

ZAP-X RADIOSURGERY® SYSTEM

SITE PREPARATION GUIDE



TABLE OF CONTENTS

1	Introduction	4
1.1	Overview	4
1.2	Site Layout	4
1.3	Treatment room	5
1.4	Ceiling Requirements	7
1.5	Auxiliary Room	8
2	SITE PREPARATION	10
2.1	Radiation Safety	10
2.2	Site Visits	10
3	Delivery Requirements	12
3.1	Access Requirements	12
3.2	System Weights & Dimensions	13
4	Structural Requirements	14
4.1	Treatment Floor Requirements	14
4.2	Pit Requirements	15
4.3	Pit Covers & Frame	16
4.4	Module #2 floor fixing options	18
4.4.1	Option 1 – Drop in anchor expansion bolts (suitable for most installations)	18
4.4.2	Option 2 – Epoxy Anchor Bolts	19
4.4.3	Option 3 - Embedded “H-Plate” (Recommended for seismic regions only)	20
4.5	Embedded Conduits	21
5	Electrical Requirements	23
6	HVAC Requirements	24
6.1	Operating Conditions	24
6.2	Storage Conditions	24
6.3	Equipment Heat Load	24
7	Data Requirements	25
8	CT Scanners & MRI Scanners for patient imaging	28
9	Radiation Design Considerations	31
9.1	OCCUPANCY FACTOR	31
10	Facility Interlocks and Signage	32



11	Q/A and commissioning tools and equipment	34
12	Site Preparation guide check list.....	36

LIST OF FIGURES

Figure 1 - Typical Room Layout	5
Figure 2 - Console Table	6
Figure 3 - Console Table Mounting	6
Figure 4 - Console Table - Typical position outside the scanner boundary	7
Figure 5 - Example of ceiling mount pendant arm.....	8
Figure 6 - Typical Auxiliary Equipment Room layout	9
Figure 7 - Floor covering visually defining laser scanner boundary.....	14
Figure 8 - Pit Dimensions (Top Profile)	15
Figure 9 - Pit Dimensions (Side Profile).....	15
Figure 10 - Cross section view of pit construction	16
Figure 11 - Pit Floor Frame Construction design	17
Figure 12 - Pit Frame Covers (4 Pieces).....	17
Figure 13 - Module #2 Base Ring	18
Figure 14 – Module #2 diagram showing location of 8 anchor points when using expansion bolts.....	19
Figure 15 – Module #2 diagram showing location of 12 anchor points when using epoxy anchor bolts ..	19
Figure 16 - Typical examples of Expansion Anchor & Epoxy Anchor types	20
Figure 17 - H-Plate design (refer to E0040-00168 for mechanical drawing)	20
Figure 18 - Top view of H-Plate embedded in pit floor.....	21
Figure 19 - Conduit requirement summary	22
Figure 20 - Typical Room Layout showing conduit locations/paths	22
Figure 21 - Treatment Planning PC (TPS) and SonicWall TZ300 firewall switch	26
Figure 22 - Data Requirements Diagram.....	26
Figure 23 - ZAP CT head support/CT overlay adaptor/S-Type mask.....	29
Figure 24 - Example of CT system with concave couchtop design/flat CT overlay adapter	29
Figure 25 - Example of Type-S masks.....	30
Figure 26 - CIVCO Silverman headrest	30
Figure 27 - A comparison of a traditional Linac installation and the ZAP-X system	32
Figure 28 - Example In-use light circuit.....	33

REFERENCE DOCUMENTS

Drawing E0960-00001 – Layout, Treatment Room
Drawing E0960-00003 – Layout, Auxiliary Room
Drawing E0040-00168 – H-Plate mechanical drawing (if required)
Drawing E0048-00029 – Template, Module 2 Base Anchor
Drawing E0048-00028 – Floor Template, Proximity Scanner Boundary
Drawing E0028-00001 – Bottom Pit Cover Deck (sections 1 & 2)



Drawing E0028-00002 – Top Pit Cover Deck (sections 3 & 4)

Drawing E0040-00144 – Framing Wood, Pit Deck

1 INTRODUCTION

1.1 Overview

- This guide describes the site requirements to install a ZAP-X system. If there is any question as to the use or interpretation of this information, please contact ZAP Surgical Systems directly.
- The information in this guide represents general installation conditions only. The customer must consult with local geotechnical engineering and structural engineering consultants to assess existing site conditions for each installation to determine site specific design requirements such as sub-grade preparation, including moisture protection, allowable bearing pressures, impact on existing nearby foundations, pit thickness and reinforcement, etc.

1.2 Site Layout

- The ZAP-X system is installed in two separated, but adjacent rooms.
- Figure 1 shows a typical layout for the Treatment Room and Auxiliary Room.



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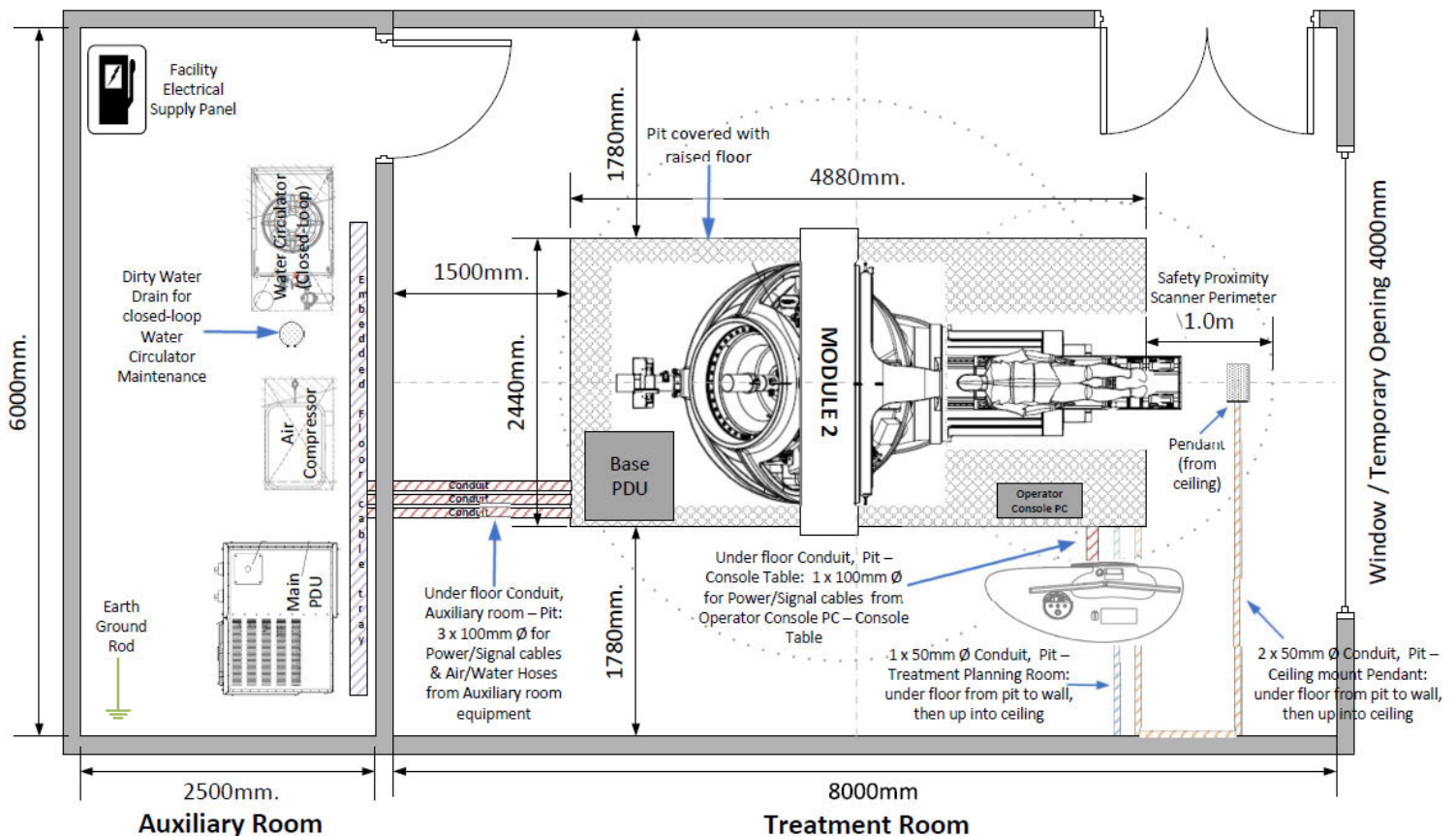


Figure 1 - Typical Room Layout

1.3 Treatment room

- The Treatment Room contains the main portion of the ZAP-X system, including the operator console.
- Minimum treatment room dimensions are 6.0 m x 8.0 m x 3.0 m high (19' 8" x 26' 3" x 9' 10" high) free of obstructions. (Recommend larger room size if space allows in design for ease of installation and system operation)
- Drawing E0960-00001 shows the system layout in the pit, and the pit with respect to the whole treatment room.
- The Treatment Room has structural flooring requirements; see [Section 4](#).
- Medical gases, if desired, are provided by the site.
- The operator console is positioned inside the treatment room in an area where radiation levels are suitable for unrestricted public access outside the 1m proximity safety scanners perimeter at the edge of the pit near the Patient Entry door of the ZAP-X system



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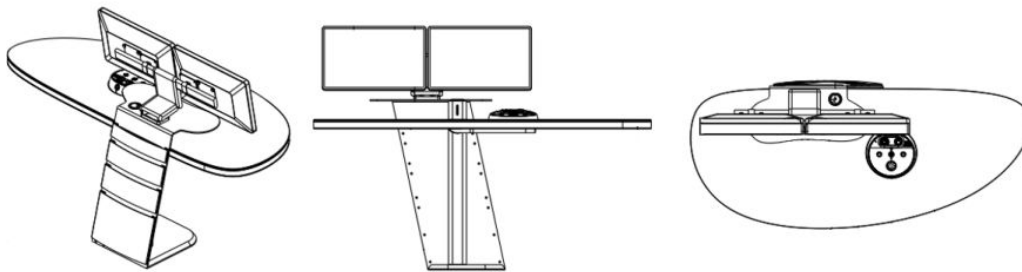


Figure 2 - Console Table

- The operator console will be positioned over the cable conduit exit point during installation and anchored to the floor using expansion anchor bolts. Refer to E0960-00001 Pg 5.

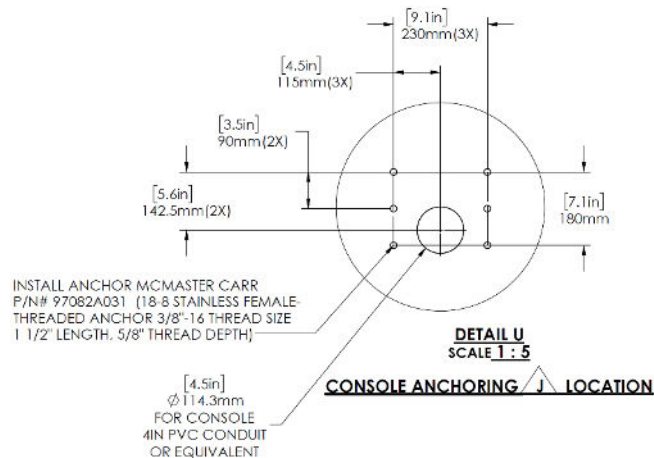


Figure 3 - Console Table Mounting

- Recommend installing standard electrical AC sockets (110/240VAC) in floor area near base of console table for use with external QA test equipment by Physicists, these sockets could be recessed in the floor or floor mounted. Ensure the location of the sockets are outside the laser scanner boundary

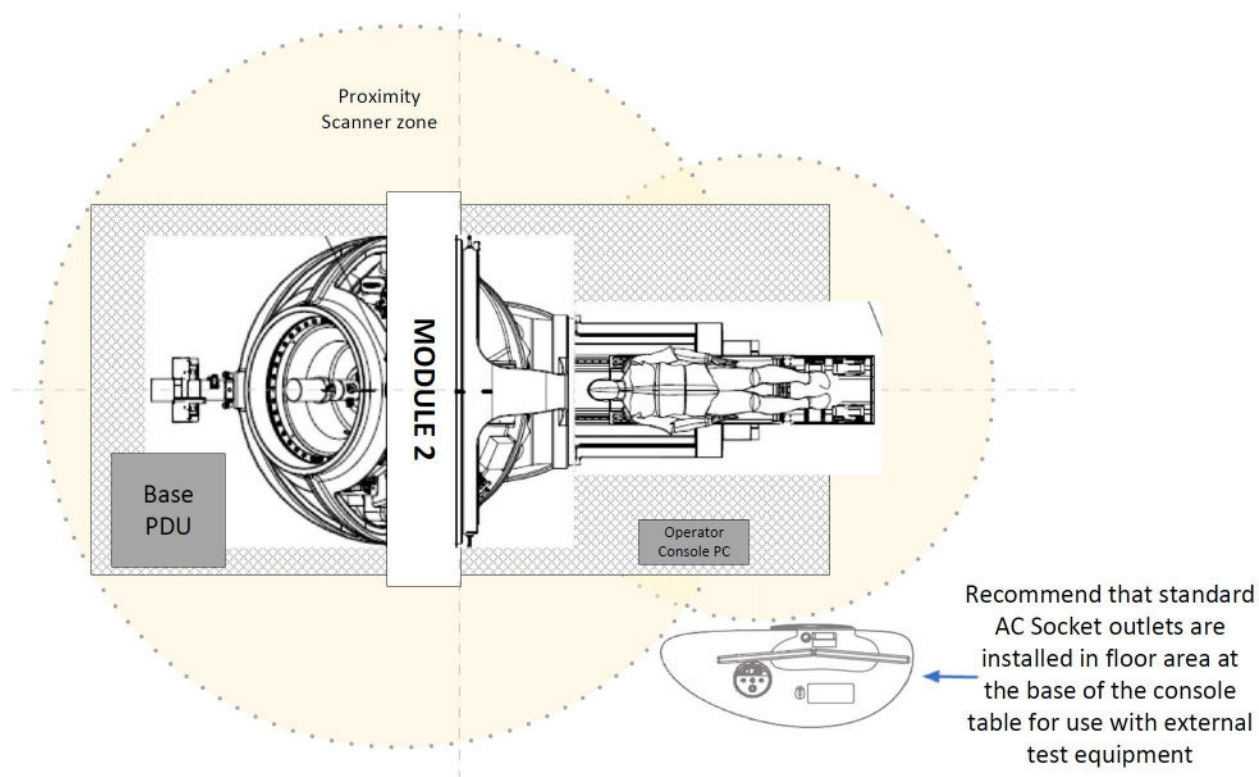


Figure 4 - Console Table - Typical position outside the scanner boundary

1.4 Ceiling Requirements

- The treatment room internal ceiling must be a minimum 3.0m (9' 10") high with no obstructions around the ZAP-X System
- The Control Pendant telescopes down from the ceiling above the patient entry door. Refer to drawing package E0960-00001 for details on the positioning requirements for the mount in the ceiling.
 - A secure mounting location must be provided for the interface plate to the Control Pendant ceiling mount swivel joint. This could be above a suspended ceiling if required. Figure below shows ceiling mount arm that will need to be mounted during installation.
 - The pendant arm has two mounting pole length options to facilitate differences in internal ceiling height – 610mm (24") / 915mm (36"), this needs to be specified prior to system shipment to customer site.

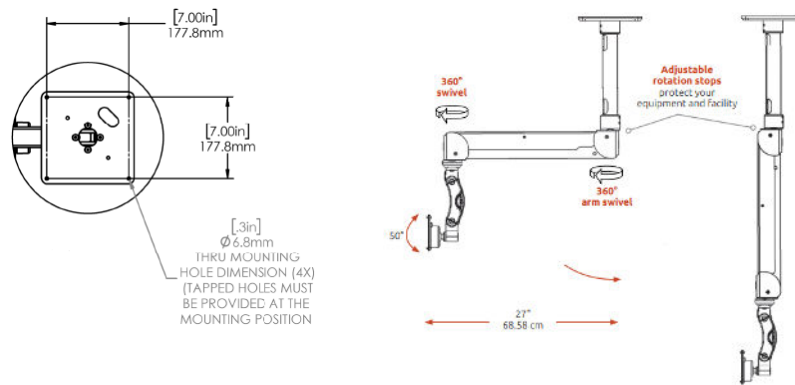


Figure 5 - Example of ceiling mount pendant arm

1.5 Auxiliary Room

- Drawing E0960-00003 shows the typical equipment and conduit layout of the auxiliary room.
- Minimum dimensions are 2.5 m x 4.5 m x 2.5m high (8' 2" x 14' 9" x 8' 2" high).
- The Auxiliary Room contains auxiliary equipment (power distribution unit, water circulator, and air compressor).
- These three (3) auxiliary units will need to be anchored to the floor after ZAP finalize positioning during delivery and installation.
- It is the customers responsibility for drilling the holes have their structural engineer calculate and determine the type of anchor bolt required in accordance with seismic anchoring requirements per the local building code.
 - Main PDU:
 - Dimensions – L 44.4 x W 38.9 x H 67.7 inch (L 1128mm x W 990mm x H 1719mm)
 - Weight – 1488lbs (675kg)
 - The Main PDU has facility electrical connection requirements; see [Section 5](#).
 - Water Circulator:
 - Dimensions – L 50.2 x W 28 x H 56.1 inch (L 1276mm x W 713mm x H 1425mm)
 - Weight – 397lbs (180kg)
 - Closed-loop System (25-litre self-contained/filled with Distilled water)
 - Operating Noise level – 68dB
 - Electrical Power – 200/230/3-phase (supplied from ZAP-X Main PDU)
 - No external facility connection needed
 - Air Compressor:



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E0920-00008 Rev C

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- Dimensions – L 38.2 x W 24.3 x H 80 inch (L 970mm x W 617mm x H 2032mm)
- Weight – 513lbs (233kg)
- Operating Noise level – 66dB
- Electrical Power – 208/230/3-phase (supplied from ZAP-X Main PDU)
- No external facility connection required

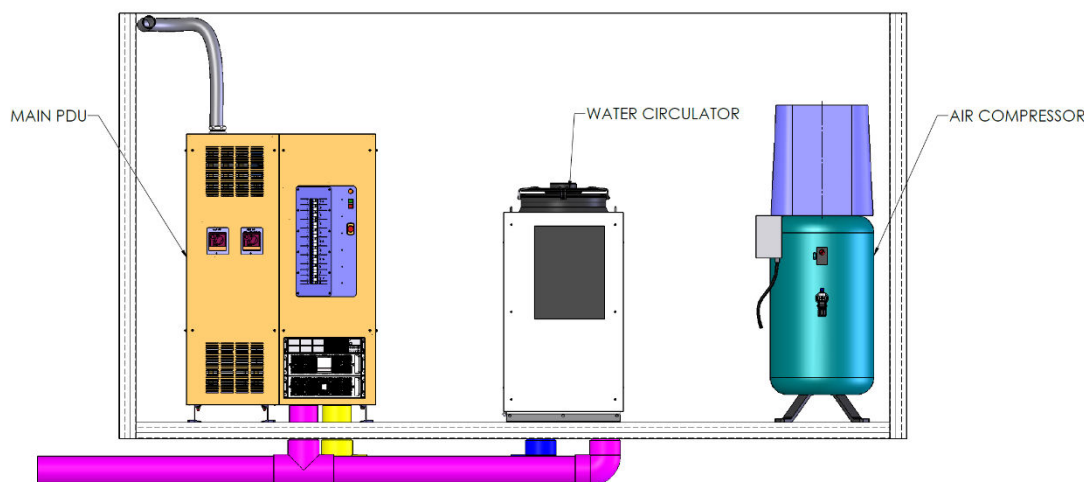


Figure 6 - Typical Auxiliary Equipment Room layout

- Noise & heat loading for all the equipment in auxiliary room are – approx. 68db. / 6 kW average watts
- The Auxiliary Room is located adjacent to the Treatment Room (see Figure 1). Three (3) 100mm (4”) conduits need to be installed under the floor between the Auxiliary Room and the Treatment Room Pit to run the Power & Signal cables, Air and water hose interconnections to the ZAP-X system.
- The Auxiliary Room must include a floor drain within 10 feet of the chiller for maintenance purposes. (Only used periodically to drain used distilled chiller water from the closed loop-System water circulator)
- Fire detection and suppression must follow local fire code requirements. Avoid fire sprinklers to be placed directly above ZAP-X auxiliary components. Use of Fire Alarms and Smoke Detectors are recommended.



2 SITE PREPARATION

2.1 Radiation Safety

The ZAP-X is a self-contained and first-of-its-kind self-shielded therapeutic radiation device dedicated to brain as well as head and neck stereotactic radiosurgery (SRS). The patient chamber inside ZAP-X is equivalent to a “Bunker” for a traditional linear accelerator system and is equipped with integrated shielding and interlocks that prevent both motion and radiation while the patient chamber door is open.

No external room shielding is required for a given heavy workload. The treatment room around the outside of the ZAP-X system safety zone is an area where radiation levels are suitable for unrestricted public access. See [Section 9](#) for more details.

State Regulations for Radiation Safety

Customers should connect with state health agency regarding obtaining permit to operate the ZAP-X system. Each state and country will have specific guidelines for radiation safety. It is customary to have to prepare a Shielding Design and Evaluation report approximately 60 days prior to construction.

2.2 Site Visits

Prior to any site visit the Zap Field Service & Operations team will work closely with the on-site construction team to plan/finalize the auxiliary room and treatment room layouts in accordance with our requirements. The ZAP operations team may be in close contact with the related customer engineers, architects, construction team and project manager to plan the final design requirements for the ZAP-X system.

There are typically two onsite visits prior to installation.

Site Visit #1: Construction phase

During this site visit the Zap engineer will meet with the on-site construction team and walk the site to take measurements of the treatment and auxiliary rooms and check for any discrepancies to the originally agreed plan. In addition, the first site visit will be an opportunity to verify access requirements for installation and delivery of the ZAP-X system.

- Review drawings and ZAP-X requirements
- Review auxiliary and treatment room locations, dimensions and layouts
- Review conduit size, locations and necessary cable routing
- Review pit and Anchor Bolt or H-plate installation options and required dimensions
- Review specification required for flatness and smoothness of pit and ground floor
- Review electrical, HVAC, and IT requirements and locations
- Discuss potential site access options for vehicles and ZAP-X modules/transport unloading.
- Verify customers’ existing CT System / MRI System

After the site visit is completed, the Zap engineer will review with the customer any areas of concern or areas that need mitigation before installation can occur.



Site Visit #2: Site Verification and Rigging Requirements

The second site visit will take place just before installation. The ZAP field service team, along with the rigging company personnel, will review the final construction result, verify any corrections identified during site visit 1 have been completed and verify site readiness for installation. This site visit includes the following items to be checked (but not limited to):

- Verify all site requirements are met
- Verify final layout per agreed plan/drawings
- Verify pit dimensions and pit floor flatness are in spec
- Verify ground floor area smoothness/finish around pit to enable smooth motion of air caster transports during installation
- Determine access pathways and staging area requirements for delivery and installation equipment (Trucks, Heavy Duty Forklift/Cranes, Rigging equipment, Crates etc)
- Determine equipment needed by Rigging company for ZAP-X module transit/final positioning
- Determine necessary permits, etc. for delivery, installation and inspection
- Confirm final construction timelines
- Confirm installation date and shipping timelines
- Confirm schedule for installation, system commissioning and testing
- Confirm anticipated dates for training



3 DELIVERY REQUIREMENTS

3.1 Access Requirements

- The Treatment Room must be at ground level with access to a minimum 3.7 m (12' 0") wide x 3.0 m (9' 10") high exterior building opening for installation of the ZAP-X system. The opening may be temporary for the installation phase. (Recommended width of opening 4.0m wide x 3.0m high for ease of access for transport modules, additionally it is recommended that the opening is aligned with the pit center line) See Figure 1 - Typical Room Layout.
- For installation, the four major ZAP-X "modules" are unloaded from a truck by forklift (15-ton capacity) to a staging area near the building opening.
- The forklift transports the ZAP-X modules (mounted on their air castor transport modules) onto the floor of the Treatment Room through the exterior building opening. The modules are positioned using floating air castors and mechanically joined together inside the Treatment Room, after which the module transports are removed, and the exterior building opening may be closed.
- The staging area and ground in front of the temporary opening should be stable and as level as possible to facilitate the easy transport and delivery of the modules into the building by forklift truck. Considerations should be given that an unlevel staging area may require the height of the building opening to be increased to accommodate the safe delivery.
- The floor of the treatment room should be flat/level and covered with thin (1-2mm max) plastic or aluminum sheeting to protect the treatment room floor when the ZAP-X modules are positioned using their air castor transports.
- If a 15-ton capacity forklift truck is not used and instead a crane used to lift the modules into place, then a suitable raised/level staging area of size and capability for supporting the weight of the modules will need to be constructed in front of the opening.
- The auxiliary equipment (power distribution unit, water circulator, and air compressor) are unloaded and positioned in the Auxiliary Room. These units will be anchored to the floor using drop-in anchor bolts during final positioning and installation.



ZAP-X Radiosurgery System

E0920-00008 Rev C

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3.2 System Weights & Dimensions

The installed ZAP-X system weighs approximately 58,367lbs (26,475 kg) after the transit fixtures are removed and the accessories are installed. The approximate shipping weights & dimensions of the ZAP-X system components are:

Description/Content	Crate Size (L x W x H) / Weight	Crate Packaging Material	Total Shipping Weight include crate and modules
• Assy Module #1, E0010-00050, 10,727 Kg <ul style="list-style-type: none"> Module #1 Transport Assy, E0010-00321, 2895 Kg (355cm*229cm*120cm) 	Container O.D.:238 x 96 x 114 inch (605cm*244cm*290cm) (3307Kg / 7275 lbs)	20' ISO Steel Container (Side Opening)	16,929 Kg / 37,245 lbs
• Assy Module #2, E0010-00046, 4,790 Kg <ul style="list-style-type: none"> Module #2 Transport Assy E0010-00358, 1482 Kg (355cm*214cm*197cm) 	Container O.D.:240 x 96 x 109inch (609cm*244cm*278cm) (2377Kg / 5230 lbs)	20' ISO – Open Top Steel Container	8,650 Kg / 19,030 lbs
• Assy Module #3, E0010-00116, 5,872 Kg <ul style="list-style-type: none"> Module #3 Transport Assy E0010-00322, 2737 Kg (355cm*230cm*120cm) 	Container O.D.:238 x 96 x 114 inch (605cm*244cm*290cm) (3307Kg / 7275 lbs)	20' ISO Steel Container (Side Opening)	11,865 Kg / 26,103 lbs
• Assy Module #4, E0010-00266, 4,209 Kg <ul style="list-style-type: none"> Module #4 Transport Assy E0010-00324, 2627Kg (355cm*228cm*120cm) 	Container O.D.:238 x 96 x 114 inch (605cm*244cm*290cm) (3307Kg / 7275 lbs)	20' ISO Steel Container (Side Opening)	10,143 Kg / 22,315 lbs
• Assy Vertical door (E0010-00222), 796 Kg	Crate O.D.:59 x 47 x 40 inch (150cm*119cm*102cm) (82Kg / 180 lbs)	ATA Transit Case	959 Kg / 2,110 lbs
• Main PDU, E0011-00011, 922Kg	Crate O.D.:51 x 46 x 81 inch (130cm*117cm*206cm) (114Kg / 250 lbs)	ATA Transit Case	1013Kg / 2,230 lbs
• Utilities/Accessories <ul style="list-style-type: none"> Assy, Utility Stand, E0010-00114 Axial Rotary Feedthru, Electrical & Water (E0700-00216) Assy, Proximity Scanner, Patient Right (E0010-00372) Assy, Proximity Scanner, Patient Left (E0010-00426) Assy, Axial motor Coils (E0010-0248/E0010-0249) Kit, Outer Panels, E0240-00001 Front Panels, E0240-00058 Kit, Vertical Door covers, E0240-0051 Kit, Assy Utility Stand Covers, E0010-00371 Floor Cover, Rotary Shell Motor, E0040-00172 Kit, QA Apparatus fixtures, E0240-00003 Console Table, E0240-00062 Base PDU, E0011-00018 Console Monitors, E0700-00351 Assy, Database PC, E0011-00034 Assy, Operator PC, E0011-00026 Misc. System cable kits and hoses 	Crate O.D.:90 x 82 x 72 inch (229cm*208cm*183cm) (84Kg / 185 lbs)	ATA Transit Case	931 Kg / 2050 lbs
• Water Circulator, E0240-00037, 156Kg	Crate O.D.:58 x 36 x 70 inch (147cm*92cm*178cm) (68Kg / 150 lbs)	ATA Transit Case	340 Kg / 750 lbs
• Air Compressor, E0240-00043, 232Kg	Crate O.D.:50 x 34 x 90 inch (127cm*86cm*229cm) (102Kg / 225 lbs)	ATA Transit Case	404 Kg / 890 lbs



4 STRUCTURAL REQUIREMENTS

4.1 Treatment Floor Requirements

- The structural flooring must be engineered to support the ZAP-X system weight during, and after installation, according to local soil and building conditions and local regulations.
- If there is an existing slab, it must be removed and replaced with a new engineered floor and pit to properly support the ZAP-X system.
- The pit and the surrounding structural floor are constructed of concrete and must remain watertight in the local conditions.
- The surface of the floor outside the pit is flat and smooth so air casters can be used to move and position the ZAP-X modules (for example, a seamless epoxy coating on the concrete).
- The main treatment room concrete floor and raised floor may be covered with a finish of the site's choosing after the ZAP-X installation is completed.
 - Refer to Drawing E0048-00028 – Floor Template, Proximity Scanner Boundary, ZAP will supply the template after system installation so that the floor can be marked for the final floor covering (eg Vinyl). The covering should be laid in two different colors to visually define the laser scanner boundary around the ZAP-X system.

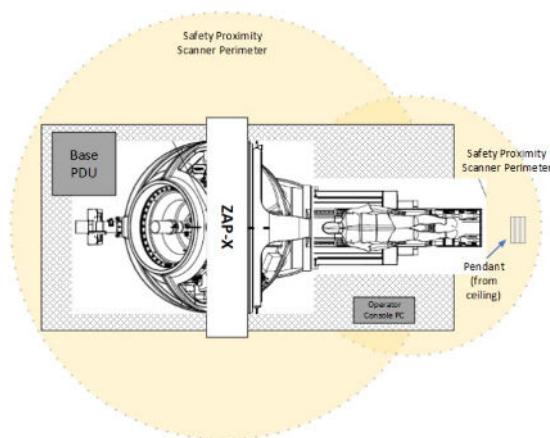
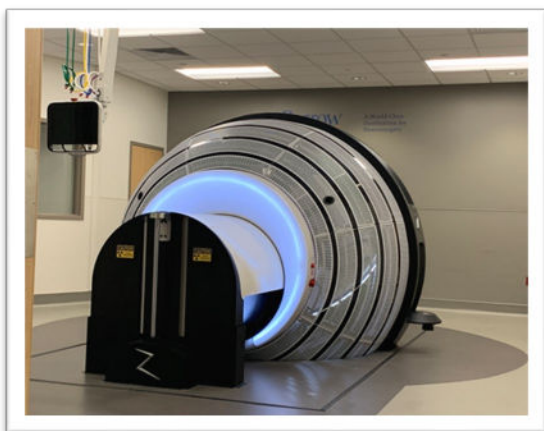


Figure 7 - Floor covering visually defining laser scanner boundary

4.2 Pit Requirements

- Refer to drawing package E0960-00001 for detail drawings of the construction requirements for the Pit and Sub-pit
- The ZAP-X system is installed 609.6mm(24") below the ground surface level to achieve a comfortable height of the treatment table for patient loading and unloading. This is achieved by constructing a pit within the floor of the Treatment Room.
- The main pit is 2.44 m x 4.88 m x 0.61 m deep (8' x 16' x 2' deep).

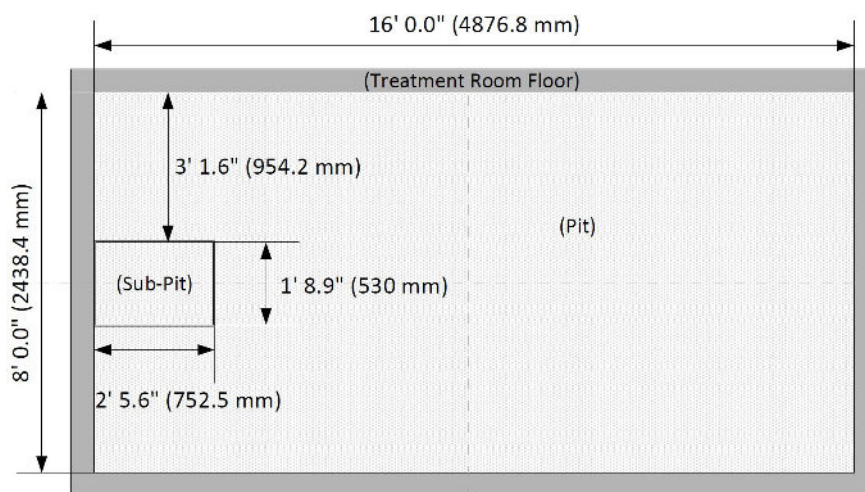


Figure 8 - Pit Dimensions (Top Profile)

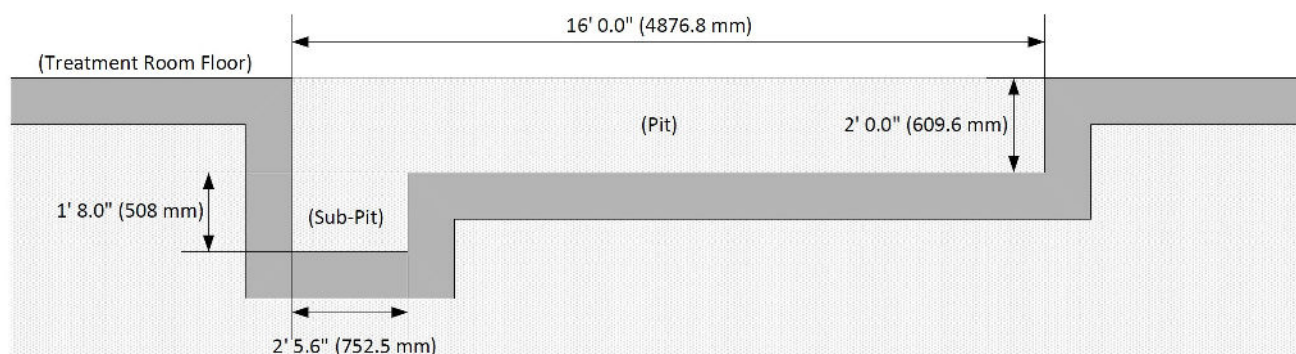


Figure 9 - Pit Dimensions (Side Profile)

- Tolerance on the pit construction dimensions is $\pm 3\text{mm}$
- The base floor of the main pit floor must be flat and level (Spec: 1/16" over 10ft / 1.6mm deviation over 3 meter)
- At one end of the main pit, there is a Sub-pit 752.5mm x 530mm (29.6" x 20.9") x 508mm (20.0") deeper than the rest of the main pit floor. This sub-pit allows the patient entry door to lower out of view when loading a patient.

- **Important** - Rebars in the pit construction must avoid locations marked in E00960-00001 (for Module #2, operator console and vertical door frame fixing points) to allow anchoring of equipment.
- The main support frame (Module #2) and the Patient entry door frame of the ZAP-X system must each be anchored to the pit floor for normal operation and to resist motion in accordance with the local building code.
- The pit floor and walls should be painted matte black (color definition is: RAL 9011 Graphite Black, 3% Gloss).
- Floor finish must be very smooth and high-grade flatness

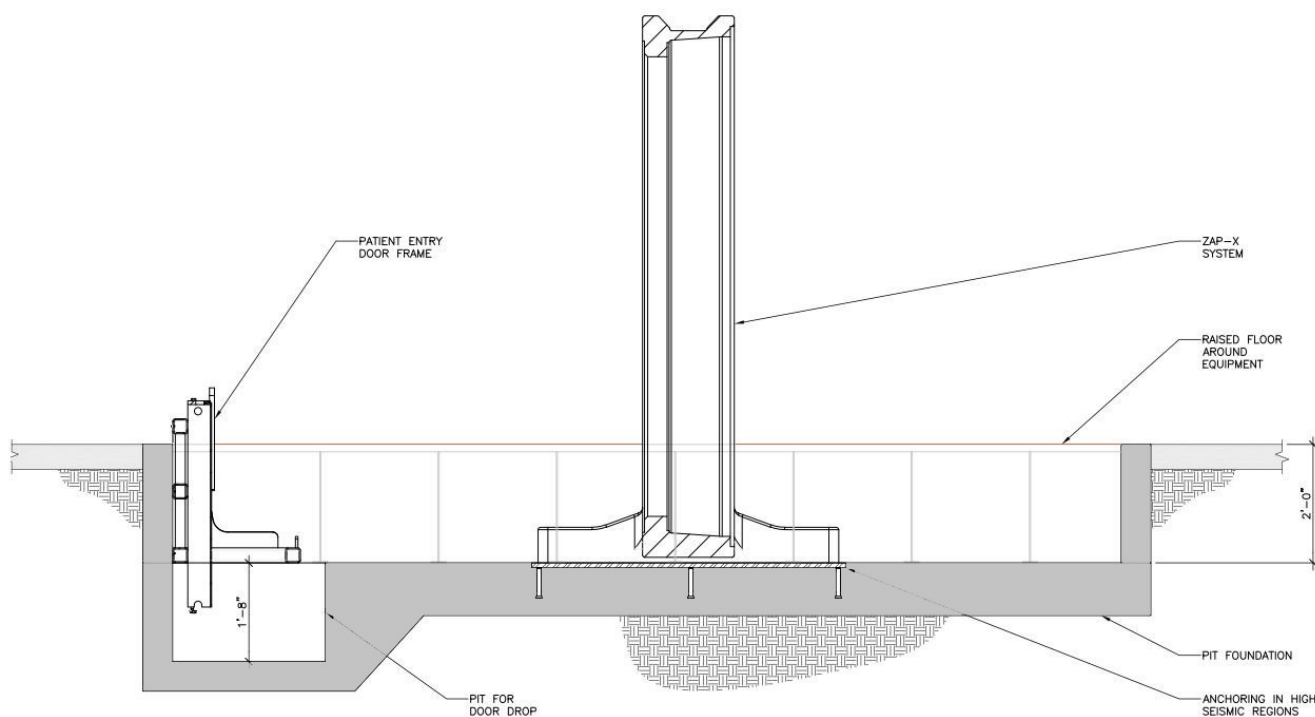


Figure 10 - Cross section view of pit construction

4.3 Pit Covers & Frame

- After the ZAP-X system is installed, the pit is covered with a raised floor that can be removed to allow access inside the pit for service.
 - It is the customers responsibility to construct the raised floor frame and floor panels, details of how to construct the raised floor can be found in drawing package E0960-00001 Pg. 8/9

- Construction of the pit floor frame is usually done in wood and after the ZAP-X system is installed to allow it to be built around the system pit components.

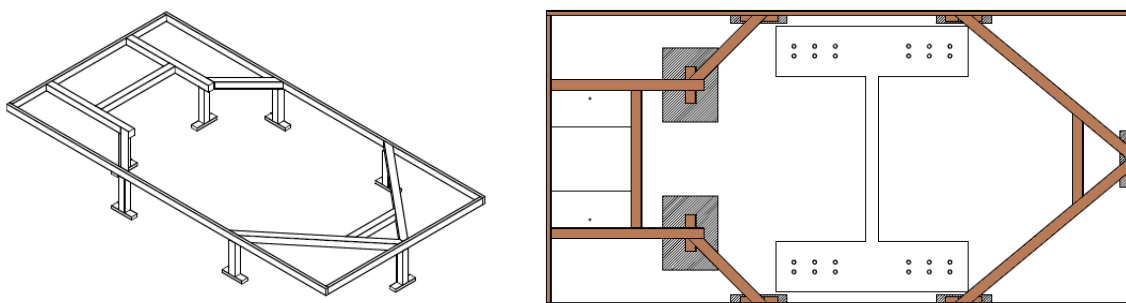


Figure 11 - Pit Floor Frame Construction design

- After the Frame is constructed the pit area around the ZAP-X system it needs to be covered to create a stable floor at the same level as the treatment room floor.
- Refer to drawings E0960-00001, E0028-00001, E0028-00002 and E0040-00144 for details on how to construct the panels, they are made in 4 sections each with a specific shape that fit precisely around the ZAP-X system on top of the pit frame.
 - Typically, they are made from wood and covered with the same type of final floor covering as the treatment room (eg. Vinyl)
 - Handles should be mounted on each panel surface to aid lifting when servicing the system.

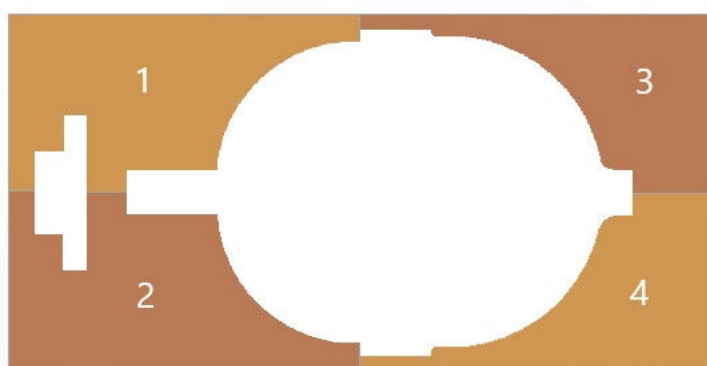


Figure 12 - Pit Frame Covers (4 Pieces)

4.4 Module #2 floor fixing options

The main support frame (Module #2) of the ZAP-X system must each be anchored to the pit floor for normal operation and to resist motion in accordance with the local building code.

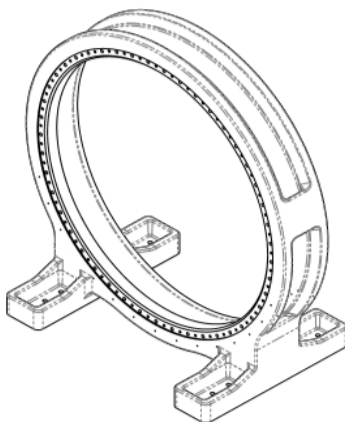


Figure 13 - Module #2 Base Ring

ZAP recommend three (3) different methods for anchoring the system as detailed below.

The method, material, fabrication, and installation of the chosen anchoring option is the responsibility of the customer. It also must be approved by a structural engineer licensed in the local building jurisdiction for the site.

4.4.1 Option 1 – Drop in anchor expansion bolts (suitable for most installations)

- 3/4"Ø – 10 pitch (M20 Ø x 2.5mm pitch) EXPANSION BOLT with minimum 6" (15cm) NOMINAL EMBEDDED in concrete (2 PER CORNER, 8 TOTAL).

It is the customers responsibility to have their structural engineer calculate and determine the type of anchor bolt required in accordance with seismic anchoring requirements per the local building code.

- Reference Figure below for location of fixing points in the base of Module #2 using drop-in anchors.
- The threaded protrusion of the anchor should be sufficient to allow enough thread length through the 40mm base thickness of Module #2 to install the locking bolt/washer.
- **ZAP will provide customer a template for correct positioning of the holes in the pit floor. It is the customers responsibility for drilling the holes.**
- Refer to drawing E0048-00029 – Template, Module 2 Base Anchor for details

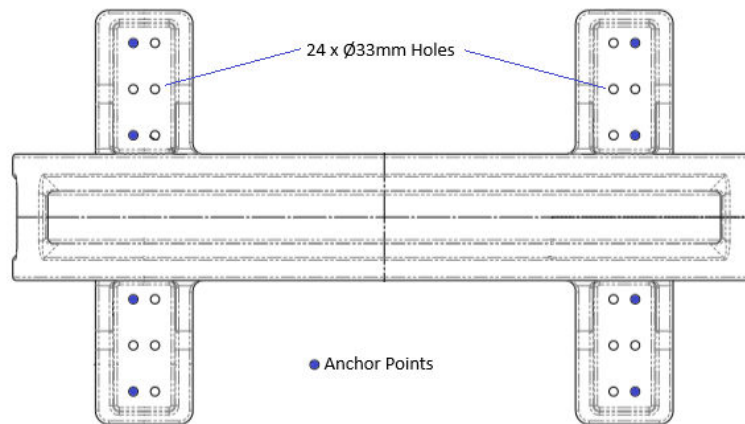


Figure 14 – Module #2 diagram showing location of 8 anchor points when using expansion bolts

4.4.2 Option 2 – Epoxy Anchor Bolts

- 1"Ø – 8 pitch (M24 Ø x 3mm pitch) EPOXY ANCHOR with 20" (50cm) EMBEDDED in concrete (3 PER CORNER, 12 TOTAL)

It is the customers responsibility to have their structural engineer calculate and determine the type of anchor bolt required in accordance with seismic anchoring requirements per the local building code.

- Reference Figure below for location of fixing points in the base of Module #2 using epoxy anchors.
- The threaded protrusion of the epoxy anchor should be approx. 4" (100mm) above the pit floor level to allow enough thread length through the 40mm base thickness of Module #2 to install the locking bolt/washer.
- **ZAP will provide customer a template for correct positioning of the holes in the pit floor. It is the customers responsibility for drilling the holes and installing the epoxy anchors in place.**
- Refer to drawing E0048-00029 – Template, Module 2 Base Anchor for details

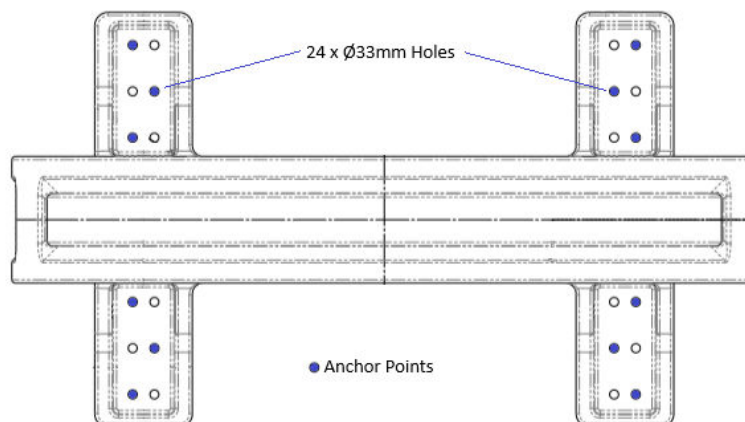


Figure 15 – Module #2 diagram showing location of 12 anchor points when using epoxy anchor bolts

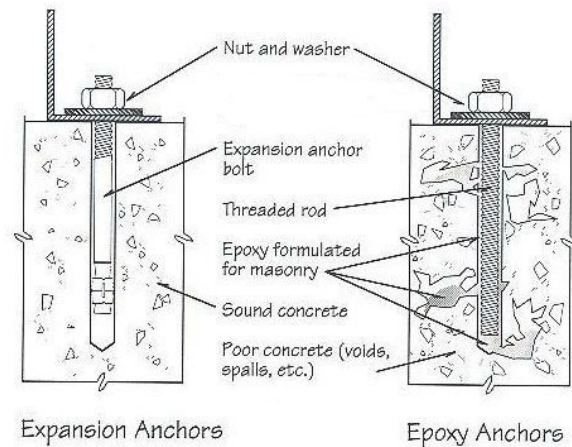


Figure 16 - Typical examples of Expansion Anchor & Epoxy Anchor types

4.4.3 Option 3 - Embedded “H-Plate” (Recommended for seismic regions only)

- A steel “H-Plate” is embedded in the concrete surface of the pit during construction for mounting of the ZAP-X system.

Important – the H-Plate needs to be installed, positioned and leveled prior to pouring concrete of the pit floor, please contact ZAP customer support for detailed instructions.

- **The material, fabrication, and installation of the “H-Plate” is the responsibility of the customer. It also must be approved by a structural engineer licensed in the local building jurisdiction for the site.**
- The main support frame (Module #2) and the patient entry door frame of the ZAP-X system must each be anchored to the pit for normal operation and to resist seismic motion in accordance with the local building code.
- Drawing E0040-00168 shows the fabrication instructions of the “H-Plate”.

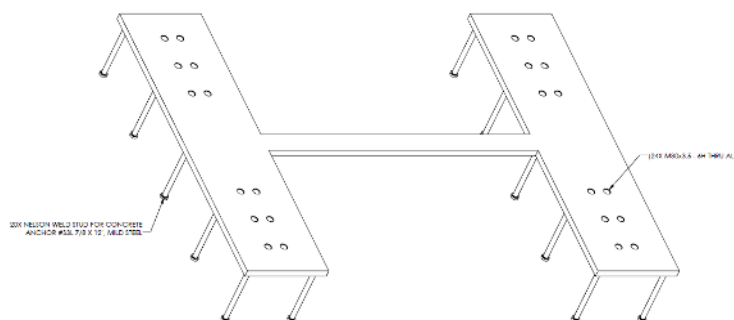


Figure 17 - H-Plate design (refer to E0040-00168 for mechanical drawing)

- Figures below shows an example sectional detail detailing the “H-Plate” embedded in the pit concrete pour.

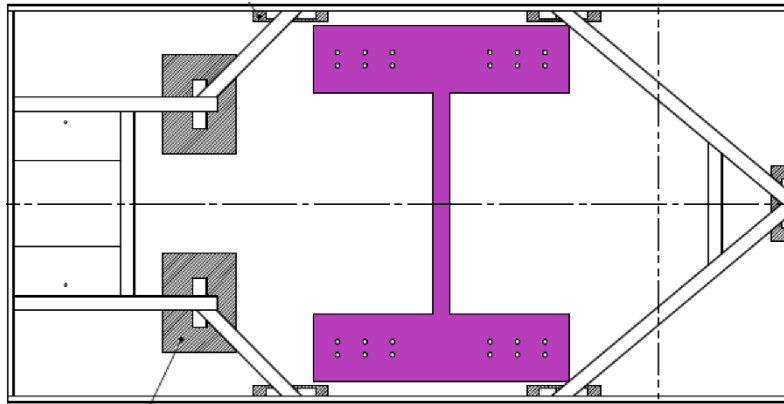


Figure 18 - Top view of H-Plate embedded in pit floor

4.5 Embedded Conduits

- From one side of the pit, (Refer to Figure 1) there are three (3) separate 100 mm (4”) diameter embedded PVC conduits for power/signal cabling and water/air hoses to run under the floor surface between the Treatment Room and the Auxiliary Room equipment.
- From one side of the pit, there is one (1) 100 mm (4”) diameter embedded PVC conduit for cabling to run under the floor surface from the pit to the operator console. The location of the operator console can be selected as shown in drawing E0960-00001, but then it is fixed as it is anchored to the concrete floor and mated with the embedded conduit.
- Next to the operator console conduits there are three (3) additional 50 mm (2”) diameter embedded PVC conduits for cabling to run under the floor surface from the pit to the edge of the room, then up to the ceiling (inside the wall is preferable).
 - Two (2) conduits channel power and data to the ceiling mounted Control Pendant.
 - One (1) conduit terminates at the Database/Planning PC location as determined by the customer (maximum path length of Ethernet Communication cable is 100m). The conduits in the wall may be PVC or metal depending on local requirements.
- There should be no obstructive bends in the conduit path to allow cables to be pulled through easily.
- Embedded depth of all conduits should be a minimum of 10” (255mm) below the surface of the finished treatment room floor where they exit into the pit. Refer to E0960-00001 drawing package for reference on positioning.



ZAP-X Radiosurgery System

E0920-00008 Rev C

ECO-000055

Embedded Conduits	Pit --> Auxiliary room (100 mm Ø x 3)
	Pit --> Operator Console (100 mm Ø x 1)
	Pit --> Ceiling mount Control Pendant Arm (50 mm Ø x 2)
	Pit --> Treatment Planning Room (50 mm Ø x 1)

Figure 19 - Conduit requirement summary

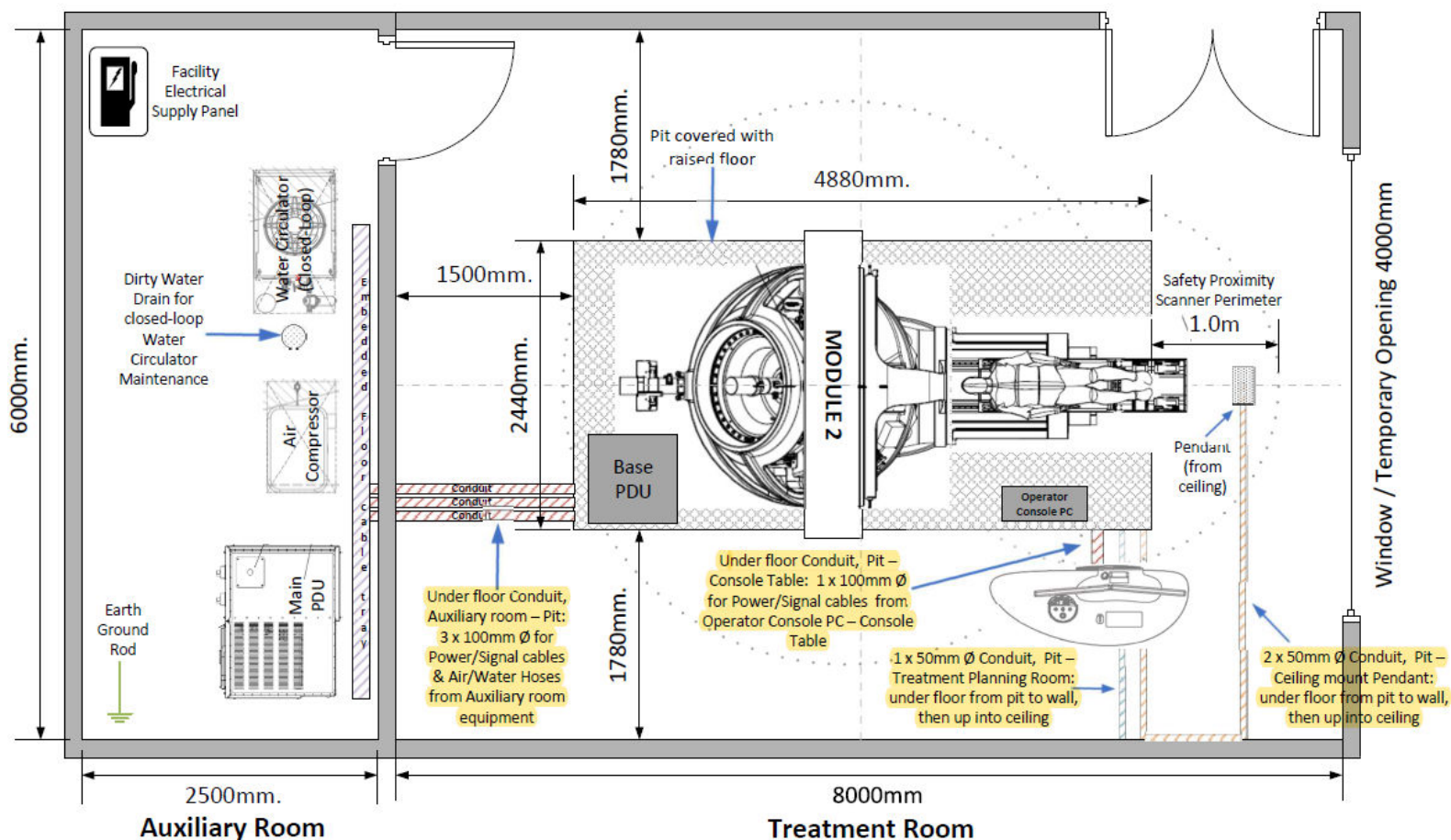


Figure 20 - Typical Room Layout showing conduit locations/paths



5 ELECTRICAL REQUIREMENTS

- The ZAP-X system will draw all required power from the main power distribution unit, located in the Auxiliary Room. Only the Database/Planning PC, monitor and firewall switch will have separate power sources, as these are in a separate area. No other site equipment should draw power from, or be connected to, the main power distribution unit.
- The main power distribution unit (Main PDU) has the following electrical requirements:
 - Incoming AC electrical supply from facility can be any of the following voltages (ZAP-X Main PDU internal transformer tap settings can be adjusted accordingly):

200/208/220/380/400/415/440/480/500 VAC $\pm 10\%$
 - 3 Phase – 50/60 Hz
 - 36 kVA peak power (in-rush current is 2 x operating current for 10 milliseconds).
 - Recommend that the facility electrical power is clean/conditioned and on UPS back up supply if available
- Customer to provide suitable power supply cord from switched facility power to the main power distribution unit, in the auxiliary room, that adheres to the local electrical code.
 - The power supply cord shall be not less robust than ordinary tough rubber-sheathed flexible cord (GB 5013.1) or ordinary polyvinyl chloride sheathed flexible cord (GB 5013.1).
 - The nominal cross-sectional area of conductors of the power supply cord shall be not less than that allowed by local electrical codes.
 - Stranded conductors shall not be soldered before being clamped into terminals.
- There must also be a conductive ground-rod embedded in concrete foundation and earth, in the auxiliary room adjacent to the main power distribution unit, that adheres to the local electrical code. However, the ZAP-X system requires a **maximum resistance to earth of 25 Ω** .
- The Database/Planning PC, monitor, and Ethernet firewall switch each will need AC power via typical office outlets at the location chosen for this equipment, as further described in [Section 7](#).



6 HVAC REQUIREMENTS

The ZAP-X system requires the following environmental conditions for normal operation and storage:

6.1 Operating Conditions

- Temperature: +17 to +23 °C (+62 to +74 °F)
- Relative humidity: 30% to 70% non-condensing
- Air quality: ISO 14644-1 cleanroom class ISO 9 (office environment)
- ZAP recommend Air conditioning/humidity/temperature control environment
- The above are requirements for the HVAC system of the Treatment Room and Auxiliary Room

6.2 Storage Conditions

- Temperature: -25 to +55 °C (-13 to +131 °F)
- Relative humidity: 10% to 85% non-condensing
- ZAP-X system components must remain sealed in packaging
- Outdoor exposure to weather (sun, wind, rain, snow, ice, dust, sand, etc.): None

6.3 Equipment Heat Load

- Auxiliary Room: 6 kW average
- Treatment Room: 10 kW average
- Above values are during operating hours. The ZAP-X system is typically turned off at night and during extended idle periods.
- Above values assume 30 minutes treatment time and 30 minutes preparation time cycling throughout the operating hours. If ZAP-X system usage will be significantly greater than or less than this, please consult Zap Surgical Systems for a custom assessment



7 DATA REQUIREMENTS

- The ZAP-X system will need two network ports, each with a public static IP address. The Database/Planning PC will connect into these. During ZAP-X system maintenance these IP addresses may be accessed by Zap Surgical Systems, including the use of remote connectivity to the Database/Planning PC, via these network ports, to retrieve equipment data.
- ZAP-X system needs to have the following ports and http protocol access, which are used by the ZAP-X system agent software to collect data. (event logs, config files)

Source	Destination	Port
ZAP-X-Mgmt-IP	TPS-Dicom Server	4242
ZAP-X-Mgmt-IP	Remote Support Access	80, 443
ZAP-X-Mgmt-IP	https://agents.zapsurgical.com	80, 443
ZAP-X-Mgmt-IP	https://api-systems.zapsurgical.com	80, 443
ZAP-X-Mgmt-IP	https://zap-system-files.s3.amazons.com	80, 443
ZAP-X-Mgmt-IP	https://zap-system-files.s3.us-west-1amazons.com	80, 443
ZAP-X-Mgmt-IP	https://s3.amazonaws.com/	80, 443
ZAP-X-Mgmt-IP	https://s3.us-west-1.amazonaws.com/	80, 443
ZAP-X-Mgmt-IP	Smtplib.office365.com	587

- ZAP Surgical Systems may also utilize remote service support through a secure 3rd party client. (such as TeamViewer). Remote support can only be initiated by the user for security purposes.
- The ZAP-X System is GDPR and HIPAA Compliant, no patient data is transmitted with the event log files.
- One Database/Planning PC is provided with the ZAP-X system and is used to run the Treatment Planning Software (TPS) to create treatment plans. These plans are then conveyed to the Treatment Delivery Software (TDS), which runs on the Operator PC (also provided) and executes the planned treatments on the ZAP-X System. Both ZAP-X system PC's run on the Windows 10 operating system.
 - The Operator PC is located in the pit and is associated with the monitors/keyboard/mouse of the Operator Console. All connections to the Operator PC are internal to the ZAP-X system.
 - The Database/Planning PC should be located where the person creating treatment plans sits. For example, this might be a nearby office, or a desk just outside the Treatment Room.
 - At the location of the Database/Planning PC, there will be the following items: Database/Planning PC, monitor, keyboard, mouse, and a hardware firewall / gateway switch (all provided with the ZAP-X system).



ZAP-X Radiosurgery System

E0920-00008 Rev C

ECO-000055

- ZAP recommend that the Database/Planning PC is additionally powered by a 600Watt/1.0kVA desktop UPS backup power supply (Customer to provide) to prevent corruption of treatment plans in the event of an unexpected power outage in the treatment planning room.
- A second Treatment Planning PC can be purchased and configured as an option if required. Speak with a ZAP sales representative to obtain more details.



Figure 21 - Treatment Planning PC (TPS) and SonicWall TZ300 firewall switch

- An ethernet cable needs to run from the Database/Planning PC room to the Base PDU in the pit. The 2" (50mm) conduit from the pit to the wall is used for the ethernet cable to enter the pit. (Maximum cable length is 100m)

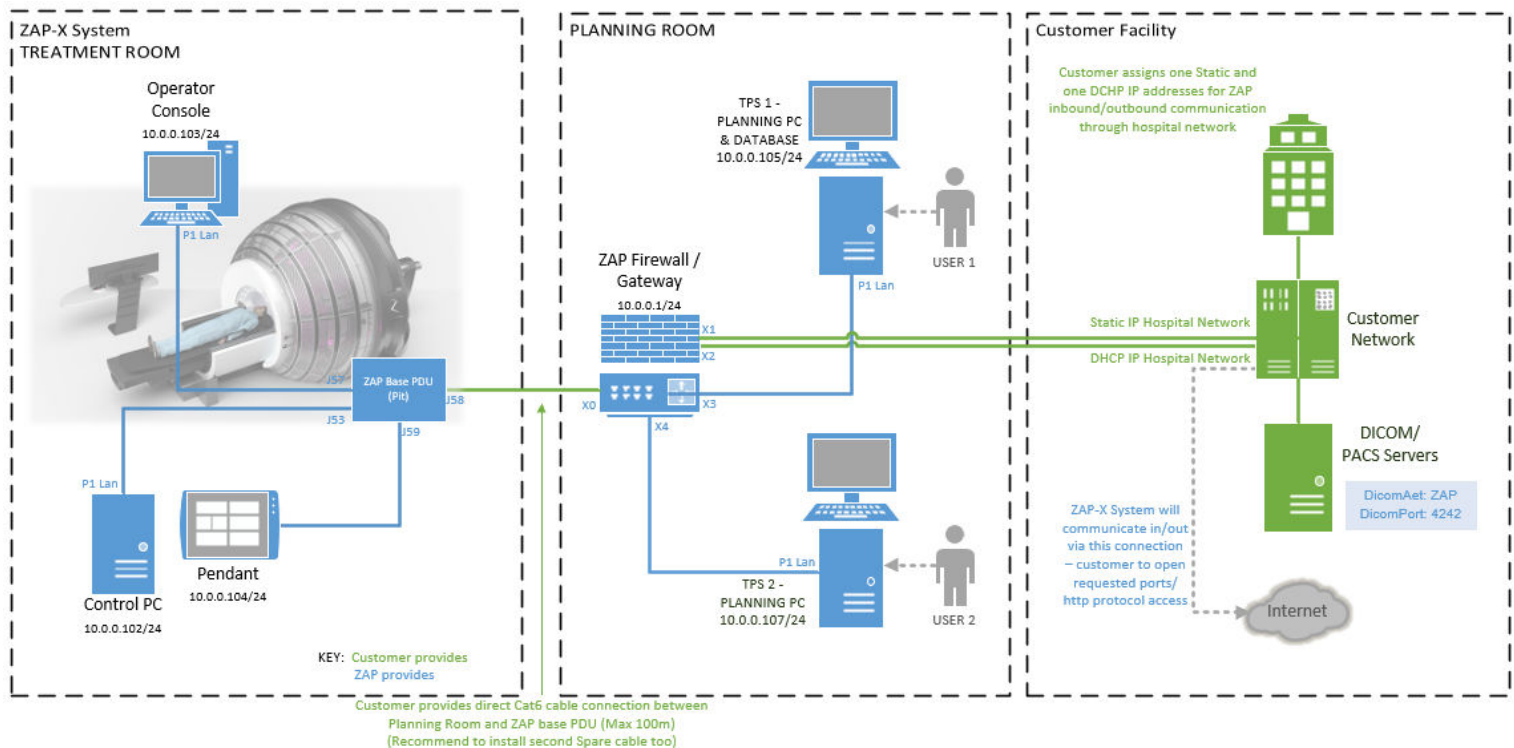


Figure 22 - Data Requirements Diagram



- **DICOM**

- Images imported into ZAP require the following DICOM fields:

BitsAllocated	(0028,0100)
BitsStored	(0028,0101)
Rows	(0028,0010)
Columns	(0028,0011)
ImageOrientationPatient	(0020,0037)
ImagePositionPatient	(0054,0410)
PixelSpacing	(0028,0030)
PixelRepresentation	(0028,0103)
Modality	(0008,0060)
RescaleIntercept	(0028,1052)
RescaleSlope	(0028,1053)
WindowCenter	(0028,1050)
WindowWidth	(0028,1051)

- During installation of the ZAP-X system, engineers will work with local IT department to configure ZAP firewall switch and DICOM settings:
 - DicomAET: ZAP
 - DicomPort: 4242



8 CT SCANNERS & MRI SCANNERS FOR PATIENT IMAGING

The ZAP-X is designed to deliver patient treatment with submillimeter accuracy. In order to ensure this high level of patient care and treatment, the image data sets that are sent from the customer's CT scanner(s) to the ZAP-X need to follow certain guidelines:

Basic Parameters for CT Imaging

Use a head and neck scanning protocol with the following settings:

- Headfirst Supine (HFS)
- 512x512 pixels per slice
- Slice thickness: 1.00mm is ideal. (1.25mm max)
- Constant slice thickness throughout the series
- Air gap surrounding patient silhouette:
 - o 10mm anterior
 - o 10mm posterior, from bottom of table to edge of CT in posterior direction
 - o 1mm superior
 - o noninferior
 - o left/right centered
- Yaw/Pitch/Roll = Approximately 0 deg.
- Use the same immobilization device as will be used during treatment delivery.
- No imaging device specific CT to density curves are applied to specific devices. A nominal CT to density conversion is applied for all imaging devices covering the range of available densities.
- CT image requirements: Push axial images only to ZAP-X system

For CT image acquisition it is essential that the patient positioning is the same as patient positioning used during the ZAP-X treatment, therefore Zap will provide an additional set of the following to be used with their CT system:

- E0040-00236 – Assy, Head support
- E0040-00238 – Adaptor, CT Table overlay adaptor
- E0040-00139 – Cushion, Patient Bed



Figure 23 - ZAP CT head support/CT overlay adaptor/S-Type mask

- Customer needs to provide/use the following in conjunction with the ZAP supplied head support:
 - If the CT system couchtop is concave, customer needs to purchase/supply flat couchtop CT Overlay adapter with a 2-pin locking bar

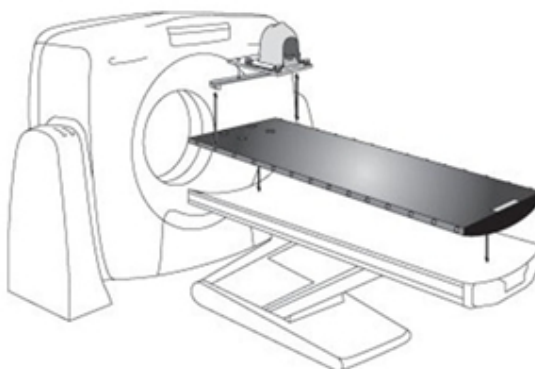


Figure 24 - Example of CT system with concave couchtop design/flat CT overlay adapter

- Any commercially available and FDA cleared mask with Type – S interface can be used with the Zap-X System.

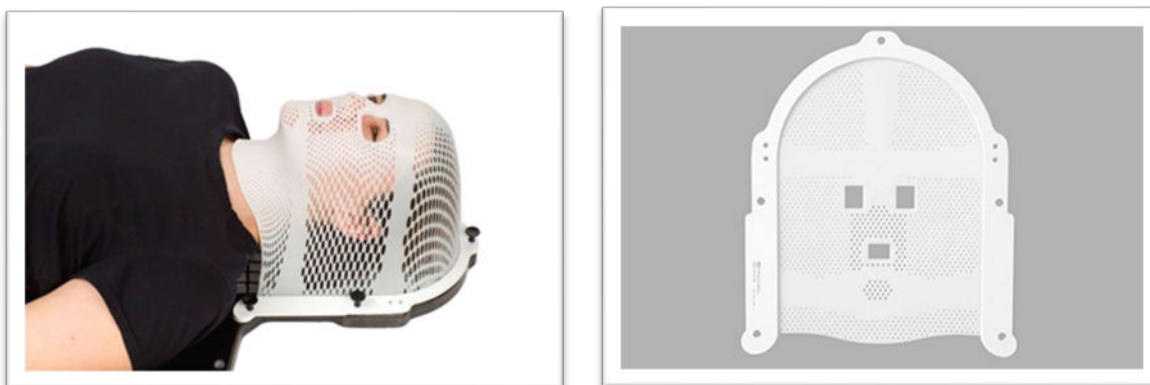


Figure 25 - Example of Type-S masks

- The use of a high transmission headrest, such as a CIVCO Silverman™, is recommended in order to optimize the silhouette of the head during alignment.

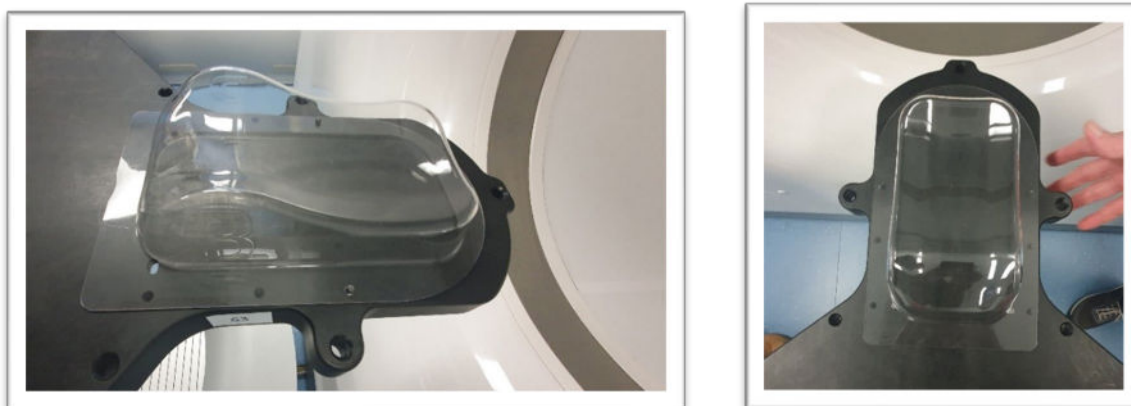


Figure 26 - CIVCO Silverman headrest

MRI Imaging Guidelines

Use the same patient immobilization setup that was used for CT imaging to ensure the same patient position in order to achieve fusion with the primary CT image study.

Zap-X Treatment Planning System supports MR image series only acquired in Axial direction.



9 RADIATION DESIGN CONSIDERATIONS

The ZAP-X system is a self-shielded, Image-Guided Stereotactic Radiosurgery System – no facility shielding (Treatment Vault) is needed.

The ZAP-X system provides self-shielding to personnel outside a 1-meter (m) safety zone from the perimeter of the ZAP-X system to levels that are acceptable to the public (1 millisievert (mSv)/year). This limit is generally applicable to radiation workers and non-radiation workers and stated by the National Council on Radiation Protection.

When choosing the location and the layout of the Treatment Room, consideration should be given to the 1m perimeter safety exclusion zone if the ZAP-X system is to be installed in a ground floor location with an occupied room above or adjacent to the system.

9.1 OCCUPANCY FACTOR

After patient loading, the operator is expected to remain at the control console during the entire treatment delivery. This is necessary to perform the required tasks prior to and during the treatment delivery. Such tasks include capturing planar diagnostic images of the patient's head for the purposes of initial patient alignment and intra-fractional position monitoring, the initiation and monitoring of the therapeutic radiation being delivered, visual monitoring the patient, monitoring of the in-vivo transit dose detected by the MV imager, and if necessary remote patient realignment and communication with the patient.

The control station will be occupied by the Radiation Therapists continuously and the Occupancy Factor of $T = 1.0$ is assigned to this station.

Assuming the access to the treatment room is unrestricted and the maximum dose per year inside the treatment room but outside the 1m perimeter line does not exceed 1.0 mSv, the public will be potentially allowed to move freely about the inside of the treatment room, staying clear, however, of the area within the 1m perimeter line. The public given access to the inside of the treatment during radiation delivery (depending on exact hospital Radiation Safety guidelines) are expected to be family members and friends of the patient, Physicians involved in the patient care or otherwise interested Physicians, other Department and hospital staff eager to witness the novel procedure, the press, administrators, and sales. All such visits by the public, as described above, are expected to focus on a single patient treatment or very few patient treatments.

Occupancy Factor calculation example:

With a given machine workload of 600 single-fraction patient treatments per year, up to 37.5 treatments per year could be attended by a member of that public, situated at the point of maximum dose rate along the 1m perimeter line to achieve an occupancy Factor of $T = 0.0625$. It is expected that no member of the groups described above would attend more than 37.5 treatment per year. Such attendance would constitute 15.6 days (over three weeks) of full-time attendance out of 250 treatment days per year.

If, however, it must be assumed that such attendance levels by the public will be necessary or would be exceeded, the occupancy factor shall be adjusted accordingly.



10 FACILITY INTERLOCKS AND SIGNAGE

The patient chamber inside ZAP-X is equivalent to the “bunker” for a traditional linear accelerator system and is equipped with integrated interlocks that prevent both motion and radiation while the patient chamber door is open or the proximity scanners are interrupted.

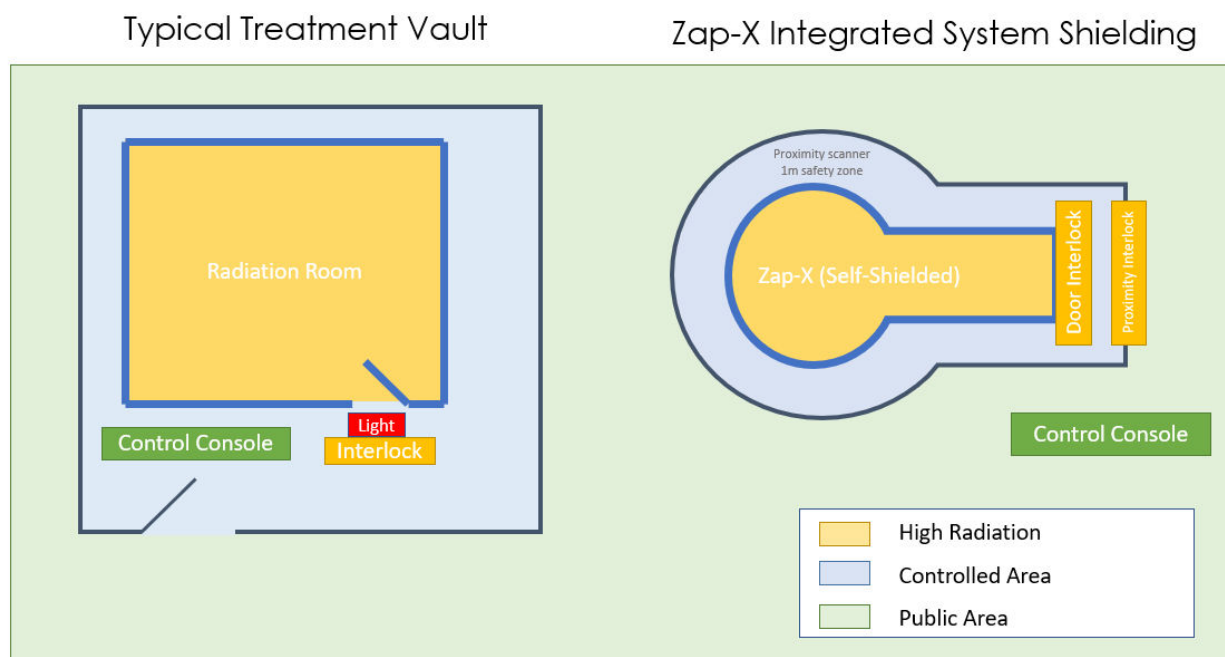


Figure 27 - A comparison of a traditional Linac installation and the ZAP-X system

The treatment room around the outside of the ZAP-X system is an area where radiation levels are suitable for unrestricted public access.

There are proximity scanners around the ZAP-X system that prevent machine operation when someone moves into an area approximately 1m away from the system. This ensures that any time a person approaches the point of entry to the system the beam is disabled. Furthermore, the control panel is equipped with lights that indicate when the beam is on.

The patient entry door to the ZAP-X is equipped with an interlock and must be closed for the beam to be activated. At the beginning of treatment and following any interruption (including a door interlock), exposure may only be resumed by manual action at the control panel

Due to the self-shielded and integrated interlock nature of the ZAP-X system, traditional entry restrictions and warning signage are not typically required.



ZAP-X Radiosurgery System

E0920-00008 Rev C

ECO-000055

In the rare event that, local regulations require additional signage or interlocks, please contact ZAP Customer Service and we can provide an output signal to activate an external facility light when a radiosurgery treatment is in progress.

Customer Facility

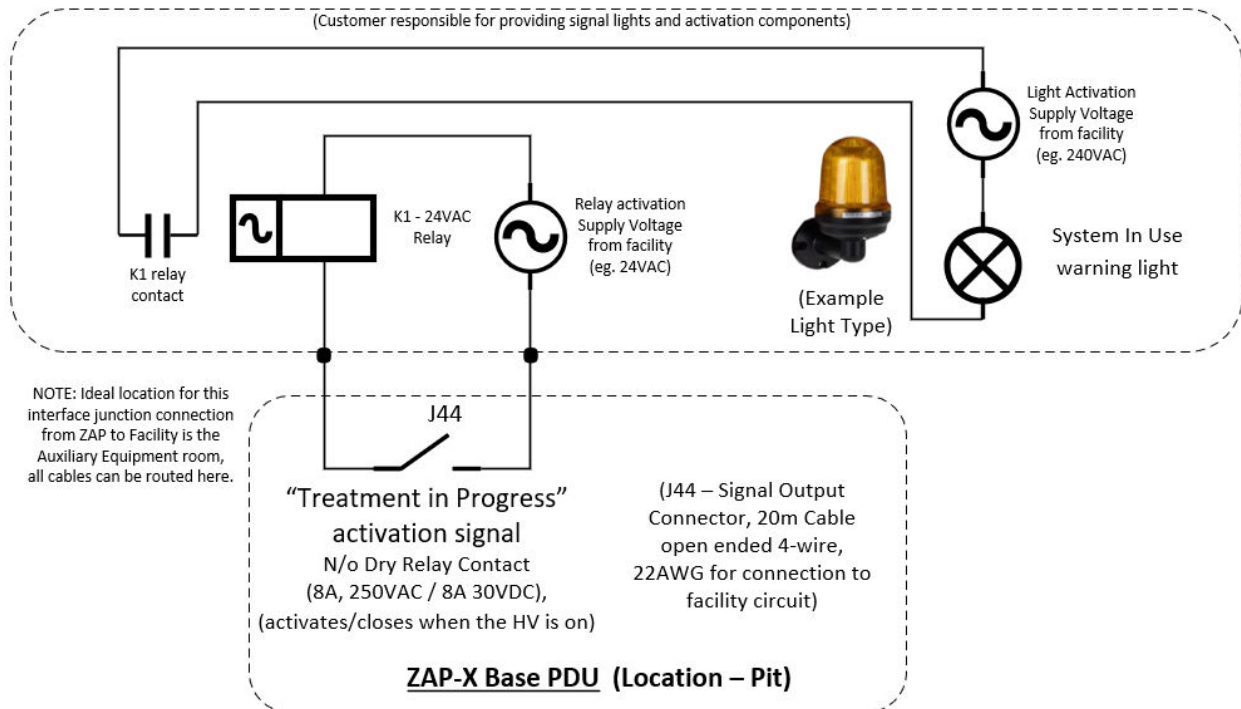


Figure 28 - Example In-use light circuit



11 Q/A AND COMMISSIONING TOOLS AND EQUIPMENT

ZAP-X comes with the following list of system specific supporting tools for QA and Commissioning:

Part Number	Qty	EQUIPMENT	USE
E0240-00026	1	SAD Calibration Kit	Beam Data and QA
E0240-00044	1	Isocenter Fixture Kit – PT Table	Beam Alignment Check & QA
E0240-00045	1	Isocenter Fixture Kit – Collimator	System Accuracy QA
E0240-00077	1	3D Water Phantom Frame	Beam Data and QA
E0023-00097	3	Film Disc, 45mm OD	System accuracy QA
E0010-00445	1	Assy, Phantom insert, 4mm Ball Cube	System accuracy QA

The following is a separate list of required equipment the customer needs to have/purchase for QA and Commissioning for the ZAP-X:

EQUIPMENT	SUGGESTED VENDOR	USE
3D Water Phantom	PTW MP3-XS (200x200x307.5mm)	Beam Data and QA
Dual Channel Electrometer	PTW Tandem and Control Unit and Pendant	Beam Data and QA
Beam Analysis Software	PTW MEPHYSTO or BEAMSCAN	Beam Data and QA
Ionization Chamber	PTW model 31021 0.07ccm (with ADCL calibration), Semi-Flex 3D	Beam Output Factor Measurement
Calibrated Electrometer	PTW Unidos Series (with ADCL calibration) or equivalent	Delivered Dose measurement QA
Detector Positioning System	PTW Trufix (Detector Positioning (for all chambers and diodes used)	Beam Data
MicroSilicon Diode	PTW SRS Type 60023 (with Holder)	Beam Profile Measurement
Reference Ionization Chamber	PTW T-REF Chamber 34091	Beam Profile and PDD Measurement
Digital Inclinator	Mitutoyo – Pro 3600 or equivalent with 2 decimal places	Water Tank Phantom leveling tool
Thermometer barometer	EXTECH Datalogger, Barometric Pressure, Temp, Humidity or equivalent	Beam Data and QA
Thermometer	CNMC Analog thermometer (for use in water & air) or equivalent	Beam Data and QA
Anthropomorphic Phantom Head (Inc. Ball Cube II)	ZAP optional or equivalent	System accuracy QA



ZAP-X Radiosurgery System

E0920-00008 Rev C

ECO-000055

OPTIONAL:

EQUIPMENT	SUGGESTED VENDOR	USE
Film Scanner	Epson V850 or equivalent, (only if films are used)	End-to-End Film analysis
kV Imaging QA Equipment	Leeds PIX-13	kV characteristics
PSQA tool	SUN NUCLEAR SRS Film QA or equivalent	Patient specific test film analysis
Survey Meter	Fluke Victoreen Model 451 or equivalent	Radiation Leakage Measurement
Solid Water Blocks / Sheets	Selection including 5cm to 1mm thickness	Beam Data and QA



12 SITE PREPARATION GUIDE CHECK LIST

The below checklist is for guidance only and not exhaustive of the specific steps a particular site may require

ZAP-X Site Preparation Checklist			
	GENERAL		
...	Task	Responsible /Notes (Eg. Customer/ZAP/Contractor)	% Complete
1	Review ZAP-X room design/layout plan/CAD drawings		
2	Remote/On-site meeting with the Contractors/Project team		
3	Review ZAP-X module delivery simulation plan		
5	Access requirements for ZAP on-site staff during installation		
6	Verify the CT & MRI System Make/Model that will be used in conjunction with the ZAP-X		
7	Customer ordered required QA equipment		
...	Radiation Considerations		
8	Local radiation permit application submitted by customer		
9	Customer RSO meeting	Agree Treatment room layout and Operator Console positioning	
		Understand Self-shielding capability of ZAP-X	
		Agree minimal interlocks/signage requirements for ZAP-X System/treatment room	
10	Radiation Shielding Calculations		
11	Shielding design and Evaluation report completed		
	Treatment Room		
12	Treatment Room Layout/Critical dimensions finalized		
13	Confirm ceiling height >10ft (3m), no obstructions around ZAP-X System		
14	Define Pit and Sub Pit dimension/requirements		
15	Module #2 Pit Floor Anchoring	Define anchoring method (Expansion Bolt/Epoxy Bolt/H-Plate)	
		ZAP supply template/fixture for drilling (Expansion/Epoxy bolts only)	
		On-site preparation/leveling prior to pit floor concrete pouring (H-Plate only)	
16	Embedded conduits	Pit --> Auxiliary room (100 mm Ø x 3)	
		Pit --> Operator Console (50 mm Ø x 2)	
		Pit --> Ceiling mount Control Pendant Arm (50 mm Ø x 2)	
		Pit --> Treatment Planning Room (50 mm Ø x 1)	



ZAP-X Radiosurgery System

E0920-00008 Rev C

ECO-000055

17	Console Table positioning/location			
18	HVAC requirements (10 kW heat load)			
19	On-site Visit #1 - Installation Readiness	Verify Pit critical dimensions/finish		
		Verify Pit floor level/flatness (max deviation 1mm / 1m)		
		Verify anchor holes drilled correctly/critical dimensions (Expansion/Epoxy Bolts only)		
		Verify H-Plate level/critical dimensions (H-Plate installation only)		
		Verify conduits		
		Verify ceiling mount for Pendant Arm		
20	Pit Frame manufacture/installation			
21	Pit Cover manufacture/installation			
22	Room finishing timeline (E.g. Closing opening, final floor covering)			
...	Auxiliary Room			
23	Position/Location of Main PDU/Circulator/Air Compressor			
24	Additional embedded floor conduits/channels as needed			
25	Main PDU Requirements	Conductive Earth ground-rod embedded in concrete foundation and earth (<25 Ω)		
		AC power cable connection from facility switched supply		
		Facility AC supply Voltage (200/208/220/380/400/415/440/480/500 VAC ±10%, 3-Phase)		
		Floor Anchoring - expansion Bolts		
26	Water Circulator Requirements	Dirty Water Drain (for chiller maintenance only)		
		Floor Anchoring - expansion Bolts		
27	Air Compressor Requirements	Floor Anchoring - expansion Bolts		
28	HVAC requirement (6 kW heat load)			
29	On-site Visit #1 - Installation Readiness	Verify Electrical requirements		
		Verify floor drain		
		Verify conduits		
...	Treatment Planning Room			
30	Confirm Location of Treatment Planning Room			
31	Confirm path for ethernet cable <100m (Pit --> Treatment Planning Room)			
32	Database Planning PC - Location/mounting			
33	Customer provision of computer desk/monitor/keyboard/mouse			
34	Standard AC Power Supply sockets for Database PC/peripherals (minimum 3 required for Database workstation)			
35	2 x RJ45 Network ports			
		Static public IP address/port assignment		
		ZAP Firewall switch / Customer Network Configuration		



ZAP-X Radiosurgery System

E0920-00008 Rev C

ECO-000055

...	Delivery/Staging Area			
36	Delivery Vehicle/Truck Access			
37	Temporary exterior building opening for delivery of modules - dimensions/readiness			
38	Onsite Visit #2 - Rigging Requirements	Site inspection - ZAP/Rigging company/Construction Team/Project Manager		
		Define Staging Area requirements		
		Define Rigging/Heavy Lifting Equipment requirements for site		
		Treatment Room Structural Floor Requirements (smooth flat finish for air casters)		
		Permits to Work required?		
39	Agree delivery/Installation Dates			
...	Post Installation Planning			
40	Electrical/Safety testing evaluation/acceptance (Eg. NRTL (USA) or other local regulated body)			
41	Customer acceptance/Handover			
42	Beam Commissioning			
43	Access requirements for ZAP on-site staff			
44	Customer Training dates			