

## **ZAP-X RADIOSURGERY® SYSTEM**

### **SITE PREPARATION GUIDE**



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## REFERENCE DOCUMENTS

Drawing E0960-00001 – Layout, Treatment Room  
Drawing E0960-00003 – Layout, Auxiliary Room  
Drawing E0040-00168 – H-Plate, Installation  
Drawing E0048-00029 – Template, Module 2 Base Anchor



## 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.

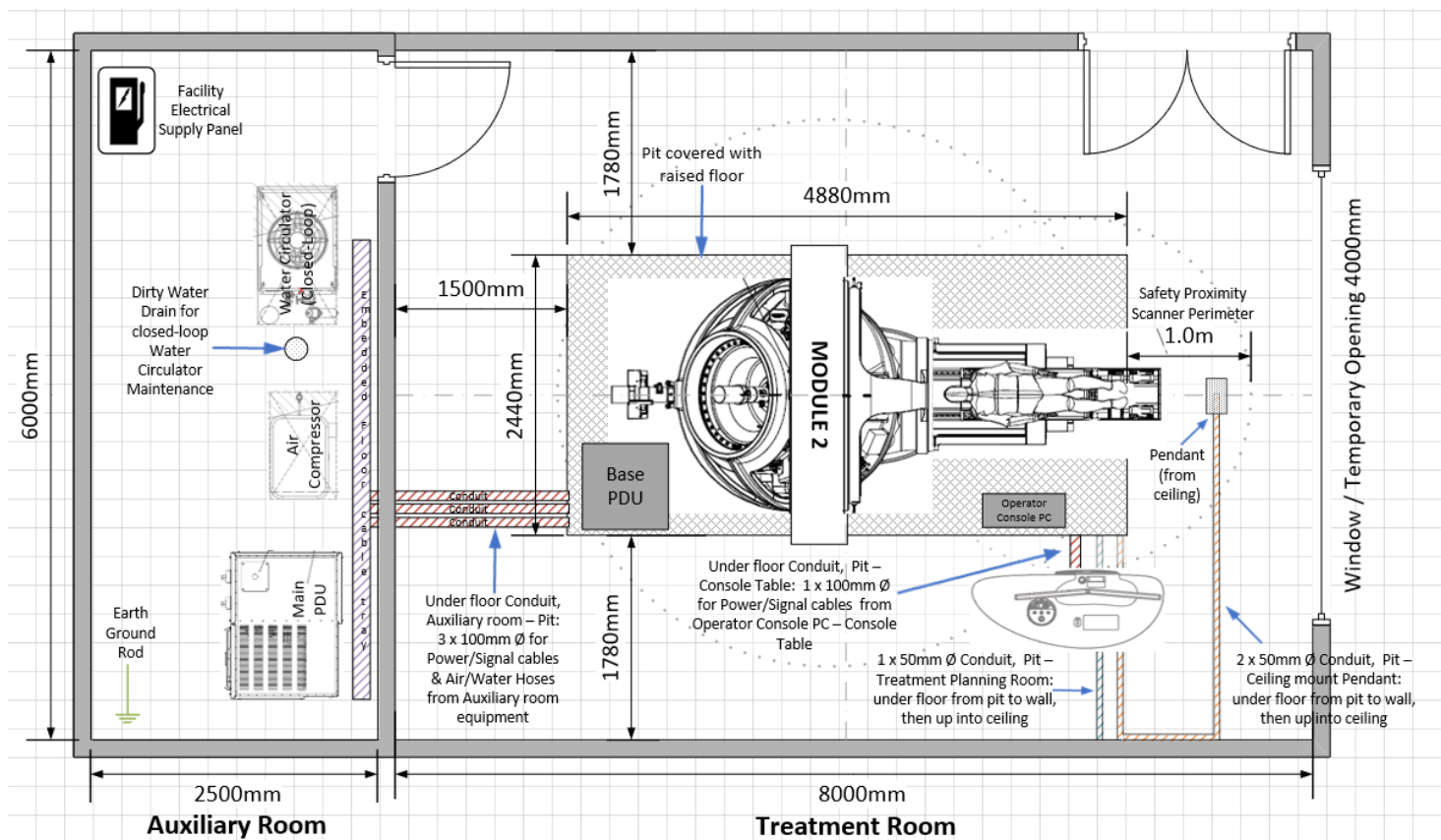


Figure 1 - Typical Room Layout



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

### 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, as shown in drawing E0960-00001.
  - 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.

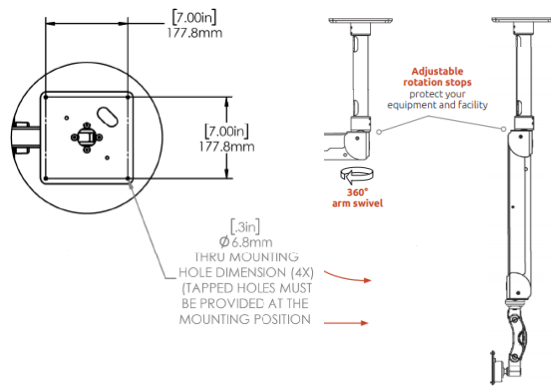


Figure 2 - Example of ceiling mount pendant arm

## 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:
    - Dimensions – L 38.2 x W 24.3 x H 80 inch (L 970mm x W 617mm x H 2032mm)



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- Weight – 513lbs (233kg)
- Operating Noise level – 66dB
- Electrical Power – 208/230/3-phase (supplied from ZAP-X Main PDU)
- No external facility connection required

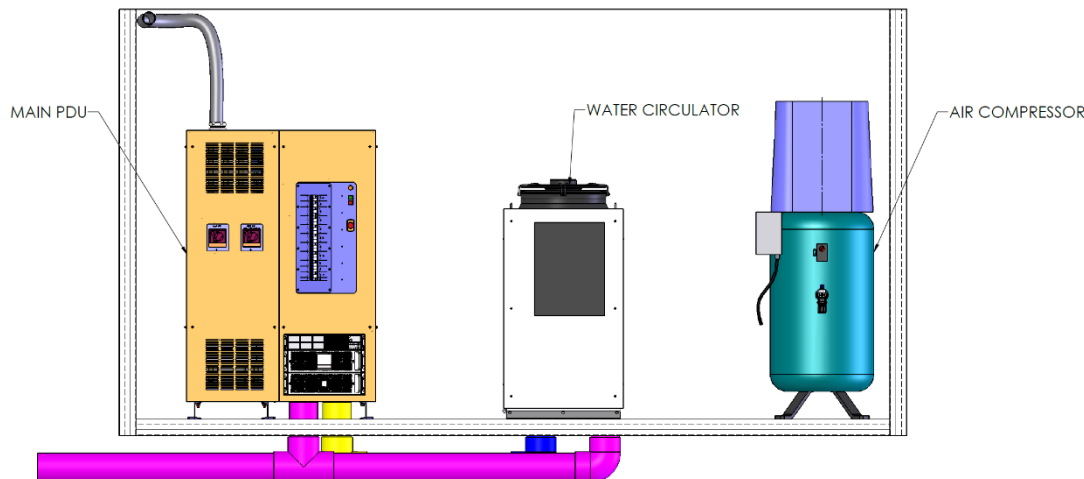


Figure 3 - Typical Auxiliary Equipment Room layout

- 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
- Verify auxiliary and treatment room locations, dimensions and layouts
- Verify conduit size, locations and necessary cable routing
- Verify pit and Anchor Bolt or H-plate installation options and required dimensions
- Verify 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





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.



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### 3.2 System Weights & Dimensions

- The installed ZAP-X system weighs approximately 60,627lbs (27,500 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
<b>• Assy Module #1, E0010-00050, 10,713 Kg</b> <ul style="list-style-type: none"> <li>Module #1 Transport Assy, E0010-00321, 2935 Kg (355cm*244cm*120cm)</li> </ul>	Crate O.D.:170 x 114 x 120.5 inch (432cm*290cm*305cm) (544Kg / 1200 lbs)	Wooden Crate	14,192 Kg / 31,288 lbs
<b>• Assy Module #2, E0010-00046, 3,980 Kg</b> <ul style="list-style-type: none"> <li>Module #2 Transport Assy E0010-00358, 2936 Kg (355cm*244cm*197cm)</li> </ul>	Crate O.D.:166 x 114 x 135inch (422cm*290cm*343cm) (544Kg / 1200 lbs)	Wooden Crate	7,460 Kg / 16,447 lbs
<b>• Assy Module #3, E0010-00116, 5,981 Kg</b> <ul style="list-style-type: none"> <li>Module #3 Transport Assy E0010-00322, 2737 Kg (355cm*244cm*120cm)</li> <li>Hydraulic Control Pump Unit, E0700-00289</li> </ul>	Crate O.D.:166 x 114 x 125inch (422cm*290cm*318cm) (544Kg / 1200 lbs)	Wooden Crate	9,462 Kg / 20,860 lbs
<b>• Assy Module #4, E0010-00266, 4,252 Kg</b> <ul style="list-style-type: none"> <li>Module #4 Transport Assy E0010-00324, 2631Kg (355cm*244cm*120cm)</li> </ul>	Crate O.D.:166 x 114 x 125inch (422cm*290cm*318cm) (544Kg / 1200 lbs)	Wooden Crate	7,427 Kg / 16,374 lbs
<b>• Assy Vertical door (E0010-00222), 796 Kg</b> <ul style="list-style-type: none"> <li>Misc. System cable kits and hoses</li> </ul>	Crate O.D.:73 x 52 x 86 inch (185cm*132cm*219cm) (82Kg / 180 lbs)	ATA Transit Case (E0205-00003)	878 Kg / 1,936 lbs
<b>• Kit, Outer Panels, E0240-00001</b> <ul style="list-style-type: none"> <li>Front Panels, E0240-00058</li> <li>Kit, Vertical Door covers, E0240-0051</li> <li>Kit, Assy Utility Stand Covers, E0010-00371</li> <li>Floor Cover, Rotary Shell Motor, E0040-00172</li> </ul>	Crate O.D.:62 x 52 x 58 inch (158cm*132cm*147cm) (73Kg / 160 lbs)	ATA Transit Case (E0205-00002)	253 Kg / 558 lbs
<b>• Main PDU, E0011-00011, 675Kg</b>	Crate O.D.:56 x 50 x 80 inch (142cm*127cm*203cm) (114Kg / 250 lbs)	ATA Transit Case (E0205-00007)	789 Kg / 1,740 lbs
<b>• BASE-PDU, E011-0018, 88Kg</b>	Crate O.D.:50 x 47 x 27 inch (127cm*119cm*69cm) (27Kg / 60 lbs)	ATA Transit Case (E0205-00009)	115 Kg / 254 lbs
<b>• Assy, Utility Stand, E0010-00114</b> <ul style="list-style-type: none"> <li>Axial Rotary Feedthru, Electrical &amp; Water (E0700-00216)</li> <li>Assy, Proximity Scanner, Patient Right (E0010-00372)</li> <li>Assy, Proximity Scanner, Patient Left (E0010-00426)</li> <li>Assy, Axial motor Coils (E0010-0248/E0010-0249)</li> </ul>	Crate O.D.:73 x 57 x 48 inch (185cm*145cm*122cm) (84Kg / 185 lbs)	ATA Transit Case (E0205-00005)	185 Kg / 408 lbs
<b>• Console Table, E0240-00062</b> <ul style="list-style-type: none"> <li>Console Monitors, E0700-00351</li> <li>Assy, Database PC, E0011-00034</li> <li>Assy, Operator PC, E0011-00026</li> </ul>	Crate O.D.:72 x 38 x 56 inch (183cm*97cm*142cm) (80Kg / 175 lbs)	ATA Transit Case (E0205-00008)	325 Kg / 717 lbs
<b>• Water Circulator, E0240-00037, 156Kg</b>	Crate O.D.:62 x 41 x 67 inch (158cm*104cm*170cm) (68Kg / 150 lbs)	ATA Transit Case (E0205-00004)	224 Kg / 494 lbs
<b>• Air Compressor, E0240-00043, 232Kg</b>	Crate O.D.:47 x 40 x 86 inch (119cm*102cm*219cm) (102Kg / 225 lbs)	ATA Transit Case (E0205-00006)	334 Kg / 736 lbs
<b>• Kit, QA Apparatus</b> <ul style="list-style-type: none"> <li>Kit, QA Apparatus fixtures, E0240-00003</li> </ul>	Crate O.D.: 31 x 29 x 24 inch (79cm*74cm*61cm) (34Kg/ 75 lbs)	ATA Transit Case (E0205-00010)	109 Kg / 240 lbs



## **4 STRUCTURAL REQUIREMENTS**

### **4.1 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 concrete floor and raised floor may be covered with a finish of the site's choosing after the ZAP-X installation is completed.

### **4.2 Pit Requirements**

- The ZAP-X system is installed 0.6 m (24") below the ground surface level to achieve a comfortable height of the treatment table for patient loading and unloading. This is achieved with a pit within the floor of the Treatment Room.
- The pit is 2.44 m x 4.88 m x 0.6 m deep (8' x 16' x 2' deep). At one end of the pit, there is a 0.6 m x 0.6 m (2' x 2') area that is 0.5 m (20") deeper than the rest of the pit. This sub-pit allows the patient entry door to lower out of view when loading a patient. Refer to drawing E0960-00001
- The base floor of the pit must be flat and level (Spec: 1/16" over 10ft / 1.6mm deviation over 3 meter)
- 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, details of how to construct the raised floor can be found in drawing E0960-00001
- **Important** - Rebars in the pit construction must avoid locations marked in E0960-00001 (for Module #2, operator console and vertical door frame fixing points) to allow anchoring of equipment.
- 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
- 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.

## 4.3 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.

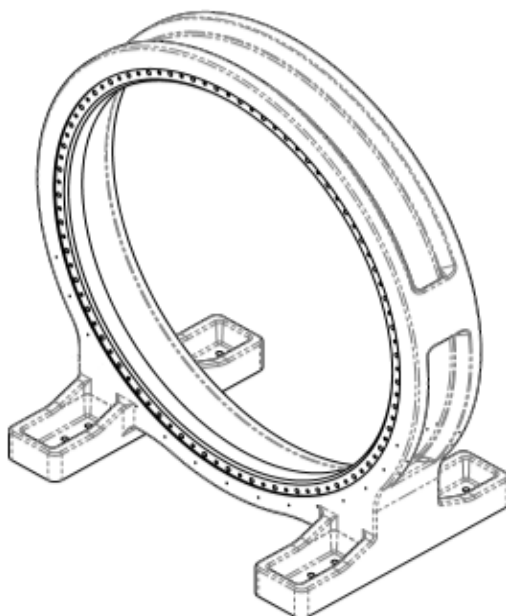


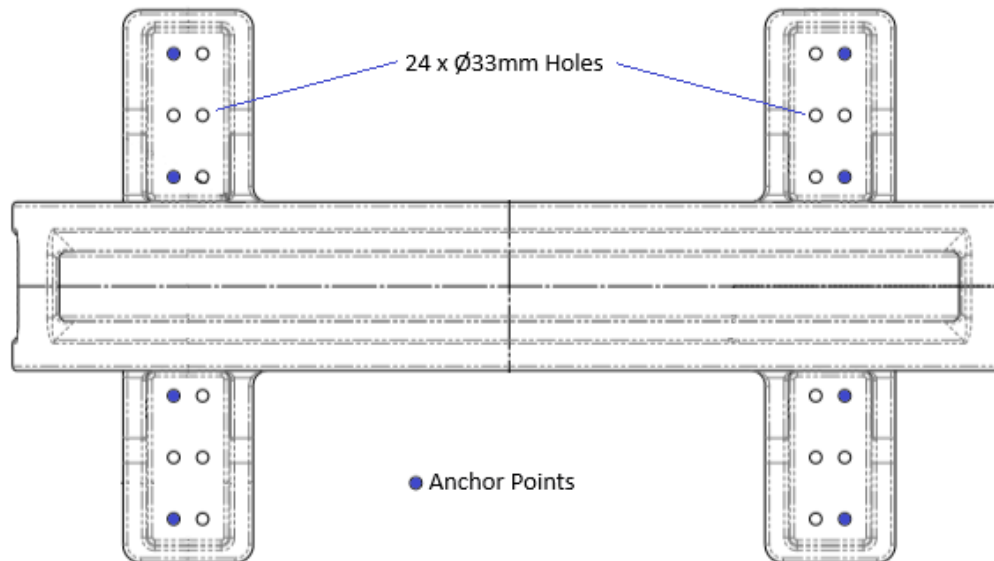
Figure 4 - Module #2 Base Ring

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.

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

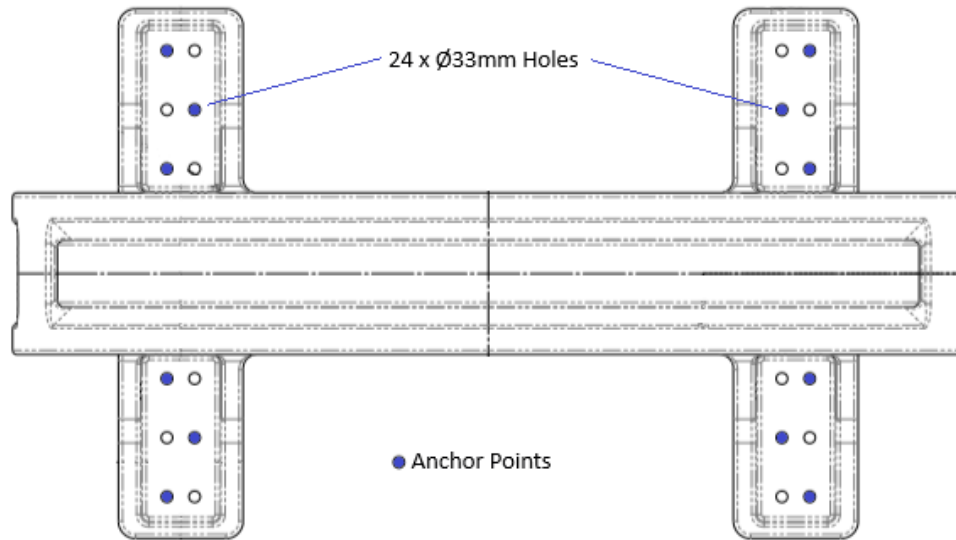
- 3/4"Ø – 10 pitch (M20 Ø x 2.5mm pitch) EXPANSION BOLT with minimum 6" (15cm) NOMINAL EMBEDDED in concrete (2 PER CORNER, 8 TOTAL).  
**It is the customers responsibility to have their structural engineer calculate and determine the type of anchor bolt required in accordance with seismic anchoring requirements per the local building code.**
- Reference Figure 5 for location of fixing points in the base of Module #2 using drop in anchors.
- 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



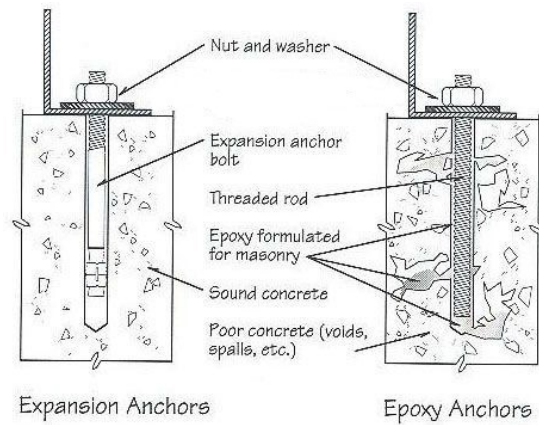
**Figure 5 – Module #2 diagram showing location of 8 anchor points when using expansion bolts**

#### 4.3.2 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 6 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 base 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 6 – Module #2 diagram showing location of 12 anchor points when using epoxy anchor bolts**



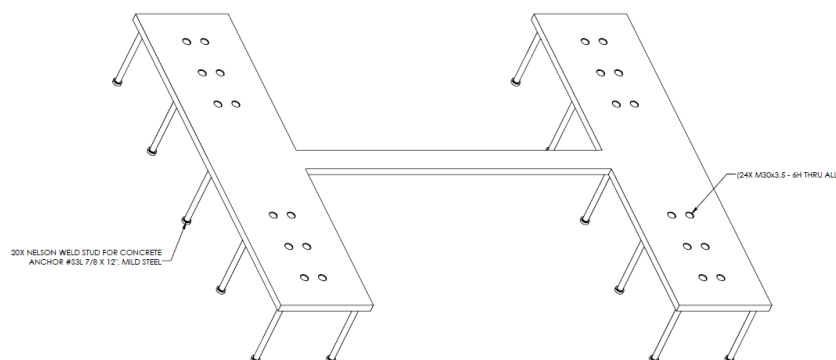
**Figure 7 - Typical examples of Expansion Anchor & Epoxy Anchor types**

## 4.3.3 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.

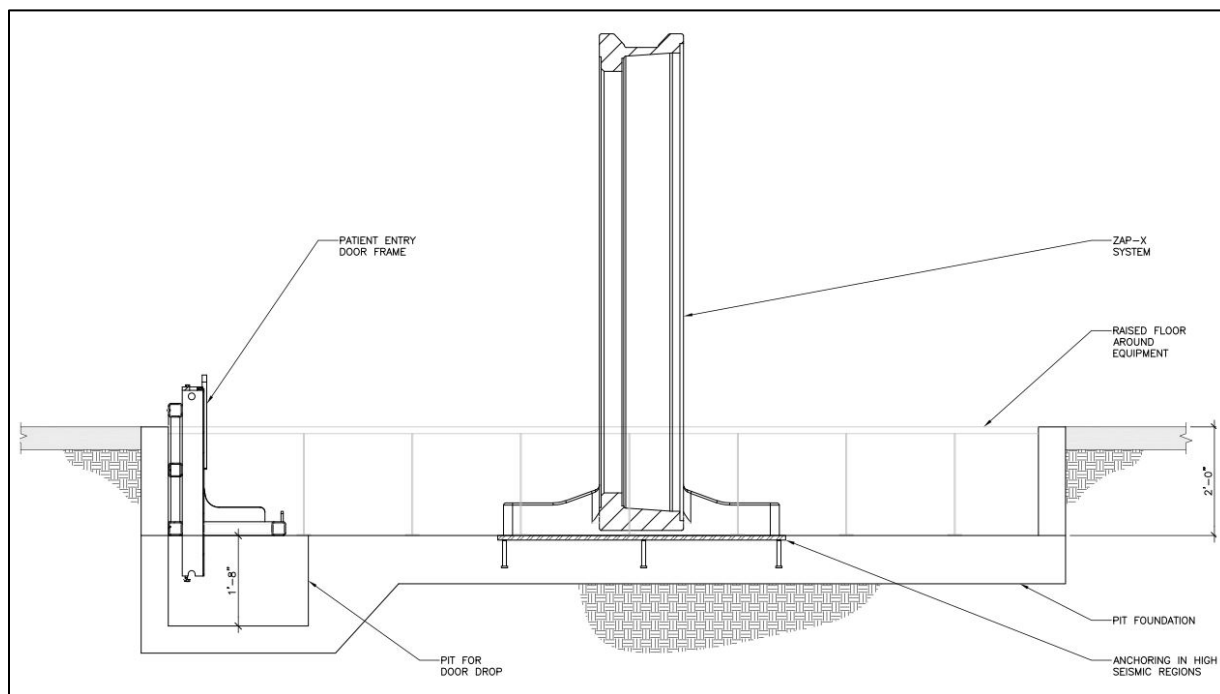
- **The material, fabrication, and installation of the “H-Plate” is the responsibility of the customer. It also must be approved by a structural engineer licensed in the local building jurisdiction for the site.**
- The main support frame (Module #2) and the patient entry door frame of the ZAP-X system 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”.



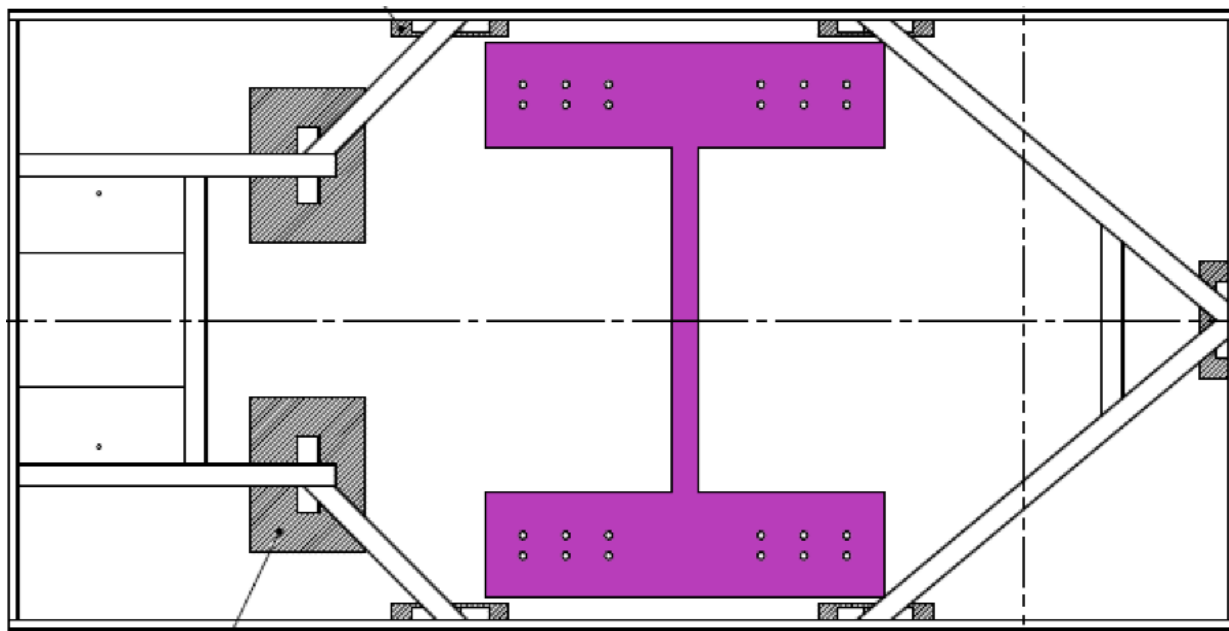
**Figure 8 - H-Plate design (refer to E0040-00168 for mechanical drawing)**

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





**Figure 9 – Cross-sectional detail of pit**



**Figure 10 - Top view of H-Plate embedded in pit floor**

**4.4 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.

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 11 - Conduit requirement summary**



## **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  $\Omega$** .
- 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)
- Recommend Air conditioning/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	104, 4242
ZAP-X-Mgmt-IP	Remote Support Access	80, 443
ZAP-X-Mgmt-IP	<a href="https://agents.zapsurgical.com">https://agents.zapsurgical.com</a>	80, 443
ZAP-X-Mgmt-IP	<a href="https://api-systems.zapsurgical.com">https://api-systems.zapsurgical.com</a>	80, 443
ZAP-X-Mgmt-IP	<a href="https://zap-system-files.s3.amazons.com">https://zap-system-files.s3.amazons.com</a>	80, 443
ZAP-X-Mgmt-IP	<a href="https://zap-system-files.s3.us-west-1amazons.com">https://zap-system-files.s3.us-west-1amazons.com</a>	80, 443
ZAP-X-Mgmt-IP	<a href="https://s3.amazonaws.com/">https://s3.amazonaws.com/</a>	80, 443
ZAP-X-Mgmt-IP	<a href="https://s3.us-west-1.amazonaws.com/">https://s3.us-west-1.amazonaws.com/</a>	80, 443

- ZAP Surgical Systems may also utilize remote service support through a secure 3<sup>rd</sup> party client. (such as TeamViewer or Splashtop). 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.
- The 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).
- An ethernet cable needs to run from the Database/Planning PC to 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 100m)



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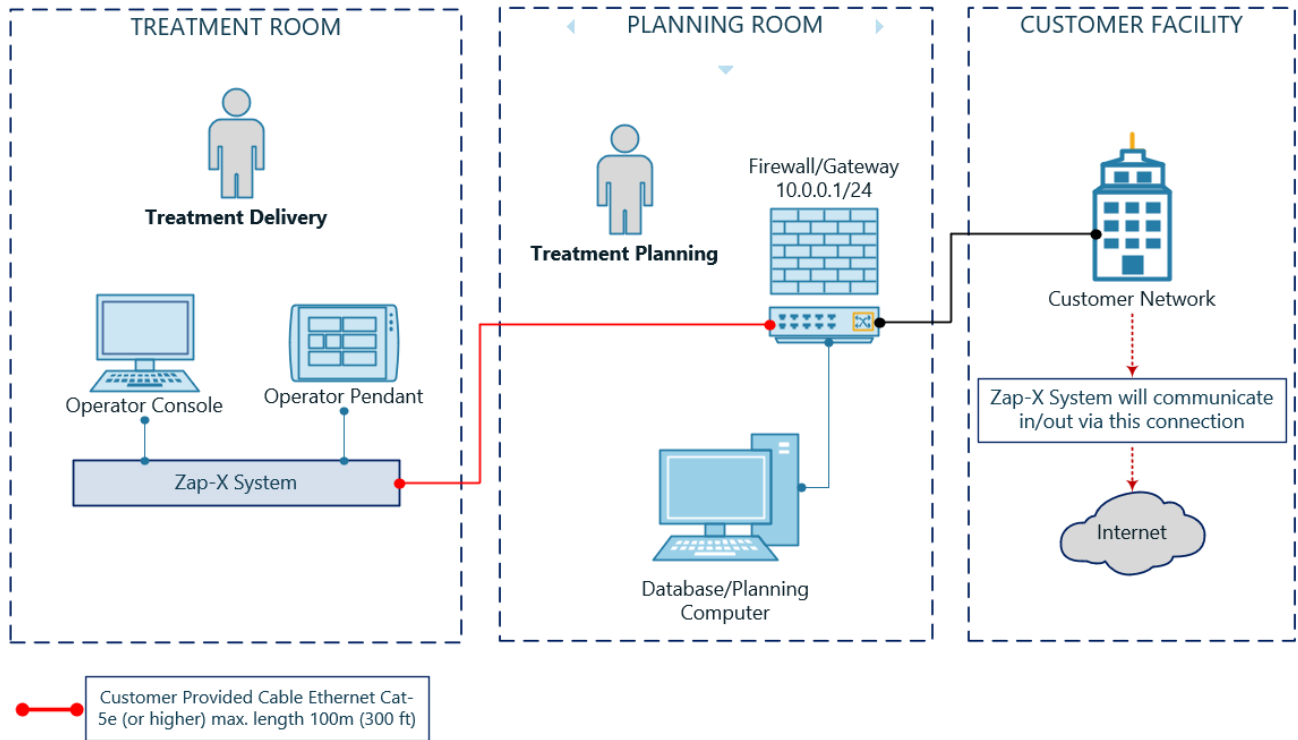


Figure 12 - Data Requirements Diagram



## **8 CT 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:

- Head First Supine (HFS)
- 512x512 pixels per slice
- Slice thickness: 1.00mm is ideal.
- 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 none inferior
  - 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.



## 9 RADIATION DESIGN CONSIDERATIONS

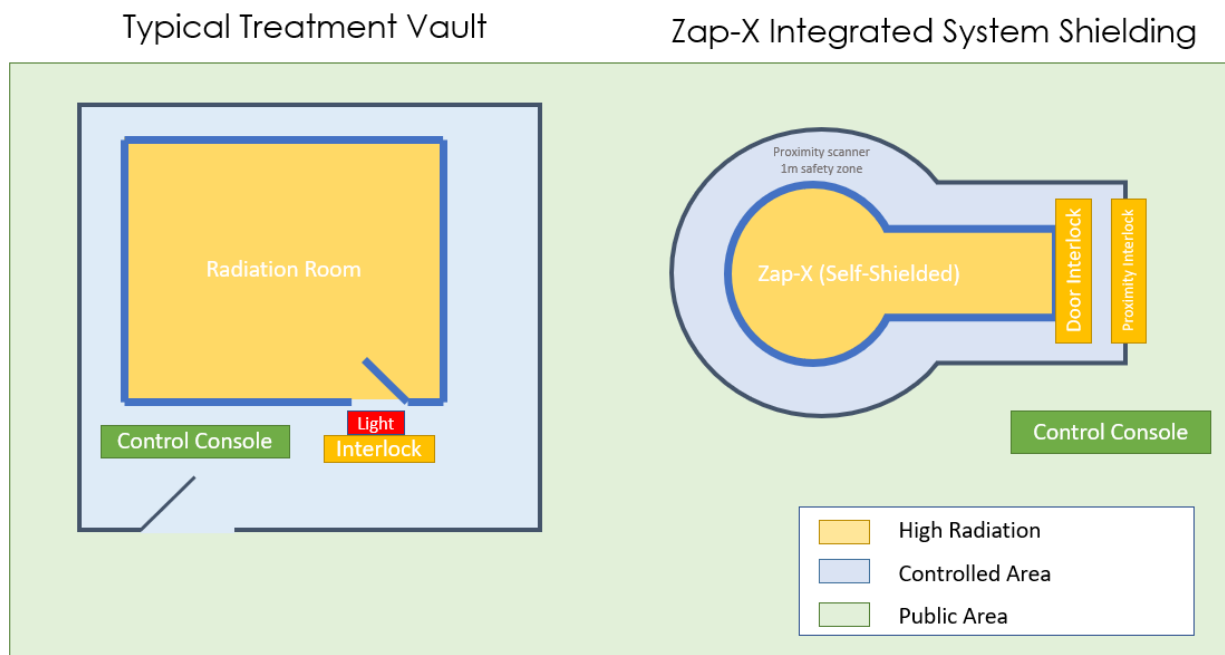
The ZAP-X system is a self-shielded, Image-Guided Stereotactic Radiosurgery System – no facility shielding (Treatment Vault) is needed.

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.

## 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 13 - 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.





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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 an 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 in order 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.

In the rare event that local regulations require additional signage or interlocks, please contact ZAP Customer Service.

### 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	Beam Collimation Alignment Check & QA
E0240-00077	1	3D Water Phantom Frame	Beam Data and QA
E0023-00097	3	Film Disc, 45mm OD	Beam Data and QA
E0010-00445	1	4mm Ball Insert Cube	Beam and Imager Alignment Check & QA

The following is a list of customer required equipment for QA and Commissioning for the ZAP-X:

EQUIPMENT	SUGGESTED VENDOR	USE
3D Water Phantom	PTW MP3-XS (200x200x307.5mm)	Beam Data and QA
2 Channel Electrometer	MP3 Tandem	Beam Data and QA
Semiflex 3D	PTW model 31021	Beam Output Factor Measurement
MicroSilicon Diode	PTW SRS Type 60023	Beam Profile Measurement
Reference Ion Chamber	PTW T-REF 34091	Beam Profile and PDD Measurement
Calibrated Electrometer	PTW Unidos E or equivalent	Delivered Dose Measurement QA
Digital Inclinator	Mitutoyo – Pro 3600 or equivalent with 2 decimal places	Water Phantom levelness tool



## 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			May 2020	
	GENERAL			
...	Task		Responsible (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 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)		



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		Pit --> Ceiling mount Control Pendant Arm (50 mm Ø x 2)		
		Pit --> Treatment Planning Room (50 mm Ø x 1)		
17	Console Table positioning/location			
18	HVAC requirements (10 kW heat load)			
19	<b>On-site Visit #1 - Installation Readiness</b>	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)			
...	<b>Auxiliary Room</b>			
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	<b>On-site Visit #1 - Installation Readiness</b>	Verify Electrical requirements		
		Verify floor drain		
		Verify conduits		
...	<b>Treatment Planning Room</b>			
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)			



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35	2 x RJ45 Network ports			
		Static public IP address/port assignment		
		ZAP Firewall switch / Customer Network Configuration		
...	<b>Delivery/Staging Area</b>			
36	Delivery Vehicle/Truck Access			
37	Temporary exterior building opening for delivery of modules - dimensions/readiness			
38	<b>Onsite Visit #2 - Rigging Requirements</b>	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			
...	<b>Post Installation Planning</b>			
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			