



# CYBERKNIFE® TREATMENT DELIVERY SYSTEM

Technical Specifications



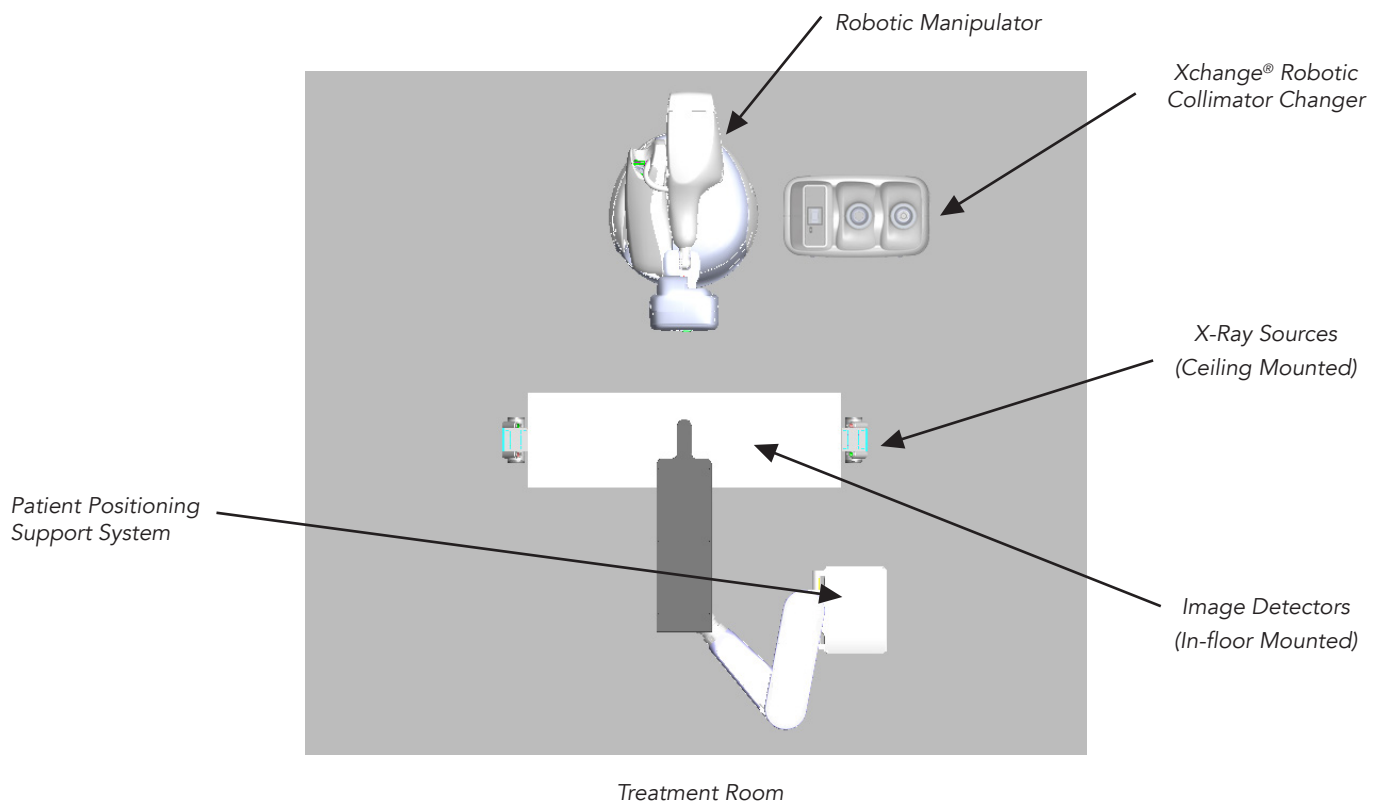
**CyberKnife®**

The CyberKnife® Treatment Delivery System offers a comprehensive toolkit of clinical features. Indication-specific tumor tracking with automatic correction throughout treatment; true robotic mobility and advanced secondary collimation integrate seamlessly into the only system to stay on target despite patient and tumor movement. Accurately treat tumors throughout the body with confidence and without compromise.

#### Key Features and Benefits:

- Every treatment is delivered in an industry exclusive 3D workspace featuring the flexibility to treat patients with robotic precision utilizing scores of beam angles in non-coplanar, isocentric or non-isocentric environments. This flexibility and precision instill great confidence in clinicians who treat patients with CyberKnife Treatment Delivery System technology.
- Fully integrated, indication-specific tracking applications precisely monitor patient motion, as well as static tumors and tumors in motion. Constant intra-fraction position tracking and correction provide confidence that the target is being treated to the prescribed dose. The industry-leading targeting and delivery technology can help to improve patient outcomes.
- Clinical studies have indicated that the CyberKnife Treatment Delivery System's unrivaled ability to precisely target and treat disease helps clinicians destroy the tumors and not healthy tissue or organs at risk, thus potentially reducing patient side effects.
- The CyberKnife Treatment Delivery System provides more flexibility than ever with the InCise2™ Multileaf Collimator (MLC): faster treatment times, improved patient handling processes, streamlined setup and treatment, and an optimized linear accelerator workspace, to help improve clinician and patient experience.

## Treatment System Overview



## Installation

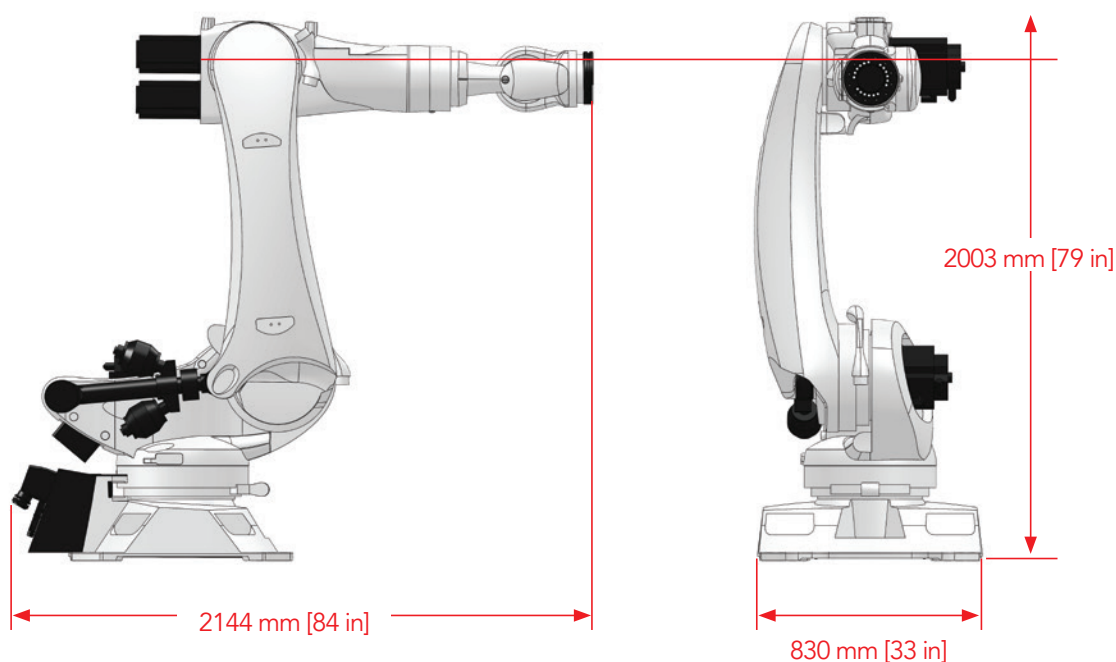
### Treatment Vault Environment

Temperature:	10-35° C
Pressure:	103 kPa to 65 kPa
Humidity:	30% to 75% RH (non-condensing)

### Mechanical Features

#### Robotic Manipulator

- 6-axis robotic manipulator mounted on a pedestal at the head of patient area
- SmartPAD Teach Pendant with a touch screen interface



### ROBOTIC MANIPULATOR SPECIFICATIONS

Payload	300 kg (661 lb)
Maximum Reach	2500 mm (98 in)
Number of Axes	6
Work Envelope	41 m <sup>3</sup>
Weight	1220 kg (2690 lb)

## Patient Positioning Support

Two types of patient positioning support systems are available with the CyberKnife® Treatment Delivery System: The RoboCouch® Patient Positioning System (optional) or the Standard Treatment Couch.

	Standard Treatment Couch	RoboCouch System (Optional)
<b>Payload</b>	159 kg (350 lb)	227 kg (500 lb)
<b>Range of Motion</b> <ul style="list-style-type: none"> <li>• Anterior/Posterior</li> <li>• Right/Left</li> <li>• Superior/Inferior</li> <li>• Head Up/Head Down (pitch)</li> <li>• Right/Left Tilt (roll)</li> <li>• Yaw (CW/CCW)</li> </ul>	28 cm ±15 cm ≥91 cm ±5° ±5° N/A	42 cm (full vertical range) ±18 cm ≥100 cm ±5° ±5° ±5°
<b>Control</b>	Remote Workstation (UCC) Local Hand Pendant	Remote Workstation (UCC) Local Hand Pendant Local SmartPAD Teach Pendant
<b>Repeatability</b> <ul style="list-style-type: none"> <li>• Translational</li> <li>• Rotational</li> </ul>	0.3 mm 0.3°	0.1 mm 0.1°
<b>Motion Corrections</b>	Most degrees of freedom are corrected serially	All degrees of freedom are corrected simultaneously
<b>Point of Rotation</b>	Fixed: Determined by mechanical assembly of the actuators	Variable: All axes can move simultaneously about a set point in space

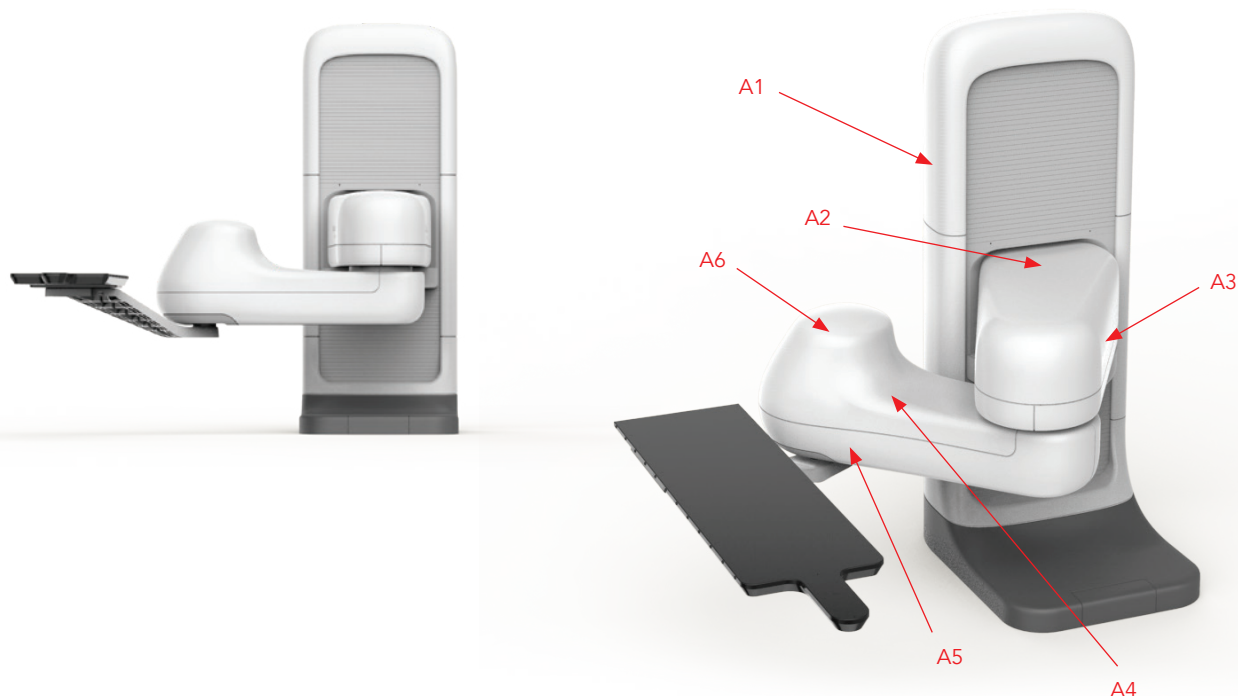
### Treatment Couch Top Specifications

<b>Radiolucency</b>	Maximum: <1.1 mm aluminum equivalence at 120 kVp for the length of at least 62 inches from the superior most point
<b>Immobilization (Compatibility)</b>	Alpha Cradle® Vacuum Lock Bags Thermoplastic masks
<b>Indexing</b>	Compatible with CIVCO indexing systems

	Flat with Standard	Flat with RoboCouch® System
<b>Minimum Load Height</b>	≤64 cm (25 in)	≤56 cm (22 in)
<b>Dimensions</b>	Length: 213 cm (84 in) Width: 53 cm (21 in) Thickness: 7.6 cm (3 in)	Length: 206 cm (81 in) Width: 53 cm (21 in) Thickness: 5.7 cm (2.25 in)

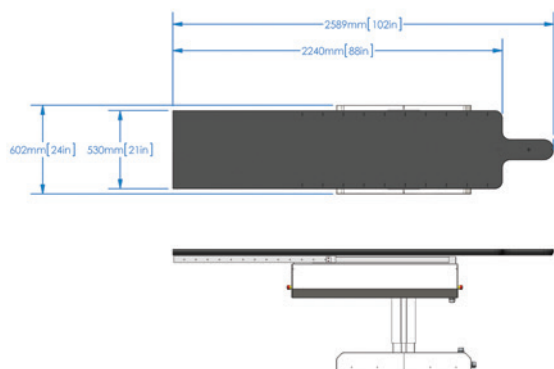
## RoboCouch® Robotic Patient Positioning System (OPTIONAL)

The RoboCouch System provides a highly flexible six degrees-of-freedom (DOF) mechanism for automatically positioning the patient. The combination of the RoboCouch System and the robotic manipulator for linac positioning enables the CyberKnife® Treatment Delivery System to deliver dose precisely and to the right location automatically. The upper manipulator arm (between axes A2 and A3) integrates a contact sensor on its outer surface and an E-STOP is triggered if an object comes in contact with it. The RoboCouch System is available with a flat carbon fiber couch top (standard with the RoboCouch System). The RoboCouch System has five rotational axes and one linear axis.



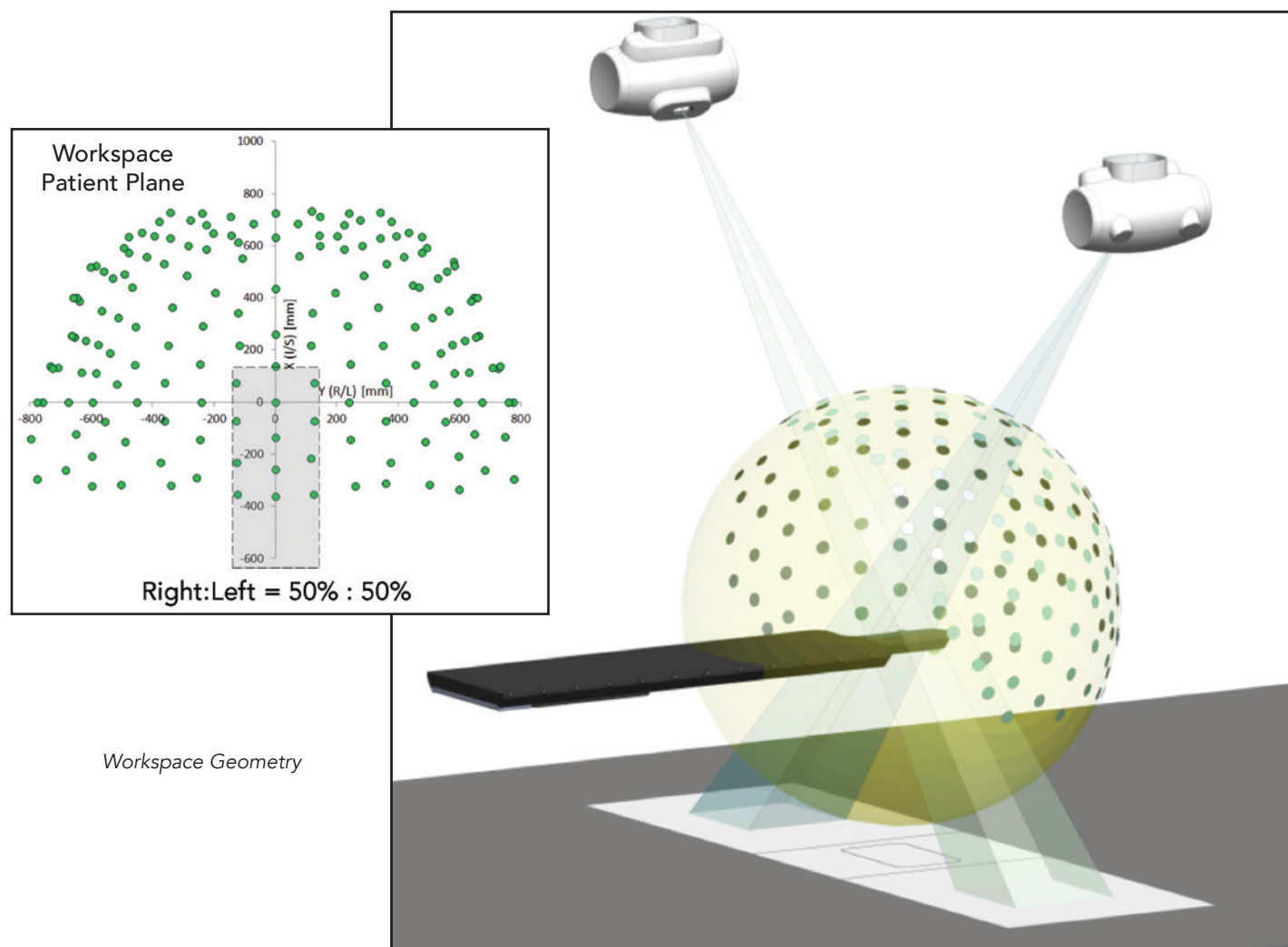
## Standard Treatment Couch

The Standard Treatment Couch is the standard patient support system of the CyberKnife System. It provides the user with flexibility in patient positioning by providing 5 DOF motion capabilities.



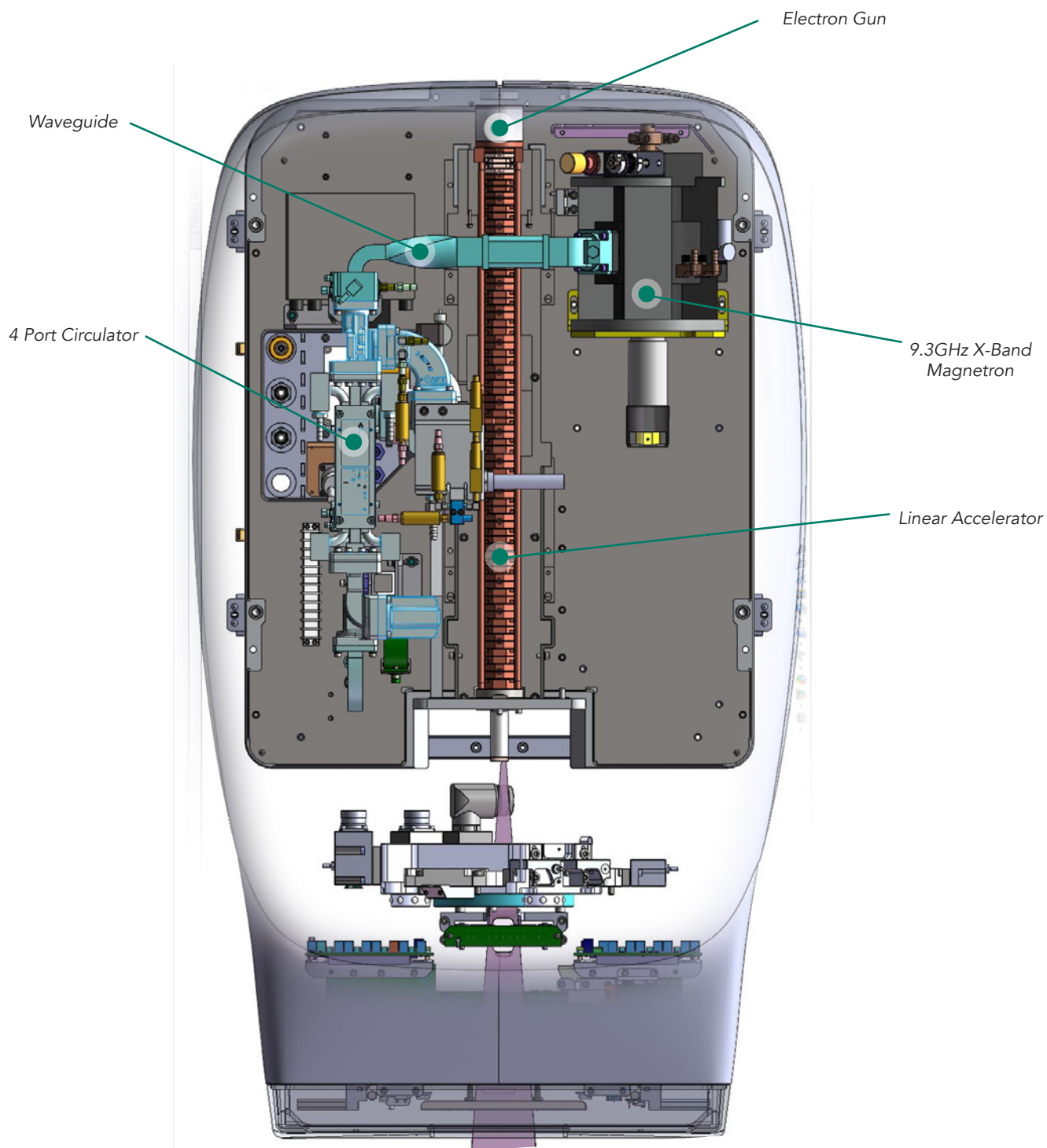
## 3D Workspace

The robotic manipulator moves within a 3D workspace. This workspace is subdivided into anatomy-specific paths through which the robotic manipulator can travel safely from one treatment position to another, accounting for the positions of objects in the treatment suite, including the treatment couch, patient, imaging components and detectors. The workspace is comprised of pre-assigned point-in-space, called nodes, from which the manipulator can deliver radiation. The linac can deliver radiation from multiple beam angles at each node position. The conceptual representations below illustrate the 3D workspace. The actual treatment path chosen by the robotic manipulator depends on many factors, including the location of the target, the size of the patient and the anatomy being treated.



## Linear Accelerator

- Nominal Source to Axis Distance (SAD) and Normal Treatment Distance (NTD) is 800 mm



*Simplified Diagram, 6MV Linear Accelerator  
(shown with InCise2™ Multileaf Collimator)*



## Dosimetry Specification

- Chamber type

Dose Chamber A: Sealed ion chamber  
Dose Chamber B: Sealed ion chamber segmented for symmetry monitoring

- Resolution

≥ 25 counts per MU

## PHOTON BEAM SPECIFICATION

### Dosimetry System

A two-channel primary/secondary dosimetry system is provided  
6MV nominal photon energy

### X-ray Energy

### Depth of Maximum Dose (D<sub>max</sub>)

15 mm ± 2 mm

### Dose Rate

1000 MU/min ± 10% measured at 800 mm SAD at a depth of 15 mm in water for a 60 mm field size

### Temperature and Pressure Adjustments

Within the specified operating temperature and pressure range, the dose rate and MU to dose calibration is independent of temperature and pressure

### Dosimetry Linearity

Dosimetry linearity with total dose is less than ±1% or ±1 cGy, whichever is greater over an accumulated range of 10 cGy to 1000 cGy, measured at 800 mm SAD within the operating temperature and pressure range

### Quality Index

TPR 20/10 ratio of dose rate in water tank at 20 to 10 cm depth

Between 0.62 and 0.67 for a 60 mm fixed collimator

### Leakage

Measured anywhere in the patient plane (800 mm SAD) in a circular area of radius 2 m centered on the beam's central axis, excluding the area within the treatment beam (as defined by IEC 60601-2-1)

Leakage in the patient plane is less than 0.2% maximum and 0.1% average

Scatter 1 m from the radiation head is less than 0.1%

The leakage values are given with respect to the absorbed dose on the central axis at the reference treatment distance of 800 mm SAD and 15 mm depth with the 60 mm fixed collimator



## Equipment Room

### EQUIPMENT ROOM COMPONENTS

**PDU (Power Distribution Unit)**

**Robot Controllers**

**Mechanical Rack, including:**

Chiller  
Air compressor  
SF6

**AMM (Advanced Magnetron Modulator) Rack, including:**

LCC (Linac Control Computer)  
LPDU (Linac Power Distribution Unit)  
MCC (Modulator Control Chassis)  
Gun driver  
Modulator  
Modulator HVPS

**Computer Rack, including:**

KVM extender  
UPS  
Iris™ temperature controller  
Monitor and keyboard  
ELCC (E-Stop Interlock Control Chassis)  
TLS (Target Locating System) workstation  
UCC (User Control Console) workstation  
SFB (Secondary Feedback) workstation  
iDMS™ Data Management System  
Storage Vault (option)  
Network delivery switch  
Network delivery firewall  
Core switch  
Gateway workstation

## UCC (User Control Console) Workstation

The UCC Workstation is installed in the Equipment Room. The workstation includes mouse, keyboard and display at the Control Console area. Power is provided to the UCC Workstation through the cabinet UPS.

### UCC WORKSTATION SPECIFICATION

**CPU**

Dual Six-Core CPUs

**Memory**

32GB DDR4 2133MHz

**Storage**

2x 300 GB SAS 2.0 15 K Drives mirrored for a total of 300 GB of storage

**Graphics Card**

Nvidia Quadro M2000

**Ethernet Port**

2x Gigabit ethernet port

**Power Supply**

Dual redundant power supply

## iDMS™ Data Management System

The iDMS System houses patient records, system commissioning data, and system licensing information and may be housed in the CyberKnife® Treatment Delivery System equipment room, or elsewhere, depending on single/multi-system configuration. The iDMS System, configured without the Storage Vault option, is intended to store at least 300 patient records. With the Storage Vault option, the iDMS System is intended to store at least 5,400 patient records (depending on plan size, these numbers may change).

### DATA SERVER SPECIFICATION

CPU	Quantity: 4, Dual Intel® Xeon E5-2620 v3
Memory (RAM)	32GB DDR4 2133 MHz
C Drive Storage	2x2TB drives configured in a RAID 1 providing ~2TB storage. Operating system host
D Drive Storage:	4x600GB SAS 15k drives configured in a RAID 6 providing ~1TB storage. Live patient database and configuration parameters host
E Drive Storage	4x2TB drives configured in a RAID 6 providing ~2TB storage. Database snapshot and archived patient records host
Operating System	Microsoft® Windows OS
Database	SQL Server 2014

## Storage Vault (OPTION)

The Storage Vault is one option that can be used for the redundant backup of the iDMS System. It is housed in the equipment room.

### STORAGE VAULT SPECIFICATION

Quad-Core CPU	Intel® Xeon 64-Bit Quad Core CPU, 4 Threads
Memory	8GB DDR3
Hard Disk Drive Configuration	SATA II, 10TB/25TB storage capacity
RAID Configuration	RAID 6
Network Interface	2 x Gigabit ethernet ports
USB Interface	4 x USB 2.0 ports, 2 x USB 3.0 ports

## Accuray Precision® Treatment Planning System

The Accuray Precision® Treatment Planning System offers a common and complete treatment planning solution for the CyberKnife® Treatment Delivery System. The Accuray Precision System is a fully featured, powerful planning workstation featuring AutoSegmentation™ (autocontouring of brain, head and neck, and male pelvis regions), multimodality image fusion with deformable registration and plan comparison/summing plans. Additionally, this planning system offers the PreciseRTX™ Retreatment Option. The Accuray Precision System utilizes a common, integrated database: The iDMS™ Data Management System.

### ACCURAY PRECISION TREATMENT PLANNING SYSTEM WORKSTATION SPECIFICATION

<b>CPU</b>	Dual Six-Core CPUs
<b>Memory</b>	48GB DDR4 2133 MHz
<b>Storage</b>	2x240GB SATA (RAID1)
<b>Ethernet Port</b>	1 Gigabit
<b>Power Supply</b>	>1000 W
<b>Monitor</b>	LCD monitor with a native resolution of 1600x1200 or 1920x1200
<b>Operating System</b>	Microsoft® Windows® 7 x64 Bit OS

## MD Suite – Physician Workstation (OPTION)

The MD Suite – Physician Workstation provides remote secure access to patient record data from the CyberKnife Treatment Delivery System database. The MD Suite workstation is housed in a remote location.

### MD SUITE WORKSTATION SPECIFICATION

<b>CPU</b>	Dual Six-Core CPUs
<b>Memory</b>	24 GB DDR4 2133 MHz
<b>Storage</b>	2x240 GB SATA (RAID 1)
<b>Ethernet Port</b>	1 Gigabit
<b>Power Supply</b>	>1000W
<b>Monitor</b>	LCD monitor with a native resolution of 1600 x 1200 or 1920 x 1200
<b>Operating System</b>	Microsoft® Windows® x64 Bit OS

## Treatment Control Area

The Treatment Control Area contains equipment necessary for operators to monitor and control the CyberKnife® Treatment Delivery System.

### TREATMENT CONTROL AREA COMPONENTS

#### Treatment Delivery System

Two high-resolution 24", 1920x1200 pixel monitors  
Keyboard and mouse for the user control computer

#### Operator Panel

MV Beam indicator  
KV Image acquisition indicator  
Remote/local control indicator  
High voltage indicator  
High voltage enable button  
Key switch to enable high voltage  
Emergency stop button  
Audible tones for KV and MV radiation



Operator Panel



Dual screens showing the Delivery Interface

# Collimation Systems

## SECONDARY COLLIMATION

The CyberKnife® Treatment Delivery System features three secondary collimator housing types: fixed, Iris™ Variable Aperture and the InCise2™ Multileaf Collimator. Collimator housing types are automatically changed by the robotic manipulator at the Xchange® table. Clinicians can choose the best collimator for the given treatment during the planning process.

## FIXED COLLIMATORS

There are 12 fixed secondary collimators with circular field sizes ranging from 5 mm to 60 mm in diameter at 800 mm SAD. These collimators can be changed manually to vary the beam size required by the treatment plan.

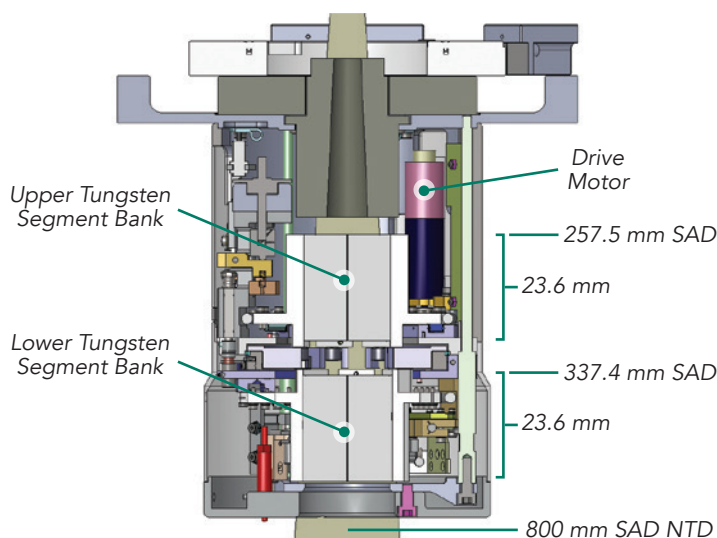
FIXED COLLIMATOR SPECIFICATION	
Collimator Transmission	X-ray transmission through the blank collimator at 800 mm SAD does not exceed 0.2% of the central axis (CAX) dose rate of a 60 mm fixed collimator
Available Apertures	Collimation sizes: 5, 7.5, 10, 12.5, 15, 20, 25, 30, 35, 40, 50 and 60 mm nominal field sizes at 800 mm SAD
Penumbra (At 800mm SAD and 50mm Depth per IEC 60976 (2007) 9.3.1)	Better than 3.5 mm for a 10 mm collimator Better than 4.5 mm for a 40 mm collimator Better than 8 mm for a 60 mm collimator



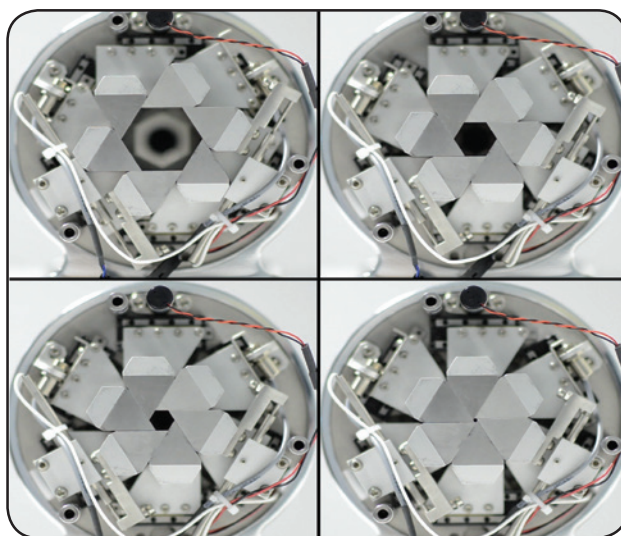
Table holding Fixed Collimators

## IRIS™ VARIABLE APERTURE COLLIMATOR (OPTION)

The Iris Variable Aperture Collimator creates beams with characteristics virtually identical to those of the fixed collimators and is only able to replicate the fixed 12 collimator sizes. The variable aperture is created by two banks of six tungsten segments, each creating a hexagonal aperture. The two banks are offset by 30°, resulting in a dodecahedral aperture (virtually circular) when viewed through the collimator.



*Iris Variable Aperture Collimator (NTD not to scale)*



*Example of Iris Variable Aperture sizes*

### IRIS VARIABLE APERTURE COLLIMATOR SPECIFICATION

#### Circularity

The standard deviation of the radial distance from the beam axis to the 50% dose level is less than 2% of the average radial distance

#### Collimator Transmission

X-ray transmission through the Iris Collimator tungsten segments at 800 mm SAD does not exceed 0.2% of the CAX dose rate of the Iris Collimator when opened to a 60 mm field

- Maximum: < 0.2% of the delivered dose rate
- Average: < 0.1% of the delivered dose rate

#### Reproducibility

Mechanical: less than 0.1 mm  
Treatment Field Size:  $\leq 0.2$  mm at 800 mm SAD distance of 800 mm SAD

#### Available Apertures

Effective collimation sizes: 5, 7.5, 10, 12.5, 15, 20, 25, 30, 35, 40, 50 and 60 mm diameter field sizes at 800 mm SAD

#### Penumbra (At 800mm SAD and 50mm Depth per IEC 60976 (2007) 9.3.1)

Better than 3.5 mm for a 10 mm collimator  
Better than 4.5 mm for a 40 mm collimator  
Better than 8 mm for a 60 mm collimator

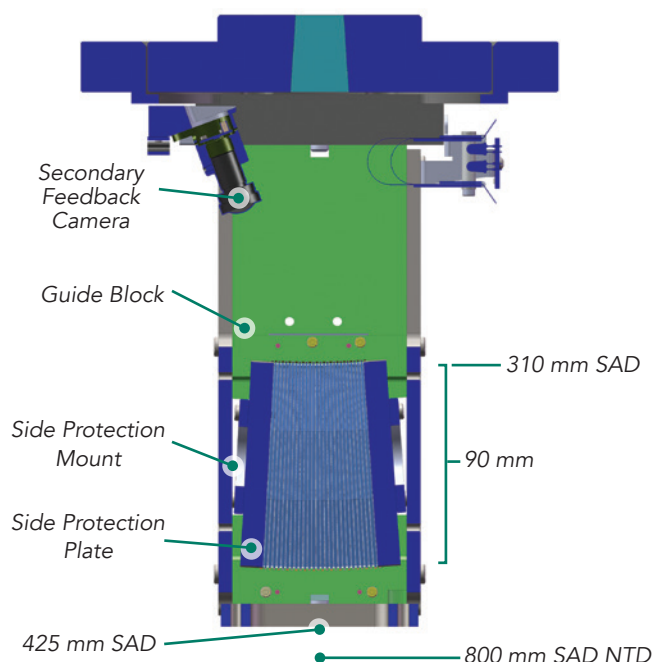


## InCise™ 2 MULTILEAF COLLIMATOR (OPTION)

The InCise™ 2 Multileaf Collimator creates highly conformal beam shapes in relation to the treatment targets and has a larger field size than the Iris™ or fixed collimators, enabling the system to treat much larger targets with significantly fewer beams and delivered MU. This results in much faster treatment times and greatly expands the clinical utility of the CyberKnife® Treatment Delivery System.



Patient's eye view of InCise 2 Multileaf Collimator



Basic beam line for InCise 2 Multileaf Collimator (NTD not to scale)

### InCise 2 MULTILEAF COLLIMATOR SPECIFICATION

#### Beam Targeting

#### Secondary Check for Leaf Position

#### Maximum Geometric Field Size

#### Leaf Tilt

#### Leaf Tip Design

#### Leaf Width

#### Leaf Material

#### Leaf Positioning Accuracy

#### Leaf Over-Travel

#### Leaf Inter-Digitation

#### Transmission

Includes intra-leaf and inter-leaf

#### Penumbra (At 800mm SAD and 50mm Depth per IEC 60976 (2007) 9.3.1)

#### Non-Coplanar beam targeting

Internal optical camera provides live images used during treatment to verify leaf position

115 mm (leaf motion direction) x 100 mm\*

Leaves tilted 0.5°

Three-Sided

3.85 mm at 800 mm SAD (normalized for leaf pitch)

Tungsten

Better than  $\pm 0.95$  mm at 800 mm SAD from either direction at all possible orientations

100%

Full Leaf Inter-Digitation

<0.3% average (<0.5% maximum) relative to a 100 mm x 100 mm field size at 800 mm SAD

Better than 3.5 mm in X and Y for 10 mm x 10 mm field size

Better than 12 mm in X and 20 mm in Y for a 100 mm x 100 mm field size

\* Configured by software

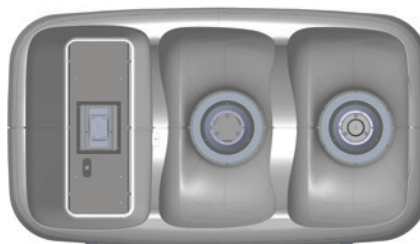


## Xchange® Robotic Collimator Changer

The Xchange® Robotic Collimator Changer gives treatment operators the ability to automatically change the collimator housing type (Fixed, Iris™, MLC), specific to the patient treatment plan.



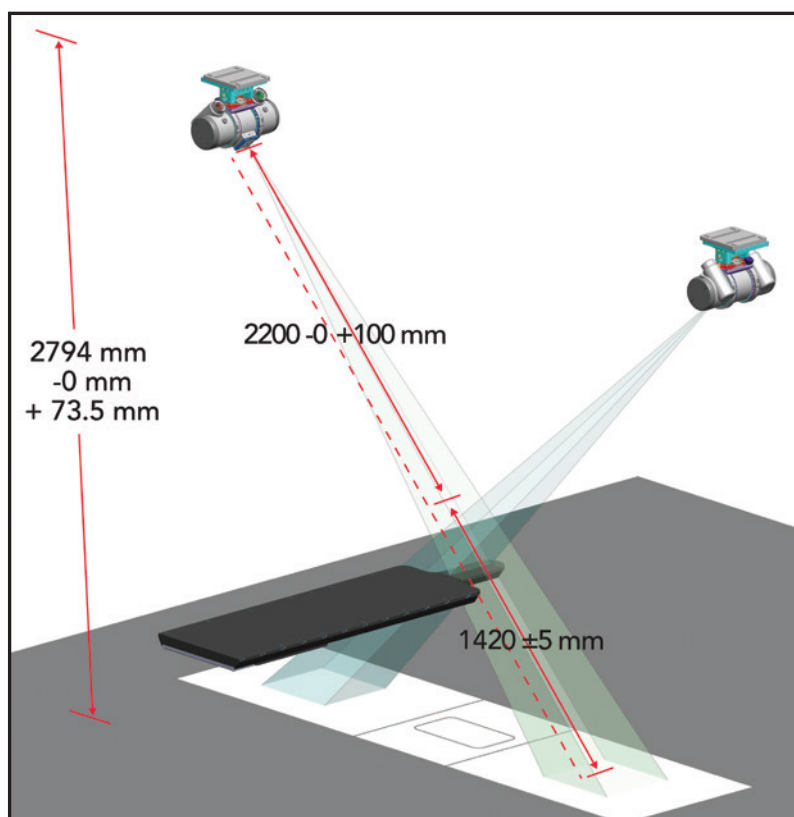
Side view of Xchange Table



Top view of Xchange Table

## Imaging System

The CyberKnife® Treatment Delivery System uses kV X-ray imaging to pinpoint and track the target throughout treatment. The imaging system consists of two ceiling-mounted X-ray sources and two corresponding in-floor image detectors. The X-ray sources are positioned at 45° such that the generated beams intersect orthogonally at an imaging center located 92 cm above the floor. Treatments on the CyberKnife Treatment Delivery System are based on the patient positioning table accurately bringing the patient to the imaging field of view. Live X-ray images are then digitized and compared with images synthesized from the patient's treatment plan. Prior to treatment starting, this imaging technology enables the system to automatically adjust the patient positioning table as target motion is detected. During treatment, the image system automatically adjusts the robot position to ensure constant beam accuracy throughout treatment.



Imaging System Geometry

## COMPACT X-RAY GENERATOR SPECIFICATIONS

Constant Potential Power Rating	50.0 kW
Radiographic Range	40-150 kVp $\pm$ (5% + 1 kVp)

## X-RAY SOURCES SPECIFICATIONS

### Electrical

• Nominal Tube Voltage	40-150 kV
• Nominal Focal Spot Value	Large focus: 1.2 mm Small focus: 0.6 mm
• Nominal Anode Input Power	Large focus: 100 kW Small focus: 40 kW

Aluminum Filter	2.5 mm
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Collimator Type	Fixed Aperture
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## X-RAY DETECTOR SPECIFICATIONS

	<b>Lower Spec Limit</b>
Detector Type	Amorphous silicon with cesium iodide scintillator
Pixel Pitch	400 $\mu$ m
Total Area	40 x 40 cm <sup>2</sup>
MTF @ 0.25 lp/mm	80%
MTF @ 1 lp/mm	33%
DQE @ 0.25 lp/mm, 1 $\mu$ Gy	56%
DQE @ 1 lp/mm, 1 $\mu$ Gy	28%

## System Targeting Accuracy

System targeting accuracy is a function of many contributing attributes including system calibrations, imaging alignment and efficacy of clinical elements (patient CT acquisition, treatment planning, delivery). System targeting accuracy can be impacted by errors generated by these attributes and others like dose delivery. Overall, these elements combine to comprise the clinically relevant LINAC pointing accuracy, also termed the CyberKnife® Treatment Delivery System total targeting error (TTE). The CyberKnife Treatment Delivery System TTE for each tracking algorithm and collimator housing is shown to be less than 0.95 mm root mean square (RMS) when a planning CT slice spacing of 1.25 mm or less is used.

## Target Tracking

Accurate target tracking and compensating for target motion are an integral part of the CyberKnife® Treatment Delivery System and its capabilities. The target is tracked throughout the treatment and delivery is automatically altered to compensate for any motion.

### CT REQUIREMENTS FOR TARGET TRACKING

Maximum Slices	512
kVp	120
mAs	Scanner maximum (minimum 400)
Slice Thickness	Contiguous slice (no gaps); < 1.25 mm slice thickness

## Target Tracking Method

### 6D SKULL TRACKING SYSTEM

The 6D Skull Tracking System enables direct tracking of the bony anatomy of the skull when treating intracranial lesions. Target tracking and motion compensation are accomplished by using image intensity and brightness differences between the DRR and live images.

### FIDUCIAL TRACKING

For extracranial lesions, targets can be tracked in soft tissue through the use of fiducials.

- General guidelines for fiducials:
  - Gold seeds or gold sphere
  - Diameter: 0.7 mm to 1.2 mm
  - Length: 3 mm to 6 mm
- A minimum of three fiducials are required for 6D target tracking correction (X, Y, Z, Roll, Pitch and Yaw).

### XSIGHT® SPINE TRACKING SYSTEM

The Xsight Spine Tracking System, with the patient in the supine position, enables the tracking of skeletal structures in the cervical, thoracic, lumbar and sacral regions of the spine without the need for implanted fiducials.

### XSIGHT SPINE PRONE TRACKING SYSTEM (OPTION)

The Xsight Spine Prone Tracking System provides support for treating spine targets with the patient in the prone position. The tracking mode combines the Xsight Spine Tracking algorithm with the Synchrony® Respiratory Tracking System to offer continuous real-time tracking and compensation for target motion resulting from respiration. In this tracking mode, the patient is first aligned using the Xsight Spine Tracking workflow, then a Synchrony correlation model is created to compensate for target translational motion during delivery.

### XSIGHT LUNG TRACKING SYSTEM (OPTION)

The Xsight Lung Tracking System (also called 2-View Lung Tracking) tracks tumors in the lung without the use of implanted fiducials by identifying image intensity differences between the lesion and the background. The patient is initially aligned using the Xsight Spine Tracking workflow. After the lesion has been identified, a Synchrony correlation model is created to compensate for target translational motion during delivery.

## LUNG OPTIMIZED TREATMENT: 1-VIEW LUNG TRACKING AND 0-VIEW LUNG TRACKING (OPTION)

Lung Optimized Treatment includes a simulation application and two tracking modes: 1-View Lung Tracking and 0-View Lung Tracking. These two tracking methods supplement the fiducial-free capability of Xsight® Lung, regardless of the location of the tumor.

- The simulation application provides a workflow to select the most appropriate tracking mode
- 1-View Lung Tracking is used when the treatment target is visible and can be tracked in only one X-ray projection
  - Provides direct tracking of lung lesions in two dimensions
  - Uses an ITV in the non-visible third dimension
- 0-View Lung Tracking is used when the treatment target is not visible in either X-ray projection. The system tracks the bony anatomy of the vertebral column during treatment
  - Provides direct tracking of the spine without fiducials
  - Uses an ITV in all dimensions to compensate for respiratory motion of the tumor

## Motion Tracking

Motion tracking on the CyberKnife® Treatment Delivery System uses the Synchrony® Respiratory Tracking or the InTempo™ Adaptive Imaging System. Motion tracking is used in conjunction with an applicable target tracking method.

### SYNCHRONY RESPIRATORY TRACKING SYSTEM WITH IMAGE BURST

The Synchrony Respiratory Tracking System continuously synchronizes treatment beam delivery to the motion of a target that is moving with respiration. The Synchrony System can be used in conjunction with the following target tracking methods: Fiducial Tracking, Xsight Lung Tracking, Xsight Spine Prone Tracking and 1-View Tracking.

The Synchrony System creates a correlation model between the patient's breathing pattern (monitored in real-time) and the precise location of the target (from the imaging system) at various points in the respiration cycle. The target location is determined from X-ray imaging, while the breathing pattern is tracked and monitored using external markers (LED-based, fiber optic tracking markers with a tracking frequency of > 25 Hz) in real-time.

The system automatically determines the best correlation model for the treatment which minimizes overall correlation error. The model is chosen from linear, curvilinear, and bi-curvilinear (dual-poly) forms. The model is based on the latest 15 sets of X-ray images and is updated every time a new image is acquired. This update is further enhanced by the Image Burst feature, which provides a 3x increase in the imaging data points that are used to update the breathing model during inter-beam, in-treatment, imaging. This equates to a robust breathing model that stays relevant and accurate for the duration of the treatment, ensuring confidence in the treatment of moving targets.

### INTEMPO™ ADAPTIVE IMAGING SYSTEM (OPTION)

The InTempo Adaptive Imaging System is a time-based technology used to compensate for non-periodic intra-fraction motion of the target. The InTempo System can be used in conjunction with the following target tracking methods: Fiducial Tracking, 6D Skull Tracking and Xsight Spine Tracking.

#### Image Age

Image age is the time elapsed since the most recent image acquisition. The system uses the image age parameter to ensure that no treatment beam is delivered based on an image that is older than that user-specified value.

#### Adaptive Imaging

The user may optionally enable the system to trigger adaptive imaging in the event that the target motion is greater than a user-defined threshold, which automatically reduces the image age to 15 seconds.

## Safety Features

- Contact Detection
  - o Contact detection sensor at the distal end of the secondary collimator housing on the linac
  - o Contact detection sensor on back of robot arm
  - o Contact with the sensor causes an Emergency Stop (E-STOP) condition halting all motion of the system
- Safety Zones: The robot workspace also takes into consideration the position of the patient and is designed to avoid contact with the patient. This is achieved by creation of a safety zone around the patient and the treatment couch. The safety zone consists of two elements: Fixed and Dynamic.
  - o The fixed safety zone is rigidly attached to the imaging center and thereby the part of the patient body being treated
  - o The dynamic safety zone is designed to encompass the entire patient body and always lies within the fixed safety zone
  - o The size of the dynamic safety zone is user selectable based on individual patient sizes (small, medium or large)

# Network

## System Interfaces

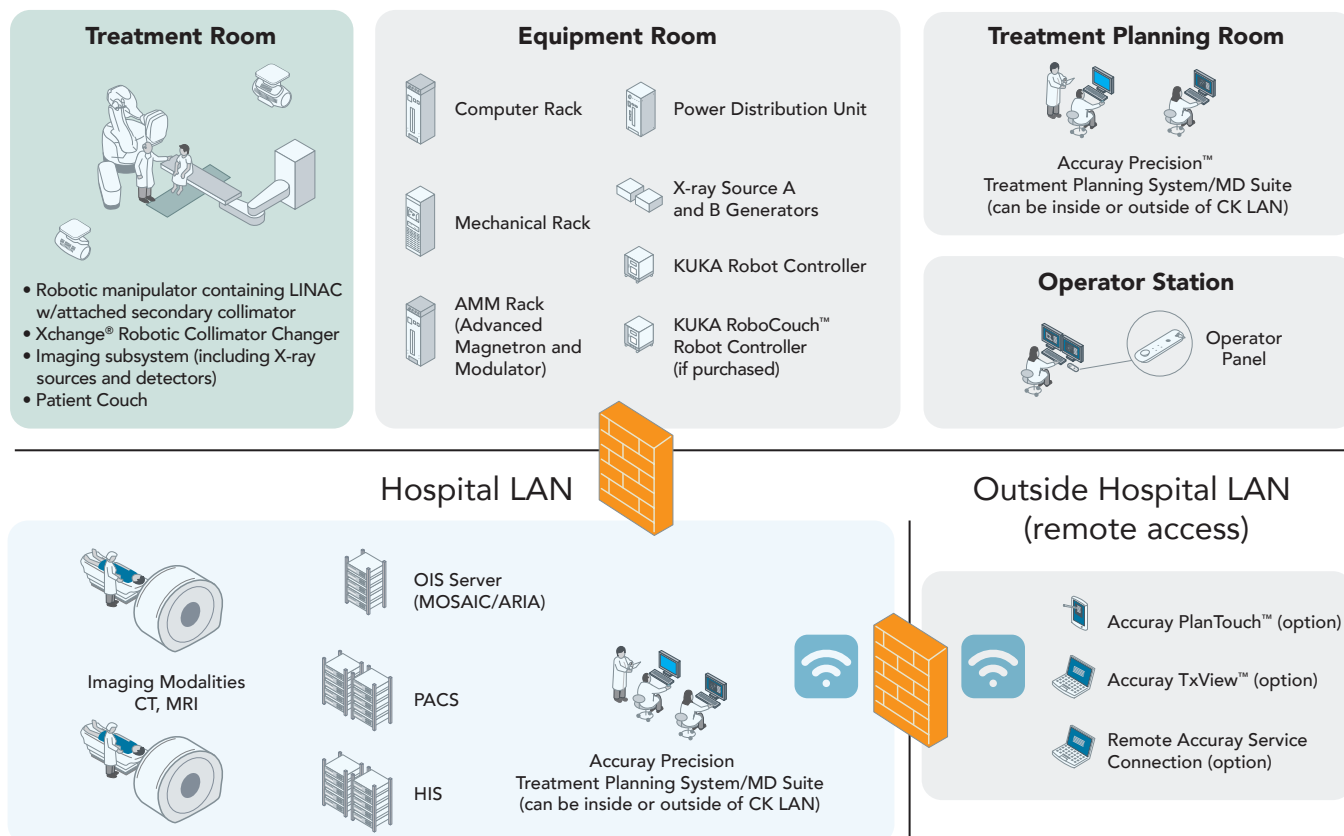
- DICOM Import/Export included:
  - DICOM Image Import
  - DICOM RT Structure Set Import
  - DICOM Image Export
  - DICOM RT Structure Set Export
  - DICOM RT Dose Export
- OIS License Required to generate objects:
  - DICOM RT Plan Export

## OIS Requirements\*

	ARIA® Oncology Information System	MOSAIQ® Oncology Information System
Requirements for OIS interface	CyberKnife® System: CK version 9.6 or higher	CyberKnife® System: CK version 9.6 or higher
OIS Software	ARIA version 10.0 - 11.0	MOSAIQ version 2.3 - 2.6
Network	RTPLAN export: TCP port 57347 RTRECORD export: TCP port 57345 WorkList Server: TCP port 50505	RTPLAN export: TCP port 104 RTRECORD export: TCP port 10401 WorkList Server: TCP port 10401
License	iDMS License with OIS enabled ARIA License enabling interface with CyberKnife System	iDMS License with OIS enabled MOSAIQ License enabling interface with CyberKnife System

\* OIS requirements shown are a generic example of how network may be setup; actual configuration site-to-site may change.

## CyberKnife System LAN



Network Diagram

## M6 Base System Configurations

Feature	M6 FIM	M6 FI+	M6 FM	M6 FI
Image Guidance System	●	●	●	●
Robotic Manipulator	●	●	●	●
Treatment Delivery Control Console	●	●	●	●
1000 MU/min linac	●	●	●	●
Fixed Collimators	●	●	●	●
Iris™ Variable Aperture Collimator	●	●	○	●
InCise™ 2 MultiLeaf Collimator	●	○	●	○
Xchange® Robotic Collimator Changer	●	●	●	●
Standard Treatment Couch	●	●	●	●
RoboCouch® Patient Positioning System	○	○	○	○
Fiducial Tracking System	●	●	●	●
CNS Package Including: <ul style="list-style-type: none"> <li>6D Skull Tracking System</li> <li>Xsight® Spine Tracking System</li> <li>Brain AutoSegmentation™</li> </ul>	●	●	●	●
Prostate Package <ul style="list-style-type: none"> <li>Male Pelvis AutoSegmentation™</li> <li>In Tempo™ Adaptive Imaging System</li> </ul>	●	●	○	○
Spine Prone Package <ul style="list-style-type: none"> <li>Synchrony® Respiratory Tracking System</li> <li>Xsight Spine Prone Tracking</li> </ul>	○	○	○	○
Lung Package <ul style="list-style-type: none"> <li>Synchrony® Respiratory Tracking System</li> <li>Xsight Lung Tracking System</li> <li>Lung Optimized Treatment</li> <li>Monte Carlo Dose Calculation</li> <li>4D Treatment Optimization and Planning System</li> </ul>	○	○	○	○

● – STANDARD FEATURE

○ – OPTIONAL FEATURE



## M6 Base System Configurations

Feature	M6 FIM	M6 FI+	M6 FM	M6 FI
Spine Prone + Lung Package <ul style="list-style-type: none"> <li>• Xsight Spine Prone Tracking</li> <li>• Synchrony® Respiratory Tracking System</li> <li>• Xsight® Lung Tracking System</li> <li>• Lung Optimized Treatment</li> <li>• Monte Carlo Dose Calculation</li> <li>• 4D Treatment Optimization and Planning System</li> </ul>	•	•	○	○
Accuray Precision® Treatment Planning Workstation (x2)	•	•	•	•
Additional Accuray Precision Treatment Planning Workstation	○	○	○	○
PlanTouch™ iPad Plan Review & Authorization Application	○	○	○	○
MD Suite	○	○	○	○
iDMS™ Data Management System	•	•	•	•
Radiosurgery DICOM Interface (ARIA or MOSAIQ)	•	•	○	○
Clinical Efficiency Package <ul style="list-style-type: none"> <li>• Report Administration Application</li> <li>• Storage Vault</li> <li>• TxView™</li> </ul>	•	•	○	○

• – STANDARD FEATURE

○ – OPTIONAL FEATURE

## Regulatory Classification

The CyberKnife® System is classified as follows:

- Protection against electric shock: Class I, permanently connected
- Applied part: Patient treatment table only, Type B
- Protection against harmful ingress of water: IPX0 – no protection against ingress of water
- Methods of sterilization or disinfection: Not required
- Degree of safety in the presence of flammable mixtures: Not suitable for use in the presence of flammable mixtures
- Mode of operation: Continuous

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## Important Safety Information

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