ACCURAY

CYBERKNIFE® M6™ TREATMENT DELIVERY SYSTEM

Technical Specifications

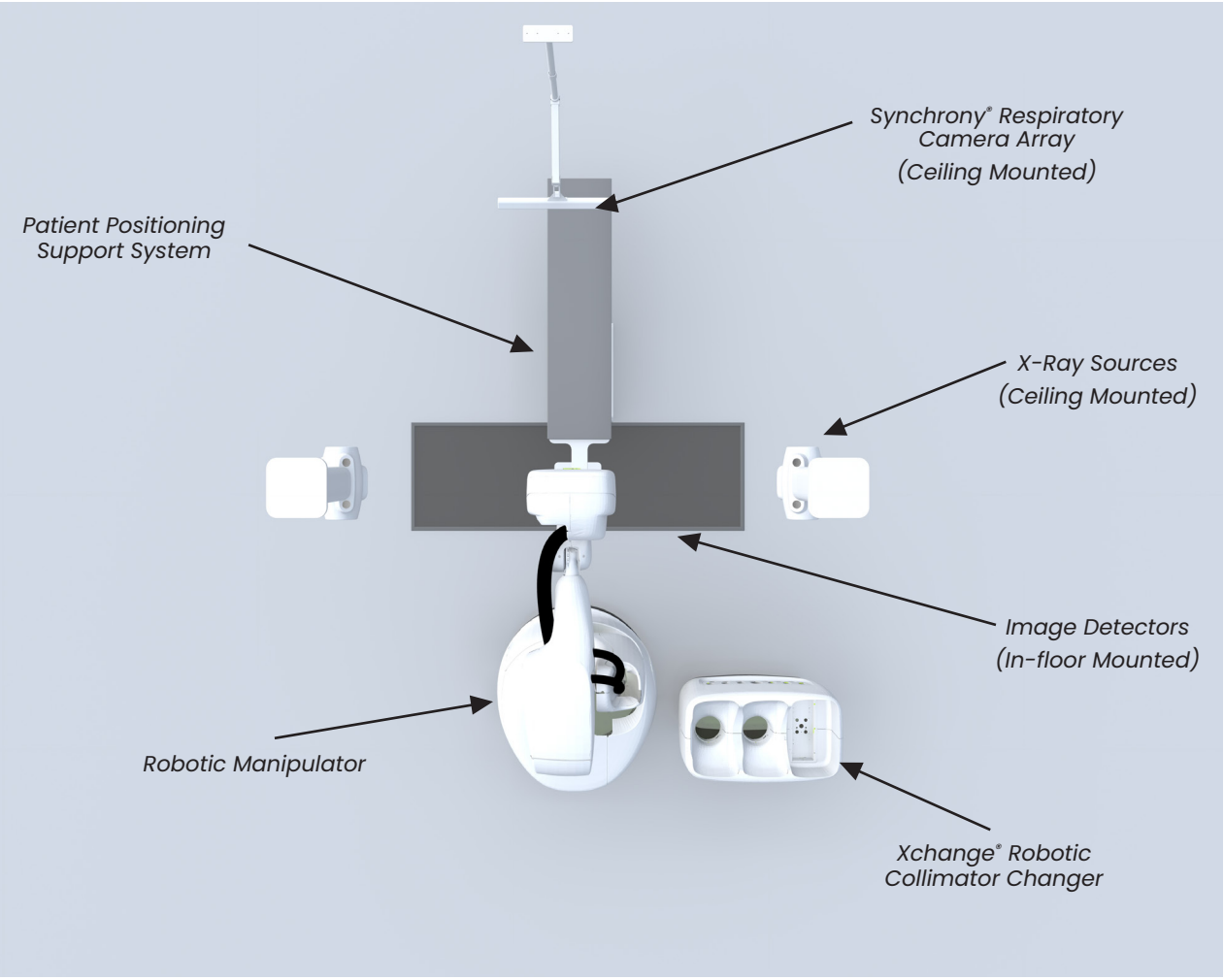
CyberKnife®

Introduction

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.

TECHNICAL SPECIFICATIONS

Treatment System Overview



Treatment Room

Installation

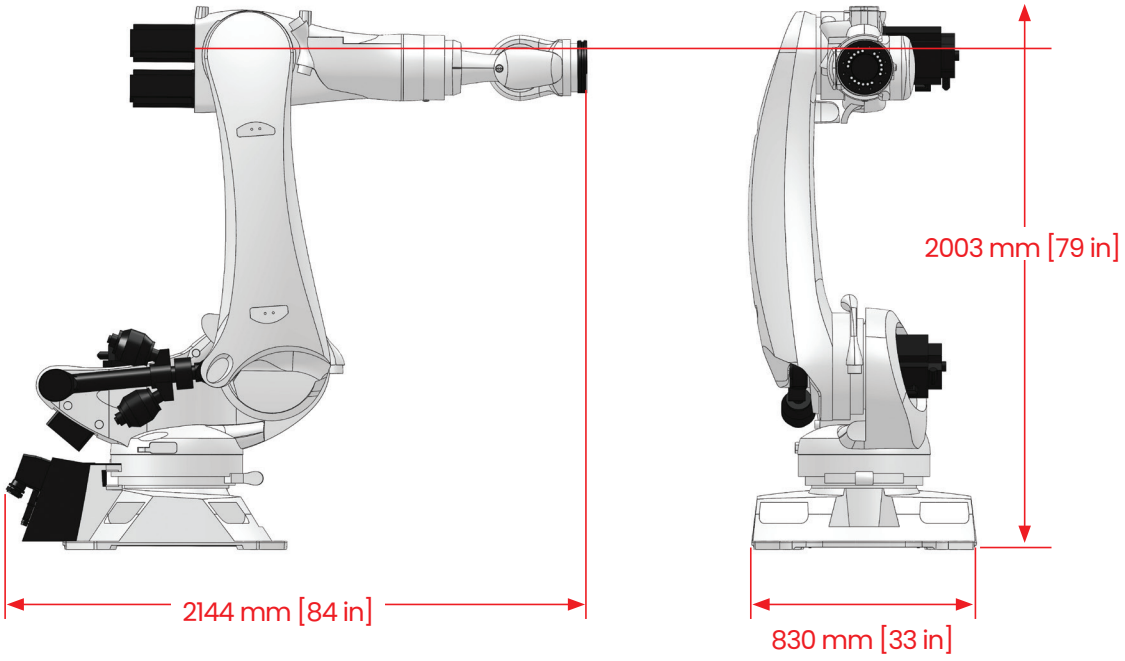
Treatment Vault Environment

Temperature	10-35˚ C
Pressure	103 kPa to 72 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^3
Weight	1220 kg (2690 lb)

Patient Positioning Support

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

Payload	Standard Treatment Couch	RoboCouch System (Optional)
	159 kg (350 lb)	227 kg (500 lb)
Range of Motion		
• Anterior/Posterior	28 cm	42 cm (full vertical range)
• Right/Left	±15 cm	±18 cm
• Superior/Inferior	≥91 cm	≥100 cm
• Head Up/Head Down (pitch)	±5˚	±5˚
• Right/Left Tilt (roll)	±5˚	±5˚
• Yaw (CW/CCW)	N/A	±5˚
Control	Remote Workstation (UCC) Local Hand Pendant	Remote Workstation (UCC) Local Hand Pendant Local SmartPAD Teach Pendant
Repeatability		
• Translational	0.3 mm	0.1 mm
• Rotational	0.3˚	0.1˚
Motion Corrections	Most degrees of freedom are corrected serially	All degrees of freedom are corrected simultaneously
Point of Rotation	Fixed: Determined by mechanical assembly of the actuators	Variable: All axes can move simultaneously about a set point in space

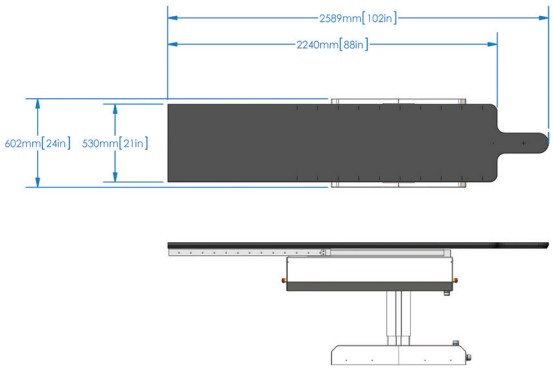
Treatment Couch Top Specifications

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

	Flat with Standard	Flat with RoboCouch® System
Minimum Load Height	≤64 cm (25 in)	≤56 cm (22 in)
Dimensions	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)

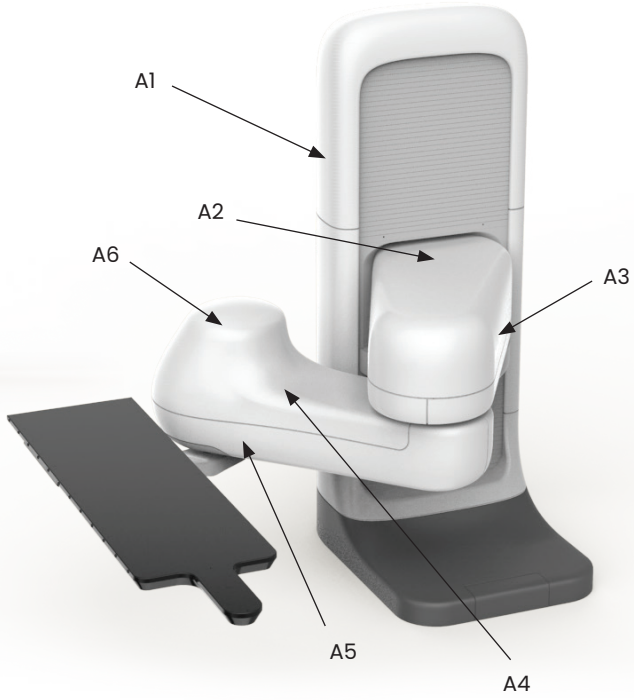
Standard Treatment Couch

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 five degrees-of-freedom (DOF) motion capabilities.



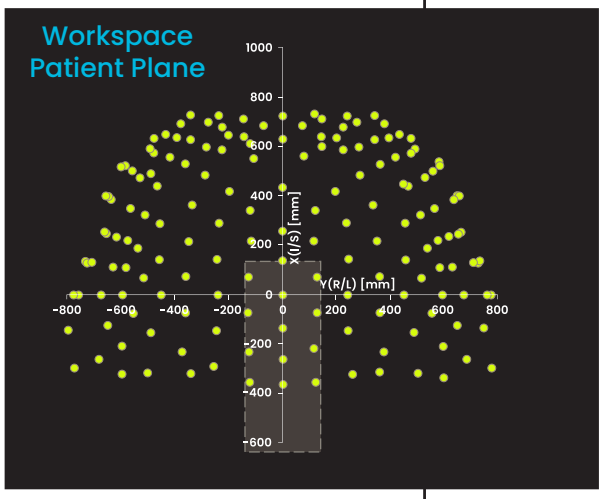
RoboCouch® Robotic Patient Positioning System (OPTIONAL)

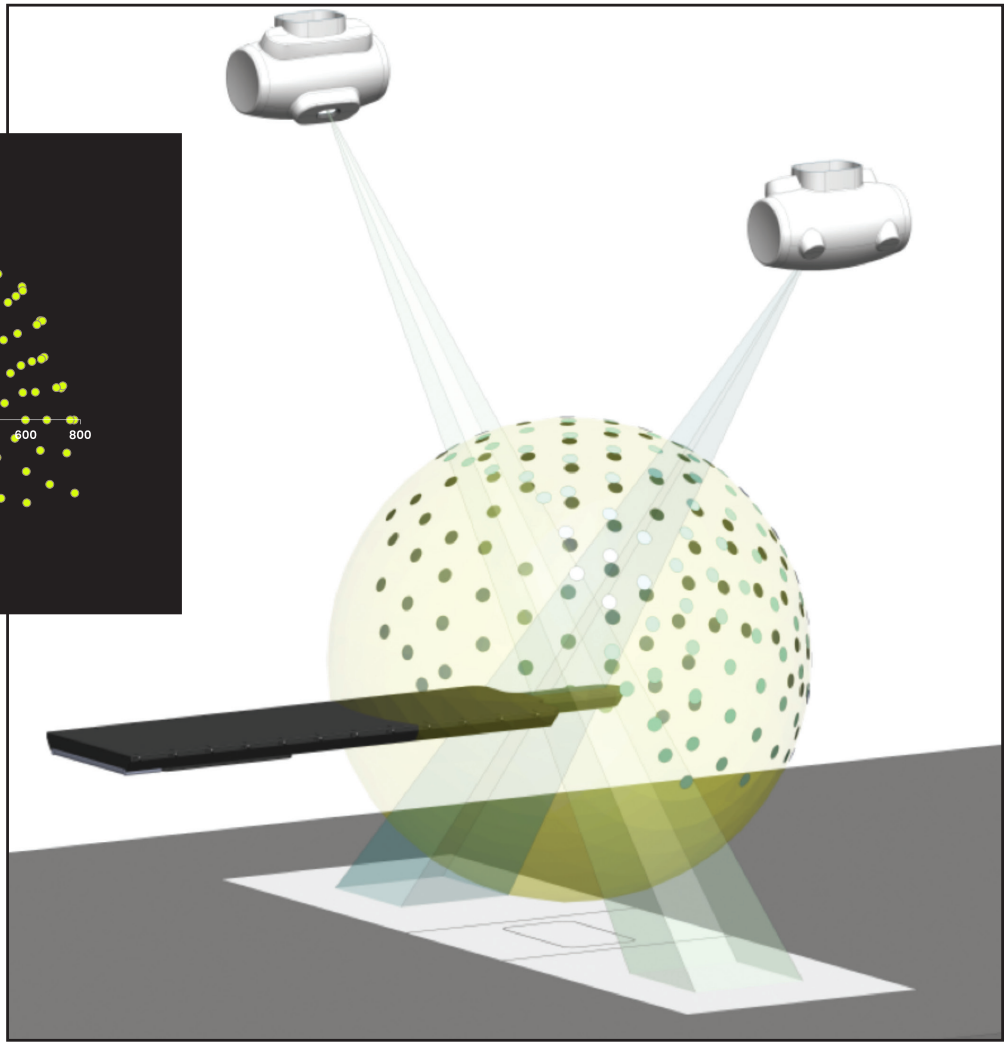
The RoboCouch System provides a highly flexible six degrees-of-freedom (DOF) mechanism for automatically positioning the patient. The upper manipulator arm (between axes A2 and A3) integrates a contact sensor on its outer surface and an E-STOP is triggered if an object comes in contact with it. The RoboCouch 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.



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 points-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.

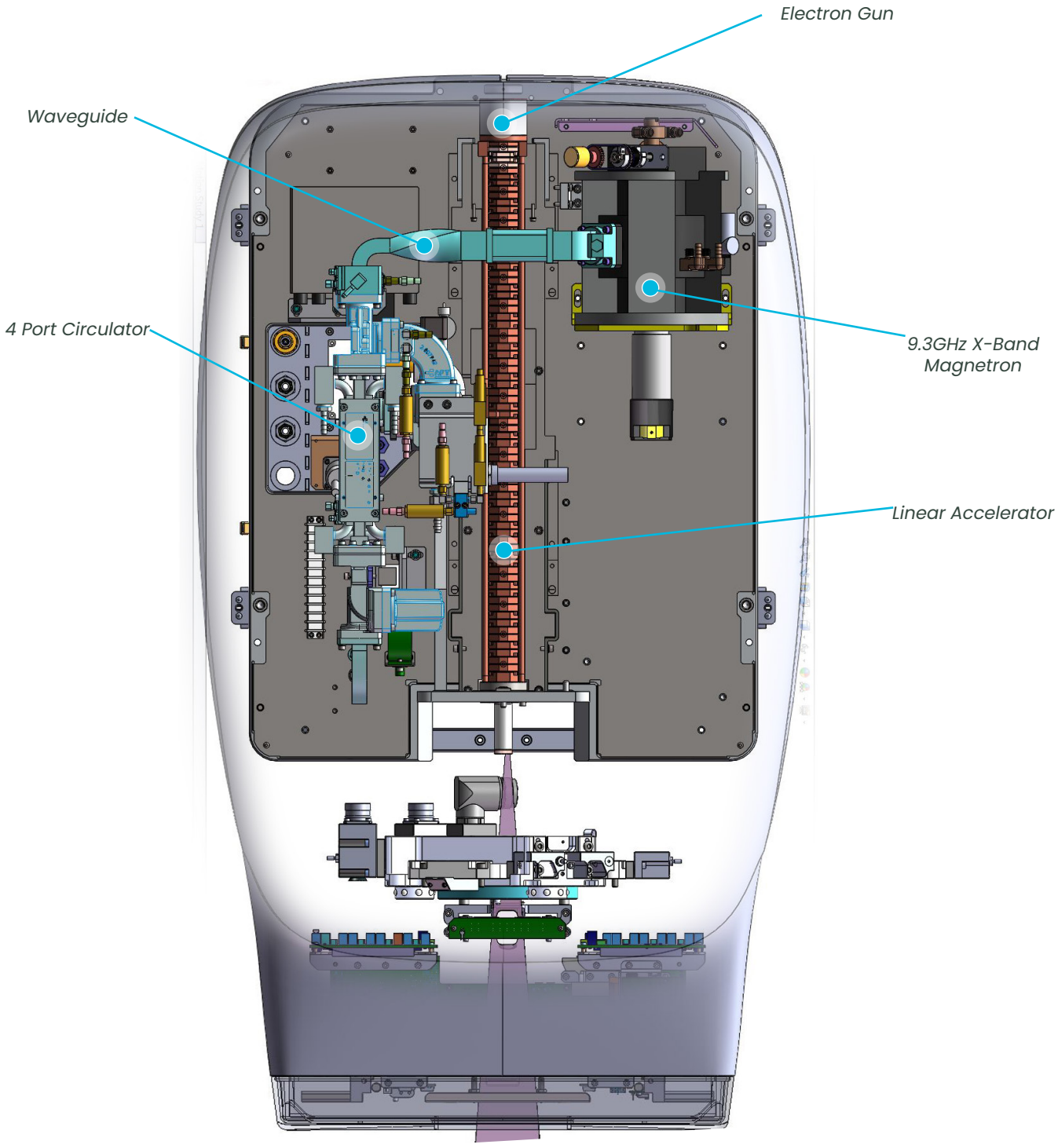




Workspace Geometry

Linear Accelerator

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



Simplified Diagram, 6MV Linear Accelerator (shown with InCise™ 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
X-ray Energy	6MV nominal flattening filter free
Depth of Maximum Dose (Dmax)	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	Between 0.62 and 0.67 for a 60 mm fixed collimator TPR 20/10 ratio of dose rate in water tank at 20 to 10 cm depth
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) 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	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%

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

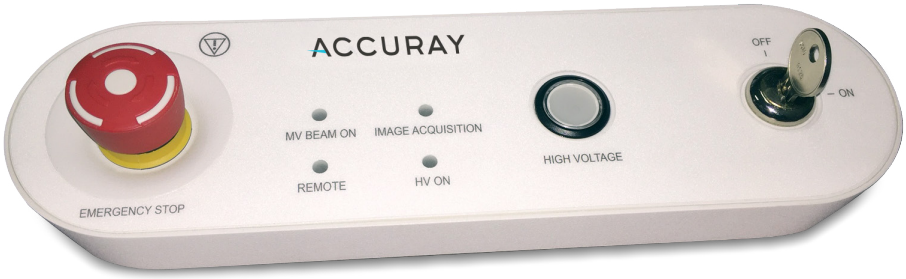
The UCC Workstation is installed in the equipment room. The workstation includes mouse, keyboard and display at the control console area. Power is provided to the UCC Workstation through the cabinet UPS.

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

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 InCise™ 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

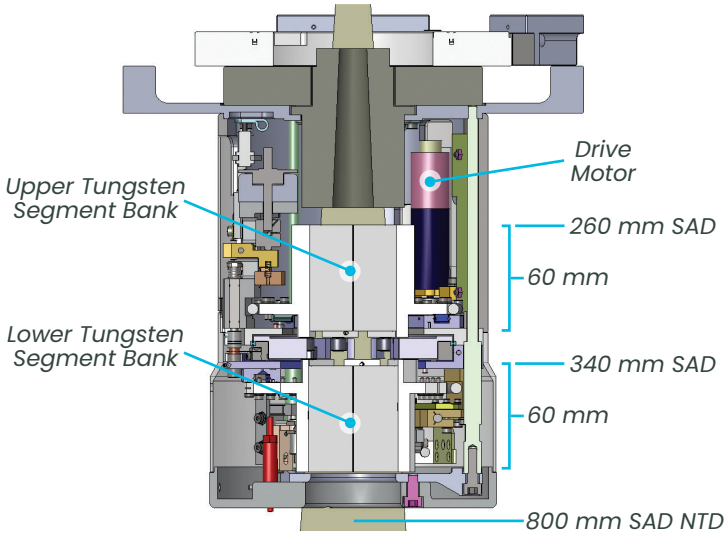
There are 12 fixed secondary collimators with circular field sizes ranging from 5 mm to 60 mm in diameter at 800 mm SAD. These collimators can be changed manually to vary the beam size required by the treatment plan.

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

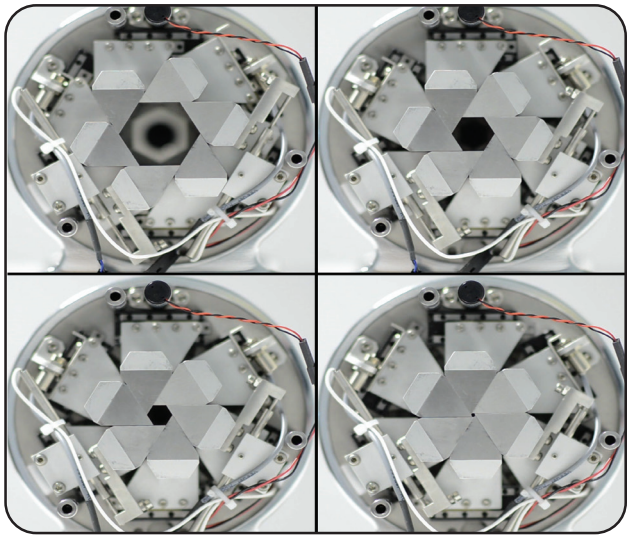
Table holding fixed collimators

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

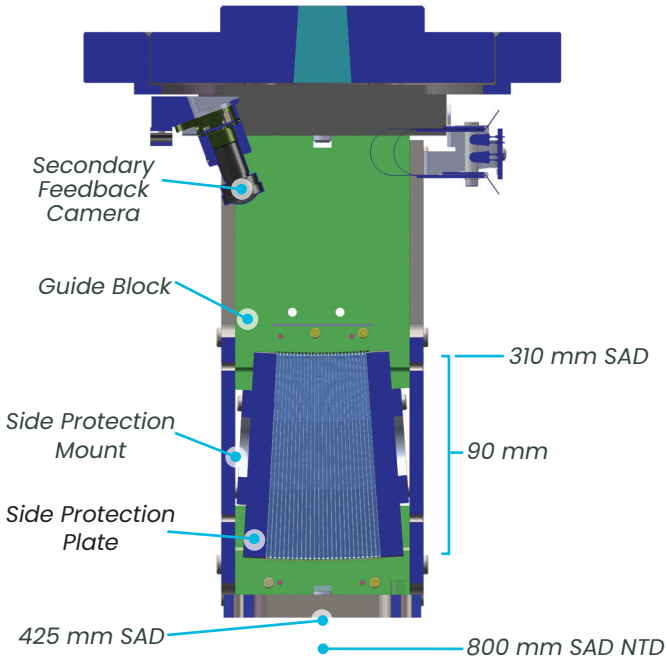
IRIS VARIABLE APERTURE COLLIMATOR SPECIFICATION

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 ofthe 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: ≤ 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™ MULTILEAF COLLIMATOR (OPTION)

The InCise™ 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 Multileaf Collimator



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

InCise MULTILEAF COLLIMATOR SPECIFICATION

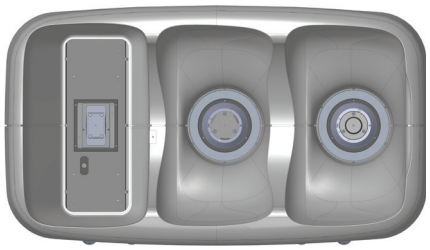
Beam Targeting	Non-coplanar beam targeting
Secondary Check for Leaf Position	Internal optical camera provides live images used during treatment to verify leaf position
Maximum Geometric Field Size	115 mm (leaf motion direction) x 100 mm*
Leaf Tilt	Leaves tilted 0.5˚
Leaf Tip Design	Three-sided
Leaf Width	3.85 mm at 800 mm SAD (normalized for leaf pitch)
Leaf Material	Tungsten
Leaf Positioning Accuracy	Better than ± 0.95 mm at 800 mm SAD from either direction at all possible orientations
Leaf Over-Travel	100%
Leaf Inter-Digitation	Full leaf inter-digitation
Transmission	<0.3% average (<0.5% maximum) relative to a 100 mm x 100 mm Includes intra-leaf and inter-leaf field size at 800 mm SAD
Penumbra (At 800mm SAD and 50mm Depth per IEC 60976 (2007) 9.3.1)	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.

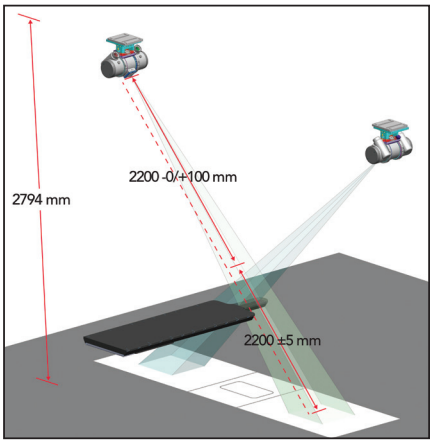
Side view of Xchange Table



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 help 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 ± (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
Collimator Type	Fixed aperture

X-RAY DETECTOR SPECIFICATIONS	Lower Spec Limit
Detector Type	Amorphous silicon with cesium iodide scintillator
Pixel Pitch	400 µm
Total Area	40 x 40 cm^2
MTF @ 0.25 lp/mm	80%
MTF @ 1 lp/mm	33%
DQE @ 0.25 lp/mm, 1 µGy	56%
DQE @ 1 lp/mm, 1 µGy	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.

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

Synchrony® Target Tracking and Motion Synchronization Modalities

REACTIVE MOTION SYNCHRONIZATION

Reactive tracking modalities track the specified target of interest. When a change in position of the target is detected by the system, the system reacts to synchronize the treatment beam position to the target's newly detected position.

MODALITY NAME	TREATMENT TARGET
Synchrony® Skull Tracking™	Intra-cranial targets
Synchrony® Fiducial Tracking™	Targets anywhere in the body where fiducial markers have been implanted
Synchrony® Spine Tracking Supine™	Spine targets with the patient in the supine position
Synchrony® Spine Tracking Prone™	Spine targets with the patient in the prone position

INTEMPO™ IMAGING SYSTEM (OPTION)

The InTempo™ Fiducial Tracking™ with InTempo Imaging System is a time-based technology for non-periodic intra-fraction motion of the target. The InTempo Imaging System can be used in conjunction with the following target tracking methods: Synchrony Fiducial Tracking, Synchrony Skull Tracking, Synchrony Spine Tracking Prone, and Synchrony Spine Tracking Supine.

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. 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.

PROACTIVE (PREDICTIVE) MOTION SYNCHRONIZATION

Proactive tracking modalities track targets that have a relatively consistent or regular pattern of motion. These modalities allow the system to develop a model of what the target's motion looks like and to predict where the target should be located at any given point during a treatment. The motion model is continuously updated and adapted to observed changes so even if the regular pattern of motion changes over time, the system can still predict the target's location with a high degree of accuracy.

SYNCHRONY® RESPIRATORY MODELING™ (OPTION)

Synchrony® Respiratory Modeling™ continuously synchronizes treatment beam delivery with the motion of a target that is moving with respiration by creating a predictive correlation model. The position of the patient's chest is correlated with the position of the target tracked. The Synchrony Respiratory Modeling option must be used in conjunction with the one of the following target tracking methods: Synchrony® Fiducial Tracking™, Synchrony® Lung Tracking™ (1-view & 2-view), or Synchrony® Spine Tracking Prone™. The correlation model enables the system to predict the targets location during treatment and to continuously synchronize the treatment beam with the predicted target location with a high degree of accuracy throughout treatment delivery, even if the patients breathing pattern changes.

MODALITY NAME	TREATMENT TARGET
Synchrony Fiducial Tracking with Respiratory Modeling	Targets anywhere in the body where fiducial markers have been implanted that move with respiration
Synchrony Lung Tracking with Respiratory Modeling	Targets within the lung that move with respiration
Synchrony Spine Tracking Prone with Respiratory Modeling	Spine targets that move with respiration

Safety Features

- Contact Detection
  - Contact detection sensor at the distal end of the secondary collimator housing on the linac
  - Contact detection sensor on back of robot arm
  - 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.
  - The fixed safety zone is rigidly attached to the imaging center and thereby the part of the patient body being treated
  - The dynamic safety zone is designed to encompass the entire patient body and always lies within the fixed safety zone
  - The size of the dynamic safety zone is user selectable based on individual patient sizes (small, medium or large)

Network

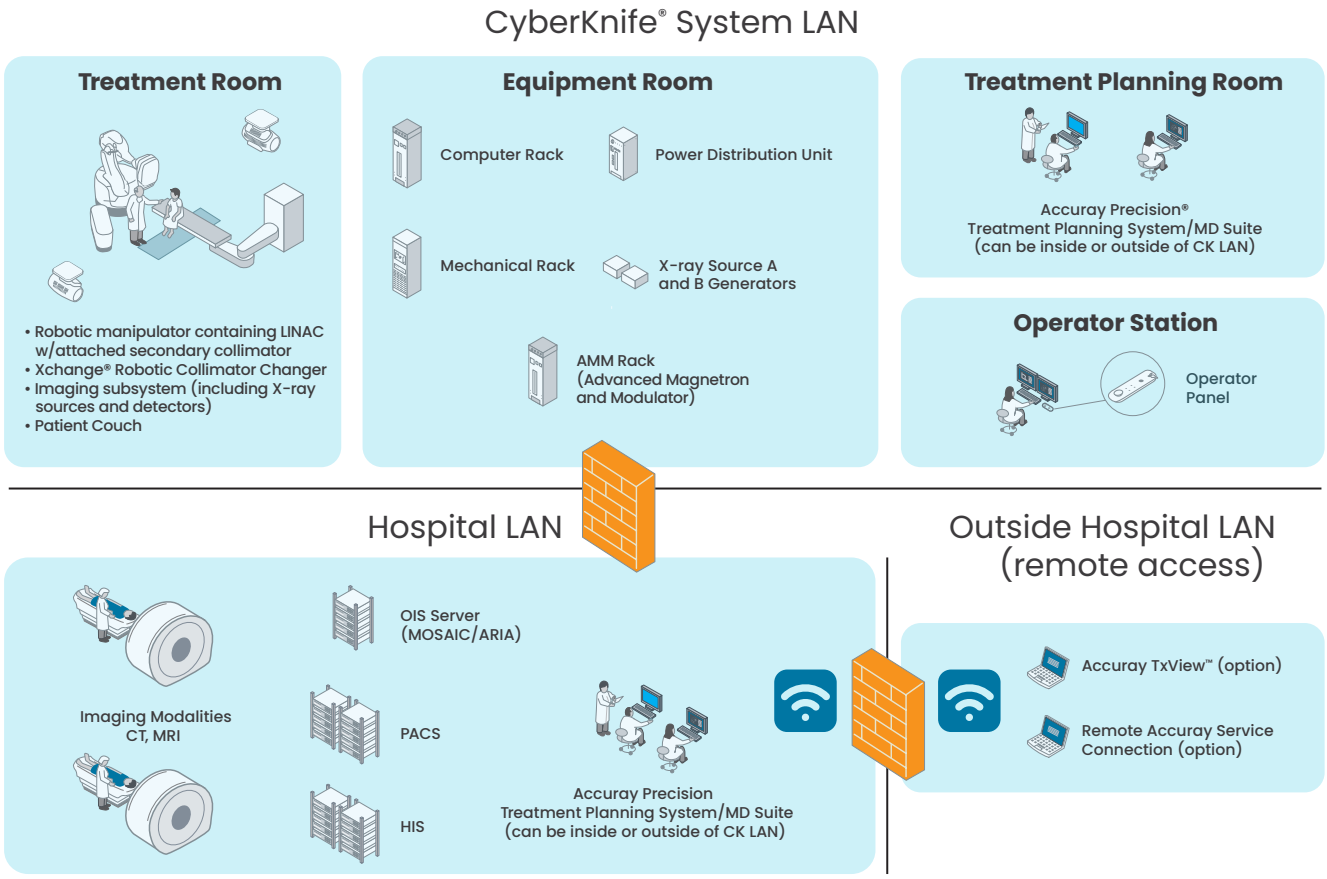
System Interfaces

- 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.



Network Diagram

CyberKnife® M6™ Base System Configurations

Feature	M6 FIM	M6 FI+	M6 FM	M6 FI
Image Guidance System	●	●	●	●
Robotic Manipulator	●	●	●	●
Treatment Delivery Control Console	●	●	●	●
Compact Linac	●	●	●	●
Fixed Collimators	●	●	●	●
Iris™ Variable Aperture Collimator	●	●	○	●
InCise™ MultiLeaf Collimator	●	○	●	○
Xchange® Robotic Collimator Changer	●	●	●	●
Standard Treatment Couch	●	●	●	●
RoboCouch® Patient Positioning System	○	○	○	○
Synchrony® Fiducial Tracking™	●	●	●	●
CNS Package Including: • Synchrony® Skull Tracking™ • Synchrony® Spine Tracking Supine™ • Synchrony® Spine Tracking Prone™ • Brain AutoSegmentation™	●	●	●	●
Prostate Package • Male Pelvis AutoSegmentation™ • InTempo™ Imaging System	●	●	○	○
Spine Prone Package • Synchrony® Spine Tracking Prone™ with Respiratory Modeling	NA	NA	○	○
Lung Package • Synchrony® Fiducial Tracking™ with Respiratory Modeling • Synchrony® Lung Tracking™ with Respiratory Modeling • Monte Carlo Dose Calculation • 4D Treatment Optimization and Planning System	NA	NA	○	○

● – STANDARD FEATURE ○ – OPTIONAL FEATURE

CyberKnife® M6™ Base System Configurations

Feature	M6 FIM	M6 FI+	M6 FM	M6 FI
Spine Prone + Lung Package • Synchrony® Spine Tracking Prone™ with Respiratory Modeling • Synchrony® Fiducial Tracking™ with Respiratory Modeling • Synchrony® Lung Tracking™ with Respiratory Modeling • Monte Carlo Dose Calculation • 4D Treatment Optimization and Planning System	●	●	○	○
Accuray Precision® Treatment Planning Workstation (x2)	●	●	●	●
Additional Accuray Precision Treatment Planning Workstation	○	○	○	○
MD Suite	○	○	○	○
iDMS® Data Management System	●	●	●	●
Radiosurgery DICOM Interface (ARIA or MOSAIQ)	●	●	○	○
Clinical Efficiency Package • Report Administration Application • Storage Vault • TxView™	●	●	○	○

● – 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: IPXO – 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

CyberKnife®

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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.