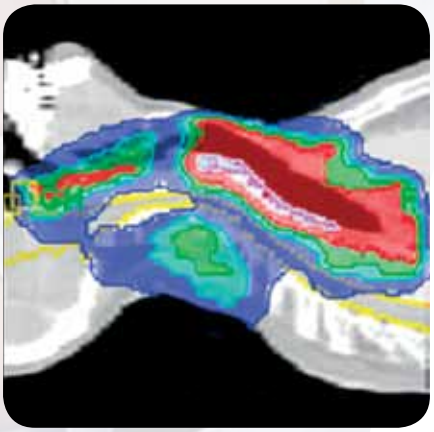
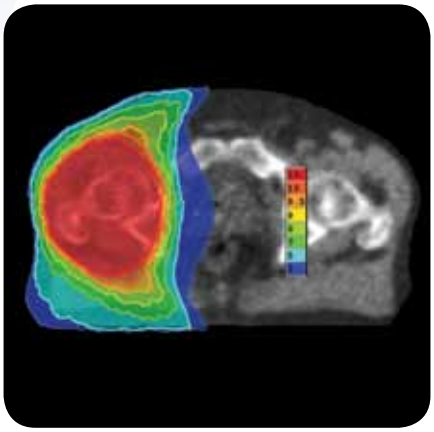
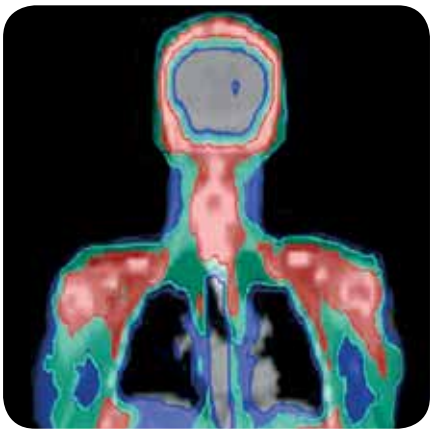
Product Data Sheet

TomoTherapy® Hi·Art® System







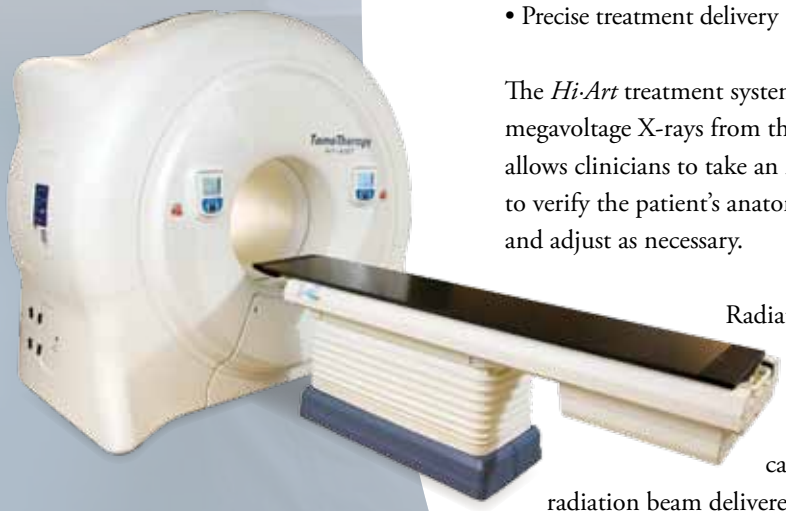
The *TomoTherapy Hi·Art* treatment system incorporates unique design features that combine to deliver highly conformal radiation therapy guided by a specialized multileaf collimator (MLC). Four key advantages include:

- Complete system integration
- CTrue™ imaging technology
- Helical pattern delivery
- Discrete-angle, sliding beam delivery (optional)

At the heart of the *Hi·Art* treatment system is a common database that facilitates the entire therapy process from planning to treatments to archive. The central database facilitates:

- Fast CT-guided dose targeting
- Precise treatment delivery
- Effective adaptive planning
- Easy treatment planning for common and complex cases

The *Hi·Art* treatment system creates verification *CTrue* images using low-intensity megavoltage X-rays from the same linear accelerator used to treat the patient. This allows clinicians to take an MVCT scan immediately prior to any treatment fraction to verify the patient's anatomy and position as compared to the original treatment plan, and adjust as necessary.



Radiation delivery is aided by a sophisticated MLC. This patented device opens and closes quickly to permit (or block) the passage of radiation, dividing the radiation beam into many smaller beams. The pattern of movement is precisely calculated before treatment begins, so the intensity of the radiation beam delivered conforms to the patient's tumor and helps avoid critical structures as the machine rotates 360 degrees around the patient.

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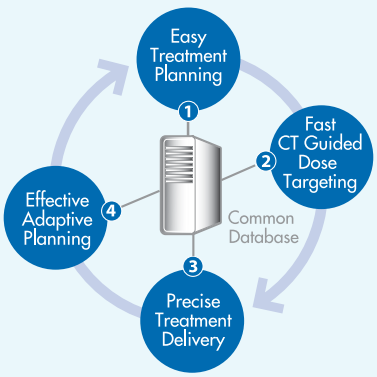
Product architecture

The *TomoTherapy Hi·Art* treatment system consists of the following completely integrated components:

- A linear accelerator and CT detector subsystem mounted to a rotating gantry
- A High Performance patient couch used to move the patient through the rotating gantry
- A laser positioning system to facilitate initial patient placement on the couch and to guide position modification, if necessary, after MVCT registration
- A Planning Station where CT acquisition and structure definition data are used to prescribe a treatment and where optimized treatment plans are evaluated and saved
- An Operator Station where MVCT acquisitions, patient positioning and treatments can be controlled
- A Status Console with a key switch to select procedure type, a start button, stop/emergency stop buttons, and status indicators
- A shared database server, containing patient and machine data used by the entire system
- A computer cluster utilizing dedicated hardware to perform plan optimization and dose calculations
- Tape backup system for the database

Total integration



Product features available from the Planning Station

The *TomoTherapy Hi·Art* Planning Station allows the user to optimize a treatment plan.

CT image import from DICOM compatible systems

The system implements DICOM CT Image Storage as an SCP (service class provider).

RT Structure Set import from DICOM compatible systems

The system implements DICOM RT Structure Set Storage as an SCP, allowing import of RT Structure Set objects (ROI information) from CT simulation systems or treatment planning systems implementing DICOM RT Structure Set Storage as an SCU (service class user).

Structure modification

Imported structure definitions can be modified using simple 2D contouring tools. This feature is not intended as a primary tool for structure definition, but rather as a means of making corrections to previously contoured structures.

Prescription and constraint definition

A prescription can be defined for the treatment, and dose constraints and objectives for both regions at risk (RARs) and targets can also be defined. These constraints and objectives are then used as input for optimized dose calculations. A fractionation schedule for the treatment delivery can also be prescribed.

Dose calculation and optimization for conformal therapy and conformal avoidance IG/IMRT

Following definition of prescription and constraints, the *TomoTherapy Hi·Art* treatment system optimizer calculates the collimator leaf delivery pattern (treatment sinogram) that most closely meets the prescribed constraints (in many cases the constraint and objective requirements may be met or surpassed).

Planned dose deposition is calculated using a collapsed-cone convolution superposition technique that addresses three dimensional scatter and inhomogeneties. This is applied for both optimization and final dose calculations. Three-dimensional dose distributions displayed on orthogonal 2D planes, and dose-volume histograms (DVHs) are available to the user as analysis tools to either accept or modify and re-optimize the planned dose.

Integrated treatment quality assurance tools

Delivery QA (DQA) is fully integrated into the planning software to allow seamless calculation of planned dose into a phantom. The DQA plan can then be selected and delivered from the Operator Station and compared with point dose and film measured in the phantom.

Hardcopy patient plan record

A printed record of the planned treatment, as well as a summary of the treatment's execution, can be created by authorized users from within the *TomoTherapy Hi·Art* software.

MVCT export to DICOM compatible systems

The system provides export of MVCT data sets by implementing DICOM CT Image Storage as an SCU.

Treatment data archiving

Use your existing IT infrastructure to store your data or use an industry-standard storage device (DVD) to archive patient data as patients complete their treatments.

TomoDirect™ or TomoHelical™ planning

Create plans using discrete-angle or helical beam delivery from the same planning system. (*TomoDirect* is an optional feature.)

Product features available from the Operator Station

The *TomoTherapy Hi·Art* Operator Station, located just outside the treatment room, allows the machine operator to control and monitor the administration of a *Hi·Art* radiation treatment. The following features are available on the Operator Station:

Verification MVCT acquisition

Prior to or following treatment, a spiral MVCT data set can be acquired using the *TomoTherapy* machine's linear accelerator as the radiation source, providing a low-intensity megavoltage beam. Images are displayed as they are acquired and reconstructed.

Set-up verification using image registration

MVCT acquisitions can be correlated with a previously acquired treatment planning CT image set to determine the repositioning adjustments for the patient. Registration can be performed automatically, then manual corrections can be applied to the initial estimate using CT data, structure contours, and dose overlays as a guide. These adjustments can then be applied by repositioning the patient, moving the couch prior to treatment (as indicated by the laser positioning system), and/or adjusting the gantry start angle.

TomoHelical CRT or IG/IMRT delivery

Image guided, intensity-modulated radiation therapy (IG-IMRT) – or 3D conformal radiation therapy (3D CRT) is delivered to the patient using the *Hi·Art* system's multileaf collimator.

TomoDirect 3D CRT or IG/IMRT delivery

Available as an option for *Hi·Art* system, *TomoDirect* technology enables efficient discrete-angle delivery with continuous couch motion.

MVCT export to DICOM compatible systems

The system provides export of MVCT data sets by implementing DICOM CT Image Storage as an SCU.

Machine calibration and quality assurance protocols

Calibration protocols are supplied, facilitating quality assurance of detector resolution, image set densities, linac output, and dose calculation.

Hard copy patient treatment record

A printed record of the performed treatment details can be created by authorized users from within the *TomoTherapy Hi·Art* software.

Treatment data archiving

An industry-standard storage device (DVD) is available to archive patient data, as patients complete their treatments.

Simplifying radiation therapy through total system integration

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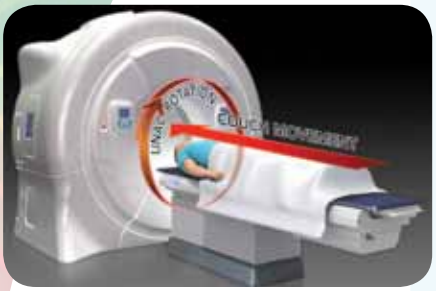
Physical Characteristics



Redefined accuracy

Treatment flexibility

Efficient throughput

Unmatched experience

Mechanical Features

SPECIFICATION	PERFORMANCE
Gantry	
Direction of rotation	Clockwise viewed from the foot of the couch
Rotational angle accuracy	Within 0.5 degrees
Target to axis distance	85 cm
Mechanical isocenter stability	<0.4 mm
Isocenter height	113 cm typical (dependent upon finished flooring)
Cooling	Integrated onboard cooling system

Photon Beam

SPECIFICATION	PERFORMANCE
Accelerator type	Standing Wave (0.3 meters)
Microwave power	2.5 MW (magnetron)
Nominal dose rate**	850 cGy/min
Nominal energy**	6 MV, single energy
Field size range at isocenter	Selectable 1.0 cm x 0.625 cm to 1.0 cm x 40 cm 2.5 cm x 0.625 cm to 2.5 cm x 40 cm 5.0 cm x 0.625 cm to 5.0 cm x 40 cm
Maximum radiation field length	150 cm with Couch at height of isocenter plane
Treatment volume - *TomoHelical*	80 cm (transverse diameter) x 135 cm (longitudinal) for typical patient set-up*
Treatment volume - *TomoDirect*	40 cm (transverse diameter) x 135 cm (longitudinal) for typical patient set-up* (*TomoDirect* is an optional feature)
Average MLC leakage	0.25% (typical)

Collimation

SPECIFICATION	PERFORMANCE
Jaw collimation	
Travel range	1.0 cm to 5.0 cm treatment field width at isocenter
Axis of travel	IEC-y (longitudinal)
Basic dimensional description	13.5 cm tungsten thickness
Multileaf collimation	
Number of leaves	64 binary interlaced leaves (tongue and groove side profile)
Basic dimensional description	10 cm leaf thickness in beam direction
Axis of travel	IEC-y (longitudinal)
Speed of travel	Binary leaf state changed within 20 msec
Resolution	0.625 cm leaf widths in IEC-x (transverse) direction at isocenter
Leaf drive mechanism	Pneumatic

CTrue™ Imaging

SPECIFICATION	PERFORMANCE
Geometry	Fan-beam
Dose per MVCT image (typical)	0.5 - 3 cGy depending on resolution and body thickness
Image resolution (xy)	512 x 512 (0.78 mm pixels)
Slice spacing available	2 mm, 4 mm, 6 mm
Scan time	Typically 2 minutes per 10 cm length at 4 mm slice spacing
Field of view (FOV)	40 cm diameter
Source to detector distance	145 cm
Spatial resolution	Nominal 0.5 lp/mm at 10% MTF
Contrast resolution	2% density for 2 cm object (typical)
Image guidance mode	Daily 3D MVCT matched with 3D kVCT

* Actual treatment volumes are variable depending upon Couch height. Volume measures based upon single set-up, without field matching.
** Performance based on 5 cm field size at SSD=85 cm.

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