ACCURAY®

# CYBERKNIFE® M6™ SERIES

Technical Specifications

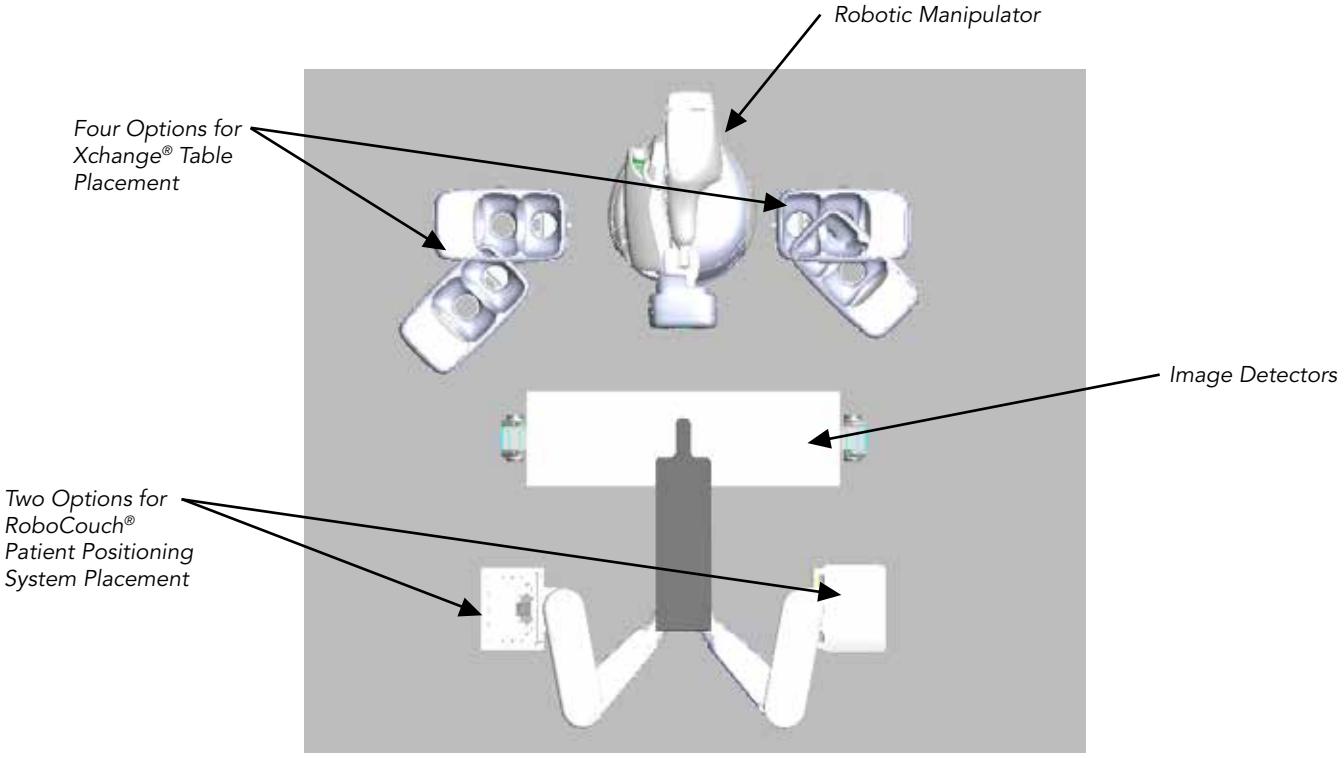
CyberKnife®

The CyberKnife® M6™ Series offers a comprehensive set of clinical features. Indication-specific tumor tracking with automatic correction throughout treatment, true robotic mobility and advanced collimation integrate seamlessly into the only system to automatically stay on target despite patient and tumor movement. 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 a non-coplanar and non-isocentric environment. This flexibility and precision instill great confidence in clinicians who prescribe, plan and treat patients with CyberKnife technology.
- Fully-integrated, indication-specific tracking applications to 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 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 M6 Series provides more flexibility than ever with new InCise™ Multileaf Collimator (MLC) delivery modes, improved patient handling process, streamlined setup and treatment and optimized linear accelerator workspace. All combine to help improve the experience and comfort of patients.

## Complete Treatment System

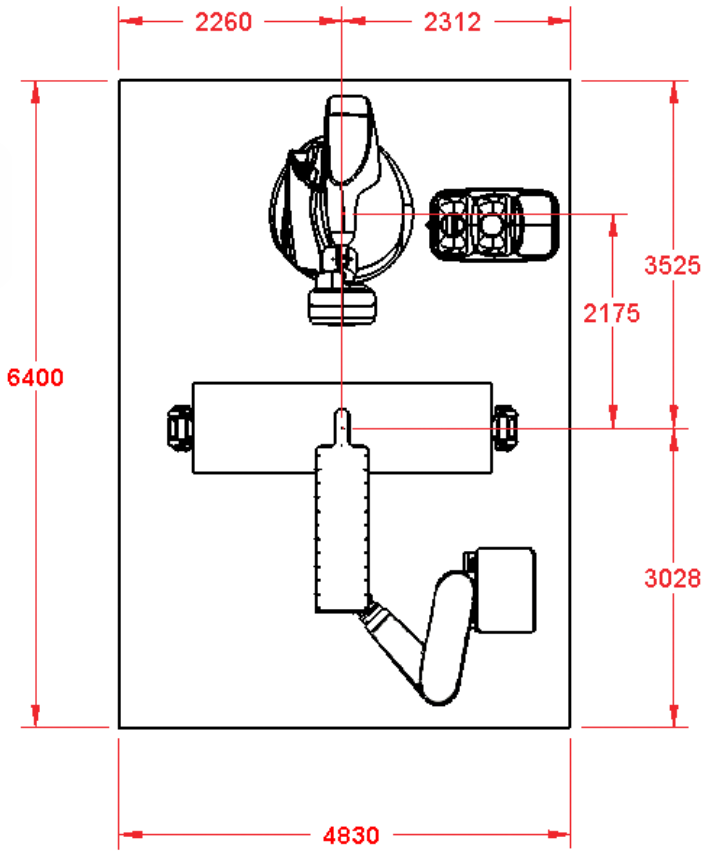



*Room diagram with all options shown*

# Installation

## Minimum Room Size

- 15 ft-10 in (4830 mm) wide/long
- 21 ft (6400 mm) wide/long
- 9 ft-7 in (2896 mm) ceiling



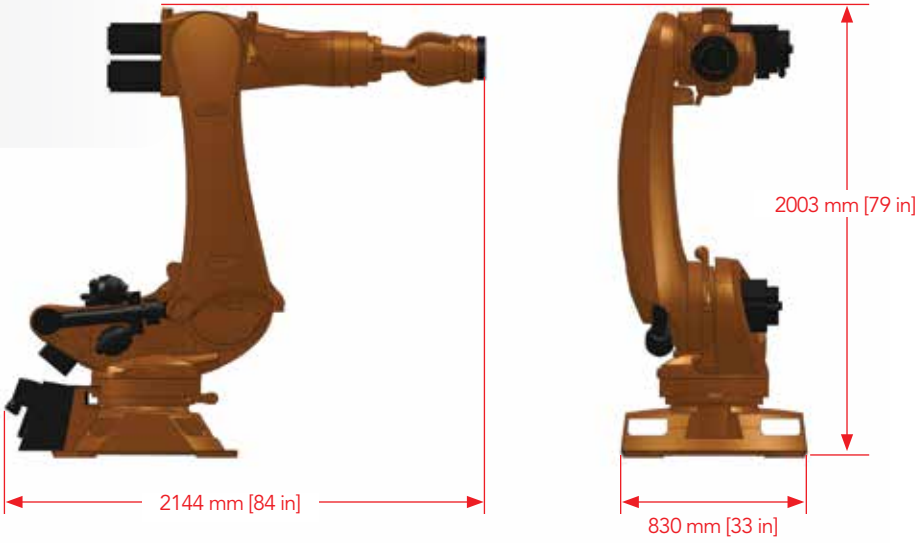

## Treatment Vault Environment

| | |
|---|---|
| Temperature: | 10˚C to 23.9˚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

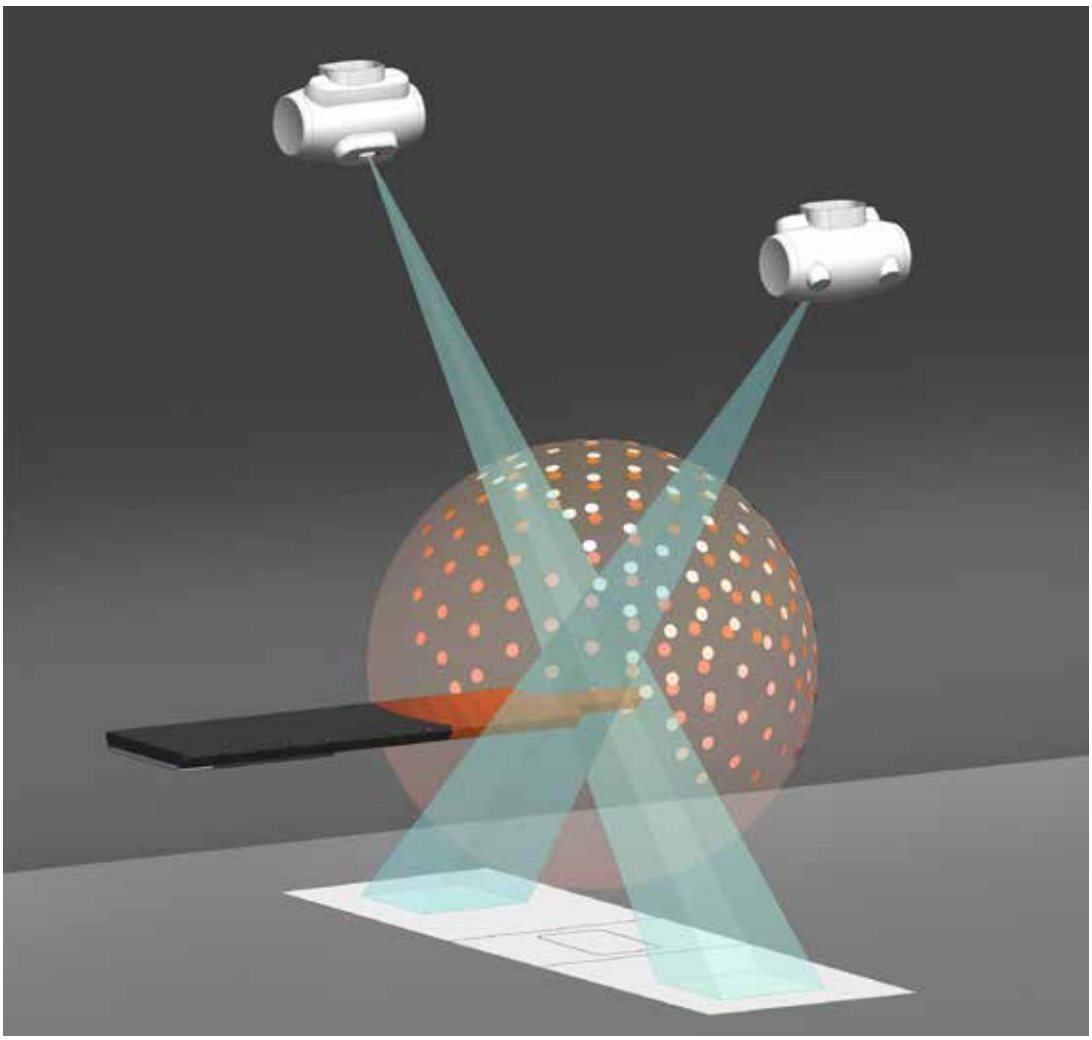


## ROBOTIC MANIPULATOR SPECIFICATIONS

| | |
|---|---|
| **Payload** | 300 kg (661 lb) |
| **Maximum Reach** | 2500 mm (98 in) |
| **Number of Axes** | 6 |
| **Work Envelope** | 41 $m^3$ |
| **Weight** | 1220 kb (2690 lb) |

# 3D Workspace

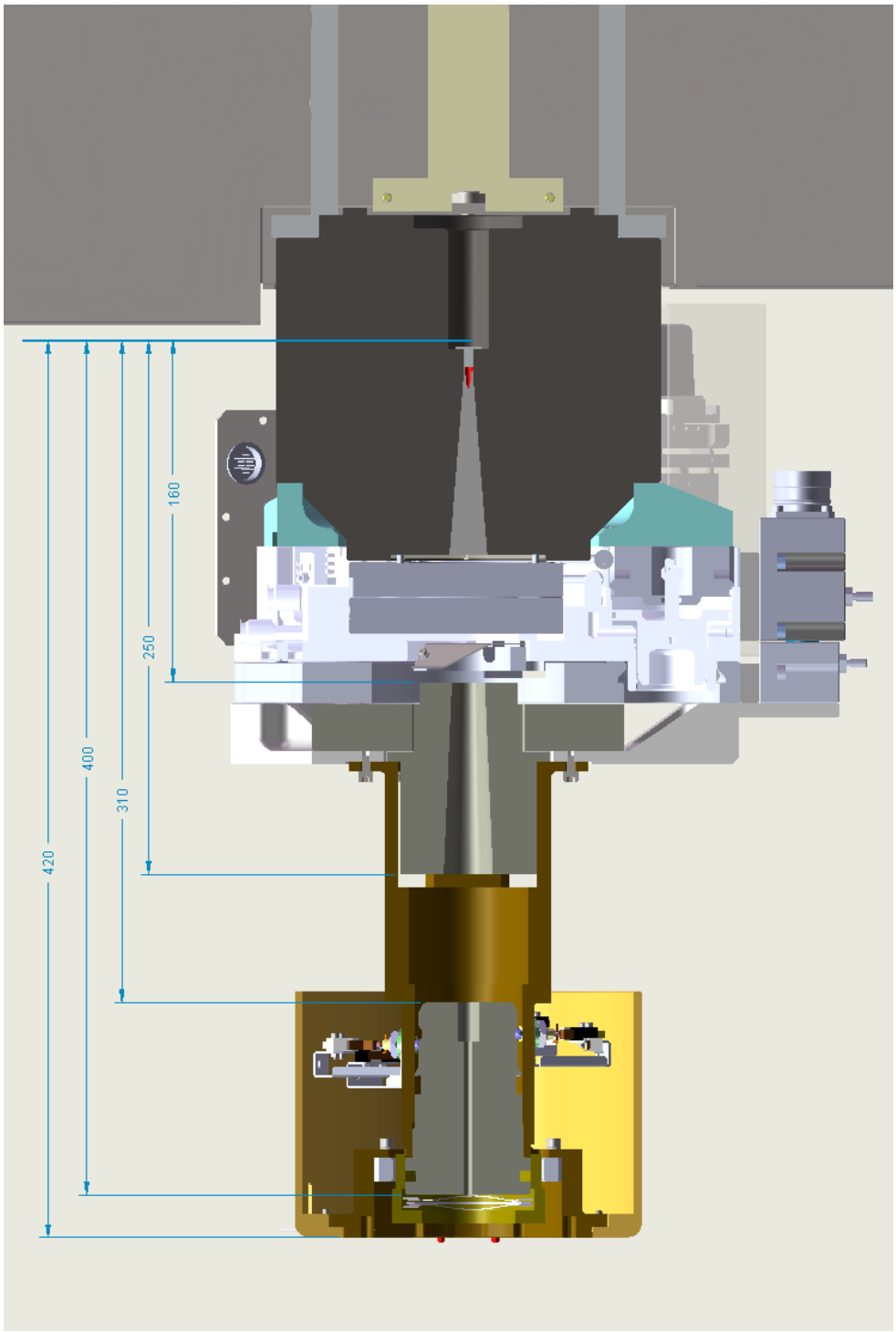
The robotic manipulator is programmed to move in a fixed and pre-determined workspace. The workspace accounts for the positions of objects in the treatment suite, including the treatment couch, the imaging sources and detectors, the floor and the ceiling, and eliminates collision hazards by creating suitable paths in which the robotic manipulator can navigate. Additionally, the workspace is comprised of pre-assigned points in space and 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*

## Linear Accelerator

- Nominal Source to Axis Distance (SAD) is 800 mm




*Basic beam line for fixed collimator*

## Dosimetry Specification

| | |
|---|---|
| • **Chamber type** | Dose Chamber A: Sealed ion chamber<br>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 Photon Energy |
| **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**<br>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**<br>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)<br><br>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<br><br>Scatter 1 m from the radiation head is less than 0.1% |
| **Collimator Transmission** | 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 and 15 mm depth<br><br>Iris™ 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 and 15 mm depth<br><br>InCise™ 2 Multileaf Collimator: Less than 0.5% maximum and 0.3% average at 800 mm SAD 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<br>Air Compressor<br>SF6 |
| **AMM (Advanced Magnetron Modulator) Rack, including:** | LCC (Linac Control Computer)<br>LPDU (Linac Power Distribution Unit)<br>MCC (Modulator Control Chassis)<br>Gun Driver<br>Modulator |
| **Computer Rack, including:** | KVM Extender<br>UPS<br>Network switch<br>Network firewall<br>Temperature controller<br>Monitor and Keyboard<br>ELCC (E-Stop Interlock Control Chassis)<br>TLS (Target Locating System) Workstation<br>UCC (User Control Console) Workstation<br>Data Server<br>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 (DMS) Data Server

The DMS 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 Uninterrupted Power Supply (UPS). Notification of power events will occur over an Ethernet connection between the UPS and the data server.

| DATA SERVER SPECIFICATION | |
|---|---|
| **CPU** | Manufacturer: Intel<br>Quantity: 4 |
| **RAM** | 4 GB |
| **SAS Hard Disk Drive** | Manufacturer: Seagate Technology<br>Quantity: 3 |
| **SATA Hard Disk Drive** | Manufacturer: Western Digital<br>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® SQL Server 2008 Standard x64 Edition (15 CALs) |
| **Third-Party Software Packages** | • Windows® Server 2003 Standard x64 Edition<br>• SQL Server 2008 x64 Standard Edition<br>• SQL Server Reporting Services<br>• 3.5 .NET Framework<br>• 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® 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® 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)

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 |
| **Operating System** | Windows 7 x64 operating system |

## Treatment Control Area

- Dual Monitors

## TREATMENT DELIVERY SYSTEM MONITOR SPECIFICATION

| | |
|---|---|
| **Monitor Type** | 2x NEC® MultiSync EA 243WM |
| **Monitor Size** | 24 inches each |
| **Resolution** | 1920 x 1200 each for a total workspace of 3840 x 1200 |
| **Monitor Stands** | 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*

# Collimation Systems

## SECONDARY COLLIMATION

The CyberKnife® M6™ 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

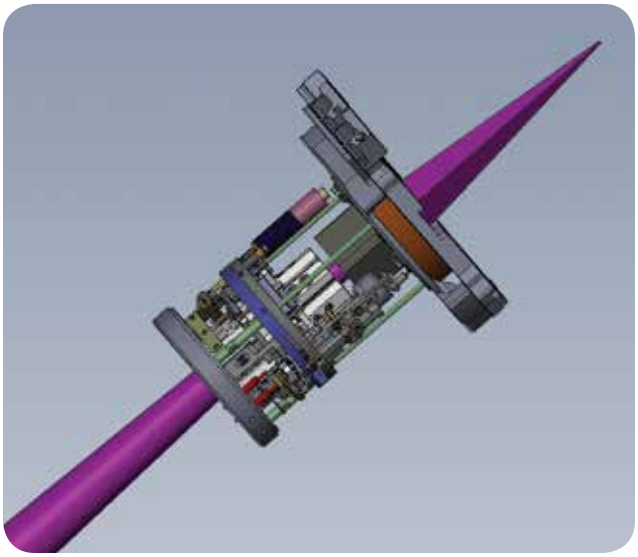
## FIXED COLLIMATORS:

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 (OPTION)

The Iris Variable Aperture Collimator creates beams with characteristics virtually identical to those of fixed collimators. It consists of two banks of six 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.

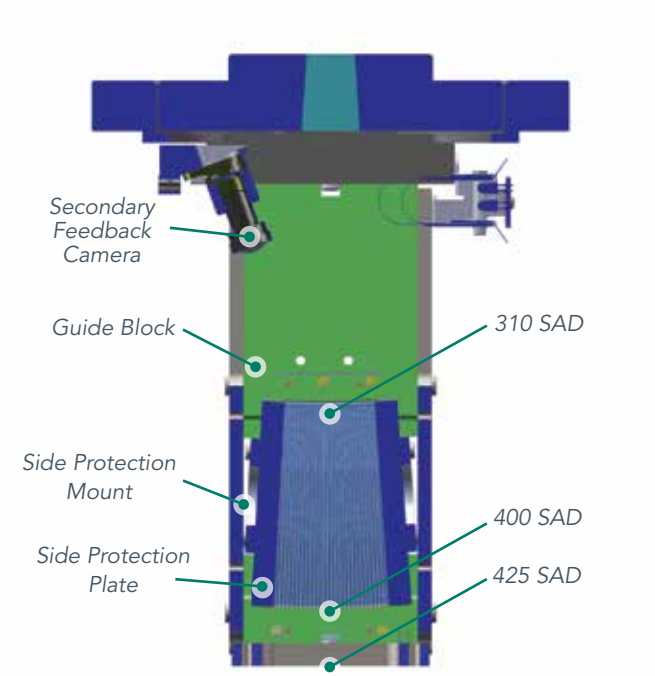


*Iris™ Variable Aperture Collimator*

### 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** | • Maximum: < 0.2% of the delivered dose rate<br>• Average: < 0.1% of the delivered dose rate |
| **Reproducibility** | • Mechanical: less than 0.1 mm<br>• Treatment field size: < 0.2 mm at the nominal treatment 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 |

## INCISE™ MULTILEAF COLLIMATOR (OPTION)




*Basic beam line for InCise™ 2 Multileaf Collimator*

### INCISE™ 2 MULTILEAF COLLIMATOR SPECIFICATION *As defined by IEC 60976*

| | |
|---|---|
| **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** Includes intra-leaf and inter-leaf | <0.3% Average (<0.5% Maximum) relative to a 100 mm x 100 mm field size at 800 mm SAD |
| **Penumbra** | Better than 3.5 mm in X and Y for 10 mm x 10 mm field size<br>Better than 12 mm X and 20 mm Y for a 100 mm x 100 mm field size |

* Configured by software

## Xchange® Robotic Collimator Changer (OPTION)

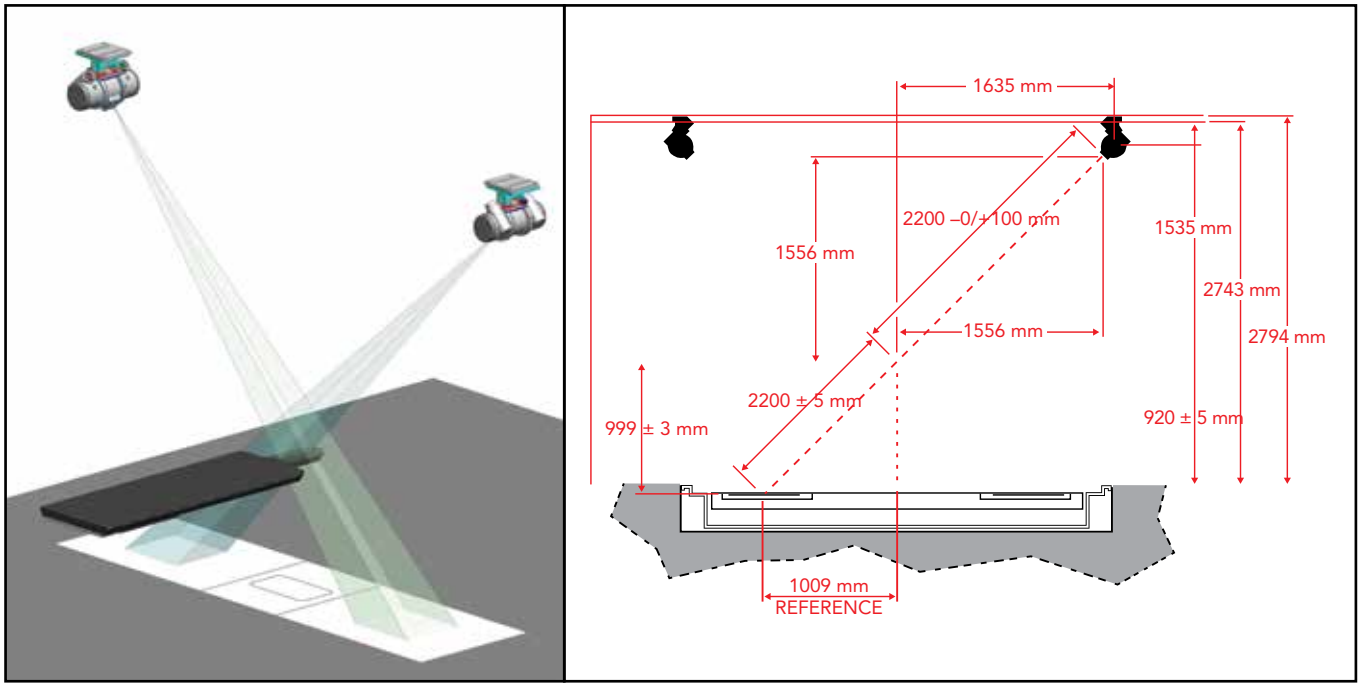
The Xchange Robotic Collimator Changer automatically changes collimator housing prior to patient treatment. The Xchange System is compatible with the Fixed Collimator housing, the Iris™ Variable Aperture Collimator and the InCise™ Multileaf Collimator.

*Side view of Xchange table*

*Top view of Xchange table*

## Imaging

The CyberKnife® M6™ 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 enables 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, 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<br>500 mA @100 kVp<br>400 mA @ 125 kVp<br>320 mA @ 150 kVp |
| **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<br>Small focus: 0.6 mm |
| **• Nominal Anode input power** | Large focus: 100 kW<br>Small focus: 40 kW |
| **Aluminum Filter** | 2.5 mm |
| **Firing Modes** | Synchronous and Asynchronous |
| **Collimator Type** | Fixed Aperture |

## X-RAY DETECTOR SPECIFICATIONS

| | **Lower Spec Limit** |
|---|---|
| **Detector Type** | Amorphous Silicon |
| **Number of Pixels** | 1024 x 1024 |
| **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 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 of these elements comprise the clinically relevant accuracy, which may be termed the overall average CyberKnife® 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.

## Target Tracking

Accurate target tracking and compensating for target motion are an integral part of the CyberKnife 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 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˚ | ± 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 System uses one of the following tracking methods: 6D Skull Tracking, Fiducial Tracking, Xsight® 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 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 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 three 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® Respiratory Tracking System to offer continuous real-time tracking and compensation for target motion because of 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 fiducialless 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 two dimensions
    - o Uses an ITV in the non-visible third 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® System uses one of these methods: The Synchrony® Respiratory Tracking System or the InTempo™ 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® Lung Tracking, Xsight Spine Prone Tracking and 1-View Tracking.

The system operates by creating a correlation model between the patient'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 (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.

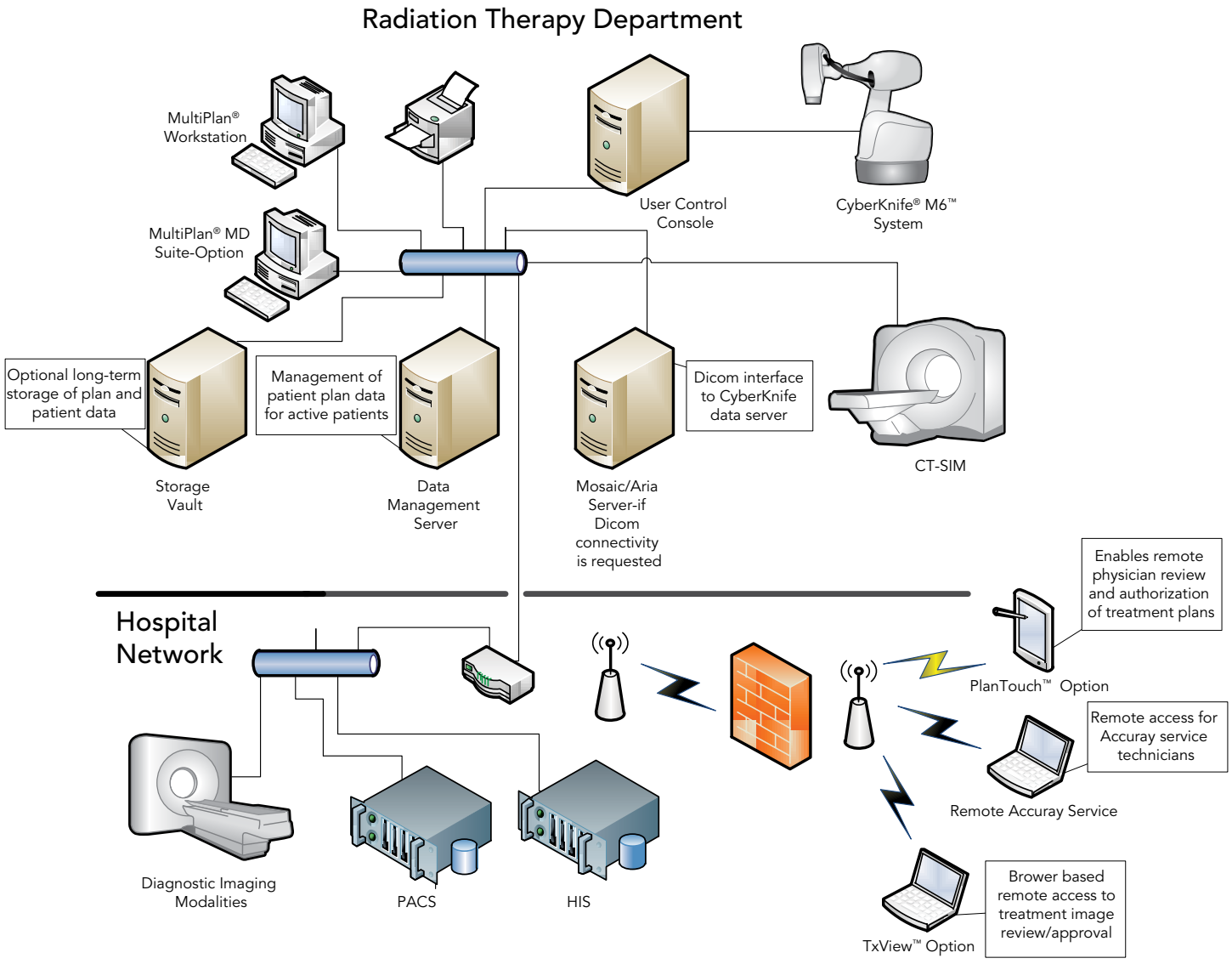
# Safety Features

- 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




*Network diagram*

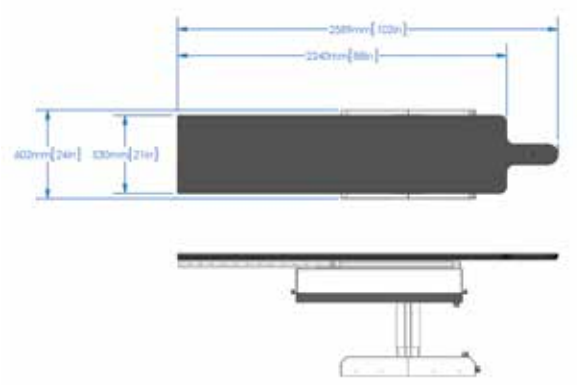
# Patient Positioning Support

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® System (Optional) |
|---|---|---|
| **Payload** | 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<br>Local Hand Pendant | Remote Workstation<br>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 |

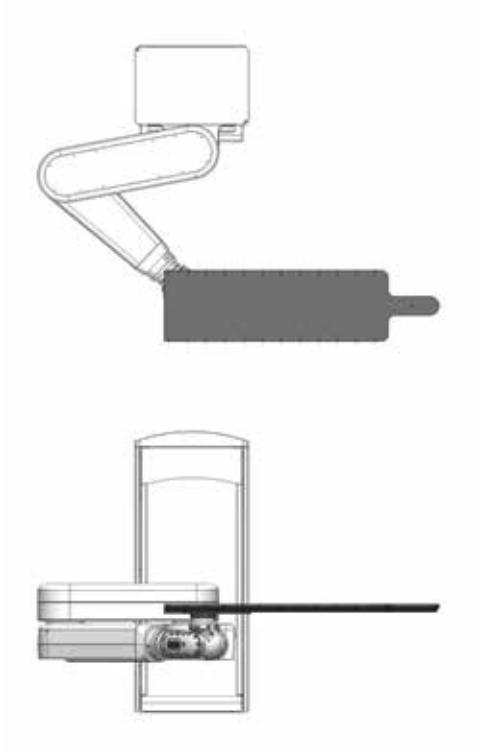
# Standard Treatment Couch

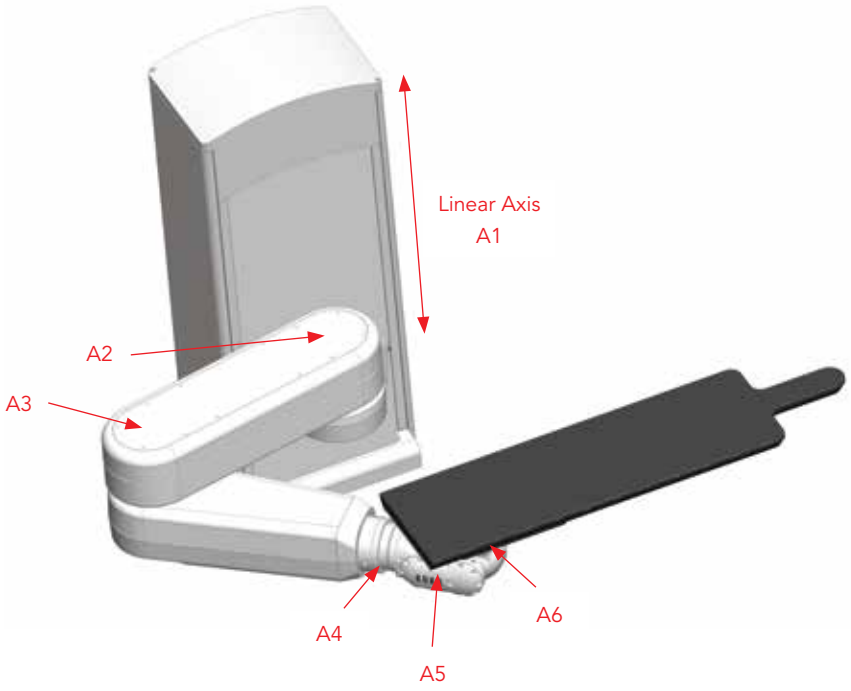
The Standard Treatment Couch is the standard patient support system of the CyberKnife System. It provides the user with flexibility in patient positioning by providing 5 DOF motion capabilities.



# RoboCouch® Robotic Patient Positioning System (OPTION)

The RoboCouch System provides a highly flexible six-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 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.






- 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

## 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®<br>• Vacuum Lock Bags<br>• 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)<br>Width: 53 cm (21 in)<br>Thickness: 7.6 cm (3 in) | Length: 206 cm (81 in)<br>Width: 53 cm (21 in)<br>Thickness: 5.7 cm (2.25 in) |

# 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®

ACCURAY®


**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

**ASIA**

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

**Accuray Asia Ltd.**
Suites 1702 - 1704, Tower 6
The Gateway, Harbour City
9 Canton Road, T.S.T.
Hong Kong
Tel: +852.2247.8688
Fax: +852.2175.5799

**Accuray Accelerator Technology**
#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