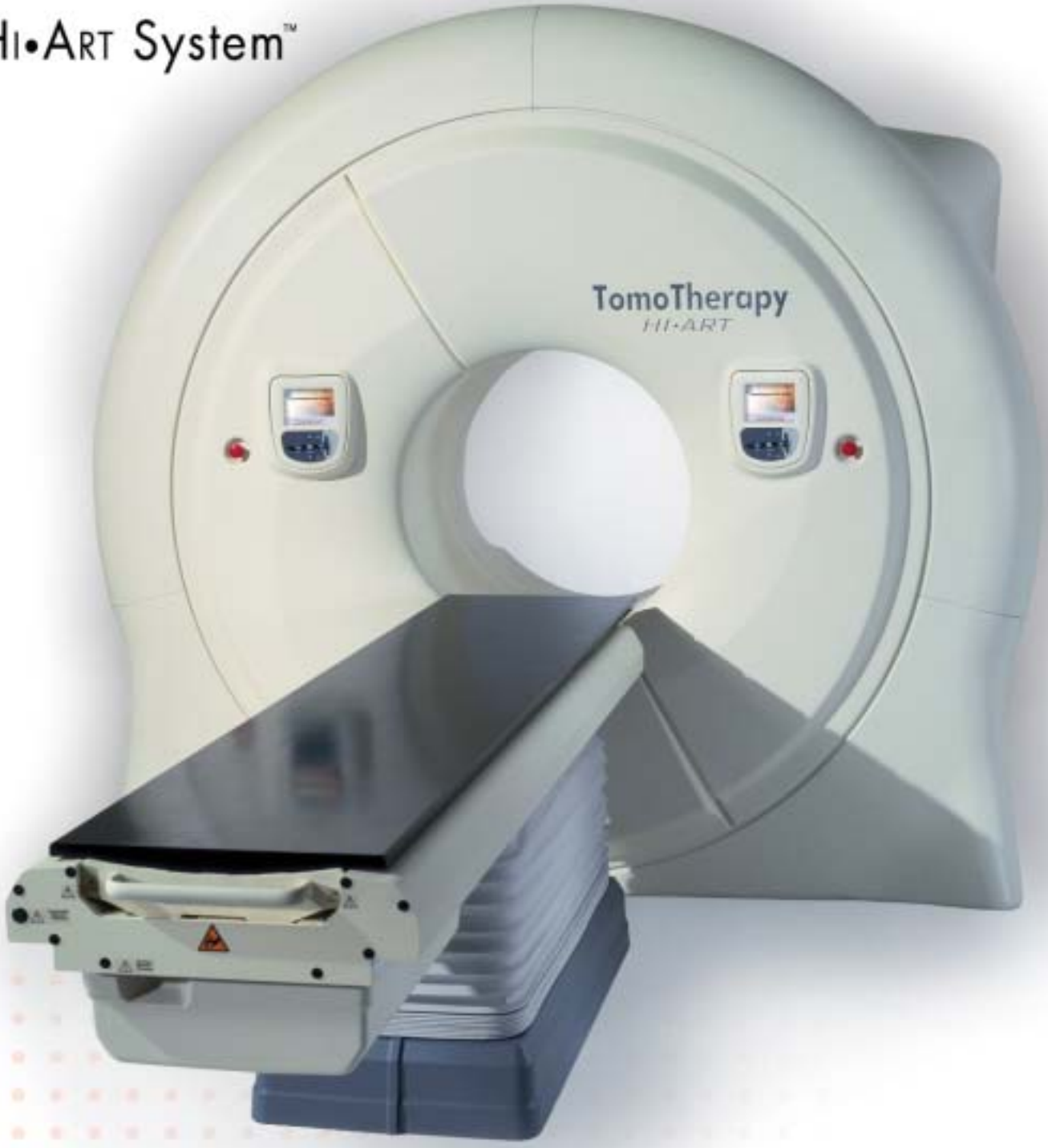
Product Data Sheet

TomoTherapy™ INCORPORATED

Hi•Art System™



TOMORROW BEGINS WITH TOMO™

Overview

The TomoTherapy Hi·Art System® delivers intensity-modulated radiotherapy (IMRT) using a multileaf collimator. One of the most important recent advances in radiation treatment, IMRT involves changing the size, shape, and intensity of the radiation beam to conform the delivered dose to the size, shape, and location of the patient's tumor while conformally avoiding normal structures. The multileaf collimator (MLC), a subsystem of the TomoTherapy Hi·Art System, is a sophisticated design for IMRT delivery.

The MLC is made up of two sets of interlaced leaves, where each leaf can open and close quickly to permit or block the passage of radiation, dividing the radiation beam into many smaller beams. The pattern of movement is based on an optimization program (calculated before treatment begins), so the pattern and intensity of the radiation beam delivered conforms to the patient's tumor and avoids critical structures as the machine rotates around the patient.

The TomoTherapy Hi·Art System also includes a computed tomography (CT) sub-system, which can verify the size, shape, and location of the patient's anatomy just prior to the time of treatment. This is particularly important for tumors next to very sensitive organs, like the eye or the spinal cord. The TomoTherapy Hi·Art System creates CT images (known as TomoImage™ data sets) using low-intensity megavoltage X-rays from the linear accelerator itself. This allows clinicians to take a TomoImage CT scan at any point in the process. By taking a scan before treatment, clinicians are able to verify the patient's anatomy and position, thereby permitting them to quickly update the set up to account for changes in either anatomy or position (or both).

Product Architecture

The TomoTherapy Hi·Art System consists of the following completely integrated components:

- A rotating gantry assembly, upon which the linear accelerator and CT detector subsystems are mounted. The temperature control subsystem is also mounted on the rotating gantry.
- A patient couch, with a composite flat couch top, used to support the patient and move the patient through the rotating gantry.
- A laser positioning system, to facilitate initial placement of the patient on the couch, and also to indicate modified patient positioning after TomoImage registration.
- An Operator Station, located just outside the treatment room, where the operator can control and monitor TomoImage acquisitions, patient positioning, and treatments.
- A Status Console, with a key switch to select procedure type, a start button, stop and emergency stop buttons, and status indicators.
- A Planning Station, where CT acquisition and structure definition data is used to prescribe a treatment, and an optimized treatment plan is evaluated and saved.
- A shared Database Server, containing the patient and machine data used by the entire system.
- An Optimization Engine, where the dose optimization and dose calculations are performed. This device uses dedicated hardware to accelerate the optimization and dose calculation processes.

Physical Characteristics

Machine Geometry

Source-axis distance	850 mm
Bore (patient opening)	850 mm (425 mm radius)
CT detector channels	764 (approx 500 used)
Couch	Variable speed, variable height, composite flat-top

Linear Accelerator

Linac energy (nominal)	6 MV
Linac mode	Photon only (target always present)
Linac pulse rate (maximum)	300 per second

Multi-leaf Collimator (MLC)

Multi-leaf collimator leaves	64 interleaved
Maximum treatment volume	40 cm diameter by 130 cm long cylinder
MLC leaf width	6.25 mm nominal
MLC leaf thickness (shielding)	100 mm
MLC leakage	0.2% outside field 0.5% in-field
MLC leaf material	Tungsten alloy (>90% W)
Maximum MLC leaf transition time	50 ms

Verification CT TomoImage

High-contrast resolution	1.6 mm for 512 x 512 image with 40 cm field of view (at 3 cGy max.)
Soft tissue contrast	3% for 30 mm objects (at 3 cGy max.)
Typical TomoImage patient dose (standard configuration)	0.5–1.5 cGy
Electron density to CT number ratio	Linear with density, including high-Z materials (e.g. bone)

Workstations and Software	
Operator Station	Intel-based, Microsoft Windows® operating system, Java user interface
Planning Station	Intel-based, Microsoft Windows® operating system, Java user interface
Database architecture	Relational (DB2), CORBA communication layer
Database hardware	Dedicated server with RAID system
Dose Optimization Engine	Dedicated parallel-processing hardware

Environmental Requirements

Electrical supply	Recommended 480 VAC, 3 phase (Δ), 60 A per phase (other voltages may be supported)
Treatment Room cooling	30,000 BTU/hr. average, 40,000 BTU/hr. peak
Computer Room cooling	18,000 BTU/hr.
Bunker	Shielded for 6MV
Bunker height (minimum)	3.00 m
Minimum bunker door entrance height	2.03 m
Minimum bunker door entrance width	1.22 m (for adjacent corridor 2.44 m wide)

Product Features available from the Planning Station

CT image import from DICOM 3 compatible systems.

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

RT Structure Set import from DICOM 3 compatible systems.

The system implements DICOM RT Structure Set Storage as an SCP (storage class provider), 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 (storage class user).

Structure modification.

Imported structure definitions can be modified using a simple 2D contouring tool. 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.

An overall prescription can be defined for the treatment, and dose constraints and objectives for both Regions at Risk (RARs) and Targets can be defined. These constraints and objectives are then used as input to the optimization engine. A fractionation schedule for the treatment delivery can also be prescribed.

Dose calculation and optimization for conformal therapy and conformal avoidance IMRT.

Following definition of prescription and constraints, the TomoTherapy dose optimizer calculates the optimized collimator leaf delivery pattern (treatment sinogram) that most closely approximates 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. 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. Pre-calculation of beamlets – the dose distribution for each leaf involved in a plan – allows interactive control of the optimization process.

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 measured dose in the phantom.

Export of TomoTherapy data.

At any stage of planning or treatment, patient data from the TomoTherapy database can be exported as a set of files in an XML format. This data can then be read by external systems.

Hardcopy patient 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 software.

Treatment data archiving.

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

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Product Features Available from the Operator Station

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

Verification CT TomoImage™ acquisition.

Prior to or following treatment, a spiral TomoImage CT 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.

Setup verification using image registration.

TomoImage 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), or adjusting the gantry start angle.

Helical TomoTherapy IMRT delivery.

Intensity-modulated radiation therapy (IMRT) is delivered to the patient using TomoTherapy's patented multileaf collimator.

Treatment restart.

In the case of an interrupted treatment fraction delivery, the undelivered portion of the scheduled fraction can be restarted and completed without manually replanning the fraction.

TomoImage export to DICOM 3 compatible systems.

The system provides export of TomoImage data sets by implementing DICOM CT Image Storage as an SCU (storage class user).

Machine calibration and quality assurance protocols.

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

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