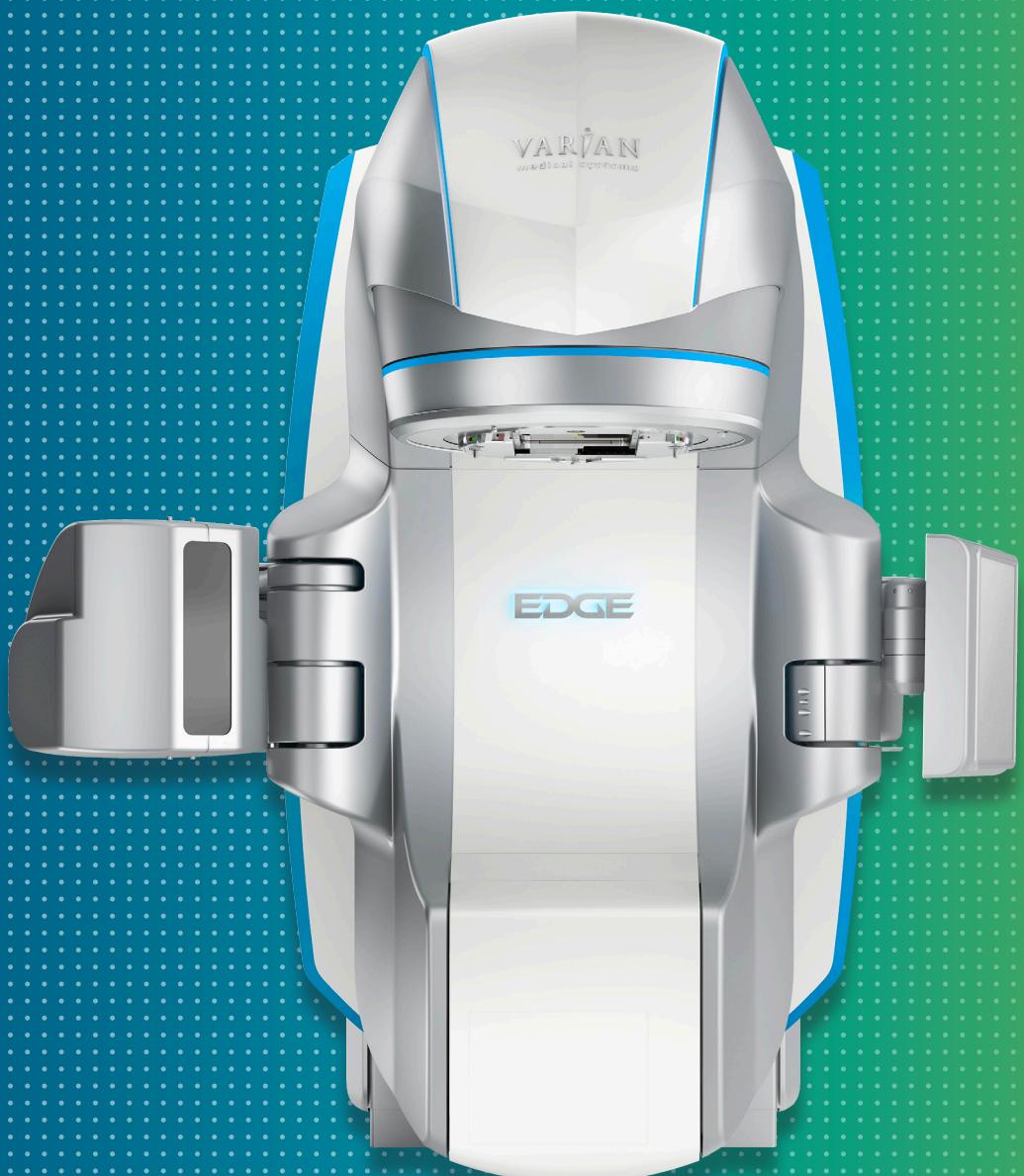


Edge™ Radiosurgery System



Specifications

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Section 1: Technology Introduction

The Edge™ radiosurgery system offers an end-to-end, clinical turnkey solution for the radiosurgery market. This technology provides clinicians with a fully integrated Varian system to deliver advanced radiosurgery treatments. Features included on the Edge radiosurgery system have been specifically designed and chosen to ensure that the stereotactic radiosurgery (SRS) requirements of a clinic are met. These innovative tools work together to create a streamlined workflow from treatment planning to real-time target tracking and precise dose delivery, giving clinicians confidence throughout the entire treatment cycle. By offering this technology as a single solution with sub-millimeter accuracy and real-time tracking capabilities, the Edge system enables clinicians to deliver a wide variety of treatments with precision and efficiency.

The system delivers radiation with a sub-millimeter accuracy* of better than 1 mm when used with a planning CT image set of minimum slice thickness of 1.25 mm. Accuracy includes an accounting of the major spatial uncertainties in clinical process including uncertainties in CT scanning, treatment planning, patient positioning and data transfer.

The Edge radiosurgery system includes the following highlights:

- Treatment Delivery System
 - Small vault configuration with integrated MV imager for High-Intensity Mode beam Portal Dosimetry
 - High-Definition 120 Multileaf Collimator (HD 120™ MLC) for the finest beam shaping and sculpting capabilities
 - High-Intensity Mode with dose rates up to 2400MU/min
 - RapidArc® radiotherapy technology delivery
 - Advanced imaging features including
- 2D/3D match
- kV Imaging based on gantry angle travelled, MU delivered, elapsed time or respiratory gated signal
- Treatment planning structures projection on pre-treatment fluoroscopic trace
- High contrast MV imaging with extended field of view
 - Integrated PerfectPitch™ 6 degrees of freedom (6DoF) couch
 - Intracranial real-time tracking (Optional)
 - Extracranial real-time tracking (Optional)
- Treatment Planning Solution
 - Eclipse™ treatment planning system
- Integrated software tools
- ARIA® oncology information system for radiation oncology (Optional)

*Functional capability of the gantry, collimator and couch; data on file.

Section 2: Treatment Delivery System

The treatment delivery features on the Edge radiosurgery system have been designed specifically to deliver stereotactic radiotherapy treatments. The power and speed of the delivery system enables clinicians to deliver accurate treatments with efficiency. Reducing the overall time it takes to treat a patient may lead to an increase in the volume of procedures performed and lower per procedure costs for the hospital when compared to traditional surgery procedures.

When delivering high doses over fewer fractions, increasing patient safety and monitoring motion throughout treatment becomes paramount. Using safety and motion monitoring tools can help assure clinicians that the target is hit. Edge is the only system that tracks the motion of the target in real-time for intracranial and extracranial treatments in all six-degrees of freedom. Automation helps guide and maintain the accuracy of treatment delivery by continually tracking patient movements and adapting treatments as the target moves during the procedure, thereby decreasing the risks of unwanted dose to adjacent organs and tissues. The tools integrated in the treatment delivery system provide the clinician with confidence to deliver stereotactic treatments with accuracy.

Section 2.1: Machine Specifications

Fast and accurate delivery of highly conformal dose distributions and steep gradients is the hallmark of the Edge system. Leveraging the highest dose rate in the industry, 2400MU/minute with High-Intensity Mode, Edge treatments allow for shorter treatment times, which may enhance patient comfort. With this high dose rate, treatments delivered by the machine must be accurate. Every step of the Edge treatment is characterized by accuracy so treatments can be delivered with confidence.

Section 2.1.1: Beam Specifications

The following energies and modes are offered:

Table 1: Output Energies

Performance Specifications	Specification
Maximum output dose rates	6X High-Intensity Mode up to 1400 MU/min (standard) 10X High-Intensity Mode up to 2400 MU/min (optional) 6 MV up to 600 MU/min (optional)

Section 2.1.2: Delivery System Specifications

The Edge system features a linear accelerator that is designed to deliver radiation with sub-millimeter accuracy. The delivery system features the Maestro control architecture that monitors the status of each of the machine sub-systems at a rate of 10Hz. This real-time infrastructure ensures that the delivery system is operating within desired specifications, providing confidence in the accuracy of treatment delivery. Automation within the system helps guide and maintain the accuracy of the treatment delivery specifications listed below.

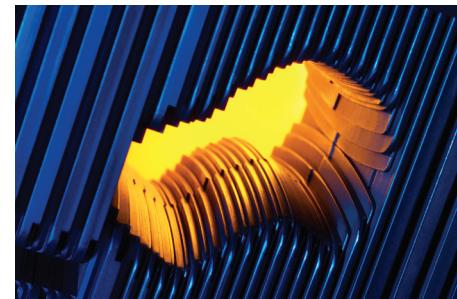


Table 2: Accuracy

Performance Specifications	Specification
Gantry rotational accuracy	≤ 0.3 degrees
Gantry rotational range	± 185° from the vertical
Gantry and collimator isocenter accuracy	≤ 0.5 mm radius
Gantry, collimator, and couch isocenter accuracy	≤ 0.75 mm radius
Descriptive Specifications	Specification
Rotation speed	Variable from 0 to 1 RPM
Target to gantry axis distance	100 ± 0.2 cm
Isocenter height (relative to the floor)	129.5 cm = 0.5 cm / -0 cm

Section 2.2: Collimation Specifications

The Edge system provides high-definition and high accuracy radiation beam collimation options. The high-definition 120 multileaf collimator (HD 120 MLC) utilizes 2.5 mm width leaves to deliver treatments directly to the tumor while potentially sparing surrounding healthy tissue. Patient safety is increased during intracranial SRS treatments by using the Integrated Conical collimator Verification & Interlock (ICVI) system. The system provides an automated and electronic correlation of plan requirements for cone sizes with the physical cone present in the system.



Section 2.2.1: High-Definition 120 Multileaf Collimator (HD 120 MLC)

Table 3: High-Definition 120 Multileaf Collimator Specifications

Performance Specifications	Specification
MLC leaf end position accuracy at all leaf positions relative to the collimator axis ¹	± 1 mm
MLC leaf end position reproducibility at all leaf positions relative to the collimator axis ¹	± 0.5 mm
Descriptive Specifications	Specification
Leaf side accuracy relative to the collimator axis, projected at isoplane (gantry at 0) ²	≤ 0.1 mm
Number of leaves	120
Central high resolution leaf width (central 8 cm, leaf width projected at isocenter)	2.5 mm
Outboard leaf width (outer 14 cm, leaf width projected at isocenter)	5 mm
Maximum static field size ³	40 cm x 22 cm
Maximum static aperture field size ³	30 cm x 22 cm
Maximum IMRT field size ³	32 cm x 22 cm
Maximum leaf retract position	20.1 cm from centerline
Maximum displacement between adjacent leaf ends at a single carriage position	15 cm
Average leaf transmission ⁴	< 2.0%
Maximum interleaf leakage ⁴	< 2.5%
Maximum combined collimator leakage (jaws and MLC closed), all energies ⁵	< 0.02%

Descriptive Specifications	Specification
Mean leakage-area product per Gy delivered ⁶	< 0.15 mGy ²
Maximum carriage speed	Variable from 0 to 12 cm/sec
Maximum leaf speed	Variable from 0 to 2.5 cm/sec
Relative leaf accuracy, leaf end to end	0.25 mm
Minimum static leaf gap (leaf end to leaf end)	0.0 mm
Minimum dynamic leaf gap (leaf end to leaf end)	0.5 mm
Leaf end penumbra at D_{max} ⁷⁻⁸	< 3.5 mm
Leaf integration	Yes
Independent leaf and carriage motion	Yes

¹ Projected at the isoplane.

² Represents alignment of MLC to collimator Y-axis, based on center leaf edge position under static conditions, gantry at 0°.

³ Maximum physical field size, projected at the isoplane.

⁴ Leakage specified as percentage of total dose per field or dose segment, measured with jaws fully retracted, using 4 MV through 10 MV High Intensity configurations. Significant reduction in interleaf transmission is provided with static jaw shielding outside the treatment aperture or dynamic jaw tracking of aperture.

⁵ Maximum combined collimator leakage includes MLC and jaws and is measured for all energies. Mean leakage is 0.01%.

⁶ Mean leakage-area product represents integral leakage dose over the combined aperture area defined by the MLC and jaws. Leakage area product is calculated based on using 1 Gy dose output, a 5 cm radial MLC aperture and a jaw aperture of 10.4 cm x 11.6 cm.

⁷ Penumbra defined as 20-80% leaf end, measured using 10 cm x 10 cm field size, 6 MV at D_{max}, 100 cm SAD.

⁸ For additional IEC performance specifications for the MLC, please refer to 100042130 TrueBeam, TrueBeam STx, and Edge IEC Type Tests, 10042132. TrueBeam, TrueBeam STx, and Edge IEC Site Tests and Procedures, 100043560, TrueBeam, TrueBeam STx, and Edge IEC 60976, Medical Accelerators – Fundamental Performance Characteristics.

Section 2.2.2: Integrated Conical Collimator Verification and Interlock (ICVI) System

The Integrated Conical Collimator Verification and Interlock System provides a robust and verifiable method of mounting and electronically verifying conical collimators. ICVI correlates the physically inserted conical collimator with the requirements of the treatment plan. An incorrect cone size triggers an interlock thereby increasing patient safety.

Features of the ICVI System are as follows:

- Integrated Conical Collimator Verification and Interlock System for electronic and automatic collimator verification with plan requirements
- 7 conical collimators of the following sizes: 4, 5, 7.5, 10, 12.5, 15 and 17.5 mm
- Jaws automatically set to 5 cm x 5 cm

Section 2.3: PerfectPitch 6 Degrees of Freedom (6DoF) Couch Specifications

The Varian PerfectPitch 6DoF couch helps to deliver advanced radiation therapy techniques with a high level of accuracy and reproducibility without compromising clinical workflow. Couch operation and verification are fully integrated into the system user interface, enabling a seamless workflow.

Features of the PerfectPitch 6-Degree of Freedom (6DoF) Couch are as follows:

- Fully-robotic position of the patient using 6-degrees of freedom
- Sub-millimeter positioning accuracy in both translations and rotations
- Fully integrated with imaging system and ARIA oncology information system for reporting patient repositioning and for facilitating delivery of robotic treatments



Table 4: Varian PerfectPitch 6DoF Couch Specifications

Weight Limit	Specification
Couch weight limit	150 kG (330 lbs), evenly distributed
Motion Range	Specification
Lateral (cm from centerline)	$\geq\pm24.5$ cm
Vertical (+1/-0 cm)	106 cm
Longitudinal	≥145 cm
Pitch and roll ($\pm0.25^\circ$)	$\pm3^\circ$
Rotational (yaw) about isocenter	$\pm95^\circ$
Accuracy	Specification
Rotational (yaw) accuracy for fine patient positioning 0° to $\pm6^\circ$	$\leq0.3^\circ$
Rotational (yaw) accuracy for large rotations, greater than $\pm6^\circ$	$\leq0.4^\circ$
Accuracy for fine patient positioning (±5 cm about mechanical isocenter with 6DoF) ¹⁻²	≤0.5 mm

¹ Performance specified for a patient weight of 30-135 kg, within a vertical travel range extending from couch top positioned at isocenter to -20 cm below isocenter.

² For patients over the entire weight range (up 150 kg) the spatial translational accuracy performance specification for small patient shifts (±5 cm) is 0.7 mm and for large patient shifts (±20 cm) is 1.9 mm.

Section 2.4: Intracranial Real-Time Tracking

It is important to deliver high doses of radiation within the brain at sub-millimeter accuracy. The Edge system goes beyond localizing and positioning the patient with accuracy. The Edge system uses real-time surface tracking to monitor target motion after patient set up has been completed. Real-time and accurate assessment of target location during beam delivery is combined with the instantaneous beam gating capability of Varian linacs. This combination can allow clinicians to reduce uncertainty margins, which is critical when delivering to challenging targets in the brain.

The Optical Surface Monitoring System (OSMS) employs proprietary 3D imaging technology to produce high resolution and accurate 3D surface data referenced to the treatment isocenter. These tools allow the user to compare the treatment position with the reference surface both inside the treatment room and remotely. The markerless system's optical guidance provides advanced real-time 3D monitoring capability which may be used remotely from the control room. A continuously updating display shows motion in all six degrees of freedom and may be viewed throughout treatment. In addition, selected regions of the patient's surface may be monitored in real time. Movements outside user-defined tolerances are detected automatically and the beam can be gated.

Table 5: Optical Surface Monitoring System Selected Specifications

Accuracy	Specification
3D surface data	Root Mean Square (RMS) error of surface data < 1 mm
Positioning accuracy	RMS target registration error (TRE) < 1 mm
FSD measurement	RMS error < 2 mm
Calibration drift	Typically < 1 mm per month
Speed	Specification
3D reconstruction time	Static capture (average processing time): ~3 seconds, monitoring mode: typically < 1 second
Auto-positioning time	~1 second (for standard corrections), acquisition time (single frame): 2 ms - 25 ms
Time from user initiation of capture until acquisition of data	< 1 second
Coverage	Specification
	Typically 10,000-20,000 3D points per reference model

Section 2.5: Extracranial Real-Time Tracking

The Calypso® system is an internal localization system designed for use during radiation therapy. It provides accurate, objective, and continuous non-ionizing target localization information for initial patient alignment and/or for target position monitoring during radiation treatment delivery. Use of Calypso for target localization is based on the system's detection of electromagnetic signals generated by electromagnetic Beacon® transponders. These transponders can be implanted in or near the treatment target, or placed on the patient's skin surface.

The Calypso system for real-time direct tumor tracking includes the following features:

- Target position update rate of 25 Hz, optimized for tracking the motion of fast moving targets
- Adaptive couch repositioning
- Treatment beam gating for precision radiation delivery

Table 6: Calypso System Specifications

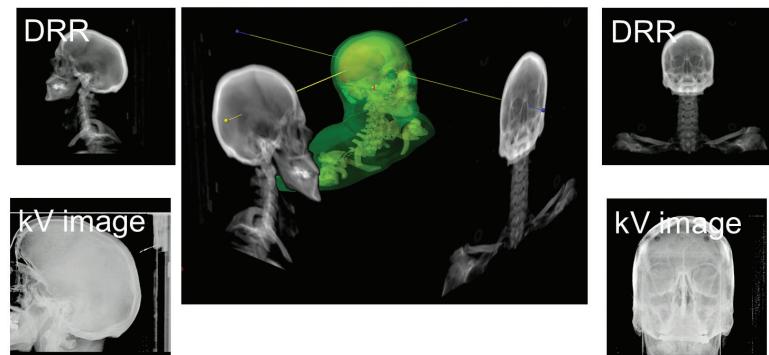
Array Attenuation and Water Equivalence	Specification
Beam attenuation	Less than 2% at 6cm depth for 6MV photons
Electron Scatter Generation	Less than 3 mm water equivalence thickness
Accuracy & Precision	Specification
Mean setup accuracy	0.68 mm
Standard deviation setup accuracy	0.27 mm
Mean peak tracking accuracy	0.80 mm
Standard deviation peak tracking accuracy	0.31 mm
Interfaces	Specification
Adaptive Couch Repositioning™	Reposition patients during tracking without entering the treatment room. Shift values are calculated based on most recently updated target positions during treatment.
Dynamic Edge Gating	Automates the response to organ motion with a continuous, real-time signal to the linear accelerator. Low tracking latency optimized for prostate applications (mean latency <350 milliseconds for recommended operating conditions)

Section 2.6: Advanced IGRT and Motion Package

Addressing the effects of motion remains one of the significant challenges facing clinicians when delivering radiation to moving targets. Correct initial patient setup and intra-fraction motion monitoring are vital when using the Edge system. The integrated advanced IGRT and motion feature incorporates a set of imaging tools designed to provide meaningful information to clinicians at the time of patient setup and treatment delivery. By using these tools, the user can have flexibility to image and deliver treatment based on target location, target motion or delivered dose considerations. Additionally, the tools give the clinician added confidence that treatment stays on target. By using these tools, clinicians are no longer constrained to image according to what was originally planned.

Standard Features:

- kV, CBCT and MV imaging at any time during a treatment session based on triggers determined by:
 - Respiratory motion
 - Delivered dose (MU)
 - Elapsed time
 - Gantry angle
- Instant imaging and 2D/3D auto matching
- Advanced reconstructor including:
 - 4D CBCT (offline feature)
 - Extended length CBCT (offline feature)
- Planning structures on pre-treatment fluoroscopic trace
- On-line image approval
- Auto beam-hold
- Auto beam-hold validated to work with gold seed (cylindrical markers) for prostate and liver



Patient Setup Capabilities:

Patient breathing can vary from day to day and this can impact target motion. Pretreatment fluoroscopic imaging is an excellent tool to evaluate this motion. The advanced IGRT and motion feature extends the toolkit to confirm target location in real-time during setup.

- Pretreatment fluoroscopy features:
 - Contours from DRR superimposed onto pre-treatment fluoroscopy images
 - Gated or non-gated overlay of planning structures on fluoroscopy image
 - All contours will blink in synchrony with respiratory gating signal
 - MLC, jaws and block field aperture definitions
 - Gating thresholds can be verified for gated treatments

The 2D/3D match feature allows the user to compare, in real time, the relationship between target location at the time of treatment planning and the location during treatment. By automatically generating DRRs, users can spend less preparation time and can use the images to determine the 2D-3D match.

- 2D/3D features:
 - Algorithm searches over a larger anatomic range to find optimal automatch position
 - Robust to out-of-plane rotations
 - Calculates pitch and roll positioning values
 - May reduce intra and inter-user variability

Imaging During Treatment Capabilities:

Much effort goes into outlining a patient's key anatomical structures during treatment planning so that clinicians can customize treatment. The advanced IGRT feature puts imaging control in the hands of users at the point of treatment. Now the outline of these 3D structures can be projected onto real-time triggered kV and fluoroscopic images for assurance of targeting accuracy. Planned structure projections will be available with all triggered options, not just gating. MLC, jaws and block field aperture definitions can be projected onto radiographic and fluoroscopic images.



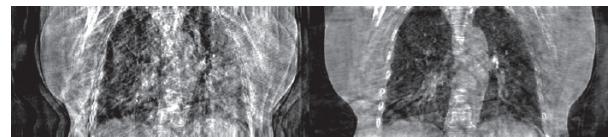
Imaging during treatment with planning structures superimposed

Additionally, clinicians have the ability to add circular regions of interest to triggered images when markers have been identified in the plan to confirm the target is within an acceptable location. By using the following tools, the clinician is no longer constrained to image according to what is planned.

- Approve images at treatment console
- The outline of 3D structures from treatment planning can be projected onto real-time triggered kV for assurance of targeting accuracy
- Structures outlined during treatment planning in 3D can be reconstructed and overlaid on to real-time, triggered kV images for assurance of targeting accuracy and desired target alignment with beam orientation
- Targets can be confirmed within the acceptable location by adding circular tolerance overlays to triggered images when markers have been identified in the treatment plan
- Triggering options:
 - Using on-demand imaging, additional kV image triggers can be deployed at any time during the treatment based on MU delivered, gantry angle, or elapsed time options for flexibility in addressing motion challenges. This provides the clinician with maximum flexibility in determining the appropriate imaging protocol based purely on the patient's unique requirements. Imaging may also be triggered by respiratory gating output with planned contour overlay.
 - Overlay of structures on triggered images confirms target location without holding beam delivery

Post-Treatment Capabilities:

Treating moving targets, such as in the lung, can be challenging. Analyzing target motion, and verifying that it stays consistent during the treatment course, is vital to successful treatments. By using the Advanced Reconstructor, the clinician has the ability to:



Basic and Advanced 4D Reconstruction Images

- Generate 4D cone-beam CT datasets to assist in determining motion of targets affected by respiration. The dataset from the improved 4D CBCT image quality can be compared with the 4D CT in the Eclipse treatment planning software.
- Generate extended length CBCTs for treatment cases that require large field images, beyond what can be captured in one image rotation. When treatment is complete, users can construct and combine several CBCTs to create a single extended length data set which can later be reviewed in Eclipse for dose recalculation, once again taking advantage of Varian's integrated radiosurgery solution.

Section 2.7: Immobilization

The following SRS and SABR immobilization packages are offered with the Edge system.

Table 7: Edge Intracranial Package

Qfix Description
Portrait Head & Neck Insert
Silverman Head support single patient, reusable
MoldCare 20 cm x 35 cm
Open Face Fiberplast Mask, 3.2 mm, perforated, Consumable, Set of 10
Stainless Steel Aquapan

Table 8: Edge Extracranial SABR Package

Qfix Description
100 cm x 70 cm Vac-Q-Fix Cushions (reusable 1 Year warranty)
Vac-Q-Fix Indexer
Locating Bar - single half moon Calypso compatible
SofTouch Elite™ Bellyboard
RT Pump and Hose for Vac Bags

Section 3: Eclipse Treatment Planning System



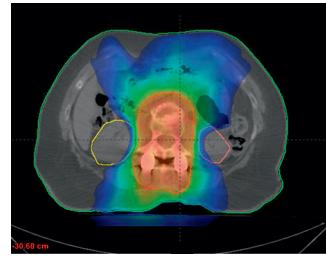
The integrated treatment planning solution provided on the Edge system plays an important role in delivering high-speed and precise treatments. The Eclipse treatment planning system is the foundation of the Edge treatment planning solution. The Eclipse treatment planning system simplifies the development of complex radiation treatment plans. A comprehensive toolset within Eclipse provides the infrastructure for increased consistency and efficiency in the planning process. The integrated features with Eclipse allow the clinician to customize treatment plans to the patient's individual disease.

The features that are discussed in the sections below work together to create a streamlined workflow process for all clinicians involved in the treatment planning process. Treatment planning modules provide treatment delivery decision support tools to help streamline decision-making in advance. By using these tools provided with the Edge system, clinical resources in a radiation department may be optimized.

Section 3.1: RapidArc Radiotherapy Technology

With Varian's end-to-end radiosurgery solution, the Edge system includes RapidArc radiotherapy technology fully integrated with the Eclipse treatment planning system. By using RapidArc, clinicians have the ability to deliver personalized treatments in a standard radiotherapy treatment slot. Advanced treatment plans based on automated suggestions can be created. By simultaneously shortening treatment times and enhancing treatment accuracy, RapidArc technology represents a significant advance for improved patient experience and increased efficiency of radiation oncology departments. Features of the integrated RapidArc radiotherapy technology offering include:

- With RapidArc, clinicians will be able to increase speed and efficiency in their department which presents a powerful solution for treating a broad range of cancers with the Edge system. Clinicians may use RapidArc to deliver precisely sculpted 3D dose distribution to single or multiple metastatic lesions for stereotactic ablation of inoperable and high-risk operable tumors. The speed and precision of the RapidArc solution enable clinicians to quickly adopt RapidArc to meet treatment needs by using the following features:
 - Clinicians can plan for multiple lesions and challenging treatments while optimizing planning time. Single isocenter treatments can simplify treatment planning, may expedite patient setup and can significantly reduce the time a patient spends on the treatment couch.
 - Surgeons, oncologists, dosimetrists and physicists can collaborate in real-time during plan optimization and creation and together can interact with the system to effectively personalize treatment plans.
 - Intelligent planning tools provide an easy and more streamlined planning process in a multidisciplinary setting. These features include:
- Arc Geometry Tool: Make decisions fast and improve precision. This tool suggests an optimal starting point for arc placement, taking into account tumor size and location, as well as specific accelerator parameters.
- Avoidance Sectors Tool: Multiple partial arcs can be avoided by using avoidance sectors within one arc for faster treatment delivery. Treatments are delivered in one large arc, while the beam is turned off using the avoidance sector tool.
- Planning Objective Templates: Time is saved by storing planning objectives in templates. They can later be recalled later for similar patients.
- RapidArc Verification Plan: Portal dosimetry or phantoms can be used to verify the RapidArc treatment plan and help ensure accurate plan quality and treatment delivery to the patient. Split arcs into multiple partial arcs for convenient planning QA.



Chordoma (1 ARC, 74 SEC)

- With RapidArc, clinicians can focus on precision.
 - Features give clinicians more possibilities to treat a wide variety of cases with accuracy. RapidArc is a volumetric arc therapy that delivers a precisely sculpted dose distribution. Treatments can be delivered in single, multiple and non-coplanar arc segments, depending on the clinical case. The optimization algorithm of RapidArc adjusts not only the treatment aperture, but also the rotational speed of the gantry and the delivery dose rate. These adjustments work together to maximize tumor control while minimizing dose to surrounding healthy tissues.
- The patient experience is enhanced with RapidArc. Improved treatment planning creates the opportunity for improving how a patient receives treatment. RapidArc technology uses a dynamic multileaf collimator that enables the delivery of modulated dose to tumors, while minimizing dose to surrounding healthy tissue. Shorter treatment can lessen the interruption to patients' daily lives.

Section 3.2: Eclipse Cone Planning

Eclipse cone planning provides planning and dose calculation using stereotactic cones and localization systems that are provided with the Edge system. These features allow clinicians to deliver cone-based treatment plans. Support for frame or frameless immobilization gives clinical staff the flexibility to choose the ideal treatment approach and continue to expand treatment techniques in their oncology program. The software includes advanced editing tools for arc field and arc set:

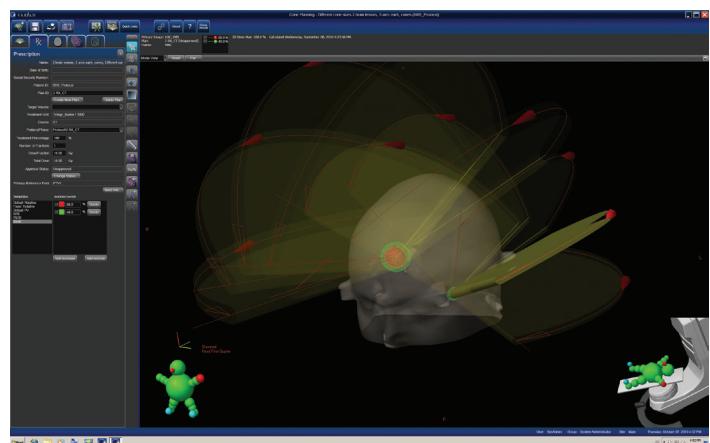
- Move single or all isocenters
- Adjust isocenter spacing and rebalance weight to help avoid hot spots between multiple isocenters
- Change order of treatment fields

Additionally, there are a number of key features within the software that assist with planning stereotactic treatments:

- Supports MR pre-planning
- Visualize immediate dose updates and display in 2D image datasets
- Provides 3D dose calculation on a distributed calculation framework

Additional features include:

- Software includes pre-defined arc set templates, plan reports and checklists
- Attached clinical protocol references
- Verify cones at the treatment console
- Open plans with multiple reference points
- Edit couch rotation graphically
- Radiosurgery absolute phantom



Section 3.3: Acuros XB

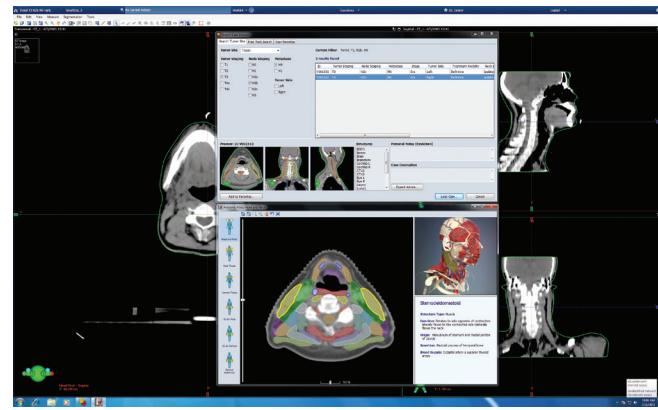
The Acuros® XB advanced dose calculation algorithm was developed to address two strategic needs of modern techniques in radiation therapy: accuracy and speed. Heterogeneities introduced by materials such as lung, bone, air, and non-biologic implants may significantly affect patient dose fields, especially in the presence of small or irregular fields that are often treated with radiosurgery. Acuros XB provides comparable accuracy to Monte Carlo methods in treatment planning for the full range of X-ray beams produced by clinical linear accelerators, 4 MV – 25 MV.

Section 3.4: SmartSegmentation Knowledge-Based Contouring

SmartSegmentation® knowledge-based contouring combines the ability to use either an atlas or model-based approach for automated and manual segmentation of patient structures. Used with the Eclipse treatment planning system, it facilitates the definition of targets and organs at risk in an efficient and consistent manner. SmartSegmentation provides the following key benefits:

- Access to a library of cases contoured by experts, including:
 - Expert case browser
 - Tumor site and stage specific search filters
 - Free text search
- Ability to create personalized expert case
- Ability to modify and edit existing expert case library
- Access to clinical commentary on tumor volume for each expert case
- Use of several 2D and 3D tools to edit structures and adapt a plan according to clinical preference
- Use of the fully integrated Eclipse treatment planning system

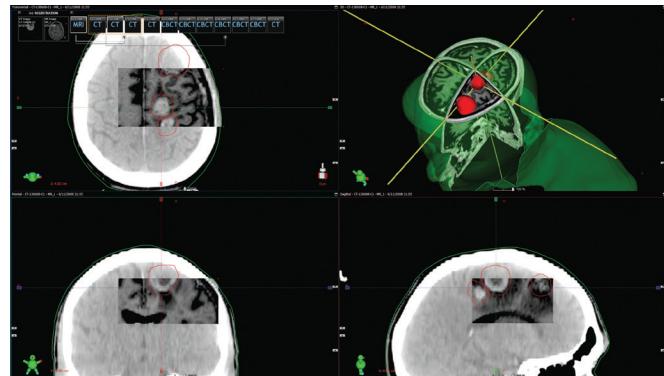
SmartSegmentation analyzes the content of CT images and automatically delineates anatomical structures relevant for radiotherapy purposes. As an automated tool, it independently segments incoming CT image series and provides structure sets in DICOM format for subsequent import by other applications.



Section 3.5: SmartAdapt

The SmartAdapt feature in Eclipse enables clinicians to easily track and adapt to interfractional changes in anatomy of the patient throughout the treatment. Some tools of SmartAdapt are as follows:

- Interactive deformable registration and segmentation tools to quickly visualize and address differences between MR, planning CT and CBCT images. Automatically deform and propagate initial contours to match the current anatomy, and edit or fine tune the changes using a variety of 2D and 3D contour editing features.
- Blending, color mapping, and difference rendering, as well as deformation-specific information
- Advanced statistics analysis tool allows tracking of relevant changes
- Multi-modality image review
- PET and relative intensity-based contouring capabilities
- Deformable image registration, MR, CT and CBCT
- Manual deformable registration editing
- Automated, manual, point-based rigid multi-modality image registration (CT, MR, PET, and CBCT), including registration chaining
- Multiple registration and constraint settings
- Automated structure propagation between registered images
- Structure editing tools for 2D and 3D
- Display of statistics for volume and center mass changes for co-registered structures
- Correlated window leveling
- Review and approval of structures
- Registration approval



Section 4: Oncology Information System (OIS) Solution (Optional)

The integrated oncology information system solution is the final integrated feature that supports the proficiency of the Edge radiosurgery system. The solution enables clinicians to make informed confident decisions throughout the course of treatment. By using this tool provided with the Edge system, radiation departments have the ability to efficiently manage their patients' journey from diagnosis through survivorship.

Section 4.1: ARIA Oncology Information System for Radiation Oncology

The ARIA oncology information system for radiation oncology is a powerful information and image management solution designed to support the needs of clinicians and patients. The tools provided in ARIA simplify the radiation therapy process and help clinicians to deliver quality, consistent care. Information from radiation, medical and surgical oncology is combined into a complete, oncology-specific EMR that allows clinicians to manage the patient's entire journey. Features of ARIA include:

- Prescription and treatment plan management, complete with up-to-date dose recording, RT treatment summaries and treatment image review
- Physics chart check functionality and other clinical process control features such as configurable checklists and barcode technology
- A unified Varian environment is created when ARIA is integrated with the Eclipse treatment planning system on the Edge system. This unified system expedites the transition from plan creation to treatment delivery by eliminating time-consuming and duplicative plan import/export and QA steps.

ARIA allows clinicians to establish dependences between specific activities to continually drive workflow using the following tools:

- User-specific home pages
 - Each staff member's personal user home screen contains all appointments and tasks assigned to them or to their group. Potential staff or equipment gaps can be rapidly identified using at-a-glance views.
- Visual care paths
 - Intuitive, template-based flow charts that provide consolidated, graphical view of each patient's treatment course, including the status and due date of all activities related to their care.
- Automatic task escalation
 - When a clinical task has been completed, the staff member responsible for the next activities in the sequence of events is automatically notified. ARIA can be configured to notify other staff members when the task is overdue. This powerful feature can accelerate care delivery in departments by uncovering any workflow bottleneck or inefficiencies that may exist.
- Radiation therapy summary
 - A summary of radiation dose and all treatment images for each patient are automatically saved in the database and graphically displayed for easier review.
- Checklists and templates
 - Systematically enforce department protocols through the use of customizable checklists and templates. The use of the tools can standardize care and help ensure compliance with the safety practices clinicians establish in their centers.
 - Configurable checklists can provide important cues and reminders to staff as they perform clinical activities that may impact patient safety. The use of checklists eliminates ambiguity about the specific steps staff are expected to perform or the information they must verify prior to the completion of any task in the treatment planning or delivery process.



Section 5: Edge Radiosurgery System Configurations

Varian offers the Edge Radiosurgery System in three configurations: Edge full-body system, Edge intracranial system and the Edge extracranial system. Each package provides optimal capabilities that have been specifically chosen to help clinicians successfully carry out desired treatments.

Section 5.1: Edge Full-Body System

The Edge system is Varian's offering into the dedicated full-body radiosurgery market. The product provides optimal capabilities for delivering state of the art intracranial SRS and extracranial SABR treatments anywhere in the body where radiation is indicated. The system offers a full, integrated solution for treatment planning, oncology informatics and treatment delivery. Characterized by sub-millimeter accuracy and real-time tracking, the Edge system can be used to deliver a wide range of treatments with efficiency anywhere in the body where radiation is indicated.

Standard features of the Edge full-body package are as follows:

- Small vault configuration
- RapidArc radiotherapy delivery
- Advanced imaging features including:
 - 2D/3D match
 - KV Imaging based on gantry angle travelled, MU delivered, elapsed time or respiratory gated signal
 - Treatment planning structures projection on pre-treatment fluoroscopic trace
- Advanced reconstructor features including:
 - 4D cone-beam CT (offline mode)
 - Extended length cone-beam CT (offline mode)
- PerfectPitch 6 degrees of freedom couch with a Calypso compatible couchtop
- 6X High-Intensity Mode for delivery of radiation at 1400MU/minute
- HD120 MLC for the finest beam shaping and sculpting capabilities
- 43 cm x 43 cm MV imager qualified for high dose rate flattening filter free radiation beams
- Developer Mode license
- Respiratory positioning package including:
 - Optical imager
 - Respiratory gating
 - Dynamic KV and MV imaging
- Enhanced beam conformance specification
- Edge Intracranial SRS package, including:
 - Optical surface monitoring solution for real-time tracking of external patient surface
 - System refresh rate optimized for tracking intracranial targets
 - Seamless integration with beam gating for out of threshold patient or target motion
 - SRS phantom for QA
 - Integrated conical collimator verification and interlock system for electronic and automatic collimator verification with plan requirements
 - Includes 7 conical collimators of the following sizes: 4, 5, 7.5, 10, 12.5, 15 and 17.5 (all sizes in millimeters)
 - Eclipse cone planning for localization and planning for cone-based treatments



- Edge Extracranial Stereotactic Ablative Radiosurgery (SABR) package:
 - Calypso system for real-time direct tumor tracking, including:
 - Target position update rate of 25Hz, optimized for tracking the motion of fast moving targets
 - Automated couch repositioning and treatment beam gating for precision radiation delivery
 - Starter kit for prostate Beacon transponders
- Body immobilization for extracranial SABR treatments
- Eclipse treatment planning system including:
 - RapidArc radiotherapy technology, Acuros XB dose calculation, SmartSegmentation knowledge-based contouring, SmartAdapt
 - Delivered in a network environment with an additional workstation for customers with existing Eclipse system
- ARIA Oncology Information System OIS (OIS), including:
 - RO SmartSpace, Disease Management SmartSpace, Oncology Imaging SmartSpace (3 licenses each)
 - Delivered as a network environment or additional workstation for existing ARIA system

Optional features of the Edge full-body package are as follows:

- 10X High-Intensity Mode for delivery of radiation at 2400 MU/minute
- Low-X imaging at 2.5MV
- 6x flat beam
- Additional ARIA workstations
- Additional Eclipse workstations

Section 5.2: Edge SRS Intracranial System

Frameless or frame-based intracranial treatments may be administered using real-time tracking capabilities in the Edge intracranial SRS package. Even slight motion has the potential to be assessed in real-time with the help of Varian optical technology and 3D surface mapping of the patient's external surface – all while minimizing dose to healthy tissue.

Section 5.3: Edge SABR Extracranial System

Equipped with real-time tracking tools, the Edge system was designed to direct tumor localization and motion assessment using the Calypso system. The integration of the Calypso system will enable more confident assessment of fast-moving targets.

Section 5.4: Overview of Edge System Configurations

Table 9: Edge Radiosurgery System Offerings

Treatment Planning System Features	Extracranial System	Intracranial System	Full Body System
Eclipse treatment planning system	Standard	Standard	Standard
RapidArc radiotherapy technology	Standard	Standard	Standard
Acuros XB dose calculation	Standard	Standard	Standard
SmartSegmentation knowledge-based contouring	Standard	Standard	Standard
SmartAdapt	Standard	Standard	Standard
Eclipse cone planning	Not available	Standard	Standard

Treatment Delivery System Features	Extracranial System	Intracranial System	Full Body System
Small vault configuration	Standard	Standard	Standard
High-Definition 120 Multileaf Collimator (HD 120 MLC)	Standard	Standard	Standard
PerfectPitch 6 degrees of freedom (6DoF) couch with Calypso compatible couchtop	Standard	Standard	Standard
6x High-Intensity Mode for delivery of radiation at 1400/min	Standard	Standard	Standard
Advanced IGRT and Motion Package (includes triggered imaging, 4D CBCT, extended length CBCT)	Standard	Standard	Standard
Developer Mode license	Standard	Standard	Standard
43 cm x 43 cm MV imager qualified for high dose rate flattening filter free radiation beams	Standard	Standard	Standard
Enhanced beam conformance	Standard	Standard	Standard
Integrated conical collimator Verification & Interlock system (including 7 conical collimators)	Not available	Standard	Standard
Respiratory positioning package (including optical imager, respiratory gating, dynamic kV and MV imaging)	Standard	Standard	Standard
Optical surface monitoring system	Not available	Standard	Standard
Intracranial immobilization package	Standard	Standard	Standard
Extracranial real-time tracking	Standard	Not available	Standard
Extracranial immobilization package	Standard	Not available	Standard
Extracranial immobilization package	Standard	Standard	Standard
10x High-Intensity Mode (2400 MU/minute)	Optional	Optional	Optional
Low-X imaging at 2.5MV	Optional	Optional	Optional
Oncology Information System (OIS) Features	Extracranial System	Intracranial System	Full Body System
ARIA oncology information system for radiation oncology	Optional	Optional	Optional

Not all features or options are available in all markets. Specifications are subject to change without notice.

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Specifications subject to change without notice

Intended Use Summary

Varian Medical Systems' linear accelerators are intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Safety

Radiation treatments may cause side effects that can vary depending on the part of the body being treated. The most frequent ones are typically temporary and may include, but are not limited to, irritation to the respiratory, digestive, urinary or reproductive systems, fatigue, nausea, skin irritation, and hair loss. In some patients, they can be severe. Treatment sessions may vary in complexity and time. Radiation treatment is not appropriate for all cancers.

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