Accelerators In The Range 1 MeV to 50 MeV	Version Edition 3.1	Date 07/01/2014
4	Standards No. 60601-1-3	Standards Organization IEC	Standards Title Medical Electrical Equipment - Part 1-3: General Requirements For Basic Safety and Essential Performance - Collateral Standard: Radiation Protection in Diagnostic X-ray Equipment	Version Edition 2.1	Date 04/19/2013
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Section 10 **Class III Summary and Certification**

This section is not applicable. The Motion Tracking and Compensation Feature for use on the Radixact Treatment Delivery System is a Class II medical device.

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Appendix W

Section 47: Clinical Testing Publications

Clinical Investigation: Thoracic Cancer

The Impact of Tumor Size on Outcomes After Stereotactic Body Radiation Therapy for Medically Inoperable Early-Stage Non-Small Cell Lung Cancer

Zishan Allibhai, MD,* Mojgan Taremi, MD,[†] Andrea Bezjak, MD, MSc,* Anthony Brade, MD, PhD,* Andrew J. Hope, MD,* Alexander Sun, MD,* and B.C. John Cho, MD, PhD*

*Department of Radiation Oncology, Princess Margaret Cancer Centre, Toronto, Canada; and [†]Department of Radiation Oncology, Stronach Regional Cancer Centre, Newmarket, Canada

Received Mar 25, 2013, and in revised form Jun 27, 2013. Accepted for publication Aug 18, 2013.

Summary

Few published data exist regarding stereotactic body radiation therapy (SBRT) for early-stage non-small cell lung cancer with large solitary primaries. We review our single-institution experience to examine the effect of tumor size on outcomes, showing that SBRT provides effective local control even for large tumors with low rates of clinically significant radiation pneumonitis. Larger tumors have higher rates of nonlocal failure and poorer survival. SBRT provides safe, effective local therapy in this patient population.

Purpose: Stereotactic body radiation therapy for medically inoperable early-stage non-small cell lung cancer (NSCLC) offers excellent control rates. Most published series deal mainly with small (usually <4 cm), peripheral, solitary tumors. Larger tumors are associated with poorer outcomes (ie, lower control rates, higher toxicity) when treated with conventional RT. It is unclear whether SBRT is sufficiently potent to control these larger tumors. We therefore evaluated and examined the influence of tumor size on treatment outcomes after SBRT.

Methods and Materials: Between October 2004 and October 2010, 185 medically inoperable patients with early (T1-T2N0M0) NSCLC were treated on a prospective research ethics board-approved single-institution protocol. Prescription doses were risk-adapted based on tumor size and location. Follow-up included prospective assessment of toxicity (as per Common Terminology Criteria for Adverse Events, version 3.0) and serial computed tomography scans. Patterns of failure, toxicity, and survival outcomes were calculated using Kaplan-Meier method, and the significance of tumor size (diameter, volume) with respect to patient, treatment, and tumor factors was tested.

Results: Median follow-up was 15.2 months. Tumor size was not associated with local failure but was associated with regional failure ($P = .011$) and distant failure ($P = .021$). Poorer overall survival ($P = .001$), disease-free survival ($P = .001$), and cause-specific survival ($P = .005$) were also significantly associated with tumor size (with tumor volume more significant than diameter). Gross tumor volume and planning target volume were significantly associated with grade 2 or worse radiation pneumonitis. However, overall rates of grade ≥ 3 pneumonitis were low and not significantly affected by tumor or target size.

Conclusions: Currently employed stereotactic body radiation therapy dose regimens can provide safe effective local therapy even for larger solitary NSCLC tumors (up to 5.7 cm in tumor diameter).

Reprint requests to: B. C. John Cho, MD, PhD, Department of Radiation Oncology, Princess Margaret Hospital, 610 University Ave, Toronto, Ontario M5G 2M9, Canada. Tel: (416) 946-2124; E-mail: john.cho@rmp.utoronto.ca

This work was partially funded by the Addie MacNaughton Chair in Thoracic Radiation Oncology and by Elekta Oncology Systems.

Conflict of interest: none.

Acknowledgments—We thank Cynthia Torres for her efforts in data collection and other contributions toward our stereotactic body radiation therapy program.

Int J Radiation Oncol Biol Phys, Vol. 87, No. 5, pp. 1064–1070, 2013
0360-3016/\$ - see front matter © 2013 Elsevier Inc. All rights reserved.
<http://dx.doi.org/10.1016/j.ijrobp.2013.08.020>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

or 100 cm³ in tumor volume) but are associated with more nonlocal failures as well as poorer survival. These observations suggest these patients may benefit from more extensive staging or consideration of adjuvant therapy. © 2013 Elsevier Inc.

Introduction

Non-small cell lung cancer (NSCLC) remains the leading cause of cancer death worldwide (1, 2). Approximately 15% to 20% of NSCLC patients present with early or localized disease (1), a figure expected to grow with increased use of low-dose computed tomography (CT) scans (2). Standard therapy for stage I (T1-2 N0 M0) NSCLC is surgical resection, usually lobectomy. Some patients, however, are medically inoperable, often due to significant cardiovascular or pulmonary comorbidities. Stereotactic body radiation therapy (SBRT) is an emerging standard, and its adoption has increased steadily (3) with reported local control rates exceeding 90% in this setting (4-6). There is growing interest in expanding indications of treatment to broader cases such as centrally situated tumors near the mediastinum (7) as well as larger tumors.

Most of the published literature pertains to relatively small primary tumors (4, 5, 8, 9) (usually ≤ 4 cm). Larger tumors were often explicitly excluded. In studies in which larger tumors were allowed (up to 6 cm), they represented only a minority of cases (10). Larger tumors treated with conventional RT regimens are at greater risk for not just local but regional and distant failures as well as toxicity due to larger irradiated volumes (9, 11, 12). It is, however, still unknown whether the SBRT fractionation regimens currently in use are sufficiently tumoricidal for these larger tumors (13) and whether a size threshold exists beyond which local control becomes compromised.

We reviewed our single-institution experience treating medically inoperable early stage NSCLC using SBRT to examine the impact of tumor size (ie, tumor diameter and volume) on failures, survival, and toxicity to test our hypothesis that larger tumors have poorer outcomes compared to smaller tumors.

Methods and Materials

Patient selection

Between October 2004 and October 2010, 185 early-stage (T1-2N0M0) NSCLC patients were treated with SBRT on a prospective research ethics board-approved single-institution protocol. All patients were deemed medically inoperable by an experienced thoracic surgeon (usually secondary to cardiopulmonary comorbidities) and underwent standard staging investigations including CT chest, F18-fluorodeoxyglucose positron emission tomography (18-FDG-PET), and gadolinium-enhanced magnetic resonance imaging scan of the brain. Selected patients underwent endobronchial ultrasound-guided biopsy of their mediastinal lymph nodes as part of their staging workup.

Treatment details

Our lung SBRT treatment process has been previously described (6, 14). In brief, patients were simulated while free breathing and immobilized (15) using 4-dimensional respiratory-correlated computed tomography scans. Gross tumor volume (GTV) was contoured on both the end exhale and end inhale phases of tidal respiration on the treatment planning system (Pinnacle³, version 9.0, Philips, Fitchburg, WI, USA) using standard window and level settings (1600 and -300 HU, respectively). Positron emission tomography data were also reviewed during GTV contouring. The clinical target volume (CTV) was defined as GTV with no expansion for microscopic clinical margin (CTV = GTV + 0 cm). The internal target volume (ITV) was defined as the inhale and exhale CTVs fused together with adjustments, as necessary,

Table 1 Clinical and tumor characteristics for all early-stage non-small cell lung cancer patients treated with stereotactic body radiation therapy

	T1	T2+	Total
N	133	52	185
Sex, female:male	68:65	25:27	92:93
Age, median (eldest) y	76.5 (89.8)	76.2 (90.7)	74.8
PS, median (range)	1 (0-3)	1 (0-3)	1
Predicted FEV1 (mean) %	66	68	66.3
Predicted DLCO (mean) %	51	60	59.3
Biopsy proven %	81.2	84.0	81.7
PET %	88.7	84.0	88.1
Invasive nodal staging %	8.8	20	10.3
Follow-up (median) mo	17.4	14.2	15.2
GTD (range) cm	0.6-3.0	3.1-5.7	2.2 (0.6-5.7)
GTV (range) cm ³	4.0 (0.6-67.1)	22.6 (8.1-98.9)	5.0 (0.6-98.9)
PTV (range) cm ³	24.6 (7.2-148.4)	72.3 (33.3-223.0)	27.9 (1.3-223.0)
V20 (range) %	3.5 (1.0-14.5)	8.0 (3.1-16.3)	4.8 (1.0-16.3)
MLD (range) Gy	3.72 (0.71-9.70)	6.51 (3.94-10.14)	4.50 (0.71-10.14)

Abbreviations: DL_{CO} = diffusing capacity for carbon monoxide; FEV₁ = forced expiratory volume in one second; GTD = gross tumor diameter; GTV = gross tumor volume; PET = positron emission tomography; PS = Eastern Cooperative Oncology Group performance status; PTV = planning target volume.

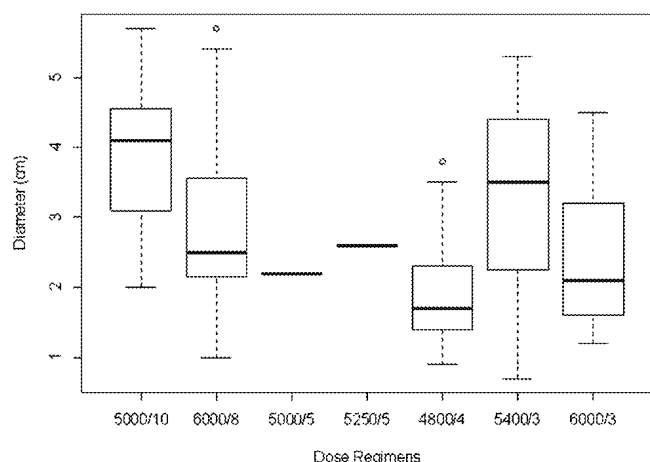


Fig. 1. Boxplots of gross tumor diameters for different stereotactic body radiation therapy dose regimens.

based on CT data sets from the maximum intensity projection and “average” projection series. The planning target volume (PTV) was defined as the ITV with a 0.5-cm isotropic setup margin ($PTV = ITV + 0.5 \text{ cm}$). Measurements of maximum gross tumor diameter (GTD), GTV, and PTV were extracted directly from the treatment plan. Previously described planning objectives for the PTV and normal structures were used (6). Originally, 8 to 11 noncoplanar 3-dimensional conformal radiation therapy beams (usually 2 sagittal beams with 15° - 30° couch kicks) underwent inverse planning to generate highly conformal dose distributions. After 2009, patients were treated with volumetric modulated arc therapy when it became clinically available.

Target doses were prescribed to the isodose covering the PTV, with heterogeneity correction. The prescribed dose fractionation was risk-adapted based on tumor size and location. Smaller tumors ($\leq 3 \text{ cm}$) received 48 Gy in 4 fractions over 1.5 weeks. Larger tumors received 54 to 60 Gy in 3 fractions over 1.5 weeks.

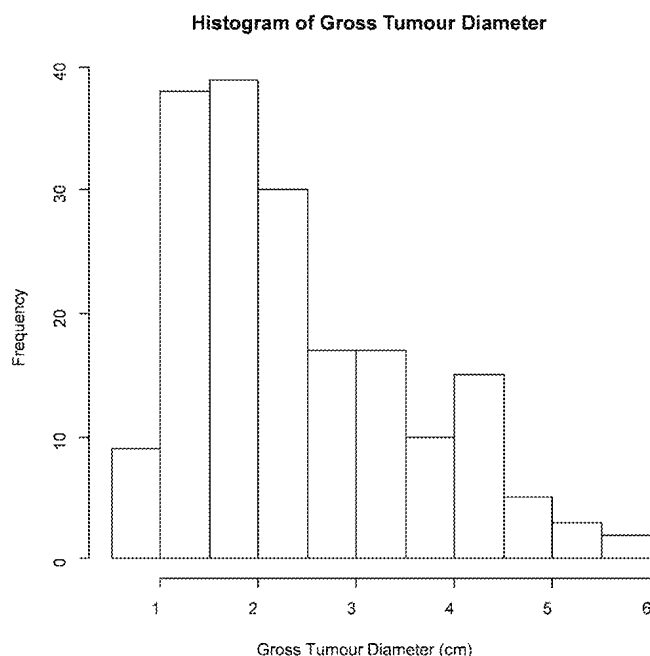
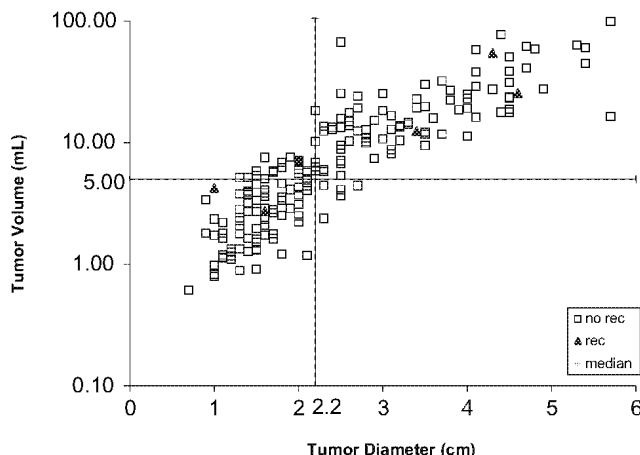


Fig. 2. Histogram of gross tumor diameter.

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(a) Tumor Size and Local Recurrence for All Regimens



(b) Tumor Size and Any Recurrence for All Regimens

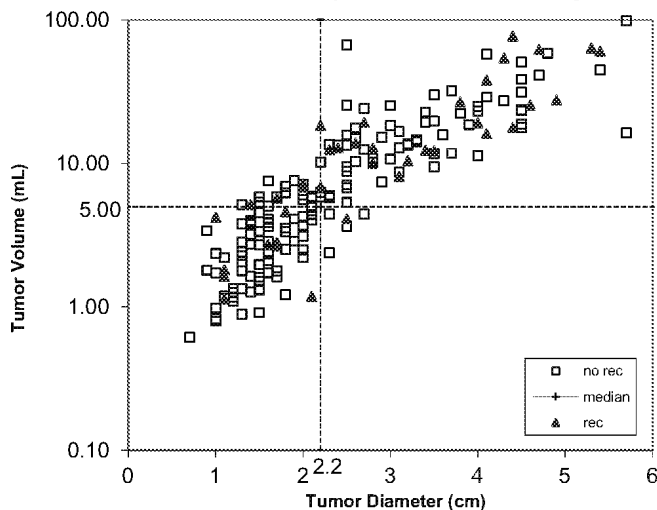


Fig. 3. Scatterplot of tumor size and local (A) and any (B) recurrences for all regimens.

Tumors adjacent ($< 2 \text{ cm}$) to mediastinal structures received 60 Gy in 8 fractions or 50 Gy in 10 daily fractions. All patients were treated on a 6-MV linac-equipped with kV cone beam CT for daily verification of tumor positioning and setup before each fraction. None received concurrent or sequential chemotherapy.

Follow-up

Patients were monitored closely following their treatment: a 6-week visit with chest x-ray, serial CT scans and clinic visits at 3 monthly intervals for the first year, 6 monthly intervals for the second year, and annually thereafter if well or more often if clinically indicated. Treatment-related toxicity was collected on each visit by a dedicated research associate and graded prospectively using Common Terminology Criteria for Adverse Events, version 3.0 (16) criteria. Local failures were defined by consensus after discussion and review of the radiologic imaging at our weekly quality assurance rounds or multidisciplinary conference. Further investigations, including repeat 18-FDG-PET-CT and/or biopsy, were ordered accordingly.

Table 2 Cox proportional hazard modeling for patterns of failure

Parameter	LRFS	RRFS	DRFS	NLRFS	DFS	OS	CSS
Dose regimen	0.049	0.722	0.910	0.688	0.366	0.015	0.015
ECOG	0.568	0.719	0.006	0.040	0.172	0.002	0.050
Age	0.290	0.465	0.138	0.078	0.138	0.578	0.032
Sex	0.234	0.636	0.672	0.474	0.557	0.011	0.943
Tumor Diameter	0.108	0.586	0.969	0.894	0.509	0.805	0.873
log(GTV)	0.458	0.038	0.244	0.204	0.105	0.055	0.102
log(PTV)	0.859	0.235	0.725	0.643	0.692	0.183	0.245
T-category	0.191	0.968	0.961	0.863	0.836	0.791	0.831

Abbreviations: CSS = cause specific survival; DFS = disease-free survival; DRFS = distant relapse-free survival; ECOG = Eastern Cooperative Oncology Group; GTV = gross tumor volume; LRFS = local relapse-free survival; NLRFS = nonlocal relapse-free survival; OS = overall survival; PTV = planning target volume; RRFS = regional relapse-free survival; STRAT = stratified. Significant factors are bolded.

Statistical analysis

The alternative hypothesis is that tumor size affects clinical outcomes. The null hypothesis is that tumor size does not influence clinical outcomes. Patterns of failure, toxicity, and survival outcomes were calculated from the start date of SBRT using Kaplan-Meier methods. Prognostic factors known to influence outcomes (age, dose regimen, Eastern Cooperative Oncology Group status, sex, tumor diameter, GTV, PTV, T-category) underwent multivariate analysis using both Cox proportional hazard regression models and a nonparametric recursive partition tree with conditional inference (17). Dose regimens were analyzed as ordered categorical data (ordinals) of increasing biological potency (ie, 50 Gy/10 fractions < 60 Gy/8 fractions < 50 Gy/5 fractions < 52.5 Gy/5 fractions < 48 Gy/4 fractions < 54 Gy/3 fractions < 60 Gy/3 fractions), assuming an alpha-beta ratio of 10 Gy. All statistical analyses were performed using the R statistical analysis software package (version 2.15.0, R Foundation for Statistical Computing, Vienna, Austria). A *P* value ≤.05 was considered statistically significant.

Results

The median follow-up period was 15.2 months (range: 6-76 months). Relevant patient, treatment and tumor characteristics are shown in Table 1. Patient characteristics for smaller (T1) versus larger (T2) tumors were comparable. Treatment characteristics between these groups, however, did differ. T2 tumors were more likely to be treated with lower bioequivalent dose (BED) regimens (ie, 50 Gy/10 fractions and 60 Gy/8 fractions) because of their proximity to dose-constraining mediastinal critical structures. Boxplots of GTD comparing different dose regimens are shown (Fig. 1). The mean GTD for the different dose regimens are significantly different (*P* < .000001).

The median tumor diameter was 2.2 cm (range: 0.6-5.7 cm). The proportion of T1 (≤3 cm) and T2 (>3 cm) patients were 72% (133 patients) and 28% (52 patients), respectively. Whereas 13.5% (25 patients) had GTD ≥ 4 cm, only 2.7% (5 patients) had GTD ≥

5 cm in maximum diameter. The GTD frequency histogram is shown in Figure 2. The median GTV and PTV were 5.0 cm³ and 27.9 cm³, respectively. Log-linear scatterplots between GTD and GTV with failures (local vs any) plotted as solid red triangles are shown in Figure 3A, B.

The results of the multivariate analysis using the Cox model are summarized in Table 2. Among the outcomes of interest, only regional relapse-free survival (RRFS) was associated with tumor size (*P* = .038). Dose regimen, however, was significantly associated with local relapse-free survival (LRFS; *P* = .049), cause-specific survival (CSS) (*P* = .015) and overall survival (OS; *P* = .015), whereas baseline Eastern Cooperative Oncology Group score was associated with distant relapse-free survival (DRFS) (*P* = .006), OS (*P* = .002), and CSS (*P* = .05). OS was also higher for male gender (*P* = .011) while CSS was higher with advanced age (*P* = .032). To better illustrate the risk of failure (local vs any) as a function of tumor size (diameter vs volume), the conditional probabilities are shown in Figure 4A–D. The plots appear consistent with the multivariate findings in that local failure curves are relatively flat, whereas the any failure curves have a negative slope, suggesting a correlation.

Recursive partition tree analysis results are shown in Figure 5. LRFS was worse for patients treated with the 50 Gy/10 fraction regimen (*P* = .033). Although tumor size did not have an impact on LRFS, it was significantly associated with RRFS, DRFS, DFS, CSS, and OS. In particular, GTV >11.79 cm³ was significantly associated with nonlocal RFS, DFS, and CSS (*P* = .004, .001, and .005, respectively).

Patients with T2 tumors had a higher rate of grade ≥2 radiation pneumonitis (RP) than T1 patients (17.9% vs 4.4%, *P* = .02), although there was no difference in high-grade RP, likely owing to the low incidence of events (1.8% rate of grade 3 RP, no grade 4 or 5). Furthermore, when tumor size was analyzed as a continuous variable, there was no correlation with the risk of RP. There was no significant association between the rate of RP and dosimetric values such as V20 and mean lung dose.

Discussion

For conventionally fractionated radiation therapy, the probability of tumor control depends on many factors, including tumor size and radiation dose regimen. All else being equal, larger tumors generally require more potent radiation doses compared with smaller tumors to achieve comparable rates of local control. An initial review of our data uncovered a potentially confounding association between tumor size and SBRT dose regimen, in which larger tumors tended to be located closer to critical dose-limiting organs at risk and were thus treated with less biologically potent SBRT dose regimens (eg, 50 Gy/10 fractions). To account for this and other potentially confounding effects, we undertook 2 separate multivariate analyses: the Cox proportional hazard model and the recursive partition tree analysis (RPA). Although the Cox model is widely used, it assumes proportional (linear) hazards, covariate independence, and covariate normality, which may not necessarily be valid. The RPA, by virtue of fewer model assumptions, can handle continuous, censored, ordered, nominal, multivariate response variables and is able to extract meaningful prognostic groups (17). The RPA was found to be more robust than the Cox analysis in our series.

We hypothesized that larger tumors treated with SBRT would have poorer rates of control and survival compared with smaller

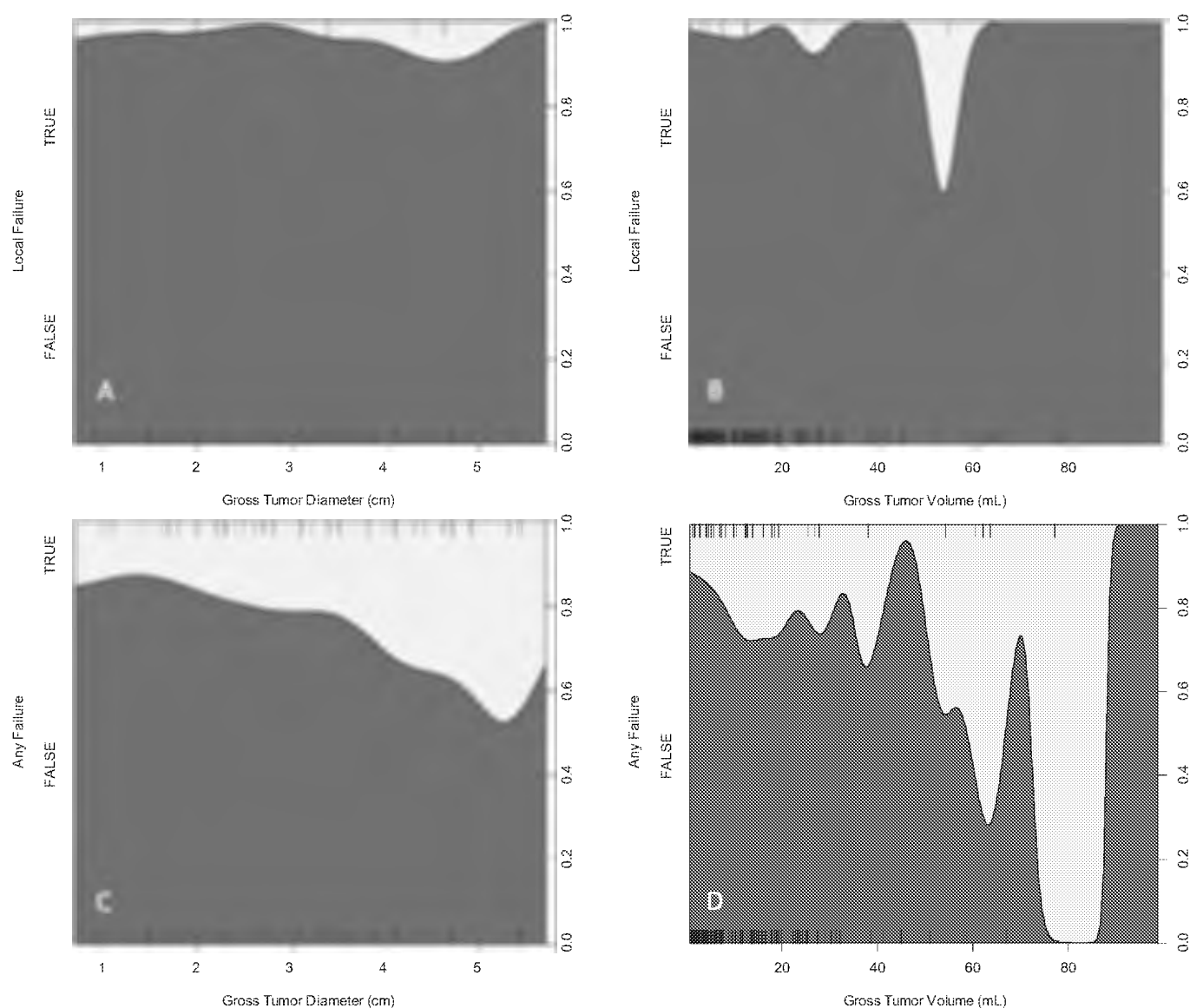


Fig. 4. Conditional probability plots of (A) local failure and gross tumor diameter, (B) local failure and gross tumor volume, (C) any failure and gross tumor diameter, and (D) any failure and gross tumor volume.

tumors. Previous publications characterized tumor size according to maximum GTD and the associated T-category, and these had yielded conflicting results in examining the effect of tumor size on local control (8, 11, 18, 19). Our study, which also includes volumetric analysis, showed that tumor size did not impact on the rate of LRFS. A larger multivariate analysis may be needed to definitively quantify the impact of tumor size on local control.

The only parameter that was significantly associated with LC (in both the Cox and RPA model) was the potency of the dose regimen, whereby LC was inferior for the least potent RT dose (50 Gy/10 fractions). In our series, patients treated with BED <100 Gy had a 16.7% risk of local failure compared with 2.3% for patients treated with BED >100 Gy, suggesting that low BED regimens (<100 Gy) should be avoided because of higher risk for local failure (20).

With the exception of 50 Gy/10 fractions, the SBRT dose regimens used in the modern era appear sufficiently potent and tumoricidal to effect adequate local control for the tumor sizes seen in this group (<6 cm), as evidenced by the overall high rate of local control (94.6%). Because we are already on the flat

plateau of the dose–effect sigmoid curve, additional dose escalation above that used within current regimens will only marginally improve local control.

Our data confirm that nonlocal failure remains the dominant pattern of relapse following SBRT for early-stage NSCLC (3). In the RPA, larger GTV was significantly associated with poorer rates of RRFS, DRFS, nonlocal relapse-free survival, DFS, OS, and CSS. Assuming idealized spherical tumors, the GTV cutpoints for these events correspond to GTDs of 4.8, 2.3, 2.8, 2.8, 2.9, and 2.8 cm, respectively. In particular, GTDs >2.8 cm (ie, approximate size cutoff for T2 tumors) had higher rates of nonlocal relapse in this study. Accordingly, patients with T2 tumors may benefit from more careful and comprehensive assessment to rule out regional and distant disease before initiation of treatment, including staging 18-FDG-PET scan, and pathologic staging of regional nodes with either mediastinoscopy or endobronchial ultrasound. In light of these findings, consideration of systemic therapy may also be warranted where feasible, particularly if SBRT is used in healthier, better-performing patients.

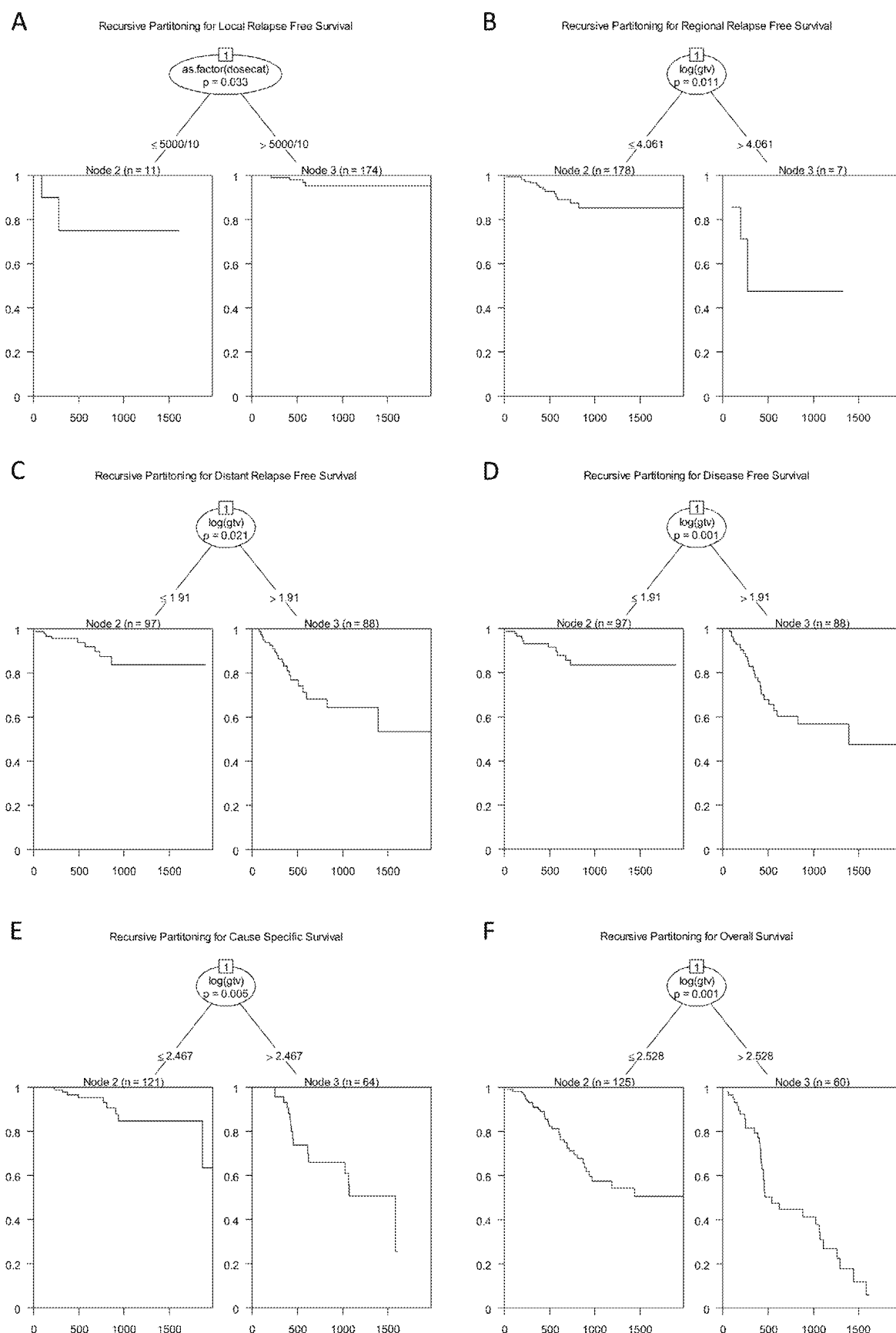


Fig. 5. Recursive partitioning analysis for survival: local relapse free (A), regional relapse free (B), distant relapse free (C), disease free (D), cause specific (E), and overall (F). GTV = gross tumor volume.

In our series, increasing tumor size did not have an impact on rates of clinically significant high-grade RP, and SBRT remains a safe and effective treatment option for patients with large NSCLC primaries. GTV is a more clinically meaningful indicator of tumor size than GTD because it (partially) accounts for the shape of the tumor and is thus more likely to accurately reflect the total number of tumor clonogens. Our series confirmed that tumor volume was more powerful at predicting outcomes (ie, more significant *P* value). Currently, GTV is not commonly referenced in clinical practice and often is not calculated before the radiation therapy planning process. Because modern radiation therapy planning routinely allows calculation of GTV, this metric could be evaluated prospectively as a way to help stratify patients for adjuvant regional or systemic therapy.

Conclusion

Current SBRT dose regimens, such as 48 Gy in 4 fractions, can provide safe effective local therapy even for larger solitary NSCLC tumors (up to 5.7 cm in tumor diameter or up to about 100 cm³ in tumor volume). However, larger tumors are associated with more nonlocal failures as well as poorer survival and higher rates of moderate (grade 2) RP (but not grade 3 RP). These observations suggest these patients may benefit from more extensive staging or consideration of adjuvant therapy.

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CLINICAL INVESTIGATION

Prostate

THREE-DIMENSIONAL INTRAFRACTIONAL MOVEMENT OF PROSTATE MEASURED DURING REAL-TIME TUMOR-TRACKING RADIOTHERAPY IN SUPINE AND PRONE TREATMENT POSITIONS

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Purpose: To quantify three-dimensional (3D) movement of the prostate gland with the patient in the supine and prone positions and to analyze the movement frequency for each treatment position.

Methods and Materials: The real-time tumor-tracking radiotherapy (RTRT) system was developed to identify the 3D position of a 2-mm gold marker implanted in the prostate 30 times/s using two sets of fluoroscopic images. The linear accelerator was triggered to irradiate the tumor only when the gold marker was located within the region of the planned coordinates relative to the isocenter. Ten patients with prostate cancer treated with RTRT were the subjects of this study. The coordinates of the gold marker were recorded every 0.033 s during RTRT in the supine treatment position for 2 min. The patient was then moved to the prone position, and the marker was tracked for 2 min to acquire data regarding movement in this position. Measurements were taken 5 times for each patient (once a week); a total of 50 sets for the 10 patients was analyzed. The raw data from the RTRT system were filtered to reduce system noise, and the amplitude of movement was then calculated. The discrete Fourier transform of the unfiltered data was performed for the frequency analysis of prostate movement.

Results: No apparent difference in movement was found among individuals. The amplitude of 3D movement was 0.1–2.7 mm in the supine and 0.4–24 mm in the prone positions. The amplitude in the supine position was statistically smaller in all directions than that in the prone position ($p < 0.0001$). The amplitude in the craniocaudal and AP directions was larger than in the left–right direction in the prone position ($p < 0.0001$). No characteristic movement frequency was detected in the supine position. The respiratory frequency was detected for all patients regarding movement in the craniocaudal and AP directions in the prone position. The results of the frequency analysis suggest that prostate movement is affected by the respiratory cycle and is influenced by bowel movement in the prone position.

Conclusion: The results of this study have confirmed that internal organ motion is less frequent in the supine position than in the prone position in the treatment of prostate cancer. RTRT would be useful in reducing uncertainty due to the effects of the respiratory cycle, especially in the prone position. © 2002 Elsevier Science Inc.

Prostate, Real-time tracking, Intrafractional motion.

INTRODUCTION

Geometric uncertainties, including setup error and organ motion, throughout the course of radiotherapy (RT) have been suspected of being problematic with regard to the resultant dose delivered (1–12). These uncertainties have been taken into consideration by including a margin around the clinical target volume (CTV) in three-dimensional (3D) conformal RT (3D-CRT). Although interfractional motion of the prostate is usually considered, intrafractional motion is often ignored in 3D-CRT. This approach, however,

should not be applied to intensity-modulated RT (IMRT), which takes significantly longer to obtain a fraction. If intrafractional motion occurs, the composite resultant dose to the CTV can be significantly altered. Therefore, the concern with intrafractional movement has been growing as the use of IMRT has become widespread as standard RT for prostate cancer.

Several methods of measuring prostate movement have been reported (1–12). One possibility is to acquire a number of repeated CT scans for each patient (1–5). Although this

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method allows for easy analysis of exact interfractional movement using the whole prostate volume, it is unsuitable for finding intrafractional continuous motion. Another possibility is other imaging modalities, including ultrasonography (6), MRI (7), and portal imaging (8, 9), to visualize the position of the prostate. These are quick and noninvasive alternatives, but it is difficult to define the origin of prostate motion in the coordinates axes, and more reliable modalities are needed to determine the precise position of the prostate. Third, radiopaque markers can be implanted in the target volume to detect the position of the prostate by portal imaging and fluoroscopy (10–12). This is deemed the most accurate and simplest approach, but additional investigations are required to analyze the exact 3D intrafractional movement in real time. Because these methods have some minor disadvantages in determining the intrafractional movement, they have not been able to provide accurate intrafractional prostate movement (12). Therefore, the issue regarding 3D intrafractional movement of the prostate gland with the patient in the supine vs. the prone position remains controversial.

However, real-time tumor-tracking RT (RTRT) (13–16) with fluoroscopy and insertion of a fiducial marker may be able to indicate which position allows for the best treatment. RTRT makes it possible to analyze organ motion in real time more accurately than any other methods. The purpose of the present study was to quantify the 3D movement of the prostate gland with the patient in the supine and prone positions and to analyze the movement frequency for each treatment position.

METHODS AND MATERIALS

The physical aspects, concept, techniques, and process for the RTRT system have been previously described in detail (13–16). In brief, the process for synchronizing the tracking of a marker with irradiation was as follows. The fluoroscopic RTRT system consists of 4 sets of diagnostic fluoroscopic, image-processor units, a trigger-control unit, an image-display unit, and a conventional linear accelerator with multileaf collimators. Using 2 of the 4 fluoroscopy image-processor units, the system determines the 3D position of the gold marker (2 mm in diameter) 30 times/s using real-time pattern recognition and calibrated projection geometry. To avoid blocking the fluoroscopic images with the gantry of the linear accelerator, any 2 of the 4 X-ray systems can be selected. The linear accelerator is triggered to irradiate the tumor only when the gold marker is located within a specified region of the planned coordinates relative to the isocenter. The process of image acquisition and processing causes a small delay of 0.09 s between marker recognition and the start of irradiation. A correction algorithm definitely predicts the marker position from the speed of the marker movement, compensating for this delay.

Ten patients with prostate cancer treated with forward-planning IMRT using accurate positioning of the real-time system (real-time IMRT) were the subjects of the present

study. The three fiducial markers were implanted into both the lobes and the apex of the prostate gland using a transurethral endoscopic approach. The coordinates of the gold marker implanted in the apex of the prostate were tracked continuously and recorded automatically to the hard disc every 0.033 s during real-time IMRT in the supine treatment position for 2 min. Subsequently, the patient was moved to the prone position, and the marker was tracked for 2 min to acquire movement data while in this position. Patients were not irradiated in the prone position and were not immobilized in either position. Measurements were taken five times for each patient (once a week); a total of 50 sets in the 10 patients was analyzed.

The recorded data were analyzed in terms of the average amplitude, 3D trajectories, and movement frequency. The following data-processing methods have been previously reported in detail (17). The raw data for the RTRT system were filtered with a 30-point median filter to reduce system noise, and the amplitude of movement was then calculated. The discrete Fourier transform of the unfiltered data was determined for the frequency analysis of prostate movement, giving us the power spectrum of the signal. Fourier analysis breaks down a signal into constituent sinusoids of different frequencies. The power of a certain frequency represents the strength of this frequency in the time signal. The movements observed in the different positions were compared using a paired *t* test. $p < 0.05$ was considered statistically significant.

RESULTS

Table 1 shows the maximal and average amplitude with standard deviation of the 3D movement for each patient in the supine and prone positions for 2 min on 5 occasions. No apparent difference in movement was found among individuals. The maximal amplitude of 3D movement was 0.1–2.7 mm in the supine and 0.4–24 mm in the prone positions. The average amplitude in the supine position was 0.1 ± 0.1 , 0.3 ± 0.2 , and 0.3 ± 0.4 mm, and those in the prone position were 0.5 ± 0.4 , 1.4 ± 0.5 , and 1.6 ± 0.4 mm in the left–right (L–R), craniocaudal (CC), and AP directions, respectively. The amplitude in the supine position was statistically smaller in all directions than that in the prone position ($p < 0.0001$). The amplitude in the CC and AP directions was larger than in the L–R direction in the prone position ($p < 0.0001$).

Figures 1 and 2 show the 3D motion of the implanted markers, which was recorded every 0.033 s for 2 min for each patient 1 day in the supine and prone positions, respectively. A difference in movement between the two treatment positions can be observed.

No characteristic movement frequency was detected in the supine position. The respiratory frequency (0.2–0.4 Hz) was detected for all patients regarding movement in the CC and AP directions in the prone position. The frequency analysis suggests that prostate movement in the CC and AP directions was affected by the respiratory cycle, and move-

Table 1. Maximal and average amplitude of movement for each patient

Pt. no.	Position	L-R (mm)		CC (mm)		AP (mm)	
		Max	Ave $\pm$ SD	Max	Ave $\pm$ SD	Max	Ave $\pm$ SD
1	Supine	0.2	0.1 $\pm$ 0.0	0.5	0.3 $\pm$ 0.1	2.7	0.2 $\pm$ 0.2
	Prone	2.3	0.5 $\pm$ 0.3	4.1	1.2 $\pm$ 0.4	5.2	1.5 $\pm$ 0.5
2	Supine	0.1	0.1 $\pm$ 0.0	0.3	0.3 $\pm$ 0.1	0.2	0.1 $\pm$ 0.1
	Prone	0.4	0.3 $\pm$ 0.1	1.5	1.0 $\pm$ 0.2	2.4	1.0 $\pm$ 0.2
3	Supine	0.2	0.1 $\pm$ 0.1	0.4	0.2 $\pm$ 0.1	0.3	0.1 $\pm$ 0.1
	Prone	2.3	0.5 $\pm$ 0.2	3.2	1.7 $\pm$ 0.5	8	2.4 $\pm$ 0.7
4	Supine	0.4	0.2 $\pm$ 0.2	0.9	0.4 $\pm$ 0.5	0.4	0.2 $\pm$ 0.2
	Prone	0.6	0.4 $\pm$ 0.1	2.9	1.7 $\pm$ 0.3	3.8	1.9 $\pm$ 0.4
5	Supine	0.5	0.3 $\pm$ 0.1	1.7	0.8 $\pm$ 0.2	3.6	1.4 $\pm$ 0.4
	Prone	22	1.4 $\pm$ 3.7	24	1.7 $\pm$ 3.8	23	1.6 $\pm$ 3.7
6	Supine	0.3	0.2 $\pm$ 0.1	0.5	0.3 $\pm$ 0.1	0.3	0.2 $\pm$ 0.1
	Prone	1.2	0.4 $\pm$ 0.2	1.3	0.8 $\pm$ 0.2	1.5	1.1 $\pm$ 0.3
7	Supine	0.3	0.1 $\pm$ 0.1	1.2	0.2 $\pm$ 0.2	3.7	0.3 $\pm$ 0.7
	Prone	0.4	0.2 $\pm$ 0.1	4.2	1.0 $\pm$ 0.5	5.3	1.3 $\pm$ 0.7
8	Supine	0.4	0.1 $\pm$ 0.1	0.4	0.2 $\pm$ 0.1	0.4	0.1 $\pm$ 0.1
	Prone	0.6	0.3 $\pm$ 0.2	1.5	1.2 $\pm$ 0.2	2.4	1.8 $\pm$ 0.2
9	Supine	0.2	0.1 $\pm$ 0.1	0.8	0.3 $\pm$ 0.1	0.3	0.1 $\pm$ 0.1
	Prone	0.7	0.4 $\pm$ 0.1	1.6	1.2 $\pm$ 0.2	2.3	1.4 $\pm$ 0.3
10	Supine	0.2	0.1 $\pm$ 0.0	0.3	0.2 $\pm$ 0.1	0.3	0.2 $\pm$ 0.0
	Prone	3	0.5 $\pm$ 0.4	3	2.2 $\pm$ 0.5	5	2.0 $\pm$ 0.3
Total	Supine		0.1 $\pm$ 0.1*		0.3 $\pm$ 0.2*		0.3 $\pm$ 0.4*
	Prone		0.5 $\pm$ 0.4*		1.4 $\pm$ 0.5*		1.6 $\pm$ 0.4*

Abbreviations: L-R = left-right; CC = craniocaudal; AP = anteroposterior; Max = maximal amplitude; Ave = average amplitude; SD = standard deviation.

* Statistically significant ($p < 0.0001$) in a paired t test.

ment in the L-R and AP directions might be influenced by slower and more irregular frequencies such as that occurring with bowel movement or patient movement in the prone position (Fig. 3).

DISCUSSION

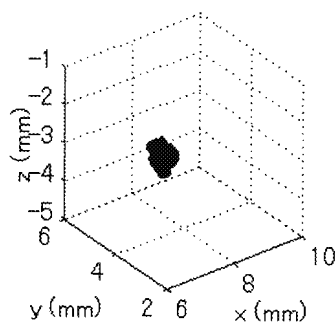
Regarding interfractional movement of the prostate gland, Stroom *et al.* (2) have assessed variations in the position of the CTV relative to bony anatomy using repeat CT and 3D chamfer matching method. In their results, compared with patients in the supine position, patients in the prone position had smaller random variations but somewhat larger systematic variations in the most important coordinates of the internal CTV position. They concluded that the estimated planning margins to account for geometrical uncertainties were therefore similar for the two treatment positions. Because of the results of their study and the purpose of this study, it is not necessary to discuss interfractional movement in detail any further.

Our results, based on data obtained during a total of 200 min, demonstrate that the amplitude in the supine position is statistically smaller in all directions than that obtained in the prone position ($p < 0.0001$). Additionally, respiratory frequency (0.2–0.4 Hz) was detected for all patients regarding movement in the CC and AP directions in the prone position. Some investigators (10, 11) have obtained similar findings by less exact methods. Malone *et al.* (10) evaluated prostate movement in both prone (with and without immo-

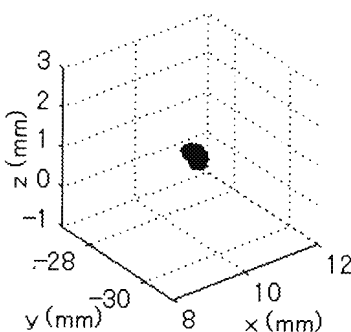
bilization) and supine (without immobilization) positions using implanted gold fiducial markers. They found fluoroscopically observed respiratory-induced movement while patients were immobilized in the prone position. Dawson *et al.* (11) compared the movement of fiducial markers in 4 different positions using two-dimensional fluoroscopic movies digitized at a rate of 30 frames/s. They have also observed that ventilatory movement of the prostate is substantial in the prone position and is reduced in the supine position. Our method using RTRT can automatically produce the recorded 3D coordinates of the tracked marker in real time at a rate of 30 times/s, even during irradiation (13–17). As such, this method is the most accurate to use in analyses of organ motion, providing us with information regarding real interfractional movement of the prostate. Our results further confirm and strongly support the findings of less rigorous experiments previously reported by other groups (10–11).

Some investigators (3, 9, 18) have, however, suggested a dosimetric advantage in having the rectum in the prone position because of the increased distance between the prostate and anterior rectal wall. It has been perceived that the increased separation of the rectum in the prone position cannot be offset by the significant interfractional breathing movement in that position. This assumption might have been accepted in the 3D conformal RT era, but it needs to be critically reviewed with regard to the IMRT that consumes much of each treatment session. Movement in the prone position as observed in the present study was several

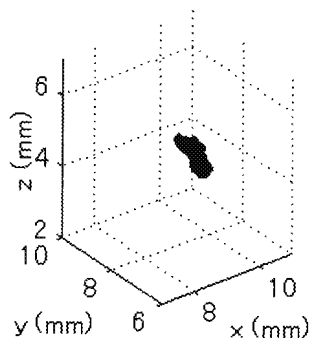
Pt. 1



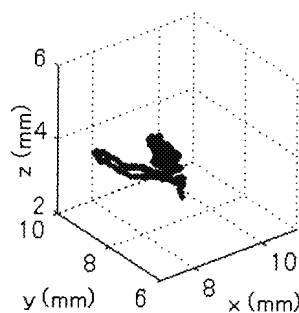
Pt. 6



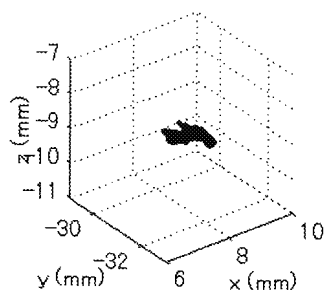
Pt. 2



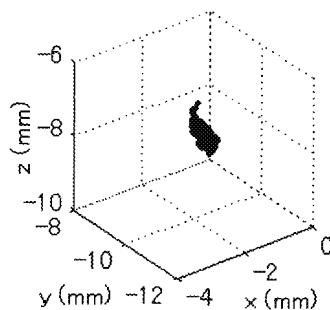
Pt. 7



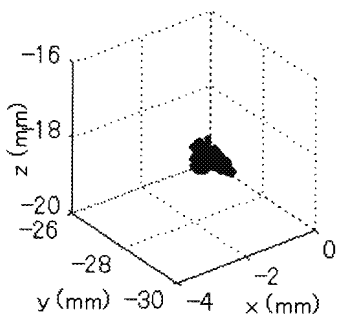
Pt. 3



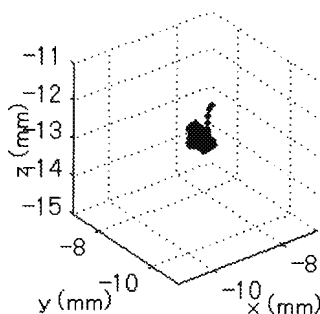
Pt. 8



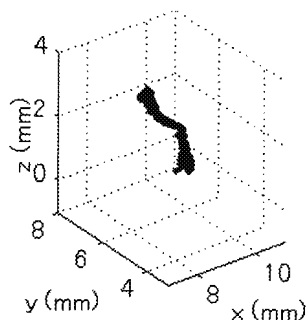
Pt. 4



Pt. 9



Pt. 5



Pt. 10

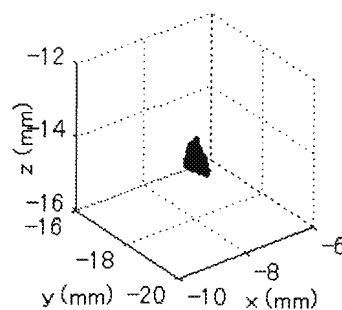


Fig. 1. 3D trajectory of prostate gland for 2 min in supine position. X, L-R; Y, CC; Z, AP. Black dots represent position of marker implanted in the apex of prostate gland, as measured every 0.033 s.

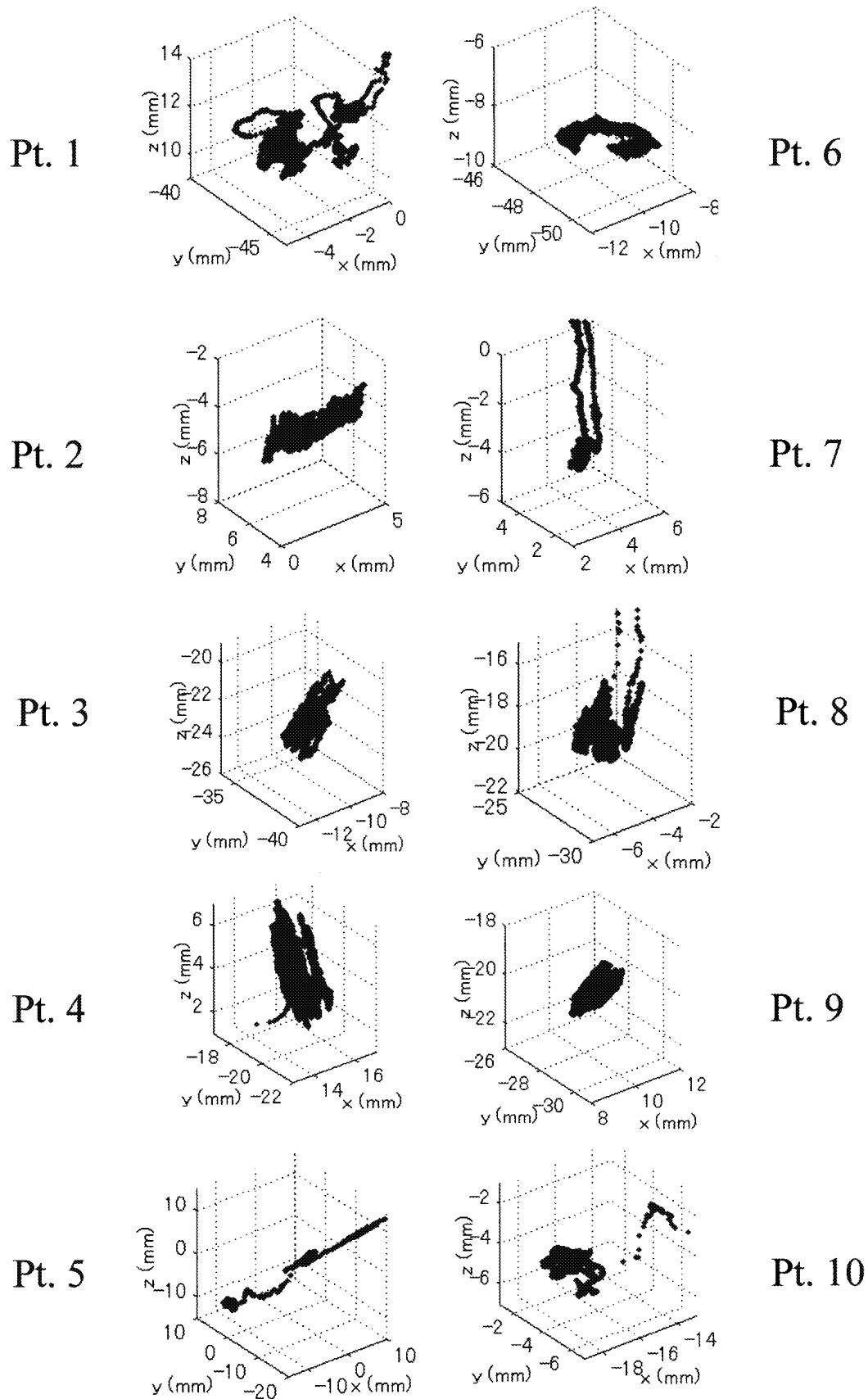


Fig. 2. 3D trajectory of prostate gland for 2 min in prone position. X, L-R; Y, CC; Z, AP. Black dots represent position of marker implanted in apex of prostate gland, as measured every 0.033 s.

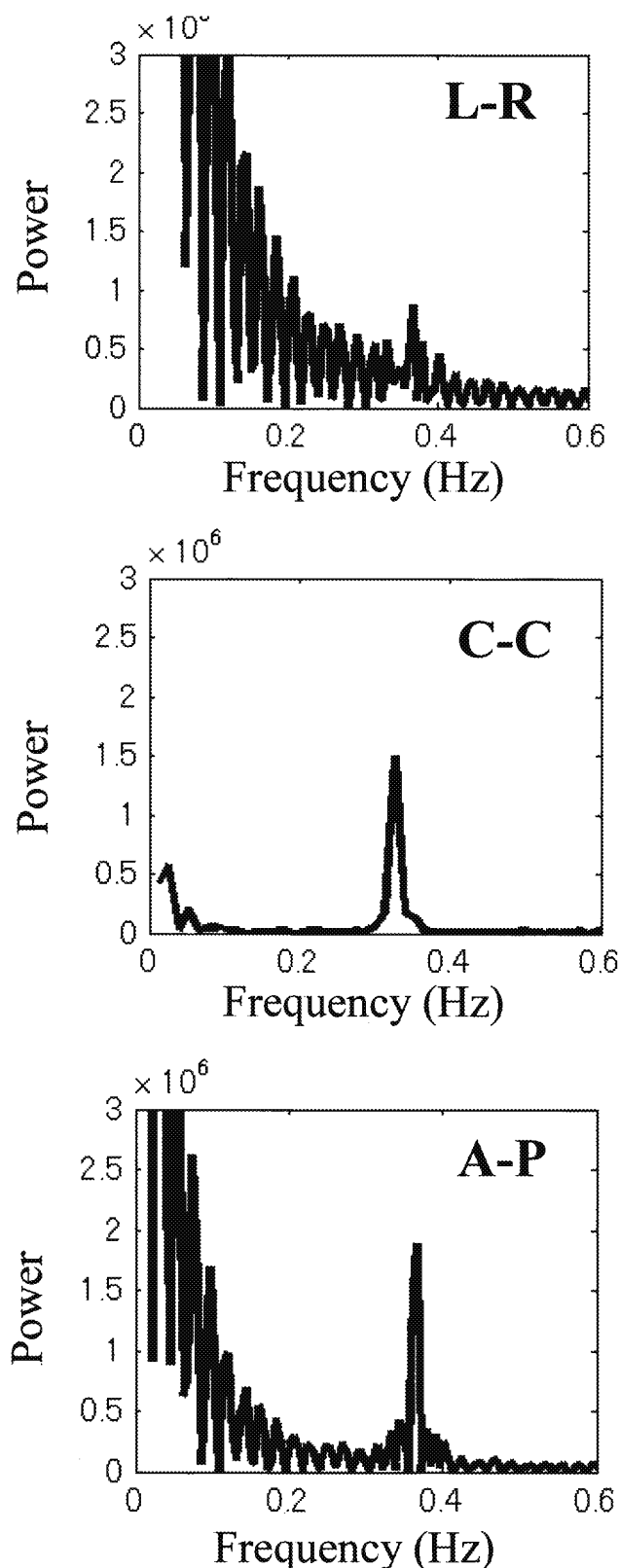


Fig. 3. Frequency analysis of prostate movement in prone position. Frequency spectrum of Patient 2 in prone position was calculated by Fourier transform. Respiratory frequency detected as 0.35 Hz for this patient with regard to movement in CC and AP directions in prone position. Respiratory frequency was unclear in L-R direction. The slower and more irregular frequency was detected in the L-R and AP directions.

times as large as that in the supine position according to our findings obtained during a period of just 2 min. Extraordinary movement was observed to occur during this period, because the maximal amplitude was >22 mm in the prone position for Patient 5. This movement was not due to respiratory motion, but to bowel movement. The best way to minimize intrafractional dosimetric errors is to decrease the delivery time. However, if it is impossible to do so in IMRT, the intrafractional movement will never be negligible, and physicians who still administer treatment in the prone position will not be able to provide a strong defense for their approach.

The RTRT system, which can continuously track tumor position, never requires any patient immobilization. Arguments regarding immobilization during RT for prostate cancer have progressed toward the perception that many immobilization devices are ineffective in reducing overall patient movement (19). Malone *et al.* (10) have suggested that the reduction in positioning errors due to the use of a thermoplastic shell must be weighted against the increase in breathing-related motion. Bentel *et al.* (4) have reported a novel approach regarding patient positioning and immobilization in patients with prostate cancer. Supine positioning with a false tabletop has been recommended to minimize intrafractional ventilatory motion of the prostate while simultaneously increasing the distance between the rectum and prostate. The argument regarding the most appropriate treatment position cannot help but lead to consideration of this method to potentially combine both of these benefits.

van Herk *et al.* (1) have demonstrated that translation of the prostate is largest along the AP axis (2.7 mm SD), that rotation is largest around the L-R axis (4.0° SD), and that both are much smaller in the other directions. It would be better to state that the prostate can move around its apex. Measured movement of the prostate using the fiducial marker must depend on the distance between the marker and apex. Consequently, where the marker is implanted is important in measuring prostate movement. Because the only marker implanted in the apex was used for tracking in our study, it must be noted that our results might lead to an underestimation of prostate movement.

Questions regarding the migration of implanted markers are commonplace, although no one has been able to provide satisfactory answers regarding this issue. We have demonstrated that no migration can be detected using repeated CT on the basis of the relationship between the organ center and the marker (20). Our method has the limitation that tracking a single marker in the prostate might not reflect the movement of the entire prostate gland, including the seminal vesicles. The simultaneous tracking of multiple markers is now being investigated and will be in practice in the near future.

CONCLUSION

The results of this study have confirmed that internal organ motion is less frequent in the supine position than in

the prone position in the treatment of prostate cancer. RTRT appears to be useful in reducing the uncertainty due to

effects of the respiratory cycle, especially in the prone position.

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Stereotactic Body Radiotherapy for Large (> 5 cm) Non—Small-Cell Lung Cancer

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Polina Khrizman,³ Gregory J. Kubicek²

Abstract

This study was undertaken to provide a better understanding of stereotactic body radiotherapy (SBRT) in nonoperable non—small-cell lung cancer with a largest tumor dimension of > 5 cm. A retrospective analysis was conducted on a prospective SBRT registry, with analysis of 41 patients. SBRT results in good local control and acceptable rates of distant control and treatment-induced toxicities in larger lung tumors.

Background: Stereotactic body radiotherapy (SBRT) is a well-established treatment option for early stage non—small-cell lung cancer (NSCLC) tumors < 5 cm. There is limited information on tumors > 5 cm. **Patients and Methods:** We performed retrospective data collection of patients enrolled onto a prospective SBRT registry study. Eligible patients for this study had node-negative NSCLC measuring > 5 cm in any dimension. Data from 41 patients were analyzed. Median patient age was 75 years, and median tumor size was 5.6 cm (range, 5.0–12.2 cm). Sixteen patients had squamous disease, 20 patients adenocarcinoma, and 1 mixed tumor; 4 patients had no biopsy. Median radiation dose per fraction was 50 Gy in 5 fractions. Radiation was prescribed to isodose line, median 66% (range, 50%–84%).

Results: Before SBRT, 6 patients had previous chemotherapy and 7 patients had previous radiation. Median follow-up for all patients was 15.2 months (range, 0.56–48.1 months). At last follow-up, 16 patients were still alive, with a median follow-up of 16.1 months for surviving patients. The median survival was 17.5 months with 1- and 2-year survivals of 65% and 34%. Two patients (4.8%) had local failure, and 13 patients (31%) had distant failure. Four patients (9.8%) had acute toxicity, and 7 patients (17.1%) had late toxicity, including 2 (4.8%) grade 3 late toxicities. **Conclusion:** SBRT for tumors > 5 cm is effective, with good local control rates and acceptable toxicity. The main pattern of failure is distant, suggesting a possible role for systemic chemotherapy in these patients.

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Keywords: > 5 cm, Large size, NSCLC, Radiosurgery, SBRT

Introduction

The standard treatment for early stage lung cancers is surgical resection. For patients who are not candidates for surgery, stereotactic body radiotherapy (SBRT) has emerged as a potential treatment option. The seminal study regarding SBRT for early stage

non—small-cell lung cancer (NSCLC) by Timmerman et al¹ enrolled nonoperable patients with peripheral T1–2N0M0 NSCLC < 5 cm. Although patients with T3 tumors (size > 5 cm) were eligible for the study, no patient with a tumor > 5 cm was actually enrolled. The study found a 3-year primary tumor control rate of 97.6%, and overall disease-free survival was 55.8% at 3 years. Multiple series have found SBRT to be safe and effective for patients with early stage disease^{2–7}—possibly better than conventional radiotherapy interventions.⁶

The literature on large-size lung tumors (> 5 cm) and SBRT treatments is scant; most of the research in this field has focused on smaller NSCLC tumors. Woody et al⁸ reported on 40 patients with nonoperable NSCLC > 5 cm, and several series examined subsets of NSCLC > 3 cm.^{7,9} Larger tumors have been associated with more nonlocal failures and worse survival rates.^{10,11} Because of the paucity

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of the data and the existing need for research in this field, we analyzed our prospective SBRT database of NSCLC tumors > 5 cm.

Materials and Methods

Inclusion Criteria

This was a retrospective review of a prospectively maintained database. The study was approved by the local institutional review board (approval 1094EX). All cases of lung cancer were reviewed. Patients eligible for this analysis had NSCLC > 5 cm as measured in at least 1 dimension via computed tomographic (CT) scan. Patients were node negative (N0) based on imaging or biopsy of suspicious lymph nodes. All patients were treated at the MD Anderson Cancer Center at Cooper Hospital (Camden, NJ) between October 2008 and November 2015. Exclusion criteria included any lung tumors that were non-NSCLC.

Treatment

All patients were treated using CyberKnife (Accuray, Sunnyvale, CA). All patients had CT scans at the end of exhale and inhale for radiation planning; this could be done with or without contrast at the discretion of treating physician. For larger tumors visible in the projected X-ray images, the XSight lung technique was used to treat the patient by continuously monitoring the tumor movement. For the rest of the patients, 2 to 5 fiducials were implanted around the tumors and were used as the surrogate for tumor tracking (Synchrony technique).

All patients had gross tumor volume (GTV) contoured based on clinical examination, CT scans, and other images (typically positron emission tomography [PET] scans) when available. Planning target volume (PTV) was an expansion of the GTV and was usually around 5 mm in all directions. Peripheral tumors were treated on consecutive days, while central tumors were treated every other day. Treatments were prescribed to an isodose line. Organ-at-risk constraints were identical to those from recent cooperative group SBRT studies.

Follow-up

Patients were typically seen every 3 months for follow-up, which included a history and a physical examination. Chest CT scans were acquired 3 months after treatment, and if necessary, PET-CT scans were performed to confirm any suspicious lesions. Any toxicities that were suspected to be a result of the SBRT therapy were graded according to the National Cancer Institute Common Terminology for Adverse Events, version 3.0 (<http://ctep.cancer.gov/>). Evaluation of toxicities and of local and distant failure were evaluated on posttreatment visits.

Results

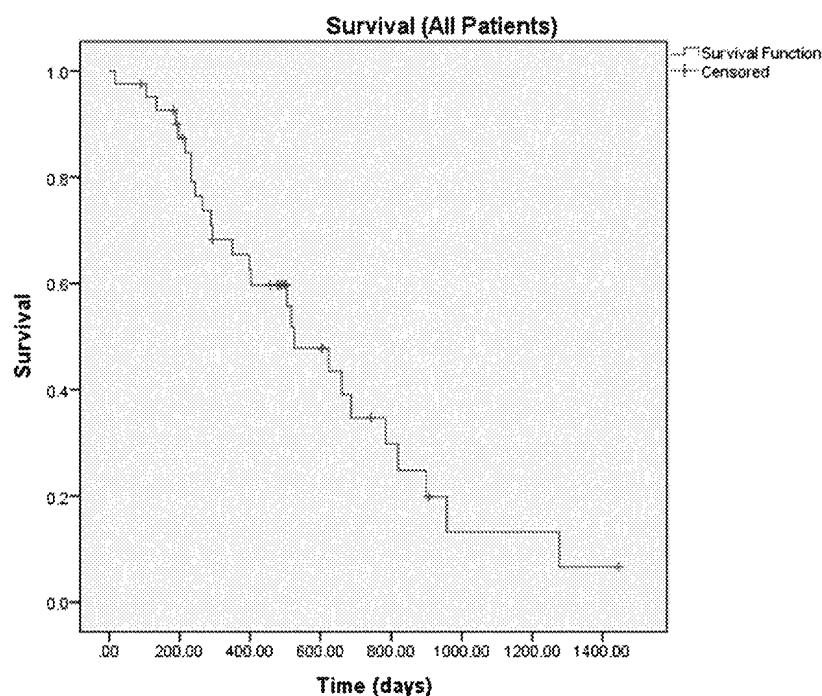
Patient and Tumor Characteristics

Forty-one patients met the inclusion criteria for this study. Our institutional standard for early stage NSCLC was surgical resection. Although the exact details for inoperability were not always recorded, all patients would have been medically unfit for surgery or refused surgical resection. Demographics and characteristics are listed in Table 1. There were 20 male and 21 female subjects with a median age of 75 years. The median Karnofsky performance status at the time of SBRT treatment was 80 (range, 50-100). Prior

Table 1 Patient Characteristics	
Characteristic	Value
Age (y)	
Median	75
Range	47-93
Sex	
Male	20 (49%)
Female	21 (51%)
Previous Chemotherapy	
Yes	6 (15%)
No	35 (85%)
Previous Radiation	
Yes	7 (17%)
No	34 (83%)
Largest Tumor Dimension (cm)	
Median	5.6
Range	5-12.2
GTV (cm³)	
Median	52.9
Range	13.820-597.8
PTV (cm³)	
Median	87.213
Range	32.6-476.9
Isodose Line (%)	
Median	66
Range	50-84
Fractions	
Median	5
Range	3-5
Radiation Dose (Gy)	
Median	50
Range	25-60
Location	
Central	26 (63%)
Peripheral	15 (37%)
Histology	
Adenocarcinoma	16 (39%)
Squamous cell	20 (48%)
No biopsy	4 (10%)
Mixed histology	1 (2%)

Abbreviations: GTV = gross tumor volume; PTV = planning target volume.

chemotherapy had been administered to 6 patients (15%), while prior radiotherapy had been administered to 7 patients (17%). Four of the patients who had received previous radiotherapy had received thoracic radiation for previous lung cancer (median dose, 60 Gy). The median largest tumor dimension was 5.6 cm, with a range of 5 to 12.2 cm. Sixteen patients had a biopsy positive for adenocarcinoma and 20 positive for squamous-cell disease; 4 patients were unable to undergo a biopsy, and 1 had mixed NSCLC histology positive for adenocarcinoma and squamous-cell carcinoma. For patients without biopsy, the decision to proceed without tissue analysis was based on radiographic progression of lung lesion in a

Figure 1 Overall Survival

patient who refused biopsy (2 patients) or who was medically unfit to undergo biopsy (2 patients). The median GTV was 52.9 cm³, while the median PTV was 87.2 cm³. The median percentage of isodose line was 66%, and all treatments were between 3 and 5 fractions. The median radiation dose was 50 Gy (range, 25-60 Gy). Nineteen patients (46%) were treated 50 Gy in 5 fractions, 10 patients (24%) were treated with 44 to 50 Gy in 4 fractions, 5 patients (12%) were treated with 40 to 45 in 5 fractions, 2 patients were treated with 54 to 60 in 3 fractions, 2 patients were treated with 25 Gy in 5 fractions, 2 patients were treated with 45 Gy in 3 fractions, and 1 patient was treated with 32 Gy in 4 fractions. Our institutional standard is to protect organs at risk above tumor coverage; in the event that organ-at-risk constraints could not be met, radiation dose could be decreased (This is why there was heterogeneity in dose prescriptions, as described above.).

The median follow-up was 15.2 months for all patients. Sixteen patients were alive at the time of analysis, with a median follow-up of 16.1 months. Median follow-up for deceased subjects was

12.4 months. Overall survival was 65% and 34% at 1 and 2 years, respectively (Figure 1).

Of the 41 patients in our study, 26 patients experienced no disease recurrence (63.4%). Two (4.8%) of 41 patients had local failure. The size of the 2 tumors with local failure were 5 and 7.7 cm, respectively. PTV for local failure cases was 32.6 and 50.2 cm³ compared to a median PTV of 87.2 cm³ for the entire study population. Radiation dose for the 2 local failures included 1 patient treated 25 Gy in 5 fractions and 48 Gy in 4 fractions.

Distant failure was noted in 13 patients (31.7%). Median maximal tumor diameter of patients experiencing distant failure was 5.6 cm, which is identical to the median diameter of the overall study population. Similarly, median PTV volume of these patients was not significantly different than the overall population. Of the distant failures, 30.8% of the tumors were peripherally located and 69.2% were centrally located. Histologic type was squamous cell for 5 subjects (38.5%) and adenocarcinoma for 7 (53.8%); 1 patient did not have identified tumor histology.

Table 2 Acute Toxicity

Grade	Toxicity	Tumor Location	Largest Tumor Dimension (cm)	PTV (cm ³)	Radiation Dose (Gy)	Fractions	IDL
2	Esophagitis	Central	5	70.9	50	5	63
2	Nausea/vomiting	Central	5.1	53.7	50	5	67
3	Shortness of breath	Central	5.1	33.9	50	5	63
3	Esophagitis	Peripheral	6.8	152.9	50	5	68

Abbreviations: IDL = isodose line; PTV = planning target volume.

Table 3 Late Toxicity							
Grade	Toxicity	Tumor Location	Largest Tumor Dimension (cm)	PTV (cm ³)	Radiation Dose (Gy)	Fractions	IDL
2	Chest wall pain	Central	5.1	66.1	54	3	68
2	Chest wall pain	peripheral	5.8	71.9	45	5	73
2	Rib fracture	Peripheral	5.2	87.9	50	4	67
2	Shortness of breath	Peripheral	5.6	45.5	54	5	77
2	Shortness of breath	Central	5.6	86.4	50	5	66
3	Shortness of breath	Central	6.1	80.2	48	4	72
3	Pneumonitis	Peripheral	7.5	106.1	50	5	67

Abbreviations: IDL = isodose line; PTV = planning target volume.

Acute toxicity was noted in 4 patients (9.7%) (Table 2). For patients with acute toxicity, the median largest tumor dimension was 5.1 cm compared to a median largest tumor dimension of 5.6 cm for the entire study population. Median PTV for acute radiation-induced toxicities was 62.3 cm³ compared to 87.2 cm³ for the entire study population.

Seven patients (17.0%) had late radiation-induced toxicities (Table 3), and 2 patients had grade 3 late toxicity (4.8%). The median largest tumor dimension for patients with late toxicity was 5.6 cm compared to a median largest tumor dimension of 5.6 cm for the entire study population. Median PTV for late radiation-induced toxicities was 80.2 cm³ compared to 87.2 cm³ for the entire study population. Three subjects had a centrally located tumor, and 4 subjects had a peripherally located tumor. Chest wall pain was typically managed with pain medication, while the patient with pneumonitis was managed with steroids.

We looked at factors predictive for failure and toxicity, including tumor size, PTV volume, tumor location, isodose line, and histology. No factor was found to be predictive on subset analysis. Of the 7 patients with previous radiation, 4 had previous thoracic radiation.

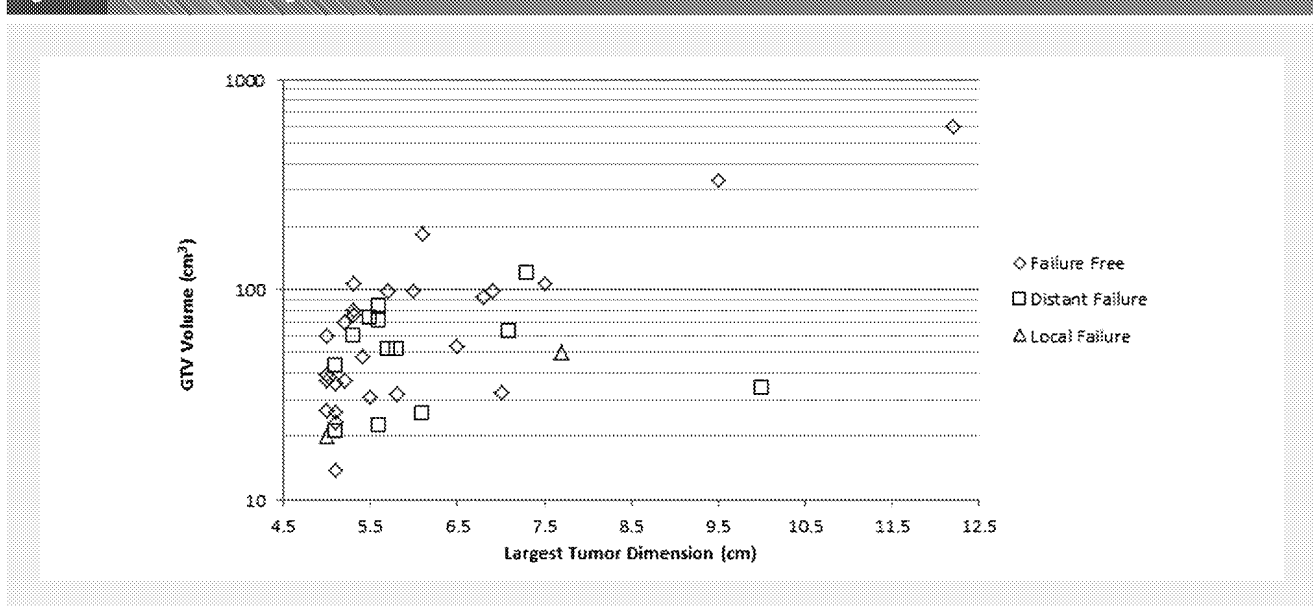
Two of the 4 patients had late toxicity (1 grade 3 shortness of breath and 1 grade 2 chest wall pain).

Discussion

While there is mounting evidence on the outcomes of SBRT in < 5 cm primary lung tumors,¹⁻⁷ outcome on tumors > 5 cm remains underreported in the literature.^{8,12} We aimed to improve the knowledge regarding this subset. Our results are similar to other series. Woody et al⁸ reported on 40 patients with medically inoperable NSCLC tumors > 5 cm; they found 91.2% local control at 18 months, which was similar to our local control rate of 95.2%; they also found a high rate of distant failure, with 32.5% of patients having distant failure, similar to our distant failure rate of 31.7%. The median follow-up in their study was 10.8 months, which is several months shorter than the median follow-up in our study. Our results and those of Woody et al⁸ are similar to another published report on NSCLC > 3 cm.⁹

Tumor histology (adenocarcinoma vs. squamous), location (peripheral vs. central), largest tumor dimension, and PTV all did not have any predictive value in identifying distant control. With only 2

Figure 2 Outcome and Target Size



subjects identified as having local failure, few conclusions can be drawn regarding risk factors for local failure.

These results are slightly worse compared to expected outcomes for NSCLC < 5 cm. (RTOG 0236 had 97.6% local control and 22.1% distant failure at 3 years.¹) It is not surprising that the larger tumors had worse outcomes; many series have shown that larger tumor dimensions and volumes correlate with worse outcomes.^{10,11,13} Despite this, an increase in primary tumor size in our population did not appear to be predictive for worsening local or distant control (Figure 2). In both our series, as well as in series by others, the predominant pattern of failure was distant. On this basis, patients in this subset should be considered for post-SBRT chemotherapy. In an unplanned subset analysis, CALGB 9633 found improved outcomes in surgically resected NSCLC > 4 cm.¹⁴ Further investigation is warranted to better understand the role adjuvant chemotherapy plays in modifying rates of distant failure in large primary lung tumors after SBRT.

The results from our study suggest that SBRT therapy in large > 5 cm primary NSCLC tumors is associated with acceptable rates of grade 2 or higher therapy-associated toxicities, comparable to reports on tumors < 5 cm.²⁻⁷ Onishi et al¹⁵ found 10.9% grade 2 or higher toxicities in 28 of 257 patients, and RTOG 0236¹ reported 15% grade 3 or higher toxicities. When judging causation for observed toxicities, it can be difficult to distinguish between disease progression and treatment effect, and this potential confounder should be recognized. Analysis of our series did not identify any effect of tumor location, size, or treatment dose on the development of toxicities. Similar to failure rates, low subset numbers made analysis difficult.

This investigation aimed to advance our understanding of SBRT for primary NSCLC tumors (> 5 cm) as measured by survival, local and distant control, and treatment-induced toxicities. Our analysis offers guidance on using targeted radiotherapy in larger lung tumors. We found acceptable local control rates and toxicity rates with this treatment.

Conclusion

The results of this study suggest that SBRT for larger primary lung lesions (> 5 cm) is feasible, with acceptable local and distant failure rates. SBRT was well tolerated with minimal grade 2 or greater associated toxicities. Further investigation is warranted due to the potential benefit this treatment option could provide patients with large tumors. Also, given the high rate of distant failure, the role of adjuvant chemotherapy should be further explored for mitigating distant failure in this population.

Clinical Practice Points

- We performed a retrospective review of a prospective SBRT database, analyzing 41 patients treated with SBRT for NSCLC > 5 cm.
- SBRT was associated with excellent local control rates (94.8%), no grade 4 or 5 toxicity, and a low rate (4.8%) of late grade 3 toxicity.
- Distant failure was the most common form of failure in this patient population (31%).
- Systemic chemotherapy may be considered after completion of SBRT.

Disclosure

The authors have stated that they have no conflict of interest.

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CLINICAL INVESTIGATION

Lung

PRECISE AND REAL-TIME MEASUREMENT OF 3D TUMOR MOTION IN LUNG DUE TO BREATHING AND HEARTBEAT, MEASURED DURING RADIOTHERAPY

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Purpose: In this work, three-dimensional (3D) motion of lung tumors during radiotherapy in real time was investigated. Understanding the behavior of tumor motion in lung tissue to model tumor movement is necessary for accurate (gated or breath-hold) radiotherapy or CT scanning.

Methods: Twenty patients were included in this study. Before treatment, a 2-mm gold marker was implanted in or near the tumor. A real-time tumor tracking system using two fluoroscopy image processor units was installed in the treatment room. The 3D position of the implanted gold marker was determined by using real-time pattern recognition and a calibrated projection geometry. The linear accelerator was triggered to irradiate the tumor only when the gold marker was located within a certain volume. The system provided the coordinates of the gold marker during beam-on and beam-off time in all directions simultaneously, at a sample rate of 30 images per second. The recorded tumor motion was analyzed in terms of the amplitude and curvature of the tumor motion in three directions, the differences in breathing level during treatment, hysteresis (the difference between the inhalation and exhalation trajectory of the tumor), and the amplitude of tumor motion induced by cardiac motion.

Results: The average amplitude of the tumor motion was greatest (12 ± 2 mm [SD]) in the cranial-caudal direction for tumors situated in the lower lobes and not attached to rigid structures such as the chest wall or vertebrae. For the lateral and anterior-posterior directions, tumor motion was small both for upper- and lower-lobe tumors (2 ± 1 mm). The time-averaged tumor position was closer to the exhale position, because the tumor spent more time in the exhalation than in the inhalation phase. The tumor motion was modeled as a sinusoidal movement with varying asymmetry. The tumor position in the exhale phase was more stable than the tumor position in the inhale phase during individual treatment fields. However, in many patients, shifts in the exhale tumor position were observed intra- and interfractionally. These shifts are the result of patient relaxation, gravity (posterior direction), setup errors, and/or patient movement.

The 3D trajectory of the tumor showed hysteresis for 10 of the 21 tumors, which ranged from 1 to 5 mm. The extent of hysteresis and the amplitude of the tumor motion remained fairly constant during the entire treatment. Changes in shape of the trajectory of the tumor were observed between subsequent treatment days for only one patient. Fourier analysis revealed that for 7 of the 21 tumors, a measurable motion in the range 1–4 mm was caused by the cardiac beat. These tumors were located near the heart or attached to the aortic arch. The motion due to the heartbeat was greatest in the lateral direction. Tumor motion due to hysteresis and heartbeat can lower treatment efficiency in real-time tumor tracking–gated treatments or lead to a geographic miss in conventional or active breathing controlled treatments.

Conclusion: The real-time tumor tracking system measured the tumor position in all three directions simultaneously, at a sampling rate that enabled detection of tumor motion due to heartbeat as well as hysteresis. Tumor motion and hysteresis could be modeled with an asymmetric function with varying asymmetry. Tumor motion due to breathing was greatest in the cranial-caudal direction for lower-lobe unfixed tumors. © 2002 Elsevier Science Inc.

Respiratory movement, Lung, Radiotherapy, Heartbeat.

INTRODUCTION

Recent developments in radiotherapy such as intensity-modulated radiotherapy, noncoplanar conformal radiother-

apy (1–5), and active breathing controlled–gated treatments (6) are all aimed at increasing the tumor dose and reducing the dose to normal tissue. Discrepancies in tumor position between treatment and a planning computed tomography

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Table 1. Patient characteristics

Patient no.	Age	KI*	Pathology	Marker location	T stage	Dose (Gy)	Tumor size (cm ³)
1	77	70	Squamous cell	Near	2	40	14
2	52	80	Squamous cell	Near	1	35	85
3	72	80	Squamous cell	In	4	40	22
4	70	80	Adenocarcinoma	Near	2	40	20
5	70	50	Squamous cell	In	3	40	10
6	72	80	Squamous cell	In	3	40	36
7	77	70	Squamous cell	Near	1	40	60
8	76	70	Adenocarcinoma	In	1	40	16
9a	83	80	Squamous cell	Near	1	40	10
9b			Adenocarcinoma	Near	1	40	14
10	43	90	Adenocystic carcinoma, metastatic	Near	—	40	8
11	69	90	Squamous cell	In	2	35	192
12	55	70	Adenocarcinoma	Near	2	35	3
13	68	40	Squamous cell	Near	2	40	135
14	57	70	Squamous cell, metastatic	In	—	35	23
15	84	80	Squamous cell	Near	1	40	14
16	41	80	Renal cell carcinoma, metastatic	In	—	40	168
17	81	80	Adenocarcinoma	In	3	35	257
18	67	90	Bronchioalveolar	In	3	35	2
19	81	80	Adenocarcinoma	Near	2	40	9
20	70	90	Squamous cell	In	1	40	25

*Karnofsky index.

(CT) scan can be caused by setup errors and organ motion (7–9). To account for these errors, a safety margin is added to the clinical target volume to obtain the planning target volume. Reducing setup error and understanding organ motion are essential in designing the tightest possible safety margin without compromising the tumor coverage. To examine the motion of lung tumors during respiration, Ekberg *et al.* (10) used fluoroscopy at the time of simulation. They demonstrated an average movement of 3.9 mm (range: 0–12 mm) in the cranial-caudal direction, 2.4 mm (range: 0–5 mm) in the mediolateral direction, and 2.4 mm (range: 0–5 mm) in the dorsoventral direction. Breath-hold (6, 11) or gated (12, 13) radiotherapy is designed to reduce tumor motion due to breathing. A novel method of accurate dose delivery to moving tumors with small margins is the real-time tumor tracking radiotherapy (RTRT) system (14–16).

Three-dimensional (3D) treatment planning is often performed on a CT scan made while the patient breathes freely, under the assumption that the CT image represents the average position of the tumor. However, breathing motion can cause misdetection of the tumor during CT scanning, especially for small tumors, resulting in a smaller planning volume or a distorted tumor shape (17). To obtain an accurate tumor image, a breath-hold CT is preferable. The ideal breathing phase in which the breath-hold CT is taken must correspond to the average tumor position. When the breathing motion of the tumor is not symmetric, the average tumor location is no longer midway between the inhale and exhale tumor position.

In this study, precise 3D recordings of tumor position were made during RTRT treatment, both beam-on and beam-off periods, at a high sampling rate to determine and

model tumor motion due to breathing, heartbeat, and patient motion.

PATIENTS AND METHODS

Twenty patients with tumors at different sites in the lung (One patient had two tumors) were included in the analysis (Table 1). Seventeen patients had non-small-cell primary lung cancer, and three had metastatic lung tumors. A typical treatment schedule consisted of 4×10 Gy with a four-field noncoplanar conformal technique using multiple static beams (4 MV) shaped with a multileaf collimator.

A 2.0-mm gold marker was implanted into or near the tumor mass using bronchial endoscopy or, when the tumor was situated near the thoracic wall, percutaneous needle insertion. Free-breathing CT scans were taken of the entire lung volume using a 5-mm slice thickness and a 5-mm slice interval. At the level of the tumor and the inserted marker, the slice thickness and slice interval were 1 mm or, if the tumor was large, 3 mm. Additionally, voluntary breath-hold CT scans were made at the inhalation and exhalation phases of tidal breathing, with the same slice thickness as for the free-breathing scan. A physician delineated the gold marker and the clinical target volume in each slice, and the position of the marker relative to the tumor was determined. Of the three CT scans, the scan that yielded the best possibility for irradiating the tumor (concerning normal tissue damage, tumor coverage, and treatment efficiency) was chosen as the planning CT scan. Three-dimensional treatment planning was performed using the Focus system (CMS, St. Louis, MO).

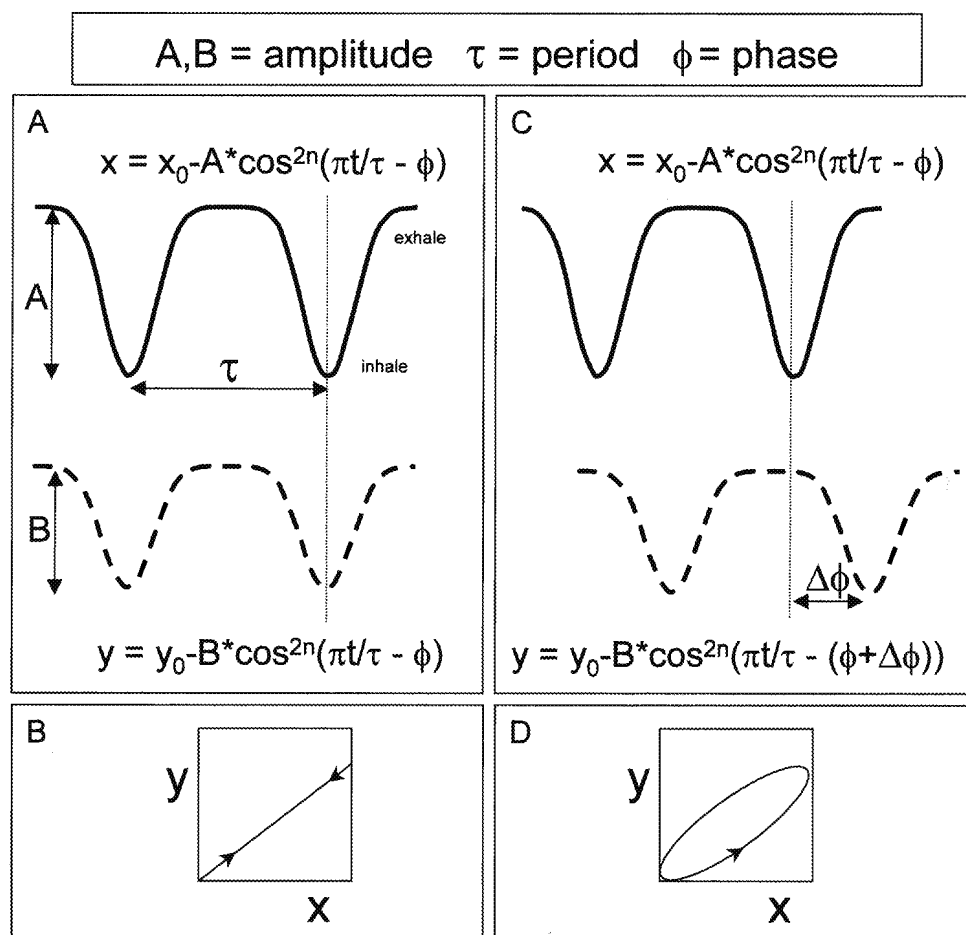


Fig. 1. The principle of hysteresis. When there is (A) no phase difference between two sinusoid signals with equal frequency, there is (B) no hysteresis; the position of the y direction is directly related to that of the x direction. When there is (C) a phase difference (ϕ), there are two possible positions where the tumor is at the same x position, depending on (D) the position in the breathing cycle. (D) The width and the shape of the hysteresis ellipsoid depend on the phase difference and the amplitude of both signals.

The fluoroscopic real-time tumor tracking radiotherapy system consists of four sets of diagnostic fluoroscopy, image processor units, a trigger control unit, an image display unit, and a conventional linear accelerator with multileaf collimators (15). Using two of the four fluoroscopy image processor units, the system determines the 3D position of the gold marker 30 times a second by using real-time pattern recognition and calibrated projection geometry. To avoid the blocking of the fluoroscopic images by the gantry of the linear accelerator, any two of the four X-ray systems may be selected. During the setup stage of each treatment fraction, the patient is positioned with skin markers. The physician judges both tumor position and motion based on two fluoroscopy images. The position of the treatment couch is adjusted when the gold marker is not found within the planned region. The zero tumor position is set by the physician at the position that best corresponds to the intended treatment breathing phase, based on the planning CT (In most cases, this was the exhale phase). Because the placement of the zero position may differ slightly from day to

day, the error made in this position is described as the "residual setup error".

During treatment, the linear accelerator was triggered to irradiate the tumor only when the gold marker was located within a specified region of the planned coordinates relative to the isocenter. The delay between recognition of the marker and the start of irradiation was 0.09 s. Radiation oncologists defined the distance of the permitted dislocation of the tumor in the lateral (LR), cranial-caudal (CC), and ventral-dorsal (AP) directions, resulting in a box around the isocenter. The permitted displacement for each patient was typically $3 \times 3 \times 3 \text{ mm}^3$.

The LR, CC, and AP coordinates of the internal marker were recorded 30 times per second during the treatment. Analog video images of the two fluoroscopic images were recorded simultaneously. All available data sets (each fraction and each beam direction) were analyzed for each patient; on average, there were 16 sets of 300 s per patient. The raw data of the RTRT system were filtered with a 30-point median filter to reduce system

Table 2. The mean amplitude of tumor motion, related to tumor location and attachment, the value of n for the fitted breathing curve, and the length of the breathing period

Patient no.	Mean amplitude* (mm $\pm$ 1 SD)			Lobe	Tumor attached to:	n	Breathing period (s $\pm$ 1 SD)
	LR	CC	AP				
20	1.8 (0.4)	<u>24.6</u> (3.8)	1.9 (0.4)	Lower		1	3.8 (0.6)
9a	1 (0.3)	<u>13.1</u> (2.7)	3.6 (0.5)	Lower		2	3.6 (0.4)
10	1.4 (0.3)	<u>11.8</u> (0.9)	2.6 (0.5)	Lower		1–2	4 (0.3)
3	0.5 (0.4)	<u>10</u> (0.8)	1.7 (0.5)	Lower		2	3 (0.3)
7	2.5 (0.3)	<u>7.7</u> (0.9)	0.9 (0.1)	Lower	Aorta	2	3.3 (0.8)
18	2 (0.4)	<u>5.4</u> (1.0)	0.9 (0.2)	Lower		3–9	6.6 (1.5)
17	0.4 (0.1)	1 (0.3)	1.7 (0.5)	Lower	Anterior chest wall	1	3.8 (0.6)
16	0.5 (0.1)	0.2 (0.1)	0.2 (0.1)	Lower	Posterior chest wall	1	4.9 (0.8)
19	1.1 (0.3)	<u>11.1</u> (2)	<u>5.8</u> (0.7)	Middle		2	3.2 (0.3)
6	0.2 (0.1)	0.7 (0.1)	1.2 (0.1)	Middle	Lateral chest wall	2	4.8 (0.5)
8	0.6 (0.1)	<u>8.7</u> (0.8)	<u>8.2</u> (0.5)	Upper		2–3	3.8 (0.3)
12	1.3 (0.2)	4.2 (0.6)	4.1 (0.5)	Upper		2	3.2 (0.4)
9b	2.8 (0.6)	3 (0.5)	2.5 (0.5)	Upper	Vertebra and aortic arch	1	3.5 (0.3)
1	2.8 (0.3)	2.8 (0.4)	1.5 (0.2)	Upper		2	2.8 (0.2)
5	0.4 (0.1)	2.8 (0.6)	0.8 (0.3)	Upper	Bronchial	2	2.7 (0.4)
11	1.7 (0.3)	2.5 (0.4)	1.4 (0.2)	Upper	Aorta	1	3.2 (0.4)
15	0.7 (0.1)	2 (0.4)	2.7 (0.2)	Upper		1	3.2 (0.3)
14	0.6 (0.1)	1.5 (0.2)	1.4 (0.2)	Upper		1–2	3.7 (0.4)
4	0.6 (0.1)	1.2 (0.2)	2 (0.4)	Upper	Lateral chest wall	1	3.2 (0.4)
2	2.4 (0.4)	1 (0.2)	1.2 (0.1)	Upper	Aorta	1	3.3 (0.3)
13	0.5 (0.1)	0.7 (0.1)	0.6 (0.1)	Upper	Aortic arch	1	3.7 (0.5)

*Tumor motion of more than 5 mm is underlined.

noise. For each data set, the individual breathing cycles were detected automatically by thresholding, after inconsistent readings of the inferred position of the marker were manually removed. These inconsistent readings occurred during about 1% of the treatment time, depending on the visibility of the gold marker on the fluoroscopic images. Different parameters were measured during the individual breathing cycles: the amplitude, the position of the tumor in the inhale and exhale phases, the average tumor position, and the length of the breathing cycle. All the individual breathing cycles recorded during one beam direction were averaged.

The position s of the tumor as a function of time t can be defined as follows (18):

$$s(t) = s_0 - S \cos^{2n}(\pi t/\tau - \phi) \quad (1)$$

where s_0 is the position of the tumor at exhalation, S is the amplitude, and hence $s_0 - S$ is the position at inhalation; τ is the period of the breathing cycle in seconds, and ϕ is the starting phase. This parameterized breathing curve was fitted (using a least-squares method) through each average breathing cycle. Hysteresis was assessed by the phase difference in the average breathing curves from two directions (Fig. 1). The amount of clinically relevant hysteresis was determined as the maximum distance between the different trajectories that the tumor followed during inhalation and exhalation.

To separate tumor motion caused by heartbeat and breathing, the discrete Fourier transform of the unfiltered data were

determined, resulting in the power spectrum of the signal. Fourier analysis breaks down a signal into constituent sinusoids of different frequencies. The power of a certain frequency represents the strength of this frequency in the time signal. Typical breathing in this data set has a frequency 0.2–0.3 Hz (a 3–5-s cycle). The heart beats with a frequency of around 1 Hz (60 bpm). The breathing frequency and the cardiac frequency do not overlap. When a peak of around 1 Hz was detected in the order of the power of the breathing signal, the raw signal was filtered with different settings (a high-pass digital filter with a cutoff of 0.5 Hz to eliminate the breathing frequency) to determine the amplitude of the motion due to heartbeat in all three directions.

RESULTS

Amplitude

For each patient, the average amplitude of the tumor motion was assessed in all three directions (Table 2). In the cranial-caudal (y) direction, tumors situated in the lower lobes and not attached to rigid structures, such as the chest wall or vertebrae, move more than upper-lobe tumors or tumors attached to rigid structures: 12 ± 6 and 2 ± 2 mm (SD), respectively, ($p = 0.005$, two-tailed, unequal variances). For tumors attached to rigid structures and for the LR and AP directions, there was no difference in amplitude between upper- and lower-lobe tumors; the motion was small in these directions: 1.2 ± 0.9 mm (SD) for the LR direction and 2.2 ± 1.9 mm (SD) for the AP direction. Two patients showed tumor motion

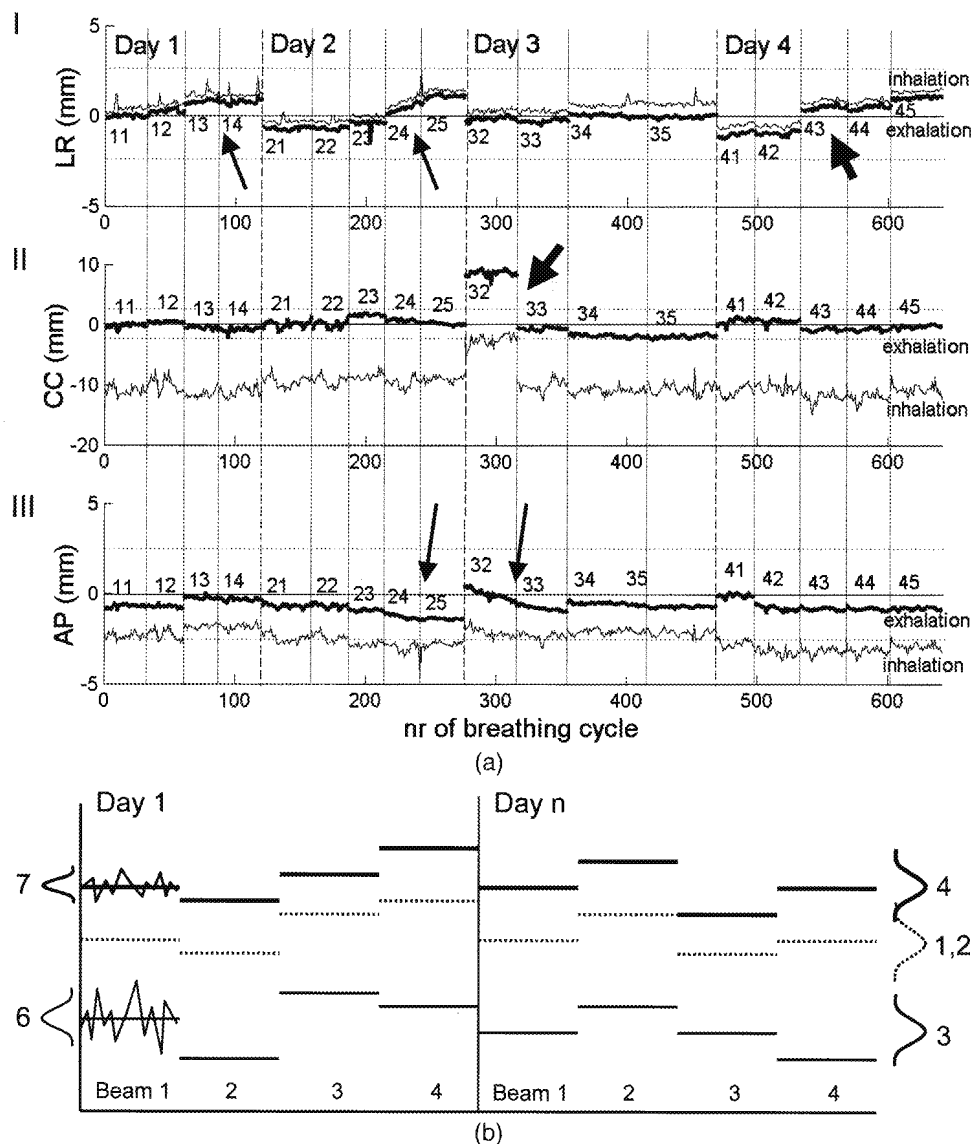


Fig. 2. (a) Position of inhalation and exhalation phase of Patient 3 during the treatment: I, LR direction; II, CC direction; and III, AP direction. The numbers represent the days and the beam directions; for example, 21 is the first beam on Day 2. The variation in the inhale position is larger than in the exhale position. Between the days and between the beams, a systematic shift in the average tumor position can be present (thick arrow). In the AP and LR directions, a gradual shift is present in the course of one treatment day (thin arrows). (The treatment efficiency of beam 15 and beam 31 was too low, and this beam was delivered without using the RTRT system with a larger margin.) (b) The different variations in tumor position that were given in Table 3 (The numbers in the figure correspond to the numbers used in Table 3) are as follows: (1) The average tumor position represents the difference between the planned zero-position and the actual tumor position during the treatment averaged over all patients. The systematic deviation from 0 is because the planned zero-position was normally the exhale and not the average tumor position. (2) The variation in the average tumor position contains variation in residual setup errors, breathing, patient movement during and between treatment days, and changes in breathing level and intensity. (3) The variation in the average inhale tumor position contains variation in residual setup errors, breathing, patient movement during and between treatment days, and changes in breathing level and intensity. (4) The variation in the average exhale tumor position, variation in residual setup errors, breathing, patient movement during and between treatment days, and changes in breathing level. (6) The variation in the inhale tumor position, corrected for its average, contains variation in patient movement *during* treatment, and changes in breathing level and intensity. (7) The variation in the exhale tumor position, corrected for its average, contains variation in patient movement *during* treatment and changes in breathing level.

of more than 5 mm in the AP direction; both tumors were located anterior and in the middle of the thorax (Patients 8 and 19). The average efficiency (total treatment time/total irradiation time) of the RTRT system is 59% for this

patient group. The efficiency depends on the amplitude of the breathing motion and the size of the box representing the permitted displacement. When the tumor motion was large, the relative amount of time that the tumor spent

outside the permitted displacement region was large, and the treatment efficiency was low. When the treatment efficiency dropped below 10%, the RTRT treatment was abandoned, and the patient was treated using a conventional treatment technique.

Average tumor position

Six patients showed a time trend in tumor position during one beam direction or during one treatment day, mostly in the posterior direction. Between the beams, shifts in the tumor position were frequently observed in all three directions (for example, Patient 3 [Fig. 2A]). Between subsequent days, the average tumor position could also shift. The trends and the shifts during one treatment day may have been caused by patient motion or internal tumor motion (change in breathing level), whereas for the shifts between subsequent days, the “residual setup error” would have played a role, as well.

The average tumor position and the variations in average tumor position, amplitude, and inhale and exhale tumor positions, averaged for each treatment beam or corrected for its average (Fig. 2B), are given in Table 3. The variations in the averages of the exhale and inhale tumor positions were comparable to the corresponding values of the average tumor position.

For the CC and AP directions, the variation in the inhale and exhale tumor positions, corrected for the average values (and thus corrected for the shifts between the beams and between the days), was smaller (p value < 0.001, paired t test) than the variation in the inhale position.

3D path of the tumor

Visualization of the 3D path of the tumor (Fig. 3A)

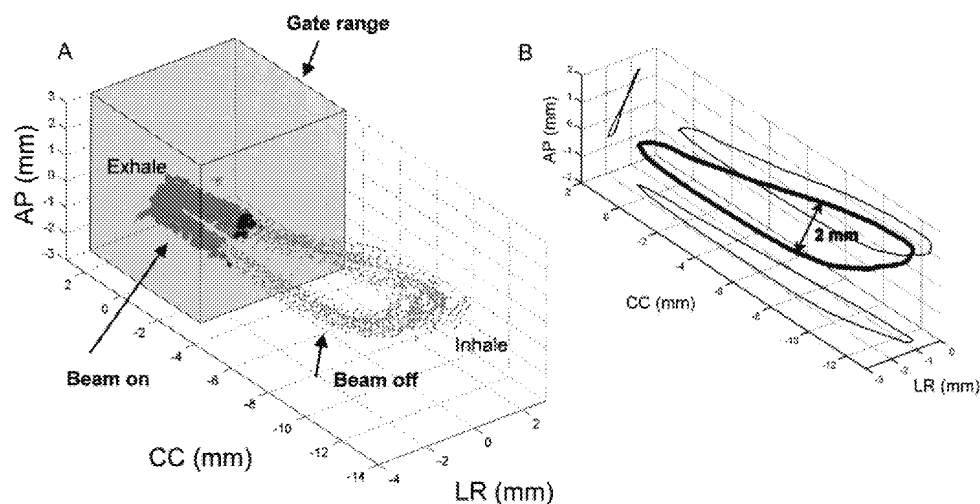


Fig. 3. (A) The 3D path of the tumor of Patient 10 during one treatment portal: The gray dots represent the tumor position throughout the treatment, and the black dots represent the tumor position as the tumor is detected to be inside the RTRT range (transparent box). The asterisk represents the planned zero position. (B) The average 3D curve of the tumor: The projections on the coronal, sagittal, and axial planes are drawn in thin black lines. Note that the tumor follows a different path during inhalation than during exhalation (hysteresis).

Table 3. Summary statistics of tumor positions (in mm): see also Fig. 2B

	LR	CC	AP
1. Average tumor position	-0.4	-1.5	-1.6
2. SD in average tumor position	0.8	1.2	1.1
3. SD in average inhale tumor position	0.9	1.3	1.1
4. SD in average exhale tumor position	0.8	1.2	1.1
5. SD in amplitude	0.2	0.8	0.3
6. SD in inhale tumor position*	0.2	0.8	0.4
7. SD in exhale tumor position*	0.2	0.4	0.3

Abbreviations: SD = standard deviation; LR = lateral; CC = cranial-caudal; AP = ventral-dorsal.

*Corrected for changes in average ex- or inhale position.

gave an impression of the hysteresis and the relation of the tumor motion to the permitted displacement (gate range). The shape of the average 3D curve (Fig. 3B) was fairly constant in time; differences were mainly because of shifts in average tumor position and changes in amplitude. The projections of the trajectories of the tumors on the coronal and sagittal plane were calculated for each patient (Fig. 4). The tumors attached to rigid structures are encircled. A change in the shape of the 3D path was observed between subsequent days in only 1 patient (Fig. 5).

Shape and length of the breathing cycle

For the patient group in this study, the average length of one breathing cycle was 3.6 ± 0.8 s (SD). The individual breathing periods and the variation during treatment are given in Table 2.

For each patient, the parameters of the sinusoid (Eq. 1) were determined. Equation 1 fitted well for the majority of the patients (Fig. 6A); the fitted values for the amplitude and

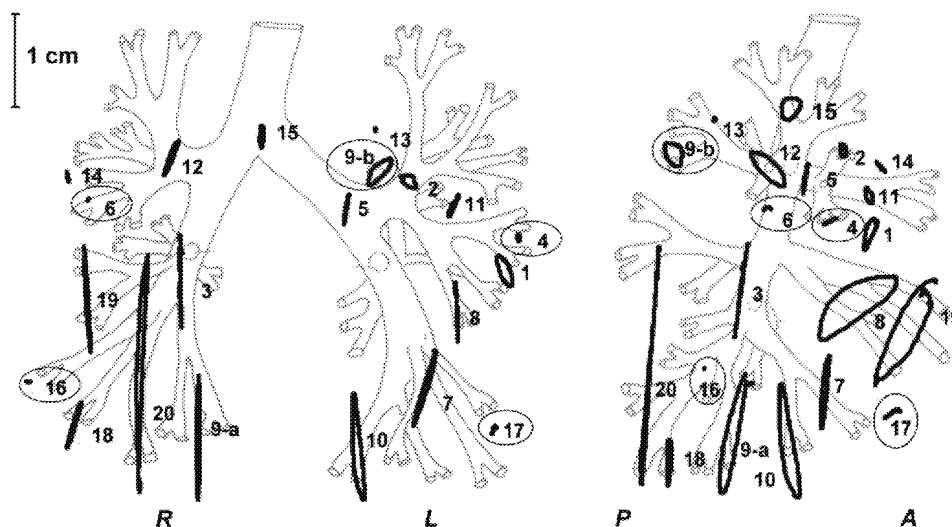


Fig. 4. Orthogonal projections of the trajectories of the 21 tumors on (left) the coronal (LR-CC) and (right) the sagittal (AP-CC) plane. The tumors are displayed at the approximate position, based on the localization mentioned in the treatment chart. Tumors that were attached to bony structures are circled.

period agreed with the measured values. The value for n varied between patients (Table 2). For 2 patients, the parameters $n = 1$ and $n = 2$ fitted equally well, suggesting that the shape of the actual breathing curve was somewhere between the two parameterized curves. In one case, the patient's breathing was very irregular, and the value for n varied between 3 and 9 (Fig. 6B), depending on the breathing period—the longer the period, the higher the value of n . However, the shape of the tumor motion for the longer period was similar to that of the shorter cycle; only the time spent in the exhale position was prolonged in the longer cycle. The value of n did not correlate with the breathing period for the whole patient group.

Hysteresis

In the (average) trajectories of the tumor, hysteresis was observed in 10 of the 20 patients: The tumor followed a different path during inhalation than during exhalation. The presence of hysteresis in one plane could be determined by calculating the phase difference between the fitted parameterized curves of the average breathing cycles of two directions (Fig. 7). When present, hysteresis was largest in the AP-CC plane (sagittal plane), but was also observed in the other planes (Table 4). A phase shift between the signals did not lead to a measurable hysteresis in four other patients, because the tumor movement was less than 1 mm.

Patient 8

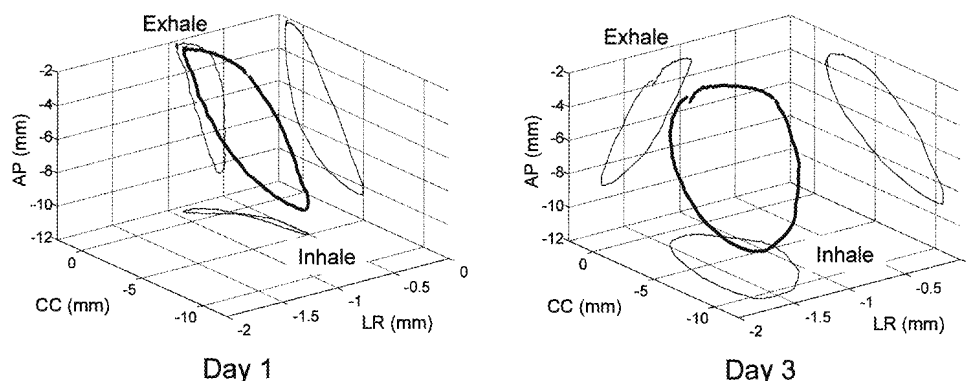


Fig. 5. The 3D trajectory of the tumor of Patient 8: (A) On Day 1, the pattern was similar to that on Day 2 and 4. (B) Day 3. The shape and direction of the motion changed between subsequent days: In the coronal plane on Day 3, hysteresis was present, whereas on Days 1, 2, and 4, this was not the case. In the transaxial (AP-LR) plane, the motion switched from left to right on Days 1, 2, and 4 and to right to left on Day 3.

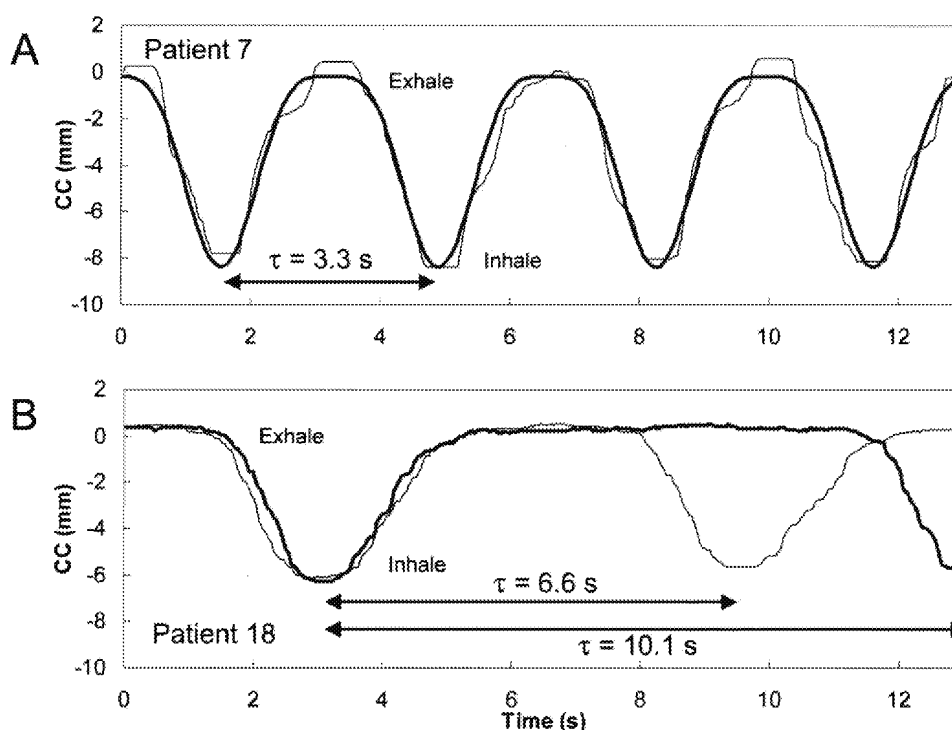


Fig. 6. (A) The time signal of the tumor motion of Patient 7 (CC direction). A curve was fitted through the data with ($\tau = 3.3$ s and $n = 2$). (B) The time signal of the tumor motion of Patient 18, who had a very irregular breathing pattern (CC direction). The thin line represents tumor motion with a period of 6.6 s, whereas later on the period was 10.1 s. The first cycle could be fitted well with $n = 3$; the second cycle was fitted with $n = 9$. Note that the shape of the tumor motion of the longer period is similar to that of the shorter cycle, only the time spent in the exhale position is prolonged in the longer cycle.

Heartbeat

In 7 of the 20 patients, the heartbeat caused a measurable tumor motion (Table 5). When the cardiac frequency was detected in the frequency analysis (Fig. 8A), the amplitude of the tumor motion was measured in the time signal (Fig. 8B). In 2 patients, tumor motion due to the heart was detected in two directions. The tumor was attached to, or near, the aorta in 6 of the 7 patients. The distance of the marker to the cardiac or aortic wall was less than 3 cm in these 6 patients. The motion due to the heartbeat was largest in the LR direction (range: 1–4 mm). In the other directions, the motion was 1–2 mm.

DISCUSSION

The RTRT system is unique in recording the tumor position in all three directions simultaneously at a high sampling rate. This enabled us to detect tumor motion due to the heartbeat, as well as hysteresis. The system measures the position of a gold marker implanted in or near the tumor. In some studies (11, 12, 19, 20, 21), the position of the chest wall or diaphragm is used to monitor breath-holding or to trigger the linear accelerator. However, the position of the tumor can be different from the position of these structures. For example, in the study by Hanley *et al.* (11), the chest wall moved with an amplitude of 2 to 2.5 mm, whereas the

diaphragm of the same patients moved 20–38 mm. Minohara *et al.* (20) measured the breathing phase with an ir-LED and a PSD camera. They found a phase difference of about 200 ms between the position of the diaphragm and the respiratory signal from the LED camera system that was placed under the left rib. In other studies, the volume of the inhaled air is used as a measure of the tumor position (6). Although these techniques are useful to determine the inhale or exhale phase of the breathing, the 3D tumor motion and the exact position of the tumor are not measured directly and must be inferred.

During real-time tumor tracking radiotherapy, the shape of the 3D path of the tumor did not change significantly over time. However, its amplitude and position in space varied because of patient shift or “setup” errors, as well as changes in breathing level and intensity. The tumor motion due to breathing is not one-dimensional, as assumed in simulation studies (18, 22), but a combination of movement in all three dimensions, sometimes resulting in hysteresis. However, tumor motion due to breathing is largest in the cranial-caudal direction, especially in unfixed lower-lobe tumors. Tumor motion in the presented patient group agrees with tumor motion found by Ekberg *et al.* (10). In the present study, the amplitude of the movement was different for tumors attached to rigid structures, such as the chest wall or vertebrae. These tumors move only slightly, in agreement

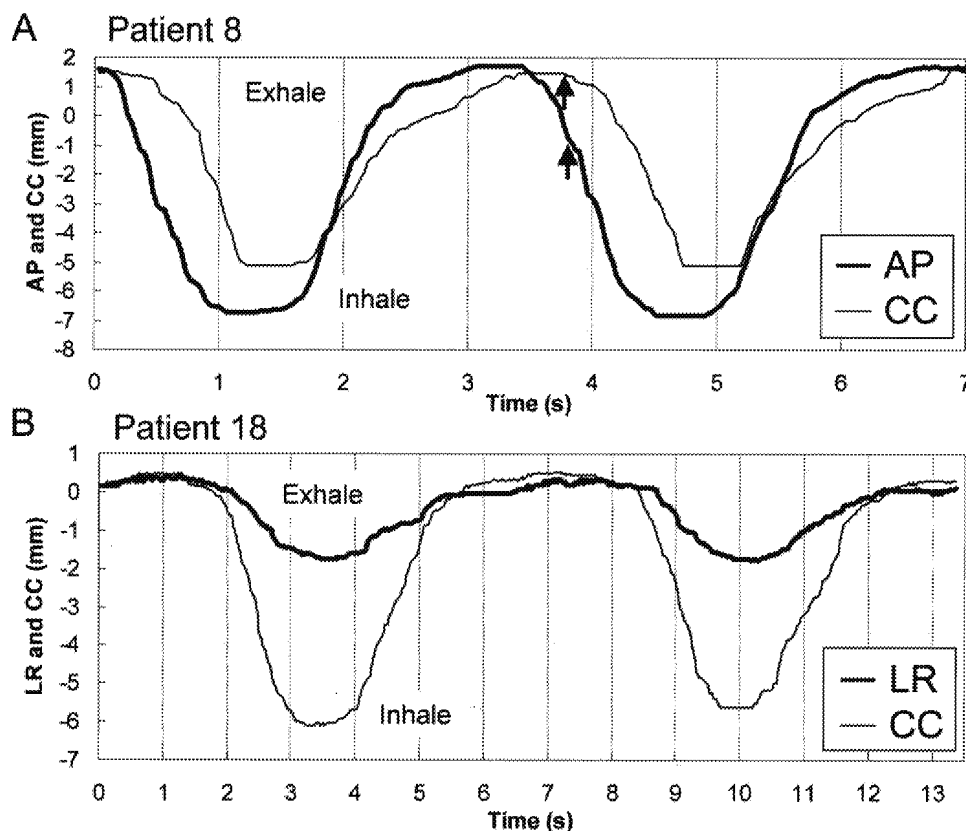


Fig. 7. (A) Time signal of Patient 8 in the AP and CC directions. There was a phase difference ($\Delta\phi$) of 0.5 s between both signals, causing hysteresis. At the arrow, the tumor in the CC direction is still in the exhale position, whereas in the AP direction, inhalation has already started. (B) Time signal of Patient 18 in the AP and CC directions. There was no measurable phase difference between both signals.

with findings by Ross *et al.* (23), who also found that tumors in upper lobes and tumors that were attached to the chest wall moved less than lower-lobe tumors.

Two patients (Patients 8 and 19) showed significant hysteresis. Both tumors were located at a similar position in the lungs, one in the left lung and one in the right (Fig. 4). One of these patients suffered from emphysema with prominent chest breathing. These findings suggest that preexisting lung disease and breathing techniques are

important for estimating the amplitude of the tumor motion.

The position of the tumor during the exhale phase of tidal breathing is considered to be the most stable and reproducible position (24). This is assumed in many gated treatment designs, and for the intrafractional period, this was confirmed by our study. However, for some tumors a systematic shift or trend between different beams and/or fractions was observed, particularly in the posterior direction. The variations in the shifts and trends were larger than the variations during one beam and do not differ for the inhalation and exhalation tumor position.

The time trends could be attributed to patient relaxation throughout the treatment (combined with a reduction in amplitude) or to gravity acting on compliant lung tissue shortly after the patient assumes a supine position. A systematic shift could result from changes in muscle tone, a slight shift in patient position, or simply a change in the level at which the patient started breathing. The shifts in exhale position between *subsequent* days can also be caused by the variation in the zero-position of the RTRT treatment. During the setup phase of the treatment, the physician assesses the tumor motion based on two fluoroscopy images. The tumor motion visible on these images is a two-dimensional projection of the real 3D

Table 4. The amount of hysteresis (in mm) in three planes

Patient no.	Coronal (mm)	Sagittal (mm)	Transaxial (mm)
1	1.5	1	1
2	1.5	1	
8		5	
9a		2	1.5
9b	2	3	
10	2		
11		1	
12		2	
15		2.5	
19		3	
20	1		

Table 5. Tumor motion due to heartbeat

Patient no.	Frequency (bpm)	Amplitude (mm)			Lobe	Tumor attached to:	Distance from the cardiac or aortic wall to the marker (mm)
		LR	CC	AP			
2	66	1			Upper	Aorta	30*
5	70	1		1.5	Upper	Bronchus	10
7	62		1		Lower	Aorta	25*
8	60		2		Upper	Free	30
9b	63	2			Upper	Vertebra and aortic arch	15*
11	60	4			Upper	Aorta	27 [†]
15	72		1.5	1	Upper	Free	65*

The discrepancies between the tumor attachment and the distance from the cardiac or the aortic wall to the marker can be explained by:

*The marker was positioned near and not in the tumor.

[†]The tumor volume was large.

Abbreviations: LR = lateral; CC = cranial-caudal; AP = ventral-dorsal.

motion. It is possible that the zero-position is chosen correctly along one direction, but not necessarily along the other directions. Additionally, it is not possible to put the zero-position at exactly the same position in the breathing cycle each day. Thus, the combination of the placement of zero-position, patient shifts, and changes in breathing level can cause a variation in the order of 1 to 1.5 mm. Improvement in the placement of the zero-position is required for improved accuracy. This can be accomplished by automatically determining the average tumor position relative to the exhale tumor position by means of a short real-time tumor tracking session before the actual treatment. However, interfraction changes in breathing level cannot be monitored with this technique.

To obtain the best treatment efficiency for RTRT treatments, as well as to determine the ideal tumor position for gated or breath-hold radiotherapy or CT, the phase of the breathing cycle representative of the average tumor position must be identified. The tumor motion can be modeled using a periodic but asymmetric function (more time spent at exhale vs. inhale [Eq. 1]). The amount of time the tumor spent in the exhale position differed per patient. The tumor motion was more asymmetric for a patient with a relatively long breathing cycle.

The 3D analysis of the tumor motion revealed also that in some patients, the trajectory of the tumor during inhalation is different from the trajectory during exhalation. This hysteresis can, for example, be induced by the breathing technique, especially when diaphragm and chest breathing are combined asymmetrically. Another possible explanation for hysteresis is the lung's dynamic properties. Because of the elasticity of the lung tissue, the tumor motion may be delayed compared to the motion of the chest wall and/or the diaphragm. It can take a while before the tumor occupies a stationary position (This is reached during the relatively long "rest" periods during the inhalation and especially the exhalation phase). Lung diseases such as emphysema, bullae, or fibrosis can influence the elasticity of lung tissue anisotropically and cause hysteresis. When hysteresis in tumor motion is

caused by the dynamic properties of lung tissue, breath-hold scans will not give the representative position of the tumor. During normal breathing, there is hysteresis; during a long breath hold, however, the tumor occupies its stationary position. Hysteresis can seriously affect the accuracy in radiotherapy, which uses the position of skin, diaphragm, or physiologic parameters for respiration gating without considering the respiration phase. During real-time tumor tracking, the tumor may be inside the permitted range for inhalation, but outside for exhalation (Fig. 9). When this occurs in two or three directions, hysteresis can increase the irradiation time considerably. The cause of hysteresis and its effect on treatment accuracy will require further study in the future.

Using discrete Fourier analysis, tumor motion due to heartbeat was detected in 7 of the 20 patients. The amplitude of this motion was 1–4 mm, mostly in the LR direction. Tumor movement with heartbeat was most significant for tumors attached to the aorta. In the fluoroscopy study by Ekberg *et al.* (10), it was observed that for tumors located close to the heart, cardiac movement was a major contributor to tumor motion. In a 20-patient study by Ross *et al.* (23) using an ultra-fast CT scanner, tumor motion of 9 ± 6 mm in the LR and AP directions was measured that was attributed to aortic pulsation, cardiac contraction, and respiration. Neither author distinguished between tumor motion caused by breathing or cardiac motion.

Although real-time tumor tracking using an implanted gold marker resulted in precise information regarding the tumor position, the technique has inherent limitations. The gold marker is not always inserted exactly into the tumor, so the motion measured with the RTRT system may not correspond exactly with the real tumor motion. Measuring marker motion relative to tumor motion during treatment is hampered because of the poor visibility of the tumor in the fluoroscopic images. When the tumor is large, some parts of the tumor may not move as a fixed, rigid structure. Tumor rotation and deformation cannot be detected using a single inserted marker. Furthermore, the presence of the gold

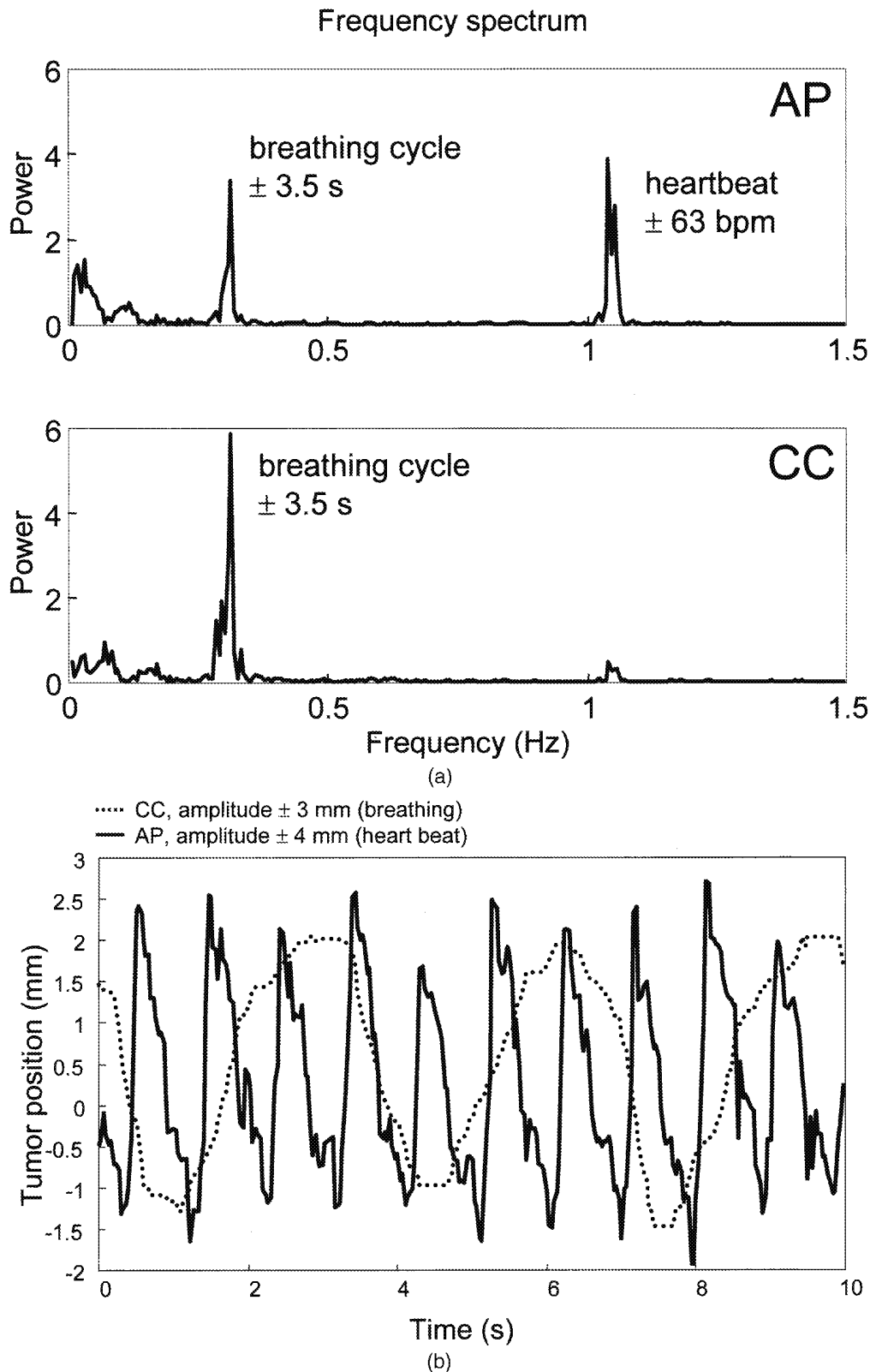


Fig. 8. (a) The frequency spectrum of the LR and CC coordinates of Patient 11. Two frequency peaks are present in the registration, one at 0.3 Hz as a result of breathing and one at 1.05 Hz as a result of the heartbeat. In the CC direction, the power of the heartbeat signal is weak compared to the power of the breathing signal; in the LR direction, the heartbeat has the largest power. (b) The time signals of the LR (solid line) and CC (dotted line) tumor positions. In the LR direction, tumor motion due to heartbeat is visible. In the CC direction, only the breathing is visible.

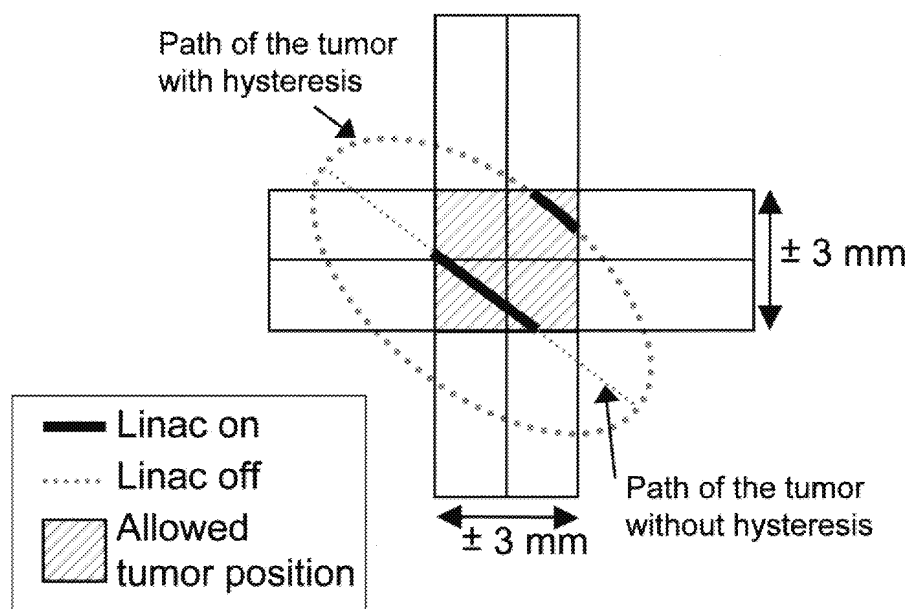


Fig. 9. The path of a moving tumor with and without hysteresis (dotted line) during RTRT treatment. The solid line represents the time that the linear accelerator is irradiating the tumor. When hysteresis is present, the tumor is irradiated during only about 10% of the treatment time; when there is no hysteresis, the tumor is irradiated about 30% of treatment time.

marker (relatively heavy compared to the lighter lung tissue) may distort the tumor motion or result in hysteresis. Migration of the internal marker was not studied in lung cancer, but was small (on the same order as CT accuracy) in prostate and liver cancer studies (25). Experiments have already begun involving implantation of three markers to measure rotation and tumor shrinkage. Breath-hold and repeat CTs will be made to assess marker migration and tumor motion relative to marker motion.

CONCLUSION

In conclusion, the RTRT system has been used to measure tumor position in all three orthogonal directions simultaneously, at a high sampling rate that enabled the detection of tumor motion due to heartbeat, as well as hysteresis. Tumor motion and hysteresis could be modeled with an asymmetric trigonometric function. Tumor motion due to breathing was greatest in the cranial-caudal direction for lower-lobe unfixed tumors.

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Prostate rotation detected from implanted markers can affect dose coverage and cannot be simply dismissed

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With implanted markers, daily prostate displacements can be automatically detected with six degrees of freedom. The reported magnitudes of the rotations, however, are often greater than the typical range of a six-degree treatment couch. The purpose of this study is to quantify geometric and dosimetric effects if the prostate rotations are not corrected (ROT_NC) and if they can be compensated with translational shifts (ROT_C). Forty-three kilovoltage cone-beam CTs (KV-CBCT) with implanted markers from five patients were available for this retrospective study. On each KV-CBCT, the prostate, bladder, and rectum were manually contoured by a physician. The prostate contours from the planning CT and CBCT were aligned manually to achieve the best overlaps. This contour registration served as the benchmark method for comparison with two marker registration methods: (a) using six degrees of freedom, but rotations were not corrected (ROT_NC); and (b) using three degrees of freedom while compensating rotations into the translational shifts (ROT_C). The center of mass distance (CMD) and overlap index (OI) were used to evaluate these two methods. The dosimetric effects were also analyzed by comparing the dose coverage of the prostate clinical target volume (CTV) in relation to the planning margins. According to our analysis, the detected rotations dominated in the left-right axis with systematic and random components of 4.6° and 4.1°, respectively. When the rotation angles were greater than 10°, the differences in CMD between the two registrations were greater than 5 mm in 85.7% of these fractions; when the rotation angles were greater than 6°, the differences of CMD were greater than 4 mm in 61.1% of these fractions. With 6 mm/4 mm posterior planning margins, the average difference between the dose to 99% (D99) of the prostate in CBCTs and the planning D99 of the prostate was $-8.0 \pm 12.3\%$ for the ROT_NC registration, and $-3.6 \pm 9.0\%$ for the ROT_C registration ($p = 0.01$). When the planning margin decreased to 4 mm/2 mm posterior, the average difference in D99 of the prostate was $-22.0 \pm 16.2\%$ and $-15.1 \pm 15.2\%$ for the ROT_NC and ROT_C methods, respectively ($p < 0.05$). In conclusion, prostate rotation cannot be simply dismissed, and the impact of the rotational errors depends on the distance between the isocenter and the centroid of implanted markers and the rotation angle.

PACS number: 87.55

Key words: prostate rotation, implanted markers, image-guided radiotherapy, IMRT, image registration

I. INTRODUCTION

During radiotherapy of patients with prostate cancer, the prostate position may vary due to the changes in the filling of the bladder and rectum.⁽¹⁻²⁾ Such variations pose a great challenge to

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the precision of treatment delivery. The use of image-guided radiotherapy (IGRT) improves treatment precision considerably by correcting daily patient setup error and internal organ motion. Most target localization corrections from IGRT, however, are limited in translation only. Rotational setup error and rotational organ motion have been reported, but often dismissed clinically.

For patient positional setup errors, which are often detected by registering bony structures from the verification images with those from the planning images, most studies reported that rotational setup errors were relatively small with a standard deviation of about 1° around each axis.⁽³⁻⁶⁾ Because of the small magnitude, some have suggested that the rotational errors can be ignored,⁽⁷⁻⁸⁾ while others have suggested use of a robotic treatment couch to correct for this magnitude of rotation.⁽⁹⁾

For intertreatment organ motion of the prostate, several studies showed that the prostate organ rotation could be greater than setup error and might have an important dosimetric impact.^(3,10-19) Large prostate rotations are often reported by registering the implanted markers between the verification and planning images. Rotations around left-right (LR) axis were found to be dominant because of influence of the filling of the rectum. Deutschmann et al.⁽¹⁸⁾ found the average LR rotation was $5.3^\circ \pm 4.9^\circ$, with maximum at 30.7° for 31 patients. Lips et al.⁽¹⁹⁾ reported rotational errors with systematic error of 6.3° and random error of 4.9° , ranging from -12.1° to 9.1° for a cohort of 19 patients.

Although using implanted markers as a surrogate to localize the prostate is a well-adopted method for daily IGRT,⁽²⁰⁻²¹⁾ large rotations reported from the implanted marker registration are beyond the maximum correction ranges for most commercially available six-degree couches. Others may even question the accuracy of such large rotations, and how the stability of the markers and their implanted locations affect the accuracy of these detected rotations. The purpose of this study is to quantify geometric and dosimetric effects with and without compensation for rotations detected based on marker registration, rather than to determine accuracy of the rotations detected from the marker registration.

II. MATERIALS AND METHODS

A. Patient selection and treatment planning

Five patients, who underwent definitive external beam radiotherapy for prostate cancer, had three electromagnetic transponders implanted in the prostate for daily IGRT, using the Calypso 4D localization system (Calypso Medical, Seattle, WA). In addition, weekly or daily kilovoltage cone-beam CTs (KV-CBCT) were also acquired to cross-check the Calypso system, as needed, upon the request of radiation oncologists. A total of 43 KV-CBCTs were available for this retrospective study.

The patients were treated with two different dose schemes: 2 Gy per fraction to a total dose of 78 Gy, and 2.5 Gy per fraction to a total dose of 70 Gy. For the purpose of this study, the prescription dose for all plans was renormalized to 2 Gy per fraction to a total dose of 78 Gy without altering IMRT optimization. The CTV was the prostate and the organs at risk (OAR) were the bladder and rectum. The clinical planning margins for these patients were 6 mm/4 mm posterior. The IMRT plans were created with the Pinnacle treatment planning system (Pinnacle³, 8.0m-9.0, Philips Radiation Oncology System, Madison, WI), using a typical five beam arrangement with 10 MV photon beams.

B. Quantification of the prostate displacement

On each KV-CBCT, the prostate, rectum, and bladder were manually contoured by a physician. Subsequently, each CBCT was registered with the corresponding planning CT using four different alignment methods (a total of 172 imaging registrations) including (i) manually align the bones using three degrees of freedom (three translations only) (Bone_T); (ii) automatically

align the three markers using six degrees of freedom (three translations and three rotations), but rotations are not corrected (ROT_NC); (iii) manually align the three markers using three degrees of freedom, which partially compensates rotations with translational shifts (ROT_C); and (iv) manually align the prostate contour using three degrees of freedom (Contour_T), which also partially compensates rotations with translational shifts. After subtracting translational shifts from the bony alignment (Bone_T), patient setup error was removed from the other three alignment methods. All the reported shifts in this paper were the prostate displacements relative to the pelvic bones.

To quantify rotations of the prostate, overall mean and standard deviation of the rotational errors were determined from the measurements of all patients. Systematic and random errors were calculated according to the method published by Remeijer et al.⁽⁵⁾ The systematic error of the entire group is the standard deviation of the individual patient means corrected for the limited and different number of measurements for each patient. The random error of the entire group is the root mean square of the individual patient standard deviation, also weighted by the number of measurements for each patient.

To investigate whether the rotations of the prostate can be compensated with translational shifts, we used the contour registration method (Contour_T) as a benchmark to evaluate the two marker registration methods (ROT_NC and ROT_C) by comparing their geometric and dosimetric indices.

C. Marker migration and false identification

Marker migration is critical for detection of the daily prostate rotation. It can be quantified by measuring the intermarker distance variation of the implanted markers between the planning CT and the daily CBCT. Besides marker migration, other causes that might produce intermarker distance variation include organ shrinkage, organ deformation, and position localization errors of the markers. These factors can affect the accuracy of the detected rotations. To examine the stability and localization error of the implanted markers, we measured the intermarker distances of the treatment day with detected rotations greater than 10° and compared them with the intermarker distances in the planning CT. We also simulated marker migration/false identification by manually adjusting the position of one of the three markers to investigate how it affects the detected rotations. For 7 fractions with rotations greater than 10° , we moved the selected marker by 1 mm and 2 mm from its original position in axial plane and moved one slice thickness (1.5 mm) superiorly and inferiorly.

D. Geometric analysis

To minimize potential prostate contour variations in daily CBCT, manually contoured prostate on each CBCT, denoted as Prostate_CBCT, was used only for contour-based alignment, not for geometric analysis. After each image registration, we used the transferred contours from the planning CT for geometric analysis. The transferred contours, denoted as Prostate_ROT_NC, Prostate_ROT_C, and Prostate_Contour_T, corresponded to the ROT_NC, ROT_C, and Contour_T registrations, respectively. All these contours were the CTV contours. For the ROT_NC registration, rotations were ignored for contour transferring, reflecting a certain clinical scenario in which a registration with six degrees of freedom was performed, but only translational shifts were corrected. Figure 1 is an example illustrating these prostate contours obtained from different registration methods.



FIG. 1. Prostate contours from different registration methods in (a) transverse, (b) coronal, and (c) sagittal views. Prostate_ROT_NC is shown in blue, Prostate_ROT_C in red, Prostate_Contour_T in purple, and Prostate_CBCT in yellow.

D.1 Center of mass distance

For each of these prostate contours, a center of mass (COM) was calculated in the same CBCT frame. As a global measure of daily prostate displacement, the center-of-mass distance (CMD) of the prostate contours between the bony registration and each of the other three registration methods was calculated using the following equation:

$$d = \sqrt{(x - x_0)^2 + (y - y_0)^2 + (z - z_0)^2} \quad (1)$$

where d is the CMD, and x , y , and z are the coordinates of the COM of the transferred prostate contour after each registration method, and x_0 , y_0 , and z_0 are the coordinates of the COM of the transferred prostate contour after bony registration. Using this equation, we verified the result of the contour-based registration by calculating the relative CMD between the Prostate_CBCT and the Prostate_Contour_T.

Using the contour registration (Contour_T) as a benchmark, we compared the accuracy of the two marker registration methods (ROT_NC and ROT_C) by calculating the relative CMDs between the Prostate_Contour_T and Prostate_ROT_NC, and between the Prostate_Contour_T and Prostate_ROT_C.

D.2 Overlap index

To quantitatively evaluate the geometric properties of the two marker registration methods, we defined the volume overlap index (OI) as:

$$OI = \frac{\text{Prostate\_Contour\_T} \cap T[\text{Prostate\_CT}]}{\text{Prostate\_Contour\_T}} \quad (2)$$

where T is the transformation applied to the prostate contour from the planning CT (Prostate_CT) by the two marker registration methods, and the operator $\cap$ defines the common area between the two regions of interest. Thus we have:

$$OI_{NC} = \frac{\text{Prostate\_Contour\_T} \cap \text{Prostate\_ROT\_NC}}{\text{Prostate\_Contour\_T}} \quad (3)$$

and

$$OI_C = \frac{\text{Prostate\_Contour\_T} \cap \text{Prostate\_ROT\_C}}{\text{Prostate\_Contour\_T}} \quad (4)$$

where subscript *NC* and *C* represent the ROT_NC and ROT_C methods, respectively. OI is a volumetric measure for registration accuracy, describing the geometric overlap between the “prostate of the day” and the “prostate at planning”. Since all the contours (Prostate_Contour_T, Prostate_ROT_NC, and Prostate_ROT_C) presented in Eqs. (3) and (4) are contours transferred from the planning CT based on different registration methods, OI is a value ranging between 0 and 1. The higher the value, the more the overlap between the actual target volume and the planned target volume, and thus the better the registration outcome.

E. Dosimetric analysis

For each CBCT, three verification plans were created to calculate the radiation dose of the treatment day using the same beam configuration as the original treatment plan. The treatment isocenters for these three verification plans were placed according to the three registration methods, ROT_NC, ROT_C, and Contour_T, respectively. A total of 129 verification plans were created and analyzed. Since the Hounsfield Units (HU) in CBCT is inaccurate and unreliable for dose calculation, the electron density of the CBCT was overridden with 1 g/cm³ for voxels inside the patient external body contour, and 0 (air) for voxels outside the external contour.

The clinical planning margins for the prostate were 6 mm, except 4 mm posterior. To investigate the effect of prostate rotation with reduced planning margins, we chose not to conduct replanning for each patient using progressively reduced planning margins, which may introduce variations in initial plan quality. Instead, we created three expanded prostates (namely Prostate-CTVs) to simulate replanning with reduced margins. These Prostate-CTVs were created by three-dimensionally expanding the Prostate_CBCT contour with 2 mm, 4 mm, and 6 mm / 4 mm posterior. We calculated the doses to 99% (D99) of these Prostate-CTVs. For verification plans with 6 mm and 4 mm posterior planning margins, we also evaluated the dose to 5% and 50% (D5 and D50) of the bladder and rectum.

III. RESULTS

A. Prostate rotations

The prostate rotations detected from the ROT_NC registration were recorded and are shown in Fig. 2 for all 43 fractions. The rotations around the anterior–posterior (AP) and superior–inferior (SI) axes were relatively small and primarily within the range of -5° and $+5^\circ$, while the rotations around the left–right (LR) axis were larger, at times exceeding 10° . The overall mean and standard deviation (SD) of the rotations were $3.3^\circ \pm 5.8^\circ$, $-1.4^\circ \pm 2.9^\circ$, and $-0.8^\circ \pm 2.8^\circ$, for the LR, AP, and SI axes, respectively. The systematic SDs were 4.6° , 2.3° , and 2.1° , and the random SDs were 4.1° , 2.0° , and 2.0° for the three axes, respectively (Table 1).

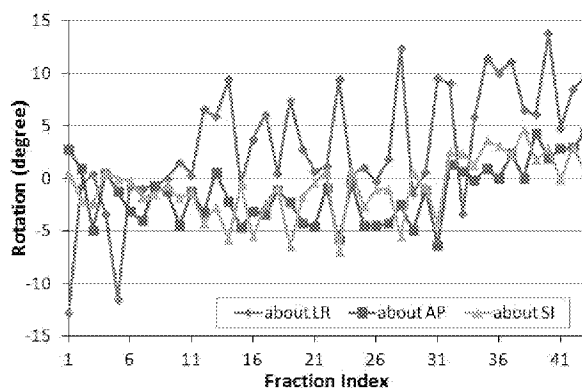


Fig. 2. Prostate rotations about the left–right (LR), anterior–posterior (AP), and superior–inferior (SI) axes for 43 fractions.

TABLE 1. Prostate rotation variations (in degrees) about the left–right (LR), anterior–posterior (AP), and superior–inferior (SI) axes.

	LR	AP	SI
Overall Mean	3.3	-1.4	-0.8
Overall SD	5.8	2.9	2.8
Systematic SD	4.6	2.3	2.1
Random SD	4.1	2.0	2.0

B. Marker migration and false identification

Among 43 fractions, 7 fractions from three patients had rotations greater than 10° . The average intermarker distance for these fractions was 23.3 ± 7.0 mm. The average absolute variation of intermarker distance was 0.8 ± 0.6 mm. Four fractions exhibited marker migrations greater than 1 mm, with a maximum of 2.4 mm. Simulation results of marker migration/false identification showed that with 1 mm variation of the marker position, variation in rotations was less than 2° ; with 2 mm variation of the marker position, the maximum variation in the rotations was 6° . Changing the marker position to its adjacent image slice (slice thickness 1.5 mm) resulted in 3° variation of the rotations.

C. Geometric analysis

The CMD between the transferred prostate contour based on contour registration and the physician drawn contour on the CBCT is shown in Fig. 3(a). This distance is a global measure of the potential prostate deformation and contouring uncertainty, which was detected to be less than 1.9 mm (1.3 ± 0.5 mm) for 95.3% of the fractions. Thus, it is reasonable to use contour-based registration as our benchmark for comparison of the two marker-based registration methods.

Figure 3(b) demonstrates the CMDs between the prostates from the contour-based registration (Contour_T) and from the marker-based registration with rotations zero out (ROT_NC), and the CMD between the prostates from the contour-based registration and from the marker-based translation only registration (ROT_C). Figure 3(b) also shows the CMD differences between the two marker-based registrations. It is observed that when compared with the prostate contour from the ROT_NC registration, the prostate contour from the ROT_C registration is closer to the prostate contour from the Contour_T registration, especially when the rotation is large. The mean CMDs were 6.6 mm and 3.9 mm, respectively. The difference between the two CMDs ranged from -0.9 mm to 8.3 mm when the maximum rotation (absolute value) from all three axes varied from 0.9° to 13.8° . When the rotation was greater than 10° , the difference in CMD between the prostates from the two marker-based registrations was greater than 5 mm in 6 of 7 (85.7%) fractions. When the rotation was greater than 6° , the difference in CMD was greater than 4 mm in 11 of 18 fractions (61.1%). The statistics of the two CMDs and their differences are summarized in Table 2.

The average OI between the transferred prostate contour based on contour registration and the physician drawn contour on the CBCT is 0.79 ± 0.06 , as shown in Fig. 4(a). This index includes the potential prostate deformation, as well as prostate contour uncertainties in the CBCTs. We were not able to separate these two factors. However, the contouring uncertainties had a smaller impact on the CMDs. As shown in Fig. 3(a), the average CMD between the Prostate_Contour_T and the Prostate_CBCT of 1.3 ± 0.5 mm indicated that the prostate deformation might be minimal.

Figure 4(b) compares the OI averaged over each patient for the two marker registration methods. In general, OI_C exhibits greater value than OI_{NC} , indicating that better geometric overlap between the “prostate of the day” and the “prostate at planning” can result from the marker registration with translational correction. In three of five patients, OI_C shows over 10% improvement of overlap when compared with OI_{NC} .

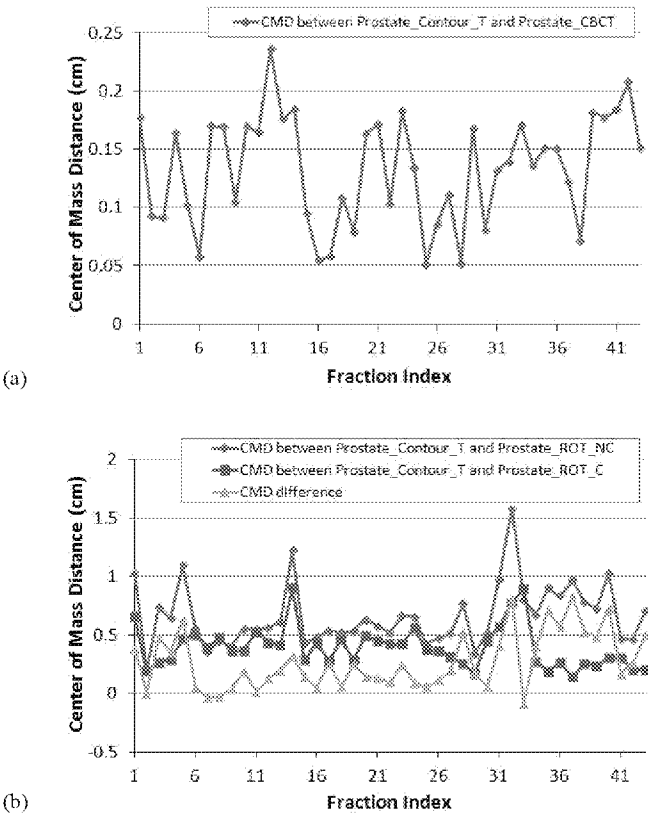


FIG. 3. Center of mass distance (CMD): (a) between the Prostate_Contour_T and Prostate_CBCT; (b) between the Prostate_Contour_T and Prostate_ROT_NC, between the Prostate_Contour_T and Prostate_ROT_C, and the difference.

TABLE 2. Center of mass distance (CMD) of prostate shifts between the contour-based and two marker-based registrations.

	<i>CMD Between ROT_NC and Contour_T⁽³⁹⁾</i>	<i>CMD Between ROT_C and Contour_T⁽³⁹⁾</i>	<i>Difference⁽³⁹⁾</i>
Max.	15.8	9.1	8.3
Min.	1.9	1.4	-0.9
Mean	6.6	3.9	2.7
SD	2.6	1.8	2.4

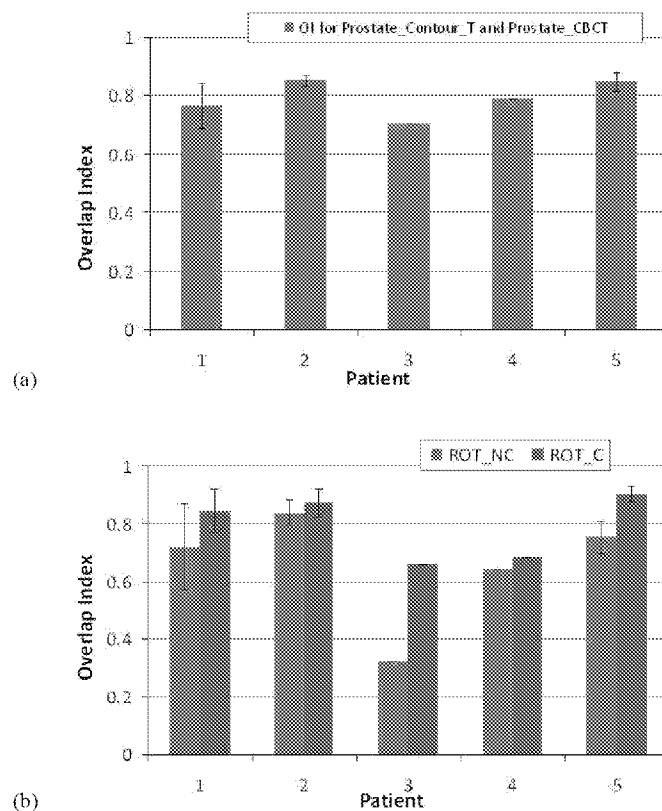


FIG. 4. Overlap index (OI): (a) the average OI for Prostate_Contour_T and Prostate_CBCT for each patient; (b) the average OI for each patient compared between the two marker-based registration methods. Error bar shows one standard deviation.

D. Dosimetric analysis

Figure 5 shows the ratios of D99 of the Prostate-CTVs from three types of verification plans to the planned D99 of the prostate with three equivalent planning margins. With 6 mm/4 mm posterior planning margins, D99 of the prostate was significantly different between the two marker registrations ($p = 0.01$) — $-3.6 \pm 9.0\%$ difference from the planned dose for the ROT_C method, compared to $-8.0 \pm 12.3\%$ for the ROT_NC method. The dose differences ($p < 0.05$) between the two methods increased as the planning margins decreased, as shown in Table 3. For example, with a 2 mm margin reduction (equivalent to a 2 mm expansion of the prostate in this study), the ROT_C method could improve dose coverage to the Prostate-CTV D99 by 6.9%. From Fig. 5, the contour-based registration achieved the best dose coverage, followed by the ROT_C method as the planning margin progressively reduced.

The dosimetric improvement of translational correction is greater when the magnitude of the rotation is large. For example, for a patient with detected rotations of $8.8^\circ \pm 2.9^\circ$ around the LR axis, the average daily D99 of the prostate was 1.99 Gy (99.7% of the planned dose, with a daily prescription dose of 2.0 Gy) with the ROT_C method, compared to 1.68 Gy (84.4% of the planned dose) with the ROT_NC method. As the planning margin decreased to 4 mm/2 mm posterior, the average daily D99 of the Prostate-CTV improved from 1.39 Gy from the ROT_NC method to 1.82 Gy from the ROT_C method, a 21.4% improvement by compensating rotations with translational shifts.

Figure 6 shows doses to 5% (D5) and 50% (D50) of the bladder and rectum for the two marker registration methods. D5 of the bladder and D50 of the rectum did not reach statistically

significant differences (p -values were 0.09 and 0.44, respectively) by the ROT_NC and ROT_C methods. D5 of the rectum was lower than the planned dose for both methods, and D50 of the bladder was significantly lower for the ROT_C method ($p = 0.004$). We also noticed that the dose variation in D50 of the bladder was largely due to the large volume variation of the bladder during the treatment course. The average dose differences for OAR from all fractions between the dose of the day and the dose of the plan are listed in Table 4.

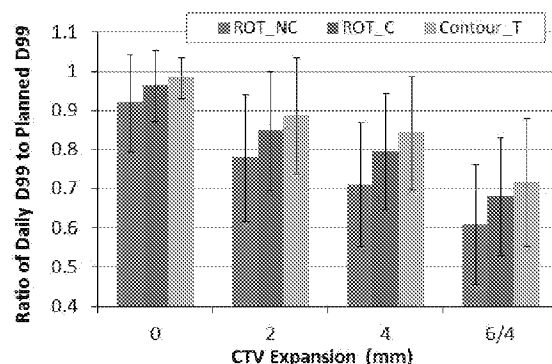


FIG. 5. Average D99 of the Prostate-CTV as a function of CTV expansion margins for the three registration methods. D99 is expressed as a ratio of the daily dose to the planned daily D99 of the prostate. Error bar represents one standard deviation.

TABLE 3. Average difference in D99 of the Prostate-CTV between the daily and planned dose.

Registration Methods	CTV Expansion ⁽³⁹⁾			
	0	2	4	6/4
ROT_NC	-8.0±12.3%	-22.0±16.2%	-28.7±15.8%	-39.0±15.3%
ROT_C	-3.6±9.0%	-15.1±15.2%	-20.4±14.7%	-31.9±15.1%
Contour_T	-1.6±5.2%	-11.3±15.0%	-15.6±14.4%	-28.3±16.3%
Improvement by correction	4.4%	6.9%	8.3%	7.1%

Note: The differences are expressed in percentage (%) of the planned D99 of the prostate as a function of CTV expansion margins. Negative mean value indicates less dose in daily D99 of the Prostate-CTV when compared to the planned dose.

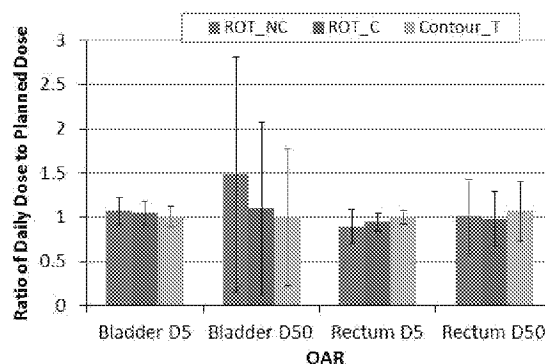


FIG. 6. Average D5 and D50 of the bladder and rectum. Column represents mean value (normalized to the planned dose) and error bar corresponds to one standard deviation.

TABLE 4. Average dose difference for OAR between the daily and planned dose.

Registration Methods	OAR Dose			
	Bladder D5	Bladder D50	Rectum D5	Rectum D50
ROT_NC	7.2±15.9%	48.5±133.4%	-10.5±19.5%	1.2±41.7%
ROT_C	4.8±13.2%	10.1±98.4%	-4.7±10.2%	-1.3±30.5%
Contour_T	0.8±11.8%	0.9±77.2%	0.2±7.9%	7.2±40.0%

Note: The differences are expressed in percentage (%) of the planned dose as the mean ± standard deviation. Negative mean value indicates better organ sparing compared with the original plan.

IV. DISCUSSION

We investigated the magnitude and distribution of the prostate interfractional rotations and evaluated the geometric and dosimetric effects of the rotations. Precisely correcting the prostate organ rotation is clinically important but challenging, especially when rotation angles are large. Recent development of six-degree treatment couches has enabled correction of the rotations,^(9,17,22-23) but such treatment couches are not widely available or able to correct large magnitude of rotations. For the purpose of patient safety, the correction range for a typical six-degree couch is about 4°–5°. Other correction strategies have been proposed, such as gantry and collimator angle adjustments to partially correct for left–right rotations,⁽²⁴⁾ offline adaptive planning,⁽²⁵⁻²⁷⁾ and dynamic MLC tracking.⁽²⁸⁾ However, most of these strategies are in the investigation stages and are not yet clinically practical.

During treatment for most patients with prostate cancer, patient positioning errors and prostate displacement are often not separated. In this study, we used a dual imaging registration method to separate the positioning errors and prostate displacement. Because reported rotation errors in patient positioning were small, we used the bony registration with translational shifts to determine the positional setup errors. Subtracting the translational shifts from the bone registration, the translational shifts and rotations from the marker registration were primarily from the displacement of the prostate, or artifact of the registration method.

Nevertheless, Table 5 compares our data with other reported data in the literature for both systematic and random components of prostate rotations detected with three imaging registration methods. The systematic component describes the variation of the mean displacement of the prostate, while the random component delineates the day-to-day position variation of the prostate. Compared to the results from marker registration, our data agree well with previous

TABLE 5. Systematic and random components (in degrees) of prostate rotations in the literature.

Authors		Systematic Components			Random Components		
		LR	AP	SI	LR	AP	SI
Contour-based Registration	Van Herk et al. ⁽²⁹⁾	N/A	N/A	N/A	4.0	1.3	2.1
	Stroom et al. ⁽¹⁰⁾	3.6	0.8	1.7	3.3	0.9	1.5
	Hoogeman et al. ⁽¹³⁾	5.1	1.3	2.2	3.6	1.6	2.0
Image-based Registration	Nijkamp et al. ⁽²⁵⁾	2.9	0.9	1.0	3.0	1.0	1.1
Marker-based Registration	Dehnad et al. ⁽¹¹⁾	4.7	2.0	2.7	3.6	1.7	1.9
	Aubry et al. ⁽¹²⁾	5.6	2.2	2.4	6.1	2	2.8
	Graf et al. ⁽¹⁷⁾	4.1	2.3	1.6	3.1	1.8	2.0
	Van der Heide et al. ⁽²⁰⁾	6.8	2.8	2.8	3.1	1.7	2.0
	Lips et al. ⁽¹⁹⁾	6.3	2.0	2.8	4.9	1.0	1.4
	Owen et al. ⁽¹⁶⁾	7.6	5.0	7.7	10.2	6.5	15.8
	Our study	4.6	2.3	2.1	4.1	2.0	2.0

results from Dehnad et al.⁽¹¹⁾ and Graf et al.⁽¹⁷⁾ Except for the study conducted by Owen et al.,⁽¹⁶⁾ prostate rotation around the LR axis was found to be the largest of the three axes. Lips et al.⁽¹⁹⁾ and van der Heide et al.⁽²⁰⁾ found larger systematic error (6.3° and 6.8°, respectively) than others around the LR axis, and Aubry et al.⁽¹²⁾ also reported greater random error (6.1°) around the LR axis.

The variation of the reported prostate rotations (Table 5) may stem from differences in treatment protocols, image registration approaches, and mathematical methods for error computation at each institute. Some studies matched the prostate contours in the planning CT with those in the repeated CT scans to get the rotations of the prostate relative to the pelvic bones,^(3,10,13) while others performed the registration based on the implanted markers.^(11-12,16-17,19-20) In addition, the mathematical equations used to compute the systematic and random errors might be slightly different from one study to another. For example, Owen et al.⁽¹⁶⁾ computed the errors using the method described by van Herk,⁽²⁹⁾ and Stroom et al.,⁽¹⁰⁾ and Hoogeman et al.⁽¹³⁾ utilized a similar method but corrected the systematic error for the finite number of measurements. Aubry et al.⁽¹²⁾ employed an approach by Remeijer et al.,⁽⁵⁾ not only considering the limited size of samples, but also accounting for the different number of measurements for each patient. In this study, we used the same method as that in the Remeijer study. Furthermore, the selection of rotation center has a strong effect on the resultant rotations. Owen and colleagues used the marker placed near the apex of the prostate as the pivot point for rotation computation, while for most of the other studies, rotations were measured at the centroid of the prostate contours or the centroid of the markers, depending on whether the contour-based or marker-based registration method is used. The Owen study reported much greater rotations (7.6°, 5.0°, and 7.7° for systematic and 10.2°, 6.5°, and 15.8° for random) than others.

In this study, the registration was performed in the treatment planning system instead of the on-board imaging system of the linear accelerator. Daily CBCT and the planning CT are served as the primary and secondary image for fusion, respectively. The secondary image is translated and rotated to match the primary image. The resultant rotations were measured around the image volume center of the secondary image (planning CT). Rotations could also be measured at the treatment isocenter.⁽³⁰⁾ However, the centroid of the markers, which in general represents the center of mass of the prostate organ, could be different from the treatment isocenter or the image center. For example, for concurrent treatment of the prostate and pelvic lymph nodes, the isocenter is usually placed outside of the prostate. Isocenter may also be adjusted away from the center of the prostate because of practical reasons. In these cases, if rotations are measured around the isocenter, or any point other than the centroid of the markers (e.g., image volume center), ignoring such rotation will introduce a translational error at the centroid of the markers, indicating prostate displacement from its supposed position. For instance, Linthout et al.⁽²³⁾ reported that a tilt rotation of 2.5° at the foot end of the couch could lead to a vertical shift of 4.5 cm at the isocenter for a standard prostate cancer patient positioning (where the isocenter is close to the center of the prostate).

The ROT_NC method obtains a six-degree-of-freedom solution, but only applies the translational components of the solution for correction. In the scenario where the rotation center is different from the centroid of the markers, only the rotation center is corrected precisely with the ROT_NC method (under the assumption of no prostate deformation and other uncertainties such as marker migration). For all the other points in the image, especially for points inside the prostate which we are interested in, there will be a translational error produced by the uncorrected rotation. The magnitude of the error depends on the distance to the rotation center and the detected rotation at that point. Mathematically, the translational error at the centroid of the markers due to uncorrected rotations can be estimated roughly by Eq. (5) according to the law of cosines in Euclidean geometry:

$$\text{error} = D\sqrt{2(1 - \cos\theta)} \quad (5)$$

where D is the distance between the centroid of the markers and the rotation center, and θ is the rotation angle about the LR axis (assuming rotations about the AP and SI axes are small enough to be neglected). Figure 7 shows the magnitude of the measured and estimated error of the ROT_NC method at the centroid of the markers from its true position where rotations are corrected precisely. Except for a few fractions where the assumption of small rotations about the other two axes was not satisfied, the measured errors agreed well with the estimated ones for the majority of fractions. A greater distance D and/or larger rotation angle θ creates larger error. For example, for a patient with $D = 7.3$ cm and $\theta = 4.9^\circ$, the measured translational error associated with the ROT_NC method was 6.8 mm; for another patient with $D = 3.5$ cm and $\theta = 4.5^\circ$, the error was 2.2 mm. For the same patient with $D = 3.5$ cm, the error was 4.0 mm when the detected rotation was 9.4° , compared to 0.5 mm error when the rotation was less than 1° .

On the other hand, the ROT_C method uses only three degrees of freedom for correction. The resultant translational solution contains two separable components. The first component corrects the initial translational error (three translations from the six-degree-of-freedom solution) to the rotation center; and the second component compensates for translations caused by the rotation for points in the prostate by matching the three markers. Therefore, the centroid of the three implanted markers is precisely corrected (theoretically, with the same assumption as above). For other points inside the prostate, the second translational component only partially corrects for rotations. Thus, the residual translational errors of the prostate from the ROT_C method are smaller than those from the ROT_NC method. Using contour-based registration as our benchmark, the displacement of the prostate from its supposed position after correction by the two marker-based registration methods was quantified by the center of mass distance and overlap index (Figs. 3 and 4). In the scenario where the rotation center is the centroid of the prostate, the ROT_NC method will produce the same results as that of the ROT_C method. To avoid substantial shifts of the prostate centroid caused by the ROT_NC method, placing the isocenter close to the centroid of the implanted markers is recommended. Otherwise, using the ROT_C method is recommended.

The detected rotations from marker registration may depend on spatial relationship of the implanted markers, marker stability within the prostate, and the accuracy of the marker identification. It is speculated that when markers are implanted close to each other, large organ rotations may be falsely rendered. Migration or localization errors of implanted markers could also lead to falsely rendered rotations. Although several studies reported that the average marker movement was very small, on the order of 1 mm,^(11,31-34) there was evidence of relatively large intermarker distance variations for individual patients. McNair et al.⁽³⁵⁾ found marker migration of more than 2 mm in 10% (3 of 30) patients; Deutschmann et al.⁽¹⁸⁾ observed 24 of 342 patients had intraprostatic migrations of one of four markers greater than 3 mm, and 10 greater

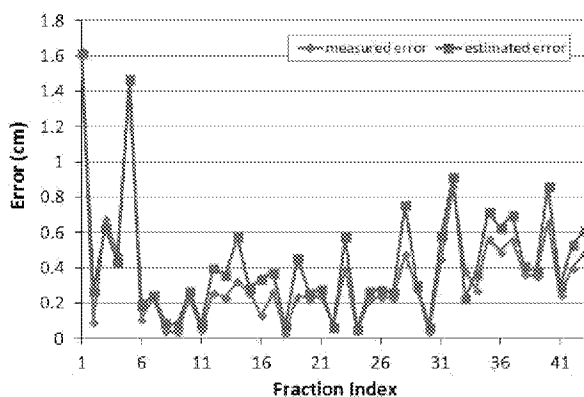


Fig. 7. The magnitude of measured and estimated errors associated with the ROT_NC method.

than 4 mm; while Kupelian et al.⁽³⁴⁾ reported that in 47 of 56 patients (84%), the maximum intermarker distance variation was at least 2 mm, and the percentage for 3, 4, 5 mm variation were 41%, 18%, and 9%, respectively. They also reported that the maximum standard deviation of the intermarker distance was 4.2 mm and the maximum observed variation was 10.2 mm. The infrequent yet potential marker migrations may have more profound effect on the resulted rotations than translations.⁽¹⁸⁾

By examining the intermarker distance variation of fractions with detected rotations greater than 10° , we observed the maximum variation of the Calypso transponders exceeded 2 mm in two patients. Studies have shown that the migration of Calypso transponders is within the similar range of gold markers routinely implanted for prostate treatment.⁽³⁶⁾ When large intermarker distance variations (up to a few millimeters) occurred, either substantial marker migration or significant organ deformation was indicated.^(31,34) In these cases, the rotations detected by marker registration may not truly represent the actual organ displacement. Our simulation experiment reported up to 6° of rotation variation resulted from 2 mm marker migration/false identification, indicating that a small migration of the implanted markers or a small localization error in marker positions may result in a large degree of rotation. Such uncertainties in rotation detection will further hamper the accuracy of rotation correction. On the other hand, marker migrations and false identification will have less influence on the accuracy of the translational shifts. Using translational shifts to compensate for rotational error of the prostate is a safe strategy which will not be affected substantially by the potential marker migration or localization errors of the marker positions.

Mutanga et al.⁽³⁷⁾ found the benefit of rotation corrections was insignificant for systematic error around the LR axis of 4.3° and random error of 4.5° for patients receiving treatment to the prostate only. With 3 mm uniform planning margin, they reported the average increase in population $D_{\min}$ with rotation corrections was only 0.3 ± 0.8 Gy. However, Lips et al.⁽¹⁹⁾ observed patients with large rotations had considerable dose reduction in the CTV in a study with planning margins of 2, 4, 6, and 8 mm. It was concluded that without correcting the rotation errors, online translational correction produced little improvement compared with off-line verification for complex prostate IMRT plans. A study by Li et al.⁽³⁰⁾ also shown that the dosimetric impact of prostate rotation was more significant than the impact of translational shifts in intrafractional motion. They concluded that the treatment margin can be reduced substantially if the residual rotational errors can be managed within 1° in any direction. In our study, we found that correcting rotation errors becomes more important when a smaller planning margin is used to reduce normal tissue toxicity, as well as for patients with greater distances between the centroid of the markers and the rotation center, and patients with large rotation angles. For example, for patients with distances 7.3 cm and 3.5 cm, the daily D99 of the prostate was 1.82 Gy (90.9% of the planned dose) and 1.91 Gy (95.3% of the planned dose), respectively, for the ROT_NC method when the rotation was about 4° for both cases. As the planning margin decreased from 6 mm/4 mm to 4 mm/2 mm, and further to 2 mm/0 mm posterior, the improvement of D99 of the prostate with translational correction increased from 4.4% to 6.9%, and further to 8.3% (Table 3). Such improvement in D99 is even greater for patients exhibiting large rotations. For example, for a selected patient with rotations of $8.8^\circ \pm 2.9^\circ$, $2.0^\circ \pm 1.7^\circ$, and $2.3^\circ \pm 1.5^\circ$ around the LR, AP, and SI axes, for planning margins of 6 mm/4 mm, 4 mm/2 mm, and 2 mm/0 mm posterior, the translational correction method improved D99 of the prostate by 15.3%, 21.4%, and 25.9%, respectively.

It should be noted that, in this study, we only investigated the rotations from the prostate motion alone. We did not specifically examine the movement of the seminal vesicles because fiducial markers were not routinely implanted in the seminal vesicles to monitor the organ motion. However, the dosimetric impact of rotation errors on seminal vesicles is worthy of further investigation, since it is known that the seminal vesicles move even more than the prostate.⁽³⁸⁾

V. CONCLUSIONS

This study indicates that the rotation of the prostate resulting from marker registration may be substantial. Without correcting the rotation error, inadequate dosimetric coverage to the prostate may result, especially when the rotations are large. Purposely placing the isocenter, which is presumed to be the rotation center of the image registration method, close to the centroid of the implanted markers can minimize the potential rotation error when an automatic marker registration method is applied without a six-degree couch. Otherwise, manually registering the implanted markers with translational shifts, which partially compensates rotations, is recommended, especially when the magnitude of the rotation is large.

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Physics Contribution

Six Degrees-of-Freedom Prostate and Lung Tumor Motion Measurements Using Kilovoltage Intrafraction Monitoring

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Summary

Tumor intrafractional motion deteriorates radiation therapy efficacy. This report presents new data on prostate and lung tumor 6 degrees-of-freedom motion measured by kilovoltage intrafraction monitoring. Prostate and lung tumors rotated more than 5° for about a third of time. Different patterns of rotation and respiration-induced tumor rotation were observed. This study is important for designing a 6 degrees-of-freedom tumor motion adaptation system to improve treatment conformity and reduce margins in radiation therapy.

Purpose: Tumor positional uncertainty has been identified as a major issue that deteriorates the efficacy of radiation therapy. Tumor rotational movement, which is not well understood, can result in significant geometric and dosimetric inaccuracies. The objective of this study was to measure 6 degrees-of-freedom (6 DoF) prostate and lung tumor motion, focusing on the more novel rotation, using kilovoltage intrafraction monitoring (KIM).

Methods and Materials: Continuous kilovoltage (kV) projections of tumors with gold fiducial markers were acquired during radiation therapy for 267 fractions from 10 prostate cancer patients and immediately before or after radiation therapy for 50 fractions from 3 lung cancer patients. The 6 DoF motion measurements were determined from the individual 3-dimensional (3D) marker positions, after using methods to reject spurious and smooth noisy data, using an iterative closest point algorithm.

Results: There were large variations in the magnitude of the tumor rotation among different fractions and patients. Various rotational patterns were observed. The average prostate rotation angles around the left-right (LR), superior-inferior (SI), and anterior-posterior (AP) axes were $1.0 \pm 5.0^\circ$, $0.6 \pm 3.3^\circ$, and $0.3 \pm 2.0^\circ$, respectively. For 35% of the time, the prostate rotated more than 5° about the LR axis, indicating the need for intrafractional adaptation during radiation delivery. For lung patients, the average LR, SI, and AP rotation angles were $0.8 \pm 4.2^\circ$, $-0.8 \pm 4.5^\circ$, and $1.7 \pm 3.1^\circ$, respectively. For about 30% of the time, the lung tumors rotated more than 5° around the SI axis. Respiration-induced rotation was detected in 2 of the 3 lung patients.

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Conflict of interest: Drs Tehrani and Keall have filed a US patent application for this technology. The patent application is unlicensed.

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Conclusions: The prostate and lung tumors were found to undergo rotations of more than 5° for about a third of the time. The lung tumor data represent the first 6 DoF tumor motion measured by kV images. The 6 DoF KIM method can enable rotational and translational adaptive radiation therapy and potentially reduce treatment margins. © 2014 Elsevier Inc.

Introduction

Thoracic, abdominal, and pelvic tumors are not static inside the human body; they undergo translational and rotational motion. Uncorrected tumor movement can cause the tumor to become misaligned with the radiation beam, compromising cancer control and increasing normal tissue toxicity. Methods of correcting for intrafractional tumor translation have previously been reported (1-3). However, increasing evidence suggests that intrafractional tumor motion corrections should be applied not only to tumor translation but also to rotation (4, 5). It has previously been shown that a small off-center rotation of an elongated target can result in a displacement of 13% of the target beyond the planning tumor volume (PTV) (4) and that uncorrected prostate tumor rotations of 15° can result in a 12% underdose to the tumor (6). As tighter PTV margins are applied and fractionation regimens are shortened (largely owing to translational compensation), factors such as tumor rotation will become the dominant concern for accurate tumor targeting. The aim of this study was to quantify the intrafractional tumor rotation in patients with prostate and lung cancer and to understand the requirements for a real-time tumor rotation adaptation system.

Intrafractional tumor rotations of the prostate have previously been measured using electromagnetic tracking (Calypso transponder) (5, 7) and MV images with gold fiducial markers (8). Each study reported similar magnitudes of prostate rotation, with the predominant rotation being about the LR axis. The only previous study regarding lung tumor rotation reported slow breathing measurements with magnetic resonance imaging (MRI), wherein a maximum rotation of more than 45° was observed (9). Novel monitoring methods and further investigation into the intrafractional tumor rotation are needed.

A recently developed method that is capable of monitoring real-time tumor motion is kilovoltage intrafraction monitoring (KIM) (10). KIM demonstrated high accuracy under clinical conditions, and a comparison between KIM and Calypso was summarized by XXX et al (11). The current work extends the KIM system by including tumor rotation monitoring. Tumor rotation calculations using KIM have been previously carried out by the iterative closest point (ICP) algorithm but have been applied to only 1 fraction of each of 10 prostate cancer patients (12). The purpose of this study was to perform 6 degrees-of-freedom (DoF) prostate and lung tumor motion measurements using KIM.

Methods and Materials

Rotation measurement

An overview of the 6 DoF monitoring method is shown in Figure 1. Briefly, a series of 2-dimensional (2D) x-ray projections are acquired during radiation therapy by a single kV imager (Fig. 1A and 1B). Our in-house software will segment the gold fiducial markers (Fig. 1C) and reconstruct their 3-dimensional (3D) positions using the maximum likelihood estimation of a 3D probability density function (Fig. 1D) (10). With the marker 3D position information, tumor rotation and translation are calculated by the ICP algorithm (12, 13) (Fig. 1E). The ICP algorithm performs matching for each fiducial marker based on the nearest neighbor algorithm and generates a rotation matrix and translation vector (14). Rotation angles about 3 orthogonal axes (LR, SI, AP) were determined with the pivot set at the centroid of the 3 markers. In this study, rotation angles were calculated between the current time and a reference time at the beginning of each fraction to determine intrafraction rotation and also at the beginning of treatment to quantify the interfraction and intrafraction rotation. Inasmuch as tumor translation has been much more widely studied, and the patient database used in this study have been published for the prostate (11) and the lung (15), the results here focus on the rotation measurements.

Patient database

In the KIM prostate tumor motion study, 10 prostate cancer patients had 3 cylindrical gold fiducial markers (1×3 mm) implanted and treated with fractionated double-arc volumetric modulated arc therapy (11). Continuous kV images were acquired using a kV imager (OBI, Varian) when the treatment beam was on. The exposure parameters were 125 kVp, 80 mA, and 13 ms. To reduce patient dose, a field size of 6×6 cm² was chosen as the minimum necessary to cover the marker positions from all gantry angles. The image frequency was 5 Hz or 10 Hz depending on the desired image quality. The imaging dose from KIM was quantified to be 185 mGy over the course of a prostate intensity-modulated radiation therapy for 120 kV (1.04 mAs) imaging at 1 Hz, a small portion of the total treatment dose (16).

In a 7-lung tumor motion study, 4 patients had 3 markers (3 patients) or 4 markers (1 patient) implanted. However, 2 of these patients had 2 markers implanted within close proximity, 1 with 3 markers and 1 with 4 markers. Differentiation between these markers was not possible (15). Therefore, 1 of the

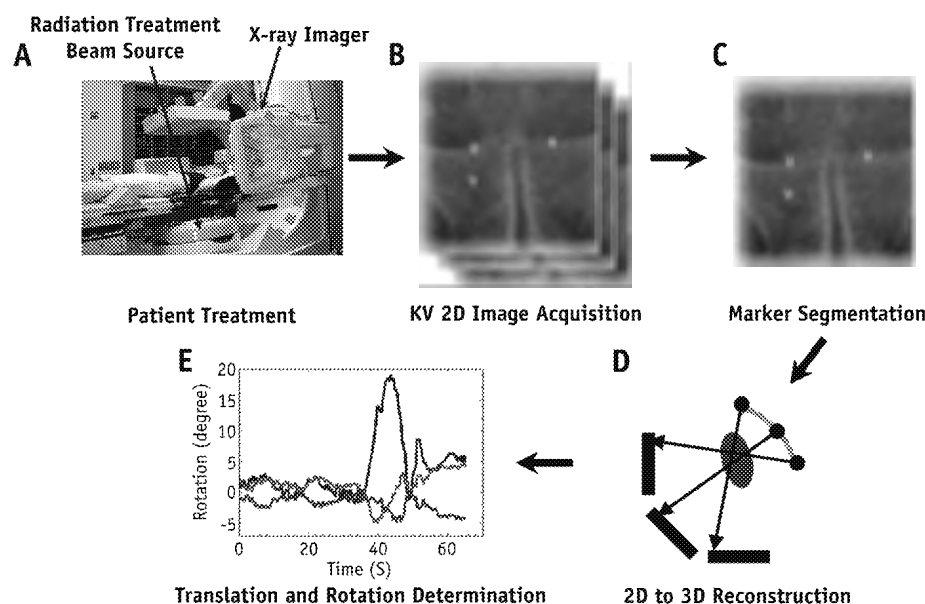


Fig. 1. Overview of the 6 degrees-of-freedom tumor motion monitoring strategy. (A) Patient undergoing radiation therapy. (B) kV 2-dimensional (2D) images are acquired continuously during radiation therapy. (C) Gold fiducial markers on each kV image are segmented. (D) Marker 3-dimensional (3D) positions are reconstructed. (E) Tumor rotation and translation (6 DoF) motion are calculated.

3-marker patients was excluded, leaving 3 patients remaining. No patients were excluded for image quality; however, 11 of the 61 fractions were excluded because of poor image quality. The tumor location in 2 patients was the right hilum, and in the third it was the left lower lobe. Fiducial gold coils (0.35×10 or 20 mm) were implanted into the lung. For each of the treatment fractions, 8-minute kV imaging sequences, corresponding to the duration of a typical radiation treatment, were taken by the kV imager at 10 Hz immediately before or after treatment. The exposure parameters were 125 kVp, 20 mA, and 20 ms per projection. We estimate the lung imaging dose (more projections, less dose per projection) for a 6×6 cm² field size (reducing the field size to only show the lung markers) at 1 Hz to also be approximately 190 mGy.

Data acceptance and noise filtering methods

The ICP algorithm takes individual 3D marker position as input. However, the accuracy of the marker coordinates is subject to variable image quality, the accuracy of the 2D marker segmentation, and the 3D reconstruction algorithm. To improve marker position fidelity for each fraction before calculating tumor rotation, we implemented 4 methods to reject spurious and smooth noisy data. Each step is briefly described here.

Correlation

In the marker segmentation step, marker position was determined as the position with the highest normalized cross-correlation between the template and the projection image (17). Data are prone to noise if the correlation is low.

In this study, the correlation threshold value was set at 0.3 for prostate patients (0.3% of data removed) and 0.4 for lung patients (8.1% removed).

Despiking

A phase-space thresholding method (18) was used to remove spikes from the marker trajectory. Normally, valid data are tightly clumped within an ellipsoid cloud in phase space (3D plots of velocity, u , and approximations of acceleration and jerk, Δu and $\Delta^2 u$, respectively). Spikes or the points outside the phase-space thresholds are iteratively removed. A universal threshold parameter $\sqrt{2} \ln n$ was applied to the lung data series (7.3% removed), and 2 times the universal threshold was applied to the prostate data series (0.6% removed).

Rigidity

The area defined by vertices of the triangle formed by the 3 fiducial markers was calculated over time. Tumor rigidity was calculated based on the change in the area of the triangles. The data were regarded as being false positive if the change in the triangle area was beyond a set threshold. For the prostate, the rigidity threshold was set as 5% (0.1% removed). For lung patients, the rigidity threshold was set at 10% because larger changes are expected from respiratory induced motion in the lung (0.1% removed).

L1 trend filtering

The L1 trend filtering method was used to smooth the original noisy data series. The L1 filtering method can be

Table 1 Prostate and lung tumor rotation measurements of this study along with previously published studies

Study	Tumor site [no. of patients]	Measurement method	Reference image	Rotation angle, °		
				LR	SI	AP
This study	Prostate [10]	Gold marker with kV image	Intrafraction	0.0 ± 1.8	0.1 ± 1.0	0.2 ± 0.8
			Interfraction and intrafraction	0.7 ± 5.5	0.8 ± 3.0	0.1 ± 2.0
Olsen et al (7)	Prostate [15]	Calypso	Simulation CT	5.7 ± 5.0	2.0 ± 2.0	1.6 ± 1.0
Li et al (20)	Prostate [29]	Calypso	First treatment	1.5 ± 5.2	0.4 ± 1.7	0.8 ± 1.6
Aubry et al (8)	Prostate [7]	Gold marker with MV image	Compare 2 reconstructions in the same fraction	−0.5 ± 5.8	0.5 ± 3.8	0.4 ± 2.0
Deutschmann et al (21)	Prostate [39]	Gold marker with MV image	Intrafraction	2.5 ± 2.3	2.3 ± 2.0	2.4 ± 2.1
Tehrani et al (12)	Prostate [10]	Gold marker with kV image	Intrafraction	0.1 ± 2.3	0.2 ± 0.9	−0.01 ± 0.7
This study	Lung [3]	Gold marker with kV image	Intrafraction	−0.4 ± 2.6	−0.3 ± 3.0	0.0 ± 1.8
			Interfraction and intrafraction	1.0 ± 2.9	−0.9 ± 4.6	0.5 ± 3.0
Plathow et al (9)	Lung [5]	MRI	Maximum value from single session slow breathing measurement with maximal expiration	25.4 ± 13.4	18.9 ± 11.8	23.1 ± 8.5

Abbreviations: AP = anterior-posterior; CT = computed tomography; LR = left-right; MRI = magnetic resonance imaging; SI = superior-inferior. For intrafraction rotation of this study, the first image of each fraction was used as the reference. For interfraction and intrafraction rotation of this study, the first image of the first treatment fraction was used as the reference.

used for real-time trend filtering with a smaller filter window size. It generates trend estimates that are smooth in the sense of being piecewise linear. For a given time series y_t , $t = 1, \dots, n$ with an underlying slowly varying trend x_t , L1 chooses the trend estimate as the minimizer of the weighted sum objective function $(\frac{1}{2})\sum_{t=1}^n (y_t - x_t)^2 + \lambda \sum_{t=2}^{n-1} |x_{t-1} - 2x_t + x_{t+1}|$ (19). A regularization parameter λ controls the tradeoff between the smoothness of the trend and the size of the residual. In this work, λ was set to 0.1.

Sensitivity analysis

Each of the 4 steps involves setting a parameter. The final values were determined heuristically with the goal of maintaining the maximum amount of original data while removing obvious noise and spurious results. A sensitivity analysis was performed by increasing and decreasing the parameter values in each of the 4 steps by at least $\pm 33\%$. Even with these large changes, the mean value changed by $\leq 0.1^\circ$ and standard deviation (SD) $\leq 0.15^\circ$, indicating that the mean and SD are not sensitive to the selection of the parameters. The differences lie in the amount of data that were removed ($\leq 34\%$) and the values of the maximal and minimal rotation.

Results

Prostate and lung tumor rotation

Continuous prostate and lung rotation was calculated. Table 1 lists the mean and SD of intrafraction and

intrafraction and interfraction for prostate and lung from this study and also compares the current results with those of previous studies (7-9, 12, 20, 21).

For prostate cancer patients, the SD of interfractional and intrafractional rotation was 5.5° , 3.0° , and 2.0° about the LR, SI, and AP axes, respectively, which was larger than intrafractional rotation. Prostate rotation about the LR axis was the most predominant of the 3 rotation axes and was in agreement with previous published results. For lung cancer patients, the SD of interfractional and intrafractional rotation was 2.9° , 4.6° and 3.0° about the LR, SI, and AP axes, respectively. Rotation around the SI axis was the major rotation among all 3 axes.

The prostate and lung tumor interfraction and intrafraction translation and rotation distributions are shown in the matrix diagonal of Figure 2. The prostate rotated more than 5° about the LR axis for more than 35% of the time, highlighting the desirability of applying tumor rotational corrections during radiation delivery. Lung tumors were found to rotate more than 5° about the SI axis for about 30% of the time. Prostate and lung tumor rotations of more than 30° were observed, but the exact maximal rotation angle depends strongly on the data acceptance and noise filtering methods applied. If stricter thresholds or higher λ values in the L1 filtering method were applied, more data would be rejected, and the trajectory would become smoother, thus resulting in a reduced maximum rotation angle.

The kV images of a rotated prostate and lung were selected to show intrafractional tumor rotation in Figure 3. The images are of the same prostate and lung taken at the same gantry angle at different time points.

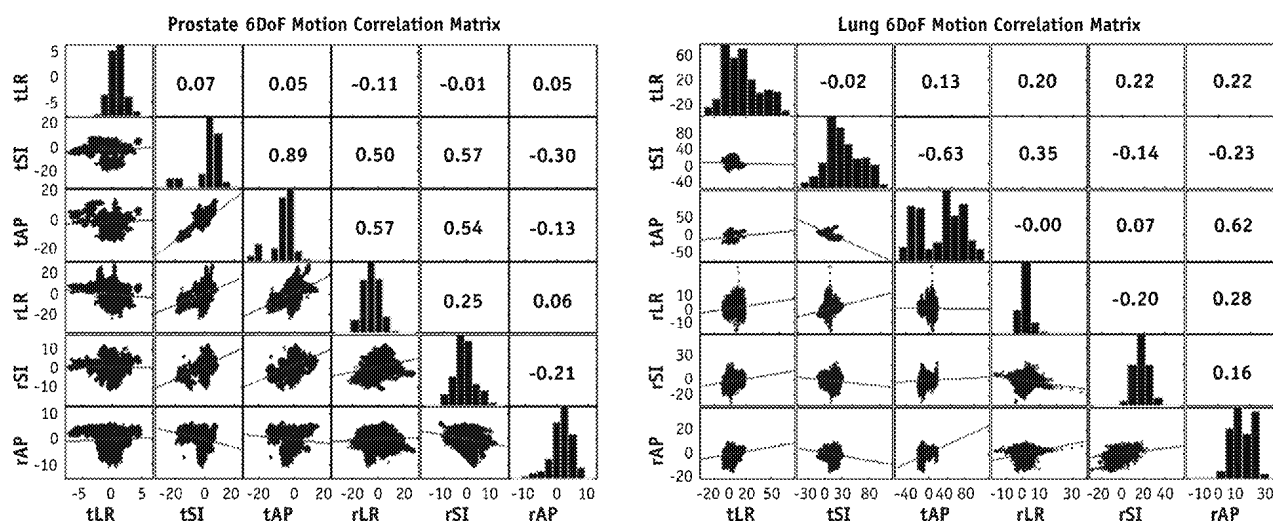


Fig. 2. Correlation matrix of prostate (left) and lung (right) 6 degrees-of-freedom motion. tLR, tSI, and tAP denote LR, SI, and AP translation, respectively; rLR, rSI, and rAP denote LR, SI, and AP rotation, respectively. Histograms of each 3 DoF translation (mm) and 3 DoF rotation ($^{\circ}$) are along the matrix diagonal. The slopes of the least-squares reference lines in the scatterplots are equal to the displayed correlation coefficients.

Rotation patterns

Tumors were observed to undergo variable rotational behavior over time among the patients. Rotation analogues of the translational motion types described initially by Kupelian et al (3) for Calypso and Ng et al (11) for KIM were observed. These classifications are important for designing the rotation adaptation system because the management of each pattern of rotation is different. Examples of these rotation patterns are shown in Figure 4 for prostate and lung.

The magnitude of prostate and lung tumor rotation also differed greatly from fraction to fraction and patient to patient. The dosimetric effect of tumor rotation is therefore expected to be significantly larger for a given subgroup of patients. Of particular note are tumors within the class of lung persistent rotation (Fig. 4), in which >6 of LR rotation was observed for most of the treatment time, indicating a large geometric uncertainty.

Respiratory component in lung tumor rotation

From the lung rotation traces in Figure 4, respiratory cycles could be readily observed. To further analyze the effect of breathing in lung tumor rotation, the power spectrum corresponding to SI rotation was plotted for each patient.

Peaks at ~ 0.3 Hz were observed in the power spectrum for 2 lung patients (Fig. 5); 0.3 Hz is equivalent to a signal cycle of every 3.3 seconds, which is a typical respiratory cycle for patients. However, this phenomenon was not observed in patient 2, which may be a result of the tumor location (left lower lobe vs right hilum) and could also be a result of atelectasis experienced by the patient during the treatment period (15). Interestingly, no predominant peaks were observed around 0.5 to 1 Hz, indicating that the

cardiac cycle did not introduce tumor rotation for these patients.

Correlation of 6 DoF tumor motion

Pearson linear correlation coefficients were calculated between all sets of tumor 6 DoF motion for the prostate and lung patients separately (Fig. 2). Histograms of each 3 DoF translation (mm) and 3 DoF rotation ($^{\circ}$) are along the matrix diagonal; scatter plots of variable pairs appear off-diagonal with the unit of millimeter.

High correlations were observed between the prostate AP translation and the SI translation (0.89), between the lung tumor AP and the SI translation (-0.63), and between the AP translation and rotation (0.62). These 6 DoF tumor motion correlation values are population based, and the correlations are different for individual patients.

Discussion

In this report, we describe 6 DoF tumor motion measurements using the KIM method, focusing on the more novel rotational motion results. Tumor rotation about 3 axes was calculated by determining the position of gold fiducial markers in successive 2D kV images acquired continuously during treatment or before or after treatment. This method is widely applicable because the majority of radiation therapy linear accelerators purchased today incorporate gantry-mounted kV imagers. In addition, the implantation of gold fiducial markers is the current clinical standard of care for prostate patient setup before radiation therapy (22). The tumor motion monitoring and adaptation based on the KIM method can be performed at no additional cost in terms of linac hardware; however, implanting lung fiducial markers does require additional procedures and may introduce side effects.

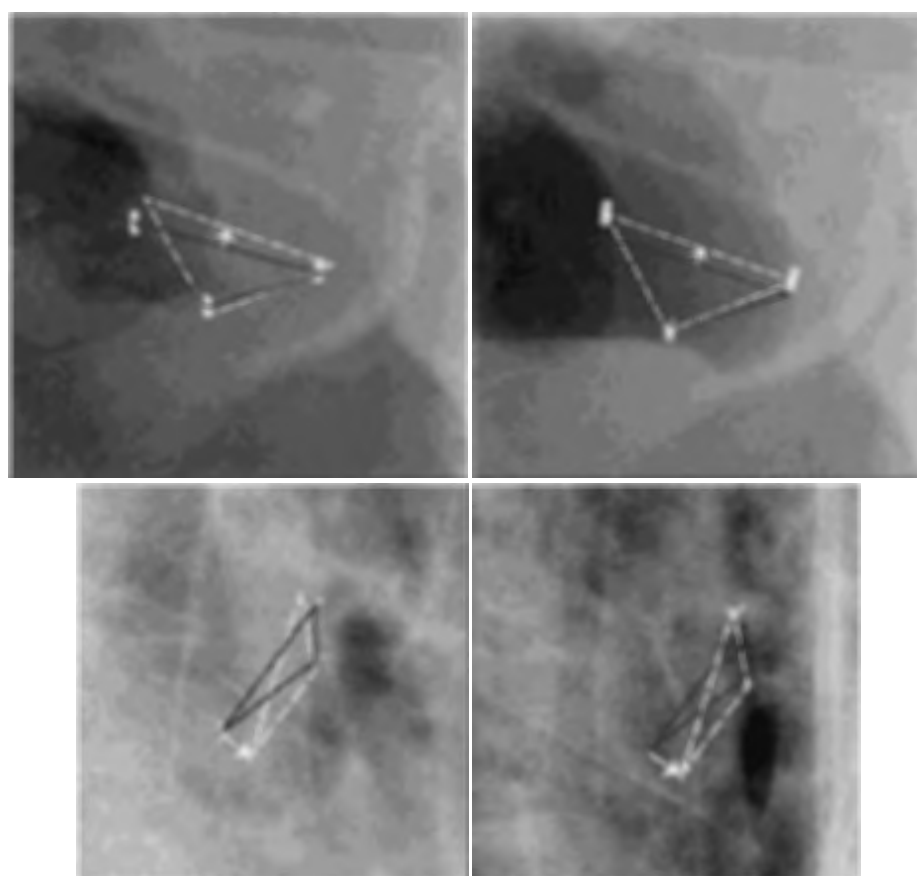


Fig. 3. kV images of a rotated prostate and lung. Compared with the initial position (left) the prostate has rotated -15.2° , 0.8° , and 0.9° about the left-right, superior-inferior, and anterior-posterior axes (upper right), and the lung tumor has rotated 0.9° , -12.3° , and -4.1° (lower right). Blue triangles represent the tumor initial position. Yellow arrows and dashed triangles denote the rotation direction and the rotated tumor positions. A color version of this figure is available at www.redjournal.org.

We show that for both prostate and lung tumors, the SDs of interfractional and intrafractional rotation are larger than intrafractional rotation because of greater day-by-day tumor position variation. Our results also demonstrate that intrafractional tumor rotation during radiation therapy can be unpredictable, with rotation patterns ranging greatly from small rotation, continuous rotation, transient rotation, persistent rotation, and high-frequency rotation to erratic rotation, or a combination thereof. Tumor intrafractional motion caused by the patient's spontaneous rectum and bladder filling, flatulence, muscle contractions, and breathing is hard to exclude. Thus, the adaptation to intrafractional tumor motion is best handled by modern tracking techniques, such as dynamic multileaf collimator tracking, Cyberknife, and Gimbaled system (23).

Diaphragm (24) and lung tumor rotation (25) was observed in 4-dimensional computed tomography but not quantified. Given the complexity of lung motion, we present the first attempt to demonstrate high-frequency respiratory-induced rotation from general lung movement. The rotation power spectrum peak at 0.3 Hz (or 3.3 seconds), which is a typical breathing cycle, indicates that there is a respiratory component to lung tumor rotational movement. Our 50 fractions of images show that the strength of the respiratory signal in rotation appears to depend on the

tumor position within the lung, although a strong conclusion would need more patient data; only 3 patients are included in this analysis. The effect of marker position deformation was accounted for by a data acceptance method: rigidity in this study. Tumor rigidity was calculated based on the change in the area of the triangles. We showed that for intrafractional rotation, less than 0.1% of data was removed by rigidity thresholding.

The KIM measured prostate rotation is similar to the values measured by other methods (Table 1). The lung tumor rotation result is different from the MRI measured result, and this could be due to the different measurement methods. The KIM rotation calculation method is highly accurate. First, the KIM method achieved 0.46 mm accuracy in the prostate cancer patient clinical trial (11). Second, the root mean square error of the ICP algorithm in a simulation study has previously been reported as 0.004° (12). However, the present study was affected by the kV image quality. Markers are generally more difficult to identify in kV images taken through the lateral side of a patient, and their identification is especially difficult in larger patients because of increased photon scattering. Furthermore, for certain lung patients, the spine, medical wires, and other objects can partially obstruct the radiation beam and cause marker segmentation problems at certain

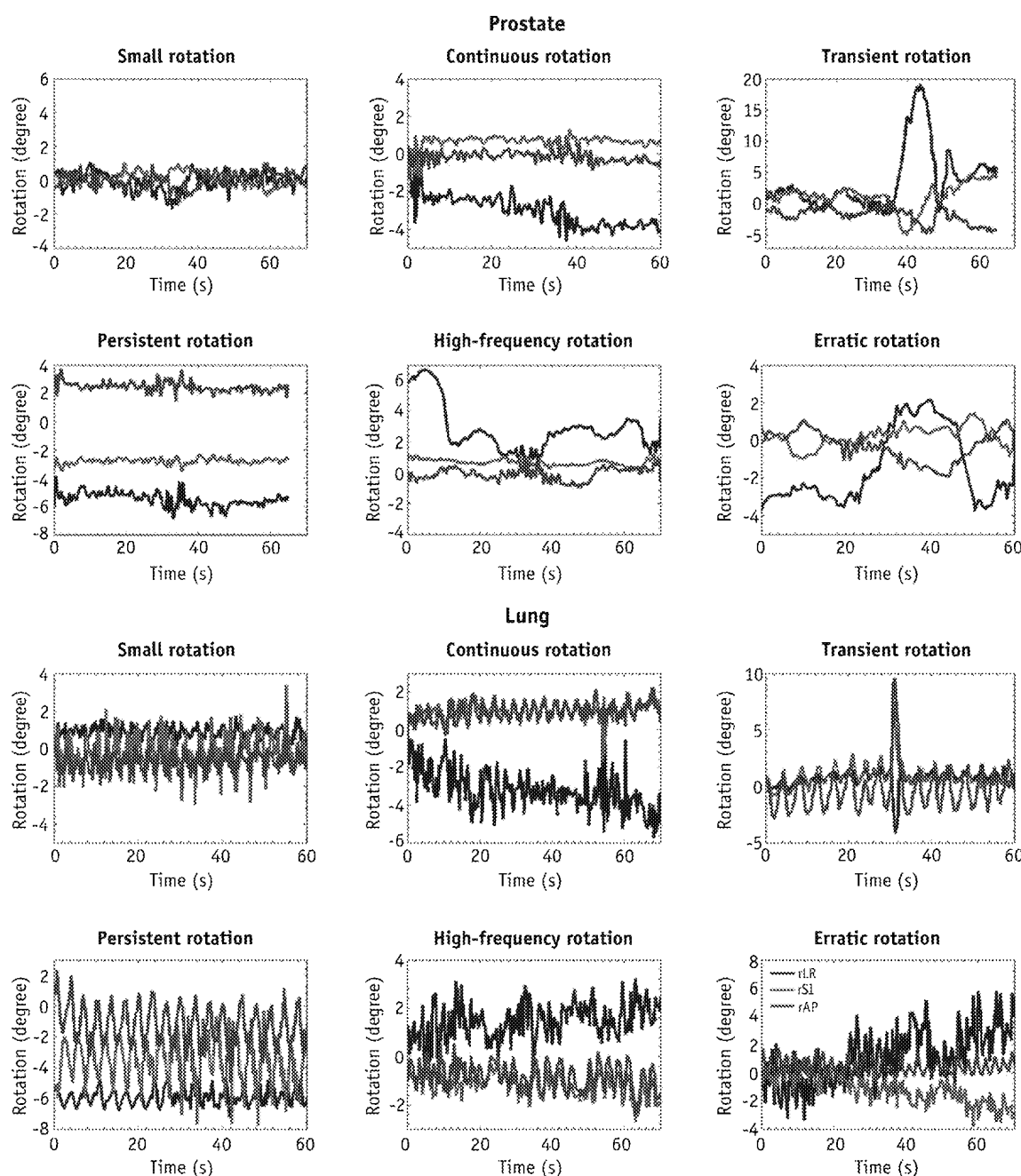


Fig. 4. Examples of observed intrafractional prostate (upper 2 rows) and lung (lower 2 rows) tumor rotation pattern. The left-right (red), superior-inferior (green), and anterior-posterior (blue) rotations are shown. A color version of this figure is available at www.redjournal.org.

projection angles. With extra image quality enhancement steps, the marker-based localization method can be greatly improved.

Monitoring tumor rotation is the first step toward real-time rotation adaptive radiation therapy. Independent studies have shown that considering tumor rotation reductions in the treatment margin by 2 to 3 mm is possible (20, 26). There are higher accuracy requirements for the emerging stereotactic body radiation therapy (SBRT), wherein the radiation treatment is hypofractionated and each fraction delivers a higher dose of radiation over a longer period of time (27). The ability to track target tumor motion by considering not

only translation but also rotation could potentially address the high precision requirement of SBRT.

Conclusions

This study examined the use of a gantry-mounted kV imager to measure 6 DoF tumor motion by KIM. The lung tumor data represent the first 6 DoF motion measured by kV images. The prostate tumor data represent the most comprehensive 6 DoF motion measurements with KIM. In both prostate and lung cancer patients, tumors were found

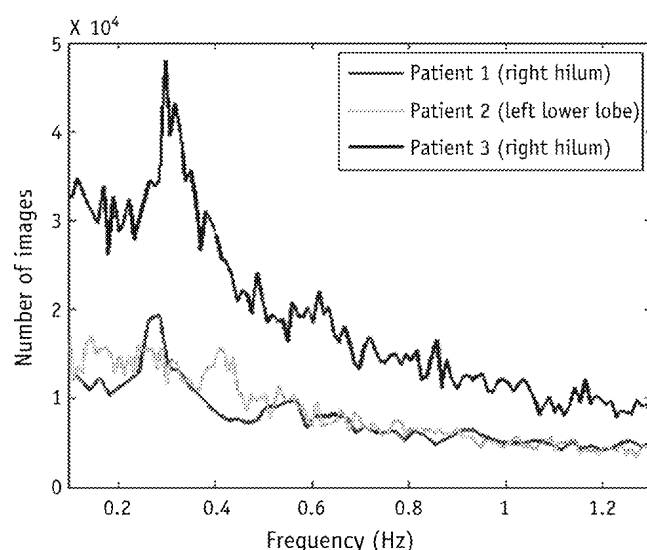


Fig. 5. Power spectrum of lung tumor superior-inferior rotation.

to undergo rotations of more than 5° for about a third of the total treatment time. Various of rotation patterns were observed, with LR rotation for prostate and SI rotation for lung patients having the highest magnitude. Inasmuch as gantry-mounted kV imagers are present in most new cancer radiation therapy systems, there is potential for the technique to be widely used. The 6 DoF KIM method can enable rotational and translational adaptive radiation therapy and potentially reduce treatment margins.

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Comparison of Tumor Density by CT Scan Based on Histologic Type in Lung Cancer Patients

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ABSTRACT

Aim: to investigate the differences of tumor density of lung cancer by CT scan based on histopathologic type of cancer cell.

Methods: subjects were lung cancer patients at Dr. Kariadi hospital Semarang between January 2002 and December 2003. Diagnosis was made based on clinical symptoms, histologic examination and lateral chest radiograph, and thorax CT scan. Density of tumor was measured within area which had most enhancements before and after contrast administration. Then, it was followed by transthoracic fine needle aspiration (TNFNAB) and histopathologic examination. Study design was a cross sectional study. Inclusion criteria were primary lung cancer and exclusion criteria were non lung cancer, metastatic cancer, histopathologic non interpreted. Estimated number of samples was 41 patients. Density value before and after contrast were analyzed using Wilcoxon signed rank test. Difference of tumor density for each type of cancer cell was analyzed using chi-square test with significant level at $p < 0.05$ and confidence interval of 95%.

Results: forty one patients with lung cancer were enrolled in this study. There were 30 males (73.2%) and 11 females (26.8%). Histopathologic types of cell cancer were epidermoid in 17 patients (41.5%), adenocarcinoma 8 patients (19.5%), large cell 7 patients (17.1%), small cell 7 patients (17.1%) and undifferentiated cell 2 patients (4.5%). Mean of increasing HU before and after contrast in epidermoid carcinoma was 26.8 (10.4) HU, adenocarcinoma 17.2 (7.1) HU, large cell 8.7 (4.5) HU, small cell 9.9 (4.1) HU and undifferentiated cell 23.5 (1.5) HU with overall increase of all cancer cell types was 17.3 (9.2) HU, $p < 0.001$. Histopathologic type of non small cell lung carcinoma (NSCLC) with density < 60 HU was found in 30 patients (73.2%) and small cell lung carcinoma with density > 60 HU was found in 5 patient (12.2%), $p=0.01$.

Conclusion: there was evident increase of density in all histopathologic type of cell cancer; $p < 0.0001$, with mean of density after contrast administration was 17.2 (7.1). There was significant difference between NSCLC and SCLC group and tumor density > 60 HU and < 60 HU, $p=0.01$.

Key words: density of lung cancer; hounsfield unit.

INTRODUCTION

Lung cancer is a serious health problem in the world and has had a high mortality rate in the past 2 decades. Number of lung cancer patients from time to time in developed and developing countries has been arising significantly. In US (2002), it was approximately 169,400 new cases of lung cancer, while in the same year 154,900 people were dead due to lung cancer. Five years survival rate of lung cancer was still below 1.5%.^{1,2,3}

High mortality rate and low 5 years survival rate in lung cancer was caused by lack of early detection. Generally, patient coming already in advanced stage of disease. Ironically, late diagnosis was not only caused by the patients but also late diagnosis confirmation by physicians.

Measurement of tissue density by CT scan uses hounsfield unit (HU). Each organ or tissue in thoracic cavity has a different density. It could differentiate soft tissue, solid or fluid. Density measurement by CT can be done before and after contrast administration. Tumor mass will have different density depending on its solidity and tumor cell type.

There have been only few studies regarding this matter in Indonesia and even worldwide. A multicenter study by Stephen JS et al on 356 patients with malignancy revealed that there was an increased density of more than 15 HU before and after contrast, while the increase in patient with benign tumor was < 15 HU.^{5,6}

Based on these facts, the aim of this study was to investigate the differences of density based on CT scan for each histopathologic type of cancer cell. Density patterns of lung cancer hopefully would help physicians or radiologists to predict cell types of lung cancer.

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METHODS

This was a cross-sectional study in subjects being patients with lung cancer at the outpatient clinic and internal medicine ward in Dr. Kariadi Hospital Semarang, during period of January 2002 and December 2003. Diagnosis of tumor was made based on physical examination, chest x-ray and CT scan. We measured tumor density before and after administration of contrast. The measurement was within area with highest HU level or enhancement. In that area, we conducted TFNAB, and then cytologic examination done by pathologists.

All primary lung cancer patients were included in this study. Exclusion criteria were non lung cancer, metastatic cancer, cytologically unidentified cancer. Sample estimation was 41 patients. All data were analyzed using software program SPSS 10. Categorical data were expressed in frequency and proportion (n and %). Density value of lung cancer based on CT scan before/after contrast administration and cancer cell type were analyzed using Wilcoxon rank test. Differences in tumor density of each cancer cell type were analyzed using chi-square with significance level of $p < 0.05$ and confidence interval of 95%.

RESULTS

There were 45 patients with lung cancer based on physical and chest x-ray examination. After TFNAB, there were only 41 patients who fulfilled inclusion criteria. Other 4 patients were excluded due to non primary lung cancer (Table 1).

Table 1. Distribution of Age and Sex of Subjects with Lung Cancer

Age	Male	Female	Number
	n (%)	n (%)	n (%)
< 20	1 (3,3)	0 (0)	1 (2,4)
21 – 29	1 (3,3)	0 (0)	1 (2,4)
30 – 39	1 (3,3)	1 (9,1)	2 (4,9)
40 – 49	6 (20,0)	3 (27,3)	9 (21,5)
50 – 59	8 (26,7)	4 (36,4)	12 (29,3)
60 – 69	6 (20,0)	3 (27,3)	9 (21,9)
> 70	8 (2,7)	0 (0)	8 (18,4)
Total	30 (73,2)	11 (26,8)	41 (100)

Age distribution in lung cancer revealed 1 patient aged < 20 years old (2.4%), 8 patients aged 70 years old (18.4%), and the most frequent was in age group of 50-59 years old (12 patients; 29.3%). Number of male patients was 30 (73.2%), more frequent than female patients (11 patients or 26.8%). Histopathologic examination of TFNAB and cancer cell type is shown in figure 1.

Epidermoid carcinoma or squamous cell carcinoma were the most frequent cancer cell types and found in 17 patients (41.5%), followed by adenocarcinoma in 8 patients (19.5%), large cell in 7 patients (17.1%), small cell in 7 patients (17.1%), and undifferentiated cell in 2 patients (4.5%).

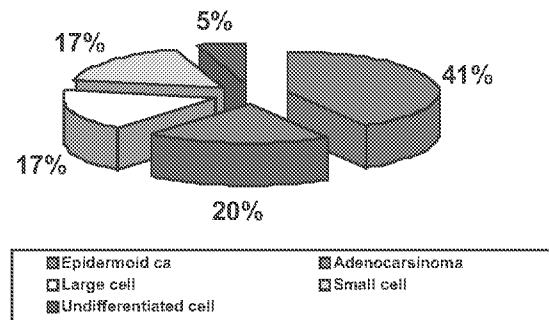


Figure 1. Distribution of Histopathologic Type of Cancer Cell

We found varied result based on density measurement using CT scan before and after contrast administration. Table 2 showed that there was significant increase of density before and after contrast using Wilcoxon signed rank test on different histopathologic type of cancer cell ($p < 0.0001$). Highest mean value of tumor density before contrast was 60.0 HU (SD 13.8) and after contrast was 86.8 HU (SD 13.0). Highest mean value of increased density was 26.8 (SD 10.4) HU compared to other cell type. Mean of overall increase of tumor density in all histopathologic type of cancer cell was 17.3 (SD 9.2) HU.

Classification of primary lung cancer histopathologically is categorized into 2 major types: small cell lung cancer (SCLC) and non small cell lung cancer (NSCLC). NSCLC includes squamous cell carcinoma, adenocarcinoma, large cell carcinoma, carcinoid, carcinoid carcinoma and bronchial gland carcinoma. To differentiate tumor density on both types of cancer cells, cut-off point was made at 60 HU. We predicted that it would be significantly different at cut-off point level of 60 HU (Table 3).

In group of patients with NSCLC, 30 patients (73.2%) had density level > 60 HU, while in SCLC group was found 5 patients (12.2%) with density level < 60 HU. We found statistically significant difference between tumor density level < 60 HU and those who had density level > 60 HU based on histopathologic type of cancer cell SCLC and NSCLC ($p = 0.01$).

DISCUSSION

The characteristics of patients in this study were not much different from those in other local or foreign studies. Lung cancer was more prevalent in male aged more than 40 years old. This was in accordance with

Table 2. Mean of Tumor Density of Lung Cancer by CT Scan Based on Cancer Cell Type Before and After Contrast Administration

Histopathologic type of cell cancer	Before contrast	After contrast	Tumor density increase
	Mean HU (SD)	Mean HU (SD)	Mean HU (SD)
Epidermoid carcinoma	60,0(13,8)	86,8(13,0)	26,8(10,4)
Adenocarcinoma	51,5(9,6)	68,7(5,6)	17,2(7,1)
Large cell	53,4(5,4)	62,1(1,8)	8,7(4,5)
Small cell	50,3(16,6)	60,2(6,0)	9,9(4,1)
Undifferentiated	32,3(0,2)	55,8(1,4)	23,5(1,5)
Malignant cell			
Mean	49,5(12,4)	66,7(12,9)	17,3(9,2)

Z (Wilcoxon Signed Ranks test) = - 5.086, p < 0,0001

HU = Hounsfield Unit; SD = Standard Deviation

Tabel 3. Tumor Density Level Using Contrast on Different Histopathologic Type of Cancer Cell

Tumor density (HU)	Small cell carcinoma	Non small cell carcinoma	Total
	n (%)	n (%)	n (%)
< 60	5 (12,2)	4 (9,6)	9 (21,8)
> 60	2 (4,9)	30 (73,2)	32 (78,2)
Total	7(17,1)	34 (82,9)	41(100)

 $\chi^2 = 5,569$, df = 1, p = 0,01

risk factor of lung cancer which was usually found in age more than 40 years old. Male patient was more prevalent in smokers, environment with expanded industrialization and air pollution. In more developed countries with expanded industrialization, women would be at an increased risk to have lung cancer.

The pattern of lung cancer in this study showed that epidermoid carcinoma/squamous cell carcinoma was the most prevalent, as high as 41 %. In the US, this type had also been the most frequent as much as 30 %. It was presumed that this type is related to tobacco or smoking. If lung cancer was categorized into 2 major types: NSCLC and SCLC, then NSCLC were the most frequently found (83%). In the USA, it had reached 70% in both types.^{7,8,9}

The standard density level of each organ or tissue is different. For example: bone tissue ≥ 250 HU, muscle 45 ± 5 HU, liver 65 ± 5 HU, spleen 45 ± 5 HU, lymph node 45 ± 5 HU, transudate/exudates 18 ± 2 HU, plasma 27 ± 2 HU, Ringer solution 12 ± 2 HU. These differences showed different level of density of tissue or organ. The more solid then would be higher density level it has. Lung cancer has tumor density ranging from 45 – 80 HU after contrast administration and it was similar to those of liver or muscle. In this study, highest tumor density after contrast administration was epidermoid carcinoma 86.8

(13.0) HU and the lowest was undifferentiated malignant cell 55.8 (1.4) HU.

Density level or tumor solidity alone is not sufficient to predict malignancy but it must include the increase in density before and after contrast administration. In other malignancies, abnormal growth of tissue is usually followed by increased vascularization in pace with tumor mass development. By using contrast, tumor density will increased obviously compared to those which are benign tumor. This study revealed that increased tumor density was different for each cancer cell type after giving contrast. It showed that each type of cancer had different vascularization. The highest increase was shown in epidermoid carcinoma 26.8 (10.4) HU and the lowest was large cell carcinoma 8.7 (4.5) HU. Wilcoxon rank sum test resulted in evident increase of tumor density before and after contrast administration for each histopathologic type of cancer (p<0.0001). Mean of tumor density increase in each histopathologic type of lung cancer was 17.3 (10.2) HU. There was significant difference of tumor density after contrast administration between NSCLC and SCLC. If tumor density ≥ 60 HU, was more likely to be NSCLC, and tumor density <60 HU was SCLC.^{6, 10-12}

A study in Mayo clinic, on lung nodule enhancement at CT: Prospective findings in 107 cases showed statistically significant density increase of malignant nodule (mean 46.5 HU) and neoplasm (mean 8 HU) (p<0.01). Multicenter study reported by Stephen, in 2000 on 356 patients with neoplasm or malignancy showed increased density around 15 HU on CT scan with and without contrast. In this study we could not compare between neoplasm and malignancy because all patients had already had histopathologic examination and the result revealed that all patients had malignancies.^{6,7,13}

CONCLUSION

Forty one patients who fulfilled inclusion criteria were enrolled in this study. After TFNAB and histopathologic examination revealed primary lung cancer distribution: epidermoid carcinoma 17 patients (41.5%), adenocarcinoma 8 patients (19.5%), large cell 7 patients (17.1%), small cell 7 patients (17.1%) and undifferentiated carcinoma 2 patients (4.5%).

Result of tumor density measurement by CT scan before and after contrast administration showed evident increase in each histopathologic type of cancer cell: There was statistically significant difference of tumor density >60 HU and <60 HU after contrast administration between histopathologic type of cancer cell SCLC and NSCLC ($p < 0.05$).

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SCIENTIFIC REPORTS

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The Value of CBCT-based Tumor Density and Volume Variations in Prediction of Early Response to Chemoradiation Therapy in Advanced NSCLC

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The correlations between early responses and the variations in physical density and primary tumor volume (TV) according to cone-beam computed tomography (CBCT) during chemoradiotherapy for non-small cell lung cancer (NSCLC) patients were investigated. 54 patients with inoperable and locally advanced NSCLC were included in this study. The CT numbers (CTN) and TV were measured on each of the seven observation points. The changes in the mean CTN values and the variation ratios of TV during the treatment course were analysed and correlated with the clinical outcomes, as evaluated by the RECIST criteria. For patients who responded to treatment, the CTN and TV change ratio decreased by 28.44 ± 13.12 HU and 32.01% (range, 8.46–61.67%); these values were significantly higher than those in the non-responding patients, with 19.63 ± 8.67 HU and 23.20% (range, –15.57–38%) ($p = 0.016$, $p = 0.048$), respectively. The area under curve for the combination of CTN and TV was larger than either alone ($AUC = 0.751$, $p = 0.002$). The differences between response and non-response were most significant between Fraction 10 and Fraction 15 for CTN changes and between Fraction 5 and Fraction 10 for the TV regression ratio. The changes in CTN and TV obtained from CBCT images have the potential capability to predict an early response of NSCLC.

Non-small cell lung cancer (NSCLC) is the main subtype of lung cancer and accounts for 80% of all lung cancers. Approximately 80% of all NSCLC cases were diagnosed at an advanced stage due to non-specific recognized symptom at an early stage¹. Chemoradiation therapy (CRT) could provide a survival benefit for inoperable or locally advanced patients, with a median overall survival ranging from 25–35 months^{2,3}.

Currently, the Response Evaluation Criteria in Solid Tumors (RECIST) has been widely applied in the clinical setting and has been introduced in evaluation tumor response to anti-cancer therapy^{4–6}, although some limitations are being recognized. First, changes in the longest axis of targeted lesion is the main evaluation criterion in RECIST, which ignores changes in other forms to a certain extent, such as the short axis and tumor volume^{7,8}. These morphologic changes based on uni-dimensional measurements neglect the molecular changes and cannot effectively reflect biologic alternations in tumors, which may lead to inaccurate predictions of treatment response. Second, the RECIST criteria are generally performed two or three months after treatment, which might delay the detection of disease progression and recurrence.

With advances in computed tomography (CT) technology, quantitative image analysis could provide CT density (HU, Hounsfield Unit) measurements within a region of interest (ROI). Regarding the tumor density decrease, Yang *et al.* and Mayer *et al.* proposed a reliable quantitative method to assess tumor response and predict clinical outcomes^{9,10}. Previous studies have correlated the variation in the CT number (CTN) with radiation-induced pulmonary toxicity¹¹ and breast cancer metastasis to axillary lymph nodes¹².

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Imaging-based three-dimensional measurement of tumor size change might more accurately and directly assess the response during the course of treatment. There is evidence that a change in tumor volume could be detected as early as 3 weeks after gefitinib administration in lung cancer, but the World Health Organization (WHO) criteria and RECIST cannot identify responses in that timeframe¹³. Hou *et al.* demonstrated that the early reduction of gross tumor volume had a statistically significant difference ($p = 0.045$) between treatment outcomes in head and neck cancer patients¹⁴. Therefore, changes in tumor volume have the potential to be an early surrogate marker of tumor regression or progression.

Rescanning and replanning via periodic CT scanning are not ideal due to the time required and additional irradiation¹⁵. As part of image-guided radiation therapy (IGRT), kilovoltage cone-beam computed tomography (KV-CBCT) could provide the capability to monitor the tumor density changes and volume regression during the course of chemoradiotherapy. Therefore, this study proposed to investigate the correlations between chemoradiation treatment response and variations in primary CTN and TV by KV-CBCT in NSCLC patients and to determine the appropriate time points for prediction.

Materials and Methods

Patient eligibility. From February 2014 to April 2015, 61 patients with locally advanced stage III NSCLC diagnosed by cytology or histology were included in this study. The inclusion criteria were as follows: (1) no previous anti-cancer treatment; (2) standard evaluation before treatment included CT imaging of chest and abdomen and brain magnetic resonance (MR); (3) good Eastern Cooperative Oncology Group performance status (ECOG PS) of 0 to 2 and good lung function ($DLCO \geq 50\%$ and $FEV_1 \geq 50\%$); and (4) a visible tumor on CT. Stage was defined according to the American Joint Committee on Cancer (AJCC, 6th edition) staging system. Three patients were excluded from our study due to small tumor size (<1 cm in diameter), and four patients were excluded with a PS score of 3. In total, 54 patients who received concurrent CRT and serial KV-CBCTs as part of conventional fractionation radiotherapy were included in our study.

The study was approved by the Research Ethics Committee of Shandong Cancer Hospital, China. All protocols and methods were in accordance with the guidelines and regulations. Informed consent was provided by all participants.

Chemoradiation therapy and follow-up. The chemotherapy regimens included etoposide 50 mg/m² on D1–5, D29–33 and 50 mg/m² on days 1, 8, 29, 36 for cisplatin. Paclitaxel plus carboplatin was administered as paclitaxel 40 mg/m² weekly and AUC 2 for carboplatin. Pemetrexed with cisplatin was given as 500 mg/m² on day 1 every 21 days for 3 cycles and 75 mg/m² on day 1 for cisplatin. Chemotherapy doses were modified on account of toxicity levels and blood counts. Additional 4-dimensional CT (4D CT) scans were utilized for respiratory motion and tumor delineation. Contouring gross tumor volume (GTV) was performed on each of the 10 respiratory phases of the 4D CT data set, and the GTVs were combined to obtain the internal target volume (ITV). Radiotherapy plans were generated on the Varian treatment planning system (Varian Medical System, Inc., Palo Alto, California, USA). The radiation dose was 60 Gy over 6 to 7 weeks, as a 2 Gy/fraction to the primary tumor, with 5 fractions per week.

Follow-up data were obtained from Shandong Cancer Hospital and Institute medical records. For clinical examinations, chest CT imaging was performed at the first month after treatment, with follow-up imaging every two or three months in the first year, then every six months in the second and following years. Brain magnetic resonance (MR) and bone scintigraphy were not compulsory and were only administered if clinically indicated. Clinical response was evaluated for all patients based on the RECIST criteria systems, and the therapeutic response was evaluated as complete response (CR), partial response (PR), stable disease (SD) or progression disease (PD).

CBCT scan and image analysis. CBCT images of the chest area were acquired prior to radiation delivery as part of the standard radiotherapy course. We acquired CBCT images to assess the changes in primary tumor density and volume during the course of therapy. KV-CBCT projection images were obtained with a voltage of 110 kV, tube current of 20 mA and a F0 filter. The detector size and source to detector distance were 25 cm $\times$ 25 cm and 150 cm, respectively. The 2.5-mm contiguous axial images were transferred to the Varian workstation and reconstructed into a 250 $\times$ 250 $\times$ 200 mm field of view. Scatter correction and ring artefact correction were used for each serial CBCT image. As suggested by Altörjai *et al.*, a window/level setting of $-600/1000$ HU was used for lung lesion contouring¹⁶. Contours of the primary tumor were obtained from the KV-CBCT, which were automatically generated by 3D Slicer (a free open-source software platform for biomedical imaging research, www.slicer.org) and modified manually if necessary by two independent radiation oncologists (SXD, with 25 years of experience, and MX, with 10 years of experience). The CBCT serials with corresponding contours were analysed using the open-source Imaging Biomarker EXplorer (IBEX) software on the 1st, 5th, 10th, 15th, 20th, 25th and 30th fractions (F1, F5, F10, F15, F20, F25 and F30), which supported the CTN and TV variation value of the primary tumor as the average and standard deviation or median with range. To minimize the variations in outlines generated in this study, CTN numbers less than -200 HU or greater than 400 HU were excluded from analysis. In the same condition, delineation did not dramatically influence the analysis because only changes in density and volume were investigated.

In order to ensure CTN stability, the CBCT scan equipment was calibrated monthly by CIRS062m. There was no dramatic or detectable change in the CT number, which meant that no variation in KV-CBCT resulted in CTN changes in NSCLC patients.

Characteristics	N (%)
Age	
Median (range)	62 (32–78)
Gender	
Male	30 (55.6%)
Female	24 (44.4%)
Smoking	
Yes	37 (68.5%)
No	17 (31.5%)
Stage	
III A	30 (55.6%)
III B	24 (44.4%)
ECOG PS	
2	11 (20.4%)
0–1	43 (79.6%)
Histology	
Squamous	32 (59.3%)
Adenocarcinoma	22 (40.7%)
Chemotherapy regimens	
Etoposide + Cisplatin	23 (42.6%)
Paclitaxel + Carboplatin	21 (38.9%)
Pemetrexed + Cisplatin	10 (18.5%)

Table 1. Patient demographics and treatment characteristics. *Abbreviations:* ECOG PS = Eastern Cooperative Oncology Group performance status.

Statistics analysis. All statistical analyses were performed using the SPSS Ver. 19.0 software for windows (IBM SPSS Inc, Chicago, IL, USA). The correlation between the CTN and volume changes for the primary tumor, and the correlation between the CTN change and radiation dose were analysed using linear analysis. Categorized characteristics were compared between two groups using a Chi-squared test, and continuous variables were compared using a t-test. To combine the changes in CTN and TV, a logistic regression model was employed that allowed discriminating between response and non-response. A t-test was used to determine whether the response was significantly different from the non-response. Receiver operator characteristics (ROC) curves were created to identify the most powerful predictive period and establish a cut-off value for distinguishing response patients from non-response patients. All p-values were two-sided at a significance level of 95%, and $p < 0.05$ was considered statistically significant.

Results

Patient characteristics. The demographics and disease characteristics of all 54 patients are summarized in Table 1. The median follow-up period in this trial was 16.3 months (range, 5.0–30.1 months). The median age of all cases was 62 years (range, 32–78 years). Patients aged less than 65 years old accounted for 75.9%. Thirty-three patients with stage IIIA were included, as were 21 stage IIIB patients.

CTN and tumor volume variations. The mean CTN exacted from the first CBCT (before first time radiotherapy) was 63.21 ± 28.93 HU, and the mean CTN extracted from last CBCT (before last time radiotherapy) was 38.29 ± 19.91 HU. Among the 54 cases, 61.1% of patients decreased at least 20 HU, and 12 patients' CTN reduction fluctuated by approximately 10 (10 ± 5) HU. The difference in CTN between the first and last fractions on KV-CBCT was statistically significant ($p < 0.001$). The corresponding primary tumor volume was reduced for most of the patients. The tumor size decreased from 84.94 cm^3 (range, 19.96 cm^3 – 218.37 cm^3) to 60.26 cm^3 (range, 14.25 cm^3 – 147.29 cm^3) from the start to the end of radiation. 26 patients displayed a regression of the tumor size of $>30\%$. A significant change in tumor volume was detected between the 1st and 30th fractions among all patients ($p < 0.001$).

For all patients in the study, the mean CTN value reduction was significantly related to the radiation dose with $R^2 = 0.879 \pm 0.164$ and $p = 0.002$. The correlation data of three representative patients, randomly selected from the 54 patients, are presented in Fig. 1. The relationship between mean CTN value change and volume reduction ratio was $R^2 = 0.343$ and $p < 0.001$ (Fig. 2).

Prediction of CTN and tumor volume for response. Out of the 54 patients, 31 presented PR, 2 patients presented CR, 20 patients experienced SD and only one patient reported PD according to RECIST criteria.

The tumor clinical variables between the response group and non-response group are detailed in Table 2. In the univariate analysis of all factors, each characteristic was compared between the groups, and only CTN reduction and volume changes were associated with outcome. No other clinical variables had an effect on response. Although response rate tended to be lower in older patients (≥ 65 vs. < 65 years, $p = 0.055$), this effect was still not significant. More than half of the patients (19/33) presented an objective response; their CTN value decreased above 25 HU. In the majority of the non-response patients (10/21), the CTN reduction fluctuated

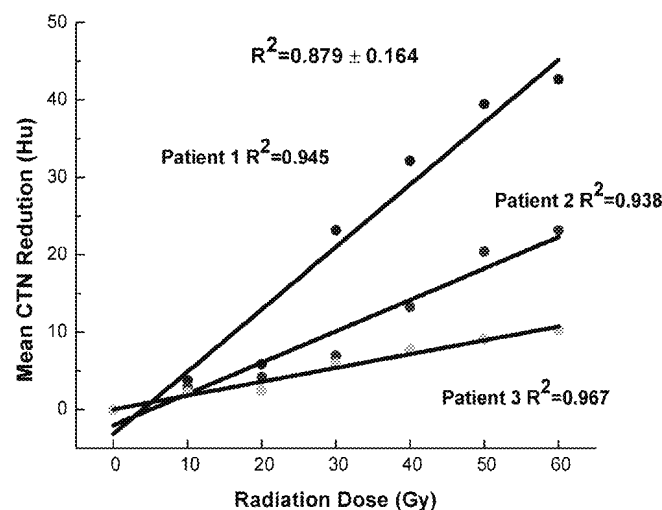


Figure 1. Details of correlation between mean CT number (CTN) changes and radiation dose delivery for three representative patients, randomly selected from 54 patients. The correlation data for all patients was $R^2 = 0.879 \pm 0.164$.

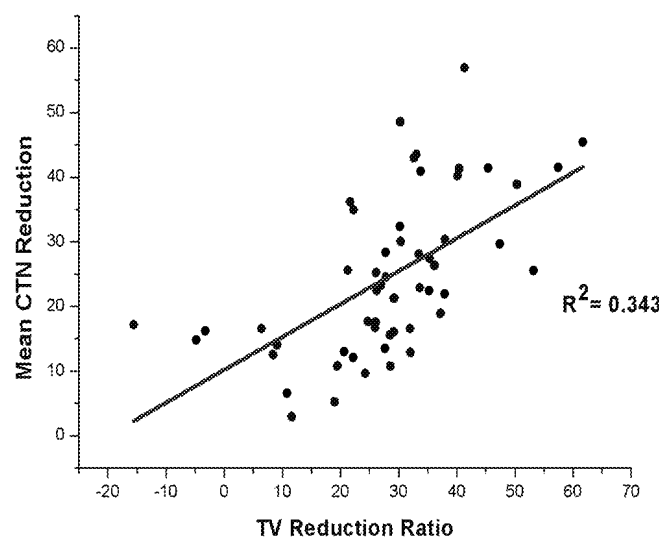


Figure 2. Correlation between mean CT number (CTN) changes and tumor volume (TV) reduction ratio for primary tumor among all patients. The correlation data for all patients was $R^2 = 0.343$.

by approximately 10 (10 ± 5) HU. The mean densities of the primary tumor at baseline in the two groups were 67.62 ± 30.14 HU and 56.43 ± 25.52 HU, respectively. The CT density before radiotherapy was not significantly different between the groups ($p = 0.149$). However, after 60 Gy of conventional fractionation radiotherapy, the CTN variations were more significant in the response group (28.44 ± 13.12 HU vs. 19.63 ± 8.67 HU, $p = 0.005$).

The tumor volumes of the two groups at baseline did not differ before radiation therapy with $p = 0.314$. Nevertheless, an obvious heterogeneity of the change in tumor volume was observed in the radiotherapy procedure. The tumor volume in patients who had a response diminished by 32.01% (range, 8.46–61.67%), and patients who were categorized as non-response had tumor volumes that dropped by 23.20% (range, -15.57–38.00%) ($p = 0.026$). The patients whose primary tumor volume reduced by $>50\%$ were all from the response group, and the patients with regression ratio below 20% all belonged to the non-response group. In the multivariate analysis, the difference between the groups still showed statistical significance in the changes in CTN ($p = 0.016$) and TV ($p = 0.048$).

This result illustrated that both CTN change and tumor volume regression could distinguish responding patients from non-responding patients, with $p = 0.037$ and $p = 0.016$, respectively (Fig. 3). Further, the logistic regression model and ROC analysis implied that the combination of change of CT density value and tumor volume had a higher AUC ($AUC = 0.751$) than CTN ($AUC = 0.666$) or tumor size ($AUC = 0.693$) alone for assessing treatment early response ($p = 0.002$). The sensitivity, specificity, positive predictive and negative predictive values were 58.8%, 86.4%, 87.16% and 57.17%, respectively.

Characteristics	Response (33)	Non-response (21)	p-value
Gender			
Male	18	12	0.851
Female	15	9	
Age			
≥65	5	8	0.055
<65	28	13	
Smoking			
Yes	21	16	0.333
No	12	5	
Stage			
IIIA	19	11	0.708
IIIB	14	10	
ECOG PS			
2	6	5	0.617
0–1	27	16	
Histology			
Squamous	21	11	0.412
Adenocarcinoma	12	10	
Chemotherapy regimens			
Etoposide + Cisplatin	16	7	0.491
Paclitaxel + Carboplatin	11	10	
Pemetrexed + Cisplatin	6	4	
CTN Baseline (HU)	67.62 ± 30.14	56.43 ± 25.52	0.149
CTN Change (HU)	28.44 ± 13.12	19.63 ± 8.67	0.005
Volume Baseline (cm ³)	98.59 (19.96–218.37)	72.11 (32.01–182.39)	0.314
Volume Change ratio	32.01% (8.46–61.67%)	23.20% (–15.57–38.0%)	0.026

Table 2. Univariate analysis of demographic and morphologic factors for NSCLC patients with response. *Abbreviations:* ECOG PS = Eastern Cooperative Oncology Group performance status; CTN = computed tomography number.

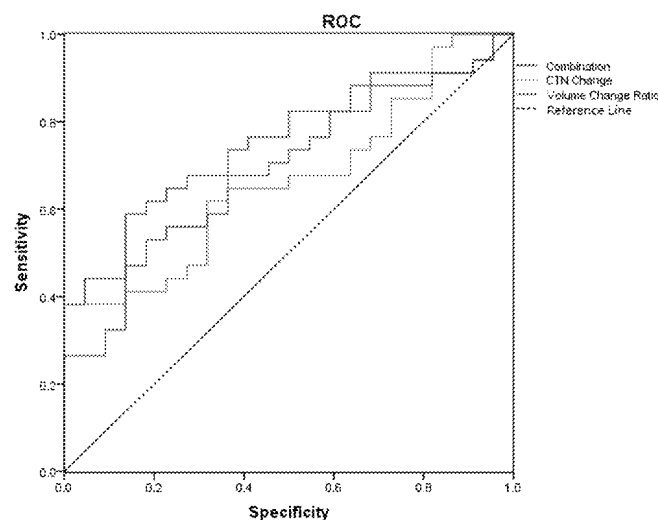


Figure 3. Receiver operating characteristic (ROC) curves for early response prediction. The area under the curve (AUC) for the models is shown in the figure.

Factors effect on CTN and volume changes. Univariate analysis results demonstrated that both the CTN value and TV varied with histology. The change in the mean CTN in the squamous group (28.08 ± 11.28 HU) was much higher than that in the adenocarcinoma group (20.69 ± 12.40 HU) ($p = 0.019$). For the volume reduction ratio, we found that patients who were diagnosed as squamous (28.63%) had dramatically decreased volumes ($p = 0.046$), compared to the adenocarcinoma group (23.04%). However, we did not find any difference among the various chemotherapy regimen groups with the respect to CTN ($p = 0.144$) or volume ($p = 0.213$).

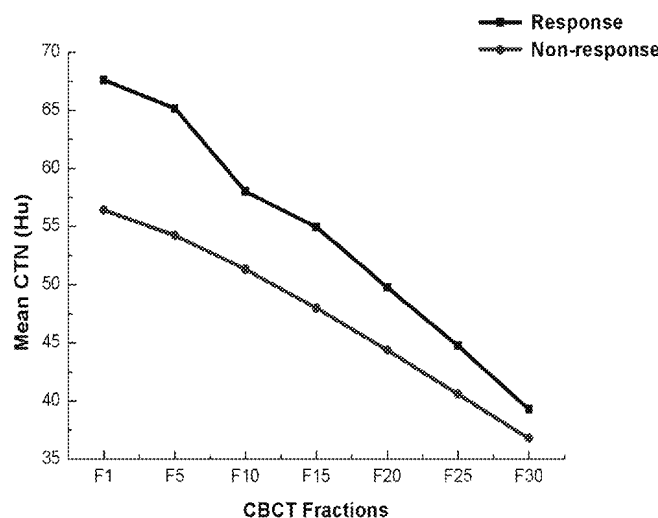


Figure 4. Tumor CT number (CTN) changes over radiotherapy (RT) course. The mean CTN changes in response group and non-response group were 67.62 ± 30.14 Hu and 56.43 ± 25.52 Hu.

	CTN (Δ HU/Gy)			Volume (Δ TV ratio/Gy)		
	TTEST	AUC	p-value	TTEST	AUC	p-value
F1- F5	0.665	0.531	0.7	0.364	0.571	0.374
F1-F10	0.094	0.678	0.026	0.083	0.628	0.046
F1-F15	0.149	0.592	0.247	0.377	0.548	0.546
F5-F10	0.001	0.75	0.002	0.019	0.667	0.036
F5-F15	0.004	0.721	0.006	0.121	0.596	0.339
F10-F15	<0.001	0.753	0.002	0.218	0.580	0.314

Table 3. Comparisons between periodic slopes for response prediction in NSCLC patients. *Abbreviations:* AUC = area under curve; CTN = computed tomography number; F = fraction.

In the multivariate analysis, the test showed that the histological type was an independent predictive factor for CTN reduction (OR = 1.554, 95% CI = 1.033–2.331, $p = 0.035$) but not for volume regression (OR = 1.320, 95% CI = 0.904–1.917, $p = 0.141$).

Early response. CTN reduced gradually over the course of treatment. The curve for primary tumors is shown in Fig. 4. Major changes occurred at the early stage of radiotherapy, and the tumor density decreased more significantly in the first half of radiotherapy. The predictive value of the relating various slopes to treatment response were calculated by period, which illustrated that the mean HU decrease per Gy (Δ HU/Gy) of period Fraction 1- Fraction 10 ($p = 0.094$), Fraction 5- Fraction 10 ($p = 0.001$), Fraction 5- Fraction 15 ($p = 0.004$) and Fraction 10- Fraction 15 ($p < 0.001$) showed statistically significant associations with an early response. In the ROC analyses, the predictive value of Fraction 10-Fraction 15 was much higher than the other values (AUC = 0.753, $p = 0.002$), with the best cut-off value at 0.53 (Table 3). The sensitivity and specificity values were 58.8% and 90.9%, and the positive and negative predictive values were 90.6% and 58.3%, respectively.

The volume change curve for primary tumors is displayed in Fig. 5, where the most of patients with a response presented a substantial regression in tumor volume between Fraction 1 and Fraction 15. As Table 3 indicates, the early regression of tumors was sufficient to predict a response in the period of Fraction 1- Fraction 10 ($p = 0.083$) and Fraction 5- Fraction 10 ($p = 0.019$). In the ROC analysis, Fraction 5- Fraction 10 (AUC = 0.667) was more powerful than Fraction 1- Fraction 10 (AUC = 0.628) (Table 3), with a cut-off value of 0.919. When we evaluated the change of TV for distinguishing the response from non-response, the overall sensitivity, specificity, positive and negative predictive values were 55.9%, 81.8%, 82.8% and 54.1%, respectively.

Discussion

Currently, the predictors of NSCLC treatment response are varying and unstable, so a novel strategy is required to provide earlier and more accurate information about a patient's prognosis. Most patients depend on a restaging chest and abdomen CT scan performed 4–8 weeks after the completion of therapy to determine the response results, which is a long waiting period, and the opportunity to adjust treatment plans may be missed. Through the identification of patients who will get benefit from treatment, patients may achieve equivalent results with

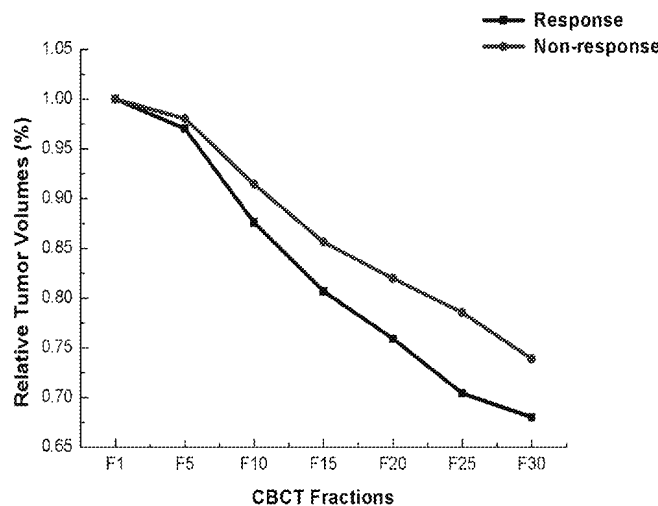


Figure 5. Tumor volume (TV) reduction ratios for patients with radiotherapy (RT). Tumor volume regressions in response group and non-response group were $31.76\% \pm 14.78\%$ and $26.12\% \pm 12.16\%$.

lower RT doses and economic cost¹⁷. In this work, we investigated the possibility of using CTN and tumor volume regression ratio via CBCT images as predictors of treatment outcomes.

The CTN changes detected during the treatment process were specific to each patient; the apparent changes did not exist in all cases, which meant that the radiation dose was just one of the elements contributing to the CTN changes. In addition to histological types, there was a correlation between decreased CTN and radiosensitivity in patients with NSCLC¹⁸. Due to the presence of tumor cell heterogeneity, tumor cells might display different degrees of radiosensitivity when they have different pathological differentiation statuses. Radiation-resistant cells were more likely to survive radiotherapy, which contributed to the disparate degrees of CTN reduction. The mechanism for radiation-induced CT number changes was still indistinct and indefinite. The reasons for this are as follows. Cao *et al.* inferred that the radiation-induced tumor microenvironment improvement increased tumor blood volume (BV), which might lead to CT number decreases in GTV in this study¹⁹. It has been revealed that an increase in BV was detected in the primary tumor at an early course of radiotherapy and the patients with local control (5.1 mL/100 g) had statistically significantly higher BV than the patients with local failure (1.0 mL/100 g). According to that study, we concluded that the tumor volume began to shrink with the delivery of radiation doses, while the BV might increase. Therefore, tumor blood volume enhancement might result in the tumor density tending to be hypodense and might contribute to the CTN reduction. Another explanation might be that with an increasing radiation dose, the tumor began to shrink as a result of tumor cell apoptosis and led to CTN reduction. Third, it has been reported that CBCT CTN extracted during radiotherapy could predict radiation-induced lung injury (RILI). The potential RILI patients whose normal lung tissues densities surrounding lung cancer were higher than that in patients with non-RILI²⁰. Consequently, RILI should be considered a factor that influences CTN reduction in further analyses. It is challenging to discriminate between recurrence and radiation-induced changes following inflammation by using CBCT. However, a study by Mattonen *et al.* demonstrated that quantitative alternations in HU and ground glass opacity (GGO) textural analysis could differentiate recurrence from RILI at 9 months post stereotactic radiotherapy (SBRT)²¹. Generally, more follow-up studies are necessary to verify this hypothesis and investigate the mechanism behind the complex phenomenon between the CTN changes and radiation doses.

Regarding tumor volume, the radiation modality and technique had an impact on size regression. Bosmans *et al.* suggested that there was no obvious shrinkage in the first 2 weeks of radiation therapy, with 1.8 Gy per fraction administered two times per day²². The reason for this finding might be that the treatment-induced inflammation counterbalanced lung cancer cell death. Hu *et al.* evaluated patients treated with SBRT, and their median TV regression reached only 15.91% on CBCTs²³, which was much lower than those of patients with IMRT. A reasonable explanation for this was an insufficient treatment time for demonstrating a tumor volume decrease with SBRT.

Although both of CTN and TV received a similar radiation dose, the correlation between them was generally weak. Mahon *et al.* observed CTN reduction in 27 lung cancer patients treated with definitive CRT or radiotherapy alone and found that the rate of tumor volume was weakly correlated with HU change²⁴. Furthermore, Feng *et al.* reported a weak correlation ($r = 0.47$) in neck and head cancer with radiation therapy²⁵. As mentioned above, the radiation dose might be just one of the factors causing variations; more factors need to be discussed.

The correlation between a patient's prognosis and variations in tumor density and volume has been widely investigated using CBCT and other imaging techniques. In previous studies, CTN was investigated in different tumor sites^{24,26}. Compared to patients with CR, Vandecaveye *et al.* noticed that volume shrinkage of the first two weeks was much lower in patients with CRT resistance, with $-2.8\% \pm 34.5$ versus $31.3\% \pm 32.1$ ($p = 0.03$)²⁷. Bhide *et al.* suggested that the most significant regression of volume occurred in the second week of radiotherapy²⁸. We herein indicate that serial CBCT images obtained during radiation-based therapy can predict the response.

Several previous studies also detected the heterogeneity of tumor volumes reduction for NSCLC by using various imaging modalities. Fox *et al.* assessed 22 patients with NSCLC using repetitive CT scanning and found a significant tumor shrinkage of 25% at 30 Gy and 44% at 50 Gy, which was larger than our median reduction of 28.28%²⁹. The reason for this difference may be the intrinsic low soft-tissue contrast of the CBCT images, especially in differentiating the primary tumor from normal tissues. As Wang *et al.* suggested³⁰, the low-contrast regions were inadequate to define the spatial transformation and volume reduction. Megavoltage computed tomography (MVCT) was also used to evaluate tumor reduction throughout radiotherapy in patients with lung cancer. Woodford *et al.* reported that daily MVCT was utilized to quantitatively assess response to helical tomotherapy at a total dose of 60–64 Gy in the conventional fraction and found GTV regression greater than 30% at any point before 40 Gy, which could dramatically improve the therapeutic ratio³¹. Our results, which were slightly different from those of Woodford *et al.*, revealed that the volume change could not be detected as a gradual linear decrease. Furthermore, we noticed that some patients experienced an increasing tumor volume in the first week or the last period of treatment. The reasons for these might be due to high tumor proliferation and radiation-induced inflammation in normal lung tissues around the tumor. In contrast to our study, Brink *et al.* showed that significant TV shrinkage was related to poor overall survival and locoregional control using CBCT³², implying that a large regression during radiotherapy could be a surrogate biomarker of tumor aggressive. Considering the instability of the tumor volume, we not only estimated tumor regression but also monitored the change in CT density. Moreover, the seven sets of CBCT images used in our study could provide more data to specifically assess tumor changes in comparison to the work of Brink *et al.* More importantly, we determined appropriate time points for early response prediction by using week-to-week CBCT data.

Decreased tumor density and TV have been used to distinguish between responders and non-responders in gastrointestinal stromal tumor (GIST), as Choi *et al.* proposed^{33,34}. They showed that a $\geq 15\%$ change in tumor density and a $\geq 10\%$ regression of tumor size were associated with better PFS than RECIST criteria. Compared to small cell lung cancer (SCLC), NSCLC is less sensitive to therapy. Anatomical changes might not manifest initially, even if the therapeutic paradigm is appropriate. Accordingly, TV assessment alone had a smaller AUC than the combination of biological and anatomical evaluation. Due to the multiplex factors effects mentioned above, especially the intrinsic limitation of CTN accuracy, CTN must be combined with TV change to predict early response.

Compared to RECIST, our criteria had two advantages for evaluating early treatment response. First, the CTN had the potential ability of assessing the internal structure changes of the tumor prior to morphological changes. Second, by combining the CTN and TV changes, the treatment response could be predicted with higher specificity and sensitivity than when using the long axis only. We noticed that the change in the long axis was much smaller than the volume change. In other words, the RECIST diameters may remain relatively stable while regression has occurred in other directions, as noted by McNitt-Gray³⁵.

The present study had some limitations. First, a relatively small sample number was included. Future studies with larger numbers of patients are necessary to validate our results. However, our cases represent a study with regular regimens. Second, the accuracy of the values was influenced by the different slice thicknesses used in CT and CBCT reconstruction and by the potential limit of CBCT in soft-tissue contrast compared with CT, which could result in uncertainties³⁶. A slower gantry speed or Monte Carlo-based scatter correction may improve the CBCT image quality^{37,38}. As Mazzola *et al.* showed, another limitation was that the CBCT CT number may not represent the real HU due to various artefacts, including body scattering³⁶. However, the utility of delta CT number could reflect the actual biological changes of tumors and minimize the interference from influencing factors, especially when we considered that the image acquisition conditions were consistent among serial CBCT. In terms of the CT number, Jin *et al.* suggested that the difference between CT and the first CBCT was not significant from -200 HU to 500 HU³⁹. Similar findings were detected by Altorjai *et al.*, who found that the grey value distribution histogram from CBCT was matched to the HU distraction histogram of CT in a fixed window with grey level of -200 and a width of 600 ¹⁶.

Conclusions

The changes of CTN and TV obtained from CBCT images have the potential capability to predict the early response of NSCLC. Fraction 10 - Fraction 15 (CTN) and Fraction 5 - Fraction 10 (TV) were two appropriate time points for early response prediction in advanced NSCLC.

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Author Contributions

Q.W. designed the study and wrote the manuscript. J.Z. participated in the study design and data collection. C.S.M. and T.B. provided the analysis of data. X.M. and X.D.S. participated in data collection and offered guidance. J.M.Y. carried out the study design and interpretation of data and drafted the manuscript. All authors read and approved the final manuscript.

Additional Information

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PHYSICS CONTRIBUTION

TARGET LOCALIZATION AND REAL-TIME TRACKING USING THE
CALYPSO 4D LOCALIZATION SYSTEM IN PATIENTS WITH LOCALIZED
PROSTATE CANCER

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Purpose: The Calypso 4D Localization System is being developed to provide accurate, precise, objective, and continuous target localization during radiotherapy. This study involves the first human use of the system, to evaluate the localization accuracy of this technique compared with radiographic localization and to assess its ability to obtain real-time prostate-motion information.

Methods and Materials: Three transponders were implanted in each of 20 patients. Eleven eligible patients of the 20 patients participated in a study arm that compared radiographic triangulated transponder locations to electromagnetically recorded transponder locations. Transponders were tracked for 8-min periods.

Results: The implantations were all successful, with no major complications. Intertransponder distances were largely stable. Comparison of the patient localization on the basis of transponder locations as per the Calypso system with the radiographic transponder localization showed an average ($\pm$ SD) 3D difference of 1.5 ± 0.9 mm. Upon tracking during 8 min, 2 of the 11 patients showed significant organ motion (>1 cm), with some motion lasting longer than 1 min.

Conclusion: Calypso transponders can be used as magnetic intraprostatic fiducials. Clinical evaluation of this novel 4D nonionizing electromagnetic localization system with transponders indicates a comparable localization accuracy to isocenter, (within 2 mm) compared with X-ray localization. © 2006 Elsevier Inc.

Prostate, Radiation, Motion, Localization, Tracking.

INTRODUCTION

Knowledge of the location of a tumor is critical during external-beam radiation therapy (EBRT) to optimize therapy and minimize complications. This requirement applies especially to emerging radiation-therapy techniques that involve dose escalation, hypofractionation, and gated therapy. Multiple factors affect the location of a radiation target, including daily internal variations caused by changes that occur between treatment days (interfraction variations) and changes that occur while the patient is on the table (intrafractional changes). In the treatment of localized prostate cancers, many studies have been done to determine the daily variations in target location throughout the course of treatment. These studies have been done with different techniques, including ultrasound, infrared cameras, X-rays, portal imaging, multiple diagnostic, and megavoltage computerized tomography (CT) (1–4). Daily prostate position variations are caused

by variations in bladder and rectal filling. These variations can also be caused by changes in the patient's surface and by surface marks that are used to traditionally align patients.

In addition to the daily prostate variations, recent studies have been done to determine the intrafraction motion that can occur while a patient is undergoing a single fraction of treatment. Motion caused by breathing and other biologic factors, such a gradual rectal distention that occurs over a few minutes, can cause the prostate to change location while the radiation is being delivered. These studies have been done by application of cine magnetic resonance imaging, by CT, or by evaluating markers in the prostate under fluoroscopy. These studies indicate that whereas breathing can induce significant prostate movement under extreme conditions (prone patients breathing deeply), the prostate does not move much with breathing when the patient is comfortable and in the supine position (5, 6). All such studies indicate that prostate motion

can occur during a treatment course. However, these motions are not as great as the daily variations and are mostly secondary to rectal peristalsis (7).

Implanted markers are frequently used to establish the position of the prostate gland at treatment during EBRT. This technique has been reported in the literature and applied by institutions that utilize kilovoltage (KV) X-rays, portal images, and either megavoltage (MV) CT or cone beam CT (1, 3, 8–10). These markers serve as proxies for prostate-gland position. With intraprostatic marker implantation becoming an increasingly routine procedure, the use of an implantable radiofrequency emitting device is being proposed as an alternative to radiopaque fiducial markers and radiographic localization to provide an objective, accurate, real-time method of localizing and monitoring target position. A prototype for electromagnetic localization has been developed and is under investigation for use in radiotherapy. This report is the first on the clinical use of this system *in vivo*, with special emphasis on the validation of the independent-signaling Calypso system and the radiographic localization of the implanted devices.

METHODS AND MATERIALS

System overview

The Calypso 4D Localization System (Calypso Medical Technologies, Seattle, WA) is designed to provide accurate, precise, objective, and continuous target localization during external-beam radiotherapy. The Calypso system consists of “wireless,” implanted Beacon transponders and a noncontact AC magnetic array. Figure 1 shows an actual transponder implant. The system is designed such that the magnetic array is localized to the room coordinate system via fixed infrared cameras that are calibrated to the machine isocenter. The array can then signal and detect the beacons and register their location to the treatment machine. The overall components of the system and its accuracy have been previously described by Balter *et al.* (11). The system display updates at a 10-Hz frequency and, therefore, can be practically considered to be a “continuous” tracking method.

Patient study

The current study describes the first human use of transponders and the Calypso system. Twenty patients were implanted with transponders under internal review board approved protocols intended to establish implanted-transponder position stability. An

additional protocol and consent was obtained to evaluate the use of the implanted Beacon transponders and Calypso system for localization and tracking. Eleven of the 20 implanted patients participated in an extension of the study to permit localization and tracking by use of the electromagnetic system. The localization and tracking session was an additional appointment in which the patient did not receive treatment. The objectives of the current analysis were the following: (1) demonstrate the functionality of the localization process with the Calypso system in actual patients; (2) compare the Calypso system’s localization guidance by an independent, radiographic alignment method (kilovoltage X-rays) by use of the Beacon transponders as radiopaque markers; and (3) illustrate the ability to continuously record transponder locations over several minutes and, thereby to track, in near real time, the position of the prostate gland at a 10-Hz frequency.

Twenty patients with localized prostate cancer scheduled to receive external-beam radiotherapy were enrolled on the study at the 3 participating institutions: the M.D. Anderson Cancer Center Orlando ($n = 10$), the University of Michigan ($n = 7$), and the University of California San Francisco ($n = 3$). Patients were implanted transrectally with 3 transponders (8 mm in length $\times$ 1.85 mm in diameter) under transrectal ultrasound guidance, by use of techniques and equipment similar to those used to obtain prostate biopsies. Preparation for implantation was similar to gold-marker implantation (i.e., prophylactic antibiotics and same day enema). The transponders were implanted by use of a 14-gauge introducer needle assembly, into the apical, left mid/base, and right mid/base regions of the prostate.

After implantation, a CT study was performed to determine the locations of the individual transponders. Transponder locations by CT were evaluated at 2 other timepoints before the treatment-planning CT, which was performed at 14 days after the implant day to avoid any potential transponder migration immediately after the implantation procedure. All CT scans through the region of interest of the transponders were acquired with the smallest slice thickness possible (either 1.5 mm or 1.0 mm, depending on the center). The coordinates of the transponder centers on the treatment-planning CT were recorded. For this study, the patient was planned to be aligned so the isocenter would correspond to the centric of the 3 transponder coordinates, as determined from the treatment-planning CT scan.

The Calypso system is designed to localize the patient at the time of treatment to match the position of treatment-planning CT. The coordinates of the beacons and the corresponding isocenter from the treatment plan are entered into the Calypso system at the treatment room. At the time of alignment, the system determines the location of each Beacon transponder and determines the best geometric fit of these transponders to the planned coordinates that were entered into the system. From this fit, the system calculates the table translations that are necessary to move the beacons to positions that best match the locations determined from the treatment-planning CT scan. These translations are shown in an easy-to-read user interface that allows the therapist to shift the table to the desired location. After alignment, a tracking session can be started that updates at 10-Hz frequency the displacement of the calculated isocenter on the basis of the transponders compared with machine isocenter.

Calypso vs. X-ray localization: Validation of Calypso coordinates

The localization study was done to compare the patient shifts calculated by use of the Calypso system with patient shifts calcu-

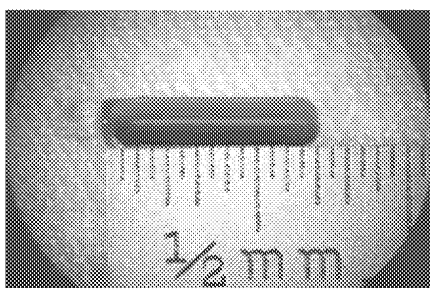


Fig. 1. Beacon transponder (8 mm in length $\times$ 1.85 mm in diameter).

lated by use of in-room KV X-ray alignment. CT with fine slice thickness (1.5 mm or 1.0 mm) was obtained 14 days after the implant of the transponders. For consistency, the isocenter was selected as the averaged coordinates of the centers of the 3 transponders. All coordinates of the transponders and planned isocenter for the Calypso system were obtained from this CT scan. The CT scans were transferred to the in-room KV localization system and the transponders were identified as radiopaque markers on the CT scan. Both the Calypso systems and the X-ray systems are calibrated independently to the isocenter of the treatment machine to within 2 mm.

For comparison purposes, the patients in the study were localized with both the Calypso system and three-dimensional X-ray, with as little time lapse as possible. The transponders are well visualized on CT scans and diagnostic X-rays. However, the transponders could not be reliably identified on megavoltage portal imagers, which was the system to be used at one of the centers (UC San Francisco). Therefore, localization data could not be obtained radiographically on the 3 patients implanted at the University of California San Francisco. The Beacon transponders were designed such that the radiographic center of the transponder corresponds to the RF signal center. By use of the same clinical routines used for localizing patients with implanted gold markers, the transponders were radiographically localized at the two other institutions (M.D. Anderson Cancer Center Orlando and University of Michigan), and the radiographic alignments were compared with the Calypso alignments.

For the patients enrolled at the M.D. Anderson Cancer Center Orlando, a commercial X-ray system (BrainLab Exactrac, Heimstetten, Germany) was used for comparison with the Calypso system. For the patients enrolled at the University of Michigan, an in-house kilovoltage X-ray system was used to localize the transponders. The system consists of 2-KV X-ray tubes, one mounted on the ceiling and the other mounted on the wall. The use of this system has been previously published (10). The transponders were well visualized in each system, as shown in Fig. 2.

For the localization portion of the study, the two different alignment modalities were used as close in time as possible. To eliminate any potential for interference of the Calypso system with the radiographs, the Calypso system was not in use during radiographs. The time delay between radiographs and Calypso was on the order of 3 to 5 min. The alignments were taken as follows. The patients were first aligned to within 0.05 cm of the isocenter, as

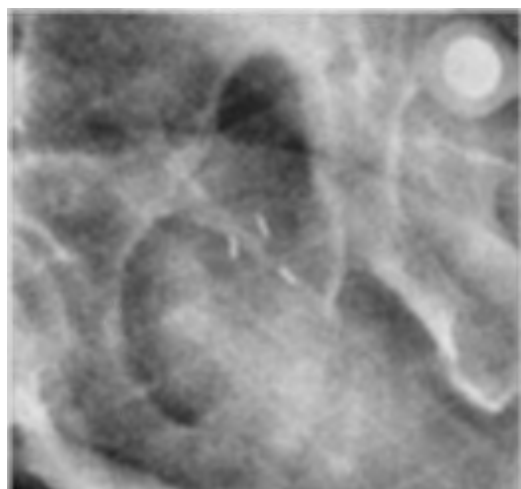


Fig. 2. Kilovoltage X-ray of the Beacon transponders.

determined by the Calypso system. The Calypso system uses the Beacon transponder coordinates to determine patient translations in 3 dimensions that best fit the planned isocenter to the machine isocenter. After this Calypso alignment, a pair of X-rays and the corresponding patient shift, as determined by radiographic position of the transponders, was calculated, but the patient was not shifted. Another Calypso alignment was obtained immediately after the X-ray alignment. The patient was then monitored for 8 min by use of the Calypso system in tracking mode (described below). The localization process was repeated at the end of the tracking sessions such that for each patient, a total of 4 Calypso calculated localizations and 2 radiographically determined localizations were obtained.

For tracking the prostate location, the transponders were monitored for 8 min to represent time periods similar to what would be typical of times patients would be on the treatment table while receiving radiation therapy. In tracking mode, the patients were asked to remain still on the table while the Calypso system was in place collecting data. At 10-Hz frequency, the Calypso system then tracks the X (lateral), Y (longitudinal—superior/inferior), Z (vertical—anterior/posterior), roll, pitch, and yaw calculated about the isocenter from the transponder locations. In the current study, only translations are reported, as the system is designed to provide an easy tool for therapists to localize patients. Further study of the rotational information is necessary. The translational information was collected and analyzed to determine the extent of prostate motion in a time period similar to treatment.

The data were collected according to the following process: (1) quality assurance verification of the Calypso system and the X-ray system, (2) patient was aligned on the treatment table by use of external marks, (3) patient was localized by the Calypso system and adjusted to the Calypso system plan isocenter, (4) X-ray localization was performed, (5) a second localization was obtained by the Calypso system, (6) prostate was then tracked continuously during an 8-minute period by the Calypso system, (7) a third set of coordinates was obtained by the Calypso system, (8) a second set of coordinates was obtained by the X-ray system, (9) a fourth and final set of coordinates was obtained by the Calypso system. This process resulted in 4 Calypso localization data points, 2 X-ray localization data points, and an 8-min continuous tracking session for each patient that recorded temporal data.

Data analysis

The Calypso system localizations were averaged and compared with the 2 X-ray localizations. The accuracy of the system was to be evaluated by examination of the distance between the shifts calculated for both systems as shown in the following formula:

$$D = [(\text{Lat}_c - \text{Lat}_r)^2 + (\text{Long}_c - \text{Long}_r)^2 + (\text{Vert}_c - \text{Vert}_r)^2]^{1/2}$$

The *in vivo* accuracy of the system is determined by intercomparison of the Calypso system to the radiographic system. Analysis of the tracking session included evaluating the rigid-body registration of the transponder geometry in real time compared with the CT scan to model the prostate motion in real time.

RESULTS

The implantation procedures were successful, with no major complications. Of the 60 implanted transponders, 1 was lost (presumably implanted in the urethra and subse-

quently voided, with the patient remaining asymptomatic), 1 transponder migrated approximately 3 cm from the apical area to the level of the seminal vesicles around the 4th day after the implant (presumably traveling within the venous plexus, with the patient remaining asymptomatic and the transponder subsequently remaining stable), and 1 transponder was found to be unresponsive. Therefore, of 60 transponders implanted, 58 were usable for localization. Even in patients with 2 transponders, localization would still be possible; however, information about rotations would not be possible.

Analysis of intertransponder distances, as a proxy for transponder migration, indicated that the transponder geometry was stable in 15 of 20 patients by the 4th day and in all patients by the 14th day after implantation. Intertransponder distances measured at 4 weeks after radiation were unremarkable. The mean of the SD of intertransponder distance variation measured at 4 days after implantation was 1.3 mm. Patients' urinary status was assessed with IPSS scores and changed before radiation in only 2 of 20 cases; both patients had relatively minor increases (around 4 points) before the start of radiation. Bleeding (any combination of hematuria, hematospermia, and hematochezia) was reported in 7 patients before radiation. These episodes were minimal and resolved spontaneously.

Of the 20 patients implanted with the transponders, 12 were eligible and consented to an additional appointment for localization and registration with the Calypso system. In 1 of the 12 patients, 1 of the 3 transponders did not produce a signal and was therefore unable to be localized under this protocol, which required all 3 transponders to produce a single coordinate for data collection. Subsequent changes have been made to the transponder manufacturing process to prevent future nonresponsive transponders. Furthermore, the Calypso system software has been updated to allow localization with only 2 transponders.

For both the Calypso system and the radiographic systems, the transponder coordinates are determined on thin-slice thickness CT scans. Previous work has determined that the accuracy of identifying coordinates of markers in CT scans to be dependent upon the slice thickness of the CT scan. Specific work to check the ability to resolve Calypso transponders in CT showed that, depending on slice thickness, individual transponder locations would be known within 0.7 mm (12).

Data are presented on 11 patients from 2 institutions and 1 phantom study. Before patient study, work in phantoms was done to determine baseline values. The localization accuracy for a phantom aligned in the same manner as the patients (Calypso followed by radiograph) showed a difference between the 2 alignment methods of 0.5 ± 0.1 mm. The localization accuracy between the 2 different Calypso sessions and the radiographic session for the patients are shown in the Table 1. The first 2 Calypso localizations were compared with the first radiographic imaging session, and the second 2 Calypso localizations were compared with the second radiographic session. Table 1

Table 1. Three-dimensional shift (mm) between the Calypso system coordinates and the radiographic coordinates

Patient	C1-R1	C2-R1	C3-R2	C4-R2
MD-08	3.3	0.7	1.0	1.3
MD-09	1.2	0.6	1.1	1.1
UM-03	3.2	2.1	1.7	0.8
UM-04	1.5	0.9	0.9	1.0
UM-02	2.2	1.3	1.4	1.9
UM-01	1.3	2.3	1.8	3.8
MD-06	0.4	0.6	0.4	0.3
MD-05	1.6	0.9	0.9	3.0
MD-10	0.8	1.5	0.6	1.1
MD-04	0.7	1.4	1.3	2.3
UM-06	2.2	2.2	2.2	2.2
ALL	1.5 ± 0.9 mm			

The first 2 Calypso system (C1 and C2) and the first radiographic (R1) observations were compared. Subsequently, the second 2 Calypso system (C1 and C2) and the second radiographic (R2) observations were compared. The combined number on the last line is the average $\pm$ S.D. of all Calypso system versus X-ray comparisons.

illustrates that the greatest discrepancy was for the first localization, but the overall comparability between the Calypso system and radiographic alignments was 1.5 ± 0.9 mm. Approximately 10 min elapsed between the 2 radiographic sessions and approximately 30 s to 1 min between each Calypso alignment and the closest radiograph. This time lapse was the result of image analysis and repositioning of the Calypso system. The three-dimensional distance between the calculated shift to isocenter from the first radiograph and the second radiograph ranged between 0.3 and 6.6 mm and showed prostate motion during the time the patient was on the table.

The 8-min tracking sessions were performed on all 11 patients. Two examples of such patient-tracking sessions are shown in Fig. 3. These graphs plot the variation in X (lateral), Y (longitudinal), and Z (vertical) positions of the calculated patient-alignment point over time for the entire 8-min session. An 8-min tracking session of a phantom under the same conditions showed maximum change in translations of 0.10 mm laterally, 0.10 mm longitudinally, and 0.31 mm vertically, which indicates the range of noise from electromagnetic interference. The majority of the patients had relatively stable transponder positions during the tracking sessions. Figures 3a and 3b are in patients in whom the prostate was relatively stable during the tracking period. However, a minority of cases (2 of 11) exhibited significant prostate motion. Figures 3c and 3d are in patients in whom the prostate displayed significant excursion during the tracking period. To characterize the real-time motion of the prostate gland, the maximum differences in the calculated centroid of the transponders was analyzed in each direction (lateral, longitudinal, and vertical), and the results are displayed in Table 2. In all 11 cases, the average ($\pm$ SD) of the maximum differences were 0.91 ± 0.35 mm, 3.61 ± 3.13 mm, and 3.92 ± 4.32 mm in the lateral, longitudinal,

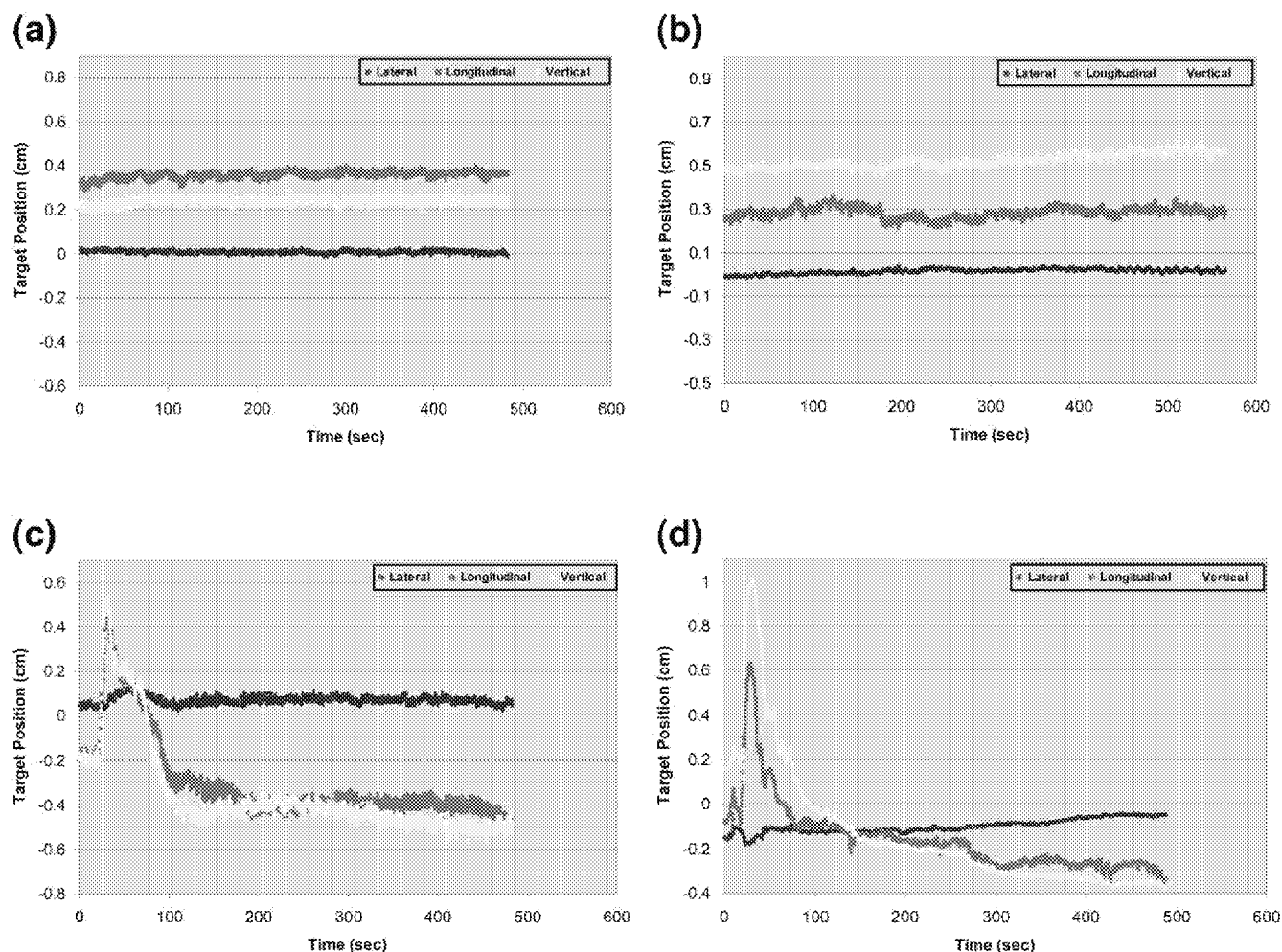


Fig. 3. Variation in X (lateral L/R, blue), Y (longitudinal S/L, yellow), and Z (vertical A/P, pink) locations over time for the entire 8-minute session in 4 of the 11 patients. (a) and (b) Patients in whom the prostate was relatively stable during the tracking period. (c) and (d) Patients in whom the prostate displayed significant excursion during the tracking period.

vertical directions, respectively. The maximum differences (in mm) were 1.40 mm, 9.88 mm, and 13.86 mm in the lateral, longitudinal, vertical directions, respectively.

Table 2. Maximum difference over the 8-min tracking sessions in each direction in millimeters

Patient	X*	Y†	Z‡
MD-04	1.03	2.94	1.63
MD-05	1.40	9.88	13.86
MD-06	0.70	2.48	2.44
MD-08	0.41	1.98	1.67
MD-09	0.44	1.19	1.11
MD-10	0.88	1.37	1.62
UM-01	0.55	1.50	1.73
UM-02	1.03	3.21	2.40
UM-03	0.97	3.38	3.07
UM-04	1.23	2.16	2.44
UM-06	1.33	9.64	11.16

* Lateral.

† Longitudinal.

‡ Vertical.

DISCUSSION

The Calypso 4D Localization System is a novel method of target localization during the course of external-beam radiation therapy. The current study constitutes the first attempt at characterizing the system in the clinical setting, specifically in patients with localized prostate cancer to be treated with external-beam radiotherapy. Compared with the two different KV X-ray localization methods used for the study, the accuracy of the Calypso system for localization was less than 1.5 mm. The current study included 11 patients for the accuracy study, with 1 appointment and 2 localizations performed per patient. The results should be validated in a larger number of cases, with several observations made per patient throughout a course of treatment. A second protocol is currently underway to achieve those goals. However, the current initial observations in the first 11 patients are clearly encouraging.

The major benefits of the Calypso system compared with more conventional localization methods are several. First is the lack of ionizing radiation to perform the localization. With X-ray-based techniques, either kilovoltage or mega-

voltage, some level of ionizing radiation is delivered to the imaged areas. In the course of treatment with external radiation, such radiation doses accumulate on a daily basis and effort needs to be spent in trying to understand, manage, and limit such radiation doses from localization procedures performed in the course of delivering external-beam radiotherapy (13). The Calypso system does not require reliance on ionizing radiation to perform imaging, which enables a virtually unlimited use of the system in patients implanted with transponders.

Second, the Calypso system does not require any complicated procedures of acquiring X-ray images (KV X-rays, portal images, or KV or MV CTs), along with an image-registration process that necessitates the repeated use of ionizing radiation to reacquire images to proceed with registration again in case of a need to verify target position. With the Calypso system, seamless and continuous positional information is available. This information is presented in an objective format that does not require significant training or interpretation by the operators, because it relays only patient position (translation) information and, thereby, decreases user dependency. The localization process is performed in a few seconds, with no image processing required. The therapists are also not required to leave the room, and then reenter the room to position the patient.

One of the greatest advantages of the Calypso system is the ability to continuously monitor target position during treatment. The system is designed in such a way that the electromagnetic array can be left in place during treatment to gain real-time information. During treatment, this information could be used to determine limits for beam-on time or could be sent to a control unit to turn the radiation on, and off when the target is not centered in the treatment field. For the first time, real-time information is available during treatment, which opens the door to numerous possible uses for this technology in modifying or adapting the delivered treatment. In the 11 patients who were evaluated within the 8-min time frames, some motion was evident in all of them in the location of the transponders, with maximum variations exceeding 1 cm. Mah *et al.* (7) used cine MRI in 46 patients with localized prostate cancer. They reported prostate displacements (mean $\pm$ SD) of 0.2 ± 2.9 mm, 0.0 ± 3.4 mm, and 0.0 ± 1.5 mm in the vertical, longitudinal, and lateral dimensions, respectively. The maximum displacement observed was 1.2 cm, similar to the 1.4 cm observed in our study. The motion was also mostly anterior and superior, again similar to the current study. However, they described the prostate motion to be mostly temporary, with the prostate moving back to its original position. As demonstrated in Figs. 3c and 3d, the transponder coordinates in those 2 patients indicated a change of position of the prostate without necessarily a return to the original position. In our study, the prostate displacements (mean $\pm$ SD) were 0.91 ± 0.35 mm, 3.61 ± 3.13 mm, and 3.92 ± 4.32 mm in the lateral, longitudinal, vertical directions, respectively. The dosimetric implications of such prostate excursions will be dependent on the actual treatment-field designs (i.e., treat-

ment margins used) and the length of time the prostate gland remains out of position. Such dosimetric consequences are difficult to determine and will be subject of a separate analysis. Finally, Kitamura *et al.* (6) described prostate motion as determined by fluoroscopic detection of intra-prostatic gold markers. They described a relatively small intrafraction motion in 10 patients, with the amplitude of the 3D motion being 0.1 to 2.7 mm in the supine position and 0.4 to 2.4 mm in the prone position. Collectively, these data demonstrate that more extensive work still needs to be performed to better characterize target motion, with more repeated observations needed over long periods of time in a larger number of patients.

The 3 potential disadvantages of the Calypso system are the following: need for implantation, transponder stability within implanted tissues, and the absence of any associated image of the targeted areas. The necessity to implant the transponders within the targeted areas and as well distributed as possible is obvious; however, the exact geometry necessary is still under investigation. Specifically, for use in prostate-cancer patients, the implantation is not different from the process already frequently used to implant conventional gold markers. The procedure is simple and well tolerated, with few (if any) contraindications. The implantation procedure itself and the presence of the transponders in the prostate gland did not seem to cause any obvious adverse effects within patients, consistent with what is expected with standard gold-marker implantation. The more important issue is the stability of the transponders within the implanted area. The mean of the SD of intertransponder distance variation measured at 4 days after implantation was 1.3 mm, identical to what has been published previously by Pouliot *et al.* (3) for 33 markers in 11 patients. The mean of the SD of intertransponder distances measured at 14 days after implantation was 0.8 mm. At the M.D. Anderson Cancer Center Orlando, intermarker distances of 168 intra-prostatic gold markers were measured in 56 patients (2,037 observations); the mean of the SD of intermarker distance variation measured throughout the course of treatment was 1.0 mm (14). Therefore, the migration of the transponders is still within the range of what is expected with routinely implanted gold markers, as observed in many other studies that looked at the stability of prostate markers (3, 10, 15, 16). The last issue is the absence of any associated image of the treated area, such as an X-ray or a CT study, with resulting complete reliance on the coordinates given by the system, rather than on an image in which associations with the surrounding anatomy can be made. Some assurance is given that the system checks the daily locations of the transponders relative to each other and would give an indication of the fit of the geometry of the transponders to the CT plan. This information could provide an indication, if necessary, to acquire additional imaging. Also, an image could always be acquired (e.g., an in-room CT), if needed. The Calypso system would be then reserved to localize and, more importantly, track during the treatment period.

In conclusion, the Calypso system is a four-dimen-

sional, nonionizing electromagnetic localization device with Beacon transponders implanted within target tissues. Initial observations of transponders implanted within the prostate in this initial group of patients indicate an overall accuracy within 2 mm compared with

X-ray localization. The ease of use, nonreliance on ionizing radiation, and ability to perform continuous tracking during the time of radiation delivery make this system an effective and unique way of evaluating interfraction and intrafraction motion of target areas.

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Characterization of free breathing patterns with 5D lung motion model

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Purpose: To determine the quiet respiration breathing motion model parameters for lung cancer and nonlung cancer patients.

Methods: 49 free breathing patient 4DCT image datasets (25 scans, cine mode) were collected with simultaneous quantitative spirometry. A cross-correlation registration technique was employed to track the lung tissue motion between scans. The registration results were applied to a lung motion model: $\vec{X} = \vec{X}_0 + \vec{\alpha}v + \vec{\beta}f$, where $\vec{X}$ is the position of a piece of tissue located at reference position $\vec{X}_0$ during a reference breathing phase (zero tidal volume v , zero airflow f). $\vec{\alpha}$ is a parameter that characterizes the motion due to air filling (motion as a function of tidal volume v) and $\vec{\beta}$ is the parameter that accounts for the motion due to the imbalance of dynamical stress distributions during inspiration and exhalation that causes lung motion hysteresis (motion as a function of airflow f). The parameters $\vec{\alpha}$ and $\vec{\beta}$ together provide a quantitative characterization of breathing motion that inherently includes the complex hysteresis interplay. The $\vec{\alpha}$ and $\vec{\beta}$ distributions were examined for each patient to determine overall general patterns and interpatient pattern variations.

Results: For 44 patients, the greatest values of $|\vec{\alpha}|$ were observed in the inferior and posterior lungs. For the rest of the patients, $|\vec{\alpha}|$ reached its maximum in the anterior lung in three patients and the lateral lung in two patients. The hysteresis motion $\vec{\beta}$ had greater variability, but for the majority of patients, $|\vec{\beta}|$ was largest in the lateral lungs.

Conclusions: This is the first report of the three-dimensional breathing motion model parameters for a large cohort of patients. The model has the potential for noninvasively predicting lung motion. The majority of patients exhibited similar $|\vec{\alpha}|$ maps and the $|\vec{\beta}|$ maps showed greater interpatient variability. The motion parameter interpatient variability will inform our need for custom radiation therapy motion models. The utility of this model depends on the parameter stability over time, which is still under investigation. © 2009 American Association of Physicists in Medicine. [DOI: 10.1118/1.3246348]

Key words: breathing motion model, free breathing

I. INTRODUCTION

Accurate radiation therapy dose delivery to lung tumors often requires management of the tumor motion due to breathing. Motion management includes free breathing^{1–7} coupled with a method for modifying the dose delivery to account for motion, breath-hold,^{8–10} and breathing coaching,¹¹ where the patient uses biofeedback to guide their breathing pattern. Of these methods, free breathing allows the user to develop a process that minimizes involvement and cooperation of the patient beyond that typically required for radiation therapy treatments. This can be important for patients with limited cognitive function or patients with impaired breathing function.

Methods for modifying the dose delivery for free breathing patients include expanding the radiation portal to account for the motion,¹² gating the radiation delivery to synchronize the radiation delivery with the position of the tumor,^{13,14} and tracking the tumor motion with the radiation portal.^{15–17}

The free breathing treatment planning strategies involve the use of a breathing motion model to develop a patient-specific strategy. Often the model is based on CT scans ac-

quired during free breathing and organized using a simultaneously acquired breathing surrogate. The surrogate is typically a noninvasive measurement device such as a pneumatic belt placed around the abdomen, camera system that monitors a marker placed on the patient's abdomen or pelvis, or pressure sensor mounted to a belt that is wrapped around the abdomen.^{6,13} There are two surrogates used in our research group when we conduct CT scans for free breathing research: A pneumatic belt placed around the abdomen and a spirometer (Interface Associates, Aliso Viejo, CA, VMM 400). The spirometer has a measurement drift that does not allow its independent use, but coupled with the pneumatic belt signal, can provide a drift-free quantitative breathing metric, the patient's tidal volume, that can be compared against the reconstructed 4D CT scans.¹⁸

Verified breathing models have not yet been established. Many investigators have relied on the periodic nature of the breathing pattern to develop mathematical models in time using the assumption that the breathing motion can be accurately described as a function of time.¹⁹ Seppenwoolde *et al.*³ modeled breathing in this way using an even power of a

cosine function with adjustable period and amplitude. They found that this was able to fit the motion of embedded clips well, but also found that changes in breathing frequency or amplitude were difficult to model.

In some applications, explicit breathing models are assumed not to be required. For example, if a 4D CT scan is gated using phase angle-based gating, then each breathing phase is assumed to occur at a constant fraction of time during the breathing cycle. This allows the treatment planner to determine linear accelerator gating efficiency by identifying the fraction of the 360° breathing cycle for which the beam will be activated. However, the phase-based model assumes that breathing patterns are consistent and reproducible, an inaccurate assumption for many lung cancer patients.²⁰

Research^{21–28} on modeling the lung dynamic motion has been conducted with limited success. Most of the work, based on Weibel's model²⁹ on bronchial anatomy, has applied the principles of fluid dynamics or viscoelasticity to modeling lung motion. However, because of lack of detailed information on lung's inner structure, their results cannot be personalized. Their work can be used to understand the mechanical behavior of lung under different circumstances. The stress distribution without considering the airway resistance was established by Mead,³⁰ indicating that tidal volume may play an important role in modeling lung motion. Lambert *et al.*²³ established that there are pressure losses in the flow along the airway, from the periphery to the flow-limiting site. A linear relationship between the pressure loss and the flow rate was selected because of the low Reynolds's number found in the bronchial tree. In general, regions with stronger or weaker air resistance, corresponding to worse or better communications, longer or shorter airways from the trachea, will have lower or higher air pressure during inspiration, respectively. The opposite would therefore occur during exhalation, namely, that the regions that had lower pressure during inhalation would have greater pressure during exhalation.

Based on the relationship between pressure and airflow, and the fact that different regions of the lungs have different resistance to airflow, hysteresis, defined as differential tissue motion between inhalation and exhalation, has been hypothesized by Low *et al.*³¹ to be caused by pressure distribution imbalances during breathing and can therefore be related to airflow. For quiet respiration, a further model approximation is made here, namely, that the hysteresis motion is caused by the pressure imbalances and that the hysteresis motion magnitude is proportional to the airflow.

Finally, the motion model by Low *et al.*³¹ assumes that during quiet respiration, the motion component due to tidal volume changes is independent of the motion component due to pressure differentials and consequently airflow. Under this assumption, hysteresis motion due to pressure imbalances will occur with the same magnitude regardless of the tidal volume, and the tidal volume lung expansion component will not depend on the rate of breathing (at a single point in time).

The use of tidal volume and airflow to describe free breathing motion allows the time dependence of the model to exist outside the mathematical description of tissue motion.

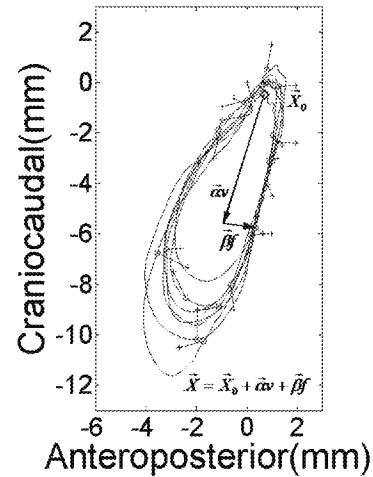


FIG. 1. The breathing motion model (circles) of a piece of tissue determined from measured positions (crosses). $\vec{X}_0$, shown as a diamond, was the location of that tissue at the reference tidal volume and airflow, 0 l and 0 l/s, respectively. The displacement vector for a selected tidal volume and airflow is decomposed into the two components, $\vec{X}_v = \vec{\alpha}v$ and $\vec{X}_f = \vec{\beta}f$, which are the tidal volume and airflow components, respectively. The lines connecting the measured and fit locations are the discrepancies. The mean discrepancy in this case was 1.25 mm.

The time dependence lies in the behavior of the tidal volume and airflow and does not explicitly exist within the model equation. The positions of lung tissues are therefore hypothesized to be functions of five independent parameters; the 3D positions of the tissue at a reference tidal volume and airflow (typically 0 ml and 0 ml/s), the tidal volume, and the airflow.^{32,33}

As Low *et al.*³¹ hypothesized, the position of lung tissues can be described by a linear approximation in tidal volume and airflow. The original mathematical description has been modified here for clarity. The position of a piece of tissue lies at $\vec{X}_0$ at the reference volume and airflow. The position $\vec{X}$ at tidal volume v and airflow f is

$$\vec{X}(v, f; \vec{X}_0) = \vec{X}_0 + \vec{\alpha}(\vec{X}_0)v + \vec{\beta}(\vec{X}_0)f, \quad (1)$$

where $\vec{\alpha}(\vec{X}_0)$ and $\vec{\beta}(\vec{X}_0)$ relate the tissue position to the tidal volume and airflow, respectively, of the tissue at $\vec{X}_0$. Figure 1 shows an illustration of the breathing motion model superimposed with the data acquired from an enrolled patient.

This manuscript reports the breathing motion model parameters for lung cancer and nonlung cancer patients under quiet respiration. The parameters $\vec{\alpha}$ and $\vec{\beta}$ together provide a quantitative characterization of breathing motion that inherently includes the complex hysteresis interplay. The $\vec{\alpha}$ and $\vec{\beta}$ distributions were examined for each patient to determine overall general patterns and interpatient pattern variations.

II. METHODS AND MATERIALS

II.A. Data acquisition protocol

49 patients were enrolled under an IRB-approved protocol and scanned using a 16-slice CT scanner (Philips 16-slice Brilliance CT) operating in cine mode using 1.5-mm-thick

slices. Each contiguous set of the simultaneously acquired 16 CT slices was termed a couch position. The scanner was operated to acquire 25 scans per couch position using a 0.42 s rotation, 360° reconstruction, and 0.32 s between successive cine acquisitions, requiring 18.2 s to acquire the 25 scans. Eight or nine abutting couch positions were typically required to cover the whole lung. The in-plane field of view was 500 mm and images were reconstructed using 512×512 voxel matrices.

The tidal volume was acquired using a calibrated digital spirometer (Interface Associates, Aliso Viejo, CA, VMM 400) that was sampled at 100 Hz with 1 ml digitization resolution.^{34,35} The spirometer drifted, so a separate drift-free metric was acquired at the same time. An abdominal pneumatic belt (Philips Medical Systems, Cleveland, OH) was placed around the patient's abdomen and attached to a pressure transducer. The pressure decreased and increased during inhalation and exhalation, respectively, and the relationship between the bellows pressure transducer voltage signal and spirometry was found to be highly correlated over 18.2 s intervals when a linear drift correction was made to the spirometry signal.²⁰ The drift-corrected spirometry signal was used to recalibrate the bellows signal such that the final recorded values were tidal volume. To quantify the zero value of the tidal volume, the fifth percentile tidal volume was selected as 0 ml.

Because of sample-to-sample noise and digitization artifacts, the airflow was determined using a moving n th-order polynomial fit. n was selected to be 5 in this manuscript based on the observation that no significant improvement would be achieved by applying polynomial fit higher than fifth order. The airflow at time t was the analytical derivative of the fifth-order polynomial of the tidal volume measurement taken over a time span of 0.41 s (41 samples) centered at the point where the airflow was determined. This method of determining the derivative was selected because it reproduced the tidal volume signal with a marked reduction in the derivative noise, allowing for a relatively smooth determination of the airflow.

II.B. Image registration

In order to determine the motion model at each point, position measurements of each point of tissue in each CT scan dataset was required. In this study, a fast normalized cross-correlation (NCC) method was employed.³⁶ In order to determine the motion of a specific point of tissue, a small region with $11 \times 11 \times 10$ pixels that surrounded the point was identified and the NCC algorithm was used to locate that same region in the other 24 scans. One advantage of using the NCC model was that the determination of the maximum NCC was not sensitive to the variation in CT Hounsfield units found between inhalation and exhalation CT scans.

The CT scan with the tidal volume closest to 0 ml (exhalation) was selected as the reference scan for purposes of motion mapping. The CT scan length of 2.4 cm limited each multislice CT dataset to a small portion of the lung, typically 1/8. The magnitude of the motion at the inferior lung was

often greater than 3.0 cm. Some tissue regions, especially those close to the diaphragm, moved out of the longitudinal coverage of the dataset because the zero tidal volume scan was selected as the reference. This would give rise to two issues that could have compromised the results. First, the region being tracked would move out of the searching region but the NCC registration method would select a region within the couch position with largest correlation coefficient and produce spurious results. Second, if the region of interest moved out of the current couch position and was not tracked, some of the 25 scans would be unused.

In this study, the registration was performed in two directions, depending on the breathing phase relative to the reference phase. During exhalation, the tissue generally moved superiorly. Therefore, the multislice CT dataset was first categorized into two groups, inhalation and exhalation, respectively. Each group was sorted according to the tidal volumes from low to high. The reference scan was divided into a 3D mesh of abutting templates consisting of $11 \times 11 \times 10$ voxels, corresponding to $10.7 \times 10.7 \times 15$ mm³. The search region, cocentered with the template, had $21 \times 21 \times 20$ voxels, corresponding to $20.5 \times 20.5 \times 30$ mm³. The registration began with the scan that had the tidal volume closest to the reference scan tidal volume. Because 25 scans were acquired during respiration, there were enough tidal volume samples to limit the tidal volume change between two successive scans to less than 100 ml. The magnitude of motion corresponding to a tidal volume change of 100 ml was usually less than 8 mm. The search range used in this study had sufficient margins to allow for this much motion. When a matching tissue was identified, the displacements were recorded and accumulated to generate the new center of search region for the next scan. When the search region was expected to cross the boundary of the current couch position, the portion that moved out was replaced by the corresponding part of the scan in the next couch position with the closest tidal volume and its accompanying airflow as the reference template.

II.C. Model fitting

The registration process typically resulted in a set of 25 (x, y, z) locations for each evaluated point, along with the tidal volume and airflow corresponding to the acquisition time for each scan. The positions, tidal volumes, and airflows were fitted to the model, employing the Nelder-Mead optimization algorithm³⁷ by minimizing the root-mean least-squares average distance between the fitting and measurements,

$$\min_{\vec{X}_0, \vec{\alpha}, \vec{\beta} \in \mathfrak{R}^3} \sum_{i=1}^{25} \|\vec{X}_i - \vec{X}_0 - \vec{\alpha}v_i - \vec{\beta}f_i\|, \quad (2)$$

where $\vec{X}_i$ was the i th location of 25 measurements, and v_i and f_i were the tidal volume and airflow, respectively, for scan i . In Eq. (1), $\vec{X}_0$, $\vec{\alpha}$, and $\vec{\beta}$, vectors in $\mathfrak{R}^3$, were the overdetermined fitting parameters. Considering three independent components for each vector, nine parameters were determined by 75 measurements (25 sets of $\vec{X}_i$).

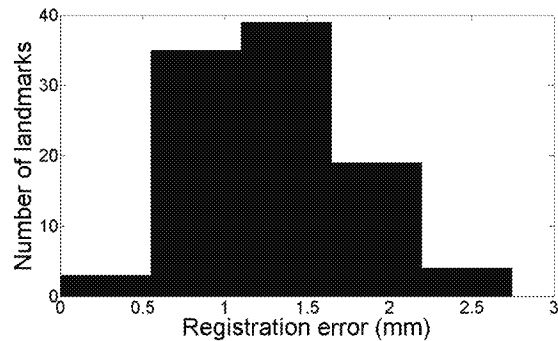


FIG. 2. The registration error of the normalized cross-correlation registration method employed in this study. The registration error is defined as the discrepancy between the displacement fields given by the registration method and manual tracking. 100 landmarks selected in the inferior part of lung from five patients were tracked and manually compared. The motion magnitudes of these landmarks varied from 10 to 30 mm.

One drawback with the Nelder–Mead method was that, like other multidimensional unconstrained optimization algorithms, it occasionally located a local minimum. To overcome this drawback and minimize the discrepancy of fitting, the fitting process was repeated at the current best point³⁸ until the difference in discrepancies between two consecutive fitting operations fell below 5% of the discrepancy obtained from the previous fitting operation.

III. RESULTS

Figure 2 shows the registration error of the NCC registration method used in this study. Registration error was defined as the discrepancy between the displacement given by the registration and that given by manual tissue tracking. 100 landmarks were selected in the inferior portion of lung from five patients. The motion magnitudes of landmarks ranged from 10 to 30 mm. The mean registration error was 1.32 mm.

Figures 3 and 4 show the coronal and sagittal planar samples of $|\vec{\alpha}|$ and $|\vec{\beta}|$ in the left and right lungs of one patient with lung cancer. $|\vec{\alpha}|$, in units of mm/l, represents the

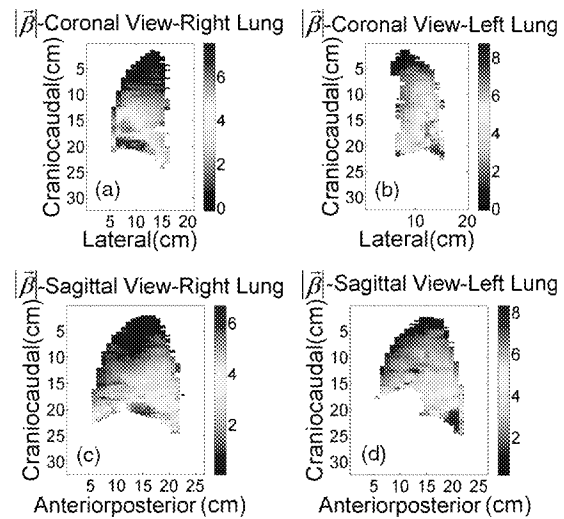


FIG. 4. Distribution of $|\vec{\beta}|$ in a normal pattern.

displacement of the tissue in the lung after inhaling 1 l. $|\vec{\beta}|$, with units of mm s/l, represents the tissue motion hysteresis at an airflow of 1 l/s. For this patient, the 85th percentile tidal volume was 665.0 ml and the airflow varied from -309.1 to 280.8 ml/s.

The result showed that $\vec{\alpha}$ was greater in the inferior and posterior portions of the lungs and smaller in the superior and anterior portions of the lungs. The craniocaudal component of $\vec{\alpha}$ dominated the displacement of the motion during the breathing cycle. $\vec{\beta}$ was greater in the lateral lungs. This pattern of $|\vec{\alpha}|$ and $|\vec{\beta}|$ distribution were observed in 44 out of 49 patients and was therefore defined as the normal pattern.

Figures 5 and 6 showed the coronal and sagittal projection of $|\vec{\alpha}|$ and $|\vec{\beta}|$ in the left and right lung of a patient that had an abnormal motion pattern. For this patient, the 85th percentile tidal volume was 460.1 ml and the airflow varied from -300.0 to 327.8 ml/s.

For this patient, in the right lung, $|\vec{\alpha}|$ was greater in the

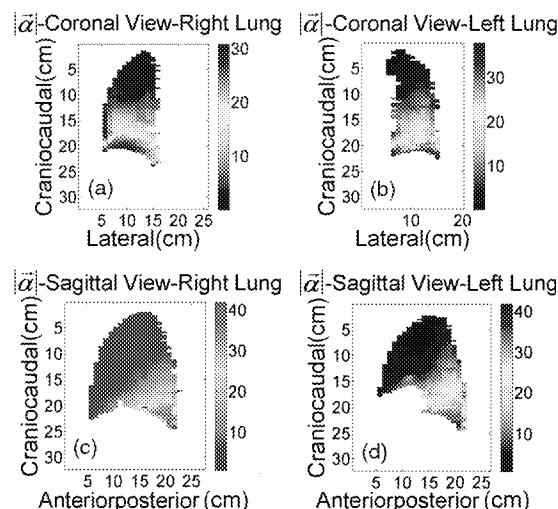


FIG. 3. Distribution of $|\vec{\alpha}|$ in a normal pattern.

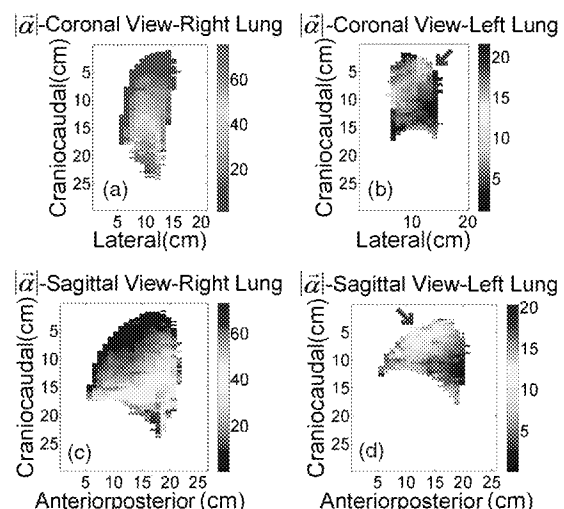


FIG. 5. Distribution of $|\vec{\alpha}|$ in an abnormal pattern.

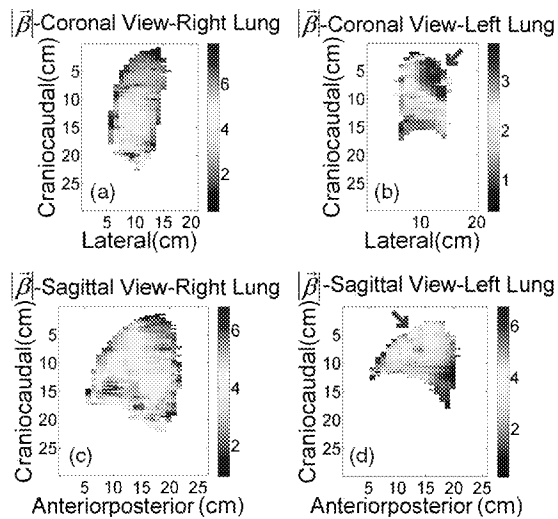


FIG. 6. Distribution of $|\vec{\beta}|$ in an abnormal pattern.

inferior and posterior portions, while $|\vec{\beta}|$ was greater in the lateral lung. Both were similar to what was observed in the normal case. However, $|\vec{\alpha}|$ and $|\vec{\beta}|$ exhibited a different pattern in the left lung. Figure 5 shows that $|\vec{\alpha}|$ was greater in the superior and anterior portions of the left lung. Figure 6 shows that $|\vec{\beta}|$, instead of being greater in the lateral lung, was greater in the superior portion of the left lung, as indicated by arrows. The craniocaudal component of $\vec{\alpha}$ dominated the displacement of the motion during the breathing cycle. CT images reconstructed at a series of tidal volumes showed that the size of the left lung was only half of the size of the right lung, and the left diaphragm barely moved during inspiration. The dysfunction of left diaphragm caused the left lung breathing to be dominated by chest expansion, so the lung expanded in the anterior-posterior direction, which was well modeled by $\vec{\alpha}$.

Of the 49 patients, $|\vec{\alpha}|$ reached its maximum in the anterior lung in three patients, while for two other patients, $|\vec{\alpha}|$ was greatest in the lateral lung. For 45 out of 49 patients, $|\vec{\alpha}|$ reached its maximum in the inferior and posterior portions of the lungs. The hysteresis motion $\vec{\beta}$ had greater variability, but for the majority of patients, $|\vec{\beta}|$ was greatest in the lateral lungs.

The values of $|\vec{\alpha}|$ and $|\vec{\beta}|$ are three-dimensional scalar fields, so a histogram of the 85th percentile values was selected to describe the interpatient variability. Figure 7 shows the histogram of the 85th percentile of $|\vec{\alpha}|$ and $|\vec{\beta}|$ in all of the patients. The mean 85th percentiles of $|\vec{\alpha}|$ in the left and right lungs were 23.2 and 26.1 mm/l, respectively. The mean 85th percentiles of $|\vec{\beta}|$ in the left and right lungs were 3.7 and 3.6 mm s/l, respectively.

Figure 8(a) shows the cumulative histogram of discrepancies between the modeled and measured locations of all 49 patient datasets. The result indicated that for 80% of the lung tissues, the discrepancies were less than 1.75 mm, and for 90%, less than 2.14 mm. Figure 8(b) shows the cumulative histogram of relative discrepancies for motion magnitudes

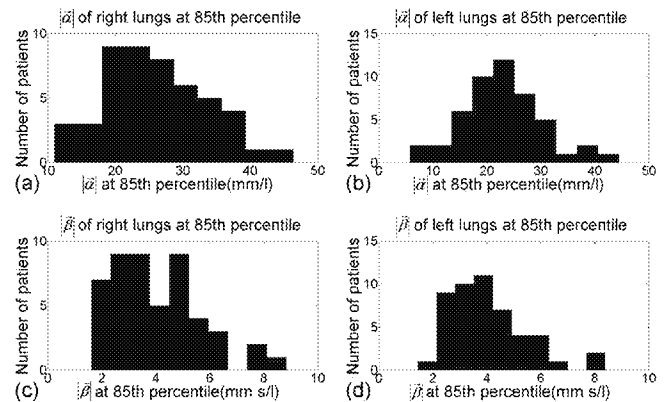


FIG. 7. Histogram of the mean $|\vec{\alpha}|$ and $|\vec{\beta}|$ at the 85th percentile for 49 patients.

greater than 15 mm. The relative discrepancy was defined as the ratio of the discrepancy to the motion magnitude. For tissues where the overall motion was greater than 15 mm, 78% and 96% of the lung tissue positions had less than 10% and 15% relative position discrepancies, respectively. Figures 8(c) and 8(d) show the cumulative histograms of relative discrepancies for motions between 10 and 15 mm and motions between 5 and 10 mm.

IV. DISCUSSION

This is the first report of the three-dimensional breathing motion model parameters for a large cohort of patients. The overall $|\vec{\alpha}|$ and $|\vec{\beta}|$ maps varied smoothly as expected. $\vec{\alpha}$ and $\vec{\beta}$ described different breathing motion characteristics. $\vec{\alpha}$ modeled local lung expansion and could be interpreted as the breathing motion as if the patient breathed infinitely slowly. $\vec{\beta}$ modeled the hysteresis motion which was hypothesized to be caused by the dynamics of breathing. The relative magnitudes of $\vec{\alpha}$ and $\vec{\beta}$ are major determinates of the motion path eccentricity. In general, regions that had greater values of $|\vec{\beta}|$ corresponded to regions with greater $|\vec{\alpha}|$. These results showed that the majority of patients exhibited similar $|\vec{\alpha}|$ maps. The $|\vec{\beta}|$ maps showed greater interpatient variability with the common feature that $|\vec{\beta}|$ was greater in the lateral lungs.

The utility of the proposed breathing motion model is to noninvasively monitor and predict the motion of lung tissues and tumors using only external surrogates. The positions of any piece of lung tissue were hypothesized to be determined by the tidal volume and airflow. The implication of this hypothesis was that the position of a specific piece of tissue or tumor would be at the same location if given the same tidal volume and airflow, regardless of the point of time. It has been shown that the position of tumors varies at exhalation,³ in apparent contradiction to the model. The model, however, is based on tidal volume, which has a zero value at a selected percentile. This value is valid only for a day-to-day single scanning or treatment session. To compare the positions of tissues between sessions, an absolute lung volume surrogate would be required, for example, the total air content. Rather

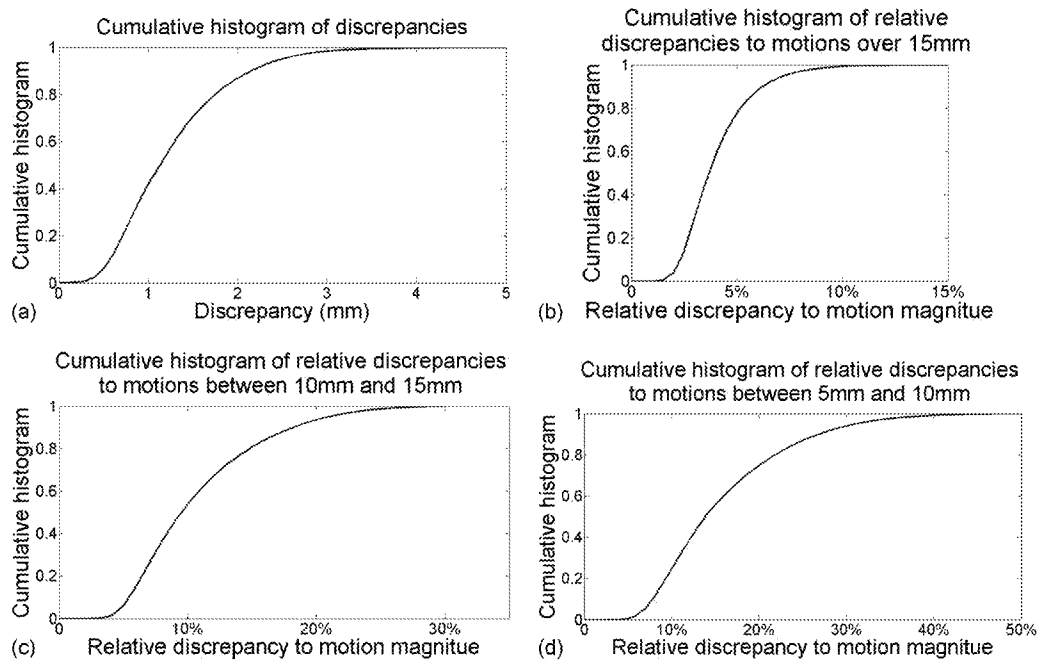


FIG. 8. (a) Cumulative histogram of discrepancies between measured and fit locations. (b) Cumulative histogram of relative discrepancies to motion magnitudes over 15 mm. (c) Cumulative histogram of relative discrepancies to motion magnitudes between 10 and 15 mm. (d) Cumulative histogram of relative discrepancies to motion magnitudes between 5 and 10 mm.

than measure the total air content, the position of a piece of tissue, using an implanted surrogate for example, could be used to shift the tidal volume definition to correspond to the original 4D CT session.

Although airflow is the time derivative of tidal volume, the breathing motion model is an explicit function only of tidal volume and airflow. The tidal volume and airflow are themselves functions of real time. The assumption is made that a first-order relationship between the displacement and the surrogates will meet the clinical requirement in precision of dose delivery or treatment planning. For this study, 25 scans were acquired and good agreement between the measurements and the predictions from the breathing motion model was observed when the motion was greater than 15 mm, as illustrated in Fig. 8(b), with more than 90% of the points having less than 15% relative discrepancy. Since the average registration error in this study is 1.32 mm as illustrated in Fig. 2, the registered trajectory tends to be more relatively dispersive in less active points, when the registration error gains more weight in the motion magnitude. Therefore, it is not surprising that the model performs worse for points that move less, as illustrated in Figs. 8(c) and 8(d). However, 90% of the points still exhibited better than 2 mm agreement.

In this study, 25 scans were acquired for each couch position, while the breathing motion model had only nine independent parameters. Theoretically, three scans acquired at different tidal volumes and airflows would have provided sufficient motion data to fit the model parameters. Errors in registration and motion-induced image artifacts would still cause errors in motion parameter determinations. The use of additional CT scans was expected to reduce the impact of

individual registration errors, but at the cost of dose to the patient. The minimum number of scans and optimization of the breathing phases of those scans remains an open question.

The ultimate utility of the motion model will be a function of its stability. If the breathing motion model parameters change significantly between sessions (either imaging or treatment), the specific motion model would be useful only for single-session activities, such as removing motion artifacts from nuclear medicine images. If the motion model parameters are stable for weeks exclusive of disease progression or treatment response, it would be useful for supporting radiation therapy treatment planning, including optimization of linear accelerator gating windows. If the model was stable over timescales consistent with the course of radiation therapy for unirradiated and healthy lungs, changes in the model might be used to monitor disease progression or radiation response. We are currently conducting scans in series to determine the model stability.

ACKNOWLEDGMENT

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U.S. FOOD & DRUG
ADMINISTRATION

Accuray Incorporated
% Keith Picker
Senior Regulatory Affairs Specialist
1240 Deming Way
MADISON WI 53717

November 23, 2018

Re: K182687

Trade/Device Name: Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System

Regulation Number: 21 CFR 892.5050

Regulation Name: Medical charged-particle radiation therapy system

Regulatory Class: Class II

Product Code: IYE

Dated: September 25, 2018

Received: September 26, 2018

Dear Mr. Picker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in dark ink, appearing to read "Robert A. Ochs", is written over a large, light gray, semi-transparent watermark that says "DRAFT".

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K182687

Device Name
Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System

Indications for Use (Describe)

The Motion Tracking and Compensation Feature is an option within the indications for use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is indicated for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K182687

Section 8 510(k) Summary

Submitter

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Contact: Keith Picker
Date Prepared: September 25, 2018

Device Identification

Device Name:	Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System
Trade & Brand Names:	Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System
Common Name:	Radiation Therapy System
Regulation Number:	21 CFR 892.5050
Regulation Name:	Medical charged-particle radiation therapy system
Regulatory Class:	Class II
Product Code:	IYE

Predicate Device

Radixact Treatment Delivery System (K161146)

Device Description

The Motion Tracking and Compensation Feature is designed for use with the predicate Radixact Treatment Delivery System last cleared on K161146. The Motion Tracking and Compensation Feature measures tumor location and motion using images provided by a kV imaging subsystem and predicts tumor location based upon a respiration amplitude measurement device. The Radixact Treatment Delivery System then compensates for tumor motion by making real-time adjustments.

The Radixact Treatment Delivery System is a radiation therapy delivery system that provides Image Guided Radiation Therapy (IGRT) using integral megavoltage CT imaging capabilities and delivers helical (rotational) and fixed-angle (non-rotational) radiation therapy to tumors and other targeted tissues.

Neither the Radixact Treatment Delivery System nor the Motion Tracking and Compensation Feature diagnose disease, recommend treatment regimens or quantify treatment effectiveness. Accordingly, they are not intended for diagnostic use.

Intended Use

The Motion Tracking and Compensation Feature is an option within the intended use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is intended to be used for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues. The megavoltage x-ray radiation is delivered using rotational, non-rotational, intensity modulated (IMRT), or non-modulated (non-IMRT/three dimensional conformal) treatment techniques and using image-guided (IGRT) or non-image-guided workflows in accordance with the physician approved plan.

Indications for Use

The Motion Tracking and Compensation Feature is an option within the indications for use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is indicated for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner.

The intended use and indications for use statements for the Motion Tracking and Compensation Feature (shown above) are the same as for the Radixact Treatment Delivery System (last cleared on K161146), except for the addition of the introductory sentence.

Technological Characteristics

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature has imaging and treatment capabilities equivalent to those of the predicate Radixact Treatment Delivery System. It also has a similar functionally-equivalent CT style gantry and patient couch.

The intended use and indications for use of the Motion Tracking and Compensation Feature fit within those of the predicate Radixact Treatment Delivery System. Additionally, the predicate and subject devices have substantially equivalent performance specifications and technological characteristics. Further, the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature and the predicate device employ the same fundamental scientific principles and have substantially equivalent principles of operation. The main difference between the predicate and the subject device is the use of the motion tracking and compensation feature. Where there are technological differences between the subject and predicate devices, those differences do not raise different questions of safety or effectiveness.

A substantial equivalence table comparing the similarities and differences between the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature and the predicate device is presented below. The minor differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

Device Comparison Table: Radixact Treatment Delivery System with Motion Tracking and Compensation Feature

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
System Description			
Intended Use	Omitted for brevity. Reference 510(k) Summary (Section 8 of 510(k) submission)	Same as predicate	Identical
Indications for Use	Omitted for brevity. Reference 510(k) Summary (Section 8 of 510(k) submission)	Same as predicate	Identical
System Configuration	Stand-alone radiation delivery system (does not include data management system or planning system)	Stand-alone radiation delivery system with kV imaging and motion tracking and compensation added (does not include data management system or planning system)	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not raise different issues of safety or effectiveness.
Vault (Treatment Room)			
Minimum Room Dimensions (H*W*L)	274 x 462 x 602 cm	274.3 x 463 x 602 cm	Substantially equivalent. Minor differences are negligible.
Device Dimensions (gantry and couch) (H*W*L)	255 x 280 x 473 cm	255 x 280 x 470.5 cm	Substantially equivalent. Minor differences are negligible.
Device Mass (kg)	6580 kg	6580 kg plus 235 kg for kV subsystem components	The weight added due to the kV subsystem does not result in different questions of safety or effectiveness.

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
Line Voltage	380 – 480 V _{ac} 3-Phase	Same as predicate	Identical
Ambient Room Temperature	20 – 24 °C	Same as predicate	Identical
Relative Humidity (non-condensing)	30 – 60 %	Same as predicate	Identical
Gantry Mechanical Features			
Bore Diameter	85 cm	Same as predicate	Identical
Degrees of Rotation	Continuous rotation around Y- axis (axes per IEC 61217)	Same as predicate	Identical
Direction of Rotation	Clockwise (as viewed from the foot of the couch)	Same as predicate	Identical
Rotational Speed (Treatment)	1 – 5 RPM	Same as predicate	Identical
Rotational Speed (Imaging)	10 RPM	Same as predicate	Identical
Couch Support in Bore	Provided	Same as predicate	Identical
Radiation Delivery Modes			
Description	Helical, Direct	Same as predicate	Identical
Photon Beam			
Accelerator Type	Standing wave	Same as predicate	Identical
RF Source	Magnetron	Same as predicate	Identical
Nominal Energy	6 MV	Same as predicate	Identical
Fixed Field Size	1.0 cm x 40 cm 2.5 cm x 40 cm 5.0 cm x 40 cm	Same as predicate	Identical
Dynamic Field Size	1.0 – 2.5 cm x 40 cm 1.0 – 5.0 cm x 40 cm	Same as predicate	Identical
Dose Rate	850 cGy/min standard 1000 cGy/min optional	Same as predicate	Identical
Collimation			
Description	Primary collimation, jaws and multi-leaf	Primary collimation, jaws and multi-leaf collimator	Substantially equivalent. Jaws have

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
	collimator		a new dynamic behavior for motion managed plans. Jaws will continually be adjusted to repoint the beam at the moving target (in IEC-Y) while maintaining the same field size.
MVCT Imaging			
Source	Megavoltage Computed Tomography (MVCT)	Same as predicate	Identical
Field of View (MVCT)	39 cm diameter	Same as predicate	Identical
Dose per MVCT Image (typical)	0.5 – 3.0 cGy	Same as predicate	Identical
Slice Spacing (MVCT)	1, 2, 3, 4 and 6 mm reconstruction intervals	Same as predicate	Identical
Spatial Resolution (MVCT)	1.6 mm	Same as predicate	Identical
kV Imaging			
Source	Feature not present	50-150 kV Radiography Class I (60601-2-28) X-ray tube assembly	The kV Imaging subsystem provides two-dimensional low-dose radiographic images used for patient alignment and measurement of tumor motion during treatment delivery. The functionality is provided by hardware and driver software. A kV radiograph can be performed at any arbitrary angle. A stable calibration from
Field of View	Feature not present	20 cm x 20 cm	
Spatial Resolution (kV)	Feature not present	< 1 mm	
Approximate Dose per kV x-ray image (range)	Feature not present	0.08 – 0.20 mGy	
Small Focal Spot Size	Feature not present	0.6 mm x 0.6 mm	
Large Focus Spot Size	Feature not present	1.0 mm x 1.0 mm	
Current Range (mA)	Feature not present	5 - 500 mA	

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
			the kV Imaging coordinate system to the machine coordinate system is made during configuration of the TDS. The new kV imaging components meet applicable safety requirements in the IEC 60601 series.
Motion Management			
Tracking Algorithm	Not present	Radixact Motion Tracking	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature is based on the core tracking algorithm introduced in K120233, Synchrony Respiratory Tracking System.
Compensation Algorithm	Not present	Radixact Motion Compensation	The compensation algorithm uses the jaws and MLC to effectively repoint the beam to accommodate for motion in a method substantially equivalent to K120233, Synchrony Respiratory Tracking System. Does not result in different questions of safety or effectiveness.
Synchrony Camera	Not present	Radixact Synchrony Motion Tracking	Substantially equivalent. The Synchrony camera has

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
			been in use for over ten years and was included most recently in K120233, Synchrony Respiratory Tracking System.
Laser System			
Stationary	Green lasers identify virtual and actual isocenter	Substantially equivalent	Minor differences are negligible and do not result in different questions of safety or effectiveness.
Moveable (for patient positioning and registration)	Red lasers identify offset from virtual isocenter	Substantially equivalent	Minor differences are negligible and do not result in different questions of safety or effectiveness.
Patient Couch			
Motion	Independent of each of the other axes	Independent of each of the other axes	Identical
Biocompatibility			
Couch Top	Carbon-fiber top	Carbon-fiber top	Identical
Synchrony Vest	Not Used	Same vest cleared under K120233, Synchrony Respiratory Tracking System	No new biocompatibility issues
Power Distribution			
Isolation	Transformer	Transformer	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature did not introduce changes to this subsystem.
UPS for Data Back-up	Provided	Provided	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
			did not introduce changes to this design
Operator Station (Treatment Delivery Console)			
Description	User interface to system functions (i.e., patient and procedure selection, and procedure delivery)	User interface to system functions (i.e., patient and procedure selection, and procedure delivery)	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not modify this architecture.
Machine Control Software			
Description	Controls radiation delivery and positioning systems (referred to as the ECS – Embedded Controls Subsystem)	Controls radiation delivery and positioning systems (referred to as the ECS – Embedded Controls Subsystem)	Substantially equivalent. The Motion Tracking and Compensation functionality was added to the existing design. No different issues of safety or effectiveness.
Data Interfaces Operator Station	Provides measurements and status during operation	Provides measurements and status during operation	Substantially equivalent. The Motion Tracking and Compensation functionality was added to the existing design. No different issues of safety or effectiveness.
Database			
Description	External database used for gathering operational data and storage of procedure data	External database used for gathering operational data and storage of procedure data	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not modify this design outside of accommodating for more data.

Device Characteristic	Predicate Device Radixact Treatment Delivery System (K161146)	Subject Device Radixact Treatment Delivery System with Motion Tracking and Compensation Feature	Analysis
Safety Features			
Interlock Subsystems	Present	Present	Substantially equivalent. kV subsystem integrated into the Safety Interlocks. No different issues of safety or effectiveness.
Data integrity checking	Present	Present	Substantially equivalent. The introduction of the Motion Tracking and Compensation Feature does not modify this design.

Performance Data

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature was tested and shown to comply with the requirements of applicable FDA recognized consensus safety standards for radiation therapy equipment. Results of verification and validation testing confirm that the use of the Motion Tracking and Compensation Feature on the Radixact Treatment Delivery System conforms to design specifications and meets the needs of the intended users.

No animal or clinical tests were required to establish substantial equivalence with the predicate device. The performance data demonstrate that the Motion Tracking and Compensation Feature is compatible with the Radixact Treatment Delivery System, and the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is as safe and effective and performs as well as the predicate device. Further, these test results demonstrate that the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature has substantially equivalent safety and performance characteristics in comparison to the predicate device.

Conclusion

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is substantially equivalent to the predicate device. The intended use and indications for use of the Motion Tracking and Compensation Feature fit within those of the predicate Radixact Treatment Delivery System. Additionally, the major technological characteristics and the principles of operation of the Radixact Treatment

Delivery System with the use of the Motion Tracking and Compensation Feature are substantially equivalent to those of the predicate device. Minor differences do not raise different questions of safety and effectiveness of the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature in comparison to the predicate device. Further, the performance data demonstrate that the Motion Tracking and Compensation Feature is compatible with the Radixact Treatment Delivery System, and the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is as safe and effective and performs as well as the predicate device. Therefore, the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is substantially equivalent to the predicate device.

Appendix V

Section 46: Standards Test Reports

(b)(4)

Records processed under FOIA Request 2023-9786; Released by CDRH on 05-28-2024

ACCURAY Inc. or **(b)(4)**

PROJECT LETTER REPORT

SCOPE OF WORKs

(b)(4)

REPORT NUMBER

(b)(4)

PAGES

45

DOCUMENT CONTROL NUMBER

(b)(4)

(b)(4)

(b)(4)

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Records processed under FOIA Request 2023-9786; Released by CDRH on 05-28-2024

TEST REPORT

Report Number: **(b)(4)**

Project Number: **(b)(4)**

Testing performed on the
Radixact System with
Optional Motion Compensation Subsystem REF **(b)(4)**
to
EN 60601-1-2:2007 / IEC 60601-1-2(ed.3)
Class A for Emissions,
Immunity for Non - Life-Supporting Equipment

For
Accuray Incorporated

Test Performed by:

(b)(4)

Test Authorized by:

Accuray Incorporated
1209 Deming Way
Madison, WI 53717, USA

Prepared by:

(b)(4)

Reviewed by:

(b)(4)

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Test Report issued under the responsibility of:



TEST REPORT IEC 60601-1-3 Medical electrical equipment Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment	
Report Reference No.....	(b)(4)
Date of issue.....	8/23/2018
Total number of pages	46
CB Testing Laboratory.....	N/A
Address	1209 Deming Way Madison, WI 53717
Applicant's name	Accuray Incorporated
Address	1209 Deming Way Madison, WI 53717
Test specification:	
Standard	IEC 60601-1-3:2008 (Second Edition) + A1:2013 for use in conjunction with IEC 60601-1:2005 (Third Edition) + A1:2012
Test procedure	IEC Test Report
Non-standard test method.....	N/A
Test Report Form No.....	(b)(4)
Test Report Form(s) Originator	(b)(4)
Master TRF	(b)(4)
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Guidance and Manufacturer's Declaration – Electromagnetic Emissions – EMC Table 201

(b)(4)

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Appendix I

Section 33: Feature Risk Management Report



(b)(4)

Motion Tracking and Compensation Feature Risk Management Report (FRMR)

Document Name:

(b)(4)

TDS Software Version:

Internal TDS Development Software Version:

(b)(4)

Document ID:

(b)(4)

Revision:

(b)(4)

Revised on:

(b)(4)

(b)(4)

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Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K182687

Date Received by DCC: Sep 26, 2018

Lead Reviewer: N. Wersto

Branch: NMRT

Division: DRH

Center/Office: CDRH/OIR

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)

Yes No N/A

1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?

If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."

X

Comments:

2. Is the submission with the appropriate Center?

If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."

X

Comments:

3) If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?

If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.*

If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."

X

Comments:

4) Is this device type eligible for a 510(k) submission? Records processed under FOIA Request 2023-9786; Released by CDRH on 05-28-2024 If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X		
Comments:			
5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X	
Comments:			
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm If no clinical studies have been submitted, mark "N/A."			X
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
- If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
- If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
- If the answer to 6 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special).	X		

Comments:

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						Yes	No	N/A	Comment	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.										
A. Administrative										
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)						×				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):										
a) Device trade/proprietary name						×				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion						×				
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") See recommended format, (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).						×				
4) Submission contains a 510(k) Summary or 510(k) Statement.						×				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) See recommended format, (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).						×				
6) Submission is a Class III 510(k) device.								×		
7) Submission contains clinical data								×		
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). OR States that there were no prior submissions for the subject device.						×				
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.								×		
B. Device Description										
9) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.								×		
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).						×				
11) The submission includes descriptive information for the device, including the following:										
a) A description of the principle of operation or mechanism of action for achieving the intended effect.						×				
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.						×				
c) A list and description of each device for which clearance is requested.								×		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

Records processed under FOIA Request 2023-9786; Released by CDRH on 05-28-2024

*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.

Yes

No

N/A

Comment

*Page #

d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device.

OR

Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).

×

12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.

×

C. Substantial Equivalence Discussion

13) Submitter has identified a predicate device(s), including the following information:

a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device).

For predicates that are preamendments devices, information is provided to document preamendments status.

Information regarding documenting preamendment status is available online. (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm>).

×

b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).

×

14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)]

See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.

a) Indications for Use

×

b) Technology, including features, materials, and principles of operation

×

D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)

15) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).

×

×

a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).

×

b) Labeling includes:

- Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5)

AND

- Includes adequate directions for use (see 21 CFR 801.5)

OR

- Submission states that device qualifies for exemption per 21 CFR 801 Subpart D

×

Comments:

Questions? Contact FDA/CDRH/OCE/DID at CDRHFOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
Records processed under FOIA Request 2023-9786; Released by CDRH on 05-28-2024					
	Yes	No	N/A	Comment	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
16) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	×				
17) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements").	×				
18) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device.			×		
19) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			×		
E. Sterilization					
If an <i>in vitro</i> diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			×		
F. Shelf Life					
24) Proposed shelf life/expiration date stated OR Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	×				
25) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.			×		
26) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). OR Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	×				
G. Biocompatibility					
If an <i>in vitro</i> diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that there: (one of the below must be checked)				×	
☒ Are direct or indirect patient-contacting components.					
☐ Are no direct or indirect patient-contacting components.					
Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
☐	Patient contact information not needed for this device (e.g., software-only device)				
☐	Patient contact information needed or need unclear				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
Comments: (b)(4)					
27) Submission includes a list identifying each of patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.				×	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. Records processed under FOIA Request 2023-9786; Released by CDRH on 05-28-2024						Yes	No	N/A	Comment	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.										
Comments: Synchrony vest and motion sensors were reviewed and cleared by K120233.										
28) Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter)						×				
29) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. OR A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).						×			×	
Comments: Synchrony vest and motion sensors were reviewed and cleared by K120233.										
H. Software										
Submission states that the device: (one of the below must be checked)										
☒ Does contain software/firmware										
☐ Does not contain software/firmware										
Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)										
☐ Software/firmware information not needed for this device (e.g., surgical suture, condom)										
☐ Software/firmware information is needed or need unclear										
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.										
30) Submission includes a statement of software level of concern and rationale for the software level of concern.						×				
31) All applicable software documentation provided based on level of concern identified by the submitter, as described in <u>Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices</u> , or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).						×				
I. Electrical Safety and EMC										
Electrical Safety										
Submission states that the device: (one of the below must be checked)										
☒ Does require electrical safety evaluation										
☐ Does not require electrical safety evaluation										
Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)										
☐ Electrical safety information not needed for this device (e.g., surgical suture, condom)										
☐ Electrical safety information is needed or need unclear										

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA or 301-796-8118

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.		Yes	No	N/A	Comment	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.						
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.						
32) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard), OR Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).		×				
EMC Submission states that the device: (one of the below must be checked)						
☒ Does require EMC evaluation						
☐ Does not require EMC evaluation						
Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)						
☐ EMC information not needed for this device (e.g., surgical suture, condom)						
☐ EMC information is needed or need unclear						
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.						
33) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).		×				
J. Performance Data - General						
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.						
34) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions.		×				
a) Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).		×				
35) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding performance data that is applicable to the subject device.				×		
36) If literature is referenced in the submission, submission includes:				×	×	
Comments: (b)(4) Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118.						

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. Records processed under FOIA Request 2023-9786. Released by CDRH on 05-28-2024		Yes	No	N/A	Comment	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.						
(b)(4)						
37) For each completed animal study, the submission provides the following:				X		
K. Performance Characteristics - In Vitro Diagnostic Devices Only (Also see 21 CFR 809.10(b)(12))						
Submission states that the device: (one of the below must be checked)						
☐ is an in vitro diagnostic device.						
☒ is not an in vitro diagnostic device.						
<i>If "is not" is selected, the performance data-related criteria below are omitted from the checklist.</i>						

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Nancy G. Wersto -S 2018.10.02 13:06:20 -04'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	
* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.	

Appendix E

Section 29: Software Requirements Specification

(b)(4)

Embedded Control System - Software Requirements Specification

Version: **(b)(4)**

Printed by:

Printed on:

(b)(4)

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Section 21 Performance Testing - Bench

The testing of the Motion Tracking and Compensation Feature for use with the Radixact Treatment Delivery System was implemented as a bench level suite of tests conducted on systems equivalent to production level systems. The testing described in the software section of this premarket submission identifies the software bench testing performed. Please reference Section 19 for details.

The Motion Tracking and Compensation Feature for use with the Radixact Treatment Delivery System is not an in vitro diagnostic device (IVD).

Section 18 Biocompatibility

The biocompatibility considerations of the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature are substantially equivalent to the predicate Radixact Treatment Delivery System cleared under K161146.

The patient contact material of the couch top is identical to that of the predicate device. Therefore, the biocompatibility documentation for the couch of the predicate device applies equally to the Radixact Treatment Delivery System with the Motion Tracking and Compensation Feature.

The only other patient contact material used with the Motion Tracking and Compensation Feature is the synchrony vest that was cleared under K120233.

Note that the nature of body contact is intact skin for both the couch top and the synchrony vest. The patient contact with the surface of the couch and the vest is limited to the duration of the patient treatment (generally much less than one hour per treatment fraction).

Based on this assessment, additional biocompatibility evidence is unnecessary.

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k)#: K

Date Received by DCC:

Lead Reviewer:

Branch:

Division:

Center/Office:

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

<u>Preliminary Questions</u>			
Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)			
	Yes	No	N/A
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If the product does not appear to be a device or such a combination product, mark "No."	X ☐	☐	
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If submission should not be reviewed by your Center mark "No."	X ☐	☐	
Comments: CDRH			

Contains Nonbinding Recommendations

3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide summary of Jurisdictional Officer's/Liaison's determination.</i> If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☐
Comments: Not Applicable			
4. Is the submission for a combination product that contains as a constituent part an approved drug that is under exclusive marketing rights? (503(g)(5)) If "Yes," then contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison, provide a summary of the discussion with them, and indicate their recommendation/action.	☐	☐	☐
Comments: No			
5. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X ☐	☐	
Comments:			
6. Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.	☐	☐	
Comments: No			
7. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm.	☐	☐	☐

Contains Nonbinding Recommendations

If no clinical studies have been submitted, mark "N/A."			
Comments: Not Applicable			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
- If the answer to 4 is "Yes," then contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison, provide a summary of the discussion with them, and indicate their recommendation/action.
- If the answer to 5 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
- If the answer to 6 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
- If the answer to 7 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.

<u>Organizational Elements</u>				
Failure to include these items should not result in an RTA designation.				
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	*Page #
1.	Submission contains a Table of Contents.	☒	☐	Section 1
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	☒	☐	All Sections
3.	All pages of the submission are numbered. <i>All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).</i>	☒	☐	All Pages
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) <i>If type of 510(k) is not designated, review as a Traditional 510(k).</i>	☒	☐	Sections 4 and 6
Comments: Section numbers and appendices are given under the "Page #" column to identify the location of the requested elements. These location identifiers are applied throughout this checklist.				

<u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u> Submission should be designated RTA if not addressed

Contains Nonbinding Recommendations

- Any “No” answer will result in a “Refuse to Accept” decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
A.	Administrative				
1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).	☒	☐		All Pages
	Comments:				
2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):				
a.	Device trade/proprietary name	☒	☐		
b.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	☒	☐		
	Comments: Above information is included in Section 4 - CDRH Premarket Review Submission Cover Sheet Form (FDA 3514).				
3.	Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA’s guidance “ Alternative to Certain Prescription Devices Labeling Requirements .”) <i>See recommended format</i> <i>(http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).</i>	☒	☐		
	Comments: Indications for Use Statement is included in Section 7 - Indications for Use Form (FDA 3881).				
4.	Submission contains a 510(k) Summary or 510(k) Statement. <i>Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.</i>	☒	☐		

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
	Comments: Section 8 contains the 510(k) Summary.				
5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k). <i>See recommended format</i> (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).	X ☐	☐		
	Comments: Section 9 contains the Truthful and Accuracy Statement.				
6.	Submission is a Class III 510(k) Device. <i>Select "N/A" only if submission is not a Class III 510(k).</i>	☐		☐	
a.	Contains Class III Summary and Certification <i>See recommended content</i> (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm). <i>Select "N/A" only if submission is not a Class III 510(k).</i>	☐	☐	☐	
	Comments: Section 10 states that this section is not applicable since the subject device is a class II medical device.				
7.	Submission contains clinical data. <i>Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a and b below are omitted from the checklist.</i>	☐		☐	
a.	Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. <i>Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the <u>Guidance for Industry- Financial Disclosures by Clinical Investigators</u>.</i>	☐	☐	☐	
b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. <i>Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in <u>Title VIII of FDAAA, Sec. 801(j)</u></i>	☐	☐	☐	
	Comments: 7.a. - Section 11 states: This section is not applicable. No data from clinical studies is submitted with this 510(k) premarket notification. 7.b. - Section 5 contains the Certification of Compliance form (FDA 3674).				

Traditional RTA Checklist

5

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
8.	The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). OR States that there were no prior submissions for the subject device. <i>Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514). This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).</i>	X ☐	☐		Section 6 - Cover Letter
a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. <i>To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.</i> <i>Select "N/A" if the submitter states there were no prior submissions.</i>	☐	☐	X ☐	
Comments:					
Combination Product Provisions – Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison.		Not Applicable		☐	
9.	Submission identifies the product as a combination product.	☐	☐		

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			Yes	No	N/A	*Page #
10.	The combination product contains as a constituent part an approved drug as defined in 21 USC 503(g)(5)(B). Select "N/A" if the combination product does not contain as a constituent part an approved drug. Please also select "N/A" if a right of reference or use for the drug constituent part(s) is included with the submission. If "N/A" is selected, part a below is omitted from the checklist.		☐		X ☐	
a.	The submission includes appropriate patent statement or certification and a statement that the applicant will give notice, as applicable. 21 USC 503(g)(5)(A)&(C).		☐	☐		
Comments: Items 9 and 10 are not applicable, as the device is not a combination product.						
B. Device Description						
11.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>		☐		☐	
a.	The submission addresses device description recommendations outlined in the device-specific guidance. <u>OR</u> The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.</i>		☐	☐	☐	

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
	b. The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.</i>	☐	☐	☐	
Comments: Item 11 is not applicable.					
	12. Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	☐ X	☐		
Comments: Descriptive information is contained in Section 14 - Device Description.					
	13. The submission includes descriptive information for the device, including the following:				
	a. A description of the principle of operation or mechanism of action for achieving the intended effect.	☐ X	☐		
	b. A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X ☐	☐		
	c. A list and description of each device for which clearance is requested.	☐	☐	☐	
<i>Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.</i>					

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
	d. Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. OR Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device). <i>In lieu of engineering drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.</i>	X ☐	☐		
Comments: Section 14 - Device Description contains the information required for items 13.a., b. and d. Item 13.c. is not applicable.					
14.	Device is intended to be marketed with multiple components, accessories, and/or as part of a system. <i>Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system. If "N/A" is selected, parts a-c below are omitted from the checklist.</i>	X ☐		☐	
	a. Submission includes a list of all components and accessories to be marketed with the subject device.	☒	☐		
	b. Submission includes a description (as detailed in item 11a., 11b., and 11d. above) of each component or accessory. <i>Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.</i>	☐	☐	☐	
	c. A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance AND A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	X ☐	☐		
Comments: Item 14.b is not applicable as the listed components were cleared under K120233.					
C.	Substantial Equivalence Discussion				

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			Yes	No	N/A	*Page #
15.	Submitter has identified a predicate device(s), including the following information:					
	a.	Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding <u>documenting preamendment status</u> is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).</i>	X ☐	☐		Section 15 - Substantial Equivalence
	b.	The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X ☐	☐		Section 8 - 510(k) Summary and Section 15 - Substantial Equivalence
	Comments:					
16.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] <i>See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.</i>					
	a.	Indications for use <i>If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.</i>	X ☐	☐		

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
	b. Technology, including features, materials, and principles of operation <i>Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.</i> <i>FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.</i>	X ☐	☐		
Comments: Section 15 - Substantial Equivalence includes the required information for items 16.a. and b.					
D. Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)					
17.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		
a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	☐ X	☐		
b.	Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) <u>AND</u> - Includes adequate directions for use (see 21 CFR 801.5) <u>OR</u> - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X ☐	☐		
Comments: Required information is included in Section 16 - Proposed Labeling and Appendix A - Labeling.					
18.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	☒	☐		
Comments: The required information is included in Appendix A - Labeling.					

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			Yes	No	N/A	*Page #
19.	Labeling includes the prescription statement (see 21 CFR 801.109(b)(1)) or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements"). <i>Select "N/A" if not indicated for prescription use.</i>		X ☐	☐	☐	
	Comments: Required information is included in Section 16 - Proposed Labeling and Appendix A - Labeling.					
20.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>		☐		☐	
	a.	The submission addresses labeling recommendations outlined in the device-specific guidance. <u>OR</u> The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.</i>	☐	☐	☐	

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
	b. The submission includes labeling information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.</i>	☐	☐	☐	
	Comments: Item 20 is not applicable.				
	21. If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. Select "N/A" if not an in vitro diagnostic device.	☐	☐	☐	
	Comment: Item 21 is not applicable.				
E.	Sterilization <i>If an in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.</i>	Not Appli cable		☐	

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
Submission states that the device, and/or accessories, and/or components are: <i>(one of the below must be checked)</i> ☐ Provided sterile, intended to be single-use ☐ Requires processing during its use-life ☐ Non-sterile when used (and no processing required) ☐ Information regarding the sterility status of the device is not provided (if this box is checked, please also check one of the two boxes below) ☐ Sterility status not needed for this device (e.g., software-only device) ☐ Sterility status needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "non-sterile when used" or "not provided and not needed" is selected, the sterility-related criteria below are omitted from the checklist.</i> <i>If information on sterility status is not provided, and it is needed or the need for this information is unclear, select "No."</i> <i>The "Requires processing during its use-life" option refers to devices falling into one of the four categories below:</i> • <i>Supplied sterile and requires reprocessing prior to subsequent patient use</i> • <i>Supplied non-sterile and requires user to process the device for initial use, as well as to reprocess the device after each use</i> • <i>Reusable medical device (single-user) reprocessed between each use</i> • <i>Single-use medical devices initially supplied as non-sterile to the user, and requiring the user to process the device prior to its use</i> <i>Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.</i>		☐			
Comments: Sterilization is not applicable. See statement in Section 17 of the submission.					
22.	Assessment of the need for cleaning and subsequent disinfection or sterilization information.				
a.	Identification of device, and/or accessories, and/or components that are provided sterile. <i>Select "N/A" if no part of the device, accessories, or components is provided sterile.</i>	☐	☐	☐	

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
	b. Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected. <i>Select "N/A" if no part of the device, accessories, or components is end user sterilized or disinfected.</i>	☐	☐	☐	
	c. Identification of device, and/or accessories, and/or components that are reusable. <i>Select "N/A" if no part of the device, accessories, or components is reusable.</i>	☐	☐	☐	
Comments: Item 22 is not applicable. See statement in Section 17 of the submission.					
23.	If the device, and/or accessory, and/or a component is provided sterile: <i>Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-f below.</i>			☐	
	a. Sterilization method is stated for each component (including dose for radiation sterilization)	☐	☐		
	b. A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date). <i>Note: the sterilization validation report is not required.</i>	☐	☐		
	c. For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. <i>Select "N/A" if not sterilized using chemical sterilants.</i>	☐	☐	☐	
	d. Sterility Assurance Level (SAL) stated	☐	☐		
	e. Submission includes description of packaging	☐	☐		
	f. For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amoebocyte lysate [LAL]). <i>Select "N/A" if not labeled "non-pyrogenic."</i>	☐	☐	☐	
Comments: Item 23 is not applicable. See statement in Section 17 of the submission.					

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			Yes	No	N/A	*Page #
24.	If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected: <i>Select "N/A" if no part of the device, accessories, or components are reusable or end user sterilized or disinfected, otherwise complete a-d below.</i>				☐	
	a.	Cleaning method is provided in labeling for each device, and/or accessory, and/or component. <i>Select "N/A" if not reusable and does not need cleaning prior to disinfection or sterilization</i>	☐	☐	☐	
	b.	Disinfection method is provided in labeling for each device, and/or accessory, and/or component. <i>Select "N/A" if not disinfected (i.e., undergoes terminal sterilization) prior to use</i>	☐	☐	☐	
	c.	Sterilization method is provided in labeling for each device and/or accessory, and/or component. <i>Select "N/A" if not sterilized (i.e., undergoes disinfection) prior to use</i>	☐	☐	☐	
	d.	Device types in this submission are listed in Appendix E of the FDA's guidance " Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling ." <i>Device types identified in Appendix E of the reprocessing guidance represent devices posing a greater likelihood of microbial transmission and represent a high risk of infection. Select "N/A" if the device type in the submission is not included in Appendix E of the reprocessing guidance.</i>	☐		☐	
	i.	If device types in this submission are included in Appendix E of the reprocessing guidance, the submission includes protocols and test reports for validating the reprocessing instructions. <i>Select "N/A" if the device type in the submission is not included in Appendix E of the reprocessing guidance.</i>	☐	☐	☐	
Comments: Item 24 is not applicable. See statement in Section 17 of the submission.						

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
25.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>	☐		☐	
a.	The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. <u>OR</u> The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.</i>	☐	☐	☐	
b.	The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. <u>OR</u> The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.</i>	☐	☐	☐	
Comments: Item 25 is not applicable. See statement in Section 17 of the submission.					
F.	Shelf-Life				

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			Yes	No	N/A	*Page #
26.	Proposed shelf life/ expiration date stated OR Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	X ☐	☐			Section 17
	Comments:					
27.	For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf-life. <i>Select "N/A" if the device is not provided sterile.</i>	☐	☐	☐		
	Comments:	Not Applicable				
28.	Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). OR Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☐	☐			
	Comments: Items 27 and 28 are not applicable. Please see Section 17 - Sterilization and Shelf Life of the submission for explanation.					
G.	Biocompatibility <i>If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.</i>			☐		

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
Submission states that there: <i>(one of the below must be checked)</i> ☐ Are direct or indirect patient-contacting components ☐ Are no direct or indirect patient-contacting components ☐ Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below) ☐ Patient contact information not needed for this device (e.g., software-only device) ☐ Patient contact information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "are no" or "not provided and not needed" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information on the patient-contact status is not provided, and contact information is needed or its contact status is unclear, select "No."</i> <i>An example of a direct patient-contacting device would be an implant that has direct contact with patient tissues during use. An example of an indirect patient-contacting device would be fluid entering the patient's body following passing through device/device components not in direct contact with the patient.</i>			☐		Section 18 - Biocompatibility
Comments: The required information is included in Section 18 - Biocompatibility of the submission. (Note: This form is not sufficiently interactive, so would not allow checking the box above.)					
29.	Submission includes a list identifying each patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	X ☐	☐		
Comments: Reference Section 18 - Biocompatibility.					
30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter).	☐ X	☐		
Comments: Reference Section 18 - Biocompatibility.					

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
31.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. OR A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X ☐	☐		
Comments: Reference Section 18 - Biocompatibility.					
H.	Software				
	Submission states that the device: <i>(one of the below must be checked)</i> ☐ Does contain software/firmware ☐ Does not contain software/firmware ☐ Information on whether device contains software/firmware is not provided (if this box checked, please also check one of the two boxes below) ☐ Software/firmware information not needed for this device (e.g., surgical suture, condom) ☐ Software/firmware information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "does not contain" or "not provided and not needed" is selected, the software-related criteria below are omitted from the checklist. If information on software is not provided, and this information is needed or the need is unclear, select "No."</i>		☐		
Comments: Submission states that the device does contain software/firmware. Reference Section 19 - Software. (Note: This form is not sufficiently interactive, so would not allow checking the box above.)					
32.	Submission includes a statement of software level of concern and rationale for the software level of concern	☒	☐		
Comments: Reference Section 19 - Software.					

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			Yes	No	N/A	*Page #
33.	All applicable software documentation provided based on level of concern identified by the submitter, as described in <u>Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices</u>, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale). <i>Note: This element is also applicable to non-internally generated or off-the-shelf (OTS) software used in the device.</i>	☒	☐			Section 19 - Software.
	Comments:					
I.	Electrical Safety and EMC					
	Electrical Safety: Submission states that the device: <i>(one of the below must be checked)</i> ☐ Does require electrical safety evaluation ☐ Does not require electrical safety evaluation ☐ Information on whether device requires electrical safety evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ Electrical safety information not needed for this device (e.g., surgical suture, condom) ☐ Electrical safety information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "does not require" or "not provided and not needed" is selected, the electrical safety criteria below are omitted from the checklist. If information on electrical safety is not provided, and it is needed or the need for this information is unclear, select "No."</i>		☐			
	Comments: Submission states that the device does require electrical safety evaluation. Reference Section 20 - Electromagnetic Compatibility and Electrical Safety. (Note: This form is not sufficiently interactive, so would not allow checking the box above.)					

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			Yes	No	N/A	*Page #
34.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard). OR Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	X ☐	☐			
Comments: Reference Section 20 - Electromagnetic Compatibility and Electrical Safety.						
EMC: Submission states that the device: <i>(one of the below must be checked)</i> ☐ Does require EMC evaluation ☐ Does not require EMC evaluation ☐ Information on whether device requires EMC evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ EMC information not needed for this device (e.g., surgical suture, condom) ☐ EMC information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "does not require" or "not provided and not needed" is selected, the EMC criteria below are omitted from the checklist. If information on EMC is not provided, and it is needed or the need for this information is unclear, select "No."</i>			☐			
Comments: Submission states that the device does require EMC evaluation. Reference Section 20 - Electromagnetic Compatibility and Electrical Safety. (Note: This form is not sufficiently interactive, so would not allow checking the box above.)						

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
35.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, a device-specific standard). OR Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	X ☐	☐		
Comments: Reference Section 20 - Electromagnetic Compatibility and Electrical Safety.					
J.	Performance Data General <i>If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.</i>			☐	
Comments:					
36.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions. <i>Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.</i>	X ☐	☐	☐	
a.	Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.). <i>Select "N/A" if the submission does not include performance data.</i>	X ☐	☐	☐	
Comments: See Section 21 - Performance Testing - Bench and the referenced appendices. See also, Section 15 - Substantial Equivalence.					

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			Yes	No	N/A	*Page #
37.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding performance data that is applicable to the subject device <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>		☐		X ☐	
a.	The submission addresses performance data recommendations outlined in the device-specific guidance. <u>OR</u> The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.</i>		☐	☐	☐	
b.	The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. <u>OR</u> The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.</i>		☐	☐	☐	
Comments: Item 37 is not applicable.						

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			Yes	No	N/A	*Page #
	38.	If literature is referenced in the submission, submission includes: <i>Select "N/A" if the submission does not reference literature. If "N/A" is selected, parts a and b below are omitted from the checklist.</i> <i>Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.</i>			☒	
	a.	Legible reprints or a summary of each article.	☐	☐		
	b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☐	☐		
	Comments:					
	39.	For each completed animal study, the submission provides the following: <i>Select "N/A" if no animal study was conducted. If "N/A" is selected, parts a-c below are omitted from the checklist. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist.</i>			☐	
	a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	☐	☐		
	b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185	☐	☐		
	c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☐	☐		
	Comments: Item 39 is not applicable. Reference Section 22 - Performance Testing - Animal.					
K.	Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))					

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
	Submission indicates that device: <i>(one of the below must be checked)</i> ☐ Is an in vitro diagnostic device ☐ Is not an in vitro diagnostic device <i>If "is not" is selected, the performance data-related criteria below are omitted from the checklist.</i>	X		Submission states the device is not an in vitro diagnostic device	Section 21 - Performance Testing - Bench
40.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:				Not Applicable
	a. Precision/reproducibility	☐	☐	☒	
	b. Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff).	☐	☐	X ☐	
	c. Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☐	☐	Not Applicable
	d. Analytical specificity	☐	☐	☒	
Comments: Submission indicates that the device is not an in vitro diagnostic device. Reference Section 21 - Performance Testing - Bench. (Note: This form is not sufficiently interactive, so would not allow checking the box above.)					
41.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulations regarding performance data that is applicable to the subject device. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>	☐	☐	☐	

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
a.	The submission addresses performance data recommendations outlined in the device-specific guidance. <u>OR</u> The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.</i>	☐	☐	X ☐	
b.	The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. <u>OR</u> The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.</i>	☐	☐	X ☐	
Comments: Items 40 and 41 are not applicable.					

Decision: Accept_____ Refuse to Accept_____

If Accept, notify the applicant

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	

Traditional RTA Checklist

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Contains Nonbinding Recommendations

Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

*Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

From: Keith Picker <kpicker@accuray.com>
Sent: Tuesday, November 20, 2018 3:50 PM
To: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov>
Cc: Michael Preto <mpreto@accuray.com>; Daniel Biank <dbiank@accuray.com>
Subject: RE: K182687 - Quick question

Hi Nancy,

(b)(4)

Please let me know if this satisfies what you are looking for or if you need anything else.

Thank you for your patience.

Sincerely,

Keith

[cid:image002.png@01D480E0.4DBE1700]

[cid:image004.png@01D480E0.4DBE1700] <<https://www.facebook.com/AccurayIncorporated/>>

[cid:image006.png@01D480E0.4DBE1700] <<https://twitter.com/accuray?lang=fr>>

[cid:image008.png@01D480E0.4DBE1700] <<https://fr.linkedin.com/company/accuray>>

[cid:image010.png@01D480E0.4DBE1700] <<https://www.youtube.com/user/AccurayIncorporated>>

Keith Picker

Senior Regulatory Affairs Specialist

One Erdman Place

Madison, WI 53717

USA

Phone: 608-824-3069

kpicker@accuray.com<<mailto:kpicker@accuray.com>>

From: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov<<mailto:Nancy.Wersto@fda.hhs.gov>>>

Sent: Tuesday, November 20, 2018 11:55 AM

To: Keith Picker <kpicker@accuray.com<mailto:kpicker@accuray.com>>

Subject: FW: K182687 - Quick question

Hi Keith,

Sorry to bother you again. I am nearly done with the review of K182687.

(b)(4)

(b)(4)

Thank you so much,

Nancy

From: Keith Picker <kpicker@accuray.com<mailto:kpicker@accuray.com>>

Sent: Tuesday, November 06, 2018 3:55 PM

To: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov<mailto:Nancy.Wersto@fda.hhs.gov>>

Cc: Daniel Biank <dbiank@accuray.com<mailto:dbiank@accuray.com>>

Subject: RE: K182687 - Quick question

Hi Nancy,

Thank you for the update on the review of our 510(k) submission K182687.

(b)(4)

Please feel free to let me know if you have any other questions.

Best Regards,

Keith

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[cid:image021.png@01D480DD.9FEE7680]

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Keith Picker
Senior Regulatory Affairs Specialist
One Erdman Place
Madison, WI 53717
USA
Phone: 608-824-3069
kpicker@accuray.com<mailto:kpicker@accuray.com>

From: Wersto, Nancy <Nancy.Wersto@fda.hhs.gov<mailto:Nancy.Wersto@fda.hhs.gov>>
Sent: Tuesday, November 6, 2018 2:09 PM
To: Keith Picker <kpicker@accuray.com<mailto:kpicker@accuray.com>>
Subject: K182687 - Quick question

Hi Keith,

Our review of K182687 is moving along, and several consultants are helping me on your submission. It does not appear that there are any major issues for which additional information will be needed; (b)(4)

(b)(4)

Kind regards,

Nancy

Nancy Wersto, M.S., DABR
Scientific Reviewer/Senior Team Leader
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-6548
e-mail: nancy.wersto@fda.hhs.gov<mailto:nancy.wersto@fda.hhs.gov>

[cid:image026.jpg@01D480DD.9FEE7680]

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?ID=1974&S=E>
[research.net]<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.research.net_s_cdrhcustomerservice-3FID-3D1974-26S-3DE&d=DwMFAg&c=xPsIBl5KrHsS6I-OqwKVfQ&r=W3bGvwIaqXpM-o93Whdq6qu8ba9d3R_BLPF04tV5v6w&m=SVkj2PEKkTgto_9rRTVTYh3M7Iwdr9OpHrNZvUSIUPI&s=CxdfmuyV5JlGWTi6bs6U3olCxZxp8OUIMM5HTWZ3N3I&e=>>.

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-- WARNING - CONFIDENTIAL INFORMATION: The information contained in the e-mail may contain confidential and privileged information and is intended solely for the use of the intended recipient(s). Access for any review, re-transmission, dissemination or other use of, or taking of any action in regard and reliance upon this e-mail by persons or entities other than the intended recipient(s) is unauthorized and prohibited. If you are not the intended recipient, please contact the sender by reply e-mail and destroy all copies of the original message and any attachments.

Appendix C

Section 27: User Requirements Specification

(b)(4)

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Records processed under FOIA Request 2023-9786; Released by CDRH on 05-28-2024

ID

Treatment Delivery System User Requirements Specification

ObjectType

(b)(4)

(b)(4)

Accuray Incorporated

Item Number: (b)(4)

Revision: (b)(4)

Description:



ACCURAY®

(b)(4)

Treatment Delivery System Motion Tracking and Compensation Feature

User Requirements Specification

Release: (b)(4)

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510(k) Premarket Notification

Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System

September 25, 2018

**Accuray Incorporated
1209 Deming Way
Madison, WI 53717**

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Section 39: Validation Test Report

Accuray Incorporated

Part Number: (b)(4)

Revision: (b)(4)

(b)(4)



ACCURAY®

(b)(4)

Treatment Delivery System Motion Tracking and Compensation Feature Validation Test Summary Report

Release: (b)(4)

Doc Revision: (b)(4)

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Precise, innovative solutions. RECEIVED

September 25, 2018

K182687

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

RE: Traditional 510(k) Premarket Notification Submission
Motion Tracking and Compensation for the Radixact Treatment Delivery System
Medical Device User Fee Payment Identification Number: (b)(4)

Dear Sir or Madam:

Accuray Incorporated is submitting a Traditional 510(k) Premarket Notification for a Motion Tracking and Compensation Feature to be used on the Radixact Treatment Delivery System. Accuray Incorporated is submitting this 510(k) in accordance with 21 CFR Part 807, Subpart E – Premarket Notification Procedures and FDA's guidance on "How To Market Your Device". There were no prior submissions for this new feature.

For your reference, the FDA Establishment Registration Number for our manufacturing facility is 3003873069.

A paper copy and an electronic copy (eCopy) are being provided with this submission in accordance with the instructions found in the FDA guidance document entitled "eCopy Program for Medical Device Submissions", issued on December 3, 2015. The eCopy is an exact duplicate of the paper copy.

Based upon device characteristics, indications for use and the predicate device, Accuray Incorporated suggests that the Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System be classified by the Radiology review panel as a Class II medical device under regulation number 21 CFR 892.5050 (medical charged-particle radiation therapy system) with a product code IYE.

The Motion Tracking and Compensation Feature is designed for use with the predicate Radixact Treatment Delivery System last cleared on K161146. The Motion Tracking and Compensation Feature measures tumor location and motion using images provided by a kV imaging subsystem and predicts tumor location based upon a respiration amplitude measurement device. The Radixact Treatment Delivery System then compensates for tumor motion by making real-time adjustments.

Neither the Radixact Treatment Delivery System nor the Motion Tracking and Compensation Feature diagnose disease, recommend treatment regimens or quantify treatment effectiveness. Accordingly, they are not intended for diagnostic use.

75

The Motion Tracking and Compensation Feature is an option within the intended use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is intended to be used for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues. The megavoltage x-ray radiation is delivered using rotational, non-rotational, intensity modulated (IMRT), or non-modulated (non-IMRT/three dimensional conformal) treatment techniques and using image-guided (IGRT) or non-image-guided workflows in accordance with the physician approved plan.

The Motion Tracking and Compensation Feature is an option within the indications for use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is indicated for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner.

The intended use and indications for use statements for the Motion Tracking and Compensation Feature (shown above) are the same as for the Radixact Treatment Delivery System (last cleared on K161146), except for the addition of the introductory sentence.

Some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61, and therefore not disclosable under the Freedom of Information Act even after the existence of this application becomes public. We ask that you consult with Accuray Incorporated as provided in 21 C.F.R. § 20.47 before making any part of this submission publicly available.

The principle factors concerning the design and use of the Motion Tracking and Compensation Feature are summarized in the following table:

Design and Use of the Device

Question	Yes	No
Intended for prescription use (21 CFR 801 Subpart D)	X	
Intended for over-the-counter use (21 CFR 807 Subpart C)		X
Contains components derived from a tissue or other biologic source		X
Provided sterile		X
Intended for single use		X
A reprocessed single use device		X
require reprocessed validation data		X
Contains a drug		X
Contains a biologic		X
Uses software	X	
Submission includes clinical information		X
Device is implanted		X

All other required cover letter information is included in the CDRH Premarket Review Submission Cover Sheet (FDA 3514) located in Section 4 of this premarket submission.

If you have questions regarding this 510(k) premarket submission or require additional information, please contact me using the following contact information:

Keith Picker
Senior Regulatory Affairs Specialist
Accuray Incorporated
1240 Deming Way
Madison, WI 53717
Phone: 608-824-3069
Fax: 608-830-3778
Email: kpicker@accuray.com

Sincerely,

(b)(6)

Keith Picker
Senior Regulatory Affairs Specialist

cc: Michael S. Preto, Regulatory Affairs Program Manager, Accuray Incorporated
Daniel Biank, Vice President Regulatory Affairs, Accuray Incorporated

Appendix U

Section 45: Standards Data Reports (FDA 3654)

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION



Traditional



Special



Abbreviated

STANDARD TITLE ¹

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²? ☒ ☐

FDA Recognition number³ #19-4

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☒ ☐

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐

Does this standard include acceptance criteria? ☒ ☐
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? ☐ ☒
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?..... ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? ☐ ☐

Were deviations or adaptations made beyond what is specified in the FDA SIS?..... ☐ ☐
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?..... ☐ ☒
If yes, was the guidance document followed in preparation of this 510k? ☐ ☐

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)

CONFORMANCE WITH STANDARD SECTIONS***SECTION NUMBER**

All Sections

SECTION TITLE**CONFORMANCE?**☒ Yes ☐ No ☐ N/A**TYPE OF DEVIATION OR OPTION SELECTED ***

No Deviations

DESCRIPTION**JUSTIFICATION**

Tested to all applicable sections of the standard.

SECTION NUMBER**SECTION TITLE****CONFORMANCE?**☐ Yes ☐ No ☐ N/A**TYPE OF DEVIATION OR OPTION SELECTED *****DESCRIPTION****JUSTIFICATION****SECTION NUMBER****SECTION TITLE****CONFORMANCE?**☐ Yes ☐ No ☐ N/A**TYPE OF DEVIATION OR OPTION SELECTED *****DESCRIPTION****JUSTIFICATION**

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION



Traditional



Special



Abbreviated

STANDARD TITLE ¹

IEC 60601-1-2 Edition 3: 2007-03, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²? ☒ ☐

FDA Recognition number ³ #19-1

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☒ ☐

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐

Does this standard include acceptance criteria? ☒ ☐
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? ☐ ☒
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? ☐ ☐

Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard? ☐ ☒
If yes, was the guidance document followed in preparation of this 510k? ☐ ☐

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-1-2 Edition 3: 2007-03, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER All	SECTION TITLE	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * No Deviations		
DESCRIPTION		
JUSTIFICATION Tested to all applicable sections of the standard.		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASupport@fda.hhs.gov

*"An agency may not conduct or sponsor, and
a person is not required to respond to, a
collection of information unless it displays a
currently valid OMB control number."*

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION



Traditional



Special



Abbreviated

STANDARD TITLE ¹

IEC 60601-1-3 Edition 2.1 2013-04, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²? ☒ ☐

FDA Recognition number ³ #12-269

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☐ ☒

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐

Does this standard include acceptance criteria? ☒ ☐
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? ☐ ☒
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? ☐ ☒

Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard? ☐ ☒
If yes, was the guidance document followed in preparation of this 510k? ☐ ☐

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-1-3 Edition 2.1 2013-04, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment

CONFORMANCE WITH STANDARD SECTIONS***SECTION NUMBER**

All Sections

SECTION TITLE**CONFORMANCE?**☒ Yes ☐ No ☐ N/A**TYPE OF DEVIATION OR OPTION SELECTED ***

No Deviations

DESCRIPTION**JUSTIFICATION**

Tested to all applicable sections of the standard.

SECTION NUMBER**SECTION TITLE****CONFORMANCE?**☐ Yes ☐ No ☐ N/A**TYPE OF DEVIATION OR OPTION SELECTED *****DESCRIPTION****JUSTIFICATION****SECTION NUMBER****SECTION TITLE****CONFORMANCE?**☐ Yes ☐ No ☐ N/A**TYPE OF DEVIATION OR OPTION SELECTED *****DESCRIPTION****JUSTIFICATION**

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASupport@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION



Traditional



Special



Abbreviated

STANDARD TITLE ¹

IEC 60601-2-1 Edition 3.1 2014-07, Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²? ☒ ☐

FDA Recognition number³ #12-285

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☐ ☒

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐

Does this standard include acceptance criteria? ☒ ☐
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? ☐ ☒
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?..... ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? ☐ ☐

Were deviations or adaptations made beyond what is specified in the FDA SIS?..... ☐ ☒
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?..... ☐ ☒
If yes, was the guidance document followed in preparation of this 510k? ☐ ☐

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-2-1 Edition 3.1 2014-07, Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER All Sections	SECTION TITLE	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * No Deviations		
DESCRIPTION		
JUSTIFICATION Tested to all applicable sections of the standard.		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Section 19 Software

The Motion Tracking and Compensation Feature for use on the Radixact Treatment Delivery System does contain software/firmware.

Terminology and Conventions

(b)(4)

19.1 Level of Concern

The level of concern for the Motion Tracking and Compensation Feature for use on the Radixact Treatment Delivery System functionality is: (b)(4)

(b)(4)

19.2 Software Description

A comprehensive overview of the device features that are controlled by software, including identification of operationally significant elements, hardware platforms, operating systems, programming language and off-the-shelf software can be found in the following documents.

- System Architecture Description document: (b)(4) A copy is provided in Appendix B.
- Software Design Documents: See the Software Design Specification subsection 19.6 below for the Software Design Description Documents.
- Version Description Document and Software Build Instructions (b)(4) A copy is provided in Appendix G.

The software tools, such as the compilers and software version control system, utilized during the software lifecycle are identified in the software Version Description Document (VDD) and Software Build Instructions (SBI). This document also identifies the location of the third-party software within the software build/branch management system. A copy of the software Version Description Document (VDD) and Software Build Instructions (SBI) is provided in Appendix G.

Off-the-shelf software (SOUP) documents describe the specifics of the third-party software incorporated into the product software. A copy of the Embedded Control System SOUP Software Requirements Specification (b)(4) is located in Appendix H.

19.3 Device Hazard Analysis

A copy of the Motion Tracking and Compensation Feature Risk Management Report (b)(4) is provided in Appendix I. This report includes the following information:

- Risk Evaluation Table
- Risk Mitigation Verification Traceability Table

(b)(4)

(b)(4) See the Traceability Analysis subsection 19.7 below for additional information regarding the tracing of risk mitigations.

19.4 Software Requirements Specification

The software requirements that define the Motion Tracking and Compensation Feature for use on the Radixact Treatment Delivery System functionality are captured in the Software Requirements Specifications (SRS). A copy of the Embedded Control Subsystem (ECS) Software Requirements Specification: (b)(4) for the Motion Tracking and Compensation Feature is provided in Appendix E.

19.5 Architecture Design Chart

Refer to the System Architecture Description document: (b)(4) for the Radixact Treatment Delivery System with the Motion Tracking and Compensation Feature provided in Appendix B.

19.6 Software Design Specification

The specification of the software design output is contained in the software design description (SDD) documents: (b)(4)

(b)(4) Copies of the following software design description documents for the Embedded Control Subsystem (ECS) are provided in Appendix F.

- ECS Delivery Interface SDD (b)(4)
- ECS Jaws SDD (b)(4)
- TT-ECS-MLC-SDD-0700 (b)(4)

19.7 Traceability Analysis

The Requirements Traceability Matrices (RTM's) contain line items that link user, system and software requirements to the test case(s) used to verify a compliant implementation of the requirement. The following Requirements Traceability Matrices are provided in Appendix K:

- System Requirements Verification As Run Traceability Matrix (b)(4)
- User Requirements Validation As Run Traceability Matrix (b)(4)

(b)(4)

Section 4 of the Unit Test Report (b)(4) includes a trace matrix that traces both the Embedded Control Subsystem (ECS) Software Requirements Specifications (b)(4) and SOUP requirements (b)(4) to the associated Unit Test Cases (b)(4). A copy of the Unit Test Report is provided in Appendix Q.

19.8 Software Development Environment Description

The Motion Tracking and Compensation Feature for use on the Radixact Treatment Delivery System was developed per the requirements of the Accuray Incorporated Product Development Process (b)(4). A copy of this procedure is provided in Appendix S (Design Control Procedure).

The software development lifecycle and required software control/baseline documents generated are defined within the referenced product development process. These documents include:

- Software Design Description
- Risk Management Report
- System Architecture Document

- System Requirements Specification
- Verification Plan and Report
- Validation Plan and Report
- Requirements Traceability Matrices

(b)(4)

19.9 Verification and Validation Documentation

The results of testing confirm that the Motion Tracking and Compensation Feature for use on the Radixact Treatment Delivery System software meets its input requirements, is suitable for its intended uses and fulfills the needs of the user.

Design qualification documents that describe the planning and summarize the execution and results of the testing effort at the system and unit levels are identified below.

Copies of the system and user level test documents are provided in the Appendices noted below:

- Titan 2.0 Verification Test Plan (b)(4): Appendix L
- Titan 2.0 Verification Test Summary Report (b)(4) Appendix M
- Titan 2.0 Validation Test Plan (b)(4): Appendix N
- Titan 2.0 Validation Test Summary Report (b)(4): Appendix O

In accordance with guidance document *Content of Premarket Submissions for Software Contained in Medical Devices* (issued May 11, 2005), the following examples of unit testing and summary of results are included with this submission. The ECS Unit Test Report (b)(4)

(b)(4)

(b)(4) Copies of the example ECS unit test documents are provided in the Appendices as noted below:

- Unit Test Plan: (b)(4) Appendix P
- Unit Test Report: (b)(4) Appendix Q
- Unit Test Case: (b)(4) Appendix R
- Unit Test Case: (b)(4) Appendix R

- Unit Test Case: (b)(4) Appendix R
- Unit Test Case: (b)(4): Appendix R

19.10 Revision Level History

The software revision history information is contained in the Verification and Validation Test Reports referenced in subsection 19.9 above.

19.11 Unresolved Anomalies

All unresolved (deferred) anomalies are listed in the Verification Test Report (Appendix M) and Validation Test Report (Appendix O). (b)(4)

(b)(4)

Details on the deferred anomalies are documented in the Accuray Incorporated anomaly database.

Further details on the handling of anomalies are available in the Accuray Incorporated Anomaly Handling (b)(4). A copy of this SOP is provided in Appendix T.

Section 14 Device Description

Accuray Incorporated is seeking clearance for a Motion Tracking and Compensation Feature to be used with the predicate Radixact Treatment Delivery System last cleared on K161146. Accuray suggests that the Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System be classified by the Radiology review panel as a Class II medical device under regulation number 21 CFR 892.5050 (medical charged-particle radiation therapy system) with a product code IYE.

14.1 Narrative Description

The Motion Tracking and Compensation Feature is designed for use with the predicate Radixact Treatment Delivery System last cleared on K161146. The Motion Tracking and Compensation Feature measures tumor location and motion using images provided by a kV imaging subsystem and predicts tumor location based upon a respiration amplitude measurement device. The Radixact Treatment Delivery System then compensates for tumor motion by making real-time adjustments.

The Radixact Treatment Delivery System is a radiation therapy delivery system that provides Image Guided Radiation Therapy (IGRT) using integral megavoltage CT imaging capabilities and delivers helical (rotational) and fixed-angle (non-rotational) radiation therapy to tumors and other targeted tissues.

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature has imaging and treatment capabilities equivalent to those of the predicate Radixact Treatment Delivery System. It also has a similar functionally-equivalent CT style gantry and patient couch.

In both the predicate Radixact Treatment Delivery System and the subject Motion Tracking and Compensation Feature for the Radixact Treatment Delivery System, the major elements of the system are a functionally-equivalent radiation delivery gantry, patient couch and operator workstation.

(b)(4)

(b)(4)

Neither the Radixact Treatment Delivery System nor the Motion Tracking and Compensation Feature diagnose disease, recommend treatment regimens or quantify treatment effectiveness. Accordingly, they are not intended for diagnostic use.

The Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature and the predicate device employ the same fundamental scientific principles and have substantially equivalent technological characteristics and principles of operation. The main difference between the predicate and the subject device is the use of the motion tracking and compensation feature. For further description of the similarities and differences between the predicate Radixact Treatment Delivery System (K161146) and the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature, please see the Substantial Equivalence discussion (Section 15) in this submission.

14.1.1 Intended Use

The Motion Tracking and Compensation Feature is an option within the intended use of the Radixact Treatment Delivery System. Radixact Treatment Delivery System is intended to be used for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues. The megavoltage x-ray radiation is delivered using rotational, non-rotational, intensity modulated (IMRT), or non-modulated (non-IMRT/three dimensional conformal) treatment techniques and using image-guided (IGRT) or non-image-guided workflows in accordance with the physician approved plan.

14.1.2 Indications for Use

The Motion Tracking and Compensation Feature is an option within the indications for use of the Radixact Treatment Delivery System. The Radixact Treatment Delivery System is indicated for the delivery of radiation therapy, stereotactic radiotherapy or stereotactic radiosurgery to tumors or other targeted tissues anywhere in the body under the direction of a licensed medical practitioner.

14.2 Physical and Technical Description

An illustration of the Radixact Treatment Delivery System gantry and couch is shown below:

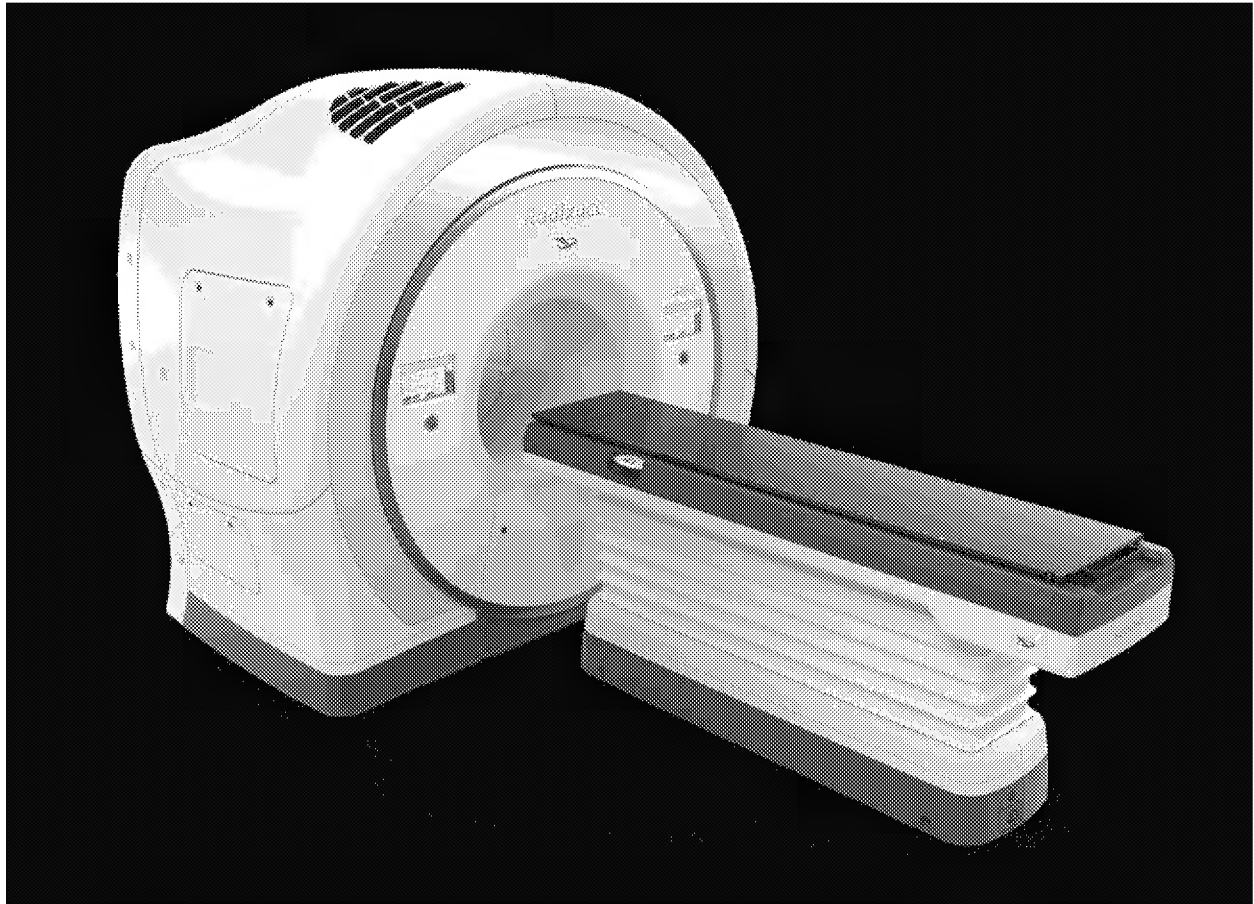


Figure 1: Illustration of the Radixact Treatment Delivery System Gantry and Couch

(b)(4)

(b)(4)

14.2.1 Terminology and Conventions

(b)(4)

14.2.2 Design References

14.2.2.1 System Architecture

A copy of the System Architecture Description (b)(4) for the Radixact Treatment Delivery System with the use of the Motion Tracking and Compensation Feature is provided in Appendix B.

14.2.2.2 Input Requirements

(b)(4)

14.2.3 Radixact Treatment Delivery System Design Elements

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

14.3 Auxiliary Components

The following items were introduced with Accuray's CyberKnife Robotic Radiosurgery System's Synchrony Respiratory Tracking System 510(k) submission cleared under K120233.

14.3.1 Synchrony Camera

The Synchrony camera is mounted near the foot end of the couch attached to the wall or to the ceiling, depending on the site configuration. The Synchrony camera array consists of three sensors that detect the motion of the patient by monitoring the position of the Tracking Markers. Tracking markers move with patient breathing, and these signals from the Synchrony camera array are used to track and display patient breathing patterns on the Treatment Delivery Console.

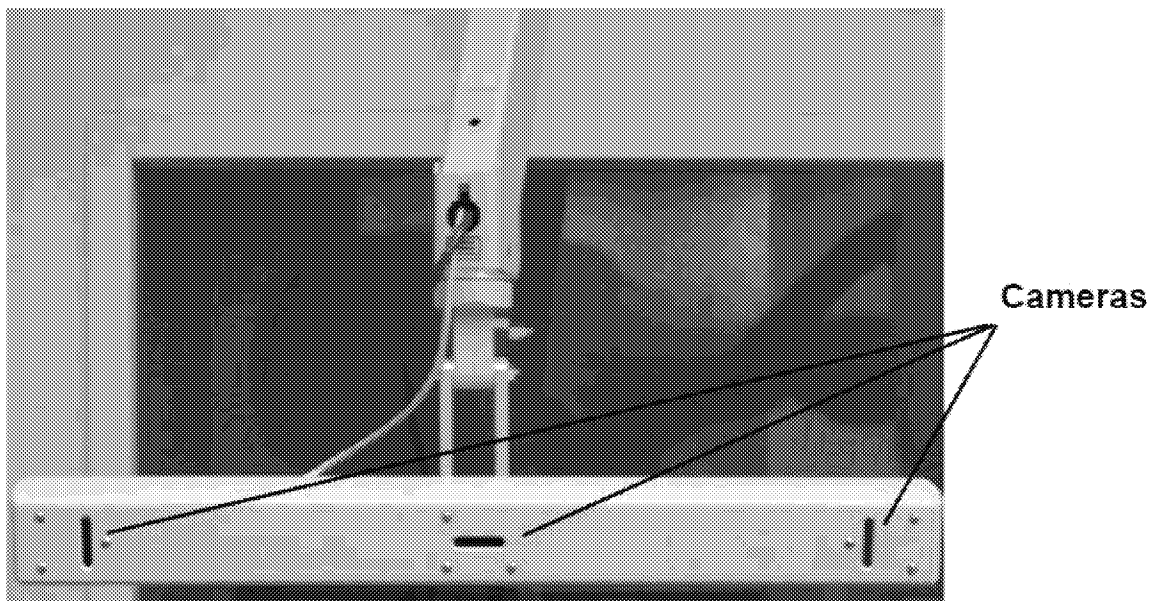


Figure 6: Synchrony Camera

14.3.2 Synchrony Vest

The patient wears the Synchrony Tracking Vest during pre-treatment scanning. The Synchrony Tracking Vest is shown in the figure below. The three tracking marker LEDs attach to the Velcro on the vest.

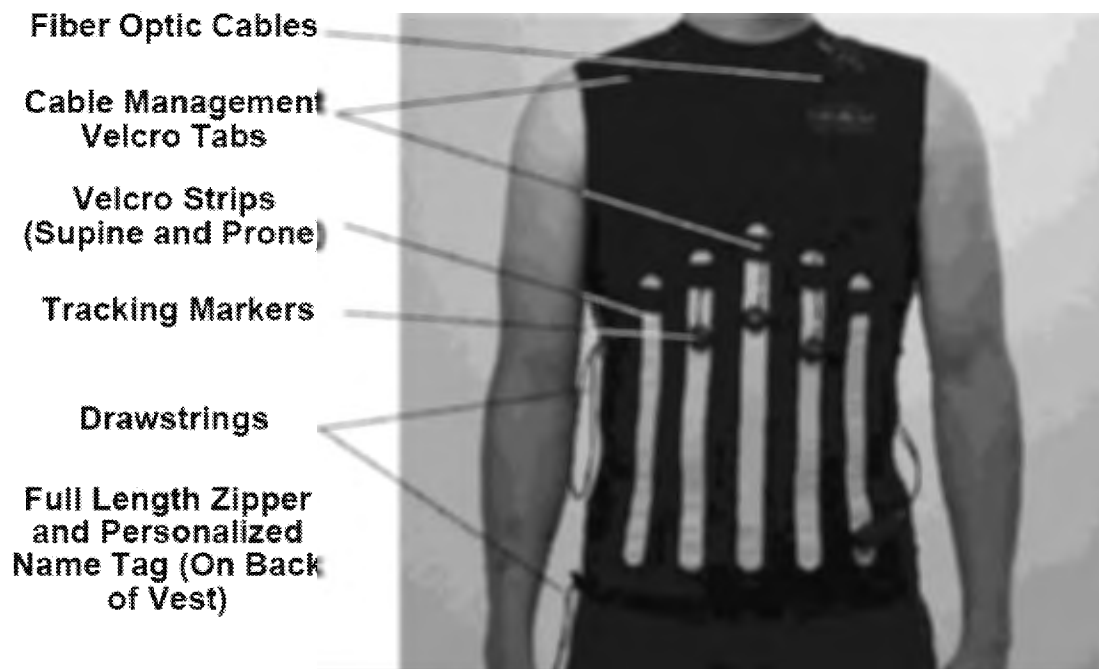


Figure 7: Synchrony Vest

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)