ZAP-X Radiosurgery System
Treatment Delivery Manual

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Preface

ZAP Surgical Systems provides this guide without warranty of any kind, either implied or expressed, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. ZAP Surgical Systems and its directors, officers, representatives, subsidiaries, employees, agents, heirs and assignees assume no responsibility or liability, either expressed or implied, for injury, death or losses to consumers, users or service personnel resulting from improper handling of the Radiosurgery products by unauthorized, untrained or otherwise unqualified personnel. ZAP Surgical Systems expressly denies any responsibility or liability for abuse, neglect, misuse or tampering with Radiosurgery system components by persons not authorized, trained or associated with ZAP Surgical Systems.

If any products are modified in any manner, all warranties associated with such products shall become null and void. ZAP Surgical Systems does not assume any responsibility or liability with respect to unauthorized modification or substitution of subsystems or components.

With proper care and maintenance, the expected operating life of the system is 10 years.

This manual applies to the ZAP-X Radiosurgery System ("The system" or "ZAP-X System"). This manual was originally written in English.

Notice to user and/or patient: Any serious incident that has occurred in relation to the device should be reported to ZAP Surgical Systems, or authorized representative, and to the competent authority of the Member State in which the user and/or patient is established.

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System Information

⚠️ **Caution: In the United States, law restricts this device to sale by or on the order of a physician.**

Notice:

The user manuals contain instructions for multiple features of the ZAP-X Radiosurgery System. Since some features of the Radiosurgery System are optional, some of the instructions in the user manuals may not apply to your system.

The availability of options is dependent on regulatory approvals in a particular country and varies from country to country.

ZAP Surgical Systems reserves the right to revise this publication and to make changes in content from time to time as necessary to ensure proper operation and use of the ZAP-X Radiosurgery System.

Device Description

The ZAP-X® Radiosurgery System ("ZAP-X System" or "System") is a computer-controlled system for performing non-invasive stereotactic radiosurgery that is self-shielded for ionizing radiation. A gantry-mounted linear accelerator provides the ZAP-X System with a source of therapeutic radiation and a kV imaging system is used to accurately locate the treatment target. At the start of treatment, a table with three degrees of freedom moves the patient head to the isocenter of the system, and the system door and shell close to complete the shielding. X-ray images of patient skeletal anatomy serve to align the treatment target with respect to the system isocenter. During radiosurgical treatment, the kV imaging system of the ZAP-X System tracks patient movement and adjusts the table precisely to compensate for such movement.

Indications for Use and Intended Users

The ZAP-X Radiosurgery System is intended to provide treatment planning and image-guided stereotactic radiosurgery and precision radiotherapy for tumors, lesions and conditions in the brain, head and neck when radiation treatment is indicated.

No contra-indications for use have been identified.

The system is intended to be used by Physicians, Medical Physicists and Radiation Therapists, all trained in the clinical applications of radiosurgery.

The system is intended for use for treatments in the head and neck on patients that are between the size of a 5th percentile female to a 95th percentile male, with a maximum patient weight of 135kg.

Clinical benefits: Advances in radiation therapy have contributed to improvements in long-term outcomes for cancer patients. New technologies have the goal to improve cancer outcomes in two major ways, by focused irradiation of localized cancerous tissues and by reducing doses to surrounding healthy tissues and reduce treatment complications. Advanced technologies such as stereotactic radiosurgery (SRS) have

been implemented to use sophisticated, 3-D-computerized imaging to precisely focus modulated photon beams and deliver a highly-concentrated dose of radiation to a precise target area. In many cases, these target areas are not easily reachable through conventional invasive surgery. This specific treatment has the benefit of permitting maximum dose delivery to the affected area while minimizing radiation dose to the surrounding healthy tissue.

Safety Precautions and Warnings

Residual risks associated with treatment using the ZAP-X Radiosurgery System include (1) delivery of treatment dose to incorrect location and (2) possible collision of moving parts with patient. These potential risks are common to all radiosurgery systems and although represent a high severity, are deemed acceptable given the extremely low likelihood of occurrence (improbable). Risk analysis methods performed on the ZAP-X System estimates the likelihood of occurrence of either of these two risks to be < 1 in a million treatments.

Safe Operation of the Radiosurgery System requires careful attention to the serious hazards associated with the use of linear accelerators and other complex radiosurgery and radiotherapy equipment and ways to avoid or minimize the hazards, and familiarity with emergency procedures. Untrained or careless operation of the Radiosurgery System can damage the system, its components, or other property; cause poor performance; or lead to serious bodily injury and possibly death. Anyone who operates, services, maintains, or is otherwise associated with the Radiosurgery System must read, understand and be thoroughly familiar with the information in this manual, and take precautions to protect themselves, their associates, patients, and the equipment. At each step in the installation, specific warnings and cautions are given for specifications. Only authorized personnel are allowed to install the system.

Personnel must be trained by ZAP-X Surgical Systems before the Radiosurgery System is used for clinical purposes.

Only qualified service personnel should service or maintain hardware components. If you feel that Radiosurgery System hardware components or associated Treatment Planning System features, or functions do not perform as expected, or they provide results that are inconsistent with your established clinical protocols, contact ZAP Surgical Systems, Inc.

A Customer Release Note is provided by ZAP. It includes feature descriptions and known issues and limitations.

Device Disposal

When the system reaches the end of its useful life and your facility desires to remove the device, contact ZAP Customer Support to decommission, uninstall, and appropriately dispose of the components.

The ZAP-X system does not contain any radioactive material.

Maintenance

No regular user maintenance is required on the ZAP-X system. The MV imager is designed to be replaced by the user as needed. See section 11.3 for details.

Regulatory Classification

The ZAP-X Radiosurgery System is classified by the following:

- o   Protection against electric shock: Class I, permanently connected.
- o   Applied part: patient treatment table only. Type B.
- o   Methods of sterilization or disinfection: Not required.
- o   Degree of safety in the presence of flammable mixtures: Not suitable for use in the presence of flammable mixtures.
- o   Mode of operation: Continuous operation with intermittent loading.

The ZAP-X Radiosurgery System conforms to all applicable standards under FDA 21 CFR Subchapter J - Radiological Health.

Manuals

ZAP Surgical Systems provides a set of user manuals (instructions for use) for the ZAP-X Radiosurgery System. Treatment Planning Manual and Treatment Delivery Manual in the documentation set are described below.

Warning: Example data depicted in this manual are not intended to represent realistic clinical data. Use of example data for treatment planning or delivery could result in patient mistreatment. The user is solely responsible for determining appropriate data values for any given situation.

> **Note**: In countries where required, the manuals have been translated by ZAP Surgical Systems into the native language.

> **Note**: Images in the manuals may not exactly match your system.

Treatment Planning Manual: (p/n E0920-00003) provides information about using the Treatment Planning System to load image studies; create, modify, and evaluate treatment plans; create and modify treatment plan templates; work beam data acquisition tools; export data; and print plan data.

Treatment Delivery Manual: (this document) Provides information on treatment delivery, including safety information, system startup and shutdown procedures, treatment delivery system overview, patient preparation, treatment room operations, treatment delivery procedures, and other topics.

Quality Assurance Manual: (p/n E0920-00005) provides complete information about performing QA procedures.

Beam Data Manual: The Beam Data Manual (p/n E0920-00002) describes the procedures to acquire and analyze beam data.

Electronic versions of pertinent manuals may be downloaded from
www.zapsurgical.com/instructions-for-use. Please contact your service representative
for password access.

Conventions

The conventions described below are used in this manual. Familiarize yourself with
these conventions before using the system.

Left/Right Mouse button

This manual will assume that the primary mouse button is the left mouse button. Some
computers may be configured to use the right mouse button as primary. It is your
responsibility to map the described action accordingly.

Numeric Display Format

The ZAP-X Radiosurgery System software and the Treatment Planning System can be
configured to use either of the following notation conventions to display numbers:

- The period character (.) used as a decimal separator and the comma as
  the thousands separator.
- The comma character (,) used as a decimal separator and the period as
  the thousands separator.

**Warning: Make sure you know and follow the configuration of your system.
Incorrect entry of numeric data could result in incorrect treatment or patient
harm.**

Date Display Format

The Treatment Planning Software (TPS) and the Treatment Delivery Software (TDS) by
default use a date format of DD-MMM-YYYY, where MMM is a 3 character abbreviation
of the month, such as 25-Dec-2018. Consult with your ZAP service engineer to adjust to
a different format.

Warning, Caution, and Note Symbols

This manual uses the special notations below to bring your attention to important
information.

**Warning: Is a statement that alerts the user to the possibility of injury, death, or
other serious adverse reactions associated with the use or misuse of the device.**

Caution: Is a statement that alerts the user to the possibility of a problem with the device
associated with its use or misuse. The caution statement includes the precaution that
should be taken to avoid the hazard.

Note: Provides more information about a subject.

General Warnings:

In this document warnings about a specific feature or treatment step are in the section that describes that feature or step. The following warnings apply across the whole system use.

Warning: System can emit lethal doses of radiation at high energy. There is a risk of permanent injury or death if there is a significant overdose. Read and understand this manual, and in particular Chapter 2 (Safety) before use.

Warning: The assemblies contain high voltage circuits that can deliver lethal electric shocks. Always observe safety precautions when operating or working on the Radiosurgery System.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Read and understand this manual, in particular the Safety Chapter, (Chapter 2) before using the system.

Warning: Operators should wear radiation monitoring badges while using the system. Consult institution and local regulatory bodies for policies regarding radiation monitoring.

Table of Contents

1. System Overview

This chapter provides an overview of system operation. It is provided as orientation and does not provide sufficient information to use the system.

1.1.   Overview: Equipment and Locations

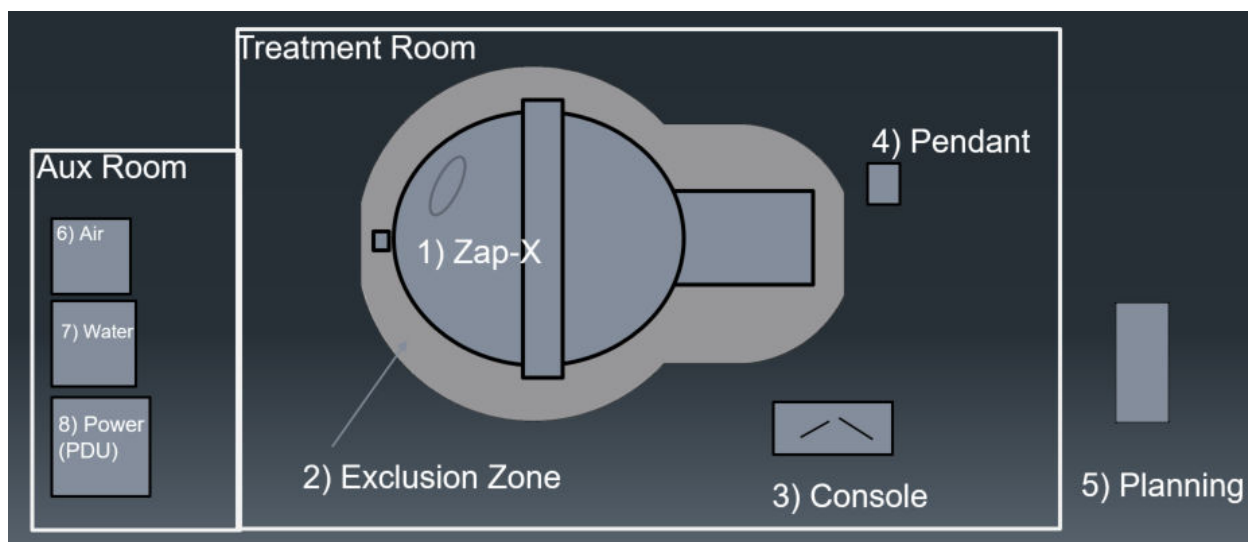Figure 1.1.1 shows a simple diagram of a typical installation configuration. Your installation may differ.

Figure 1.1.1. A typical room configuration.

In the main treatment room:

1. The Main System. See below for details.
2. Exclusion zone: An E-Stop is generated if you walk into this zone. See Chapter 2 for E-Stop details.
3. Operator Console station. This desk station contains the following:
    o   Treatment Delivery Software (TDS) Main Screen (See Section 8.5).
    o   TDS Video monitoring screen (See section 8.6).
    o   Keyboard and Mouse for running the TDS GUI.
    o   Console Hard keys (See section 8.7).
4. Pendant: A touchscreen computer used to insert and extract the patient.

For a given heavy workload of 2250 isocenters treated in one year, the radiation exposure levels both for the occupationally exposed personnel at the control console and the public are expected not to exceed 1.0 mSv per year.

Outside the treatment room:

5. The planning station is on a computer outside of the treatment room, but on the same local network. It will typically be near the treatment room.

Auxiliary Room: This is typically a small room adjacent to the treatment room.

6. An air compressor is used to supply pneumatic power to the system door. This pneumatic control ensures that the door can be opened even if there is a complete loss of power.
7. Water: A water circulator ensures that the system electronics are at a constant temperature.
8. Power Distribution Unit (PDU): Distributes power to all system components.

The Exterior of the Main System:

Figure 1.1.2 shows the outside of the main system.

Figure 1.1.2. The outside of the ZAP-X system.

- **Gantry**: This is the portion of the system that moves the collimator into position to provide treatment. It can move on 2 axes. Together these provide an extensive range of motion for the collimator.
    - o Axial: Rotates the gantry along an axis parallel to the table.
    - o Oblique: Rotates the gantry along an axis 45 degrees from the axial axis.
- **E-Stop**: Shown here is one of 5 E-Stop buttons on the system. Two are on opposite sides of the table, one is near the rear axial gantry, and on the pendant and Operator Console.
- **Shell**: A tube-shaped shield around the table. It can be opened to provide patient access or closed to provide part of the shielding.
- **Door**: Provides shielding at the foot of the table.
- **Table**: The patient lies on this table and is inserted into the system for treatment. Insertion and extraction are performed at the pendant.

The Interior of the Main System:

Figure 1.1.3 shows the inside of the system as viewed from the table entrance.
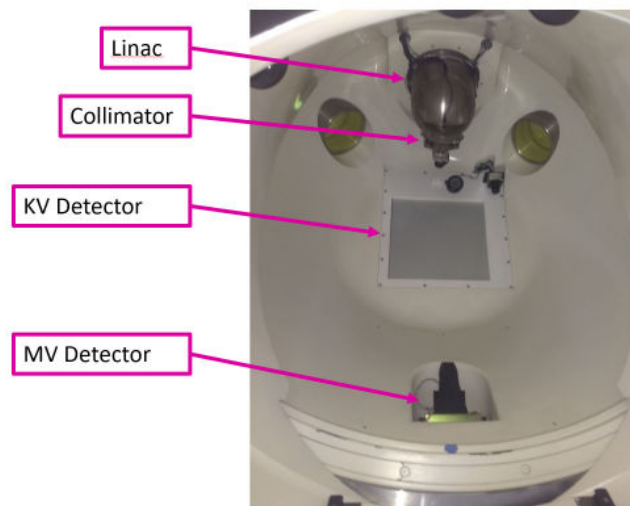
Figure 1.1.3. The inside of the ZAP-X system.

- **Linac**: Inside the system is the linear accelerator which delivers the treatment beam (Figure 1.1.3 shows the Linac enclosure).
- **Collimator**: The collimator is a tungsten disk with a series of circular holes drilled through the diameter. As the disk rotates these holes become the aperture of the beam, from 4 to 25mm.
- **MV imager**: Opposite the Linac is the MV imager which provides a picture of each beam as it is delivered. It also monitors the beam strength in real time.
- **kV imager**: This provides an X-Ray image of the patient to ensure that the patient is positioned correctly.

Operator Console
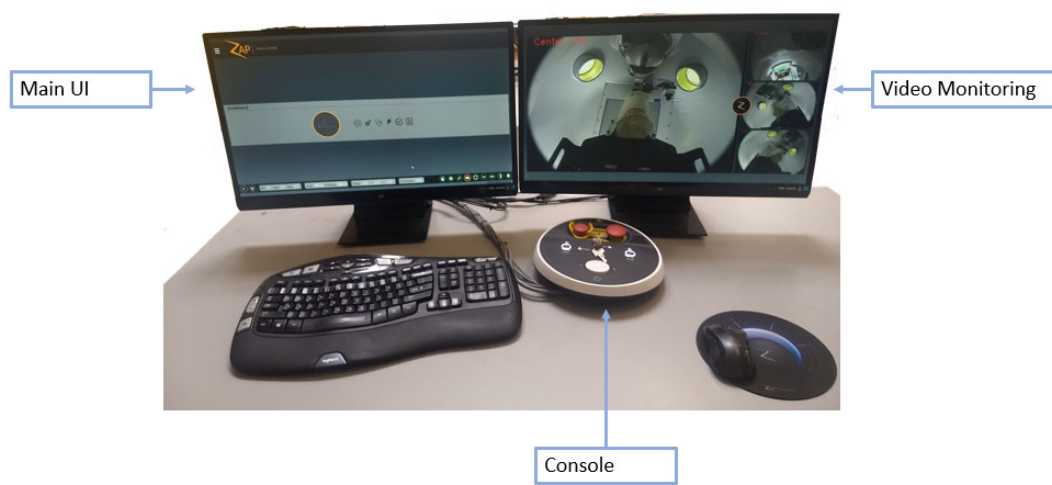Figure 1.1.4 shows the Operator Console:

Figure 1.1.4. Operator Console.

- **Main UI Screen**: (typically the left screen) This screen will guide you through the steps of treatment delivery when treatment is selected.
- **Video Monitoring Screen**: (typically the right screen) This has video cameras monitoring the inside of the system. You can configure which video source appears in each part of the screen.
- The **Operator Console:** This has a small number of hard key controls that primarily provides safety interlocks required to deliver treatment.

Pendant

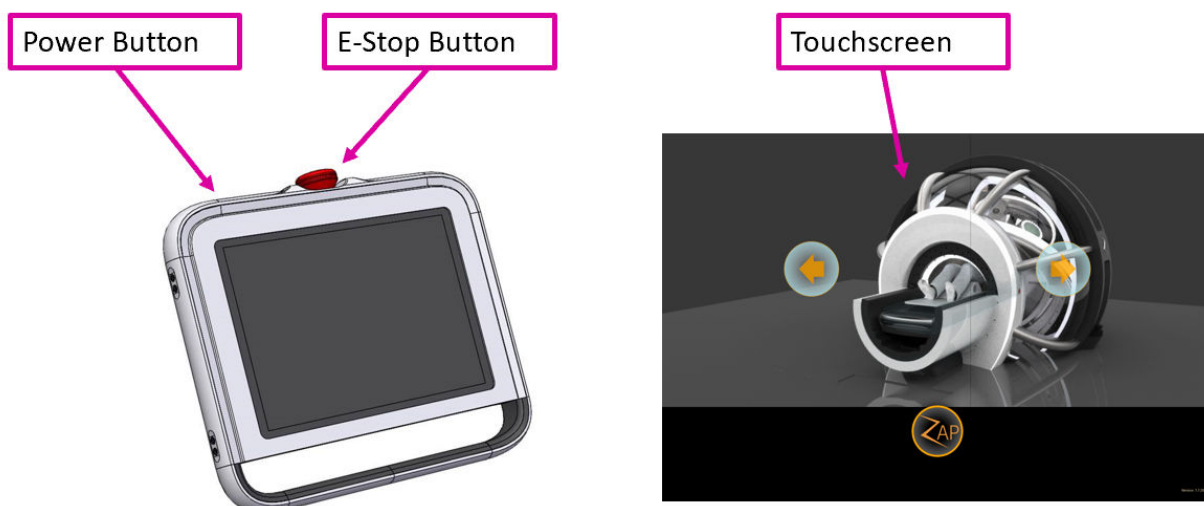Figure 1.1.5 shows the Pendant. It is used to insert and extract the patient.

Figure 1.1.5. Pendant.

- **Power Button**: Press this to wake up the pendant at the beginning of the day.
- **E-Stop**: 1 of the 5 system E-Stop buttons is on the pendant. See section 1.1 for details.
- **Touchscreen UI**: Used to insert/extract the patient, as well as to clear E-Stops.

1.2.   Common UI elements

These are a few standard UI elements that are used across multiple workflow steps that are worth describing in an overview.

Workflow Wheel

Figure 1.2.1 shows an example of the Workflow Wheel.

Figure 1.2.1. Example Workflow Wheel.

The workflow of treatment delivery is organized into steps, with each step controlled by the Workflow Wheel. The bottom portion of the wheel typically shows the action that is needed in the current step. The example above is from the treatment delivery step, and the bottom of the wheel is showing the icon to start delivery.

The workflow wheel also has a left button to go back a step, a right button to go forward a step, and a home button to return to the patient selection home page.

E-Stop Wheel

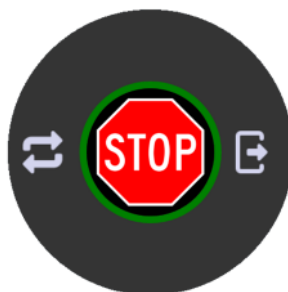Figure 1.2.2 shows an example of the E-Stop wheel.

Figure 1.2.2. Example E-Stop wheel.

The E-Stop Wheel has identical contents for every step of treatment delivery:

Function	Icon	Description
STOP		Generates a software E-Stop to put the system into a safe state. This is the same safe state as hitting an E-Stop hard key.
Clear		Clears a software E-Stop, allowing treatment to continue. Note: if an E-Stop hard key had been pressed that hard key needs to be physically released first.
Extract		Opens the door and shell and extracts the table out of the system.

Dashboard

Figure 1.2.3 shows an example of the system Dashboard:

Figure 1.2.3. The System Dashboard.

The Dashboard is the starting place for the UI. It is what appears when startup is complete. All workflow starts at the Dashboard, and in general when a workflow task is complete you return to the Dashboard.

Function	Icon	Description
Power On/Off		Turns the system on and off. (Chapter 3)
Initialize		Initializes the gantry, collimator, and patient table. (Chapter 3)
Self-Check		Performs a self-check of important subsystems including E-Stop, Gantry, Table, Shell, Door, Linac proximity detection, kV and MV imaging. (Chapter 3)
Treatment		Starts the multi-step process of delivering treatment. (Chapters 6-9)
Daily QA		Provides tools for routine QA procedures. (Chapter 4)
Report		View, print, email, and save a report for any delivered or partially delivered plan. (Chapter10)

1.3.   Overview of Plan Organization

A plan is composed of one or more fractions. Each fraction is delivered independently of other fractions. Each fraction contains one or more isocenters where each isocenter can have a different dose and a different collimator size. Every fraction in a plan contains the same isocenters.

Every isocenter in a fraction is delivered one after another as part of a treatment session. Each isocenter has a path that is defined by the system during planning. The path determines which gantry locations are used to deliver treatment (nodes), and the gantry movement between these locations.

The path can vary between isocenters and is determined by the system based on the target location. The path is designed to keep moving parts away from the patient while at the same time delivering beams from a wide range of node locations.

1.4.   A Simple Treatment Walkthrough

This section walks through the workflow steps of a simple one-isocenter treatment. Each step in this section includes a reference to the chapter where the detailed operation is described.

1. **Before the start of a treatment**: Before starting treatment, make sure the system is powered up, initialized, and self-check has been run (these are covered in Chapter 3). Also run any Daily QA per your institution's protocol. (Chapter 4).
2. **Launch Treatment Workflow:** Click on the Treatment button on the Dashboard. (Chapter 5)
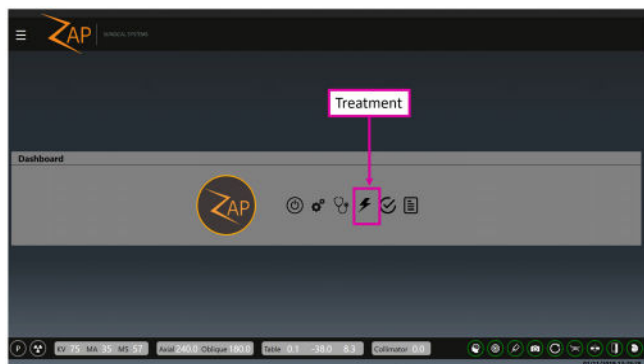

Step 2: Select Treatment from the Dashboard.

3. **Select a Patient:** Click on a patient to select it (Chapter 5). In this document we'll be treating the patient "Demo Dan"
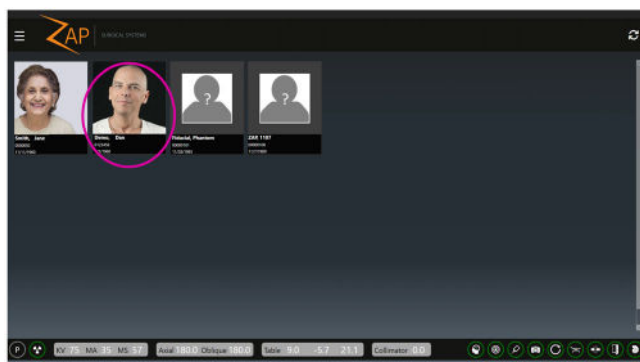
Step 3: Select the Patient.

4. **Select a Plan and Fraction**: As soon as you click on a patient the system will display the plan or plans approved for this patient, along with every fraction for every plan. Select (A) the fraction for the plan you want to treat and (B) the "Next" icon on the Workflow Wheel (Chapter 5). Confirm the selection in the displayed confirmation box.
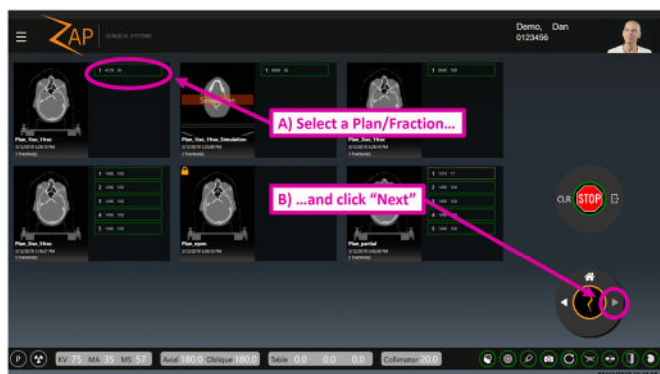
Step 4: Plan and fraction selection.

5. **Home Position:** If the gantry is not at the home position, click on the spinning Z and use the home position icon to home the gantry.
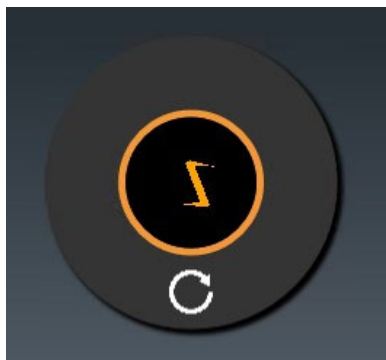

Step 5: Home position.

 Home position icon

6. **Align the Patient:** This involves 2 steps. (Chapter 7)
    - Click on the auto-align icon and confirm the alignment on review page. (Left, below).
    - Click on the Next icon to move to the next step.

    During these steps the gantry will move, and some kV images will be taken. The result will be that the patient head will align with the planning CT.

Step 6: The 2 steps of the Align process.

7. **Initiate treatment:** Click on the "Start Delivery" icon (Chapter 8).
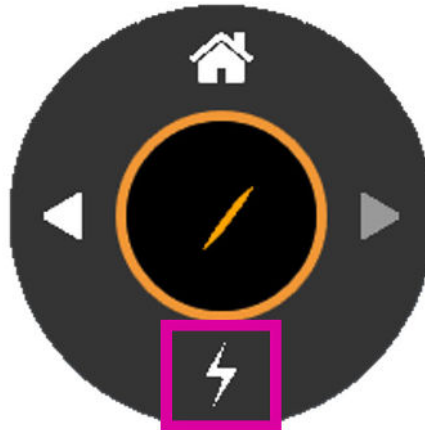
Step 7: Start Treatment.

8. **Start Beam:** The system will display a dialog to start high voltage (below left). Press the "HV On" hard key on the console (below right).
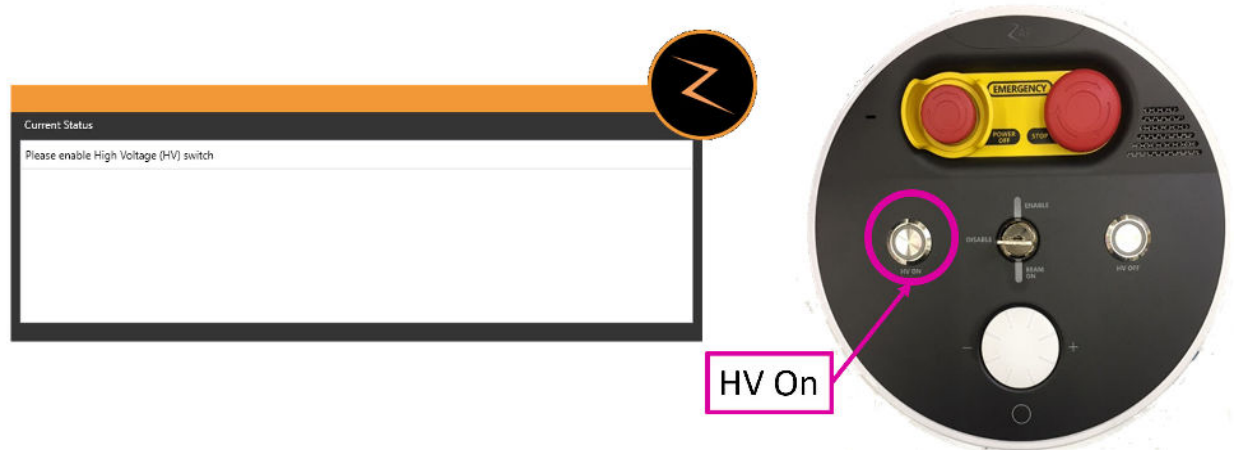
Step 8: "HV on" dialog and the console button.

9. **Monitor Treatment**: At this point the treatment will proceed automatically. Monitor the patient for movement via the video monitors.
10. **Next Isocenter**: When all beams for the current isocenter have been delivered the software will advance to the next isocenter automatically. Click the "Start Delivery" icon, and when prompted press the "HV on" button on the console. Treatment will then proceed automatically.
11. **End Treatment**: When all beams have been delivered the user will be presented with the option to extract the patient or return to the plan selection screen to select a new plan.

2. Safety

This chapter provides information about the emergency procedures and safety features of the ZAP-X Radiosurgery System and describes safe operating practices. Review the information in this chapter before using the equipment. It is the customer's responsibility to schedule regular preventative maintenance by ZAP Surgical Systems personnel or other qualified personnel designated by ZAP Surgical Systems.

Warning: The ZAP-X Radiosurgery System is a highly complex product. It is your responsibility to operate the equipment knowledgeably and safely and to ensure the service and the quality assurance (QA) of each component that may be required, as detailed in this user manual. Improper operation or service can result in injury or death of the user or patient.

Warning: Do not alter the software or any of the components in the ZAP-X Radiosurgery System.

Warning: All users must be trained prior to using the ZAP-X Radiosurgery System or associated computers

Warning: Review the meaning and location of system labels. See chapter 12.

2.1.   Emergency Stops (E-Stop)

An E-Stop pauses system operation in a way that is safe and easily recoverable. The E-Stop system is easily recoverable and can be used whenever there is any doubt about safe operation.

E-Stop Basics

When an E-Stop is engaged the following occurs:

- No radiation is emitted. This includes both the MV therapeutic radiation and the kV imaging X-rays. The HV voltage is turned off.

- All system motion stops. This includes the gantry, the table, the shell and the door.

- The main console remains on and receives status from the rest of the system.

During an E-Stop the electronics stay on. The system is ready to resume full functionality as soon as the E-Stop is cleared. It is easy to recover from an E-Stop, so don't hesitate to generate an E-Stop, even if you are not sure if anything is wrong.

⚠️ **Warning: If any situation has the appearance of an emergency, immediately stop movement and radiation by pressing the nearest E-Stop button.**

Note: Do not hesitate to press the E-Stop button, even if you are unsure of the severity of the situation.

There are five sources of E-Stops:

1) Physical E-Stop buttons
2) Exclusion Zone E-Stop
3) Collimator Collision Sensor E-Stop
4) System E-Stop
5) E-Stop Wheel

These are described in the following sections:

1) Physical E-Stop button

You can generate an E-Stop at any time by pressing on any of the 5 E-Stop buttons located around the system. These buttons must be physically cleared before the E-Stop can be cleared. The button is cleared by twisting the button clockwise. (See Figure 2.1.1). The E-Stops are located as follows:

- E-Stop Button1: On the main system at the back of the system.
- E-Stop Button2: At system entrance on patient's right.
- E-Stop Button3: At system entrance on patient's left.
- E-Stop Button4: On the pendant.
- E-Stop Operator Console: At the operator console.

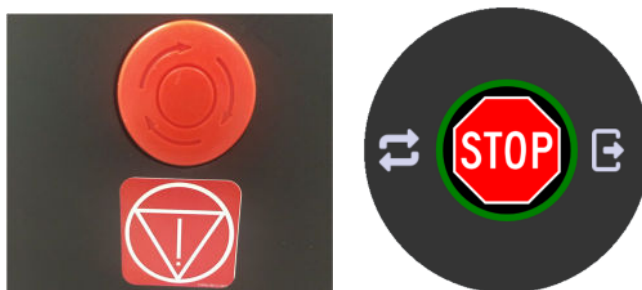You can also generate an E-Stop by clicking the E-Stop icon on the user interface.

Figure 2.1.1. E-Stop Hard Key (left) and UI icon (Right).

⚠️ **Warning: Always monitor system operation during use. Press the nearest E-Stop if you are not certain of system safety.**

2) Exclusion Zone E-Stop

There are two external proximity sensors located on either side of the main system (see Figure 2.1.2). An E-Stop is generated if somebody or something is adjacent to the system. The exclusion zone must be clear before system operation can resume. Note this means that an E-Stop is generated when the patient is being helped onto the table, and that E-Stop must be cleared before the patient is inserted.
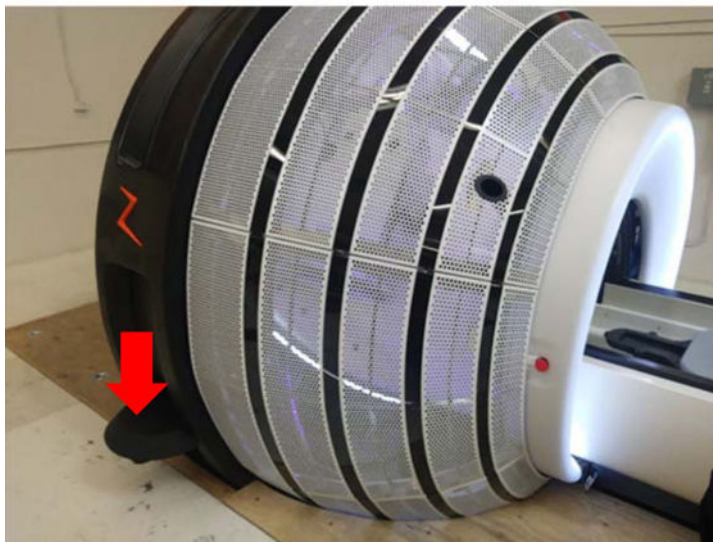

Figure 2.1.2. Exclusion Zone Sensor.

3) Collimator Collision Sensor E-Stop

A laser scanner is positioned inside the system behind the collimator (see Figure 2.1.3). This scanner is designed to detect when the collimator is getting too close to the patient. If a potential collision is detected an E-Stop is generated.

Figure 2.1.3. Collimator Collision Sensor.

4) System E-Stop

The system itself can generate an E-Stop if it detects a potential safety issue. Examples include if the Linac temperature drops below its threshold, or if internal system communication is abnormal. See the section below on monitoring and clearing errors for more information.

5) E-Stop Wheel

The E-Stop Wheel is displayed on most screens of the TDS GUI. See Section 1.2 for details. You can generate an E-Stop by clicking on the Stop button in the center of the wheel. This works just like a physical E-Stop button except it does not have to be twisted prior to clearing the E-Stop.

Monitoring and Clearing Errors

The System Messages Window is automatically invoked when an E-Stop is generated. When there is an error it can also be manually invoked by clicking a red circular icon that appears in the lower right corner of the main screen. This window is divided into two sections (see Figure 2.1.4):

- The Current Status is shown in the top half of the screen. This tells you what needs to be addressed before system use can continue.
- The Events history is shown in the lower half of the screen. This shows the event that caused the current status, and a timestamp of that event. See appendix A for a full list of possible events, and what to do to clear each one.
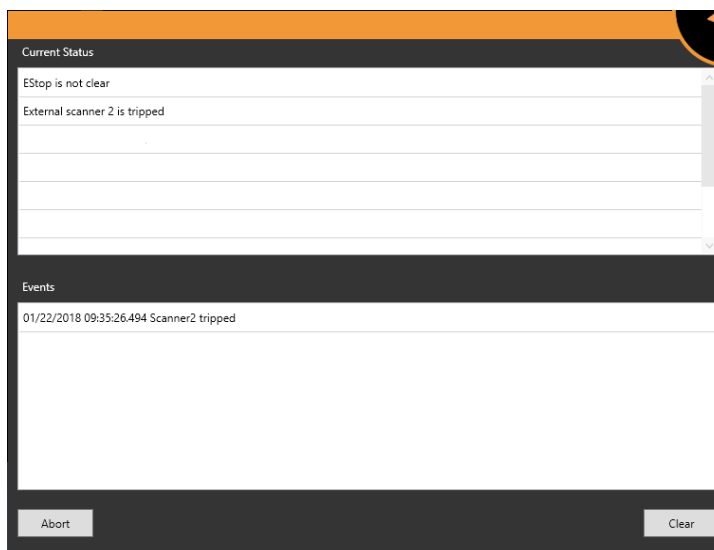

Figure 2.1.4. The System Messages Window.

To Clear an E-Stop:

- **Physical E-Stop:** If a physical E-Stop button was pressed you can release it by turning it clockwise. Then the associated software E-Stop can be cleared from the System Messages Window.
- **System Generated E-Stop**: Check the System Messages Window for instructions. If the error is unrecoverable, you cannot clear the interlock and have to terminate the treatment session. In this case, a make-up fraction will be created. For more information on how to respond to specific errors see Appendix A.
- **Collimator Collision E-stop**: Extract the patient and reposition. During this process, carefully monitor the patient to ensure that moving the table does not cause a collision.
- **Exclusion zone E-Stop**: Make sure the exclusion zone is clear of all obstructions. The E-Stop can then be cleared by either clicking the Clear button on the System Messages Window, or by pressing the E-Stop hard key on the pendant.

2.2.   Emergency Power Off

The Emergency Power Off (EPO) buttons will remove power from all system. The UPS battery will continue to supply power to the operator console computer for a limited time, but no system use will be possible. There are 2 EPO buttons, as shown in Figure 2.2.1.

Figure 2.2.1. The EPO button on the PDU (left) and on the operator console (right).
Note that the button on the PDU is labeled "EMO" ("Emergency Motion Off").

An EPO is different from an E-Stop.

The Emergency Power Off:

- The button has a yellow guard surrounding it. Pushing this button is the only way to generate an EPO.
- Shuts down power to system components other than the console computer.
- Will interrupt a procedure as it will take some time to reboot the system.
- If a patient is in the system they must be extracted manually (see Section 2.4).

An E-Stop:

- Can be generated by an E-Stop button or by the system.
- Stops movement and radiation while maintaining power to the system.
- Can be cleared quickly as soon as the underlying issue has been addressed.

⚠ **Warning: In case of fire or electric shock, press the nearest Emergency Power Off button to immediately shut off power to all non-computer equipment and minimize injury to the user or patient as much as possible.**

Restarting from an EPO may take an extended amount of time since the system was not shut down in an orderly manner.

To shut off power to equipment in an urgent situation do one of the following as applicable:

- Press the Emergency Power Off button to shut off power to non-computer equipment.

   Or

- Turn off the main circuit breaker in your facility.
  Note: When the main circuit breaker in the facility is turned off the system UPS units will continue to supply power to the control electronics of the system. While this enables the shell to be opened, thereby simplifying patient extraction, it does leave portions of the system energized.
  Note: All users must know the location of the main circuit breaker in their facility.

After actuating the Emergency Power Off button, follow the steps for loss of power described in the Power Failure section.

In the unlikely event that it is necessary to shut off power to the console computer as well, turn off the UPS using the power switch on the UPS front panel.

2.3.   HV Enable Key

Another safety feature is the HV Enable key (see Figure 2.3.1). This key must be inserted and turned clockwise to enable the high voltage circuit.

When the HV Enable key is turned on an "Enable" LED is lit above the key.

The HV Enable key does not turn on the high voltage ("HV" or the system ready state). If the system is in a state where HV is allowed, then it can be turned on by pressing the "HV On" button to the left of the key. When HV is on the following feedback is provided:

- There is a clearly audible sound coming from the system.
- Any external signage provided by your site is illuminated (see Section 2.5)

When the MV therapeutic beam is on the following feedback is provided:

- A "Beam On" LED is lit below the key.
- The "Beam Progress" indicator on the main UI is illuminated (see Section 8.4)

The HV Enable key should be removed and stored in a secure location when the system is not in use.

Figure 2.3.1. The HV Enable key.

2.4.   Emergency Patient Extraction

⚠️ Warning: Users entering the scanner boundary will cause the system to stop while extracting a patient. If a patient must be extracted rapidly, all personnel must remain outside the scanner boundary until the door and shell have opened enough to allow sufficient access to the patient.

If the system has power the best and fastest way to extract the patient is to use the Pendant to open the shell/door and move the table out. Even if there is a power-outage the UPS battery will provide enough power to extract the patient and safely shut down the system.

The following steps should only be performed if there is no power to the system or if the software is not working.

➢ **To Ext**r**act Patient from the Delivery System:**
  • Release the vertical door bypass valve on the side of the patient entry ring to open the door (see Figure 2.4.1)

Figure 2.4.1. Bypass Valve.

- If the patient is capable of doing so safely, ask the patient to remove the mask.
- Check to see that the patient is clear from any equipment so that the treatment table can be extracted from the treatment chamber.
    - If the patient is clear: pull the treatment table out of the treatment chamber. Reach into the shell to remove the mask and carefully help the patient off the treatment table.
    - If the patient is not clear: swing the table to the left or to the right to avoid the equipment that is in the way. Then proceed to assist the patient out of the treatment chamber as described above.

⚠️ **Warning: Once the bypass valve is open, do not close it until the patient is extracted and all personnel are clear of the system.**

2.5.   Facility Responsibilities

This section describes your responsibilities for setting up emergency and safety procedures for ZAP-X System operations.

External Connections

Depending on your local regulations, you may need to implement one or both of the following:

External Signage: The system supports a relay mechanism that closes a circuit when High Voltage is active (The "Ready State" before and during beam delivery). Contact ZAP service for assistance in connecting this to an external display.

Room Interlock: If local regulations require additional shielding, the system supports an input signal that will cause beam delivery and High Voltage to stop. For example, this supports a door interlock that shuts down the beam when the room door is opened. It is your responsibility to implement the input to this signal in a manner consistent with local regulation; for example, by using a time delay device to permit exit and door closure after checking that, apart from the patient, no one remains in the controlled area.

General Use

Use the following guidelines for routine use of the ZAP-X System:

- Keep a logbook of maintenance activities and record all unusual events related to the system.
- Always observe the standard startup and shutdown procedures.
- Test Emergency Stop procedures regularly, at least weekly
- While no sterilization or disinfection of the system is required between uses, common clinical practice would include covering the cushion with clean linens for each patient and/or cleaning it periodically with an alcohol wipe. Refer to Appendix B for the manual cleaning instructions of the cushion cover.

Safety Operations

You must provide and train your technical, service, and support staff in the following safety operations.

- Fire extinguishers should be present in the Treatment Room and near the operator console, per local fire code.
- The Treatment Room and operator console area must have emergency lighting. in addition, flashlights must be on site as a back-up during emergencies.
- Hazard signs regarding radiation exposure, high voltage, laser light hazards, and pacemaker hazards must be posted where appropriate, near the Treatment Room, near the operator console, and on the system components.
- Patient load should not exceed the maximum table load.

⚠️ **Warning: MAXIMUM TABLE LOAD: 297 lbs./135 kg**

2.6.   Other Safety Procedures

Power Failure

The Uninterruptible Power Supply (UPS) is located in the PDU. It provides power to workstations and the system for approximately ten minutes under the nominal operating load. For more information, see Chapter 3, "System Startup and Shutdown".

- The UPS automatically switches to battery operation if utility power fails and supplies power to connected equipment until the battery is fully discharged.

- In event of a power failure, immediately end treatment delivery and extract the patient.

Once power has been restored:

- Wait for the UPS to be recharged before continuing treatment.
- Follow the instructions for a cold-start of the system (see Section 3.1).
- If there was a treatment in progress, it can be resumed (see Section 8.8).

Fire or Fumes

⚠️ **Warning: Equipment not suitable for use in the presence of flammable mixtures.**

⚠️ **Warning: Equipment not suitable for oxygen rich environments.**

If you smell smoke or fumes, or if you detect a fire, initiate the emergency shutdown procedure below.

➢ **To shut down immediately:**
1. Press any E-stop button
2. If a patient is inside the system, extract them using either the on-screen extract button or the pendant.
3. Press the nearest Emergency Power Off button.
4. Activate the fire alarm in the facility.
5. Evacuate everyone from the facility according to facility protocols.
6. If in treatment mode, verify that the system has executed the abort sequence. All the treatment information is recorded automatically, and the remaining undelivered dose will be saved as a make-up treatment plan for use later.
7. If the smoke or fumes are coming from the computer equipment, manually turn off the Uninterruptible Power Supply (UPS).

Emergency and Safety Training

All personnel who work with the system must have initial training and periodic refresher courses for the following:

- Emergency Stop (E-Stop) procedures.
- Emergency Power Off procedures.
- Location of the main circuit breaker as a backup for emergency power off.
- Evacuation procedures and egress routes in case of fire, fumes, or other threatening situations.
- Emergency procedures in case of earthquake or other natural disasters likely at the facility's location.
- Emergency lighting system activation and the location of backup flashlights.
- How to assist a patient to get out of the treatment chamber and out of the facility.
- List of people to contact in case of a fire, medical, or technical emergency.
- How to restart the system after an emergency shutdown.

⚠️ **Warning: In the case of a natural disaster such as earthquake, do not use the system for treatment until it has been thoroughly inspected and tested for accuracy.**

Radiation Overexposure

➢ **In the case of a radiation overexposure:**
   1. Seek emergency treatment for the victim.
   2. Contact the local radiation safety officer according to facility protocols.
   3. Notify the local, state, and federal authorities in accordance with your institutional procedures.
   4. Consult with medical experts in radiation exposure treatment.
   5. Notify ZAP Customer Service as soon as possible.

Software Controls Not Functional

In the event of software control no longer functional for any reason, manual procedures are required to extract the patient.

   1. Press the nearest E-stop button.
   2. Carefully help the patient off the treatment table.
      • Release the vertical door bypass valve to open the door (see Figure 2.4.1).
      • Follow the procedure when recovering from a power failure described in Section 2.4 of this chapter and help patient out of the treatment chamber.

Treatment Side Effects

By its nature SRS delivers large doses of radiation to the body. Risks of side effects are inherent in this process and should be communicated to the patient prior to treatment.

Caution: Prevalence and intensity of side effects experienced by patients during radiotherapy vary based on the type of condition being treated, the frequency of radiation therapy and individual patients. There are short term side effects that occur during and shortly after irradiation and there are some longer term affects that may occur. The four most common side effects are identified as Fatigue, Nausea, Depression and Pain. These four most frequent side effects have significantly higher frequency than other side effects.

3. System Startup and Shutdown

There are three steps to starting the system:

- Powering up and launching the software.
- Initializing the system.
- Performing a self-check and checking E-stops.

Your site may also include other site-specific steps at Startup. ZAP recommends that each site develop and document a startup checklist that is appropriate to your site.

Caution: The integrity and security of patient information requires use of passwords that are securely recoverable.

Caution: To preserve system security, log out of the TPS computer after each use.

3.1.   Power-up

The preferred way to power-up the system is to set the next power-up time when you shut down the system (see Section 3.4). By setting the power-up time to be about half an hour before your arrival, the system will be powered up and warmed up when you arrive. In that case, enter your user name and password (see Figure 3.1.1) and you are ready to move on to initialization (see Section 3.2).
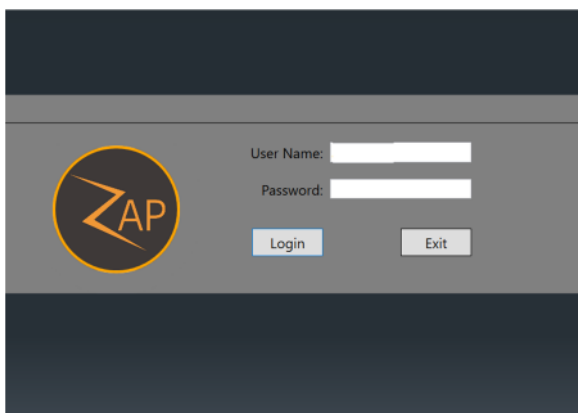
Figure 3.1.1. The login screen.

Power-up from cold start

Follow these steps if you were not able to pre-set the power-up time.

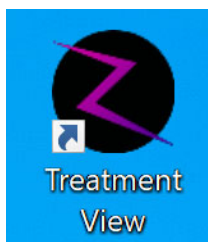1) Double click on the ZAP Treatment View Application on the main console computer.

Figure 3.1.2. The Treatment View Application.

Note: ZAP recommends that the main console computer be left powered on at all times. If for some reason it was powered off, there is a power switch on the back of the operator console.

2) The Main UI screen will display the Dashboard in the powered-off state. (Figure 3.1.3) Click on the Power button to initiate system power-up.
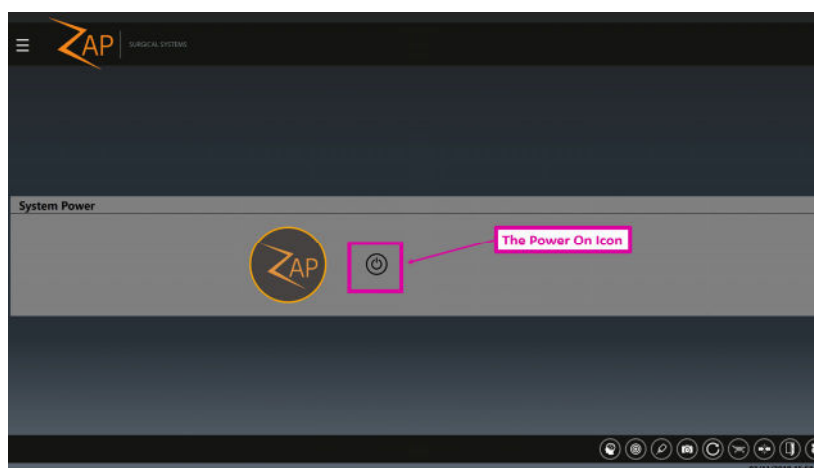

Figure 3.1.3. The Power-On Icon.

3) The Power-On sequence will start. After a few minutes a login screen will appear. After you login the Main UI screen will display the full Dashboard. Note that it may take a few minutes for the Dashboard to display. As the system powers on it is normal for some temporary errors to appear as system components coordinate with each other. These will generally resolve themselves as the power-on sequence completes.

After a cold start it will take about half an hour for the water circulator to come up to temperature and warm up the Linac electronics. During that time system initialization is possible, but no MV beam can be delivered. The target temperature of the circulator, along with the current temperature, are displayed on the front panel of the water circulator in the auxiliary room.

3.2.   Initialization

Initialization of the hardware is required before other system features are available. This is done by pressing the initialization button on the main Dashboard (see Figure 3.2.1).
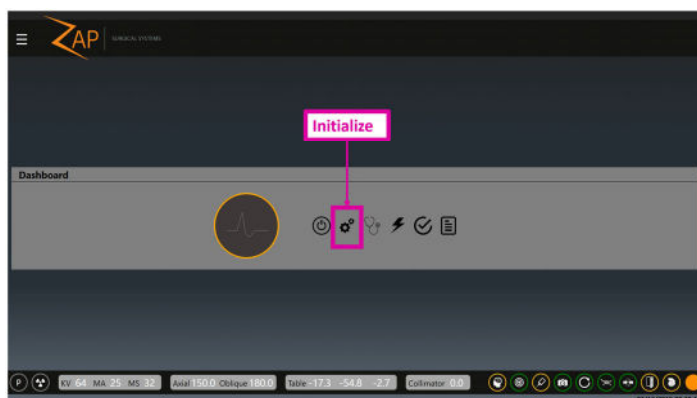
Figure 3.2.1: Initialization.

Initializing the hardware takes a few minutes. During this time the table will slowly move to each extreme of its movement, and then each gantry axis will move.

3.3.   Self-Check

Once the hardware is initialized the next step is to perform a self-check by clicking on the Self Check button from the Dashboard (see Figure 3.3.1).

The Self-Check system, along with the exclusion zone E-Stop (next section) checks the correct operation of system interlocks and radiation safety devices. ZAP recommends that both tests be done daily.

<u>Caution</u>: Make sure there is nothing on the system table prior to performing a self-check. If something such as a phantom or test fixture is on the table, it will cause the self-check to fail.

Self-check is the first step where the MV beam must be enabled:

- This test is not available until the system electronics have been warmed up. This may take about 30 minutes after a cold start.
- Make sure the HV key has been inserted into the console and turned clockwise to allow later enabling of HV.

Warning: During self-check system components will move automatically and the kV and MV beams will be briefly active. Make sure the system is clear and unobstructed.
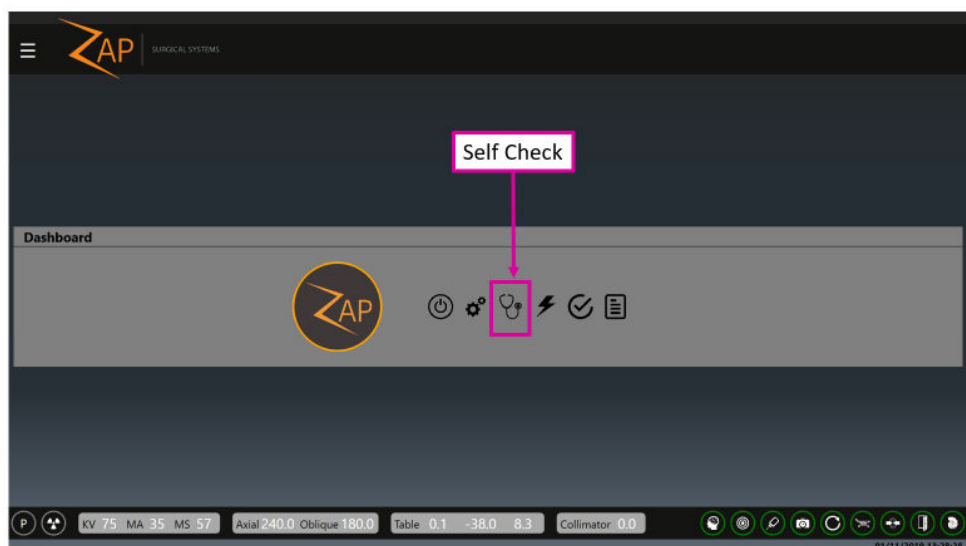
Figure 3.3.1. The Self Check Icon.

Self-Check is a series of automated steps that together ensure that critical system components are working as expected. The following table shows the steps that are done, along with the components that are tested by that step.

Test	Component tested
The system will generate a software E-Stop, and then confirm that the safety system is preventing system movement.	**Software E-Stop**
Remove E-Stop and insert the table to a known position. Close the shell and door.	**Table, Shell, and Door motors.**
Move the Gantry to predefined position.	**Gantry motors.**
Take a kV image and compare to a stored baseline. Note that the table casts a shadow at a known expected location.	**Accuracy of table position. Accuracy of gantry position. kV imaging.**
Intentionally move the table/gantry so that the collimator tries to get very close to the table.	**Collimator Collision sensor.**
Turn on HV, deliver a short MV beam, and compare to a stored MV image.	**Consistency of beam positioning and output. MV imaging.**

The system will provide status as these steps proceed. If any step fails a system message will inform you of what failed. If self-check fails, follow the following steps:

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- Make sure there is nothing on the table.
- Make sure the table cushion is correctly positioned.
- Check for other obstacles in or around the system.
- Power down the system and power it back up again.

If there is still an issue after following these steps, call ZAP service for additional support.

⚠️ **Warning: Do not proceed with treatment until self-check passes or you are instructed to do so by an authorized service representative.**

Depending on your site's startup checklist you may want to check the physical E-Stop buttons after the self-check is complete.

To check the operation of an E-Stop button, press the button and confirm that the message window on the main UI shows the E-Stop status. Confirm that the E-Stop message cannot be cleared until the button is released.

To release an E-Stop button, turn it clockwise.

3.4.   Optional Start-up Procedures

ZAP recommends that each site develop a startup checklist with site specific items to be performed before or after the steps described above.

⚠️ **WARNING: Do not use the system if any item does not pass the startup checklist. Contact your service representative for further instructions.**

The following start-up steps are to be done as your site determines:

Test Exclusion Zone E-Stop

The exclusion zone sensors generate an E-Stop if someone or something is too close to the system (see section 2.1). To test these sensors, after power-up:

- Walk up to one side of the system. Return to the operator console and confirm that an E-Stop was generated. Clear the E-Stop (see Section 2.1).
- Repeat the process on the other side of the system.

Power Distribution Unit (PDU)

The main PDU is typically located in an adjacent auxiliary room (see Figure 3.4.1). On the PDU:

- Confirm the main power switches are enabled. These switches should never be turned off unless in an emergency or if turned off by ZAP service personnel.
- Confirm that the system is connected to main power by checking the amber indicator light on the upper right of the PDU.
- Confirm that there are no error messages or alerts on the Uninterruptible Power Supply (UPS).

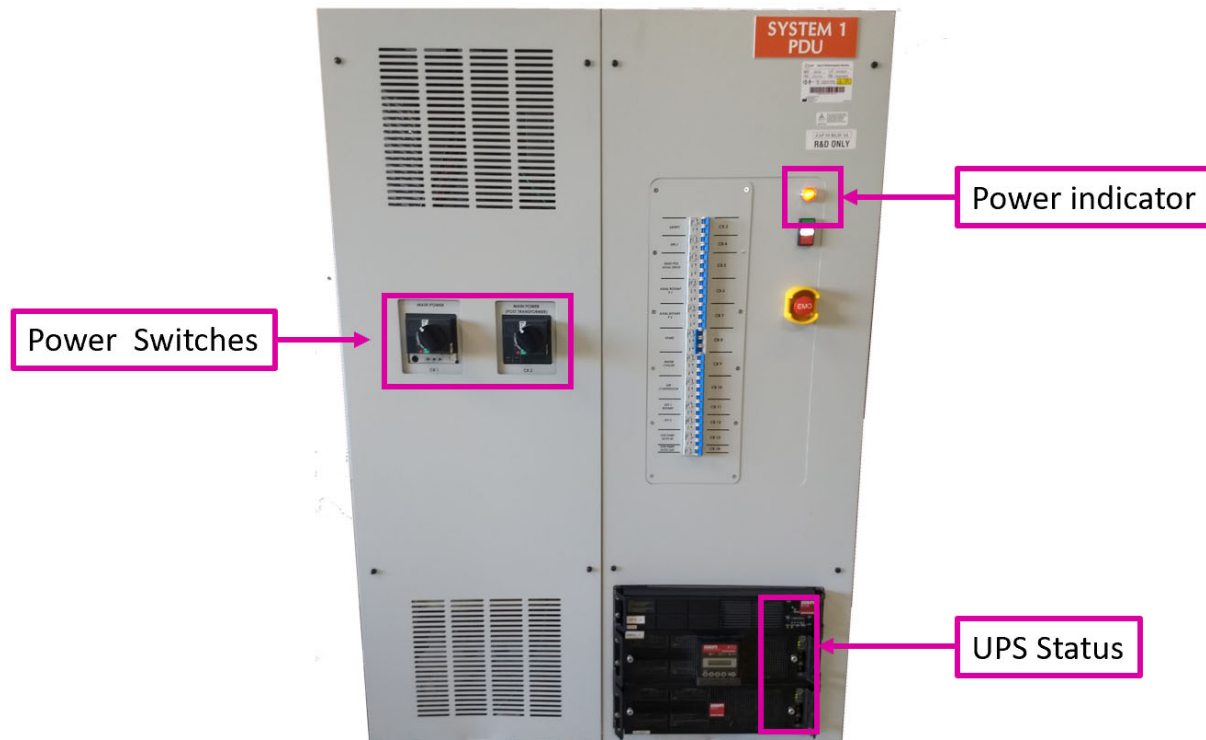Contact ZAP service if any of the above cannot be confirmed.

Figure 3.4.1. The main PDU.

Water Circulator

The water circulator is typically located in an adjacent auxiliary room (see Figure 3.4.2). Note, the brand name of the water circulator may be "Chiller"; however, it will either warm or chill the water as needed to maintain constant temperature to the system electronics.

On the water circulator:

- After the system is warmed up, confirm that the actual temperature is within 0.1 degrees of the target temperature.

Contact ZAP service if this is not the case.
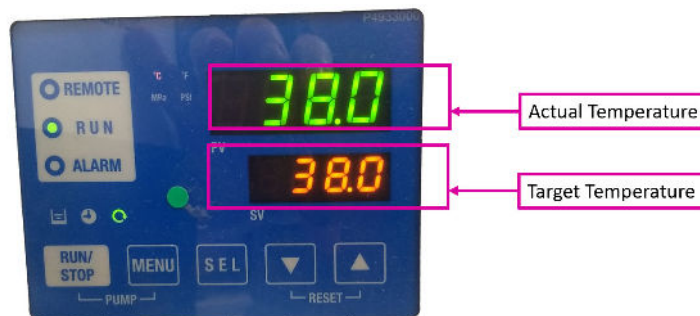
Figure 3.4.2. Water Circulator status.

3.5.   Settings Menu

If control of the system is passing from one user to another, the current user can logout by clicking on the Settings Menu (upper left of most screens, see Figure 3.5.1) and selecting the Logout option. This returns the system to the login screen for the next user.
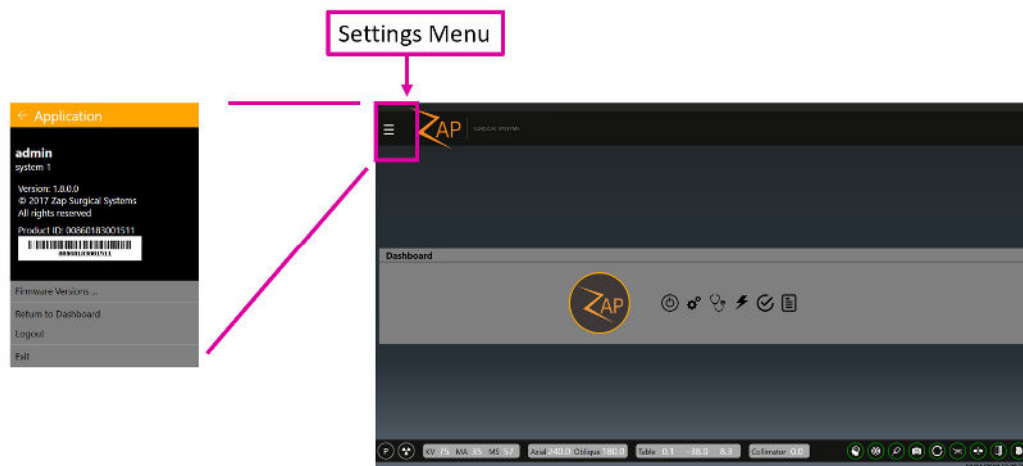
Figure 3.5.1. The settings menu and the icon used to invoke it.

The Settings Menu has the following options:

- **Firmware version:** Displays the current version of many system components. This information may be helpful when contacting ZAP service.
- **Return to Dashboard**: Returns to the main dashboard from many different screens.
- **Logout**: Exit back to the login screen so another user can log in.
- **Exit**: Exits the TDS software and returns to the Windows desktop. This should be very rare.

3.6.   Shutdown

Shut down the system at the end of the day.

- Make sure the shell and door are open before shutting down the system.
- Click on the power icon on the main dashboard.
- If desired, click the "Schedule a restart time" checkbox and set the date/time of the next scheduled start. Setting the time to 30 minutes before scheduled use will allow the system electronics to come up to operational temperature before you arrive.
- Click on the OK when the confirmation dialog-box is displayed.

- Some parts of the system will power-down almost immediately, and other parts will take a few minutes to power down. Wait for the process to complete.
- Remove the High Voltage key from the operator console. Store in a secure location.

Caution: The door should be left open between use. Keeping the door closed will put unnecessary wear on the pneumatic system.

Note: ZAP recommends that the PDU, pendant, and console PC remain powered on.
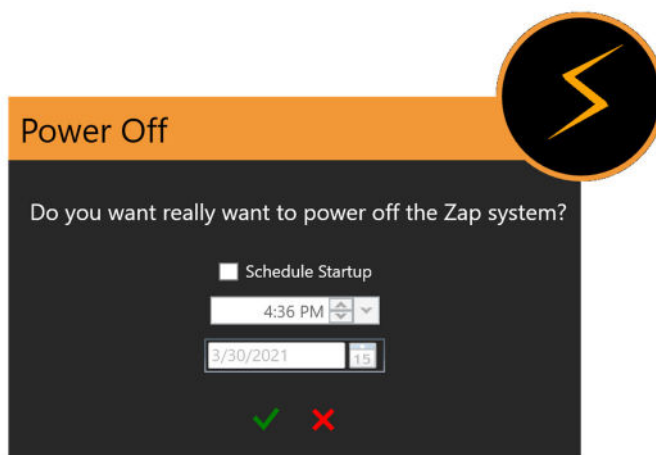

Figure 3.6.1. The Power Off button.

Figure 3.6.2. The Shutdown dialog.
Set the start time to 30 minutes before anticipated use.

4. QA

Note: The selection and timing of QA procedures must be determined by the responsible individual at each site in accordance with local regulations. This chapter describes the software tools available to assist in performing QA tasks.

Note: Please see the QA manual (p/n E0920-00005) for detailed QA procedures.

The QA function is invoked by clicking on the QA button from the main Dashboard. (see Figure 4.1)
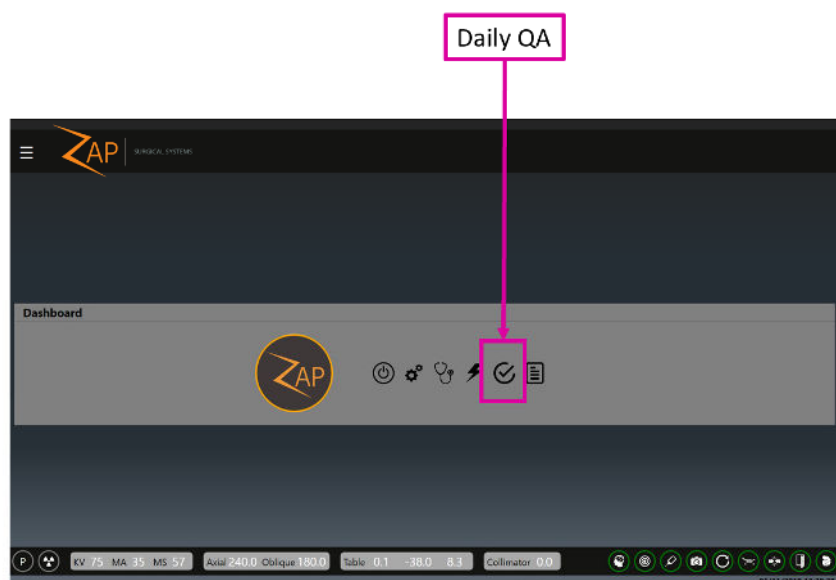
Figure 4.1. Access to Daily QA.

Clicking this button will display the QA function. There are four separate workflows in this function: Daily QA, Steel Ball, F Bracket, and Water Tank. For each of these workflows there are two sub-tabs; one to move the table/gantry, and one to deliver a dose. The details vary with each workflow.

4.1.   Daily QA

Daily QA: Table and Gantry

Figure 4.1.1 shows the Table and Gantry interaction for the Daily QA workflow. This is the default screen when the QA function is invoked from the main dashboard.
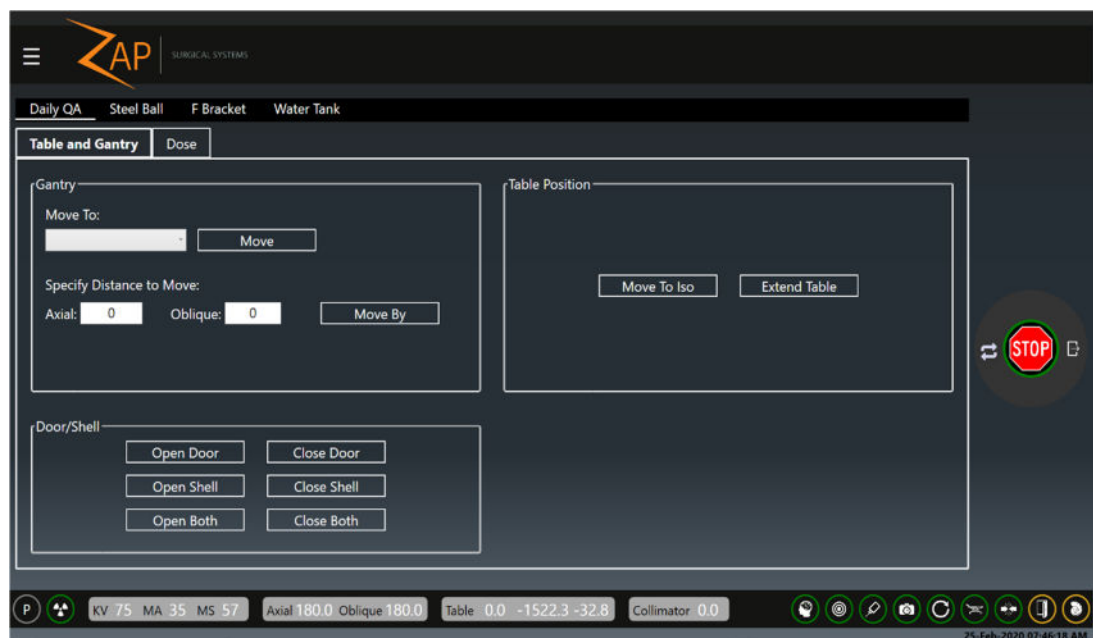
Figure 4.1.1. Daily QA workflow showing the Table and Gantry tab.

There are 3 groups of interactions here. When any of the following buttons are clicked, a dialog is displayed to confirm that the action is intended.

Gantry:

Move To: A drop-down list that includes selected pre-defined locations, along with the "Move" button to perform the selected move.

Specify Distance to Move: These 2 fields allow you to move the gantry by an arbitrary amount. Typing a number in either/both of these fields and then clicking the "Move By" button will move the gantry by the entered number of degrees. Note, these are relative movements from the current location, not absolute locations for the gantry.

Table Position:

Move to Iso: Moves the table in to the nominal treatment position where a head center would be at the isocenter.

Extend Table: Moves the table out all the way.

Door/Shell:

Open Door/Close Door: Opens and closes the system door, respectively. The table must be inserted for this to work.

Open Shell/Close Shell: Opens and closes the system shell, respectively.

Open Both/Close Both: Opens and closes the shell and door in an integrated move.

Daily QA: Dose

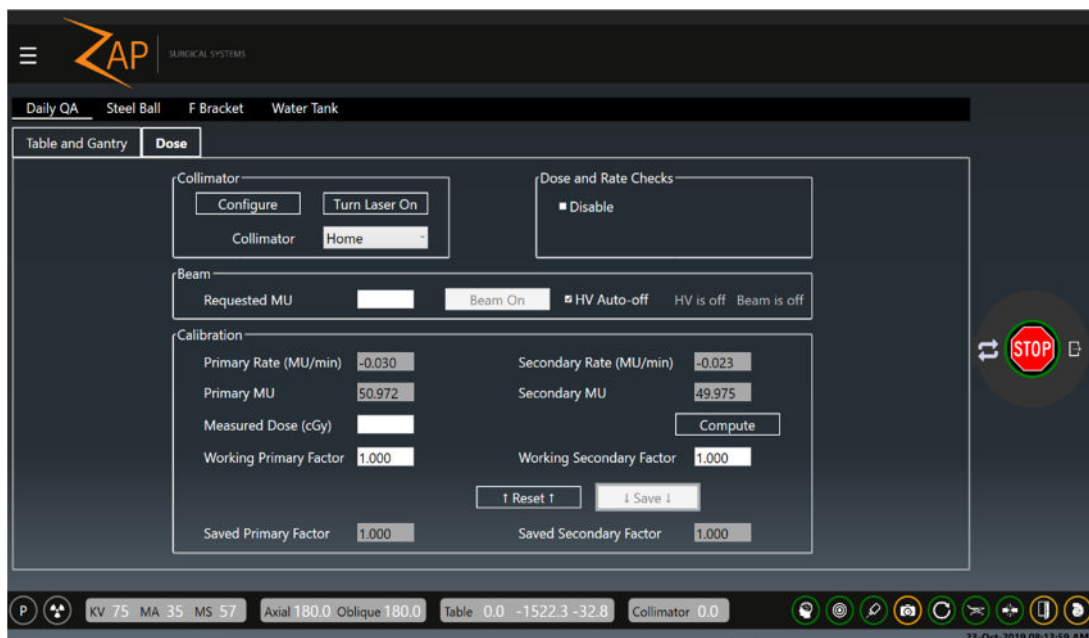Figure 4.1.2 shows the Dose interaction for the Daily QA workflow.

Figure 4.1.2. Daily QA workflow showing the Dose tab.

This allows you to fire a beam and set calibration factors.

The following are some of the interactions on this page. Please refer to the QA manual for further details:

- **Collimator**: Allows you to pick a collimator size. There is also a button to enable/disable a laser to line up a target.
- **Dose/Rate Check Disable**: Temporarily disable dose and rate checks. This is automatically reset upon exit of this UI.
- **Beam:** Allows you to enter the number of MU you want to deliver, and then turn the beam on. An option exists to automatically turn off the high voltage when the beam has finished delivery.
- **Calibration**: This section lets you adjust the system calibration between MU and cGy. Please consult the QA manual for details.

⚠️ **Warning: Changing the calibration factor will change the dose delivered. This should only be done by the site Medical Physicist or designee.**

As an example, Daily QA step, here are the steps to warm up the Linac with a pre-defined MU delivery:

1) In the Collimator section set the Collimator value to "Home" to ensure that beams are blocked.
2) In the Beam section, type in the number of MU you want to deliver.
3) Make sure that the HV-Enable key is inserted into the console and turned clockwise.

4) Press the HV-On button on the console. Note that the "Beam On" button becomes available in the Main Screen GUI.
5) Click the "Beam On" button. Note:
    o "HV is On" and "Beam is On" text appears next to the Beam On button.
    o The Primary and Secondary Rates will show a number nominally close to 1500. (the displayed number may vary)
    o The Primary and Secondary MU fields will start counting up as the beam is delivered.
6) When the target value is reached, the beam will automatically turn off, and the dose rate will drop off to close to zero.
7) Press the "HV Off" button on the console.

4.2. Steel Ball

In the Steel Ball protocol, a steel ball phantom is placed at the isocenter, and then a short MV beam is fired from multiple directions. The system finds the steel ball in the center of the MV image, and then calculates how close the measured location is to the true isocenter. This is like a simplified Winston-Lutz protocol.

The Table and Gantry interaction of this workflow is very similar to that of the Daily QA, though the list of pre-defined gantry locations may vary.

Figure 4.2.1 shows the Steel Ball screen for the Steel Ball workflow.
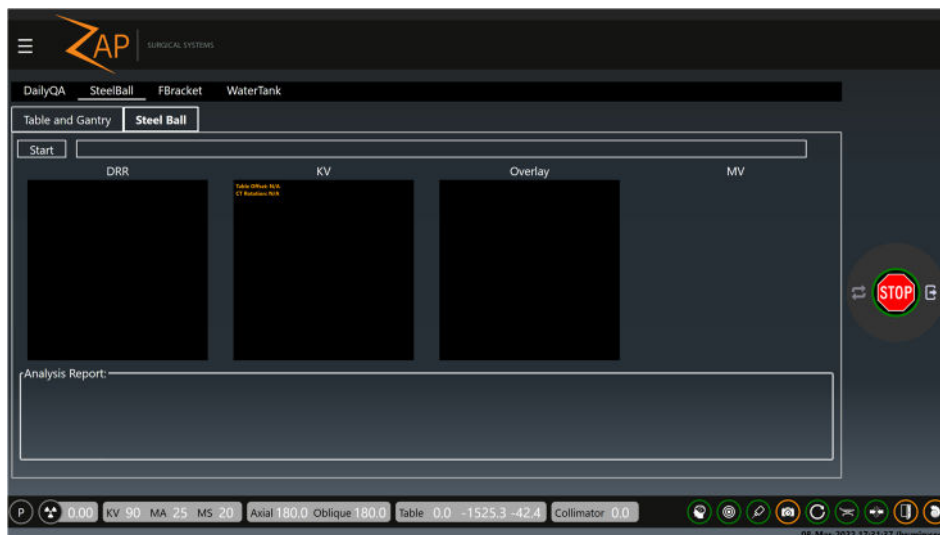
Figure 4.2.1. Steel Ball workflow showing the Steel Ball tab.

After you press the Start button the following steps occur:

- The system will go through an auto-align process (see Chapter 7) to make sure the phantom is located correctly. This will result in DRR and kV images being displayed.
- After the auto-align is complete and the HV is enabled, the gantry will move to four different locations and fire the MV beam at each location. The MV imager display will be shown in the right most window of this screen.

- After all MV images have been acquired the system will confirm the successful completion of the tracking QA and show an analysis on screen.
- If an email address has been configured, an analysis report may be sent by clicking on the email icon.

4.3.   F Bracket

The F Bracket screen shows a "Table and Gantry" screen and a "Dose" screen that are very similar to those of the Daily QA. Some of the options on drop-down menus are constrained to those that make sense when there is an F Bracket attached.
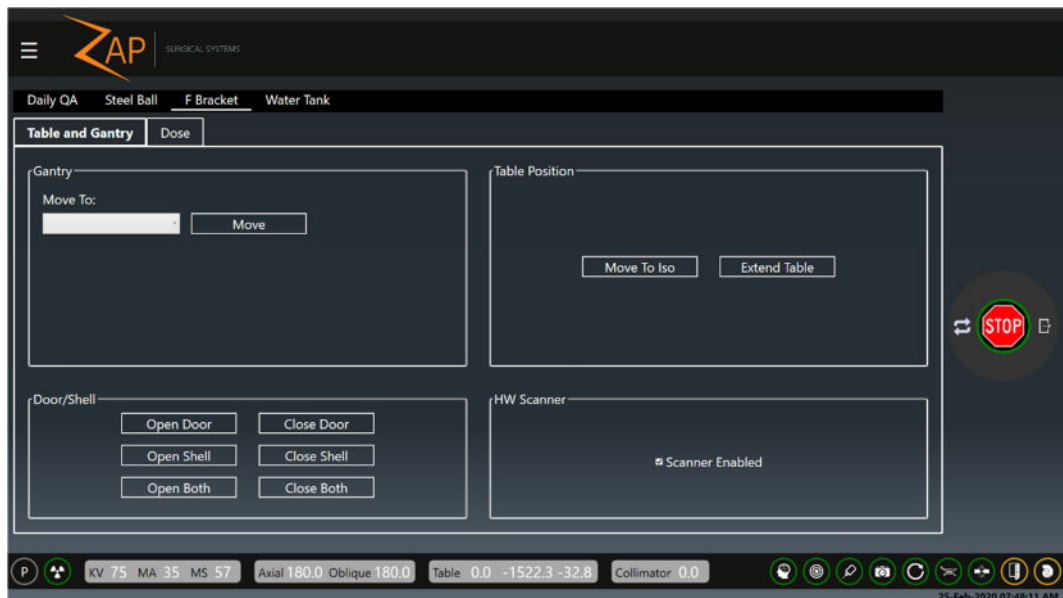

Figure 4.3.1. F-Bracket workflow screen.

There is also a "Scanner Enabled" interaction. Uncheck this to disable the proximity scanner on the collimator. This allows the system to deliver a beam with the F-bracket attached.

4.4.   Water Tank

The Water Tank screen shows a "Table and Gantry" screen and a "Dose" screen that are very similar to those of the Daily QA. Also on this screen is an interaction to adjust table pitch.

The table is enabled, and table pitch can be adjusted using the table position controls shown below. The table can't be moved by hand when setup like this.
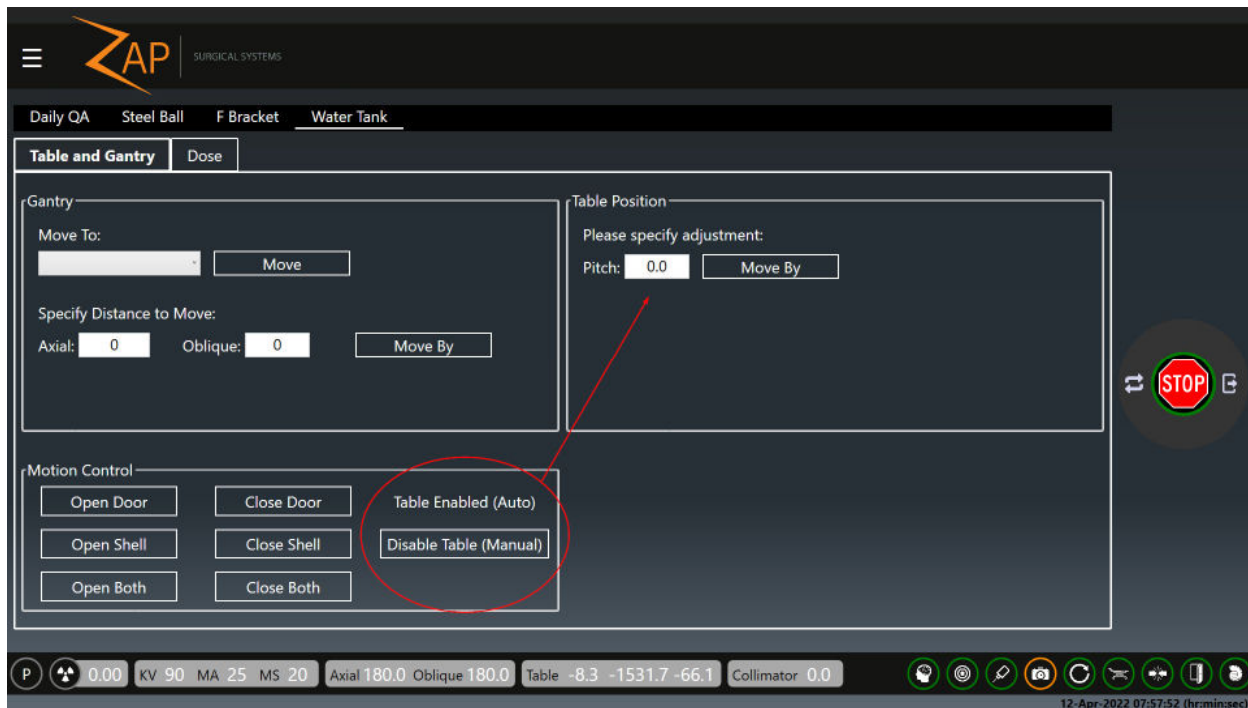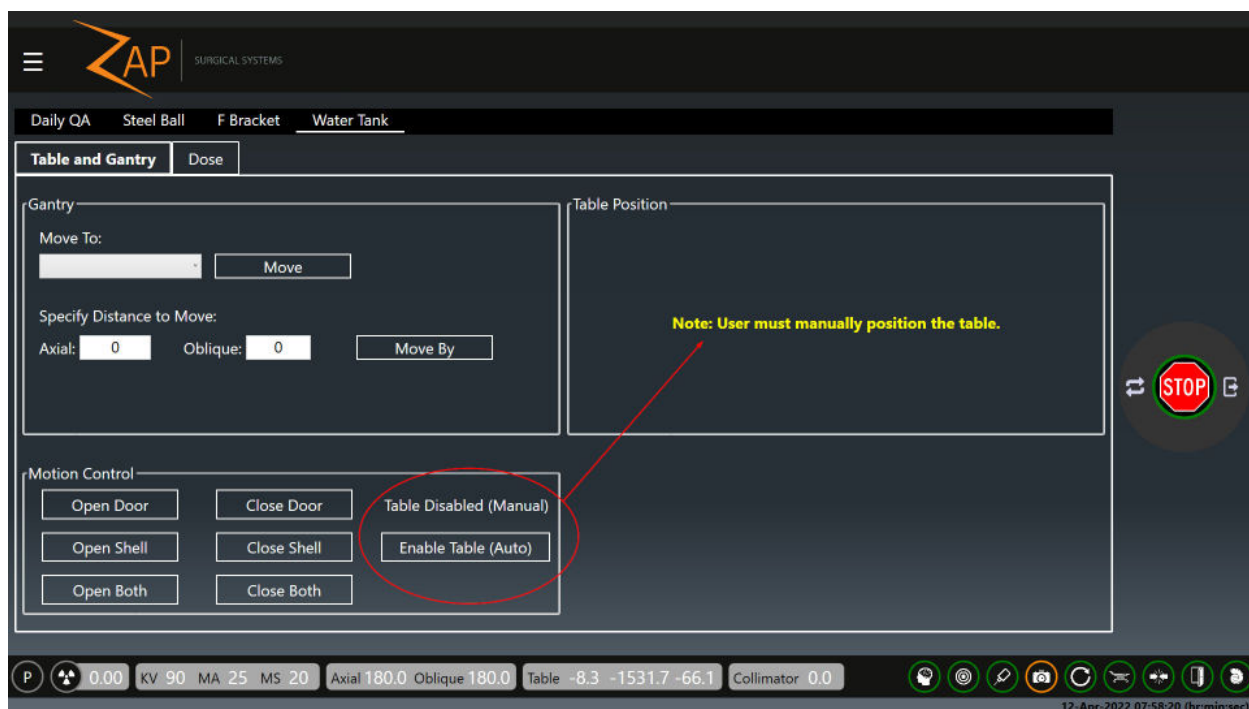

Figure 4.4.1. F-Water tank workflow screen.

Figure 4.4.2. F-Water tank workflow screen – manual adjustment.

To adjust the table manually (needed when the water tank is on the table to prevent sloshing), press the "Disable Table (Manual)" button. When disabled, the pitch adjustment option goes away, and the table can now be moved by hand.

Even if an e-stop is triggered and cleared, the table will stay in the disabled state until the "Enable Table (Auto)" button is pressed to enable the table again – this way any tripped external proximity sensors, table motion, and clearing the e-stop will still have manual control of the table (so the water won't slosh).

5. Load Plan and Fraction

This chapter assumes that:

- The system has been powered on and initialized (Chapter 3).
- Any daily QA has been done (Chapter 4).

Loading the plan can take place before or after the patient has been positioned on the table and inserted into the system (Chapter 6).

The first step in loading a plan and fraction is to click on the Treatment button from the main Dashboard (Figure 5.1)

Figure 5.1. Starting Treatment to load a plan.

5.1. Selecting the Patient

Clicking on the treatment button will display a screen showing all the patients that can be treated. (Figure 5.1.1).
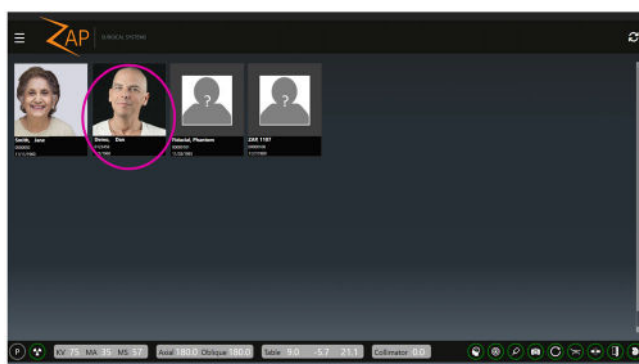
Figure 5.1.1. The Patient selection page.

This screen shows every patient that has a plan approved for delivery (See the Treatment Planning Software (TPS) manual, p/n E0920-00003, for information on approving a plan).

For each patient the system displays:

- A picture of the patient if one was imported by TPS.

- The patient ID.
- Patient date of birth.

Note: A "Patient" can also include a phantom used for QA purposes. If it has a plan that is approved for delivery, then it is shown on this screen.

If you do not see an expected patient:

- Click on the refresh icon (Upper right corner of the screen). This will update the display with the latest version of patients from the system database.
- If the patient still does not appear, review the patient at the planning system and confirm that a plan has been approved for delivery.

5.2.   Selecting the Plan/Fraction

With the ZAP software there is no need to select a plan and then separately select a fraction. Instead, clicking on a patient will display a screen showing all approved plans and fractions together on one screen (see Figure 5.2.1).
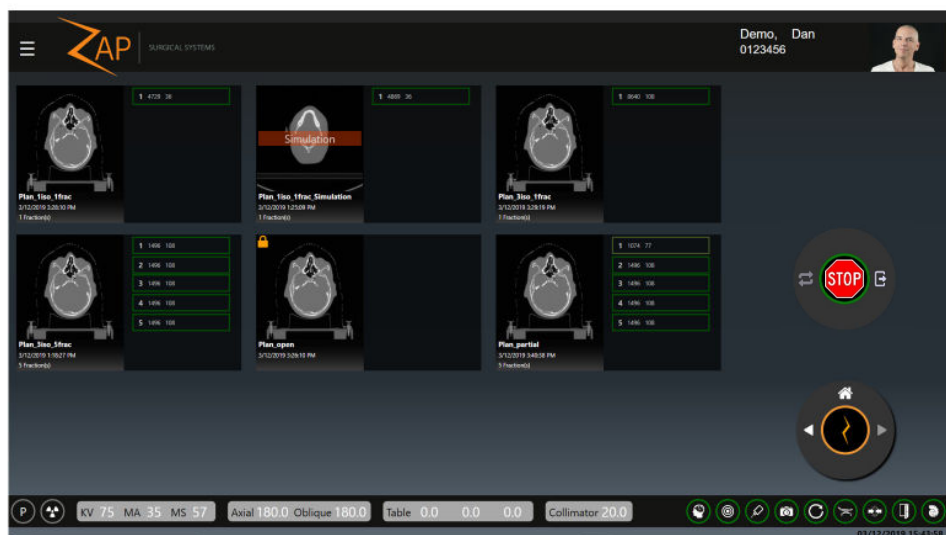
Figure 5.2.1. Selecting the Plan and Fraction.

The above figure shows 6 approved plans for this patient, with each plan having from 1 to 5 fractions (Note, these are for illustrative purposes, and are not meant to represent a realistic patient or plan). Clicking on any fraction will automatically select the plan that fraction is a part of.

Figure 5.2.2 shows a close up of one of these plans.

Figure 5.2.2. Close up of a plan.

Each plan displays the following information:

- **CT**: A thumbnail of the planning CT.
- **Plan information**: this includes the name of the plan, the date/time that the plan was last approved, and the number of fractions in the plan.
- **Fractions**: A list of fractions to be done on this plan. Completed fractions are not shown.

Each fraction shows the following information:

- **Fraction number**
- **Total Dose:** This is the dose in MU (not prescribed dose) that is delivered with the fraction.
- **Beam count**: The number of beams to be delivered in this fraction.
- **Partial Fraction**: Note that fraction 1 in Figure 5.2.2 is outlined in a lighter green, and that the beam count is less than the other fractions. These indicate that the fraction was partially delivered, and that additional delivery is needed.

Once a fraction is selected the Next icon is enabled in the Workflow Wheel, and you can proceed to either delivery or to Patient Insertion, depending on your workflow.

5.3.   Other Plan Icons

Figure 5.3.1 shows a closeup of two of the other plans for this patient:
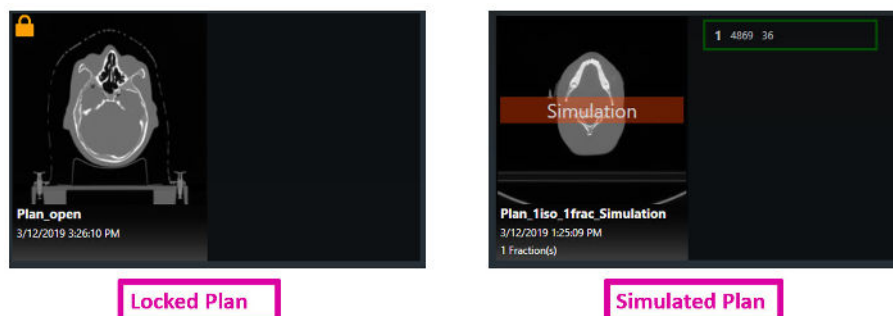

Figure 5.3.1. Locked Plan and Simulated Plan.

Locked Plan: A lock icon in the upper left corner of a plan indicates that the plan is locked. This means that it is open by some other software and can't be used for delivery. Most likely this is because it was left open on the planning computer.

Simulated Plan: A reddish-orange "Simulation" watermark on the CT thumbnail means that this is a simulated plan. A simulated plan is one that has the dose and targets of a clinical plan, but that has replaced the planning CT with a phantom CT. This supports a patient-specific QA process of delivering a clinical plan to a phantom. Please see the TPS manual for details.

Dry Run Plan: A reddish-orange "Dry-Run" watermark on the CT thumbnail means that this is a dry-run plan. A dry-run plan is one that will be delivered the same as a regular clinical plan, but no radiation dose will be delivered (the beam will remain off). I.e. the system will capture images, align the patient and move to each of the delivery nodes, but no beams will be delivered.

Note: Some simulated plans require moving the target from its clinical location to a ball-cube center or other pre-defined target location. This may result in a change to the beam path used for delivery. Please see the TPS manual for details.

6. Positioning and Loading a Patient

This chapter assumes that:

- The system has been powered on and initialized (Chapter 3).
- Any daily QA has been done (Chapter 4).
- The appropriate plan and fraction have been selected. (Chapter 5).

6.1. Patient Positioning

Safe and accurate beam delivery starts with careful positioning of the patient on the system table:

- Use the same table insert, patient mask, and patient pillow as was used to acquire the planning CT.
- When inserting the patient, take care that the patient's head is not tilted or rotated compared to the planning CT.

Most commercially available masks with Type – S interface can be used with the ZAP-X System.

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.

Several layers of bubble wrap may be added as needed for patient comfort. Start with the same number of layers during treatment delivery as were used for the planning CT. If the mask has shrunk over time it may be necessary to remove a layer of bubble wrap in order to secure the mask to the table.

Figure 6.1.1. Phantom showing the use of a Silverman headrest with bubble wrap.

➢ **To provide head and neck immobilization for treatments**:
1. The mask should fit snugly to minimize movement.
2. The mask should extend below the patient's chin.
3. Mold the bridge of the nose to reduce lateral movement.

    4.   Snap on each of the latches to secure the immobilization mask.

    5.   Visually inspect that the head is centered and not rotated.

➢ **Immobilize the patient per your institution's standards.**

➢ **Note**: Ensure that all clothing and patient covers are not extending beyond the table in any direction.

➢ **Note**: The access ports on either side of the patient entry area should be unobstructed during normal use.

⚠️ **Warning: Safe and effective treatment requires accurate patient positioning. It is your responsibility to confirm proper patient positioning.**

⚠️ **Warning: Table cushion must be used for both treatment and CT acquisition.**

Caution: Cover the table cushion with a sheet or similar covering and change that covering for each patient.

⚠️ **Warning: Ensure that the patient is properly immobilized to minimize patient movement during treatment. Collision with the moving system equipment can result in serious injury or death of the patient.**

⚠️ **Warning: Confirm that the gantry is at home and there is no tilt to the table before loading a patient. The QA interaction can be used to move the gantry to home if needed (see section 4.1).**

⚠️ **Warning: The table can slide if pushed. Brace the table to hold it in place while a patient is going onto or off it.**

6.2.   Loading the Patient

Once the patient has been carefully positioned and immobilized the Pendant is used to insert the patient. When you go to the Pendant after positioning the patient you will see that there is an E-Stop active, as shown in Figure 6.2.1. This is because both you and the patient were in the exclusion zone as part of the positioning process.

To continue, press the E-Stop on-screen indicator to clear it.

Figure 6.2.1. Pendant touchscreen with E-Stop indicator on.

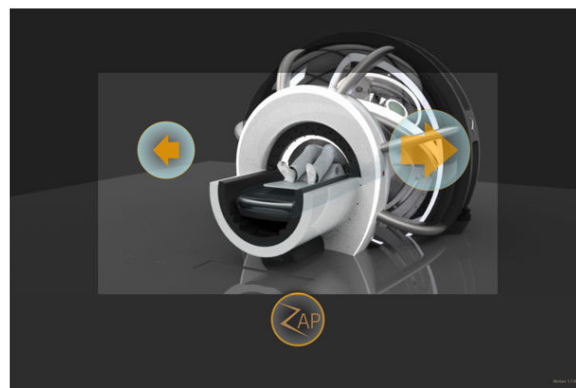Once the E-Stop is clear, the touchscreen will appear as shown on the left of Figure 6.2.2.

Figure 6.2.2. The touchscreen at rest (left) and while inserting (right).

The patient is inserted by pressing and holding the Insert icon (right arrow). Note that when the icon is pressed it becomes larger, indicating that it is active. While it remains pressed the table will move in, the shell will close, and the door will close.

WARNING: Ensure the gantry is at the home position prior to inserting the table using the pendant. Failure to ensure the gantry is at the home position may result in damage to equipment or injury to the patient.

WARNING: Always maintain visual contact with the patient while inserting them into the system. Stop insertion and/or press the E-Stop hard key if there is any risk of a pinch point between the patient and any system moving part.

⚠️ **Warning: MAXIMUM TABLE LOAD: 297 lbs./135 kg**

The pendant operates as a "dead-man" switch: the patient insertion continues while your finger is on the insert control. Moving your finger off the control will stop movement of table, shell, and door. However, while the insert icon is active a dark tint appears all around the border of the touchscreen (see Figure 6.2.2, right). This is an extension of the 'dead-man' region. You can press anywhere in this area to continue the insertion process. This allows you to change hands while the patient continues to insert.

In order to avoid an object from becoming trapped in the moving shell or door, operator vigilance and continuous activation is required. In the unlikely event that an object does become trapped perform the following:

1. Stop system motion: this may be done by releasing the pendant, stepping into the scanner boundary, or pressing an E-Stop button. No further system motion will take place until explicitly commanded. Once all E-stop buttons and the scanner boundary are clear, the E-Stop may be cleared without any additional movement occurring.
2. Evaluate whether moving the door downward will cause any additional harm to any persons, if not, release the emergency valve and allow the door to move to its fully open position.
3. Evaluate whether moving the shell in the opposite direction will cause any additional harm to any persons. If so, use the pendant to move the shell in the appropriate direction to free the object.
   a. The shell may be moved independently of other system components by long-pressing on the Z symbol and then pressing the "Shell Open" or "Shell Close" button. The Shell closes in a clockwise direction, as viewed from the Pendant.
4. If system movement is not possible without further harm to any persons, contact local emergency medical personnel. Maintain the system in a powered state so that controlled system motion may be performed if requested.

When the Pendant is being used it takes control of system movement and the UI at the console computer is unavailable. The dialog shown in 6.2.3 is displayed at the console computer. Clicking "OK" will end the Pendant's control of system movement and return control to the console computer.
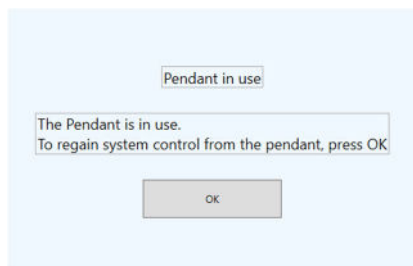

Figure 6.2.3. Console UI dialog while Pendant is in use.

Once the patient is inserted, you can move to the main console to start the patient alignment (Chapter 7).

If any tubes or wires are used to monitor or care for the patient during treatment, they can be passed through the access ports on either side of the system (Figure 6.2.4).
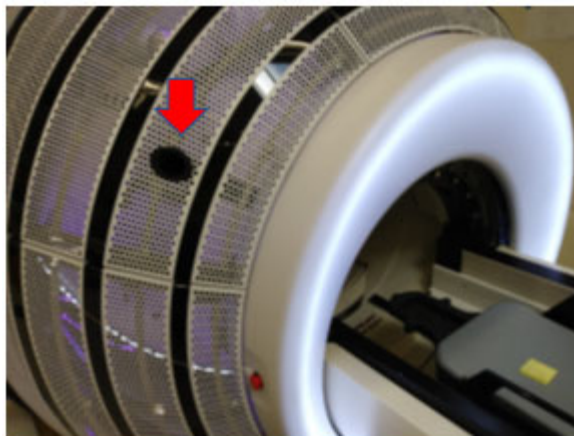

Figure 6.2.4. Access port.

Warning: Any lines passed through the access ports must be positioned carefully on the patient or patient table to avoid becoming an entanglement hazard. The user is responsible for ensuring that lines are positioned safely and monitored throughout treatment. Treatment should be stopped if a line is observed to be displaced from a known safe location.

Caution: Care must be taken to ensure the integrity of all critical lines passed through the access ports. The pathway from the access ports to the patient contains multiple potential pinch points, therefore, whenever possible methods should be used to confirm line integrity throughout treatment (i.e., signal integrity, fluid flow rates, pressures, etc.). The user is ultimately responsible for verifying line integrity throughout treatment.

Caution: Lines passed through the access ports and any additional equipment placed on the patient increase the risk the system will detect a potential collision and interrupt treatment. In extreme cases, a planned treatment location may become unreachable. Care should be taken to minimize the size and protrusion of any equipment placed on the patient, particularly near the head and shoulders.

6.3.   Pendant Details

Pendant Bezel

The Pendant housing has 2 hard key controls (Figure 6.3.1):

Power Button: Typically, the power button is only needed to re-activate the touchscreen if the Pendant screen is dark. Normally the pendant power is always left on.

E-Stop: The Pendant bezel has one of the 5 E-Stop hard keys that are located around the system. See Chapter 2 for details on the E-Stop functionality.
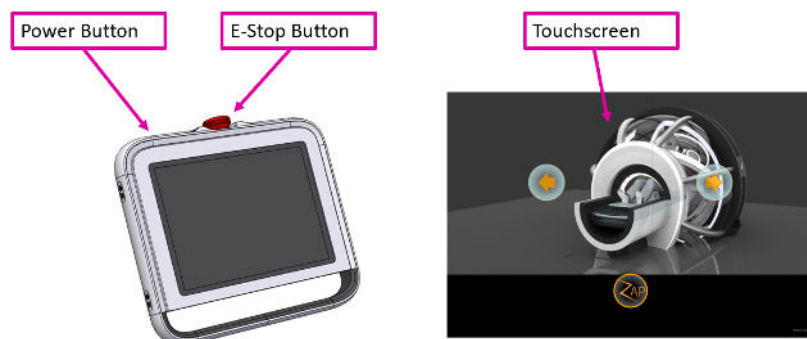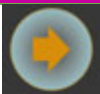

Figure 6.3.1. The Pendant.

Pendant Touchscreen

Normally, unless there is an E-Stop, the touchscreen displays the following 3 controls:

Function	Icon	Description
Insert		Pressing and holding this button will insert the patient. It will move the table in, close the shell, and close the door.
Extract		Pressing and holding this button will extract the patient. It will open the door and shell, and then move the table out.
Advanced movement		Pressing and holding the ZAP-Z icon will bring up an advanced UI where you can move the door, shell, and table separately.

If you press the ZAP-Z icon the default controls are replaced by the wheel shown on the left of Figure 6.3.2. These offer the same functionality as the default controls. If you press-and-hold the ZAP-Z icon for several seconds the wheel on the right side of Figure 6.3.2. These offer individual control for Table in/out, Shell open/close, and Door open/close.

Figure 6.3.2. Alternate Pendant Controls.

Power Cycle

There is no need to power-down the Pendant at the end of the day, and so there is typically no need to power-up the Pendant, it can be left powered up all the time. If, for some reason it has lost power, follow the following steps:

- Press and hold the power button for a few seconds to start the power-on process.
- Depending on your system configuration there might be a login required to the pendant computer. If so, please contact your site administrator for user name and password information.
- Double-tap on the Pendant icon on the windows desktop. It may take a few seconds for the touchscreen UI to boot.

7. Alignment

This chapter describes how patient alignment works on the ZAP-X system. The alignment process ensures that the target is in the expected position at the start of treatment.

This chapter will emphasize the following key points:

- The ZAP-X performs image guidance by using four types of alignment between the treatment plan CT image set and kV images acquired immediately prior to and during treatment. Automatic Alignment acquires three kV images and performs a 6D image registration with DRR for initial patient setup.   Transitional Alignment occurs at the transition between isocenters and acquires two images with an axial difference of at least 30 degrees. Transitional Alignment is triggered if Single Image Tracking (SIT) results in a table move greater 2 mm. It acquires two images with an axial difference of at least 30 degrees. Single Image Tracking acquires and analyzes a single image every 45 seconds (interval can be adjusted by the user).   The user should monitor alignments by reviewing the DRR/kV overlay presented on the screen to ensure a satisfactory match between the DRR and kV image is achieved by the algorithm.

ZAP-X provides imaging tools and an alignment review page to enable the user to monitor the tracking algorithm. The calculated table shift, and rotational offsets are shown in the upper left corners of the displayed images. These are for monitoring and assessing the patient. Display methods allow the user to assess the accuracy of alignment and tracking. For SIT a checkerboard display is used to confirm that the patient motion is being tracked by the system.   After AA, TA, and MIT there are seven display methods to confirm that the alignment has accurately determined the position and orientation of the patient prior to treatment. This chapter assumes:

- The system has gone through the power-on process (Chapter 3).
- Daily QA has been performed (Chapter 4).
- The patient has been selected and a plan/fraction has been loaded (Chapter 5).
- The patient has been placed on the table and inserted into the system (Chapter 6).

The first step in alignment is the careful positioning of the patient on the system table:

- Use the same table insert, patient mask, and patient pillow as was used to acquire the planning CT.
- When inserting the patient (Chapter 6), take care that the patient's head is not tilted or rotated compared to the planning CT.

Once the patient is setup and ready for treatment. The system goes thru several steps to ensure alignment of the positioned patient with the treatment plan. The following:

1. Auto-align (AA) – all treatments start with AA and it can be invoked when an alignment reset is necessary, such as after large patient movements.

2. Tracking and motion compensation during treatment – once treatment dose begins tracking occurs at specific time intervals.
3. Transitional Alignment (TA) and review can be used between isocenters.

7.1.   Automatic Alignment

The ZAP-X system features an automatic alignment (auto-align) function that automatically goes through the steps to align the patient. Typically, this is all that is needed to align the patient, but it is your responsibility to oversee this process and confirm the results before treatment.

After the patient is inserted and the plan/fraction is loaded, you will see a screen with the Workflow Wheel on the bottom center, and 3 blank windows above it. (See Figure 7.1.1)
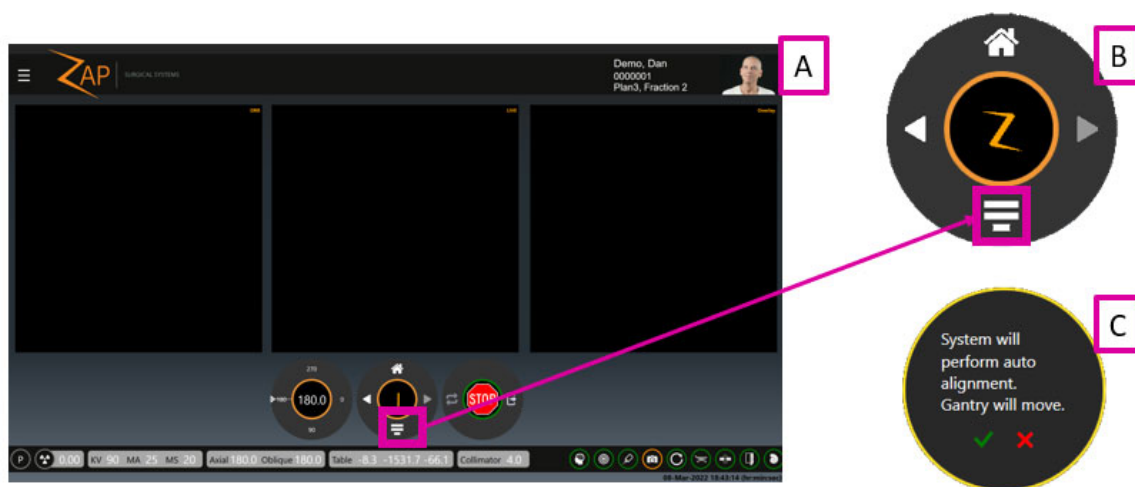
Figure 7.1.1. showing: a) the UI screen before alignment, b) close-up of the auto-align icon, and c) the subsequent confirmation dialog.

To start the auto-align process click on the auto-align icon and the following confirmation dialog box (Right of Figure 7.1.1).
Note: The alignment process works best with ZAP-defined kV settings. If the current kV settings are different, a dialog box will prompt you to permit the system to change these settings.

With the Oblique axis at 180°, the system will take 3 kV images, one each at an Axial location of 180°, 90°, and 240°. The system will then compare these images to internally generated DRR images. While this is happening, the screen will show the DRR, kV, and comparison from each angle in turn, as shown below.

If the overlay image is zoomed or panned the portion of the overall image displayed is indicated by the thumbnail at the bottom of the image. Clicking the thumbnail will reset the view of the image.
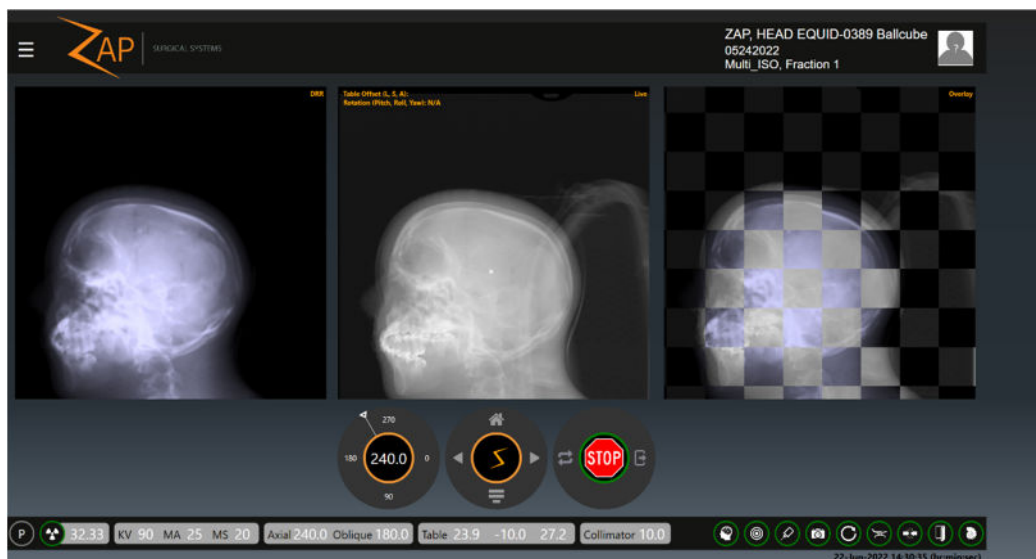
Figure 7.1.2. Auto-align in progress.

After three images, it is typical that the table needs to move to align the target correctly. If the movement is more than 2mm then kV images are acquired at the new location and the process is repeated. Once the process has completed, the system has moved the target to the system isocenter in three dimensions and determined a CT rotation that aligns the head orientation in three dimensions.
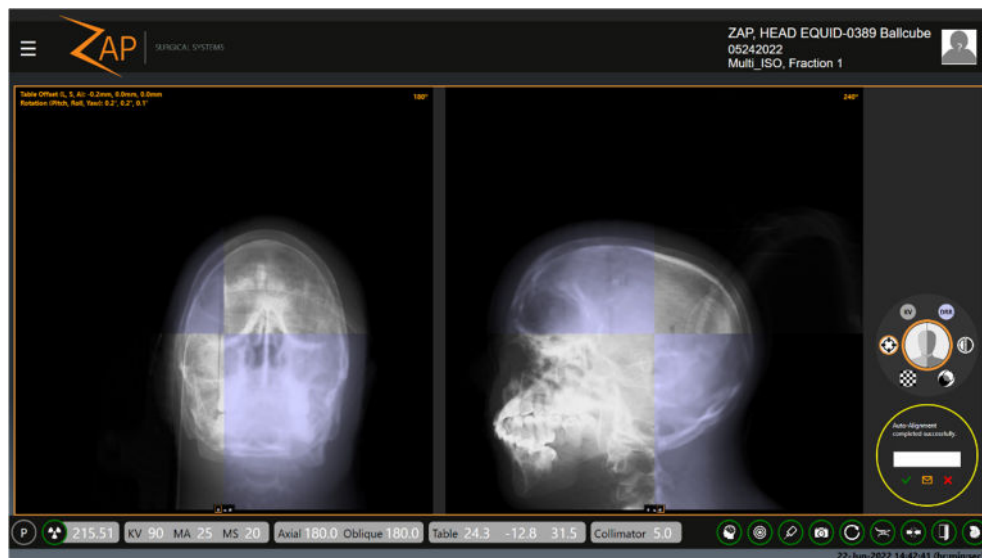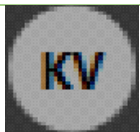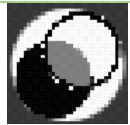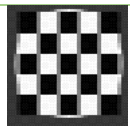

Figure 7.1.3. The completed auto-align

Figure 7.1.3 shows the output of auto-align. There are now two image windows. By default, the left window shows the most recent kV/DRR comparison from 180 degrees. The right window shows the most recent kV/DRR comparison from 240 degrees. Note each window has a set of three icons along the bottom that allow you to select any of the three angles to be displayed in either window.

The workflow wheel is displayed along the right of the screen for AA,TA, and MIT. It has the following options:

Function	Icon	Description
Crosshair		This is the default option. Each window shows a crosshair comparison of the kV/DRR from its angle. While this is displayed: • Click-and-drag to pan the image. • Click-and-release to change modes so that the cursor moves the crosshair point. • Mouse-wheel to zoom the images.
kV		Displays a kV image from each angle and provides tools to adjust the window and threshold of the kV images.
DRR		Displays a DRR image from each angle and provides tools to adjust the window and threshold of the DRR images.
Subtraction		Displays a subtraction of the two images from each angle
Blend		Blends the DRR (green) and kV (magenta) images into one image. Areas where the images match will be shown in white, whereas areas where there is a mismatch will be seen in the color of the respective images.
Checkerboard		Displays a checkerboard image that where half the images are kV and half are DRR. As with the crosshair display, you can pan/zoom the image as well as move the intersection point.

 Warning: Safe and effective treatment requires accurate patient positioning. It is your responsibility to confirm the final alignment. Carefully observe the kV image and its correlation to the DRR image.

A confirmation dialog is displayed below the workflow wheel. It contains a type-in field for you to enter the name or names of the people who have confirmed alignment. Clicking the checkmark on this dialog will dismiss the dialog and allow you to proceed with treatment. The dialog also has a "send email" icon. If this is clicked a report is sent to the pre-configured email containing a screenshot of the alignment review screen and the signatures of those individuals whose initials have been placed in the approval box (if configured). The confirmation dialog also displays a Cancel button, which returns the system to the pre-alignment state.

The screen in figure 7.1.3 does not appear until the system has determined that alignment is within a millimeter. In the unlikely event that even multiple iterations cannot achieve sub-millimeter accuracy, the system will display an error message. At that point the patient should be extracted and re-positioned before trying again.

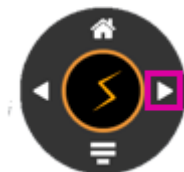Once alignment is complete, the right-arrow will be enabled to move on to treatment, as shown in 7.1.4.

Figure 7.1.4.

If the patient's head is turned in any direction by more than 3° compared to the planning CT, then the dialog shown in figure 7.1.5 will appear. Clicking the green check mark will proceed with treatment. The target will be correctly positioned at isocenter; however, the beams will enter the head at a different angle compared to the planned angle. Clicking the red X will pause progress and allow you to extract the patient and re-position.

Warning: Dose distribution throughout the head may be affected if the patient's head is not in the same orientation as during the planning CT.
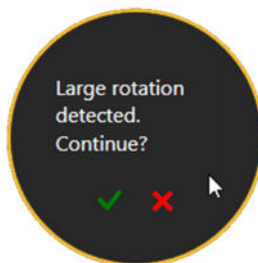

Figure 7.1.5. Patient Head Rotation.

7.1.1.   Advanced Alignment

In general, auto-align is sufficient for accurately aligning patients . If, iIn the unlikely event that the results from auto alignment to be inadequate, ZAP recommends that the patient be extracted, repositioned, and re-inserted. However, the TDS does support manual tools to perform an alignment. Use these tools carefully.

Advanced tools are invoked by clicking on ZAP logo in the center of the Workflow Wheel while in Align mode. The screen display is shown in Figure 7.2.1.
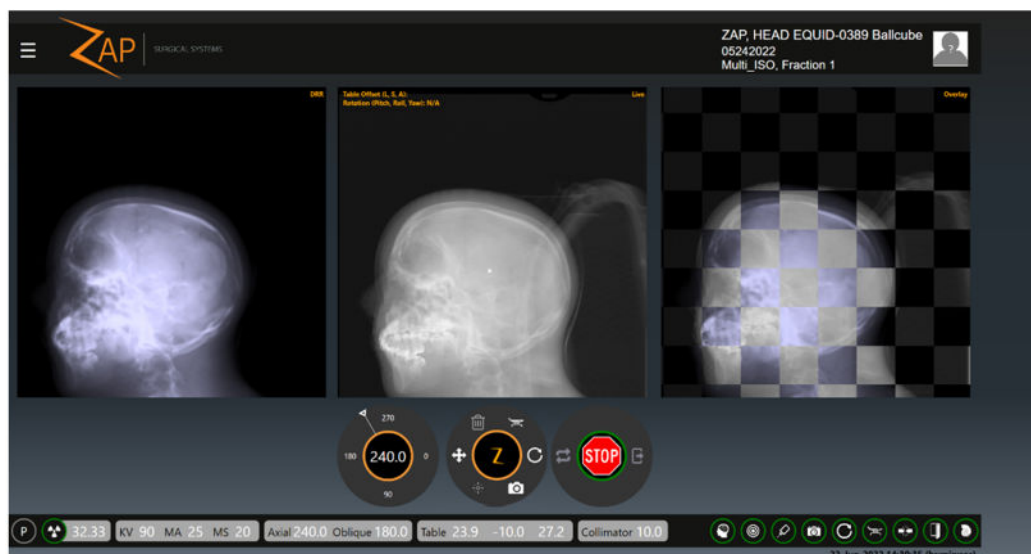
Figure 7.2.1. Advanced Align.

The advanced alignment Workflow Wheel contains the following options:

Function	Icon	Description
Move		Moves the table by the amount specified in the L, S, A, data fields shown on the left.
Acquire Image		Acquire a new kV image.
Correlate		Updates the correlation data shown in the upper left corner of the kV image but does not move the table as a result.
Rotate		Moves the gantry to the specified position.
Table init		Moves the table back to its initial location.
Clear Images		Clears previously captured images so that they will no longer be used by correlate.

7.2. Tracking and Motion Compensation

Patient movements during treatment must be tracked to make sure the target remains at isocenter during the treatment. kV images are acquired during the treatment to monitor patient movements and to calculate a correction if required.

The default interval between kV images on the ZAP-X system is 45 seconds, but this can be easily changed from 10 seconds to 120 seconds based on the user's needs. By pressing the Z logo the time intervals will show up on the dial in treatment as shown in figure below.
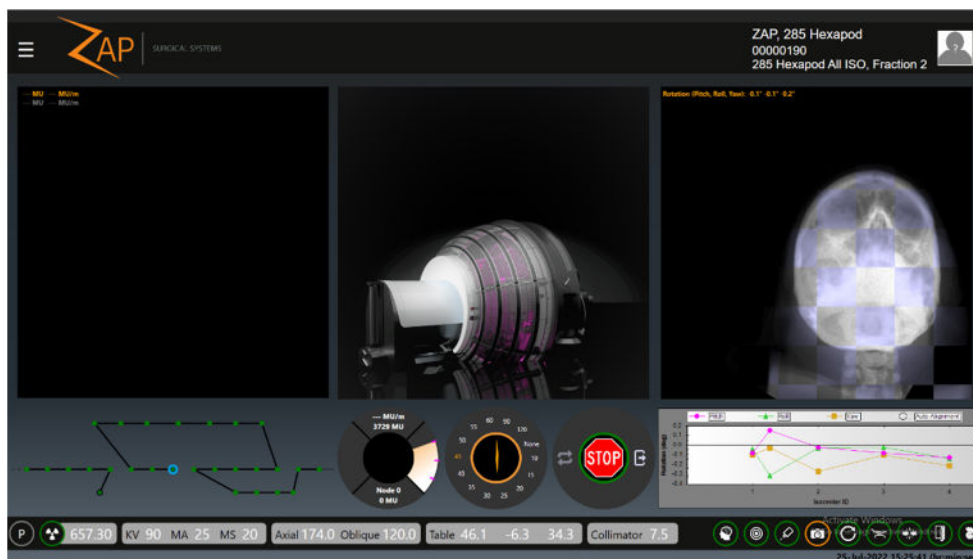
Figure 7.2.2 Screen showing time period selection between kV image acquisitions

When an image is acquired during treatment the patient position is calculated. Images should be monitored for any large movements.
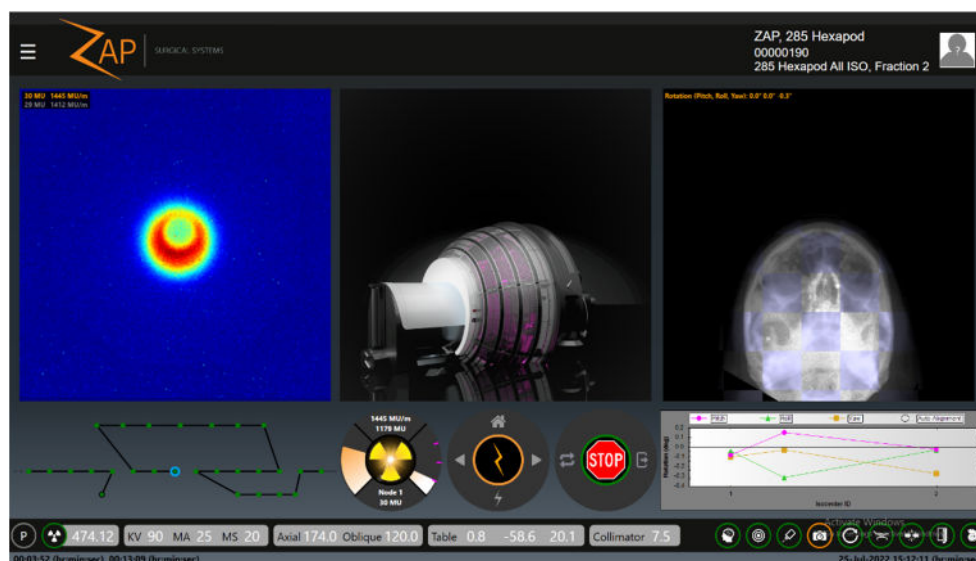

Figure 7.2.3 Screen showing review for kV images

7.3. Transitional Alignment Review

Auto-align must be done at the beginning of each fraction to ensure that the target is positioned at the machine center. Treatments often involve many target isocenters that

are close to each other. When the ZAP-X comes to the end of one target isocenter it moves the patient so that the next target isocenter is in the machine center using an operation called Transitional Alignment.

The system then acquires a kV image at the gantry position of the final beam in the previous isocenter. The gantry then follows the treatment path to the first beam that has at least a 30° difference in axial angle and acquires an image.

The two images are used to calculate the 6D offset. If the move is greater than 2 mm another round of transitional alignment is performed. For this round, images are acquired at the current gantry position and the nearest node where the axial angle is at least 30° different from the last image. However, if the solution requires a table move greater than 10 mm, then Transitional Alignment fails and Automatic Alignment is triggered. Movements less than 10 mm are made to align the patient.

When the table move made to bring the patient into alignment is less than 2 mm, Transitional Alignment is finished and the beams in the isocenter can be delivered.
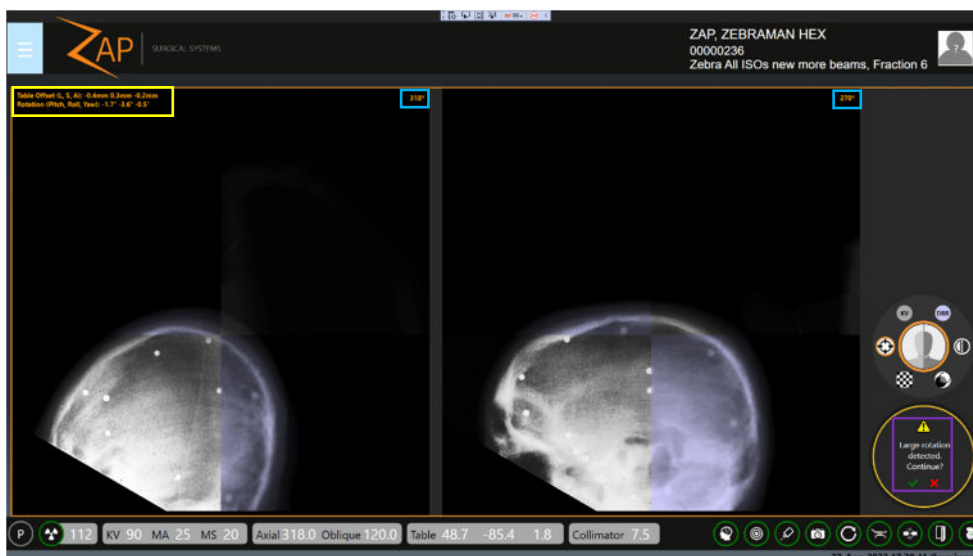

Figure 7.2.4 Screen showing TA review of kV images with DRR overlay indicating large rotation warning

⚠️ **Warning: Safe and effective treatment requires accurate patient positioning. It is your responsibility to confirm the final alignment. Carefully observe the kV image and its correlation to the DRR image.**

The yellow box on upper left provides the rotations of the CT dataset around LSA axes for the current kV image set (sign of rotations are based on correcting patient orientation at the time of CT to match DRR). The light blue boxes indicate the axial gantry angle of each kV image. And the purple box on the lower right indicates a warning issued for the user to ensure that the large angle rotation is acceptable for treatment. Hitting the green checkmark brings you to the treatment delivery view and hitting the red X will bring you to the auto-align view.
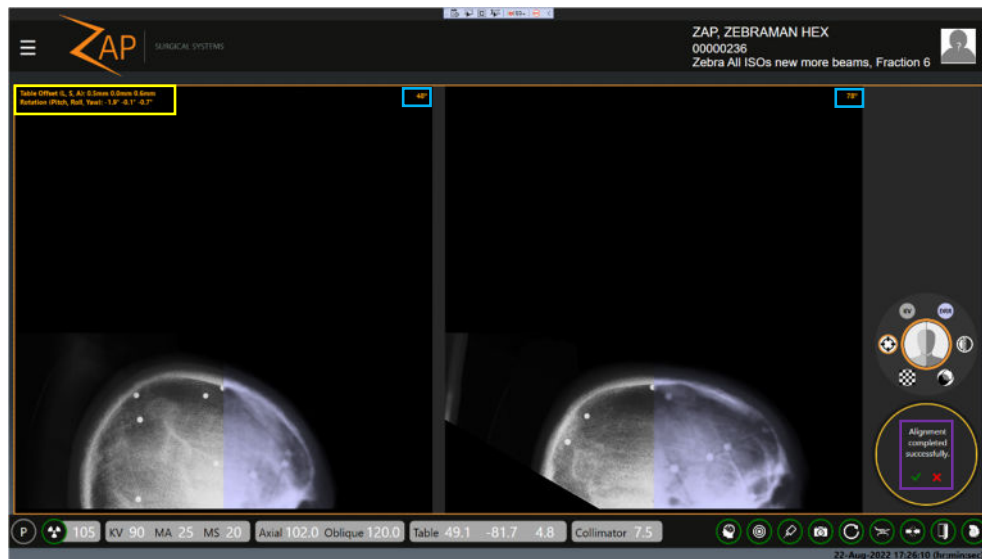
Figure 7.2.5 Screen showing TA review of kV images with DRR overlay indicating alignment status

The yellow box on upper left provides the rotations of the CT dataset around LSA axes for the current kV image set (sign of rotations are based on correcting patient orientation at the time of CT to match DRR). The light blue boxes indicate the axial gantry angle of each kV image. And the purple box on the lower right indicates completion of alignment. Checking the green checkmark will bring back the treatment delivery screen and hitting the red X will bring you to the auto-align view.

8. Delivery

This chapter describes the steps to deliver a treatment fraction to a patient.

This chapter assumes:

- The system has gone through the power-on process (Chapter 3).
- Daily QA has been performed (Chapter 4).
- The patient has been selected and a plan/fraction has been loaded (Chapter 5).
- The patient has been placed on the table and inserted into the system (Chapter 6).
- Alignment has successfully completed (Chapter 7). As a reminder, Alignment ended with a click on the "Next" icon from the alignment screen.
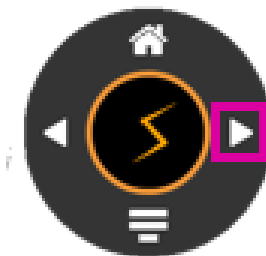
Figure 8.1. Moving from Align to Treatment.

8.1.   Overview

A plan is composed of one or more fractions. Each fraction is delivered independently of other fractions. Each fraction contains one or more isocenters where each isocenter can have a different dose and a different collimator size. Every fraction in a plan contains the same isocenters.

Each isocenter in a fraction is delivered one after another as part of one treatment session. Each isocenter has a path that is defined by the system during planning. The path determines which gantry locations are used to deliver treatment (nodes), and the gantry movement between these locations.

The path can vary between isocenters and is determined by the system based on the target location. The path is designed to keep moving parts away from the patient while at the same time delivering beams from a wide range of node locations.

8.2.   Starting Treatment: The First Isocenter

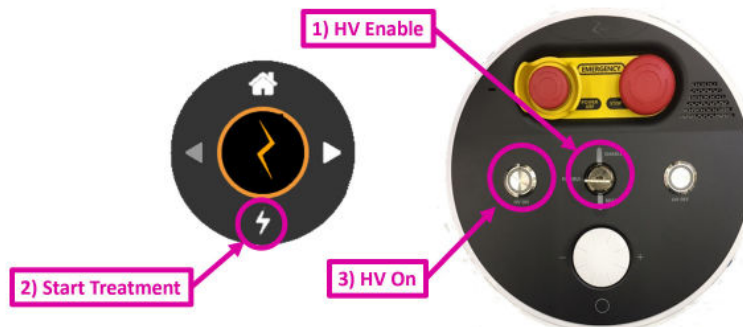Treatment is initiated with the following steps:

Figure 8.2.1. Starting a Treatment

1. Check to make sure the system key is inserted into the Operator Console and turned clockwise. This should have been done at power-up.
2. Click on the "Start Delivery" icon on the bottom of the Workflow Wheel.
3. The system will prompt you to turn on the high voltage. Press the "HV On" hard key on the Operator Console. After a few seconds you will hear the HV being active.
4. Monitor the patient throughout treatment (see sections below).
    o   Monitor the treatment progress on the main UI screen
    o   Monitor the video windows on the right screen.
    o   Listen to the patient through the built-in microphone which is always on. The volume can be adjusted through a knob on the bottom of the operator console. To talk to the patient, press the button below the volume knob.

Warning: Watch patient and equipment movement inside the treatment chamber from the video monitors on the right screen for patient movement or other issues. **If you observe any unusual proximity between patient and the equipment, press the nearest E-Stop button.**

8.3.   End of Isocenter

After the start of an isocenter delivery the system will follow the path for that isocenter, delivering the appropriate beam at each node. Typically, no operator interaction is needed while this is happening, other than the careful monitoring of the system and patient.

Once the isocenter path is complete, click on the "Next" icon on the Workflow Wheel (see Figure 8.3.1).
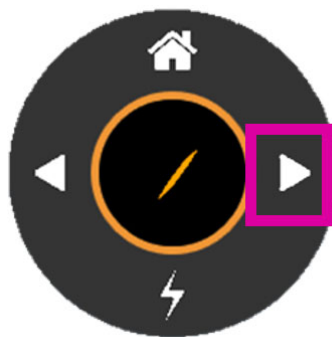
Figure 8.3.1. The "Next" Icon

If there is another isocenter in this treatment the table will move to the appropriate location for the new target. The system will then wait for the user to click the "Treat" icon, after which it will proceed to capture kV images and verify alignment at the new table position. Once this is completed the user will be prompted to press the "HV On" button and the system will start to deliver the next target.

If there are no additional isocenters the system will display a dialog to end this fraction (see Figure 8.3.2).

Figure 8.3.2. The End Fraction Dialog.

Clicking on the green checkmark will end the fraction while keeping the patient in place. You can then go to the Pendant to extract the patient from there. Clicking on the right icon will end the fraction and extract the patient.

8.4.   Proximity Errors

If a potential collision is detected during delivery the system will perform up to 3 attempts (see figures 8.4.1 and 8.4.2) to find a safe path around the potential collision and proceed to the next beam. If the system is unable to reach a delivery position that beam will be skipped, and the system will attempt to move to the next beam in the plan (see Figure 8.4.3). Any skipped beams will be placed in a make-up fraction that can be subsequently delivered. A reminder that a make-up fraction has been created will be displayed at the end of the fraction (see Figure 8.4.5).
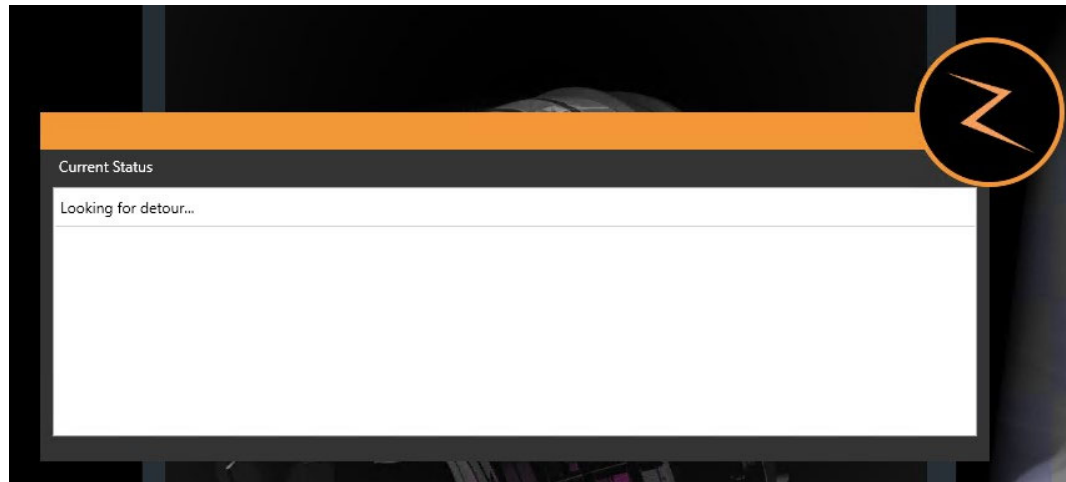
Figure 8.4.1. Detour attempts and after three failures, the beam will be skipped.
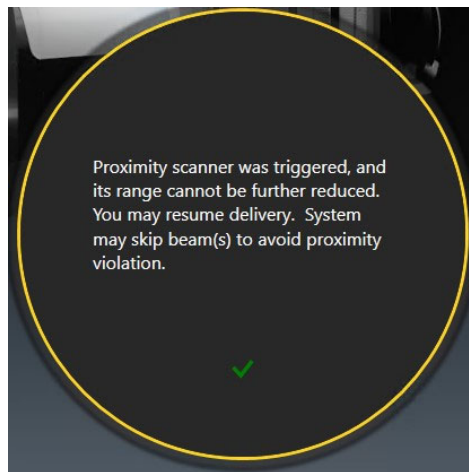

Proximity scanner was triggered, and its range cannot be further reduced. You may resume delivery. System may skip beam(s) to avoid proximity violation.

Figure 8.4.2. Selected during detour attempt to continue.

Skipping beam, and looking for detour to next beam ...
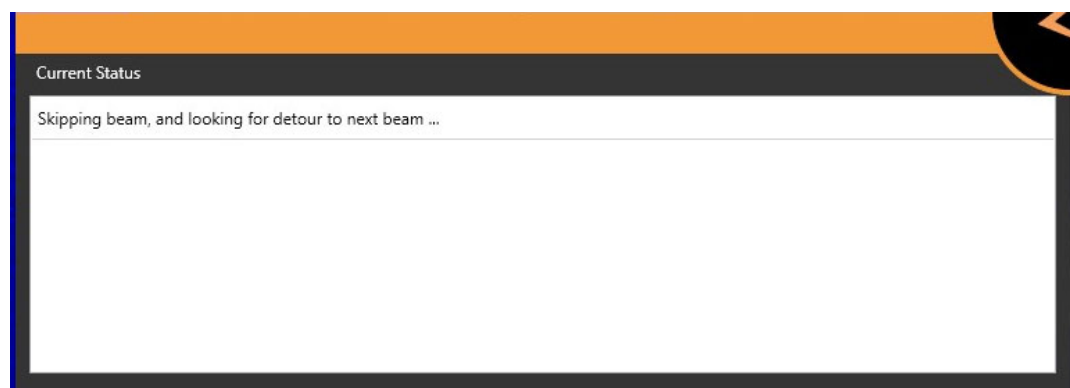
Figure 8.4.3. Message indicating a treatment beam has been skipped.
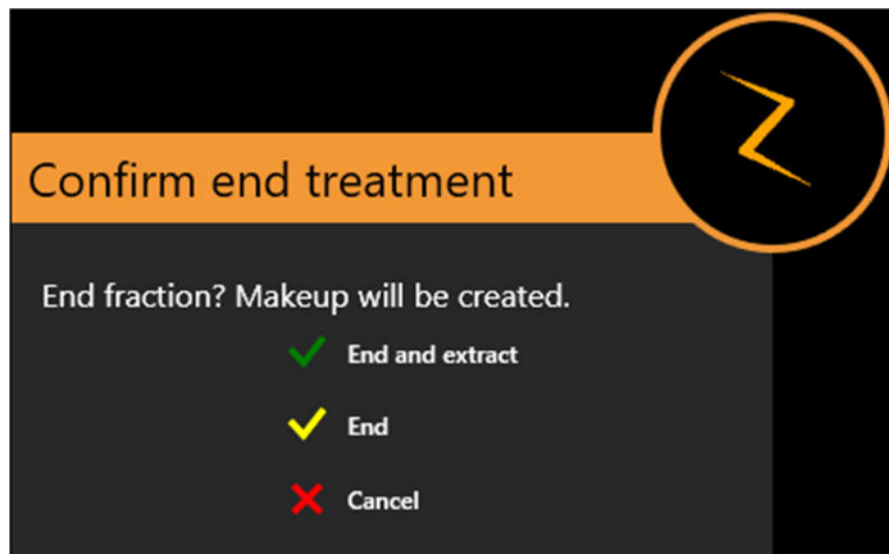
Figure 8.4.4. Confirm that a make-up fraction to be created.

Figure 8.4.5. Message at the end of a fraction indicating that a make-up fraction has been created.

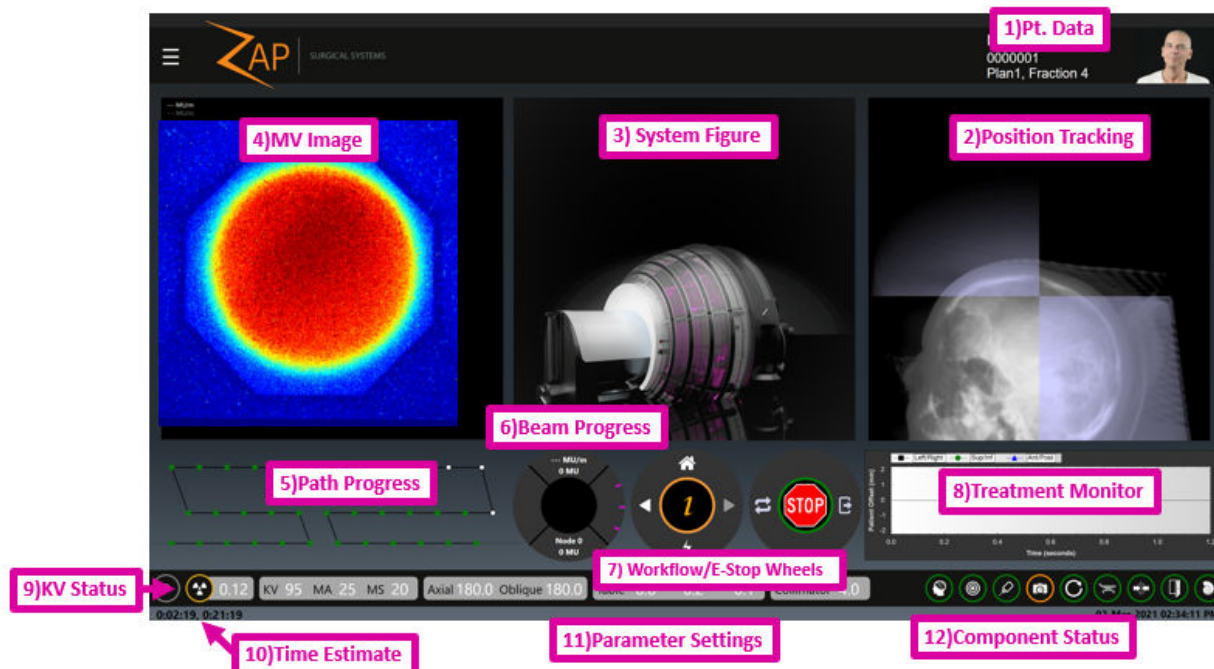# 8.5.   The Treatment Main UI Screen

Figure 8.5.1. The treatment delivery screen.

Figure 8.5.1 shows a typical treatment delivery screen, showing the elements described in the following sections:

Patient Data

The following data is shown in the upper right corner of the screen:

- A picture of the patient.
- The patient name.
- Patient ID.
- The plan name followed by the fraction number.

⚠ **Warning: Follow your institution procedures for verifying patient and plan information before starting delivery.**
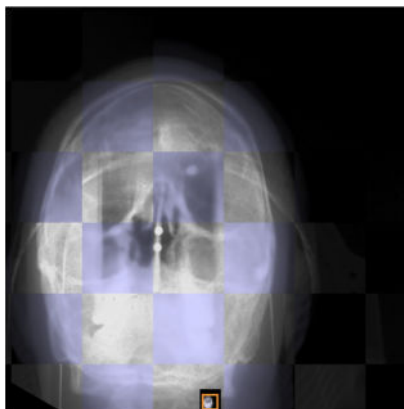
Position tracking

Figure 8.5.2. Position Tracking.

Updated kV images are regularly taken during treatment. This window compares the latest kV against a DRR from the same angle so that you can monitor possible patient movement. If the kV/DRR image display is zoomed or panned the thumbnail at the bottom of the image indicates which portion of the overall image is displayed. The view may be reset by clicking on the thumbnail.

The system will determine and apply small corrections to the table position based on each captured image. If the system determines that a new alignment is needed (such as if the patient moved) then additional kV images are taken from multiple locations and the table moved to correct alignment. No therapeutic radiation is delivered from the time that the need for a new alignment is determined until the time that the new alignment is complete.

⚠️ **Warning: Visually monitor patient movement before and during treatment delivery. If unexpected patient movement occurs, pause treatment and acquire Live X-ray images to confirm patient alignment prior to proceeding.**

A new kV image is taken every 45 seconds by default. Clicking on the ZAP-Z icon in the center of the Workflow Wheel will bring up an interaction that allows you to adjust this timing.
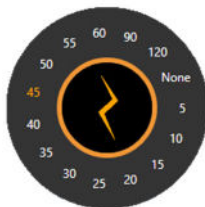

Figure 8.5.3. Advanced setting for kV timing.

⚠️ **Warning: If "None" is selected, no imaging will take place during the delivery of each isocenter, and patient motion will not be tracked. The user then becomes entirely responsible for determining whether the patient remains in the proper position. Images will still be captured at the transition between isocenters.**
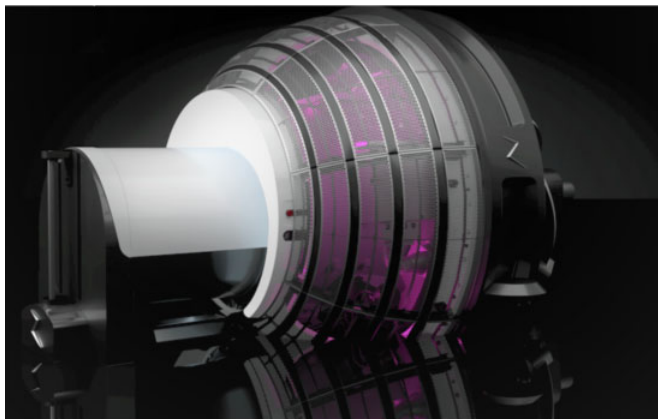
System Figure

Figure 8.5.4. System figure.

This shows a graphic representation of the system.
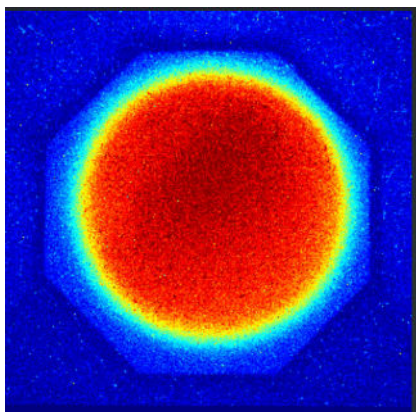
MV Image

Figure 8.5.5. The MV image.

This provides a live image of the treatment beam that has passed through the patient, providing another ongoing monitor of treatment quality.

The system will generate an E-Stop if the intensity of the measured beam is different than the expected amount. The expected amount is based on the delivered dose, minus the expected attenuation calculated from the planning CT. If the geometry of the beam is such that some of it passes through the body inferior to the bottom of the CT, the system will not be able to calculate the expected attenuation. Since the system knows the geometry of the beam it knows not to generate an E-Stop in this situation.

Depending on your system configuration, the MV Image window may also display the primary and secondary MU value.
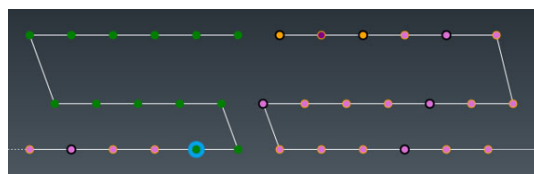
Path Progress

Figure 8.5.6. Path Progress.

Each isocenter has a pre-defined path of nodes, where each node is a unique gantry location delivering the planned dose for that location. This graphic shows the progress of treatment through the planned gantry positions.

The horizontal axis is the axial location, with 180 degrees at the center. The vertical axis is the oblique location, with 180 degrees at the top. For each node:

- o   Green dots are nodes with beams to be delivered.
- o   Blue circle indicates the current node.
- o   Orange dots are nodes already delivered.
- o   Black circle indicates that an X-Ray tracking image was taken at that node.
- o   A purple dot indicates that this MV image won't be used to assess the exit dose. (see previous section)
- o   A pink dot indicates that at the measured exit dose for that node did not agree with the expected exit dose.
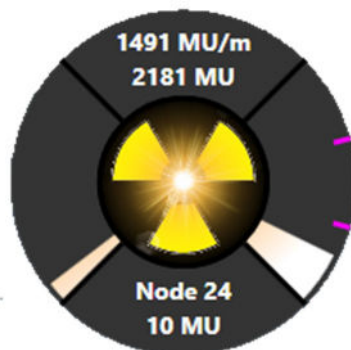
Beam Progress

Figure 8.5.7. Beam Progress.

The beam progress wheel shows the following information (clockwise from top):

- The top quadrant shows the delivery rate of the beam in MU/min. This will nominally be 1500MU/m while the beam is active, although some variability is normal. The second row shows the total MU delivered in this treatment.
- Dose information the secondary dosimeter can be viewed by placing the cursor over the top quadrant. It is also displayed in the upper left corner of the MV Image display.
- The right quadrant shows progress in this treatment session. If there are multiple isocenters then this quadrant is divided into sections by a small pink notch. Each section is one isocenter. (See Figure 8.5.7 shows 3 isocenters)

- The bottom quadrant shows the current node and how much radiation is being delivered in that node.
- The left quadrant is showing progress in delivering the current node.
- Note: the progress bar does not match the isocenter section mark if there were skipped beams.

The center of the wheel is illuminated when beam is being delivered.
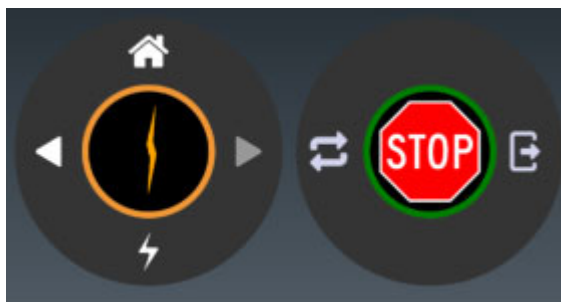
Workflow and E-Stop Wheels

Figure 8.5.8. The Workflow and E-Stop Wheels.

While treatment delivery is in progress the Workflow Wheel is greyed out, there are no further workflow options until the isocenter is complete. Clicking on the center of this wheel shows the advanced UI feature that changes the frequency of kV imaging (see section 3).

The E-Stop wheel has 3 components:

- The center shows the Stop sign. This is a software E-Stop that behaves the same as hitting an E-Stop button.
- Clear: This will clear an active E-Stop
- Extract: During an E-Stop, or at the end of the treatment, clicking this will extract the patient. Regardless of whether patient extraction is initiated from here or the pendant, the user must carefully monitor the patient during extraction.

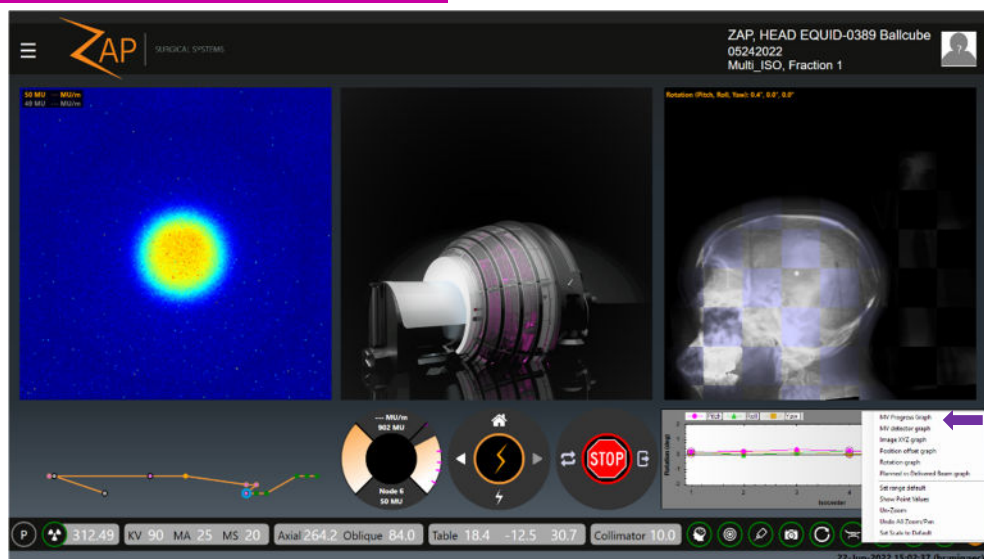## Treatment Monitor Graph

Figure 8.5.9. Treatment Monitor

The treatment monitor can show one of several different graphs tracking various quality measures as the treatment proceeds. By default, it shows an ongoing graph of the patient offset as measured by the tracking process. Separate lines show the 3 axes of potential patient movement.

Right clicking on the graph will allow you to switch to one of the following graphs:

- **MV Progress Graph**: A monotonically increasing graph showing the total MV dose detected so far in the treatment.
- **MV Detector Graph**: For each node this shows the difference between the predicted MV imager dose and the measured MV imager dose. Note that if the geometry of the beam is such that some of it passes through the body inferior to the bottom of the CT, the system will not be able to calculate the expected attenuation. These points on the graph are expected to be outliers and will be marked with an X to indicate this.
- **Image XYZ Graph**: Shows the offset between kV images and DRR images shown in image space coordinates.
- **Position Offset Graph**: Shows the offset between kV images and DRR images shown in table coordinates. Separate lines are drawn for each axis of table motion.
- **Rotation Graph**: Shows the offset between kV images and DRR images shown in table CT rotation angles. Separate lines are drawn for each axis of rotation – Pitch, Roll, and Yaw.
- **Planned vs. Delivered Beam Graph**: Shows the difference between the planned beam and the delivered beam (in MU).

X-Ray Image Status

Figure 8.5.10. kV Status.

The kV status shows the following items:

- The small radiation symbol in this section is lit while there is an X-ray exposure. This lighting persists for at least 100ms even if the actual exposure is less.
- The circle around the radiation symbol shows green when the system is in the X-ray image prep stage.
- The current setting for the next kV image, showing kV, MA, and exposure time (MS).

In general, no adjustments to kV technique should be made during treatment. If adjustments are needed for QA activities, they may be adjusted as described below.

Right-clicking on the X-ray image values will bring up sliders to adjust them. The voltage can be adjusted between 40 and 125 kV. The current can be adjusted between 20 and 125mA. The duration can be adjusted between 20 and 200ms. The following restrictions exist on these settings:
- The total power (kV * mA) cannot exceed 15 KW.
- The total current (mA * ms) cannot exceed 600.mAs.
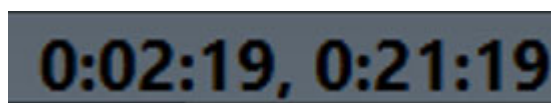
Time Estimate

Figure 8.5.11. Time Estimate.

The time estimate shows two values:

- The left side shows an estimate of the time remaining in the current isocenter.
- The right side shows an estimate of the time remaining in the current fraction. Note, this component does not count down during the time between isocenter. That time requires some operator interaction that cannot be modeled by the system.

Parameter Settings

Figure 8.5.12. Parameter Settings.

The Parameter Settings contain the following information:

- Current Gantry location: This shows the location of the Linac as indicated by the current axial and oblique axis location. Displayed units are degrees.
- Table location: This shows the current table location in LSA coordinates. Displayed units are in mm.
- Collimator: The currently selected collimator diameter, or nominal field size at isocenter. Possible sizes of the collimator in mm are: 4, 5, 7.5, 10, 12.5, 15, 20, and 25. All collimators are circular. There is also a 'Home' position which blocks beam delivery.

Component Status

Figure 8.5.13. Component Status.

This shows the status of several system components. From left to right:

- kV Imaging system
- MV Imaging system
- Linac
- Video Monitoring Cameras
- Gantry
- Table
- The Collision monitoring system
- Door
- Shell

In addition, if there is an E-Stop or system error then the System Status icon is displayed. Clicking on the System Status icon brings up the System Message Window (See Appendix A). The System Status icon does not display if there are no system messages.

For each one of the above components the following color coding is used:

- Orange: Device Not Ready.
- Green: Device Ready.
- Red: Communication with the device has failed.
- Gray: Communication with the device is not established yet.

8.6.   Video Monitoring Screen

The video monitoring screen is usually the right screen. There are seven cameras inside the system: 4 around the inside of the door pointing in, 2 on either side of the collimator, and 1 at the detector. The video monitoring screen has 4 windows. You can choose which camera feed goes to which window.

Warning: Make sure you have an unobstructed view of the patient before and during treatment.

Figure 8.6.1. The video monitoring screen.

- Double clicking on any window will put that video feed into the main window.
- Right clicking on any window displays a choice of video feeds for that window.
- Clicking on the ZAP-Z icon will toggle to a different layout of 4 equal sized windows.

8.7.   Operator Console

The Operator Console is a compact set of hardware controls that are primarily focused on safety systems. See figure 8.7.1.

Figure 8.7.1. The operator Console.

Reviewing the controls left-to-right, top-to-bottom:

- **EPO**: Emergency Power Off. This is intended for clear emergencies such as fire or flooding. It will result in a total and complete shutdown where the patient will have to be manually extracted.
- **E**-**Stop**: This is intended for routine use whenever any unexpected situation occurs. It puts the system into a safe state that is easy to recovery from.
- **HV ON**: This physical key needs to be pressed to turn on the High Voltage supply to the Linac prior to any high energy beam delivery. A few seconds after pressing this you will hear the sound of the HV supply coming from the system. It may take a few seconds after that for it to stabilize and the beam be delivered.
- **HV OFF**: You can always turn off the HV supply and end beam delivery with this button. Generally the system workflow will turn it off for you, but sometimes you will have to turn it off manually.
- **Interlock key**: This key needs to be inserted and turned on for the system to deliver the radiotherapy beam. Remove this key and keep it in a secure place when the system is not in use. The lock mechanism also has a light that turns on whenever the beam is active.
- **Volume**: Audio is always on from inside the system. This enables you to hear anything the patient is saying. Turn this volume control clockwise to increase the volume.
- **Intercom Talk**: Pressing this button lets you talk to the patient. Press and hold to continue talking.

8.8.   Interrupted and Make-up Treatment

The treatment can be interrupted at any time by pressing any E-Stop button or clicking on the E-Stop icon on the main UI. Figure 8.8.1 shows the workflow and E-Stop wheel as they look when there is an active E-Stop.

Figure 8.8.1. E-Stop icon and Workflow Wheel.

There are few controls of note in this user interface:

Clear E-Stop: This will clear any E-Stop that can be immediately cleared. The System Message box will also be displayed to provide any action that is needed to be done before the E-Stop can be cleared (See Section 2.1).

Resume Delivery: Once the E-Stop is cleared you can click the Delivery icon to resume treatment delivery. In this case there is no need to reselect the treatment parameters. The system will prompt you to press the HV button to enter the preparation state, and the system will automatically resume treatment delivery where it was.

Extract Patient: This will open the door and shell and extract the patient from the system. For example, you may need to do this if the patient had moved and needs to be re-positioned. In this case you may need to return to the home screen and select the fraction again. The system will remember which beams have been delivered. The plan will still appear in the plan/fraction selection UI (see Chapter 5).
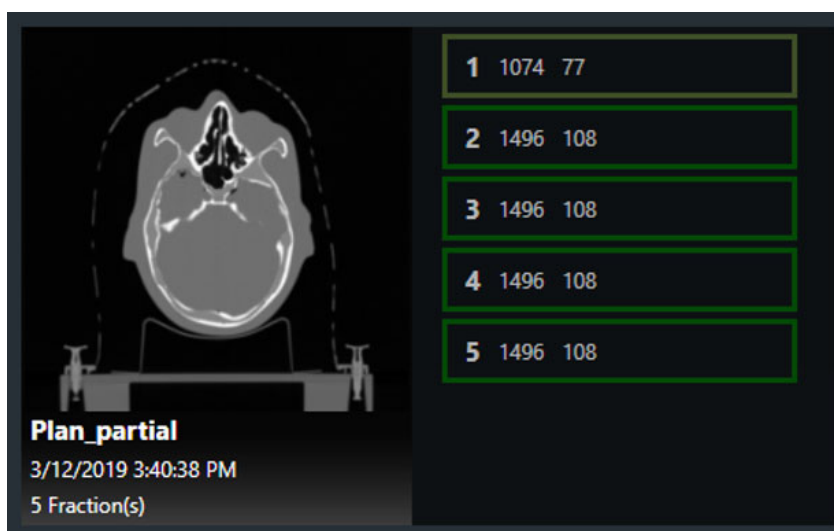

Figure 8.8.2. Partially Delivered Fraction.

Figure 8.8.2 shows a partially delivered fraction. Note that the outline around fraction 1 shows in a lighter shade of green, and the beam count is reduced. These indicate that the fraction was partially delivered, and 77 of the original 108 beams still need to be delivered.

This partially delivered fraction is now a make-up fraction. It can be selected and delivered just like any other fraction, but only the previously undelivered beams will be delivered. The patient alignment process will need to be repeated (see Chapter 7).

When this fraction is in the delivery stage the Path Progress shows the complete original path, but any delivered beams show up as white nodes. These nodes will be skipped, and the delivery will resume with the first undelivered beam. Figure 8.8.3 shows the Path Progress display for a make-up fraction that has 5 nodes remaining.

Figure 8.8.3. The Path Progress Display for a make-up fraction.

9. Extracting the patient

When a treatment is complete the Workflow Wheel will present a dialog with the following options:

- Complete this treatment. This can be used, for example, if the patient has multiple treatments scheduled. This keeps the patient in the system for the next treatment.
- Complete and extract. This is generally the more common choice. It will end the treatment and start the process of extracting the patient.

Figure 9.1. The End Fraction Dialog.

You can also extract the patient from the pendant.

If desired, an alcohol wipe may be used to clean the cushion and table surface between uses.

⚠ **WARNING: Always maintain visual contact with the patient while extracting them out of the system. Stop extraction and/or press the E-Stop hard key if there is any risk of a pinch point between the patient and any system moving part.**

10. Reporting

The Report button is the final icon on the main dashboard. It provides access to two different types of report:

- Treatment reports for specific patients and plans.
- System reports for a history of radiation and gantry angles for a range of dates.

10.1. Treatment Reports

After the treatment is complete it is common to print or save a report summarizing the treatment.

The Report button is the final icon on the main dashboard. Clicking that button brings up a user interface that lets you pick the patient, plan and fraction that you want to report on. (See figure 10.1.1)
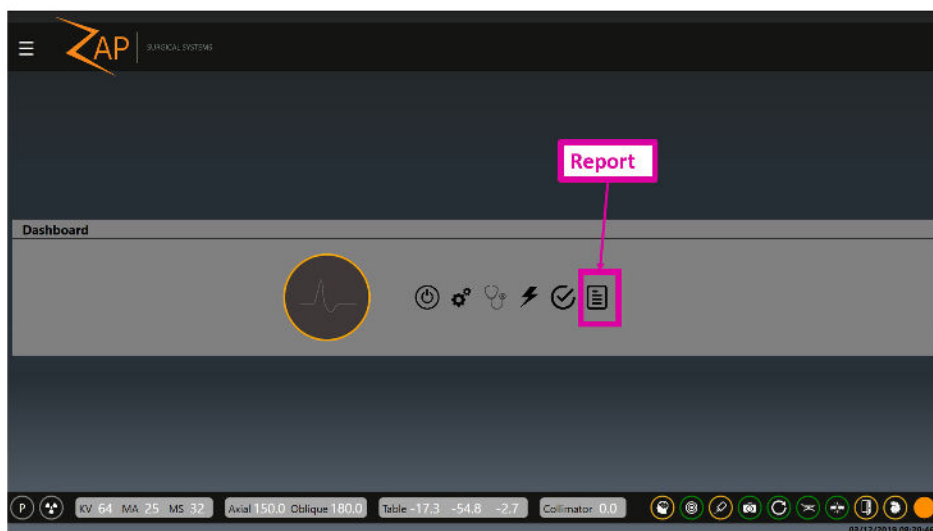
Figure 10.1.1. The Report Button.

The first screen shows a list of all patients known to the system. Note that this can be more patients than are seen when you are selecting a plan (Chapter 5) since the report list includes all patients that have had a plan delivered or have a plan to be delivered.

When you first invoke the Report function it may take a few seconds for the list of patients to display. Once the list is displayed, click on a patient to view the plans for that patient. (See Figure 10.1.2)
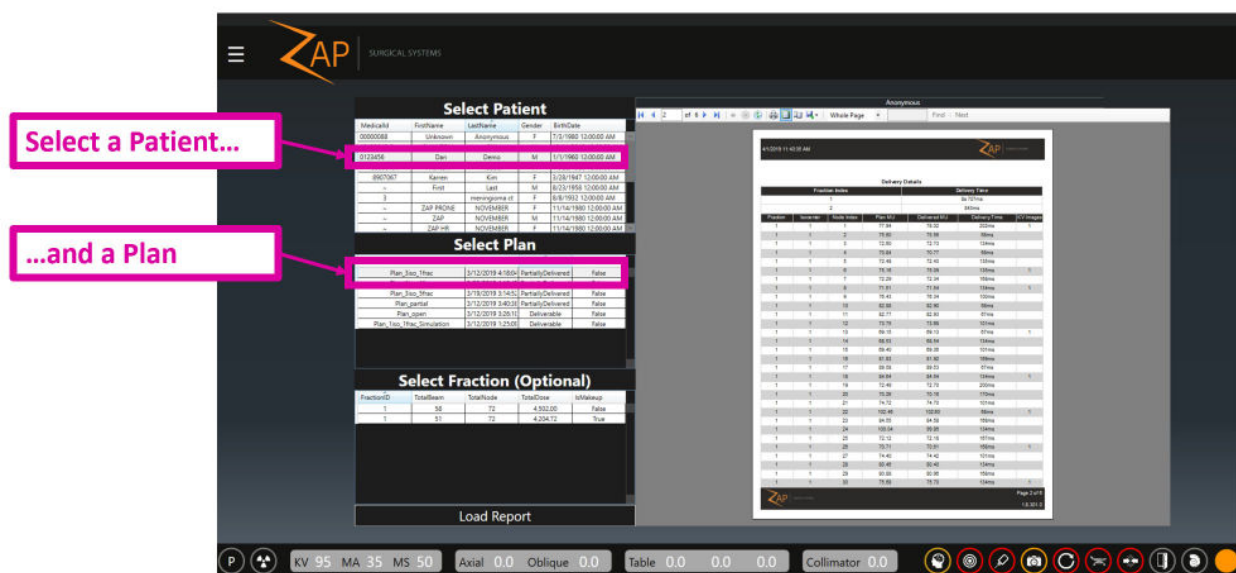
Figure 10.1.2. Selecting a Patient and Plan for a Report.

Once a plan has been selected you can either:

- Click on the Load Report button at the bottom of the page. This will load a report that includes all the fractions for that plan.
- Click on a fraction and then click on Load Report. This will load a report that includes one fraction.

➢ **To display report in single page view or double page view:**
  1. Click on the desired display button.

Figure 10.1.3. Display Options.

➢ **To print a report:**
  1. Click the Print Patient and Plan Information icon.

Figure 10.1.4. Print.

➢ **To save a report:**
  1. Click the Save Patient and Plan Information icon.

Figure 10.1.5. Save.

➢ **To email a report:**
  1. Click the Email icon.

2. Select whether you want PDF, Excel, or Word format for the document. Ask your service representative to configure the list of recipients.

The Report contains Patient Information, System Information, the Plan Summary generated from the Treatment Planning System, the Fraction Summary, and the Delivery Summary.

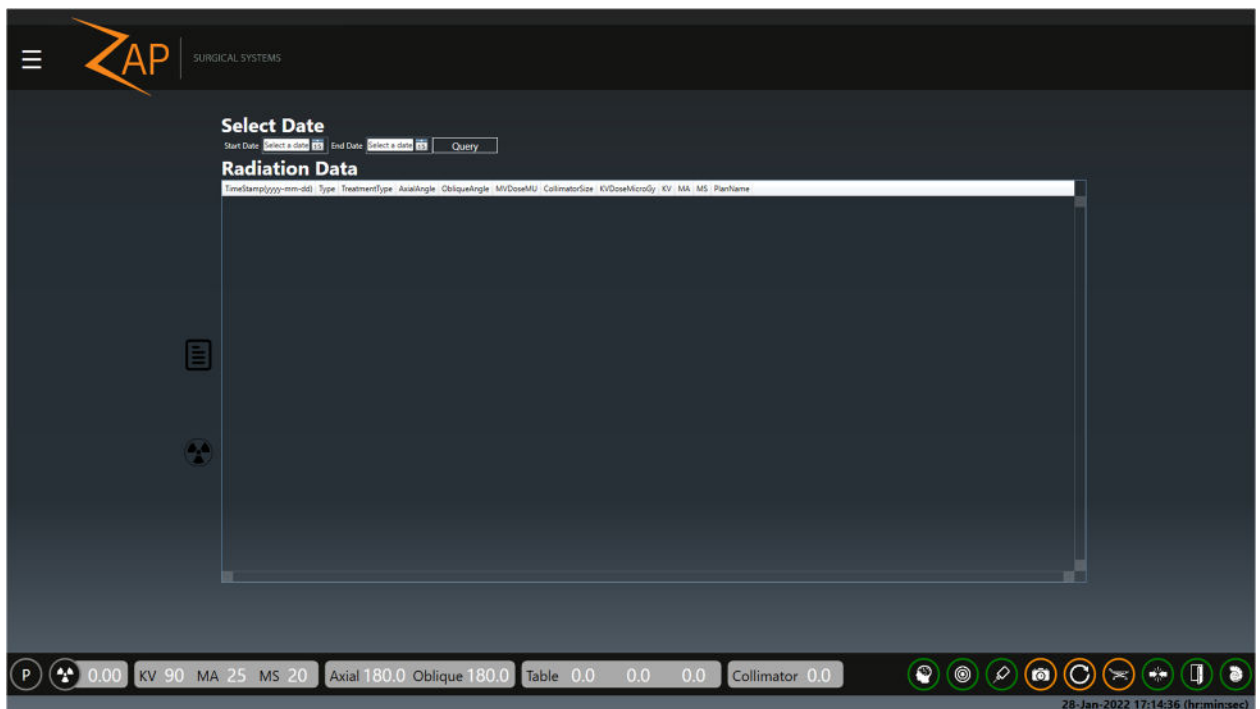**Figure 10.1.6. ZAP-X Surgical Treatment Report.**

10.2. System Reports

System Reports are accessed by clicking on the Load System Report icon on the left side of the screen.

Figure 10.2.1. System Report icon.

The Load System Report icon opens a report to allow query of kV and MV events between selected dates.

Select a start date and end date that you want the data collected from.

Click on Query to generate the report:

Click on Download to save a csv file of the data.

11. Component Details

11.1.   Understanding Gantry Motion

The Gantry consists of 2 rotating spheres, one inside the other. Each of these spheres has one of the two gantry axes of rotation. Figure 11.1.1 shows a simplified graphic that removes the shielding and other elements on the sphere, and just shows the two axes of rotation.

Note: in the following diagrams the black support stand, orange axial gimble and grey oblique gimble are all symbols to show how the gantry moves. They do not represent the real support structures of the system.
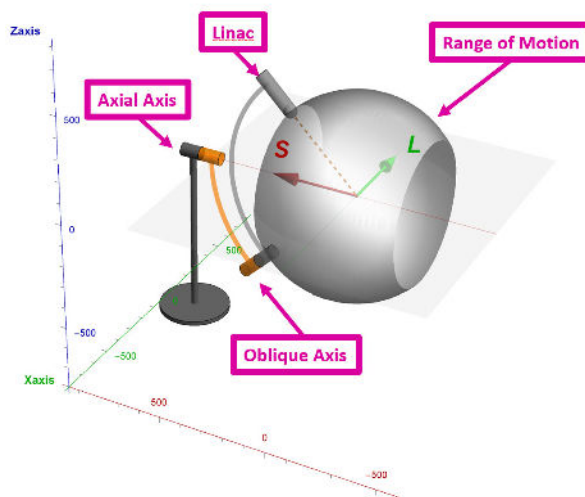
Figure 11.1.1. The Axes of Rotation.

This figure shows the system in the home position, with both axial and oblique axes at 180 degrees. The grey sphere-like graphic is the maximum range of motion for the Linac.

Axial Axis

The axial axis is aligned along the long axis of the system, going through the patient's head and feet. The axis mounting point is attached to the treatment room floor. As the gantry rotates about this axis the Linac traces a circle that is perpendicular to the axis, and thus perpendicular to the patient. Figure 11.1.2. shows the circle that the Linac moves through as the Axial Axis (orange) is rotated 360º from the home position.

89
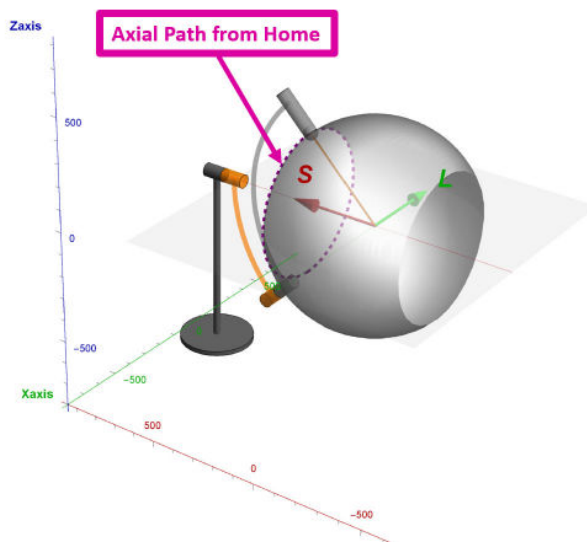
Figure 11.1.2. The Axial Path from Home Position.

Oblique Axis

The oblique axis is aligned 45º offset from the axial axis. The axis mounting point is attached to the sphere of the axial axis. As the gantry rotates about the oblique axis the Linac traces a circle that is slanted with respect to the patient, and thus it moves superior/inferior as it goes through the circle. At all times during this movement the Linac is pointed at the isocenter. Figure 11.1.3. shows the circle that the Linac moves through as the Oblique Axis (grey) is rotated 360º from the home position.
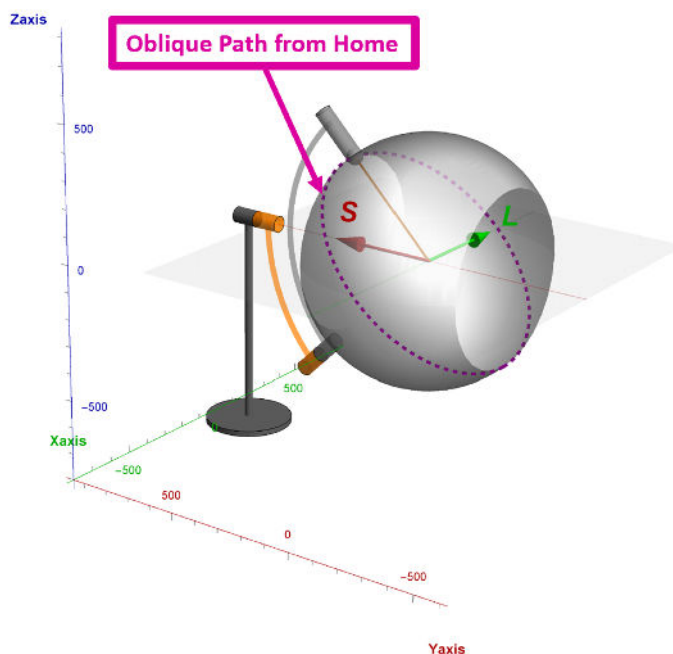
Figure 11.1.3. The Oblique Path from Home Position.

Combining the Axes

As the Oblique axis rotates, the Linac moves relative to the patient's superior/inferior line. For each Oblique location the Axial axis can rotate around a circle that is perpendicular to the patient. For example, Figure 11.1.4 shows the oblique angle rotated 90°, and the dotted line shows the circle the Linac goes through as the Axial axis is rotated from there.
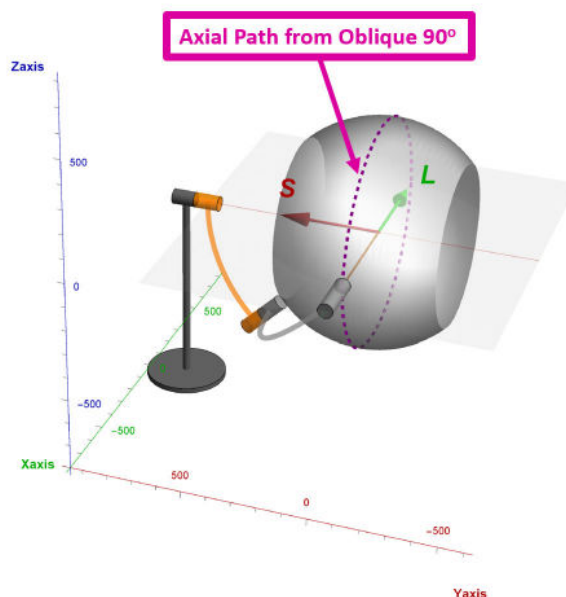
Figure 11.1.4. Axial Path when Oblique is at 90°

For each oblique angle, the axial axis will rotate around a different circle, where each circle is on the axial plane of the patient at a different superior/inferior point. When all the axial circles from all the oblique angle values are put together, it sums up to a solid angle greater than 2 x pi. This solid angle is shown as the grey sphere-like structure in these figures. This is the maximum solid angle that can be reached by the system. The actual solid angle for any plan will depend on the patient size and target location.

At all times during this motion the Linac is always pointing directly at the isocenter.

IEC 61217 Equivalence

IEC 61217 provides standards for uniform coordinate systems in radiotherapy equipment. Unfortunately, the standard does not conceive of a dual gantry system similar to the ZAP-X. However, in order to aid users in understanding the movement of the radiation source relative to the patient, the following paragraphs will describe the motions of the ZAP-X in the coordinate system described in IEC 61217. It is important to note that there are two combinations of gantry positions for each position of the source relative to the patient.

The ZAP-X Axial axis is resembled, most closely by the Gantry Rotation axis (Axis 1 in Figure 13a of IEC 61217). The motion of the oblique axis results in isocentric pitch of the

source. This motion is most closely resembled by Radiation Head Pitch (Axis 3 in figure 13a of IEC 61217), with the important difference that the center of rotation is at the isocenter. For a pure pitch motion, motion of both axes is required. For a pure roll motion, only the axial axis must move.

In order to assist the user in understanding the equivalence between the ZAP-X gantries and the IEC coordinate system, the following table is provided.

ZAP-X		IEC 61217	
Axial	Oblique	Roll (Axis 1)	Pitch (Axis 3, isocentric)
270	90	0	0
0	90	90	0
90	90	180	0
180	90	270	0
180	180	0	45
0	0	0	315

11.2.   Understanding Table Coordinates

The system table moves to position the target at the system isocenter. It has 3 degrees of movement. These are tracked using LSA coordinates:

- L: "Left" Positive values will move the table to the patient left.
- S: "Sagittal" Positive values will move the patient sagittal, further into the system.
- A: "Anterior" Positive values will move the patient anterior, further up in the system.

All three axes have a 200mm range of motion that is measured as +/-100mm from a nominal center point. However, this cube-shaped range of motion has some rounded edges, with some extreme edges not reachable. This is because, although motion is measured in rectilinear coordinates, the actual table movement side-to-side and up-down are rotations (yaw and pitch). For example, if an anterior movement is commanded the table might insert a small amount before rotating up. In this example the combination of insert and pitch-up puts the target directly up from the starting point. The small amount of target rotation introduced by this movement is accounted for in the planning and delivery software.

11.3.   The MV Imager

An exclusive feature of the ZAP-X system is the system's ability to provide an MV image. This provides a unique cross-check to the to beam delivery, ensuring that the dose that has passed through the patient is within tolerances of the prescribed dose. This MV

imager is subject to regular replacement and is a user serviceable part. The service interval is determined by its performance. As it degrades the detected dose will no longer match the expected dose, which will generate an error message. Replace the MV imager if the following message is seen: "MV Imager measurement inconsistent with delivered dose".
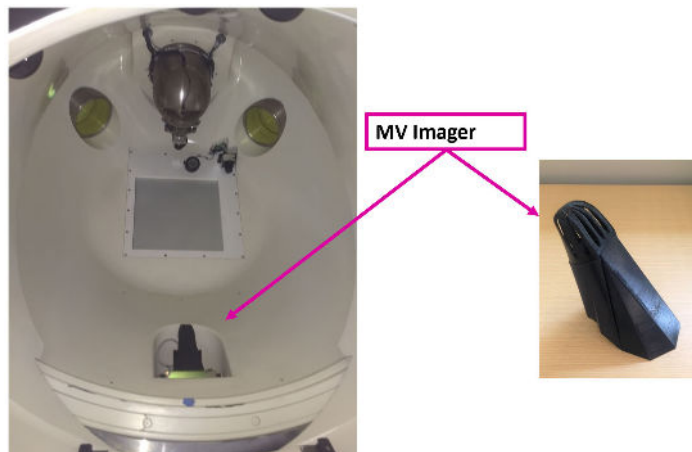
Figure 11.3. The MV Imager inside (L) and out of (R) the system.

The MV imager is held in place magnetically. It can be removed by simply grabbing it and pulling. Make sure the replacement is oriented the same way and place it in the same location. The magnets on both the imager and the system should ensure that the position is correct.
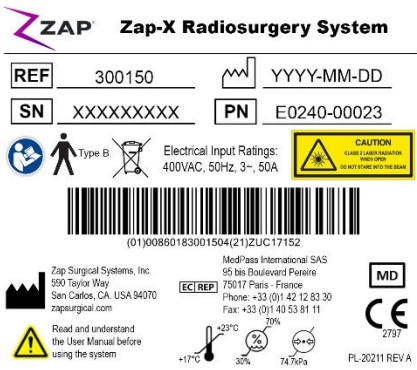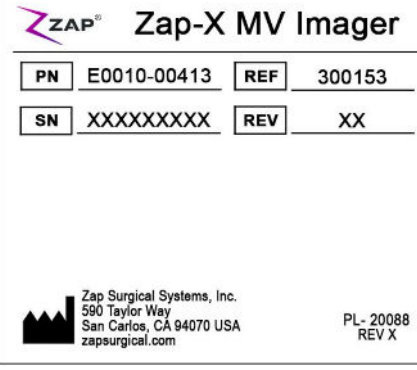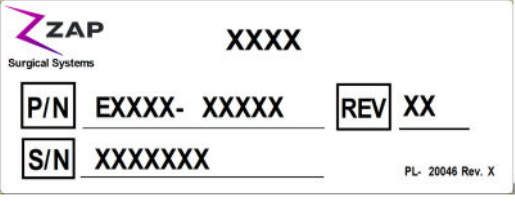
11.4.   Ionization Chambers

The ZAP-X is unique in that the dual ionization chamber is located less than 3cm downstream from the X-ray target and the ceramic based ion chamber represents a considerable beam attenuation. Therefore, the detection volumes of the primary and secondary dose monitor chambers' detection volumes are expected to detect significantly different charge signals for a given amount of dose. Any significant change in energy (20%) is expected to change the signal differential between primary and secondary chamber significantly.

As the primary chamber governs the radiation delivery, with a change in energy, the signal of the secondary chamber and the detected dose rate will be significantly different. Both absolute signal and signal rate (current or dose rate) are monitored and interlocked at 5% for dose and 10% for dose rate. This type of monitoring represents an implicit way to also monitor the energy of the beam.

12. Equipment Labels

The ZAP-X Radiosurgery System includes several symbols designed to convey safety and usage information.

	System Label Placed on Main Power Distribution Unit (PDU) (Example input ratings, UDI and label part # shown).
	ZAP-X MV Imager Label Placed on the MV Imager.
	System Sub-Assembly Label Placed on: Treatment Assembly Base Ring Axial Shield Patient Entry Main PDU Base PDU Axial PDU Axial Junction PDU Oblique PDU Axial Motor Coils, left and right Dosimeter Board Assembly Linac Control Board AFC Control Board Assembly

⚠CAUTION MAXIMUM FLOW RATE 45.42 L/M (12 GPM)	Water Circulator Rated Flow Rate Label Placed on water circulator.
⚠CAUTION Maximum Inlet Air Pressure 827 kPa (120 psi) www.ComplianceSigns.com	Vertical door Inlet Air Pressure Label Placed on air compressor near air outlet.
⚠CAUTION Use Authorized SF6 Gas Cylinder Only ⚠	SF6 Gas Cylinder Replacement Label Placed on bracket that secures SF6 cylinder, viewable upon removal of cylinder.
⚠	Electrical Hazard Label Placed on: kV Generator Pulse Unit (1x) kV Generator Control Unit (2x) Base PDU (3x) Axial PDU
⚠DANGER HIGH VOLTAGE	High Voltage Label Placed on Gun Driver
CAUTION PINCH POINT KEEP HANDS CLEAR	Pinch Point Label Placed on: Top of vertical door, one label each side, viewable when open (2x). Front of vertical door, one label each side, viewable when closed (2x). Patient table, one label each side of front end, one label each side of back end on top of rail, and one label at end on handle surface (5x).

⚠ WARNING DO NOT EXCEED WEIGHT LIMIT 300LBS/135KG ⚠	**Patient Table Maximum Load Label** Placed on patient table at loading area, one label each side (2x).
(E-Stop symbol)	**E-Stop Label (1.75" x 1.75")** Placed adjacent to E-Stop buttons around treatment chamber (3x), operator control panel and E-Stop box near control pendant
⚠ WARNING IONIZING RADIATION ☢	**Ionizing Radiation Warning Label** Placed inside treatment chamber, visible to patient.
⚠ CAUTION EMERGENCY DOOR OPEN ⚠	**Emergency Door Open Label** Placed on the treatment chamber loading stand below the red turn knob.
CAUTION X-RAY RADIATION ☢	**X-Ray Radiation Caution Label** Placed on vertical door front side, left and right (2x).
(person symbol)	**Type B Applied Part Label** Placed under handle of patient table.

	Laser Class 2 Caution Label Placed inside treatment chamber.
	Console Power Strip Label Placed on power strip in Operator Console.
~	Alternating Current
REF	Catalog Number
	Follow Instructions for Use
	Date of Manufacture
	Legal Manufacturer
	Earth Ground
	Fuses
	Neutral Electrode Isolated from Earth at High Frequency
	Potential Equalization Terminal

⭘	Power OFF
|	Power ON
♲̸	Separate Collection
SN	Serial Number
EC REP	Authorized Representative

13. Appendix A: Error Messages

⚠️ **Warning: Any hardware or software related problems should be recorded in the appropriate log and reported to ZAP as soon as possible. Failure to do so may result in injury or death to users or the patient.**

The ZAP-X Radiosurgery System displays four types of errors: recoverable interlocks, unrecoverable interlocks, recoverable Emergency Stops (E-Stops), and Soft Stops. The Error Handling screen displays information about E-stops and interlocks.

Figure A-1 shows an example Error Handling screen for a recoverable interlock. The example shows the event or events that tripped the interlock. It is important to review the entire list to understand what triggered the error. You can correct recoverable errors. If several errors have the same timestamp, correct the earliest error in the list first, because it may be the cause of the others. The most recent error is listed at the top of the list.

Some errors can be caused by hardware or software. All software-related errors and hardware errors can be either recoverable or unrecoverable. A ZAP-X Service Engineer must correct unrecoverable errors. An example of an unrecoverable software error is an incorrect data file.

The following types of error messages are described below:

- **System Messages Window**
- **Delivery Phase Error Messages**
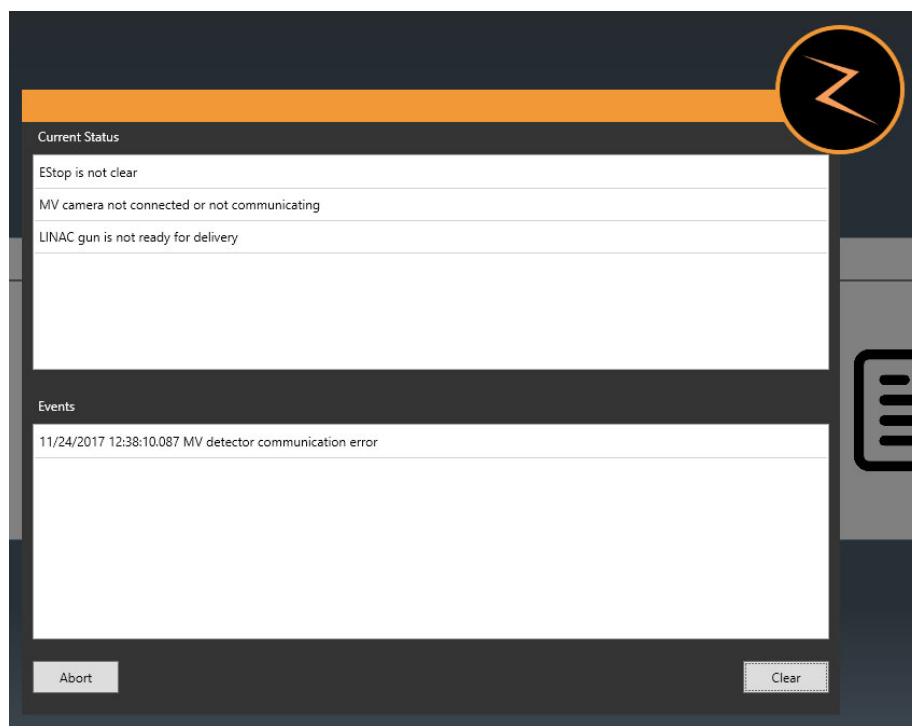
Figure A-1. System Messages Window.

An E-Stop or interlock causes termination of treatment table movement, gantry movement, and radiation delivery. If a recoverable E-Stop/Interlock occurs and is corrected, you must reset the System to continue operation. Resetting the System involves clearing all E-Stops, interlocks, and

error detection systems. After the System has been successfully reset, you can either resume treatment or a make-up fraction can be created.

Error Handling Screen Errors

Table A-1 lists all presently known errors of the System that are displayed in the Error Handling screen. Follow the suggested resolution for correcting the problem.

Table A-1. ZAP-X Radiosurgery System Error Handling Error Messages.

Error message	Resolution
Table move not allowed due to proximity violation	Clear E-Stop, and follow the prompted instruction
Table motion timed out	Clear E-Stop and retry.
Table move not allowed because table is not calibrated	Re-Initialize, and then try to move table.
Table communication error	Clear E-Stop and retry
Invalid table motion request	Acquire and correlate a new image, and use new correlation results to align the patient.
Table motion failed	Retry.
Table calibration error	Calibrate table again.
Table calibration data not found	Calibrate table again.
Table lost homing	Calibrate table again.
Table calibration failed	Calibrate table again.
Table X1 commutation failed	Calibrate table again.
Table X2 commutation failed	Calibrate table again.
Table Yaw commutation failed	Calibrate table again.
Table Pitch commutation failed	Calibrate table again.
Table X1 calibration failed	Manually drag or push the table X1 a little bit and retry table calibration.
Table X2 calibration failed	Manually drag or push the table X2 a little bit and retry table calibration.
Table Yaw calibration failed	Manually push the table left or right a little bit and retry table calibration.
Table Pitch calibration failed	Calibrate table again.
Table device init failed - check EtherCAT	Check EtherCAT connection.
Table X1 axis primary encoder error	Re-initialize the system.

Table X2 axis primary encoder error	Re-initialize the system.
Table Pitch axis primary encoder error	Calibrate table again.
Table Yaw axis primary encoder error	Calibrate table again.
Table X1 axis secondary encoder error	Calibrate table again.
Table X2 axis secondary encoder error	Calibrate table again.
Table Pitch axis secondary encoder error	Calibrate table again.
Table Yaw axis secondary encoder error	Calibrate table again.
Requested table X1 move exceeds limit	Calibrate table again.
Requested table X2 move exceeds limit	Calibrate table again.
Requested table pitch move exceeds limit	Calibrate table again.
Requested table yaw move exceeds limit	Calibrate table again.
Invalid DRR or XRay images	Acquire image again.
Image acquisition timed out	Acquire image again.
Correlation timed out	Check that live image and DRR are valid. Correlate again. If problem repeats, acquire new image.
Correlation out of bounds	Clear E-Stop and resume treatment delivery. If problem recurs, go to Setup screen and realign patient.
kV EtherCAT reading timed out	Clear E-Stop, retry
Correlation failed	Check that DRR and live image appear valid. If necessary, use manual offset mode to move table so that kV image is more closely aligned with DRR. Acquire new image and correlate.
Too many failed correlations	Clear E-Stop and resume treatment delivery. If problem recurs, go to Setup screen and realign patient.
Image acquisition failed - no plan fraction has been loaded	Select plan desired plan fraction, load again.
kV Detector cannot acquire images	Clear E-Stop, retry.
TDCS received error signal from kV generator	Clear E-Stop, retry.
kV Generator did not respond to signals	Clear E-Stop, retry.

Another E-Stop already tripped during exposure	Clear E-Stop and retry. If problem persists, call service.
kV subsystem communication error	Clear E-Stop, retry.
kV image acquisition failed	Clear E-Stop, retry.
kV image did not arrive in 4 seconds	Clear E-Stop and retry. If problem persists, call service.
Acquired partially exposed kV image	Clear E-Stop, retry.
Safety output do not allow to acquire kV image	Clear E-Stop, retry.
Correlation Detected Too Much Patient Motion	Clear E-Stop, retry.
Collimator initialization timed out	Clear E-Stop, retry.
Collimator change timed out	Clear E-Stop and retry. If problem persists, call service.
Beam delivery timed out	Clear E-Stop and resume delivery. If problem persists, call service.
HV on timed out	Clear E-Stop and resume delivery. If problem persists, call service.
Beam on timed out	Clear E-Stop and retry. If problem persists, call service.
HV turned off unexpectedly	Clear E-Stop and resume delivery. If problem persists, call service.
Collimator error while beam on	Clear E-Stop and resume delivery. If problem persists, call service.
Table not in position for beam	Clear E-Stop and resume delivery. If problem persists, call service.
Gantry not in position for beam	Clear E-Stop and resume delivery. If problem persists, call service.
Beam on too long	Clear E-Stop. Turn on beam again.
MV Imager measurement inconsistent with delivered dose	Clear E-Stop and resume delivery. If problem persists, replace the MV imager (See section 11.3)
MV detector communication error	Clear E-Stop and resume delivery. If problem persists, call service.
LINAC communication error	Clear E-Stop and resume delivery. If problem persists, call service.
MV imager calibration file not found or invalid	Call service.

MV imager measurement timed out	Clear E-Stop and resume delivery. If problem persists, call service.
MV imager camera not connected or faulty	Clear E-Stop and resume delivery. If problem persists, call service.
LINAC unexpectedly changed to not ready state	Clear E-Stop and resume delivery. If problem persists, call service.
Error attempting to turn beam on	Clear E-Stop and resume delivery. If problem persists, call service.
Error occurred during beam off	Clear E-Stop and resume delivery. If problem persists, call service.
Beam detected timed out	Clear E-Stop and resume delivery. If problem persists, call service.
Possible water leak. Extract patient immediately! Shut off chiller.	Clear E-Stop and resume delivery. If problem persists, call service.
Secondary dosimeter terminated beam - LINAC may need calibration	Clear E-Stop and resume delivery. If problem persists, call service.
Too many secondary dosimeter terminated beam errors - LINAC may need calibration	Clear E-Stop and resume delivery. If problem persists, call service.
Invalid MV imager dose prediction	Clear E-Stop and resume delivery. If problem persists, call service.
TDCS failed to login to broker	Retry. If problem persists, call service.
Plan load Failed at TDCS side	Retry. If problem persists, call service.
Failed to load plan - Could not setup TDCS with broker	Retry. If problem persists, call service.
Delivery automation logic error	Current delivery will abort, and a make-up plan will be created. The make-up plan can be delivered. Call service to report the error.
Invalid plan data	Recalculate and resave the plan. If problem persists, call service.
Plan load Failed at App side	Recalculate and resave the plan. If problem persists, call service.
Database error	Restart the software. If problem persists, call service.
Cannot create offline delivered beam folder	Restart the software. If problem persists, call service.
Gantry motion timed out	Clear E-Stop and resume delivery. If problem persists, call service.

Gantry motion not allowed because gantry origin has not been defined	Initialize gantry first, and then retry.
Gantry or table motion is already in progress	Clear E-Stop and resume delivery. If problem persists, call service.
Next motion would trigger proximity violation	Clear E-Stop and follow the prompted instruction.
Gantry communication error	Clear E-Stop and resume delivery. If problem persists, call service.
Gantry motion error	Clear E-Stop, retry.
Gantry lost homing	Clear E-Stop. Initialize gantry again.
Gantry homing error	Clear E-Stop. Initialize gantry again. If problem persists, call service.
Gantry device init failed - check EtherCAT!	Check EtherCAT connection.
Gantry moved unexpectedly	Clear E-Stop and resume delivery. If problem persists, call service.
Gantry axial encoder error	Calibrate gantry again.
Gantry axial secondary encoder error - system power cycle required	Calibrate gantry again.
Gantry axial drive fault	Calibrate gantry again.
Gantry oblique encoder error	Calibrate gantry again.
Gantry oblique secondary encoder error - system power cycle required	Calibrate gantry again.
Gantry oblique drive fault	Calibrate gantry again.
Proximity violation - software	Clear E-Stop and follow prompted instruction.
Proximity violation - scanner	Clear E-Stop and follow prompted instruction.
Simultaneous software and scanner proximity violation	Clear E-Stop. Abort delivery.
Collision subsystem communication error - delivery must be aborted	Clear E-Stop. If problem persists, call service.
Patient video monitoring system communication error	Clear E-Stop. If problem persists, call service.
User pressed Software E-Stop button	Check safety, and then clear E-Stop.
User pressed Pause button	Clear E-Stop, resume delivery.
Pendant has acquired E-Stop ownership	After pendant operations are completed, clear E-Stop,

ACS Watchdog timed out	Clear E-Stop. If problem persists, call service.
There is no user/hardware activity	Clear E-Stop, and log in again.
System initialization timed out	Clear E-Stop and resume delivery. If problem persists, call service.
Cannot connect to control computer	Clear E-Stop and resume delivery. If problem persists, call service.
E-Stop ownership changed while system in motion	Clear E-Stop and resume delivery. If problem persists, call service.
Hard E-Stop button OCC pressed	Check safety first, and then release the E-Stop button and clear Estop from Treatment App UI.
Hard E-Stop button 1 pressed	Check safety first. E-Stop 1 is on the back of the system. Turn the button clockwise to release, and then clear the E-Stop from the System Messages Window.
Hard E-Stop button 2 pressed	Check safety first. E-Stop 2 is outside the entrance of the system, on the Patient's right. Turn the button clockwise to release, and then clear the E-Stop from the System Messages Window.
Hard E-Stop button 3 pressed	Check safety first. E-Stop 3 is outside the entrance of the system, on the Patient's left. Turn the button clockwise to release, and then clear the E-Stop from the System Messages Window.
Hard ESTOP button 4 pressed	Check safety first. E-Stop 4 is at the pendant. Turn the button clockwise to release, and then clear the E-Stop from the System Messages Window.
Software STOP button pressed	Check safety first, and clear E-Stop.
Timeout	Restart the application.
Scanner1 tripped	Scanner 1 is outside the system on the Patient's right. Clear field, and then Clear E-Stop.
Scanner2 tripped	Scanner 2 is outside the system on the Patient's left. Clear field, and then Clear E-Stop.
Collision1 tripped	Review the video monitors for anything that might have tripped the monitor, such as a patient's blanket. If necessary, extract the patient and re-insert.
Collision2 tripped	Review the video monitors for anything that might have tripped the monitor, such as a patient's blanket. If necessary, extract the patient and re-insert.
Alignment failed	Clear E-Stop and try again. If error persists, call service

Tracking failed	Clear E-Stop and try again. If error persists, call service
XRay imaging error	Clear E-Stop and try again. If error persists, call service
Patient motion	Clear E-Stop and try again. If error persists, call service
LINAC error	Solve corresponding Linac errors first, and clear Estop.
Door opened	Check that vertical door is closed. Clear Estop and resume delivery. If problem persists, call service.
Door pressure is too low	Call Service
Hardware movement	Clear E-Stop and try again. If error persists, call service
Shell error	Clear E-Stop and try again. If error persists, call service
Shell opened	Clear E-Stop and try again. If error persists, call service
Power error	Clear E-Stop and try again. If error persists, call service
MV image check error	Clear E-Stop and try again. If error persists, call service
MV image error	Clear E-Stop and try again. If error persists, call service
Collimator position error	Clear E-Stop and try again. If error persists, call service
Collimator calibration error	Clear E-Stop and try again. If error persists, call service
Linac verification error	Clear E-Stop and try again. If error persists, call service
Linac safety error	Clear E-Stop and try again. If error persists, call service
Application conflict	Clear E-Stop and try again. If error persists, call service
Linac Steering 1 error	Clear E-Stop and try again. If error persists, call service
Linac Steering 2 error	Clear E-Stop and try again. If error persists, call service

Linac water flow load out of bounds	Clear E-Stop and try again. If error persists, call service
Linac water flow circulator out of bounds	Clear E-Stop and try again. If error persists, call service
Linac water flow magnetron out of bounds	Clear E-Stop and try again. If error persists, call service
Linac water flow target out of bounds	Clear E-Stop and try again. If error persists, call service
Linac SF6 low	Clear E-Stop and try again. If error persists, call service
Linac SF6 high	Clear E-Stop and try again. If error persists, call service
Door close blocked: table optical sensors are not clear	Clear E-Stop and try again. If error persists, call service
Disconnecting error	Clear E-Stop and try again. If error persists, call service
Invalid request error	Clear E-Stop and try again. If error persists, call service
Dose conflict error - LINAC may need calibration	Clear E-Stop and try again. If error persists, call service
Dose threshold error - LINAC may need calibration	Clear E-Stop and try again. If error persists, call service
Dose timeout error	Clear E-Stop and try again. If error persists, call service
Table Axis X1 error	Clear E-Stop and try again. If error persists, call service
Table Axis X2 error	Clear E-Stop and try again. If error persists, call service
Table Pitch error	Clear E-Stop and try again. If error persists, call service
Table Yaw error	Clear E-Stop and try again. If error persists, call service
Gantry Motion error	Clear E-Stop and try again. If error persists, call service
Oblique Motion error	Clear E-Stop and try again. If error persists, call service
Axial anti rotation mechanism was tripped	Clear E-Stop and try again. If error persists, call service

Oblique anti rotation mechanism was tripped	Clear E-Stop and try again. If error persists, call service
PLC error	Clear E-Stop and try again. If error persists, call service
Watchdog timeout (TDCS)	Clear E-Stop and try again. If error persists, call service
Watchdog timeout (TDCSActivity)	Clear E-Stop and try again. If error persists, call service
Watchdog timeout (Pendant App)	Clear E-Stop and try again. If error persists, call service
Watchdog timeout (LinacApp)	Clear E-Stop and try again. If error persists, call service
Watchdog timeout (MotionApp)	Clear E-Stop and try again. If error persists, call service
Watchdog timeout (Primary Dosimeter)	Clear E-Stop and try again. If error persists, call service
Watchdog timeout (Secondary Dosimeter)	Clear E-Stop and try again. If error persists, call service
Gate update loop exited	Clear E-Stop and try again. If error persists, call service
Dosimeter error	Clear E-Stop and try again. If error persists, call service
AFC error	Clear E-Stop and try again. If error persists, call service
Gun driver error	Clear E-Stop and try again. If error persists, call service
TwinCAT error	Clear E-Stop and try again. If error persists, call service
ACS EtherCAT error	Clear E-Stop and try again. If error persists, call service
Script error	Clear E-Stop and try again. If error persists, call service
TDCS version and Broker version do not match!	Clear E-Stop and try again. If error persists, call service
Firmware/software of subsystem(s) does(do) not match!	Clear E-Stop and try again. If error persists, call service

14.Appendix B: Cushion Cover Cleaning Instructions

Cleaning Instructions*	
Scope	These instructions apply to the reprocessing of the Table Top Cushion (Cushion). The Cushion shall be cleaned after each patient use, using the instructions that follow.
Warnings	Do not expose the Cushion to non-approved chemical solutions (i.e., solutions not listed in this IFU).
Limitations on Reprocessing	The Cushion does not have an indefinite serviceable life. The end of life is determined by wear and damage caused during repetitive use and cleaning. Do not use damaged or defective Cushions (i.e., Cushions with tears, holes and/ or cracks).
Preparation before Cleaning	1. Cleaning procedure should begin as soon as possible following use to prevent soil from drying. 2. Remove linens from the Cushion.
Cleaning: Manual Only	The following will be required for cleaning: 1. 70% Isopropyl Alcohol (IPA) 2. Non-linting wipes Cleaning Procedure: 1. Wet a non-linting wipe with 70% IPA. 2. Thoroughly wipe all exterior surfaces of the Cushion. 3. Thoroughly wipe visibly soiled areas for a minimum of 30 seconds and until visibly cleaned. 4. Replace soiled wipes, as needed, to ensure all surfaces are visibly clean.
Drying	Thoroughly dry all surfaces using non-linting wipe(s).
Visual Inspection	1. Visually inspect the Table Top Cushion exterior surfaces for cleanliness and integrity in a well-lit area. 2. If visible soil remains, re-clean the Cushion. If the integrity of the Cushion is in question, replace the Cushion. Note: Do not use damaged or defective Cushions (i.e., Cushions with tears, holes and/ or cracks).

*These instructions have been validated by ZAP Surgical System, Inc. as being capable for preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using materials and personnel in the clinical setting, achieves the desired result.

15. Glossary

Numeric

2D: Two-dimensional image. One image from an imported series, or a DRR reconstructed from a series.

3D: Three-dimensional image. An imported series, or an image reconstructed from an imported series.

A

Automatic Fusion: Intensity-based registration of the primary image series with a secondary image series. Done during planning.

Auto align: Aligning the patient's head to the primary image series.

Axial axis: On the main gantry, the axis of movement that rotates about the centerline of the system.

B

Beam Data: Data measured during commissioning that is used to generate dose information. This includes Tissue Phantom Ratio, Off-Center Ratio, and Output Factor.

C

cGy: Centigray

Click: Press the primary mouse button. On most computers this is the left button. See also:
Ctrl-click: Hold down the CTRL key and press the primary mouse button.
Double-click: Press the primary mouse button twice in rapid succession.
Right-click: Press the secondary mouse button.
Shift-click: Hold down the Shift key and press the primary mouse button.

Commissioning: The process of importing the beam data from direct measurements, reviewing and applying the result distribution of radiation of the phantom

Critical Structure: OAR

CT: Computed Tomography

D

DICOM : Digital Imaging and Communications in Medicine

Door: The portion of system shielding that lies at the foot of the patient table.

Drag: Position the cursor over an area of interest, click, hold the button down, and move the mouse to select an area, create a window, or relocate a selected item.

DRR: Digitally Reconstructed Radiograph. A 2D image reconstructed from a 3D data set. In general, this is used to create a simulated X-ray image that corresponds to a current kV image.

DVH: Dose Volume Histogram

E

Extract: The process of removing a patient from the system.

F

Field Size: The size of the radiation field. Usually defined at a reference SAD. ZAP-X field sizes are defined at 450mm SAD.

FOV: Field of View

Focus Point: The point where the Axial, Coronal, and Sagittal views intersect.

Forward Planning: A technique for creating a treatment plan by manually specifying the isocenter location and dosimetry. In this process, the user specifies the geometry of the beams and the computer calculates the radiation effects.

Fuse: To combine two image series so they are registered to each other.

G

Gantry: The movable structure that holds the Axial axis, the Oblique axis, and associated shielding.

GUI: Graphical User Interface.

H

Hold: Press the mouse button and hold it down while you perform another function.

HV: High Voltage. The high voltage source needs to be active before the MV treatment beam is enabled.

I

Inverse Planning: A technique where the user specifies the goal dosimetry, and lets the computer determine the geometry of the beams and weights of the beams.

Isocenter: The point in space where all treatment beams intersect.

Isodose Curve: A visual representation of dose values on the patient image.

J

K

kV: KiloVolt. The unit of measure for the strength of the patient positioning imaging system.

kV image: A digital X-ray. Generally used to establish and track patient position during treatment.

L

Linac: Linear Accelerator. The source of the therapeutic radiation.

M

MR: (or MRI). Magnetic Resonance Imaging

MU: Monitor Unit

MV: MegaVolt. The unit of measure for the strength of the therapeutic radiation.

N

Node: A specific axial/oblique location of the gantry used to deliver a beam.

O

OAD: Off Axis Distance.

OAR: Organ At Risk.

OCR: Off-Center Ratio

OF: Output Factor.

Oblique axis: On the main gantry, the axis of movement that rotates about a line that is 45 degrees offset from the axial axis.

P

PDD: Percent Depth Dose

Path: The set of nodes that together make of the planned beams, along with the gantry movements that go from node to node.

Planning CT: The CT series that is used to position the patient. Another series (CT or MR) can be part of a plan to visualize the target, but the planning CT is what is used to align the planned target location with the delivered target location.

Primary Image Series: The CT series that is used to align the treatment plan to the patient position during delivery.

Q

Quadrant: The typical TPS layout shows a 4:1 image screen. Counterclockwise from upper left this includes the Axial, Coronal, and Sagittal views through the patient images.

R

Ray-Trace Planning: See Forward Planning

S

SAD: Source-Axis Distance

Scroll: Rotate the scroll wheel on the mouse.

Secondary Image Series: A second image series that can be fused with the primary image series as an aid to visualization during the planning process. This can be a CT or an MR series

Select: Place the cursor over the item of interest and click once.

Shell: The portion of system shielding that rotates over the patient table.

Simulated Plan: A plan that is developed on a real patient, and then remapped to a phantom.

SSD: Source-to-Surface Distance

T

TDS: Treatment Delivery Software. The ZAP-X software application used to manage treatment delivery.

TPR: Tissue Phantom Ratio.

TPS: Treatment Planning Software. The ZAP-X software application used to manage treatment planning.

U

V

VOI: Volume of Interest

W

Workflow Wheel: The User Interface paradigm used by both TPS and TDS is to walk through a typical workflow using the Workflow Wheel.

X

X-Ray: In this manual the term "kV Image" is used to refer to X-Ray images taken during treatment.

Y

Z

ZAP-X: The ZAP-X Radiosurgery System.

16. Specifications

The ZAP-X Surgical System complies with all national and international regulatory requirements.

Standards Applied	Standard Title
IEC 60601-1	MEE, Part 1: General requirements for basic safety and essential performance[1]
IEC 60601-1-2	Collateral standard: Electromagnetic compatibility - requirements and tests[1]
IEC 60601-1-6	MEE- Part 1-6: General requirements for safety - Collateral standard: Usability
IEC 60601-2-1	MEE- Particular requirements for safety – Specification for electron accelerators in the range 1 MeV to 50 MeV[1]
IEC 62366	Medical Devices -- Application of Usability Engineering to medical devices
IEC 60825-1	Safety of laser products - Equipment classification and requirements[1]
IEC 62083	MEE- Requirements for the safety of radiotherapy treatment of planning systems[1]
IEC 61217	Radiotherapy equipment - Coordinates, movements, and scales (12-267)
IEC 62304	Medical device software - Software life-cycle processes

Product Classification: Class I (Grounded Equipment)

Product Classification: Type B applied Part

Rated Supply Voltages: 208V/480V

Rated Frequency: 3Ph 50/60 Hz

Rated Power Input: 36kW

IPX0: "ordinary", not protected against ingress of liquids.

Equipment is considered continuous operation with intermittent loading as defined by IEC 60601-1.

16.1. Transportation and Storage

Ambient temperature: -25 °C to +55 °C
Ambient relative humidity: 10% to 85% non-condensing
Altitude (non-pressurized): <2500 meters (with respect to sea level)
System Components: Must remain in packaging until installation
Outdoor exposure to weather (sun, wind, rain, snow, ice, dust, sand, etc.): None

16.2. Operating Environment

Ambient temperature: +17 °C to +23 °C
Ambient relative humidity: 30% – 70% non-condensing
Altitude (non-pressurized): <2500 meters (with respect to sea level)

16.3. MV Specifications

Dosimetry SE87+B14:C14	A two-channel primary/secondary dosimetry system is provided
X-ray Energy	3MV Nominal Photon Energy
Depth of Maximum Dose (Dmax)	7 mm ±2 mm
Dosimetry Linearity	Dosimetry linearity with total dose is less than ±1% or ±1 cGy, whichever is greater over an accumulated range of 10 cGy to 1000 cGy, measured at 450 mm SAD within the operating temperature and pressure range
Quality Index	Quality Index is measured at two collimator settings: 25 mm Quality Index is 0.3736 and at 10 mm Quality Index is 0.3687.
Leakage	Leakage in the patient plane is less than 0.2% maximum and 0.1% average Scatter 1 m from the radiation head is less than 0.1%
Collimator Transmission	< 0.1%

Beam Targeting	ZAP-X System uses a rotating collimator wheel with 8 different collimator sizes: 4 mm, 5 mm, 7.5 mm, 10 mm, 12.5 mm, 15 mm, 20 mm, and 25 mm (all circular field diameters).
Penumbra	<2.25mm @Dmax of 7mm using 25mm field size

16.4.   kV Specifications

Constant Potential Power Rating (kw)	15
Radiographic kVp range	40-150 ± (5% + 1 kVp)
kVp Resolution	1 kVp
mA Range and Stations	10-150 mA 18 steps ± (6% + 1 mA)
Power Output	192 mA @ 78 kVp 150 mA @100 kVp 120 mA @ 125 kVp 100 mA @ 150 kVp
mAs	0.5 – 600 mAs

Circuit	3-phase
Nominal tube voltage	40 – 150 kV
Nominal focal spot value	Large focus: 0.8 mm Small focus: 0.4 mm
Nominal Anode input power	Large focus: 45 kW Small focus: 15 kW
Aluminum Filter	0.7 to 0.91 mm
Firing Modes	Synchronous and Asynchronous
Collimator Type	Fixed Aperture
Detector Type	Amorphous Silicon
Number of Pixels	2048 x 2048
Pixel Pitch	200 µm
Total Area	20 x 20 cm2
MTF @ 0.25 lp/mm	MTF 63% (1 cy/mm)
MTF @ 1 lp/mm	MTF 31% (2 cy/mm)
DQE @ 0.25 lp/mm, 1 µGy	DQE 67% (0 cy/mm)
DQE @ 1 lp/mm, 1 µGy	DQE 36% (2 cy/mm)

16.5.   Electromagnetic Compatibility

- The ZAP-X system has been tested for EMC compliance to IEC 60601-1-2: 2014 EMC standard.

The ZAP-X system has been tested and found to comply with the limits of the standard for medical devices, IEC 60601-1-2, related to patient safety. The limits are designed to provide reasonable protection against harmful interference in a hospital installation. This equipment generates, uses and can radiate radio frequency energy, and, if not installed and used in accordance with ZAP's instructions may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment causes interference with other devices, which

may be determined by turning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:

°   Reorient or relocate the device receiving the interference.
°   Increase the separation between the equipment.
°   Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
°   Consult the manufacturer or field service technician for help.

ESD Sensitivity Warning:
°   An ESD discharge may cause a network fault, which will result in an E-Stop condition and the condition will be displayed on the operator interface. Should this occur, click "Clear" to acknowledge the disruption and then remove the E-Stop condition. Once the E-Stop condition has been removed the treatment may resume from the point at which the E-Stop occurred. Should this condition continue to occur, stop the treatment and contact ZAP's technical support for assistance.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The ZAP-X System is intended for use in the electromagnetic environment specified below.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The ZAP-X System should be located in a secure room away from other equipment. It is recommended to not use cell phones or other radios in the vicinity of the system during operation.
RF Emissions CISPR 11	Class A	N/A

Guidance and Declaration - Electromagnetic Immunity			
The ZAP-X System is intended for use in the electromagnetic environment specified below.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC 60601-4-2	±6kV Contact ±8kV Air	N/A	Floors should be concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast transient / Burst IEC 61000-4-4	±2kV Power Cord ±1kV Other Cables	N/A	Mains power should be that of a hospital.

Surge IEC 61000-4-5	±1kV Line to Line ±2kV Line to Earth	N/A	Mains power should be that of a hospital.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 KHz 3 V/m	3 V 3 V/m	Portable and mobile communications systems including cellular telephones and two-way radios can interfere with ZAP-X System operation. These systems should be used no closer than 3 meters from any part of the ZAP-X System or its associated cables. Interference may occur in the vicinity of equipment marked with the following symbol: ((((•))))

The ZAP-X system's Essential Performance is to deliver accurate radiation doses to the correct location within the body. Essential Performance was not affected by the test conditions of IEC60601-1-2:2014.

Minimum recommended Separation Distances Between Portable and Mobile RF communications Equipment and the ZAP-X System		
The ZAP-X System is intended for use in an electromagnetic environment in which radiated RF disturbances are not controlled. The ZAP-X System user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ZAP-X System as recommended below, according to the maximum output power of the communications equipment.		
Rated Maximum Transmitter Output Power (Watts)	**Separation Distance According to Transmitter Frequency**		
	150Khz to 80MHz **d=1.2√P**	**80MHz to 800MHz** **d=1.2√P**	**800MHz to 2.5GHz** **d=2.3√P**
0.01	0.12 Meters	0.12 Meters	0.23 Meters
0.1	0.37 Meters	0.37 Meters	0.74 Meters
1	1.17 Meters	1.17 Meters	2.33 Meters
10	3.70 Meters	3.70 Meters	7.40 Meters

100	11.67 Meters	11.67 Meters	23.33 Meters
For transmitters rated at a maximum output power not listed above, the recommended separation distance 'd' in meters can be estimated using the equation applicable to the frequency of the transmitter, where' P' is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Notes:			
1	At 80MHz and 800 MHz, the separation distance for the higher frequency range applies.		
2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.		

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ZAP system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Contact Information

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