ACCURAY®

Site Planning Guide(SPG)

CyberKnife® Treatment Delivery System, Version 11.x, M6™ Series

CyberKnife®

Site Planning Guide
CyberKnife® Series Treatment Delivery System, Ver. 11.x, M6™ Series
M6™ Series, Version 11.x

Part number: C-SPG-0001
Revision: A
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Manufacturer's name: Accuray Incorporated
Manufacturer's address: 1310 Chesapeake Terrace, Sunnyvale, CA 94089
Type of equipment: Radiotherapy equipment
Note: Any modification of the named device without written authorization by Accuray Incorporated will invalidate this declaration.

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1.0 INTRODUCTION

1.1 Scope

This guide covers the CyberKnife® Treatment Delivery System, Version 11.x, M6™ Series

1.2 Overview

This guide was written to provide essential information to our customers and their contractors in the design and construction of their CyberKnife System suite. The information in this guide is meant to provide a starting point of general information, upon which site-specific information can be added.

Each customer will be assigned a dedicated Customer Operations Manager and Site Planner, who will provide both remote and onsite assistance.

Accuray Incorporated's goal during the site planning process is to help our customers achieve both a timely and trouble-free CyberKnife System installation.

1.3 Regulatory Requirements

In the United States, Accuray is available to assist our customers with their CON (Certificate of Need) or OSHPD (Office of Statewide Health Planning and Development) processes, if applicable to their state. The Accuray Sales representative will act as the contact for the CON process, and the Site Planner for the OSHPD process.

Internationally, Accuray, or its distributor, is available to assist our customers with any regulatory requirements that they may have.

The customer is responsible for obtaining all local, state and national permits and requirements associated with site planning, shielding, site preparation, construction, system installation and system maintenance.

Accuray customers are responsible for all reports and submissions to any governing body related to radiation surveys, radiation safety and physics reports.

In the United States, the customer is responsible for meeting any requirements of HIPAA (Health Insurance Portability & Accountability Act of 1996), which may affect the design of the CyberKnife suite and/or the control of patient data.

Please refer any regulatory questions to your Accuray Sales representative, Site Planner or Regulatory personnel.

1.4 Accuray Contact Information

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1.5 Roles and Responsibilities

The Customer Operations team will assist the customer and their representatives to successfully implement the CyberKnife System into the facility. The roles and responsibilities are defined below.

REGIONAL PROJECT MANAGER

The Customer Operations Regional Manager is your main point of contact at Accuray. He/she will coordinate the A-Z meeting, as well as introduce you to other Accuray resources, such as training, reimbursement, service and sales operations. In addition, the Customer Operations Regional Manager will assist with your project schedule, aid in achieving critical milestones and support your timeline.

SITE PLANNING RESPONSIBILITIES

- Work with you to coordinate your facility construction requirements, to help you ensure that your site is constructed to Accuray specifications.
- Work with Accuray Designer to develop a set of site-specific drawings, entailing the project specifications.
- Interface with your Architects, Engineers, Contractors, IT/IS and other facilities-related personnel.
- States may conduct site inspection or system inspection.

2.0 System Components, Descriptions and Site Planning Considerations

2.1 TREATMENT ROOM

Also known as the vault or bunker, the Treatment Room typically contains the following components:

	DESCRIPTION	L x W x H (IN)	L x W x H (MM)	WEIGHT (LBS)	WEIGHT (KGS)
1a	Treatment Manipulator	96 x 48 x 84	2807 x 1428 x 2728	4607	2094
1b	Linear Accelerator	See #1a	See #1a	726	330
1c	Interchangeable Secondary Collimators	2.75 x 2.5 x 2.5 ea	70 x 64 x 64 ea	280 (all)	127 (all)
1d	Treatment Manipulator Teach Pendant	13 x 10 x 3	330 x 254 x 76	3	1.36
1e	Iris™ Collimator (optional)	6 x 6 x 10.5	152 x 152 x 267	50	22.7
1f	InCise™ 2 Multileaf Collimator (optional)	6 x 6 x 10.5	152 x 152 x 267	105	48
2	In-Floor Image Detectors (Quantity=2) (for both)	110 x 28.5 x 10.5	2794 x 724 x 267	950	430.3
3a	X-ray Sources (Quantity=2) (each)	20 x 14 x 16	506 x 358 x 405	160	73
3b	X-ray Source Heat Exchangers (Quantity=2) (each)	9.7 x 9.2 x 4.75	244 x 232 x 121	13.5	6.13
4	X-ray Generators (Compact) (Quantity=2) (each)	24 x 15 x 27	609 x 381 x 685	332	150
5	Standard Treatment Couch	89 x 22 x 38	2260 x 560 x 970	350	159
6	Synchrony® System Camera	36 x 18 x 75	915 x 457 x 1905	25	11.34
7	RoboCouch® System (optional) w/ couch-mounted Hand Controller	101 x 47 x 95	2565 x 1194 x 2413	4000	1814
8	Xchange® Table	51 x 29 x 51	1290 x 736 x 1290	(See table 2)	(See table 2)

Table 1 Treatment Room Equipment Specifications (Accuray supplied)

Note: The CyberKnife® System numbers in first column refer to identifiers on the site-specific drawings.

Table 2 Xchange Table Weights

DESCRIPTION	WEIGHT (lbs)	WEIGHT (kgs)
Fixed Collimator Housing	307 lbs	139.3 kgs
InCise™ 2 Multileaf Collimator (optional)	105 lbs	48 kgs
Iris™ Collimator (optional)	50 lbs	22.7 kgs
All 13 Interchangeable Fixed Collimators	91 lbs	41.3 kgs

2.1.1 ACCURAY SUPPLIED (Required)

Treatment Manipulator (Item 1a – floor mounted)

Description: A six-axis manipulator used for positioning and pointing the Linear Accelerator (LINAC) for patient treatment.

Site planning considerations: The manipulator is bolted to a floor frame that is embedded in the floor concrete during the pre- installation process (See Section 5.1: Pre-Installation Process). Conduits will be installed from the floor frame to the Equipment Room (details will be shown on the site-specific drawings). The movement of the manipulator and LINAC within the room dictates room space requirements, including horizontal distances between finished walls and vertical distances between the finished floor and finished ceiling. See Section 3: Room Specifications for more information.

Linear Accelerator (LINAC) (Item 1b – mounted to the Treatment Manipulator)

Description: The LINAC delivers the radiation treatment to the patient and utilizes a compact 6MV LINAC at 1000 MU/min.

Site planning considerations: There are customer shielding considerations for the LINAC. Please see Section 2: Radiation Shielding Guidelines.

Interchangeable Secondary Collimators
(Items 1c – the collimators reside in the Xchange® Table)

Description: Fixed Collimators are in diameters of 5.0, 7.5, 10.0, 12.5, 15.0, 20.0, 25.0, 30.0, 35.0, 40.0, 50.0, and 60.0 millimeters.

Site planning considerations: These 12 collimators, plus additional solid and pinhole collimators, weigh approximately 16.1 pounds each (7.3 kg).

Treatment Manipulator Teach Pendant (Item 1d – wall mounted)

Description: A wall-mounted remote control device used to manually operate the Treatment Manipulator.

Site planning considerations: A conduit will need to be installed from the mounting frame within the slab under the Treatment Manipulator through the concrete floor to the wall and then up the wall to a single gang electrical box on the wall, located at 48 inches (1.22 m) above finished floor. A cover with at least a one inch (25 mm) center hole should be provided for the box. Accuray will provide and install the wall-mounted bracket over the box on the wall at the time of the system installation.

In-Floor Image Detectors (Quantity=2)
(Item 2 – floor mounted – at and below floor level)

Description: The detectors are used along with the X-ray Sources to correctly position the patient for treatment and to monitor patient positioning during treatment. They are installed in an Accuray-supplied fiberglass tub that sits at and below floor level, with the top of the tub covers sitting flush with the finished floor.

Site planning considerations: The fiberglass tub will be embedded in concrete during the pre-installation process. It is important for the room's finished flooring to fit up against the edges of the tub channel pieces so that the detector covers fit closely against the flooring for a finished look. See Accuray Incorporated's site-specific Drawings for more information on the relationships between the fiberglass tub, concrete floor, detector covers and the finished flooring. Also see Section 5.1: Pre-installation Process.

X-ray Sources (Quantity=2) (Item 3a – ceiling mounted)

Description: The oil-cooled X-ray Sources are used as part of a larger system to track patient positioning. They are attached to the vault ceiling, via a Unistrut, above the imaging detectors.

Site planning considerations: The Unistrut and related hardware used to support the X-ray Sources will be supplied by and attached to the vault ceiling by Accuray personnel during the pre-installation process (See Section 5.1: Pre-Installation Process). For a steel ceiling cap, the customer's contractor will need to weld adaptor plates (supplied by Accuray) to the steel ceiling. For vaults with ceiling elevations 12 ft (3.66 m) or higher Accuray will install an extension kit for the Unistrut that includes cross bracing. Conduits [6 in (150 mm) and/or 4 in (100 mm)] from each X-ray Source to the X-ray Generators will need to be installed by the customer's contractor. Details will be shown on the site-specific drawings. Accuray requires service access to the X-ray Sources and Unistrut. For servicing, Accuray recommends that the customer install an acoustical ceiling (or at minimum large access panels) in this area. Note: If the customer plans for a drywall ceiling, Accuray requires a 1 ft (30 cm) square access panel near the X-ray sources. If the space between the vault ceiling and finished ceiling is 1 ft (30 cm) or more, Accuray requires a 2 ft (60 cm) square access panel near the X-ray sources.

X-ray Source Heat Exchangers (Quantity=2) (Item 3b – ceiling mounted)

Description: The heat exchangers are oil-based and are used to cool the X-ray Sources.

Site planning considerations: The heat exchangers can be positioned almost anywhere against the vault ceiling or walls above the finished ceiling, as long as there is sufficient clearance for service and replacement. Due to cable length restrictions, they cannot be placed in the Equipment Room. Accuray will install mounting plates to the ceiling cap during the pre-installation process. The heat exchangers will be attached to the mounting plates during the system installation. Do not install HVAC, lighting or other components that will interfere with the heat exchangers. Please see Section 5.1: Pre-Installation Process for more information.

X-ray Generators (Quantity=2) (Item 4 – floor mounted)

Description: These two cabinets supply high-voltage power to the X-ray Sources.

Site planning considerations: The X-ray Generators may be located in the Treatment or Equipment Rooms. Placement of the X-ray Generators is dependent on site-specific requirements.

Standard Treatment Couch (Item 5 – floor mounted)

Description: The Standard Treatment Couch is used to position the patient during treatment using automatic patient positioning technology. The maximum patient weight load capacity of the Standard Treatment Couch is 350 lbs (159 kg). One couch pad and head base plate is included with this system. Note: It is recommended that the site purchase a secondary couch pad for use with their CT unit.

Site planning considerations: During the pre-installation process, Accuray will install a small conduit for providing cabling access from the imaging tub to the base of the table. During installation, Accuray will drill and anchor the couch to the floor.

Synchrony® Camera (Item 6 – ceiling mounted)

Description: The Synchrony® Camera is used to track, detect and correct for respiratory motion. It is attached to a suspended rod mounted to the vault ceiling near the foot of the treatment couch.

Site planning considerations: Accuray will install a plate to the concrete or steel ceiling cap during the pre-installation process. Steel ceilings require the customer's contractor to weld an adaptor plate, supplied by Accuray. Service access to the Synchrony camera and Unistrut are required. Customers should install an acoustical ceiling (or at minimum large access panels) in this area. Note: If the customer plans for a drywall ceiling, Accuray requires a 1 ft (30 cm) square access panel near the Synchrony Camera. If the space between the vault ceiling and finished ceiling is 1 ft (30 cm) or more, Accuray requires a 2 ft (60 cm) square access panel near the Synchrony Camera.

Emergency Components

Description: The Emergency Power Off (EPO) switch (quantity=1) is installed within the Treatment Room, located near the Treatment Room door. The Emergency Motion Off (EMO) switches (quantity=4) are installed on all four walls within the Treatment Room, near the center.

Site planning considerations: Accuray supplies the switch mechanisms, push buttons, covers and labels. The customer supplies the boxes, conduits, wiring and installation. All boxes are single gang electrical boxes, placed 48 in (1.22 m) above the finished floor.

Xchange® Table (Item 8 – floor mounted)

Description: The Xchange Table is positioned near the Treatment Manipulator. It houses the fixed collimators, the Iris™ Collimator and the InCise MLC, (if applicable. Site planning considerations: A small conduit [2 in (50 mm)] and electrical box [6 in square (150 mm)] should be installed in the concrete floor for the Xchange Table as shown on the site-specific drawings.

Site planning considerations:
Note: Due to light sensitivity, lights should not be placed in the ceiling directly above the Xchange Table as indicated on the Accuray site-specific drawings.

2.1.2 ACCURAY SUPPLIED (Optional)

InCise™ Multileaf Collimator [Item 1f – stored on the Xchange Table]

Description: Uses tungsten leaf pairs to shape the beam, using Non-Coplanar beam targeting.

Site planning considerations: N/A

Iris™ Variable Aperture Collimator [Item 1e – stored on the Xchange Table.

Description: Uses tungsten leaves to rapidly manipulate beam geometry.

Site planning considerations: N/A

RoboCouch® Patient Positioning System (Item 7 – floor mounted)

Description: The RoboCouch System (optional to the Standard Treatment Couch). The maximum patient weight load capacity of the RoboCouch System 7c is 500 lbs (227 kg). It comes standard with a flat top.

Site planning considerations: The RoboCouch Systems bolts to a floor frame that is embedded in concrete during the pre-installation process. Accuray will install the RoboCouch floor frame at all customer sites, regardless of purchase order. This minimizes future construction and associated costs if the option is purchased at a later date. A 6 in (150 mm) conduit is required from the RoboCouch floor frame to the Equipment Room. Details will be shown on the site-specific drawings.

2.1.3 CUSTOMER SUPPLIED ITEMS (Required)

Patient Positioning Lasers

See Section 5.7: Patient Positioning Lasers

Hands-free Patient Intercom

See Section 5.8: Intercoms

Closed Circuit TV (CCTV) Cameras

See Section 5.9: Closed Circuit TV (CCTV)

Adequate storage

Storage for QA tools, Synchrony® vests, patient masks and body immobilization devices should be taken into consideration. The site-specific drawings will indicate areas in the Treatment Room where it is acceptable to install sinks and cabinets.

2.1.4 CUSTOMER SUPPLIED (Optional)

(unless required by local regulations)

Nurse Call Button(s)

Sink

Used for patient prep and QA equipment

Medical Gas Lines

Customers may elect to install medical gas and vacuum outlets directly in the Treatment Room or use mobile gas carts. Some patients, especially children, may require anesthesia. Please consult with the site administrator and/or physicians to determine the exact needs. These installations may include:

- Oxygen
- Air
- Nitrous Oxide
- Vacuum
- Waste Anesthetic Gas Disposal

Remote Patient Monitoring

This is typically used for monitoring anesthetized or other critical patients and can be accomplished via several methods:

- The mobile monitoring system can be kept in the Treatment Room, with one of the pan/zoom cameras focused on the screen for viewing in the operator's area.
- The remote monitoring cables can be run through the physics port that exists between the Treatment Room and the Control Room.
- A separate conduit can be designed and built into the wall for the purpose of patient monitoring.
- The customer can have a system built into the Treatment Room.

2.2 CONTROL ROOM

The Control Room can be configured in many ways, depending upon the site layout and desire of the customer. Typically, it includes the following equipment:

2.2.1 ACCURAY SUPPLIED

User Control Console, Synchrony & System Administrative Workstation

(Item 9, 10 & 12 – placed on a desktop or counter top)

Description: This console consists of a dual LCD flat panel monitors, keyboard and mouse.

LINAC Control Panel (Emergency Power Off) Panel

(Item 11 – placed on a desktop or counter top)

Description: This control box sits on the Control Room counter top, within easy reach of the operator. Their overall measurement is 15 in wide x 10 in deep x 6 in high (381 mm x 254 mm x 152 mm).

EPO (Emergency Power Off) Push Button

Description: The EPO push button is supplied by Accuray and is installed by the Customer's contractor. It should be installed in the wall near the LINAC Control Panel.

2.2.2 CUSTOMER SUPPLIED (Required)

Phone with Long Distance Access

The phone is used for routine service and emergency communication. The phone number should be provided to Accuray prior to the installation.

Hands-free Main Intercom

See Section 5.8: Intercoms

Closed Circuit TV (CCTV) Monitoring System

See Section 5.9: Closed Circuit TV (CCTV)

Customer Network Data Port with Internet Access

To be used by Accuray personnel during system installation and service activities.

Emergency Components

"X-ray On" light positioned above the Treatment Room door. The customer supplies all the materials related to this light, including power. Accuray will supply the signal to the light via the CIB in the equipment room.

Physics Conduit Port (Dosimetry Tube) into the Treatment Room

This port is used for running QA and Commissioning tools and equipment cables between the Control Room and Treatment Room. It is typically a 4 in (100 mm) conduit that runs from the top of the Control Room desk to the lower wall of the Treatment Room at a 45-degree angle, both vertically and horizontally, with access boxes and/or doors on either end.

Note: For site planning considerations for the Control Room, please see Section 3: Room Specifications.

2.3 EQUIPMENT ROOM

The Equipment Room is typically located adjacent to or close to the shielded walls of the Treatment Room and is intended to hold the bulk of support equipment needed for the CyberKnife® System. The distance from the Equipment Room to both the Treatment and Control Rooms is limited by the maximum cable lengths allowed between system components.

2.3.1 ACCURAY SUPPLIED

Controller (for the Treatment Manipulator) (Item 13 – floor mounted)

Modulator (Item 14 – floor mounted (with brackets to concrete))

Computer Rack (Item 15 – floor mounted)

Power Distribution Unit (PDU) Rack (Item 16 – floor mounted)

Customer Interface Box (CIB)

This is a standard electrical wall box, approximately 12 in wide by 12 in tall x 4 in deep (300 mm wide x 300 mm tall x 100 mm deep) with an 18-20 point terminal strip inside. On one side of the terminal strip is the wiring from the EPOs, EMOs, Door switch, and "X-ray On" light circuitry. These connections are made by the customer's electrician in accordance to the Accuray site-specific drawings. Located on the other side of the terminal strip is the wiring leading to the emergency circuitry (ESCC) within the CyberKnife System. These connections are made by Accuray installers.

Mechanical Rack (Item 17 – floor mounted)

The mechanical rack includes the chiller, which is self-contained (does not require a chilled water source for operation).

Note: This equipment can either sit on the floor (on its rollers), or be anchored to the concrete slab as required by OSHPD or other seismic requirements.

Customer Network Data Port with Internet Access

To be used by Accuray personnel during system installation and service activities.

2.3.2 ACCURAY SUPPLIED (Optional)

Controller (for the optional RoboCouch® System) (Item 18 – floor mounted)

If the Standard Treatment Couch has been purchased, the controller is not needed. However, in anticipation of any potential future upgrade to the RoboCouch System, we recommend that adequate floor space be available. Please see Section 3: Room Specifications.

2.3.3 ACCURAY ITEM SPECIFICATIONS – Equipment Room

Listed in the following table are the typical specifications for the items described above.

Table 3 Equipment Room Equipment Specifications

	DESCRIPTION	L x W x H (IN)	L x W x H (MM)	WEIGHT (LBS)	WEIGHT (KGS)
13	Controller for Treatment Manipulator	23 x 32 x 61	584 x 813 x 1550	407	185
14	AMM (Modulator)	40 x 32 x 79.5	1020 x 808 x 2018	1162	528
15	Computer Rack (includes iDMS, Gateway, and Core Network hardware)	38 x 25 x 71	965 x 635 x 1803	672	305
16	Power Distribution Unit (PDU)	38 x 25 x 51	965 x 635 x 1295	957	434
17	Mechanical Rack	38 x 25 x 71	965 x 635 x 1803	530	240
18	Controller (for optional RoboCouch System)	24 x 31 x 61	600 x 790 x 1550	330	150

Note: There are operating and service clearances required around this equipment. Please refer to the site-specific drawings.

2.3.4 CUSTOMER SUPPLIED (required)

Main Power Disconnect

Please see Section 4.1: Power Requirements.

Air Conditioning Unit

Please see Section 4.2: Environmental Requirements.

Cable Management System

We typically recommend a triple-tier J-hook style cable system to be installed around the perimeter of the room, with the lowest point of the J-hooks either at 75 in (1900 mm) or 12 in (300 mm) above the finished floor. Please see the site-specific drawings for the required location in your Equipment Room and for our latest recommendations in material. Other types of cable management systems can work as well – please consult your Accuray Site Planner.

Network Drops

Three CAT-6 connections to the facility network are needed: Line 1 consists of 8 direct connections to treatment planning. Line 2 consists of two connections to the imaging modality. Line 3 consists of two connections, one to the control room and the other to the hospital network (3 static IP Addresses) Please see Section 5.4: Information Technology Needs of this document for more information, or Accuray Incorporated's *CyberKnife I.T. Guide, CK v11.X (PN 1058468)*.

2.3.5 CUSTOMER SUPPLIED (optional)

Power Conditioner (Voltage Stabilizer)

Please see Section 4.1: Power Requirements.

Note: For additional site planning considerations for the Equipment Room, please see Section 3: Room Specifications.

2.4 TREATMENT PLANNING ROOM(S)

The Treatment Planning Room(s) can be located anywhere, and configured in many ways, depending upon the site layout and desire of the customer. It is important that this room be ready for equipment and set up prior to system installation. Typically, the Treatment Planning room includes the following equipment:

2.4.1 ACCURAY SUPPLIED

Accuray Precision™ Treatment Planning System Workstation (Item 19 – placed on a desktop or counter top)

The CyberKnife® System's standard configuration comes with 2 Accuray Precision® Treatment Planning System Workstations that are normally located in a Treatment Planning Room or Physicist's office. However, they can be located in the Control Room or any other location that has direct access to the CyberKnife System network, facility network or Internet. Additional units can be purchased by the customer.

Color Laser Printer (Item 20 - placed on a desktop or counter top)

2.4.2 ACCURAY SUPPLIED (Optional)

Accuray Precision™ MD Suite Workstation (Item 21 – placed on a desktop or counter top)

One or more Accuray Precision™ MD Suite Workstation may be purchased and should be connected directly to the CyberKnife System network. The Accuray Precision™ MD Suite Workstation can be located in the Treatment Planning Room, or anywhere that can support the system with a network drop and Internet access (such as the physicist's office, a doctor's office, a home office, etc.).

2.4.3 CUSTOMER SUPPLIED

Network Drops (Optional)

A total of eight Network Drops are required. CAT-6 cable or fiber optic cable will be required if the distance between the two network drops exceeds the normal limitations (lengths greater than 328 ft (100 m).

Please see the Section 5.4: Information Technology Needs of this document, or Accuray Incorporated's *CyberKnife I.T. Guide, CK v11.X (PN 1058468)* for more information.

3.0 Radiation Shielding Guidelines

3.1 INITIAL SITE PLANNING

Primary barrier thicknesses will likely be between 48 and 60 in (1219 to 1524 mm) of standard density concrete (2.4 g/cm^3 nominal density), depending upon workload, limits, occupancy factors and local regulations. In general, all walls are considered primary barriers with a 5% use factor for fixed and iris collimators and a 7.5% use factor for the multileaf collimator. For initial site planning, we recommend using 60 in (1524 mm) on all primary barriers with adjacent public areas. We recommend using 42 in (1067 mm) on all secondary barriers, including the ceiling. For specific shielding guidelines, please see the sections below. Note: The customer is ultimately responsible for determining the proper shielding for the Treatment Room and ensuring compliance with all local, state and country regulations.

3.2 RADIATION SHIELDING FOR THE CYBERKNIFE SYSTEM

3.2.1 SYSTEM DESCRIPTION

The CyberKnife System utilizes a compact X-band LINAC mounted on a robotic manipulator arm. The CyberKnife System delivers dose from paths that are composed of a series of nodes. The specific nodes and positions of those nodes are determined when planning a CyberKnife treatment. During treatment delivery, the manipulator will move the accelerator from node to node in series while dose is delivered at only those nodes selected during the treatment planning process. The total number of nodes varies from

102-180 based on secondary collimator assembly (Fixed, Iris or MLC) and anatomical region treated (head or body/spine). There are 102 body path nodes using the MLC and 117 body path nodes using the Fixed or Iris collimator. Regarding head path nodes, there are 171 for MLC and 180 for Fixed/Iris. Figure 1 (next page) shows all possible node positions.

3.2.2 PERMISSIBLE EXPOSURE LIMITS – INTEGRATED VS. INSTANTANEOUS DOSE RATE LIMITS

Typically, integrated dose rate limits are used for radiation therapy facility barrier design: 20 µSv per week for uncontrolled areas and 100 µSv per week for controlled areas. Due to the low use factor of the CyberKnife® System, barrier design for integrated dose limits may have areas with high instantaneous dose rates. Accuray recommends consideration should be given to incorporating a 2 mrem (20 µSv) dose "in any hour" limitation for public areas such as has been adopted by many regulatory authorities.

Note: The customer is ultimately responsible for determining the maximum permissible exposure limits, and insuring compliance with all local, state, and country regulations.

3.2.3 NOMINAL TREATMENT DISTANCE

The CyberKnife System is not an isocentric treatment device. However, a room imaging center (also called alignment center) is identified, which is where the beams of the two diagnostic imaging sources intersect. The treatment volume is rarely at the room isocenter but is usually within 10 cm of the room isocenter. Treatment distances for head path cases contain nodes with SAD ranging from 650 mm – 900 mm. Treatment distances for spine and body cases range from 800 mm – 1200 mm SAD.

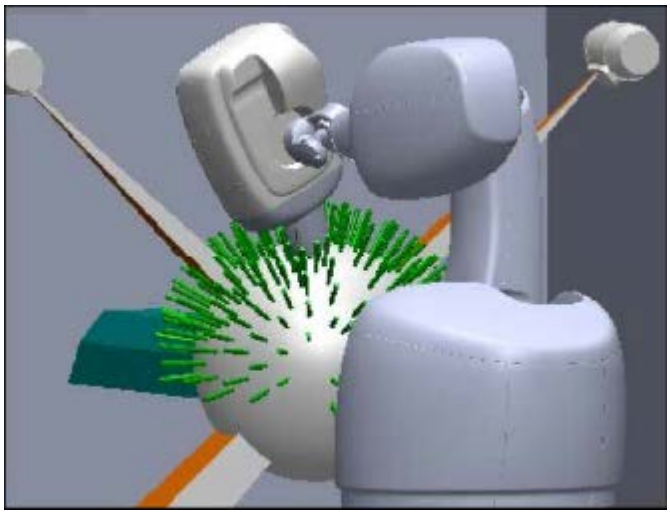

Figure 1 Possible Node Configurations for CyberKnife M6

The two objects shown above the Treatment Manipulator and LINAC are diagnostic X-ray sources (kV imagers). Images from these sources are used to determine patient position prior to and during treatment. During treatment delivery, the kV imaging system acquires images at treatment nodes that are used to determine patient position. This information is relayed to the manipulator system and any necessary corrections are made prior to treatment beam delivery.

3.2.4 CYBERKNIFE® M6™ SPECIFICATIONS

Beam Energy/Output Rates		6 MV / 1000 MU per minute (at 80 cm SAD)
Reference Calibration Condition		1 MU is nominally equal to 1 cGy at 800 mm SAD, using a 60 mm diameter secondary collimator and at 15 mm depth in water
Field Sizes	Fixed Collimator Assembly	12 collimators are available producing circular fields ranging from 5 mm to 60 mm at 800 mm SAD
	Iris™ Collimator	The IRIS collimator is designed to closely replicate the twelve fixed collimator aperture sizes.
	InCise™ Multileaf Collimator (MLC)	The variable aperture MLC has a maximum field size of 9.75 cm x 11 cm at 800 mm SAD

Table 4 CyberKnife M6 Specifications

3.2.5 WORKLOAD ESTIMATION

The following table includes recommendations for estimating the workload of a CyberKnife System for shielding design purposes. Recommended treatment times are based on clinical experience by expert users and Accuray simulations. For shielding purposes, the estimated treatment doses should be scaled to one meter and a TPR value of 0.7 should be assumed and actual treatment times vary. However, the actual TPR values vary from 0.62 - 0.67 for the 60 mm fixed collimator (M6 TPR 20,10).

Table 5 Workload Estimations

Head Treatments

	Fixed Collimator	Iris™ Collimator	InCise™ MLC
Average Treatment Time per Fraction	51 minutes	34 minutes	22 minutes

Average Fraction: 800 cGy @ 800 mm SAD Dose and Distance

Spine/Body Treatments

	Fixed Collimator	Iris™ Collimator	InCise™ MLC
Average Treatment Time per Fraction	53 minutes	35 minutes	23 minutes

Average Fraction: 970 cGy @ 1000 mm SAD Dose and Distance

Example:

Estimate the primary weekly workload at the nominal treatment distance (80 cm) for a facility that intends to treat 6 head cases and 6 spine/body cases per day, 5 days per week:

6 head treatments per day * 8.0 Gy / fraction * $(0.8 \text{ m} / 1.0 \text{ m})^2$ * 5 days / week **= 153.6 Gy / week**

6 spine/body treatments per day * 9.7 Gy / fraction * 5 days / week = **291 Gy / week**

Total primary weekly workload at 100 cm = 444.6 Gy / week

Note: Workload estimations and calculations may differ from country to country.

3.2.6 USE & MODULATION FACTORS

The CyberKnife® System can direct primary beams at all walls and at the floor. Accuray recommends a primary barrier use factor of 5% for fixed and iris collimators and 7.5% for the multileaf collimator. The beam can be directed upward at a maximum angle of 18° above the horizontal. For most facilities this means that the ceiling is a secondary barrier. Accuray recommends a modulation factor (MU per cGy) of 15 for Fixed and Iris collimators and 7 for the multileaf collimator. Figure 2 below shows the target location and reference axis for a CyberKnife M6™ System.

Note: Use and modulation factors may differ from country to country.

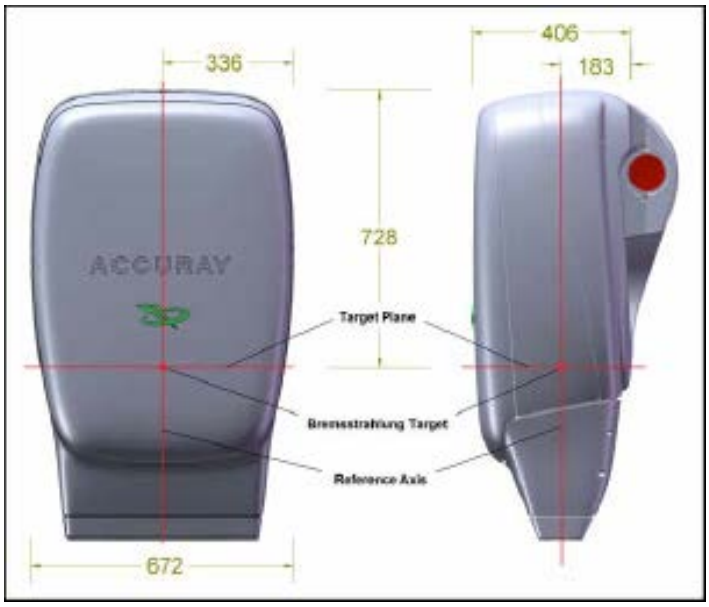

Figure 2 LINAC dimensions (mm) from key components pertinent to shielding design.

3.2.7 TENTH VALUE LAYERS (TVLs)

Rogers, et al. have used Monte Carlo techniques to estimate TVLs (primary beam) for use with the CyberKnife System. Accuray recommends using the equilibrium values (TVLe) from the table below.

Table 6 Workload Estimations

Density (g/cm^3)	2.35	2.35	11.34	11.34
SDD	4.8 m	6.8 m	3.3 m	5.3 m
TVL1 (cm)	29.4	31.2	4.8	5.1
TVLe (cm)	31.9	32.4	5.05	5.25

TVL data for ordinary concrete and lead. Ordinary concrete composition NBS04 as given by Rodgers.[4]

Note: Tenth Value Layers may differ from country to country.

3.2.8 SECONDARY RADIATION (LEAKAGE & SCATTER)

Secondary radiation shielding considerations typically include components of both system leakage and patient scatter. However, for the CyberKnife® M6™ LINAC, secondary barrier thickness requirements from patient scatter are negligible compared to

the requirements from leakage radiation, even when considering larger field sizes and greater workloads from the Multileaf Collimator. The CyberKnife is shielded to limit leakage radiation around the LINAC head and within the patient plane. Patient plane leakage fractions do not exceed 0.1% and typically average below 0.05% of the reference dose (1000 cGy/min at 800 mm SAD using a 60 mm diameter secondary collimator at a depth of 15 mm in water). Maximum values for leakage radiation at a distance of 1 meter from the electron beam path do not exceed 0.1% of the reference dose. The maximum values are typically measured in the front of the LINAC head, in the target plane at one meter from the reference axis. Both leakage and TVL values are smaller around the back, sides and top of the LINAC. Leakage TVLe around the rest of the LINAC is 29.2 +/- 0.4 cm of concrete. Typically only 50% of the leakage dose value is comprised of radiation that is of sufficient energy to penetrate more than one TVL of concrete. See *Accuray Shielding White Paper* P/N 500627.A for details on the use of “high energy leakage” value for shielding calculations.

3.2.9 GROUNDSHINE RADIATION

Groundshine radiation may be a problem under any direct shielded doors or secondary shielded walls. Please refer to Page 82 of the NCRP report 151 mentioned below for more information.

3.2.10 CYBERKNIFE SHIELDING PUBLICATIONS

NCRP report 151 has dedicated sections on CyberKnife System shielding (section 7.2 and section 5.7).

http://www.ncrppublications.org

4.0 Room Specifications

4.1 TREATMENT PLANNING ROOM(S)

4.1.1 TREATMENT ROOM SIZE SPECIFICATIONS

The CyberKnife M6 Series has two primary orientations; each orientation has 6 options:

- Option 1 - 45° Xchange® CyberKnife Vault layout
- Option 2 - 90° Xchange CyberKnife Vault layout

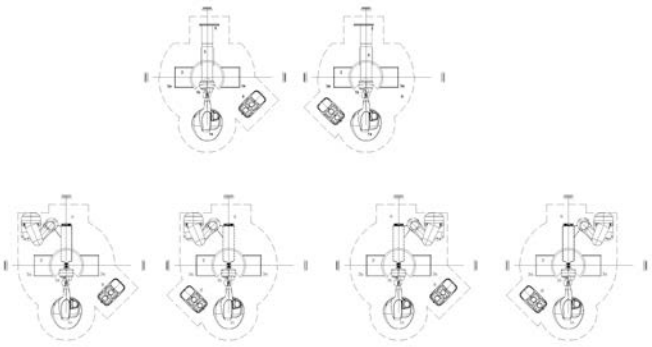

Figure 3 45° Xchange CyberKnife Vault Layout

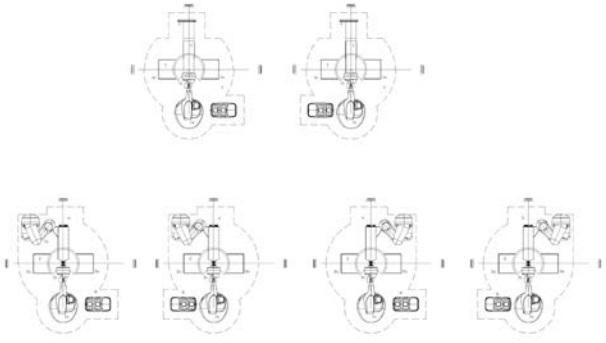

Figure 4 90° Xchange CyberKnife Vault Layout

Recommended Size

- Ideal amount of space for the CyberKnife® System to operate.
- Provides ample space for a sink, counters and storage cabinets.

Absolute Minimum Size

- Absolute minimum amount of space to accommodate the CyberKnife System.
- Provides little to no additional space for a sink, counters and storage cabinets.

4.1.2 PHYSICAL REQUIREMENTS

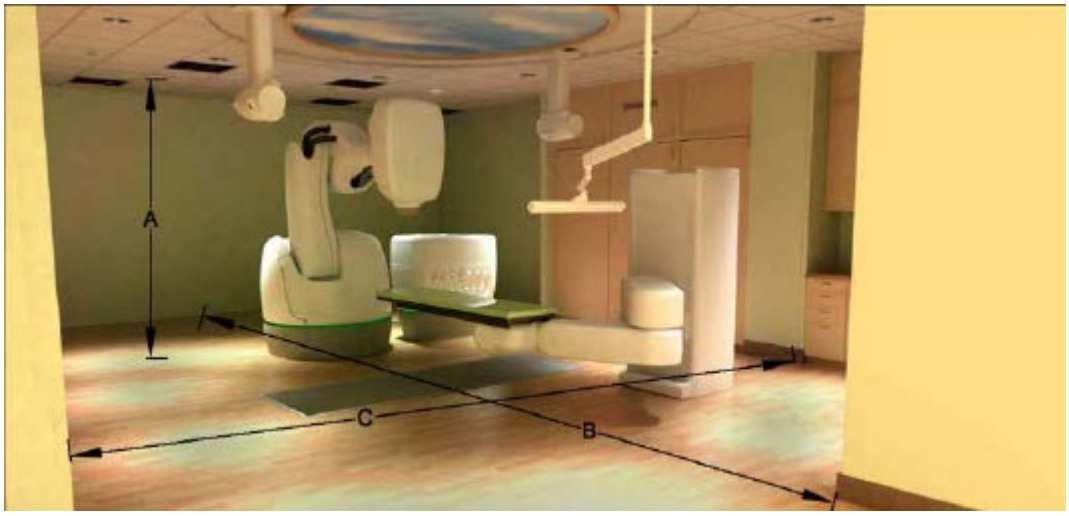

Figure 5 Reference picture for room dimensions

FLOOR SPACE:

Recommended

The recommended CyberKnife® M6™ Series dimensions for the treatment room are 24 ft (B) long x 21 ft (C) wide (7.32 m x 6.4 m) between the finished walls. If the system is on a diagonal: 23 ft-5 in x 21 ft-7 in (7.14 m x 6.58 m) between finished walls. This accommodates either the Standard Treatment Couch or optional RoboCouch® System. The recommended dimensions will provide ample space for a sink, counters and storage cabinets.

Absolute Minimum

The absolute minimum CyberKnife M6™ Series dimensions for the treatment room are 21ft (B) long x 15 ft-10 in (C) wide (6.40 m x 4.83 m) between the finished walls. If the system is on a diagonal: 20 ft-4 in x 18 ft-7 in (6.20 m x 5.67 m) between finished walls. This accommodates either the Standard Treatment Couch or optional RoboCouch® System. The recommended dimensions will provide ample space for a sink, counters and storage cabinets.

Note: The Equipment within the Treatment Room does not take up the entire square footage as noted above, but does use the majority of space within this area depending upon the configuration of the system. The Accuray customer site-specific Floor Plan drawing will show the customer where it is safe to install sinks, cabinets and other pieces of customer supplied equipment within the room.

The dotted lines on site-specific Drawing CK-A1 identify the required clearance areas for robotic movement. The clearance paths must not intersect with any wall, column or other obstruction.

The room dimensions mentioned above only include the floor space of the actual Treatment Room and do not include any floor space dedicated to a maze or the swing path of a direct-shielding door.

Ceiling Cap Height:

Recommended:

11 ft (B) or greater (3.35 m or greater) height between finished floor and rough ceiling cap (whether concrete or steel). This allow ample room for HVAC, lighting, etc. to be located between the finished ceiling and the ceiling cap.

Absolute Minimum Finished Ceiling Height:

9 ft-7 in (2.9 m) height between the finished floor and the finished ceiling within the treatment manipulator operating area.

Recommended Finished Ceiling Height:

9 ft-10 in (3.0 m) height between the finished floor and the finished ceiling within the treatment manipulator operating area.

Fixed Rule about Ceiling Height

(if optional RoboCouch® System has been purchased)

The capped free-standing cover is capped at 95 in (2.4 m) tall.

RoboCouch System Column Cover

Note: The capped free-standing cover is the default cover for the RoboCouch System. Typically, the extended free-standing cover is only used in situations where the electrical cables must be routed through the ceiling.

MINIMUM DOOR CLEARANCE

Noted below are the required rigging clearances for installation:

Recommended Minimum Clearances:

48 in wide x 84 in tall (1219 x 2134 mm).

RECOMMENDED EQUIPMENT ORIENTATION WITHIN THE TREATMENT ROOM

Your Accuray Site Planner will help to determine the optimal orientation for your CyberKnife® System based on:

- Ease of patient loading
- Exact system configuration
- System clearances
- Shielding considerations
- Ease of access to sinks and cabinets
- Customer preferences

Your Site Planner will address any questions, related to the above during the design process.

4.2 CONTROL ROOM MINIMUM FLOOR SPACE

100 square ft (9.3 square m), will provide adequate counter space for at least 2 people and 3-4 workstations. This room should be large enough to easily accommodate 4-5 people during training and Go-Live activities.

RECOMMENDED LOCATION

The Control Room should be located within view of the Treatment Room door and should be designed in accordance with the facility patient privacy policy.

MINIMUM DOOR CLEARANCE

Standard door clearances are acceptable for moving equipment into the Control Room.

Note: If the Equipment Room is located off of the Control Room, the door into the Control Room must meet the same minimum door clearance as the Equipment Room to accommodate the designated equipment.

4.3 EQUIPMENT ROOM

RECOMMENDED FLOOR SPACE

160 square ft (15 square m) if the X-ray Generators are located in the Equipment Room.

145 square ft (13.5 square m) if the X-ray Generators are located outside of the Equipment Room.

ABSOLUTE MINIMUM FLOOR SPACE

150 square ft (13.9 square m) if the X-ray Generators are located in the Equipment Room.

120 square ft (11.1 square m) if the X-ray Generators are located outside of the Equipment Room.

Note: No wall in the Equipment Room should be less than 7 ft (2.1 m) long, in order to provide adequate installation and service access to the equipment. Equipment Rooms with the minimum floor space require 10 ft (3.05 m).

FIXED RULE ABOUT FLOOR SPACE

Additional floor space must be built into the Equipment Room for any customer-supplied equipment, such as transformers, power conditioners (voltage stabilizers), floor-mounted air conditioning units, data and server equipment, phone equipment, storage cabinets, etc. Service access and regulatory requirements must be considered when planning for adequate space around each piece of Accuray or customer-supplied equipment.

RECOMMENDED LOCATION

Due to limited cable lengths between most equipment, the Equipment Room should be located adjacent to the Treatment Room, and as close to the Treatment Manipulator as possible.

Note: As a general rule, the maximum cable length run from the Treatment Manipulator to the Equipment Room pull box should be no more than 30 ft (9.1 m).

FIXED RULE ABOUT LOCATION

System operators must be able to access the Equipment Room during patient treatment. The equipment in the Equipment Room (with the exception of the X-ray Generators) cannot be located in the Treatment Room, in a room that is entered into by going through the Treatment Room, or on a different floor from the Control Room.

MINIMUM FINISHED CEILING CLEARANCE

7 ft (2.135 m) between finished floor and finished ceiling.

MINIMUM DOOR CLEARANCE

3 ft wide x 7 ft high (.914 m x 2.134 m) for rigging the equipment into the Equipment Room, door clearances for the rig path need to be the United States standard measurement of 82 in-83 in.

Note: The Equipment Room door(s) must be secure, ensuring that the room cannot be accessed during treatment by anyone other than trained operators.

4.4 TREATMENT PLANNING ROOM(S) WORKSPACE

Ensure enough workspace for two or more workstations and a desktop color laser printer. Accuray will attempt to show the exact number of purchased workstations on the customer site-specific drawings. Otherwise, we will show a generic workspace. Contact your Accuray Site Planner for additional information.

RECOMMENDED LOCATION

The Treatment Planning Room can be located anywhere in the facility. The distance between the Treatment Planning Room and the Equipment Room will determine which network cabling option is required. Please see the IT section of this document, or *Accuray Incorporated's CyberKnife I.T. Guide, CK v11.X (PN 1058468)* for more information.

4.5 SAMPLE DRAWINGS

The following two illustrations show two typical floor plan layouts. For a complete package of sample drawings and design details, please contact your Accuray Site Planner.

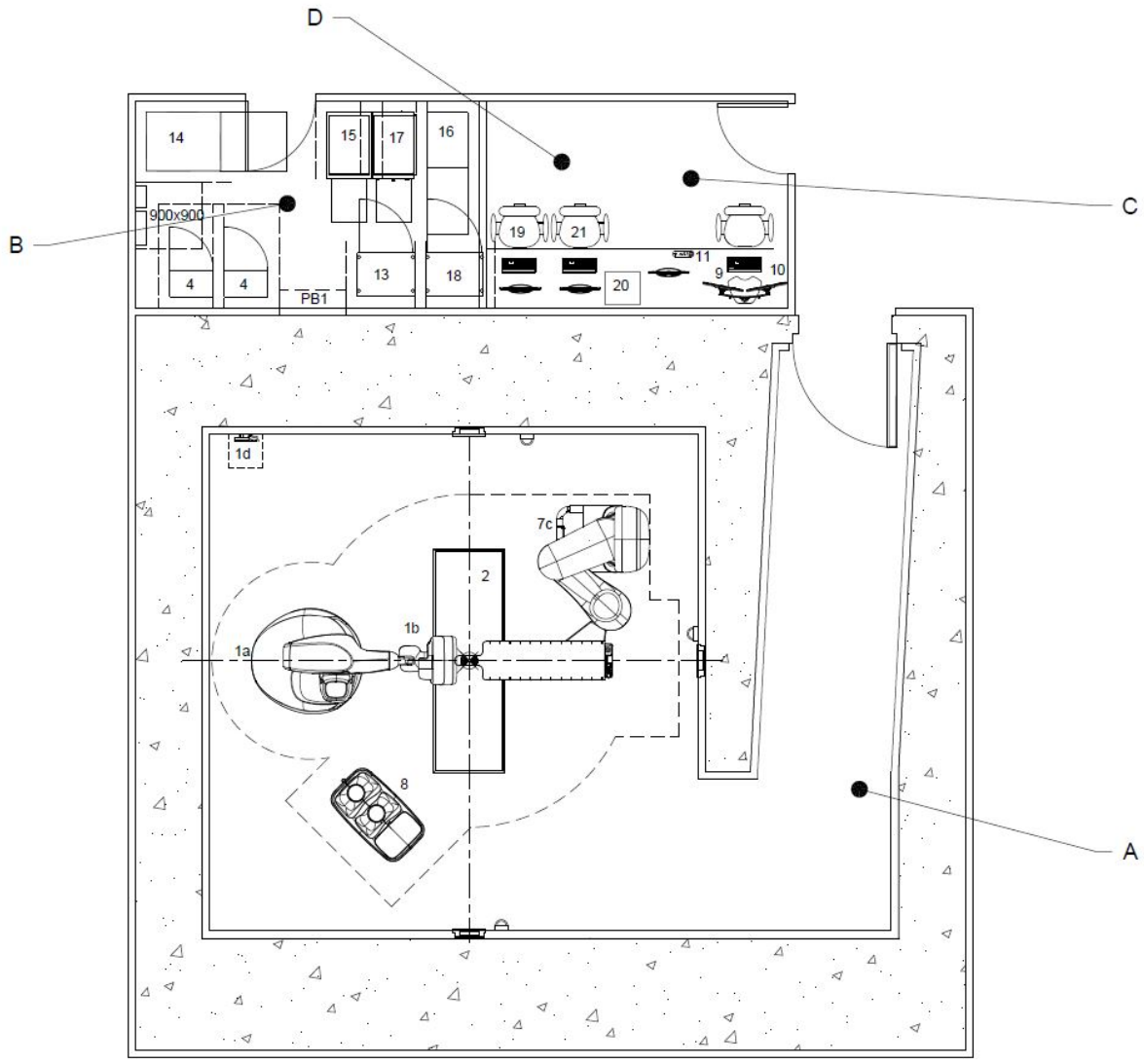

Figure 6 Typical CyberKnife® Floor Plan with Maze Walkway

Key:

A = Treatment Room (Vault) B = Equipment Room C = Control Room D = Treatment Planning Room

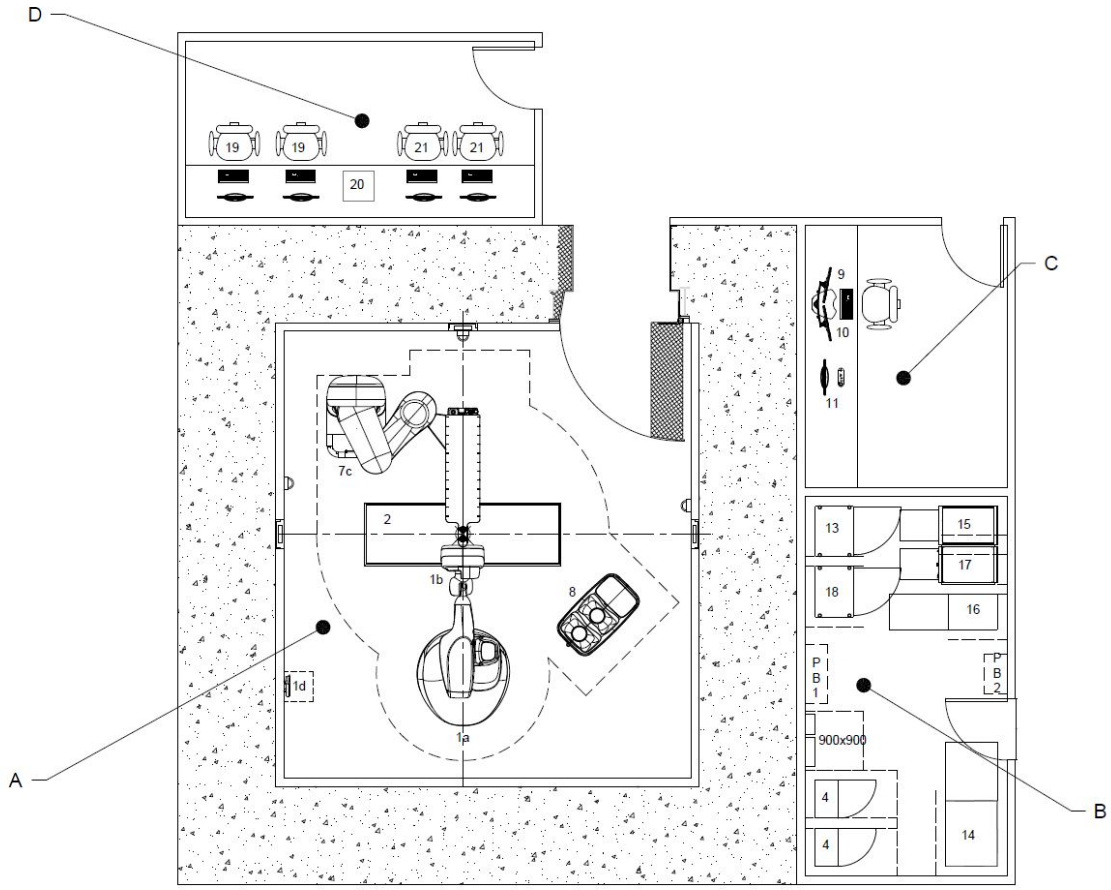

Figure 7 Typical CyberKnife Floor Plan with Direct Shielded Door

Key
A = Treatment Room (Vault) B = Equipment Room C = Control Room D = Treatment Planning Room

Note: For additional example drawings (in AutoCAD or PDF format), please contact your Accuray Site Planner.

5.0 Electrical and Environmental Requirements

5.1 ELECTRICAL

POWER REQUIREMENTS

It is recommended to supply 480 VAC, 3-phase, 100 Amps, 55 kVA power to the Main Power Disconnect. However, the CyberKnife® System Power Distribution Unit (PDU) will accept input power in the range of 200 VAC through 480 VAC. For any input voltages at 240 VAC and below, 150 Amps is required.

The Main Power Disconnect typically needs a 36 in square (914 square mm) exclusionary area directly in front of it for regulatory requirements. We recommend that it be located next to the door of the Equipment Room. The customer is responsible for the main power disconnect, fuses and all conduits and wiring from the original power source to the disconnect. Accuray will supply and run the power cable from the main power disconnect to the CyberKnife System PDU. The CyberKnife System does not use a neutral leg. A grounding lug is to be supplied by the electrical contractor with the following specifications: A 4-gauge lug terminating to grounded building steel or earth ground within the main power disconnect.

The Main Disconnect can be located on an outside wall of the Equipment Room, as long as it remains within the cable limitations of the PDU. The Accuray Site Planner can help locate the best position.

POWER CONDITIONER (VOLTAGE STABILIZER)

A power conditioner will be required of the customer if the input voltage cannot be regulated to within +/- 5% phase to phase. Please see Section 5.6: Power Conditioners for more information. The technical analysis and choice of power conditioner is the responsibility of the customer.

UNINTERRUPTABLE POWER SUPPLY (UPS)

A UPS is provided by Accuray to power the Treatment Delivery System, Data Server, LCD monitor and networking devices in the event of a power failure to reduce risk of data or damage.

A UPS is not provided for other workstations, such as the Accuray Precision™ Treatment Planning System Workstation, Accuray Precision™ MD Suite Workstation or other remote workstations. Although not required, the customer may, at their discretion and expense, provide additional UPS for protection.

5.2 ENVIRONMENTAL

GENERAL REQUIREMENTS

All CyberKnife System Equipment is rated to operate at pressures ranging from 103 to 65 kPa (equivalent to -150 m to 3,800 m (-500 ft to 12,500 ft) elevation), and can tolerate a temporary exposure to pressures of 103 to 56 kPa (equivalent to -150 m to 5,000 m (-500 ft to16,400 ft) elevation) while not in operation.
All CyberKnife System Equipment is rated to operate at temperatures ranging from 10° to 35° C (50° to 95°F), and can tolerate temporary exposure to a temperature range of -30° to 50° C (-22° to 122° F) while not in operation.
All CyberKnife System Equipment is rated to operate at humidity levels ranging from 30% - 75%, non-condensing, and can tolerate a temporary exposure to a humidity range of 10% to 90%, non-condensing, while not in operation.

TREATMENT ROOM

The Treatment Room should be kept between 50° F and 75° F (10° C and 23.9° C), twenty-four hours per day, seven days per week, with a range of 30 to 75% non-condensing humidity.
The following table identifies the heat generated by the equipment in the Treatment Room:

ITEM	DESCRIPTION	BTLU/h	KILOWATT
1a	Treatment Manipulator	0	0
1b	Linear Accelerator	0	0
1c	Interchangeable Secondary Collimators	0	0
1d	Treatment Manipulator Teach Pendant	0	0
1e	Iris™ Collimator (Optional)	0	0
1f	InCise™ Multileaf Colimator (optional)	0	0
2	In-Floor Image Detectors (Quantity=2)	1230	0.36
3a	X-ray Sources (Quantity=2)	0	0
3b	X-ray Source Heat Exchangers (Quantity=2)	2400	0.7
4	X-ray Generators (Quantity=2) (may be located in another room)	1100	0.322
5	Standard Treatment Couch	0	0
6	Synchrony® System Camera	0	0
7c	RoboCouch® System (Optional)	0	0
8	Xchange® Collimator Changer	0	0
Total with X-ray Generators in Treatment Room		**4730**	**1.382**
Total without X-ray Generators in Treatment Room		**3630**	**1.06**

CONTROL ROOM

There are no special environmental requirements with regard to the ® System in the Control Room.

EQUIPMENT ROOM

The Equipment Room must be kept less than 70° F (21.1° C), with a range of 30-70%, RH (Non-condensing) relative humidity, 24 hours per day, seven days per week. The following table identifies the heat generated by the equipment in the Equipment Room:

ITEM	DESCRIPTION	KILOWATT	BTLU/h
4	X-ray Generators (Quantity=2) (may be located in another room)	1100	.322
13	Controller (for Treatment Manipulator)	4700	1.377
14	AMM (Modulator)	11600	3.4
15	Computer Rack (includes iDMS, Gateway, and Core Network hardware)	3800	1.114
16	Power Distribution Unit (PDU) Rack	2600	.762
17	Mechanical Rack	6300	1.85
18	Controller (for RoboCouch® System)	4700	1.377
Total Maximum Cooling Requirements		**34,800**	**10.2**

Total with X-ray Generators in Equipment Room, and with optional RoboCouch Controller is 34800 (10.2)

Note: Most customers install a minimum 3-4 ton HVAC unit to meet the mechanical requirements. Please see Section 4: Electrical and Environmental Requirement for more information.

TREATMENT PLANNING ROOM(S)

There are no special environmental requirements with regard to the CyberKnife System in the Treatment Planning Room(s).

SYSTEM STORAGE (NON-OPERATING CONDITION) GUIDELINES

If the CyberKnife System must be stored for any length of time in a crated or uncrated condition, please follow these guidelines:

- Provide an environmentally protected indoor area free from dust and free from potential water damage.
- Ensure the area is temperature controlled between 40° F and 90° F (5° C and 32° C).
- Maintain less than 80% humidity, non-condensing.
- Maintain a secured area to prevent against potential theft and damage.

Note: Approximately 400 square ft (37.2 square m) is needed for storing a crated CyberKnife System.

5.3 NOISE LEVELS EQUIPMENT ROOM

The customer may choose to incorporate noise reduction in the equipment room. The noise level is measured to be 90dB.

5.4 VIBRATION ANALYSIS

The customer is responsible for any and all vibrational analysis if there is any external vibration in question that may affect the equipment.

6.0 Other System Implementation Considerations

6.1 PRE-INSTALLATION PROCESS

6.1.1 CONTENTS OF SHIPPING CRATES

The pre-install kit crates contain the Fiberglass Imaging Tub, the Treatment Manipulator floor frame, the RoboCouch® System floor frame (in rare circumstances, it may not be installed), the X-ray Source ceiling mount kits, Synchrony® System ceiling mount kit, emergency off and key switches, a dolly and other related hardware.

For any rigging or storage purposes, the crate measurements are typically:

CRATE	CONTENTS	LENGTH	WIDTH	HEIGHT	WEIGHT
Large	Fiberglass Tub	127 in 3226 mm	44 in 1118 mm	33 in 838 mm	582 lbs 264 kgs
Medium	Treatment Manipulator Frame	50 in 1270 mm	50 in 1270 mm	29 in 737 mm	655 lbs 297 kgs
Small	RoboCouch Frame (7c)	52.5 in 991 mm	32 in 813 mm	24 in 737 mm	770 lbs 283 kgs

6.1.2 SHIPPING AND RIGGING

The pre-install kit crates are normally shipped to the site when the floor pit is ready – typically at least four to five weeks before construction is completed and the CyberKnife® System is delivered. Accuray will schedule and pay for the shipment of the three crates to the customer location. We ask that the customer or their contractor receive the shipment and store it in a safe area until Accuray personnel arrive to unpack the crates and move the material into the CyberKnife System suite area. If stacking the crates, please place the medium and small crates on the ground, and stack the large crate on top.

6.1.3 SITE PREPARATION

The pre-install kit should be installed between the completion of construction on the raw concrete vault (or demolition if renovating a vault) and prior to the commencement of the work to complete the finished walls, ceiling, and above ceiling work such as HVAC, sprinklers, lighting, etc.

Accuray will need access to the ceiling cap (concrete or steel) for anchoring (or welding for steel ceilings) our X-ray Source Unistrut, plates, Synchrony plate and pole (please see site-specific Pre-Installation plan for locations) the pit be should be clean and devoid of water and debris. Construction material and equipment should be removed from the vault to allow free movement of ladders, tools and equipment by Accuray personnel. The conduits for the Treatment Manipulator and RoboCouch frames must be installed after the frames have been installed.

Contractor supplied equipment and labor:

- Ladder of sufficient height to do ceiling work (power lift for ceilings over 12 ft)
- Electricity for hand tools (typically 120V/AC in the US, or equivalent internationally)
- Wet/Dry vacuum
- Portable lighting for safe work
- Hard hats, vests and safety glasses if required
- Basic cooling/heating as necessary if temperatures are extreme
- Dust ventilation as required.
- Additional labor (1-2 people) to help lift and install the floor frames onto the anchors

6.1.4 ACCURAY PRE-INSTALLATION PROCESS

This process takes place prior to installation of the CyberKnife® System and is completed by Accuray or in some instances an approved contractor.

- Installation of the treatment manipulator frame and RoboCouch frame.
- Installation of the imaging tub.
- Installation of the X-Ray source mounts and heat exchanger mounts.
- Installation of the Synchrony® mount.

6.1.5 CUSTOMER / CONTRACTOR FOLLOW-UP WORK

Contractor is responsible for the following:

- Installation of the conduits between the frames and the equipment room.
- Backfilling the pit with concrete.

  Note: This is a critical step and care must be taken to properly distribute concrete underneath the tub.

Electrician is responsible for the following:

• Installing the CIB, EPO, EMO, and X-Ray On light relay (if needed).

For the EPO, EMO, Accuray will supply the push buttons, switches and labels for the EPO, EMO, Door Override Key Switch and the X-ray On Light Relay (if needed).

The electrician provides and installs the single gang boxes, conduits, and wiring according to the Accuray provided site specific drawings.

6.1.6 ADDITIONAL SITE WORK BY ACCURAY

After the pre-installation work is completed, Accuray will:

- Inspect and measure all cable conduits to ensure lengths are per the drawings.
- Inspect the Equipment Room to make sure that all Power Distribution Boxes, pull boxes and other customer supplied equipment
- (HVAC, Power Conditioners, etc.) are in the proper locations per the plans.
- Assess the CyberKnife System rig route and measure clearances. Review the system staging area to determine that adequate work space is available for the shipping truck, dumpster and rigging team.
- Be available to answer any questions.

6.2 CYBERKNIFE® SHIPPING AND RIGGING CONSIDERATIONS

6.2.1 CYBERKNIFE SYSTEM

Contents

The following table lists typical crate measurements for any rigging or storage purposes.

CONTENTS		DIMENSIONS	WEIGHT
1	Treatment Manipulator	96 in x 60 in x 89 in 2438 mm x 1524 mm x 2261 mm	3,836 lbs 1,740 kgs
2	Controller	29 in x 38 in x 65 in 737 mm x 965 mm x 1651 mm	592 lbs 269 kgs
3	Standard System Cables / Sub Systems	46 in x 67 in x 29 in 1168 mm x 1702 mm x 737 mm	418 lbs 190 kgs
4	System Covers	50 in x 94 in x 50 in 1270 mm x 2388 mm x 1270 mm	650 lbs 295 kgs
5	System Covers	43 in x 79 in x 26 in 1092 mm x 2007 mm x 660 mm	296 lbs 134 kgs
6	Detector Base Frame	33 in x 115 in x 12 in 838 mm x 2921 mm x 305 mm	242 lbs 110 kgs
7	Double Bay Rack, Printer, Accuray Precision™ Workstation	49 in x 86 in x 86 in 1245 mm x 2184 mm x 2184 mm	1,500 lbs 680 kgs
8	Chiller	37 in x 48 in x 64 in 940 mm x 1219 mm x 1626 mm	612 lbs 278 kgs
9	PDU	34 in x 42 in x 62 in 864 mm x 1069 mm x 1575 mm	1,176 lbs 533 kgs
10	AMM (Modulator and LINAC boxes)	48 in x 86 in x 60 in 1220 mm x 2185 mm x 1524 mm	1,750 lbs 794 kgs
11	LINAC Head	48 in x 86 in x 54 in 1220 mm x 2185 mm x 1372 mm	780 lbs 354 kgs
12	X-ray Sources and X-ray Generators	48 in x 86 in x 60 in 1220 mm x 2185 mm x 1524 mm	1,238 lbs 562 kgs
13	Generator Covers and Detectors	49 in x 86 in x 60 in 1245 mm x 2184 mm x 1524 mm	630 lbs 286 kgs
14	Imaging Tub Components, Lead Shielding	47 in x 86 in x 39 in 1194 mm x 2184 mm x 991 mm	1,014 lbs 460 kgs
15	Ladder	32 in x 110 in x 20 in 813 mm x 2794 mm x 508 mm	150 lbs 68 kgs
16	QA Tools, Documentation	47 in x 66 in x 39 in	372 lbs

	and Software	1194 mm x 1676 mm x 991 mm	169 kgs
17	Secondary Collimators	30 in x 20 in x 14 in 762 mm x 508 mm x 356 mm	170 lbs 77 kgs
18	RoboCouch System	56 in x 82 in x 92 in 1422 mm x 2083 mm x 2337 mm	4000 lbs 1814 kgs

Table 1 CyberKnife System Crate Measurements and Weights

Note: These measurements and weights may vary or change over time.

6.2.2 SHIPPING AND RIGGING

The CyberKnife® System is shipped to arrive at the site, at approximately 7:00 a.m. Installations typically start on a Tuesday but can be scheduled according to the customer's needs based on Accuray personnel availability.

Accuray will schedule and pay for the shipment of the crated system to the customer location, unless specified otherwise in sales contract.

Unless otherwise specified in the Customer's contract Accuray is responsible for rigging. The Accuray Customer Operations

Manager can answer any questions regarding contractual rigging terms.

Accuray allows a total of $8,000 (US Dollars) for standard rigging cost, unless otherwise noted. The customer will be responsible for any additional cost incurred where applicable. This occasionally occurs if a crane or other special equipment is required. In the event that the customer is responsible for rigging the Accuray Customer Operations Manager can refer rigging resources to the customer if requested.

6.2.3 RIG-IN MANPOWER AND EQUIPMENT REQUIREMENTS

Manpower

- One experienced rigger, two additional movers.
- Our installers will be present to help answer questions and assist where required.

Equipment

- One 10,000 lb (4536 kg) forklift with 8 ft (2.4 m) fork blades.
- One electric two-ton pallet jack.
- One hand-operated genie lift (>300 lbs capacity) (136 kg).
- One J-bar.

- Eight (8) four-wheel dollies.
- Two metal plates for crossing doorways.
- Floor protection for the length of the route (masonite or lexan sheets 4 ft x 8 ft) (1.2 m x 2.4 m). The Treatment Manipulator, at 2,850 lbs (1,293 kg), is the heaviest piece to move.
- Basic tools for uncrating the equipment.
- Tarps to cover or “stage” the equipment if the weather is an issue.
- Straps

Note: Because the rig-in typically starts at 7:00 a.m., it is preferred that the rigging equipment be delivered the night before the system delivery. If this is not feasible, the equipment must be on site before 7:00 a.m. on the delivery date.

6.3 CT SCANNERS USED FOR PATIENT IMAGING CT SCANNER SELECTION

The CyberKnife System has been designed to deliver patient treatment with sub-millimeter accuracy. In order to ensure this highest level of patient care and treatment, the image data sets that are sent from the customer’s CT scanner(s) to the CyberKnife System must follow specific guidelines:

Minimum Requirements

A minimum 16-slice CT scanner should be used for Synchrony® cases. This will assure reasonably short scan times, high image quality, minimal fiducial movement, and minimal artifact and movement stemming from patient breathing.

Minimum Requirements

No more than 1.5 mm slice thickness must be used in order to maximize treatment accuracy.

Note: Variable slice thickness cannot be used with the CyberKnife System.

4D Software Option

If the customer has purchased Accuray Incorporated’s 4D software option, they must have a CT scanner with a 4D option, as well. The current CT scanners supported by this option are:

• GE Discovery ST

• Siemens Sensation Open

• Philips Brilliance Big Bore

Note: If your facility’s CT scanner(s) cannot meet any of the requirements listed above, or you have any questions about these guidelines, please contact your Accuray Customer Operations Manager or Site Planner for more information.

6.3.1 CT OVERLAY KITS (CARBON FIBER TOP)

Each CT scanner used to supply image data sets to the CyberKnife System must have a Carbon Fiber Flat Overlay for the CT cradle (typically required for Radiation Oncology), a 2 in (51 mm) thick pad and a CIVCO base plate. These items should be present on the CT scanner at the time of system installation. Manufacturer lead times can be as long as 12 weeks and therefore should be ordered well in advance of the installation.

Overlay tops are not needed for other modalities used during treatment planning, such as MRI, Angio or PET imaging.

6.4 INFORMATION TECHNOLOGY NEEDS

CT SCANNER SELECTION

Please refer to the Accuray Incorporated's *CyberKnife I.T. Guide, CK v11.X* (PN 1058468) Your site planner will provide this document to you.

Note: The IT setup work must be completed prior to the system delivery.

6.5 SULFUR HEXAFLUORIDE (SF6) GAS

Accuray requires one bottle of SF6 gas, at least 99.9% pure. About 20-30 in (500 to 760 mm) long and 7 in (180 mm) in diameter. Approximately 60 lbs (27.2 kg) of gas (larger sizes are acceptable).

COMMON SUPPLIERS

- Concorde Specialty Gases, Inc. – *www.concordegas.com*
- Air Liquide – *www.airliquide.com*
- Praxair – *www.praxair.com*

Note: The SF6 gas is required to be onsite prior to the start of the system installation and will need to be ordered at least one month in advance.

6.6 POWER CONDITIONERS

EQUIPMENT NEEDED

The customer is responsible for purchasing and installing a power conditioner if the input voltage cannot be regulated to within +/- 5% phase to phase.

COMMON SUPPLIER

Transtector - *www.transtector.com* (they have a specific power conditioner identified for the CyberKnife® System)

6.7 PATIENT POSITIONING LASERS

Lasers are not absolutely necessary for use with the CyberKnife® System but are highly recommended. The customer is responsible for purchasing and installing lasers if they chose to have them.

Laser specifications are as follows: Two transverse and coronal lasers with the center line located 36-¼ in (920.75 mm) off the finished floor, one on each side of isocenter. The third laser should be a sagittal laser located 90 in (2286 mm) off the finished floor, at the foot of the patient couch, with the laser pointed down the center line of the couch top. The positions are called out on the Accuray site-specific drawings.

COMMON SUPPLIERS

- LAP – www.lap-laser.com
- Gammex – www.gammex.com
- Diacor – www.diacorinc.com

Note: The lasers are installed and aligned after the CyberKnife System has been installed. Typically, they are installed prior to system Go-Live.

6.7.1 INSTALLATION LOCATIONS

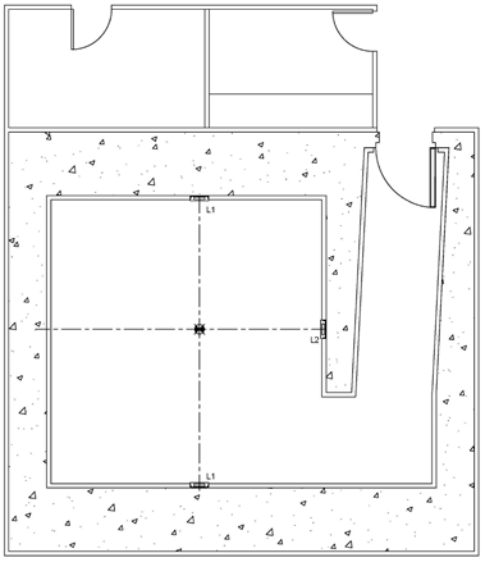

Figure 8 Laser Installation Locations

Key:

L1 = Laser crosshair centered 36-¼ in (921 mm) above finished floor

L2 = Laser beam centered 90 in (2286 mm) above finished floor.

6.8 INTERCOMS

The customer is responsible for purchasing and installing a hands-free intercom for use with the CyberKnife® System.

6.8.1 COMMON SUPPLIERS

- Aiphone – www.aiphone.com
- Nutone – www.nutone.com

Note: The intercom must be installed prior to the CyberKnife System installation.

6.9 CLOSED CIRCUIT TV (CCTV)

Accuray requires a minimum of 4 dome cameras, with at least two of them having pan/tilt/zoom capabilities located in the ceiling, a quad multiplex monitor, keyboard and speaker located in the control room. The customer is responsible to provide and install the CCTV system.

Please see the site specific drawings for specific camera locations.

6.9.1 COMMON SUPPLIERS

- General Electric – www.gesecurity.com
- Panasonic – www.panasonic/business/security.com
- Samsung – www.samsungsecurity.com
- Nuvico – www.nuvico.com

Note: The camera system must be installed prior to the CyberKnife® System installation as it is used during system testing and calibration.

6.10 QUALITY ASSURANCE AND COMMISSIONING TOOLS AND EQUIPMENT

Please consult Accuray Incorporated's *Physics Essentials Guide* for the required Customer and Accuray provided QA Tools and Equipment. All of the required tools must be on site for the CyberKnife System installation. Please consult with your Customer Operations Manager or Accuray Medical Physicist for specific requirements.

NOTES