

RADIXACT[®] SERIES

Technical Specifications Brochure





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, with the addition of components which will significantly enhance interoperability and increase patient throughput.

Key Features and Benefits:

- New Linac capable of 1,000 cGy/minute operation
- New 10 RPM operation during imaging
- New Accuray Precision® Treatment Planning System provides a comprehensive, full-featured treatment planning solution
- New iDMS[™] Data Management System offers an integrated database supporting all compatible Accuray products
- New CTrue[™] IR iterative reconstruction software provides enhanced soft-tissue imaging
- New PreciseART[™] Adaptive Radiation Therapy option utilizes daily MVCT data to monitor the effects of anatomical changes over a patient's treatment course
- New PreciseRTX[™] Re-treatment option provides tools to enhance efficiency for patients who require re-planning over a course of treatment and patients who were previously treated, even on non-Accuray* equipment
- TomoHelical[™] and TomoDirect[™] modalities deliver individualized treatments for both routine and complex indications
- TomoEDGE[™] treatment modality spares more normal tissue while enabling increased patient throughput

* Provided compatible DICOM image and DICOM RT-dose data from previous treatments are available

1. Complete Treatment System

Overall dimensions

- Height
- Width
- Length (couch, gantry and catcher)
- Weight (gantry and couch)

Approx. 255.0 cm (8 ft., 4 in.) Approx. 280.0 cm (9 ft., 2 in.) Approx. 470.5 cm (15 ft., 5 in.) Approx. 6,580 kg (14,500 lbs.)



Lateral View: System dimensions

Forward View: System dimensions

Other dimensions

- Gantry depth
- Bore diameter
- Couch maximum height
- Couch minimum height
- Couch width
- Table top width
- Couch longitudinal travel

Approx. 196.3 cm (77.3 in.) Approx. 85 cm Approx. 114.9 cm (45.2 in.) above floor Approx. 70 cm (27.6 in.) above floor Approx. 65.1 cm (25.6 in.) Approx. 53.0 cm (20.9 in.) Approx. 135 cm (53.1 in.)



Rendered view of system in room (A, B, C correspond to room dimensions below)

2. Installation

Minimum room size - requirements*

- Height (A)
- Length (B)
- Width (C)

Typical schedule (receipt of system to first treatment) Commissioning 274.3 cm (9 ft., 0 in.) 602 cm (19 ft., 9 in.) 463 cm (15 ft., 2 in.)

21 days from installation to acceptance tests procedure (ATP) sign off

System comes pre-commissioned and only needs to be verified by the customer. Following ATP, the customer is responsible for determining when the system is placed into service for clinical use.

* Refer to the Radixact® System Site Planning Guide

3. Treatment Vault Environment

ATTRIBUTE

Line voltage, VAC Ambient room temperature Relative humidity

REQUIREMENTS

380, 400, 415, 440, 460 and 480, 3-phase
20 - 24 degrees Celsius (68 - 75 degrees Fahrenheit)
30% - 60%, non-condensing

4. Mechanical Features

ATTRIBUTE

Gantry

- Degrees of rotation
- Direction of rotation
- Accuracy of set angles
- Speed of rotation
- Controls
- Source to axis distance
- Mechanical to radiation isocenter offset
- Mechanical isocenter stability
- Position indicators
- Cooling

5. Photon Beam

REQUIREMENTS ATTRIBUTE Accelerator type Standing Wave • Lenath 0.42 meters Power source Magnetron Nominal dose rate at 1.5 cm** 850 cGy/min or 1,000 cGy/min Nominal Dmax** 1.5 cm Percentage depth dose at 10 cm** 61.4% Number of beamlets Treatment plan dependent; system capable of efficiently delivering tens of thousands of beamlets which enables for very high fidelity intensity modulation Nominal energy 6 MV, single energy Field size range at isocenter – IEC-Yf x IEC-Xf Selectable 1.0 cm x 40 cm (fixed) 2.5 cm x 40 cm (fixed) 5.0 cm x 40 cm (fixed) 1.0-2.5 cm x 40 cm (optional dynamic) 1.0-5.0 cm x 40 cm (optional dynamic) Treatment volume - TomoHelical[™] Mode Maximum treatment volume length is 135 cm. The MLC (Multileaf Collimator) can deliver a 40 cm projection at isocenter which allows irradiation of all target areas within a 40 cm diameter cylinder around isocenter, throughout each 360° gantry rotation. Areas outside a 40 cm cylinder can be irradiated from a reduced, location-specific, range of gantry angles. Maximum treatment volume length is 135 cm. Target areas within a 40 cm diameter cylinder can be irradiated by beams Treatment volume - TomoDirect[™] Mode (optional) from user-defined gantry angle throughout 360°. Areas outside a 40 cm cylinder can be irradiated from a reduced, location-specific, range of gantry angles.

REQUIREMENTS

Within 0.1 degrees

Accuracy < 0.25 mm

5-axis laser system

for facility-chilled water loop

85 cm

< 0.4 mm

Rotates around IEC-Yf axis, continuous rotation

Rotational speed set during treatment planning

Integrated onboard cooling system eliminates need

Between 1 and 5.08 RPM for treatment; 10 RPM for imaging

Clockwise viewed from the foot of the couch



Accelerator and collimator subsystems

Average MLC leakage	≤ 0.5%
Primary collimation	Rectangular, fixed tungsten aperture
Jaw collimation (distances are measured at isocenter)	
 Jaw positions projected to isocenter 	0.5 cm, 1.25 cm or 2.5 cm from mid-line in static mode
	-1.5 cm (across mid-line) to 2.5 cm in optional dynamic mode
Axis of travel	IEC-Yf
• Field size mode	Static mode - jaws set to static position throughout delivery Dynamic mode - jaws set to smaller field in Yf direction near beginning and end of each target
Multileaf collimation	
Number of leaves	64 binary interlaced leaves (tongue and groove side profile)
• Leaf height	10 cm leaf thickness in beam direction
Mode of operation	Binary leaves either fully in or fully out of beam path
Axis of travel	1 axis, longitudinal direction (IEC-Yf)
Speed of travel	Binary leaf state changed in less than 30 msec
Resolution	0.625 cm leaf widths in IEC-Xf direction at isocenter
Leaf drive mechanism	Pneumatic
Position sensor	Monitors with interlock, checks that leaves open and close at correct time

6. Beam Monitoring

ATTRIBUTE

Monitor chamber type
Monitor chamber precision
Monitor chamber linearity
Beam-off interlocks

7. CTrue[™] IR Imaging

ATTRIBUTE

REQUIREMENTS

Full beam transmission, hermetically sealed dual chamber Within 1%

Within 1%

Radiation System; Dose Monitoring, Patient Table Position; Gantry Angle; Computer Communications; Vault Door; Facility E-stops, Cooling Faults

ATTRIBUTE	REQUIREMENTS
Geometry	Helical Fan-Beam
Imaging dose (absorbed)	0.5 - 3 cGy depending on acquisition pitch
Detector configuration	Single row xenon ion chamber array used for image acquisition
Image resolution (IEC Xf x Zf)	512 x 512 (0.76 mm pixels)
Slice spacing available (IEC Yf)	1 mm, 2 mm, 3 mm, 4 mm, 6 mm reconstruction intervals
Scan time	Scan pitch dependent: 1 minute per 12 cm length at 3 mm slice spacing
Field of view (FOV)	39 cm diameter
Source to detector distance	140 cm
Isocenter to detector distance	55 cm
Image noise	≤ 2%
Image uniformity	Within 25HU
Spatial resolution (IEC Xf x Zf)	1.6 mm spatial resolution
Contrast resolution	2% density for 2 cm object
Image reconstruction algorithm	Iterative reconstruction
Image reconstruction time	Real-time; slice-by-slice at time of acquisition
Image registration tools	MVCT/kVCT image overlay with adjustable checkerboard; manual or automatic registration (maximization of mutual information) using bone and/or soft tissue; translations and pitch/roll/yaw determination
Application of adjustments obtained	IEC Xf, Yf, Zf translations applied via couch, roll applied via gantry as determined by image registration
Frequency of geometric alignment between imaging and delivery devices	None required; rigid ring gantry platform
Image guidance mode	Daily 3D MVCT matched with 3D kVCT

CTrue™ Imaging (specification differences only)

Image noise	≤ 4%
Contrast resolution	3% density for 3 cm object
Image reconstruction algorithm	Filtered back projection

8. Safety Features

Single database: Multiple machines can utilize a common database for planning, imaging and treatment data

Plan data transfer: Easy plan transfer between machines using the same iDMS™ Data Management System

Common imaging and treatment beam source: Imaging geometry consistent with treatment geometry (imaging and treatment source are the same), thus avoiding the need for repeated geometric calibration of two different sources

Fully enclosed gantry: Integrated gantry enclosure protects the patient from collision with the beam delivery and imaging system components

No auxiliary beam collimation: Integrated accelerator and collimator subsystem (refer to the image on page 5) manages all beam collimation and modulation, removing the possibility of incorrect component installation and maintaining maximum physical patient clearance; also eliminates patient and therapist contact with hazardous materials during the treatment process

No bending magnet: No beam bending required, therefore eliminating the possibility of geometry errors resulting from redirection of the beam

No electron mode: The treatment system cannot be set to an unintended mode of delivery (note that helical IMRT with 6 MV x-rays can be planned to deliver treatments similar to electron mode treatments) which reduces planning and course delivery complexity

Full system integration: Level of system integration results in software for all components being designed and tested in unison, reducing concerns of disparate system interfaces and compatibility concerns across products and across companies

Noise eliminating intercom system: Facilitates clear two-way communication between the clinician and the patient, utilizing Digital Signal Processing technology, throughout the imaging and treatment process

9. TomoHelical[™] Treatment Delivery Mode

The TomoHelical[™] Treatment Delivery mode provides IMRT and 3D CRT treatment delivery in a continuous (360°) helical pattern. The TomoHelical mode is suited to the majority of clinical situations, where rotational delivery and beam modulation enhance target dose conformality and uniformity.

The user is able to create a treatment plan using inverse planning by defining dose goals and constraints for target and avoidance structures, the level of modulation for the plan, as well as the fractionation schedule.

During treatment delivery, the linear accelerator completes multiple 360° rotations around the patient while the couch passes through the bore of the system, initiated by a single turn of the operator console key.

Fixed jaw and optional dynamic jaw (TomoEDGE[™]) modes are available with the TomoHelical delivery mode. With TomoEDGE mode, field width varies during delivery to decrease the width of the dose gradient outside the target*.

COUCH MOVEMENT

The gantry rotates around the patient in TomoHelical delivery mode, delivering radiation in a continuous spiral pattern

Targets of up to 135 cm in length* can be treated, with no need to reposition the patient and with no field junctioning.

* See section 5

10. TomoDirect[™] Treatment Delivery Mode (optional)

The TomoDirect[™] Delivery mode provides IMRT and 3D CRT treatment via a discrete angle, non-rotational delivery mode. TomoDirect mode allows creation of treatment plans that include between 2 and 12 target-specific gantry angles. The TomoDirect mode complements TomoHelical Delivery mode in situations where a fixed-angle delivery is most appropriate.

During treatment delivery, beams are delivered sequentially with the couch passing through the bore of the system at an appropriate speed for each beam. The complete treatment delivery is initiated by a single turn of the operator console key.

COUCH MOVEMENT

2 – 12 discrete gantry angles can be used in TomoDirect delivery mode

Fixed jaw and optional dynamic jaw (TomoEDGE[™]) modes are available with TomoDirect mode. With TomoEDGE mode, field width varies during delivery to decrease the width of the dose gradient outside the target*. Targets of up to 135 cm in length* can be treated, with no need to reposition the patient and with no field junctioning.

* See section 5 ** Typical patient set-up; actual treatment volume lengths are variable depending upon couch height.

11. Radixact[®] Couch

The Radixact[®] Couch, with Medical Intelligence indexing system, provides sub-millimeter positioning accuracy in point-to-point and translational movements. The Radixact Couch incorporates a catcher to maintain optimal tabletop position.

Clinical efficiency is enhanced with ergonomically designed dual Couch Control Keypads mounted to each side of the couch. The Couch Control Keypads allow motorized patient position in the IEC Xf, IEC Yf and IEC Zf directions with simple, singlehanded operation.

The custom patient couch has a high strength top with an indexing system designed to accommodate immobilization systems.

12. Laser Positioning System

The Radixact Treatment Delivery System includes stationary green lasers for virtual isocenter and moveable red lasers for patient positioning and registration.

13. iDMS[™] Data Management System

The iDMS[™] Data Management System offers an integrated data management solution for all compatible Accuray systems on the same local area network. The iDMS System Detector Data DICOM Export option enables the export of detector data from a treatment plan to a specific location. The Extended Network - iDMS System option allows the connection of Accuray Precision[®] and iDMS Systems that are separated by more than 100 meters. See page 13 for details on on Wide Area Network (WAN) support.

iDMS SPECIFICATIONS (minimum system capabilities)

CPU	Intel Xeon E5-2620v3
Memory	32 GB DDR4 2133 MHz
Volume C: (operating system and application software)	2 TB (2x 2 TB RAID 1)
Volume D: (current/active patient data)	1 TB (4x 600 GB SAS RAID 6)
Volume E: (backup data)	4 TB (4x 2 TB RAID 6)
Network	Two gigabit ports
Power Supplies	Redundant power supplies
OS	Microsoft Windows Server 2012 R2
Database	Microsoft SQL Server 2014

The following items are housed in a rack enclosure (dimensions: 59 in./150 cm H x 24 in./61 cm W x 36 in./92 cm D): Data Server (iDMS System), Gateway, UPS, network components, Remote Registration Review/Approval (optional software feature), and PreciseART[™] Adaptive Radiation Therapy option (optional software feature).

14. Storage Vault (option)

The Storage Vault option provides automated storage of patient records based on user-specified configurations, such as number of days since last access or number of records in active database, and enables quick access to previously treated patient files.

STORAGE VAULT SPECIFICATIONS (minimum system capabilities)

CPU	Intel [®] quad core Xeon 3.1 GHz
Memory	4 GB DDR3 ECC DIMM
Drive Configuration	36 TB Total Storage (12 x 3 TB SATA)
RAID Configuration	RAID 6
Network Interface	2 x Gigabit Ethernet Ports
Power Supplies	2x redundant/hot swappable 350W PSUs
OS	GuardianOS®

15. Accuray Precision® Treatment Planning System

The Accuray Precision[®] Treatment Planning system offers a comprehensive treatment planning solution for the Radixact[®] Treatment Delivery System. Standard features include: multi-modality image fusion, full-featured contouring suite, plan optimization, plan review, plan summation, and QA plan generation. The Accuray Precision System Remote Planning feature allows a remote user to log in and take control of an Accuray Precision System or MD Suite workstation.

ACCURAY PRECISION[®] SYSTEM SPECIFICATIONS (minimum system capabilities)

CPU	Intel Xeon E5-2620v3 (x 2)
Memory	48 GB DDR4 2133 MHz
Graphics Card	Nvidia Quadro M4000
GPU	Nvidia Quadro M5000
Storage	240 GB SATA RAID1 SSD (x 2)
OS	Microsoft Windows 7 Professional 64-bit
Monitor	24" NEC Multisync 1920 x 1200 Native Resolution with ISP Panel Technology

16. MD Suite (option)

The MD Suite treatment planning workstation, designed with the physician in mind, includes the following features: multi-modality image fusion, full-featured contouring suite, dose calculation, plan review, and plan summation.

MD SUITE SYSTEM SPECIFICATIONS (minimum system capabilities)

CPU	Intel Xeon E5-2620v3 (x 2)
Memory	24 GB DDR4 2133 MHz
Graphics Card	Nvidia Quadro M4000
GPU	Nvidia Quadro M5000
Storage	240 GB SATA RAID1 SSD (x 2)
OS	Microsoft Windows 7 Professional 64-bit
Monitor	24" NEC Multisync 1920 x 1200 Native Resolution with ISP Panel Technology

17. Treatment Delivery Console

The Treatment Delivery Console is the workstation that connects to the treatment system and provides control of CTrue[™] MVCT imaging, patient treatment and quality assurance delivery, procedure verification functionality and delivery of calibration and QA procedures. Control of the Radixact[®] Couch is included, allowing patient shifts to be made at the Treatment Delivery Console after image registration. The Treatment Delivery Console is provided with a color printer capable of printing treatment data, plus an LCD monitor, keyboard, mouse, and required cables.

18. PreciseART[™] Adaptive Radiation Therapy and PreciseRTX[™] Re-treatment Options

The PreciseART[™] option allows users to track delivered dose relative to planned dose over the course of a multi-fraction treatment using the daily MVCT data and patient setup information. Contours are automatically generated on each treatment's scan by deforming the original plan contours onto the new images using Accuray Incorporated's propriety deformation algorithm. Daily delivered dose, dose statistics, and the current cumulative delivered dose relative to a scaled version of the original treatment plan can be reviewed at any time via customizable reports. Deviations that exceed a user-specified threshold for any delineated structure are flagged for review by the clinician. The system features a full suite of tools for examining data for a given fraction and plan (including evaluating the deformation) to enable detailed analysis of deviations from the planned treatment, along with support for re-planning.

The PreciseRTX[™] option provides tools to aid in the efficient generation of new treatment plans for patients currently or previously under treatment:

- Import patient plan data from both Accuray and non-Accuray systems
- Deform original plan contours onto a new planning CT
- Add previously delivered dose to a new treatment planning CT through deformation and dose warping

19. Remote Registration Review (option)

This network access portal allows remote review and approval of MVCT imaging and registration results from virtually any computer (client computer running Citrix[®] ICA Client) with authorized network access to the iDMS[™] Data Management System Server.

SPECIFICATIONS

CPU	Intel Xeon E5-2620v3 (x 2)
Memory	48 GB DDR4 2,133 MHz ECC
Storage	4 x 2 TB HDDs in a RAID 10 configuration
	(~4 TB total storage)
Network	Two gigabit ports
Power Supplies	Redundant power supplies
OS	Citrix XenServer, 4 x Windows 7 Professional
	virtual machines
Minimum Screen Resolution	1920x1200



20. External System Interfaces

DICOM Import

The following DICOM image studies are supported for import by the iDMS[™] Data Management System for use in treatment planning for Radixact[®] System:

ТҮРЕ	SUPPORTED PATIENT POSITIONS
Computed Tomography (CT)	Axial HFS, FFS, HFP, FFP
(Required Primary Image Set)	
Magentic Resonance (MR)	Axial HFS, Sagittal HFS, Coronal HFS
Positron Emission Tomography (PET)	Axial HFS
X-Ray Angiography (XA)	Axial HFS, Coronal HFS

In addition to the above image studies, the system may also import DICOM RT-Structure Sets allowing third-party systems to be used for contouring if required.

DICOM Export

The following DICOM objects may be exported to third-party systems and clinical/research databases:

DICOM-CT Image Set

• DICOM-RT Dose

DICOM-RT Structure Set

DICOM-RT Plan

20. System Interfaces (continued)

OIS Interface Software

The OIS Interface software provides the ability to interface the iDMS[™] Data Management System-based suite of products with a compatible Oncology Information System (OIS). Elekta MOSAIQ[®], Varian ARIA[®] and ONCOCHART[®] systems are currently supported. The software facilitates greater integration of Accuray products into the radiation oncology department by:

- Allowing scheduling of treatments on the OIS
- Allowing review of the Radixact[®] Treatment Delivery System's CTrue[™] MVCT images and registrations in 3D*
- Providing automatic capture of treatment procedures on the OIS, including dose recording and accumulation for the treatment plan's primary prescriptive target
- Aiding in charge capture and billing (where applicable)
- · Aiding in integrating treatments into patients' electronic medical records, via the OIS

The OIS Interface Software is based on DICOM-RT Worklist communication, as specified in DICOM Supplements 74 and 96 * Export of the 3D CTrue MVCT images and registration review may not be available in all Oncology Information Systems. Please check with your OIS vendor for compatibility.

Data Backup and "Disaster Recovery" Features

The iDMS[™] System includes a number of features and functionality to protect the system's data in the case of a catastrophic event:

- The iDMS System data server includes three separate data drive volumes (C: Operating system and application software, D: current/active patient data and E: backup data) to increase system redundancy and to provide efficient service and support
- All iDMS System drives are RAID6 arrays, allowing the system to stay on-line with up to two disk failures
- iDMS System software monitors iDMS System hardware/RAID configuration and posts system events in the event of failure, allowing monitoring by System Administrators on-site, plus allowing visibility by Accuray Support Personnel
- iDMS System software is equipped with full automatic backup once a day, differential backup every eight hours and transactional backup every two hours (intervals are configurable) to the E drive. Comprehensive backup is therefore performed with no requirement for user interaction, plus the configurable backup intervals allow optimization of the backup process according to the clinic workload
- iDMS System software is also equipped with Data Mirroring capabilities, allowing the iDMS System to be configured to mirror the database backup (E: drive) to a location on the facility network

Patient Data Archive and Restore

The iDMS System allows data to be archived to a network storage location configured by the site via its Patient Record Archive and Restore (PRAR) software. The iDMS System retains the root patient record in the system database and the PRAR software enables access to archived data for easy search and restore of patient records as needed.

21. Quality Assurance

Total Quality Assurance (TQA[™]) Software Packages (Machine quality assurance)

The TQA[™] application is a calendar-based tool that streamlines machine QA by providing automated data collection, analysis, and trending tools. It can save significant time by leveraging treatment delivery system sensors to allow clinicians to quickly and easily assess the day-to-day consistency of a wide variety of parameters for their Radixact Treatment Delivery System. Data generated by the TQA application are viewable from a browser window anywhere on the hospital network, and all data may be exported.

The Essential TQA Package includes the Basic Dosimetry, Air Scan and System Monitor modules.

The optional Advanced TQA package includes additional modules that check many other system parameters including: MLC performance, laser alignment, field width, dynamic jaw performance, and water tank profile analysis.

Delivery Analysis[™] (Patient treatment delivery assessment)

The optional Delivery Analysis[™] application enhances confidence in patient delivery by providing automated tools that use exit fluence data to calculate dose in the patient planning CT for every treatment plan, and to show any changes in the delivered fluence throughout the course of patient treatment. A dashboard provides an "at a glance" view of user-selectable metrics for all patient deliveries, and sophisticated visualization tools allow the clinician to correlate observed changes in exit fluence with patient setup and anatomy.

22. Installation Services

Include:

- Pre-installation Site Planning and Project Management services
- Installation (refer to section 2)
- Completion of Acceptance Test Procedure (ATP) and system hand over

23. Wide Area Network (WAN) Support

Accuray Incorporated does not encrypt network data transmissions. It is the responsibility of a facility to protect network and data transmission infrastructure from internal and external threats. This includes maintaining data security requirements and point-to-point encryption among the Accuray System firewall and the following potential data destinations or access points:

- The dedicated Virtual Local Area Network (VLAN)
- Accuray Precision[®] System workstations
- WAN Connected Treatment System
- The redundant iDMS[™] System installed on a facility Local Area Network (LAN) or WAN

The functionality requires 1 Gigabit bandwidth with less than 10ms latency.

Notes

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Important Safety Information Most side effects of radiotherapy, including radiotherapy delivered with Accuray systems, are mild and temporary, often involving fatigue, nausea, and skin irritation. Side effects can be severe, however, leading to pain, alterations in normal body functions (for example, urinary or salivary function), deterioration of quality of life, permanent injury and even death. Side effects can occur during or shortly after radiation treatment or in the months and years following radiation. The nature and severity of side effects depend on many factors, including the size and location of the treated tumor, the treatment technique (for example, the radiation dose), the patient's general medical condition, to name a few. For more details about the side effects of your radiation therapy, and if treatment with an Accuray