



TOMOTHERAPY® TomoHDA™ SYSTEM COMMERCIAL DESCRIPTION



TOMOTHERAPY® TomoHDA™ SYSTEM

GOLD STANDARD IN IMRT

Versatile, efficient and effective for
the range of radiation oncology patients

CLINICAL EXCELLENCE

- Enables planning and delivery of highly sculpted dose distributions
- Facilitates seamless daily CT image guidance for precise patient positioning, margin reduction and adaptive planning

PATIENT FOCUSED

- Provides customized and consistent treatments for every patient
- Spares more normal tissue, helping to reduce side effects

IMPROVED ECONOMICS

- Facilitates scheduling in conventional time slots
- Enables patient treatments not possible on conventional linacs
- Allows fast and flexible treatment planning for each patient
- Improves quality assurance efficiency



TomoTherapy®
RADIATION THERAPY

Description	Detailed description
<p>TomoTherapy® H™ Series Treatment System Gantry</p>	<p>TomoTherapy H Series Treatment System Gantry The gantry includes:</p> <ul style="list-style-type: none"> • a large 85 cm aperture for patient comfort and accessibility, • the radiotherapy treatment linear accelerator, • a primary collimator to define slice width and • Multileaf Collimator (MLC) to further define the treatment beam, • a high resolution detector system (used for CTrue™ image acquisition) which is coplanar with the beam, • a cooling system and electronics to control these components. Three (3) beam slice widths, 5 cm, 2.5 cm and 1.0 cm are standard.
<p>TomoTherapy H Series Treatment System Configuration</p> <ul style="list-style-type: none"> • Enclosure Assembly with Positioning Control Panels (PCP) • Integrated Noise Eliminating Intercom System • Status Console • System Power Distribution Unit (PDU) • Laser Positioning System 	<p>TomoTherapy HDA Treatment System Configuration The TomoHDA™ treatment system is a completely integrated radiation therapy platform offering treatment planning, CT image guidance and delivery of intensity modulated radiation therapy. The following major components are included:</p> <ul style="list-style-type: none"> • Enclosure Assembly with Positioning Control Panels (PCP) The gantry enclosure system includes two large 12 inch (Approx. 30 cm) integrated touch-screen Positioning Control Panels which enable electronic control and synchronization of the Patient Couch and the 3-D Laser positioning system used to align the patient for a given TomoTherapy treatment protocol. The PCPs allow high-fidelity position adjustments of 0.1 mm in X, Y and Z directions and a hands-free patient unload feature. The gantry enclosure also includes a power control panel. • Integrated Noise Eliminating Intercom System The Noise Eliminating Intercom System facilitates clear two-way communication between the clinician and the patient, utilizing Digital Signal Processing technology, throughout the TomoTherapy imaging and treatment process. The Noise Eliminating Intercom System comprises a desktop console with “push to talk” function for placement at the TomoTherapy Operator Station, a “hands-free” speaker for the treatment room and an external microphone, for suspension from the ceiling either behind or in front of the TomoTherapy treatment system gantry. The desktop console and treatment room speaker are connected via standard CAT-5 data cable. • Status Console A status console is included which is used to operate the various modes of the TomoTherapy treatment system. • System Power Distribution Unit (PDU) The PDU provides distribution of site power to various TomoTherapy components and electronics. The PDU also provides electrical isolation. • Laser Positioning System The system configuration includes stationary green lasers for virtual isocenter and moveable red lasers for patient positioning/registration. <p>TQA™ Total Package option (P/N 102837-000) is required for TomoEDGE Dynamic Jaws QA.</p>
<p>High Performance Couch for TomoTherapy H Series with Medical Intelligence indexing system</p>	<p>High Performance Couch for TomoTherapy H Series Treatment System with Medical Intelligence indexing system</p> <ul style="list-style-type: none"> • The High Performance Couch provides sub-millimeter accuracy and precision in point-to-point and translational positioning. • Clinical workflow is enhanced with ergonomically designed dual Couch Control Keypads mounted to each side of the couch. The Couch Control Keypads allow motorized patient position modification in the X, Y and Z directions with simple, single-handed operation. • The custom patient couch has a high strength carbon-fiber top with an indexing system designed to accommodate immobilization systems from Medical Intelligence.



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<p>TomoHDA™ System Software and Computing Hardware Kit</p> <ul style="list-style-type: none"> • System Software and Additional Features • Treatment System Software and Software License • TomoHelical™ Treatment Mode • TomoDirect™ Treatment Mode • TomoEDGE™ Dynamic Jaw • Operator Station Couch Control • OIS Connect™ - One (1) Client License • Data Services Package – DICOM Export • Remote Software Solutions – Base Configuration (Includes two client licenses Remote Planning and 2 client licenses TomoPortal™) • Tomo Quality Assurance (TQA™) Essentials • Computing Hardware / Data Server Assembly • Two Planning Stations • Operator Station • VoLO™ Optimization Cluster TomoTherapy H™ Series User Documentation Package (in electronic format) 	<p>TomoHDA System Software and Computing Hardware Kit</p> <ul style="list-style-type: none"> • System Software and Additional Features • Treatment System Software and Software License • TomoHelical Treatment Mode • TomoDirect Treatment Mode • TomoEDGE Dynamic Jaw • Operator Station Couch Control • OIS Connect 1 - One (1) Client License • Data Services Package – DICOM Export • Planned Adaptive™ • Remote Software Solutions - Base Configuration plus an extra seat (Incl. 2 client licenses Remote Planning and 2 client licenses TomoPortal) • Tomo Quality Assurance (TQA) Essentials • Computing Hardware • Data Server Assembly • Two Planning Stations • Operator Station • High Performance VoLO Optimization Cluster • TomoTherapy H Series User Documentation Package (in electronic format) <p>• TomoHelical Treatment Mode</p> <p>The TomoHelical mode provides IMRT treatment delivery in a continuous (360°) helical pattern, using thousands of narrow beamlets, which are individually optimized to target the tumor. The TomoHelical mode maximizes dose conformity and uniformity of dose to the tumor while minimizing exposure to healthy tissue. The user is able to create a treatment plan that defines 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. A maximum radiation treatment field length of 135 cm is possible, with no need to reposition the patient and with no field junctioning (see note).</p> <p>Note: Treatment volume for TomoHelical treatment mode: 80 cm (transverse diameter) x 135 cm (longitudinal) for typical patient set-up. Actual treatment volume is variable depending upon couch height. Region of treatment used is determined by the planning CT image field of view (FOV). Provided the FOV is 80 cm or less and all patient anatomy is present in the planning image, the TomoTherapy treatment system can import the image, plan and treat.</p> <p>• TomoDirect Treatment Mode</p> <p>The TomoDirect mode is a discrete angle, non-rotational delivery mode. TomoDirect allows creation of treatment plans that defines up to twelve target-specific gantry angles. It also allows the user to define the level of modulation for the plan, including a non-modulated 3D delivery mode. Treatment planning is completed rapidly due to the power of the system's computing platform. During treatment delivery, all beams for each target are delivered sequentially with the couch passing through the bore of the system at an appropriate speed for each gantry angle. The complete treatment delivery is initiated by a single turn of the operator console key. A maximum radiation treatment field length of 135 cm (with treatment couch at height of isocenter plane) is possible, with no need to reposition the patient and with no field junctioning.</p> <p>Note: Treatment volume for TomoDirect treatment mode: 40 cm (transverse diameter) x 135 cm (longitudinal) for typical patient set-up. Actual treatment volume is variable depending upon couch height. Region of treatment used is determined by the planning CT image field of view (FOV). Provided the FOV is 80 cm or less and all patient anatomy is present in the planning image, the TomoTherapy treatment system can import the image plan and treat.</p> <p>• Operator System Couch Control</p> <p>Following CTrue™ MVCT imaging and registration of the image to the planning CT, Operator Station Couch Control allows the user of the TomoTherapy® treatment system to move the couch to the accepted position for treatment, directly from the Operator Station software. Operator Station Couch Control offers a major workflow and efficiency enhancement for both patient and QA procedures.</p>



Description	Detailed description
	<p>• Data Services Package – OIS Connect™ - One (1) Client License The OIS Connect™ software provides the ability to interface a TomoTherapy treatment system to a compatible Oncology Information System (OIS) (see note 2). The OIS Connect software facilitates greater integration of the TomoTherapy treatment system in the radiation oncology department, by:</p> <ol style="list-style-type: none"> 1. Allowing scheduling of TomoTherapySM treatments on the OIS 2. Providing automatic capture of TomoTherapy procedures on the OIS 3. Aiding in charge capture and billing (where applicable) 4. Aiding in integrating TomoTherapy treatments into patients’ electronic medical records, via the OIS. <p>The OIS Connect software is based on DICOM RT Worklist communication, as specified in DICO Supplements 74 and 96.</p> <p>Note 1: Each OIS Connect license applies to one (1) TomoTherapy treatment system and is valid for the life of the product. Transfer or resale for the purpose of enabling the OIS Connect functionality for additional TomoTherapy treatment systems is strictly prohibited.</p> <p>Note 2: Compatible Oncology Information Systems include “MOSAIQ®” from IMPAC Medical Systems, Inc. and “ARIA®” from Varian Medical Systems, Inc. Please contact your IMPAC or Varian representatives for information on pre-requisites, required OIS software versions, and/or additional licensing requirements.</p> <p>• Data Services – DICOM Export The DICOM Export software allows the following DICOM objects to be sent from the TomoTherapy treatment system to 3rd party systems and clinical/research databases:</p> <ul style="list-style-type: none"> o DICOM-CT Image Set o DICOM-RT Structure Set o DICOM-RT Dose o DICOM-RT Plan <p>Accuray maintains compliance with current published DICOM standards and detailed information is available in our DICOM Conformance Statement. Accuray is not responsible for incompatibility of 3rd party systems and/or software with TomoTherapy’s DICOM implementation.</p> <p>• Software License – Planned Adaptive™ The Planned Adaptive software license enables simple and effective dose verification for single or multiple treatment fractions. It further enables contour generation and plan modification should there be discovery of unacceptable deviations between the previous plan and verified dose delivery.</p> <p>• Remote Software Solutions - Remote Planning - Two (2) Client License and TomoPortal™ Two (2) Client Licenses Remote Planning, a TomoTherapy Remote Software Solution, securely and easily provides TomoTherapy users fully functional operation of the TomoTherapy Planning Station application from outside of the TomoTherapy treatment system network, via the internet. It allows a remote user to operate the Planning Station application and develop plans without being physically present in the facility where the TomoTherapy treatment system is installed. The TomoPortal application also resides on the same Remote Software Solutions computer node as the Remote Planning application. The TomoPortal Remote Viewer securely and easily provides a web-enabled link to patient information stored in the TomoTherapy treatment system. It is possible to review a plan, registration, and treatment data from down the hall or across a continent. Includes server hardware and both Remote Software Solutions - Remote Planning and TomoPortal with licensing required for two (2) concurrent remote planning users and up to two (2) concurrent TomoPortal™ users.</p>



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	<p>Note 1: Client hardware is not included. The flexibility to use a laptop, desktop, or tablet PC client platform remains the choice of each licensed user. Purchased client hardware platforms must meet the minimum specifications provided by TomoTherapy Incorporated (outlined below):</p> <ul style="list-style-type: none"> • Microsoft Windows XP, Windows 7, or Mac OS X 10.6 • Minimum screen resolution of 1280 x 1024 pixels • Color quality should be set to Highest (32 bit) • Intel Core 2 processor or equivalent • Citrix® ICA Windows Desktop Receiver (DesktopReceiver.msi) version 11.1; or Mac OS X Desktop Receiver version 11.2 • Anti-virus software approved by facility IT department must be running • Network bandwidth of at least 3Mbps <p>IMPORTANT: If you do not set the resolution to 1280 x 1024 pixels, the Remote Software Solutions system cannot be used as designed.</p> <p>Note 2: Client license packages are sold solely on a per TomoTherapy® System-basis. Licenses cannot be transferred, assigned, or shared across multiple TomoTherapy systems.</p> <p>Note 3: Options to purchase up to two (2) additional Remote Planning licenses and up to six (6) additional TomoPortal Remote Viewer licenses are available.</p> <ul style="list-style-type: none"> • TomoTherapy Quality Assurance (TQA™) Essentials <ul style="list-style-type: none"> ○ TomoLink™ automated remote diagnostics and customer service access ○ User authenticated access to TQA database ○ Calendar for QA tracking and scheduling ○ Air scan ○ System diagnostics/monitor ○ Basic Dosimetry Module • Optimizer/Data Server Assembly The high performance VoLO Optimization Cluster, used for faster concurrent treatment plan optimization and dose calculation <ul style="list-style-type: none"> • The Data Server and Storage Area Network (SAN), which stores data required to run the treatment system and deliver prescribed treatments to the patient. It also stores patient planning information (CTrue™ images, contours, dose volumes). The Data Server is connected to the Optimization Server, Planning Stations, Operator Station and the Treatment Delivery System. • The TomoGateway™ system hardware enables remote system diagnostics and monitoring by TomoTherapy Technical Support (Note: Additional software may be required for remote diagnostics functionality which must be purchased separately). • A database backup solution. • KVM and LCD display for administration of the Optimizer/Data Server assembly. • Uninterruptible Power Supplies (UPS) to support the complete Optimizer/Data Server Assembly. • Network switch and Firewalls. • Two (2) Treatment Planning Stations Two TomoTherapy Inverse Planning Stations allow the definition and management of treatment plans and initiation of plan optimization. Delivery Quality Assurance (DQA) tools are also integrated into the Planning Station software. The Planning Stations further include the Data Management System application software, for archiving and management of patient data. An Uninterruptible Power Supply, high-resolution LCD monitor, keyboard & mouse plus required cables, are included with each Planning Station. A color printer for printing treatment plans and reports is also included. <p>Note: The Planning Stations may be located up to 100 m from the Optimizer/Data Server Assembly as standard. This distance may be extended up to 1,000 m with the addition of P/N 100700-000 Planning Station Extended Network Option.</p>



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	<p>• Operator Station: One TomoTherapy® Operator Station, which connects to the H™ Series database and provides control of CTrue™ MVCT imaging, patient treatment and quality assurance delivery, plus basic Record & Verify functionality. The Operator Station is provided with a color printer capable of printing CTrue images and treatment data, plus an LCD monitor, keyboard & mouse plus required cables. Note: The Operator Station may be located up to 100 m from the treatment delivery system.</p> <p>• High performance VoLO™ Technology is a new plan optimization system for the TomoTherapy platform. It features high-end graphics processing unit (GPU) hardware paired with redesigned software that takes full advantage of the GPU's parallel processing abilities to make treatment planning faster, more flexible and more interactive, making optimal TomoTherapy treatments available to more patients. With VoLO Planning, dose calculation and optimization are performed at unbelievable speed. In just a few minutes, plans can be optimized, finalized and saved, ready for quality assurance and delivery. This includes plans for large, complicated treatment volumes, or simple cases – in fact, any case with which you are presented.</p> <p>VoLO FEATURES</p> <ul style="list-style-type: none"> • GPU hardware implementation using hundreds of parallel processors • Efficient 3D representation of the beam and patient geometry • Innovative dose calculation algorithms that combine speed with accuracy <p>VoLO PLANNING BENEFITS</p> <ul style="list-style-type: none"> • Ultra-fast plan optimization – just minutes from start to finish, even for clinically complex cases • Interactive monitoring of results and fine-tuning of plan parameters during the optimization process • No need for a non-interactive pre-planning step <p>High performance VoLO CONFIGURATION The high performance configuration includes two nodes and enables planning of up to five cases at one time, with further increased efficiency. This simultaneous usage includes both dose calculation and optimization. Planning stations may be local – within the clinic – or remote via the TomoTherapy System's Remote Software Solutions product. The high performance configuration features a double node. Each node contains 448 processors that work simultaneously to calculate dose and optimize the parameters that control the treatment delivery system.</p> <p>• TomoTherapy H Series System User Documentation Includes electronic copies of each of the following user documents: Getting Started Guide, Tomo® Planning Guide, Treatment Delivery Guide, Delivery QA Guide, Planned Adaptive™ Guide, StatRT™ Guide, System Maintenance Guide, Calibration Data Tool Guide, DICOM Conformance Statement and Technical Descriptions in English.</p>
<p>Power Kit 220 240V/60Hz International</p>	
<p>Power Kit 220 240V/50Hz International</p>	
<p>Power Kit 110 120V/60Hz International</p>	



Description	Detailed description
<p>System Installation Options: ***Installation services are not included for Distributor orders; installation is the responsibility of the Distributor.***</p>	
<p>Standard Installation for the TomoTherapy® Treatment System</p>	<p>Standard Installation for the TomoTherapy Treatment System Includes:</p> <ul style="list-style-type: none"> • Pre-installation Site Planning and Project Management Services • Installation and Acceptance testing • Completion of Acceptance Test Procedure (ATP) and System handover
<p>Hardware Options</p>	
<p>Additional Planning Workstation – International Configuration – Qty 1</p>	<p>Additional Planning Workstation – International Configuration – Qty 1</p> <p>One additional Planning Workstation for connection to the standard TomoTherapy treatment system network, for international customers.</p> <p>The additional Planning Workstation provides increased flexibility for the TomoTherapy treatment system and greatly enhances workflow efficiency.</p> <p>The Planning Workstation includes the TomoTherapy planning software and Data Management System (DMS) application software and therefore provides:</p> <ul style="list-style-type: none"> • Treatment plan definition and management • Initiation of plan optimization • Treatment plan review • Delivery Quality Assurance (DQA) • Patient data archiving/management functionality. <p>Note 1: A maximum of three TomoTherapy Planning Stations (1 x Planning Station and 2 x Additional Planning Workstations) can be connected to the TomoTherapy treatment system network, in addition to the treatment system Operator Station.</p>
<p>Planning Station / Additional Planning Workstation Extended Network Option</p>	<p>This option should be selected for use with TomoTherapy Planning Stations or Additional Planning Workstations that are required to be located more than 100 meters (Approximately 300 feet) distant from the Optimization/Data Server cluster. The Planning Station / Additional Planning Workstation Extended Network Option includes:</p> <ul style="list-style-type: none"> • Network switch • Fiber-optic transceivers • Optical fiber patch cables for connection of system components <p>Note 1: Accuray recommends purchasing one (1) Planning Station / Additional Planning Workstation Extended Network Option, for each room where Planning Station(s) or Additional Planning Workstation(s) will be located.</p> <p>Note 2: The Extended Network Option allows the Planning Station(s) / Additional Planning Workstation(s) to be located up to 1,000 meters (Approximately 3,000 feet) away from the Optimization / Data Server cluster.</p>
<p>35KVA Power Conditioner System from Eaton Corporation</p>	



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Configuration / Software Options for TomoHDA™	
HIS Workflow Connectivity	The HIS Workflow connectivity software option provides the ability to interface a TomoTherapy® treatment system to a compatible Hospital Information System (HIS). <i>*Note: Please discuss with Product Marketing to determine if compatible with a specific HIS</i>
Software License – StatRT™	<p>Software License – StatRT</p> The StatRT software package provides a clinically advanced, time-efficient solution for palliative treatments or a rapid start to a fractionated treatment plan. CT scanning, treatment planning and treatment delivery are all managed from the TomoTherapy Operator Station in a simple, direct workflow. The StatRT software employs similar dose calculation methods and helical IMRT delivery as the standard TomoTherapy treatment process, so treatments performed using the StatRT software maintain highly conformal, homogeneous dose distributions and can cover a full range of patient presentations, from simple single lesions to complex multiple-lesion cases. Note: Each StatRT Software License applies to one (1) TomoTherapy treatment system and is valid for the life of the product. Transfer or resale for the purpose of enabling the StatRT option for additional TomoTherapy treatment systems is strictly prohibited.
Workstation Configuration Option for Network Data Storage	This feature allows patient archives created on the TomoTherapy treatment system to be sent to, or retrieved from, a storage location outside of the treatment system network.
DICOM Detector Signal Export	DICOM Detector Signal Export software option allows the user to export delivery information from the CT detectors of the TomoTherapy delivery system in a DICOM format. <i>Note: This is only for research purposes at this time, please discuss with Product Marketing if a customer is interested in this item</i>
Remote Software Solutions - Remote Planning - Third Client License Option	This option provides a third concurrent Remote Planning Client User License for the TomoTherapy system
TomoPortal™ License Upgrade Option for H™ Series – Two (2) to Four (4)	This option provides an additional two (2) TomoPortal user licenses for the TomoTherapy® treatment system, bringing the total number of TomoPortal concurrent user licenses included to four (4).
TomoPortal License Upgrade Option for H Series – Two (2) to Eight (8)	This option provides an additional six (6) TomoPortal user licenses for the TomoTherapy treatment system, bringing the total number of TomoPortal concurrent user licenses included to eight (8).



Quality Assurance (QA) and Delivery Quality Assurance (DQA) Options	
Standard TomoTherapy QA Package (Required for new sites – 1 per site)	Includes 'cheese' phantom, solid water phantom and two calibrated mini ion chambers and one calibrated CT slice ion chamber.
TomoTherapy Quality Assurance (TQA™) Total Package	<p>TQA Total Package</p> <p>TomoLink automated remote diagnostics and customer service access, includes:</p> <ul style="list-style-type: none"> • User authenticated access to TQA database • Calendar for QA tracking and scheduling • Air scan • System diagnostics/monitor • Basic Dosimetry Module • Daily QA Module • IEC-x Beam Alignment Module • IEC-y Beam Alignment Module • Field Width Profile • Static Step Wedge Module • Helical Step Wedge Module • Dynamic jaw field width test • Dynamic jaw sweep test <p>(Prerequisites: Must enable TomoLink and have 104940 (TomoTherapy Beam Measurement and QA Package (without water tank). See Price Book.</p>
TomoTherapy Treatment System Beam Measurement & QA Package	This dosimetry package includes beam quality analysis hardware and software tools (Water tank, TomoElectrometer™, and TEMS) designed specifically for obtaining and analyzing radiation beam data from the TomoTherapy treatment system.
TomoTherapy Treatment System Beam Measurement & QA Package (without water tank)	This dosimetry package includes beam quality analysis hardware and software tools (TomoElectrometer and TEMS) designed specifically for obtaining and analyzing radiation beam data from the TomoTherapy treatment system. Facilities often already own their own water tank.
TomoElectrometer	8-Channel electrometer for acquiring ion chamber data. Compatible with most major ionization chambers.
Calibrated Mini Ion Chamber, and Interconnect Cable	

Description	Detailed description
Calibrated CT Slice Ion Chamber, Buildup Cap and Jig, and Interconnect Cable	
Interconnect Cable - 30 meters	For use with an ion chamber when an extension is required
Film Digitizer Kit	<p>Film Digitizer Kit</p> <p>The film digitizer kit is used to digitize films acquired on the TomoTherapy® treatment system for patient-specific quality assurance (also known as "Delivery QA" or "DQA"), machine quality assurance and acceptance testing procedures.</p> <p>This kit includes:</p> <ul style="list-style-type: none"> • 1 Vidar® DosimetryPRO® Advantage (Red) film digitizer and cables • 1 personal computer, monitor, keyboard, mouse & TomoTherapy Film Analysis Software.
Film Analysis Kit for Existing Vidar DosimetryPRO Advantage or Flatbed Scanner	<p>PC & Software Kit for Existing Vidar DosimetryPRO Advantage or Flatbed Scanner</p> <p>For centers that have an existing Vidar DosimetryPRO Advantage Film Digitizer (USB interface only), or a suitable flatbed scanner with TIFF file export capability, this kit includes:</p> <p>1 Personal Computer, Monitor, Keyboard, Mouse & TomoTherapy Film Analyzer Software.</p> <p>Please provide existing DosimetryPRO Advantage Serial #_____</p> <p>The TomoTherapy Film Analysis software included in this kit is used for machine quality assurance and acceptance testing procedures, and may also be used in patient-specific quality assurance operations (also known as "Delivery QA" or "DQA").</p>



TomoTherapy[®]



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