# CYBERKNIFE<sup>®</sup> M6<sup>™</sup> SERIES Technical Specifications

CyberKnife<sup>®</sup> ACCURAY<sup>®</sup>



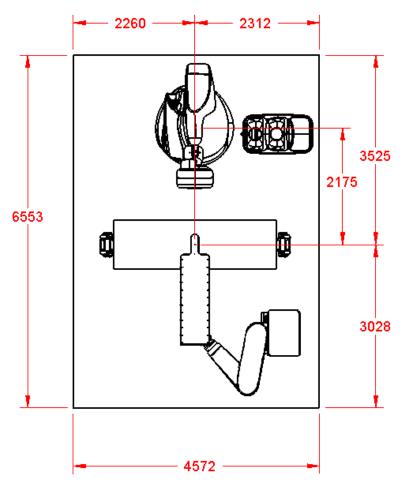
## System Targeting Accuracy

System targeting accuracy accounts for all components of the system. This may be understood as a combination of mechanical, targeting, tracking and clinical accuracy, and includes error sources from the CT scan, treatment planning, patient tracking and dose delivery systems. All these elements comprise the clinically relevant accuracy which may be termed the overall average CyberKnife<sup>®</sup> System error.

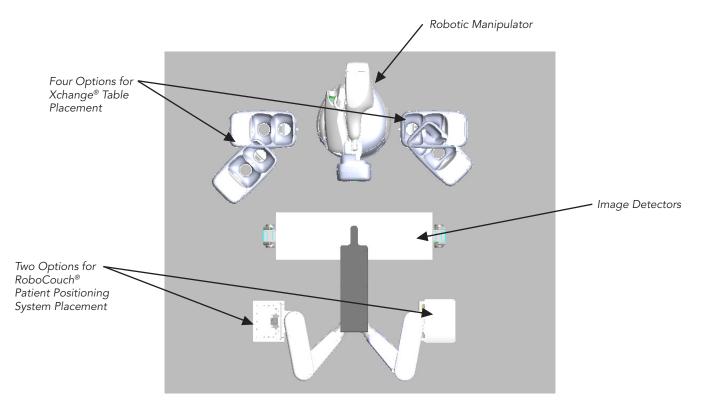
The overall average CyberKnife System error is less than 0.95 mm RMS when a planning CT slice spacing of 1.25 mm or less is used.

#### **Minimum Room Size**

- 15 ft 7 in (4572 mm) wide/long
- 21 ft 6 in (6553 mm) wide/long
- 9 ft 6 in (2896 mm) ceiling



Minimum Room Size



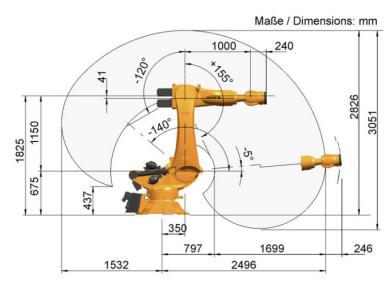
Room diagram with all options shown

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

### **Mechanical Features**

Robot

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

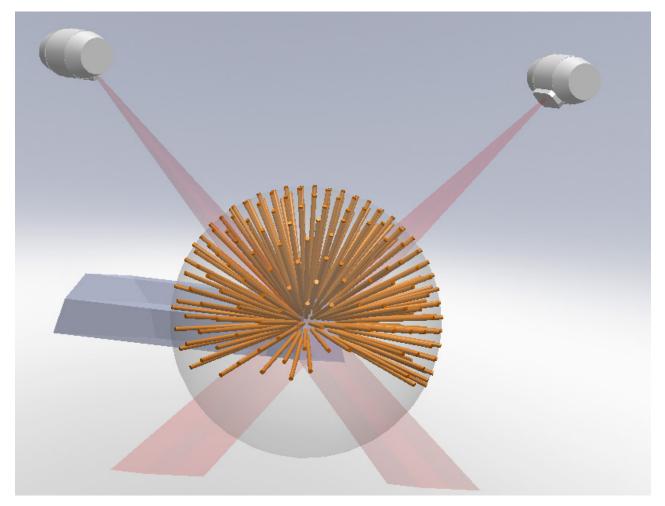


Robot Reach diagram

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 kb (2690 lb)

## Workspace

The robotic manipulator is programmed to move in a fixed and pre-determined workspace. The workspace accounts for the positions of objects in the treatment suite, including the treatment couch, the imaging sources and detectors, the floor and the ceiling, and eliminates collision hazards by creating suitable paths for the robotic manipulator to move in. Additionally, the workspace is comprised of pre-assigned points in space, termed nodes, where the manipulator is allowed to stop in order to deliver radiation. At each node, the linac can deliver radiation from multiple beam angles. It may be noted that this representation is conceptual as the workspace and the treatment paths adopted by the robotic manipulator are dependent on the location of the target and patient anatomy being treated.



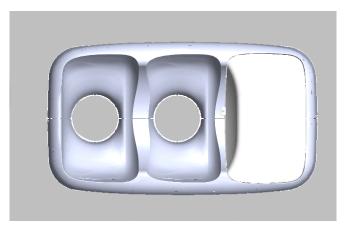
Workspace Geometry

## Xchange® Robotic Collimator Changer

The Xchange Robotic Collimator Changer automatically changes collimator housing prior to patient treatment. The Xchange System is compatible with the Fixed Collimator housing, the Iris<sup>™</sup> Variable Aperture Collimator and the InCise<sup>™</sup> Multileaf Collimator.



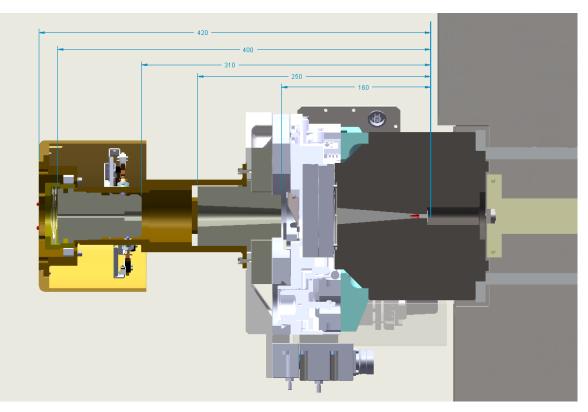
Side view of Xchange Table



Top view of Xchange Table

#### **Linear Accelerator**

• Nominal source to axis (SAD) distance is 800 mm



Basic Beam Line for Fixed Collimator

#### **Dosimetry Specification**

- Chamber type
- Resolution

### PHOTON BEAM SPECIFICATION

Dosimet	ry Sy	ystem
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X-ray Ene	ergy	
Depth of	Maximum Dose (Dmax)	

**Dose Rate** 

**Temperature And Pressure Adjustments** 

**Dosimetry Linearity** 

#### **Quality Index**

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

#### Leakage

Measured anywhere in the patient plane outside of the maximum useful beam (as defined by IEC 60601-1-2) and at 1 m from the electron beam axis that is averaged over an area no larger than 100 cm<sup>3</sup>.

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

**Collimator Transmission** 

Dual sealed ion chambers segmented for symmetry monitoring 6MV Nominal Photon Energy

A two-channel primary/secondary dosimetry system is provided

6MV Nominal Photon Energy

15 mm ±2 mm

1000 MU/min  $\pm$ 10% measured at 800 mm SAD at a depth of 15 mm in water equivalent using the 60 mm fixed collimator

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

Dosimetry linearity with total dose is less than  $\pm 5\%$  or  $\pm 1$  cGy, whichever is smaller over an accumulated range of 1 cGy to 100 cGy, measured at 800 mm SAD with 15 mm build up, within the operating temperature and pressure range

Dosimetry linearity with total dose is less than  $\pm 1\%$  or  $\pm 1$  cGy, whichever is greater over an accumulated range of 100 cGy to 1000 cGy, measured at 800 mm SAD with 15 mm build-up, within the operating temperature and pressure range

Between 0.62 and 0.67 for a 60 mm fixed collimator

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

Leakage 1 m from the electron beam axis is less than 0.1%

Fixed Collimator: The 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 at 800 mm SAD

Iris<sup>™</sup> Collimator: The x-ray transmission through an Iris Collimator's 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 at 800 mm SAD

InCise<sup>™</sup> Multileaf Collimator: Less than 0.5% maximum and 0.3% average at 15 mm depth and 800 mm SAD. Leaf tip leakage (i.e., closed leaves) at full overtravel: less than 0.5% maximum. Both relative to 100 mm x 100 mm at 800 mm SAD and 15 mm depth.

### 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
Computer Rack including:	KVM Extender UPS Network switch Network firewall Temperature controller Monitor and Keyboard ELCC (E-Stop Interlock Control Chassis) TLS (Target Locating System) Workstation UCC (User Control Console) Workstation Data Server Storage Vault (option)

### 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	2 x Intel E5645 2.4 GHz CPU (6 core) for a total of 12 physical cores
Memory	12 GB DDR3 Memory
Storage	2x 300 GB SAS 2.0 15 K Drives mirrored for a total of 300 GB of storage
Graphics Card	nVidia Quadro® 2000 Graphics Card
Ethernet Port	2x Gigabit Ethernet Port
Power Supply	Dual Redundant Power Supply

## CyberKnife® Data Management System (CDMS) Data Server

The CDMS data server is installed in the equipment room. The data server includes mouse, keyboard and display capabilities through the cabinet KVM. Power is provided to the data server through the cabinet UPS (Uninterrupted Power Supply). Notification of power events will occur over an Ethernet connection between the UPS and the data server.

DATA SERVER SPECIFICATION	
CPU	Manufacturer: Intel
	Quantity: 4
RAM	4 GB
SAS Hard Disk Drive	Manufacturer: Seagate Technology Quantity: 3
SATA Hard Disk Drive	Manufacturer: Western Digital Quantity: 3
RAID Card	Adaptec RAID 3805
Operating System	Microsoft® Server 2003 x64 (5 CALs)
Operating System License	Microsoft® Server 2008 x64 (compatible with MS Server 2003 x64)
Database	Microsoft <sup>®</sup> SQL Server 2008 Standard x64 Edition (15 CALs)
3rd party software packages	• Windows <sup>®</sup> Server 2003 Standard x64 Edition
	SQL Server 2008 x64 Standard Edition
	SQL Server Reporting Services
	• 3.5 .NET Framework
	MergeCOM-3 DICOM Libraries

### Storage Vault (Option)

The Storage Vault is an optional workstation used for archiving patient data. It is housed in the equipment room.

STORAGE VAULT SPECIFICATION	
OS	GuardianOS®
CPU	Intel <sup>®</sup> quad-core CPU
Memory	2 GB DDR3 1333 MHz Registered DIMMs
Drive Configuration	9x2 TB 7.2 K Enterprise SATA II
RAID Configuration	RAID 6, 1 Hot Swap
Network Interface	2 x Gigabit Ethernet Ports (autosensing 10/100/1000 Base-T, dual RJ-45 network connections)
USB Interface	2 x USB 2.0 ports

## MultiPlan® Treatment Planning System

The MultiPlan Treatment Planning System is a dedicated planning system for use with the CyberKnife<sup>®</sup> System. The MultiPlan hardware is housed in the "dosimetry" or "planning" room.

MULTIPLAN TREATMENT PLANNING SYSTEM WORKSTATION SPECIFICATION	
CPU	Dual Intel® quad-core CPUs
Memory	24 GB DDR3
Storage	500 GB Hard drive
Graphics Card	Nvidia Quadro 4000 and Nvidia® Tesla C2075 (for M6™ Series w/MLC only)
Ethernet Port	1 Gigabit
Power Supply	>1000 W
Monitor	LCD monitor with a native resolution of 1600x1200 or 1920x1200
Operating System	Windows® 7 x64 operating system

### MultiPlan MD Suite (Option)

**Operating System** 

The MultiPlan MD Suite provides remote secure access to patient record data from the CyberKnife System database. The MD Suite workstation is housed in the remote location.

MD SUITE WORKSTATION SPECIFICATION	
CPU	One Intel quad-core CPU
Memory	12 GB DDR3
Storage	500 GB Hard drive
Graphics Card	Nvidia Quadro 4000 and Nvidia Tesla C2075 (for M6™ Series w/MLC only)
Ethernet Port	1 Gigabit
Power Supply	>1000W
Monitor	LCD monitor with a native resolution of 1600 x 1200 or 1920 x 1200

Windows 7 x64 operating system

### **Treatment Control Area**

Dual Monitors

# TREATMENT DELIVERY SYSTEM MONITOR SPECIFICATION

**Monitor Type** 

**Monitor Size** 

Resolution

**Monitor Stands** 

2x NEC<sup>®</sup> MyltiSync EA 243WM

24 inches each

1920 x 1200 each for a total workspace of 3840 x 1200

The monitors are attached to a solid frame desktop dual monitor mount

Operator Panel, including the following:

- Indication of MV beam on
- Indication of KV image acquisition
- Indication of remote/local control
- Button to enable High Voltage
- Indication of High Voltage on
- Key switch to turn MV radiation on and off
- Emergency Stop button
- Audible sounds for KV and MV radiation



**Operator Panel** 

### Administration Workstation (Option)

The Administration Workstation provides access to a series of patient, plan and system administration applications. This workstation, including mouse, keyboard and monitor, can be housed at a remote location.

ADMINISTRATION WORKSTATION SPECIFICATION	
CPU	Intel Core 2 Duo E6400 2.13 Ghz 2 MB Cache 106 Mhz
RAM	DIMM 1024 MB 800 MHz Unbuffered DDR2 installed in Socket DIMM 1024 MB 800 MHz Unbuffered DDR2 installed in Socket 2
DVD Drive	Plextor® PX-820A DL Dual RW Int Drive
Hard Disk	Seagate Barracuda ES.2 900 GB 7200 RPM 32 MB Cache SATA 3.0 GB/S x 4
Video Card	ATI FireGL <sup>®</sup> V3600 256 MB PCI Express
Operating System	MS Windows 7 Professional (64 bit)

### **Collimation Systems**

#### SECONDARY COLLIMATION

The CyberKnife® M6<sup>™</sup> Series uses multiple secondary collimator types to deliver beams as defined by the treatment plan.

- CyberKnife M6 FI System includes the Fixed Collimators and the Iris™ Variable Aperture Collimator
- CyberKnife M6 FM System includes the Fixed Collimators and the InCise™ Multileaf Collimator
- CyberKnife M6 FIM System includes the Fixed Collimators, the Iris Variable Aperture Collimator and the InCise Multileaf Collimator

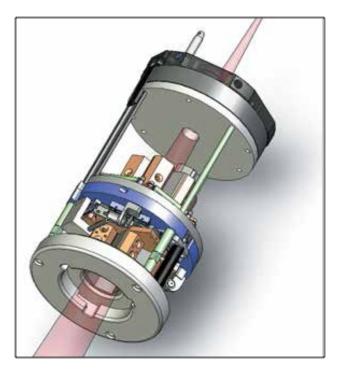
#### FIXED COLLIMATORS:

Fixed secondary collimators deliver circular field sizes of 5, 7.5, 10, 12.5, 15, 20, 25, 30, 35, 40, 50 and 60 mm diameter at 800 mm SAD. These collimators can be changed to vary the beam size as generated by the treatment plan. For each fixed collimator, the manipulator traverses a separate path.

FIXED COLLIMATOR SPECIFICATION	
Collimator Transmission	The x-ray transmission through the blank collimator at a SAD of 800 mm does not exceed 0.2% of the central axis (CAX) dose rate of a 60 mm fixed collimator at 800 mm SAD
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

#### **IRIS™ VARIABLE APERTURE COLLIMATOR**

The Iris Variable Aperture Collimator creates beams with characteristics virtually identical to those of fixed collimators. It consists of two banks of 6 tungsten segments each with each bank creating a hexagonal aperture. The two are offset by 30° relative to each other resulting in a dodecahedral (12-sided) aperture when viewed from one end of the collimator to the other. The Iris Variable Aperture Collimator replicates the existing 12 fixed collimator sizes.

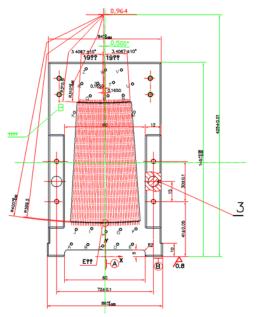


Iris<sup>™</sup> Variable Aperture Collimator

### IRIS<sup>™</sup> 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	<ul> <li>Maximum: &lt; 0.2% of the delivered dose rate</li> <li>Average: &lt; 0.1% of the delivered dose rate</li> </ul>
Reproducibility	<ul> <li>Mechanical: less than 0.1 mm</li> <li>Treatment field size: &lt; 0.2 mm at the nominal treatment distance of 800 mm SAD</li> </ul>
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

#### INCISE<sup>™</sup> MULTILEAF COLLIMATOR



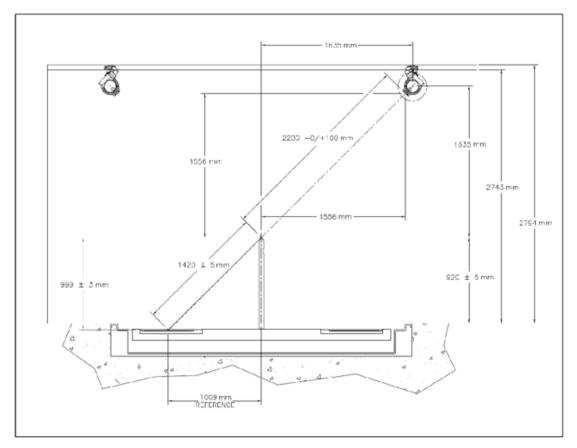
Basic Beam Line for InCise<sup>™</sup> Multileaf Collimator

### INCISE<sup>™</sup> MULTILEAF COLLIMATOR SPECIFICATION As defined by IEC 60976

Beam Targeting	Non-Isocentric, Non-Coplanar Beam Targeting
Maximum Field Size	Nominal: 120 mm (leaf motion direction) x 100 mm at 800 mm SAD
Number of Leaves	41 leaf pairs
Leaf Thickness	2.5 mm at 800 mm SAD
Leaf Tilt	Leaves tilted 0.5°
Leaf Tip Design	3-Sided
Leaf Height	90 mm
Leaf Material	Tungsten
Distal Plane of Leaves to Linac Source Distance	400 mm
Leaf Positioning Accuracy	0.5 mm at 800 mm SAD
Mechanical Accuracy	0.25 mm
Leaf Positioning Reproducibility	0.4 mm at 800 mm SAD
Mechanical Reproducibility	0.2 mm
Leaf Over-Travel	100%
Leaf Inter-Digitation	Full Leaf Inter-Digitation
Transmission Includes intra-leaf, inter-leaf and leaf tip transmission	<0.3% Average (<0.5% Maximum)
Weight	48 kg (~105 lbs)

### Imaging

The CyberKnife<sup>®</sup> M6<sup>™</sup> Series use kV X-ray imaging to provide target localization during treatment. The imaging system consists of two X-ray sources mounted to the ceiling, and corresponding image detectors mounted in the floor. The X-ray sources are positioned such that the generated beams intersect orthogonally and create an imaging center located 92 cm (36.22 in) from the floor. All treatments on the CyberKnife System are based around the imaging field of view. The live images are digitized and compared to images synthesized from the patient's CT data (Digitally Reconstructed Radiograph, or DRR). This technique allows for determination of intra-fraction target shifts and automatic compensation by the treatment manipulator during treatment delivery.



Imaging System Geometry

### COMPACT X-RAY GENERATOR SPECIFICATIONS

Constant Potential Power Rating (kw)	50.0
Radiographic kVp range	40-150 ± (5% + 1 kVp)
Resolution	1 kVp
mA Range and Stations	10, 12, 5, 16, 20, 25, 32, 40, 50, 64, 80, 100, 126, 160, 200, 250, 320, 400, 500, 640 ± (5% + 1 kVp)
Power Output	640 mA @ 78 kVp 500 mA @100 kVp 400 mA @ 125 kVp 320 mA @ 150 kVp
Exposure Time	20-640 ms + (5% + 0.1 ms)
mAs	0.1 – 640 mAs

### X-RAY SOURCES SPECIFICATIONS

#### Electrical

• Circuit	3-phase
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 min.
Firing Modes	Synchronous and Asynchronous
Collimator Type	Fixed Aperture

### X-RAY DETECTOR SPECIFICATIONS

	Lower Spec Limit
Detector Type	Amorphous Silicon
Number of Pixels	1024 × 1024
Pixel Pitch	400 µm
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 μGy	56%
DQE @ 1 lp/mm, 1 µGy	28%

### **Target Tracking**

Accurate target tracking and compensating for target motion are an integral part of the CyberKnife<sup>®</sup> 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 and motion compensation are achieved through the use of the imaging system integrated with the treatment delivery system. The image guidance system calculates the required offsets based on the patient's current position. During patient set-up, the table (the Standard Treatment Couch or the RoboCouch® Patient Positioning System) is adjusted to align the patient with the treatment plan. During the delivery of the treatment the system automatically corrects the linac position for any calculated offsets (within a specified tolerance).

### **Offset Tolerance for Intra-Fraction Robotic Corrections\***

	RoboCouch <sup>®</sup> System	RoboCouch System with Prostate Path	Standard Treatment Couch	Standard Treatment Couch with Prostate Path
X, Y, and Z	±10 mm	±10 mm	±10 mm	±10 mm
X, Y, and Z with Synchrony® Respiratory Tracking System	± 25 mm	± 25 mm	± 25 mm	± 25 mm
Pitch	± 1.5°	± 1.5°	± 1°	± 5°
Roll	± 1.5°	± 2°	± 1°	± 2°
Yaw	± 1.5°	± 3°	± 3°	± 3°

\*Subject to change based on target tracking method selection

Target tracking on the CyberKnife<sup>®</sup> System uses one of the following tracking methods: 6D Skull Tracking, Fiducial Tracking, Xsight<sup>®</sup> Spine Tracking, Xsight Spine Prone Tracking, Xsight Lung Tracking, or 1-View Tracking.

## **Target Tracking Method**

### **6D SKULL TRACKING SYSTEM**

The 6D Skull Tracking System allows 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 lesions that are located extracranially, target tracking can be carried out with the use of fiducials.

- General guidelines for fiducials:
  - o Gold Seeds or gold sphere
  - o Diameter: 0.7 mm to 1.2 mm
  - o Length: 3 mm to 6 mm

• Minimum 3 fiducials are required for 6D target tracking, including corrections for translations (x, y, z) and rotations (roll, pitch, 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.

Target tracking with the Xsight Spine System is accomplished using 2D-3D registrations on a hierarchical mesh where local displacements at each of the mesh points are estimated and combined to provide 6D corrections to the treatment manipulator.

#### 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<sup>®</sup> Respiratory Tracking System to offer continuous real-time tracking and compensation for target motion due to 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 directly without the use of fiducials by using image intensity differences between the lesion and the background. The patient is first aligned using the Xsight Spine Tracking workflow, then the Xsight Lung Tracking System tracks the translational motion of the target.

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

Lung Optimized Treatment includes a Simulation Application and these two tracking modes: 1-View Lung Tracking and 0-View Lung Tracking. Together, these two tracking methods provide fiducial-less treatments for lung SBRT patients, 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 clearly visible and can be tracked in only one X-ray projection during treatment
  - o Provides direct tracking of lung lesions in 2-dimensions o Uses an ITV in the non-visible 3rd dimension
- 0-View Lung Tracking is used when the treatment target is not clearly visible in either X-ray projection, resulting in the need to track the bony anatomy of the vertebral column during treatment
  - o Provides direct tracking of the spine without fiducials
  - o Uses an ITV in all dimensions to compensate for respiratory motion of the tumor

## **Motion Tracking**

Motion tracking on the CyberKnife<sup>®</sup> System uses one of these methods: The Synchrony<sup>®</sup> Respiratory Tracking System or the InTempo<sup>™</sup> Adaptive Imaging System. Motion tracking is used in conjunction with an applicable target tracking method.

#### SYNCHRONY® RESPIRATORY TRACKING SYSTEM

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<sup>®</sup> Lung Tracking, Xsight Spine Prone Tracking, and 1-View Tracking.

The system operates by creating a correlation model between the patients's breathing pattern, monitored in real-time, and the location of the target at various points in the respiration cycle. The location of the target is determined by using X-ray imaging to visualize the lesion 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 type to be utilized for the treatment by choosing the one that minimizes overall correlation error. The model is chosen from linear, curvilinear and bi-curvilinear forms. The model is based on the latest 15 sets of X-ray images taken and is updated every time a new image is acquired.

#### INTEMPO ADAPTIVE IMAGING SYSTEM

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 allow 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 15s.

## **Safety Features**

- Cryptzone's SE46 Virus Protection
  - o Whitelist approach instead of blacklist
  - o No updates
  - o Configuration management
  - o Will not be able to use any software that is not a part of the release
- 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

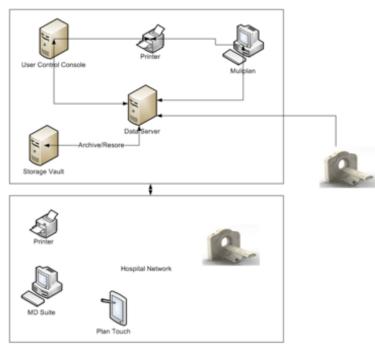
• Safety Zones: The robot workspace also takes into consideration the position of the patient and is designed to avoid contact with the patient. This is achieved by creation of a safety zone around the patient and the treatment couch. The safety zone consists of two elements: fixed and dynamic.

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:
  - o DICOM Image Import
  - o DICOM RT Structure Set Import
  - o DICOM Image Export
  - o DICOM RT Structure Set Export
  - o DICOM RT Dose Export
- OIS License Required to generate objects:
  - o DICOM RT Plan Export
  - o DICOM RT Beams Treatment Record Export



Network diagram

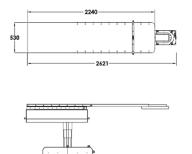
## **Patient Positioning Support**

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

	Standard Treatment Couch	RoboCouch <sup>®</sup> System (Optional)
Payload	159 kg (350 lb)	227 kg (500 lb)
Range of Motion		
Anterior/Posterior	28 cm	42 cm
• Right/Left	±15 cm	±18 cm
Superior/Inferior	≥91 cm	≥100 cm
<ul> <li>Head Up/Head Down (pitch)</li> </ul>	±5°	±5°
• Right/Left Tilt (roll)	±5°	±5°
• Yaw (CW/CCW)	N/A	±5°
Control	Remote Workstation Local Hand Pendant	Remote Workstation Local Hand 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

### **Standard Treatment Couch**

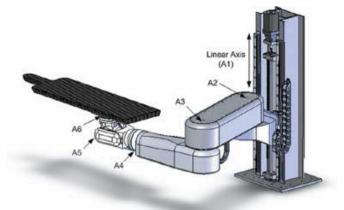
The standard Treatment Couch is the standard patient support system of the CyberKnife System. It provides the user with flexibility in patient positioning by providing 5 DOF motion capabilities.





## **RoboCouch® Robotic Patient Positioning System (option)**

The RoboCouch System provides a highly flexible 6-DOF mechanism for automatically positioning the patient. The combination of the RoboCouch System and the robotic manipulator for linac positioning enables the CyberKnife® System to deliver dose precisely, and to the right location. 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 either a flat carbon fiber couch top (standard with the RoboCouch System) or a seated load carbon fiber table top (optional). The RoboCouch System has five rotational axes and one linear axis.

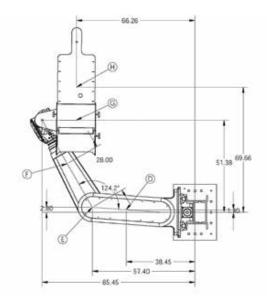


• KRC4 controller

- SmartPAD Teach Pendant with a touch screen interface
- Two possible locations in room based on the room geometry: on patient right or patient left

## Seated Load Table Top (Option)

The Seated Load Table Top option is offered for the RoboCouch System. It is an articulating couch top that allows patients to be loaded in a seated position. The seated load table top converts to a flat table top to offer flexibility in positioning and loading the patient. The patient can be treated either in a knees-flat or a knees-elevated position.





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)	<ul> <li>Alpha Cradle<sup>®</sup></li> <li>Vacuum Lock Bags</li> <li>Thermoplastic masks</li> </ul>
Indexing	Compatible with CIVCO indexing systems

	Flat with Standard	Flat With RoboCouch® System	Seated Load Option with RoboCouch System
Minimum Load Height	≤64 cm (25 in)	≤56 cm (22 in)	Seated Load: ≤ 45 cm (17.9 in) Horizontal Load: ≤ 58 cm (23 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)	Length: 212 cm (83.4 in) Width: 53 cm (21 in) Thickness: 6.4 cm (2.5 in)

## **Regulatory Classification**

The CyberKnife<sup>®</sup> 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<sup>®</sup>



#### UNITED STATES

#### Accuray Corporate Headquarters 1310 Chesapeake Terrace Sunnyvale, CA 94089 USA Tel: +1.408.716.4600 Toll Free: 1.888.522.3740 Fax: +1.408.716.4601 Email: sales@accuray.com

#### Accuray Incorporated 1240 Deming Way Madison, WI 53717 USA Tel: +1 608 824 2800 Fax: +1 608 824 2996

Shin Otemachi Building 7F 2-2-1 Otemachi, Chiyoda-ku Tokyo 100-0004 Japan Tel: +81.3.6265.1526 Fax: +81.3.3272.6166

ASIA

Accuray Japan K.K.

#### Accuray Asia Ltd. Suites 1702 - 1704, Tow The Gateway, Harbour C 9 Canton Road, T.S.T. Hong Kong Tel: +852.2247.8688

#### Accuray Accelerator Technology #39 Huatai Road, Longtan

#39 Huatai Road, Longtan Industrial Zone, Section 2 East, 3rd Ring Road, Chengdu, Sichuan 610051 People's Republic of China

#### EUROPE

Accuray International Sarl Route de la Longeraie 9 (3rd floor) CH - 1110 Morges Switzerland Tel: +41.21.545.9500 Fax: +41.21.545.9501

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