



Quality Assurance Manual
ZAP-X SYSTEM
REV. A

Zap-X Radiosurgery System Quality Assurance Manual

Zap Surgical Systems
590 Taylor Way, Suite A
San Carlos, CA 94070, USA

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 document was written in English.

Introduction

This manual describes fixtures provided by Zap that may be useful during QA procedures as well as instructions for their use. The manual also describes software features that may be useful during QA.

Quality assurance activities are ultimately the responsibility of the site Medical Physicist or designee and may have a broader scope than those listed in the manuals.

System Information



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

Notice:

The user manual contains instructions for multiple features of the Zap-X Radiosurgery System. Since some features of the Radiosurgery System are optional, some of the instructions in this manual 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 commissioning and use of the Zap-X Radiosurgery System.

Please refer to the Treatment Delivery Manual (E0920-0004) for the following information:

- Device Description
- Indications For Use
- Device Disposal
- Regulatory Classification
- List of other Manuals
- Conventions Used for Mouse Buttons, Numeric Displays and Date Displays

Safety Precautions and Warnings



Warning: System can emit lethal doses of radiation at high energy. 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: Regardless of the language translation, all numeric data that you enter or that is displayed in the software uses the period character (.) as a decimal separator. Be aware of this notation convention when interpreting or entering numeric data. Incorrect entry of numeric data could result in incorrect treatment or patient harm.

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.

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.

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.

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Chapter 1: Introduction

1.1 Quality Assurance

The ultimate goal of quality assurance (QA) in radiosurgery is to ensure that patients are consistently treated accurately and effectively. To achieve this goal, an effective QA program must span the entire patient care process and requires the active involvement of every member of the treatment team.

The Zap-X Radiosurgery System plays a vital role in the accurate delivery of treatment, and as such should be included in the overall QA plan. This document is intended to be a tool to aid in developing and maintaining those portions of the overall QA plan that are directly related to the operation of the Zap-X System.

1.2 Purpose

The purpose of this manual is to describe features of the Zap-X Radiosurgery System that may be helpful during QA procedures and suggested procedures for their use. This manual does not intend to prescribe QA tests or tolerances. A qualified Medical Physicist should consult guidelines from national and international societies as well as local regulations to determine the number and frequency of tests to be performed, as well as appropriate pass/fail criteria and plans for corrective action.

1.3 Expected Results

This manual does not contain expected results or tolerances. A qualified medical physicist should consult appropriate product documentation as well as national and local guidelines to determine these values.

1.4 Organization

This manual is organized into sections based on the various areas of interest within the Zap-X System. These include Safety, Linear Accelerator, Imaging and the integrated System.

Chapter 2: Safety Features

2.1 Introduction

This chapter describes the safety features of the Zap-X Radiosurgery (Zap-X) System and procedures for testing their proper operation.

The Zap-X System utilizes several types of safety interlocks including E-Stops, the Emergency Power-Off (EPO) switch, a key, collision detection systems and door status sensors. A brief description of each of these will be given and accompanied by an outline of steps that could be used to test their proper functionality.

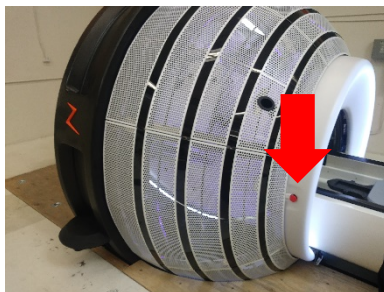
2.2 Description of Safety Features

2.2.1 Emergency-Stops (E-Stops)

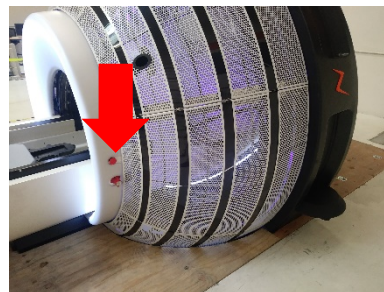
The Zap-X System is equipped with five E-Stop buttons (see Figure 2-1). One on each side of the machine, one at the operator console, one at the pendant and one at the rear of the machine (not shown). When pressed, these buttons will keep the machine fully energized, but halt all motion, activity and radiation. While all motors are deactivated, the patient table pitch axis will remain stationary while the other axis of the patient table will be free to move freely. Both the beam and high voltage will be turned off.



E-Stop at the Console



E-Stop at Patient Right



E-Stop at Patient Left

Figure 2-1. E-stop button locations on the Zap-X System.

2.2.2 Emergency Power Off (EPO)

There are two EPO switches, one is located on the operator console, the other on the main power distribution unit (PDU) located in the equipment room (see Figure 2-2). When this button is pressed all power is cut off from the system. This means that no motors are available to assist in moving any part of the system.



Emergency Power Off Button at the Console



Emergency Power Off Button at the Power Distribution Unit

Figure 2-2 Emergency Power Off button locations on the Zap-X System.

2.2.3 Key

A key is required to be in place and turned to the **ENABLE** position for high voltage to be activated. This key is located on the operator console (see Figure 2-3).



Console, key removed



Console, key enabled

Figure 2-3 Key to enable beam on the Zap-X System Operator Console.

2.2.4 External Proximity Sensors

The Zap-X System is equipped with two external proximity sensors located on either side of the System (see Figure 2-4). These sensors detect when an object is within the restricted area around the machine. When an object is detected within this area, the machine enters an E-Stop state and all motion and beam activity is inhibited.

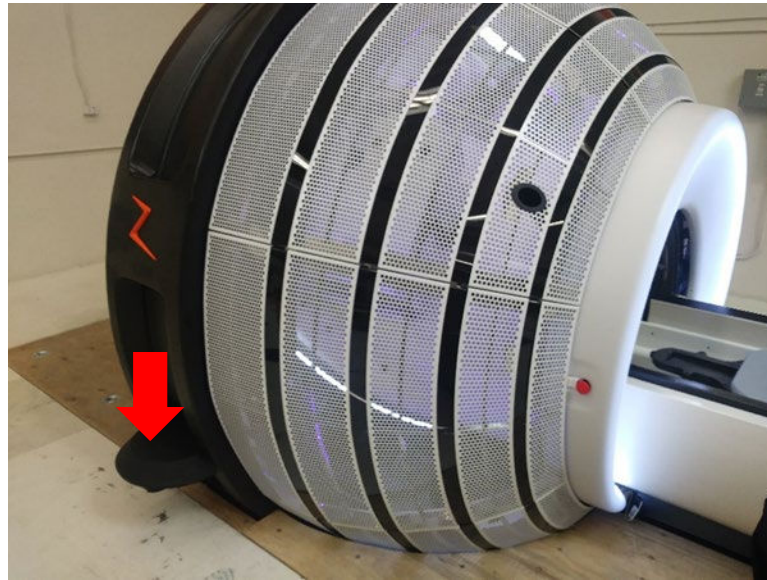


Figure 2-4 Proximity sensor on the side of the Zap-X System.

2.2.5 Collimator Collision Detection

The Zap-X System is equipped with a laser scanner positioned immediately behind the collimator (see Figure 2-5). This scanner is designed to detect when an object is nearing a location where it will collide with the collimator. If a potential collision is detected, all System motion will be halted.

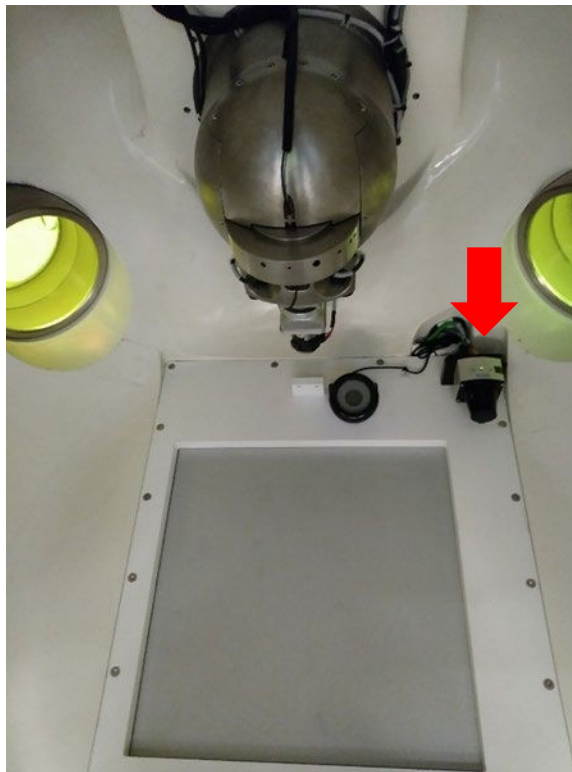


Figure 2-5 Collimator collision detection scanner.

2.2.6 Audio/Visual Patient Monitoring

The Zap-X System is equipped with several cameras that enable monitoring of patients inside the System. These may be viewed at the Operator Console.

Two-way audio communication is also provided at the console (see Figure 2-6).

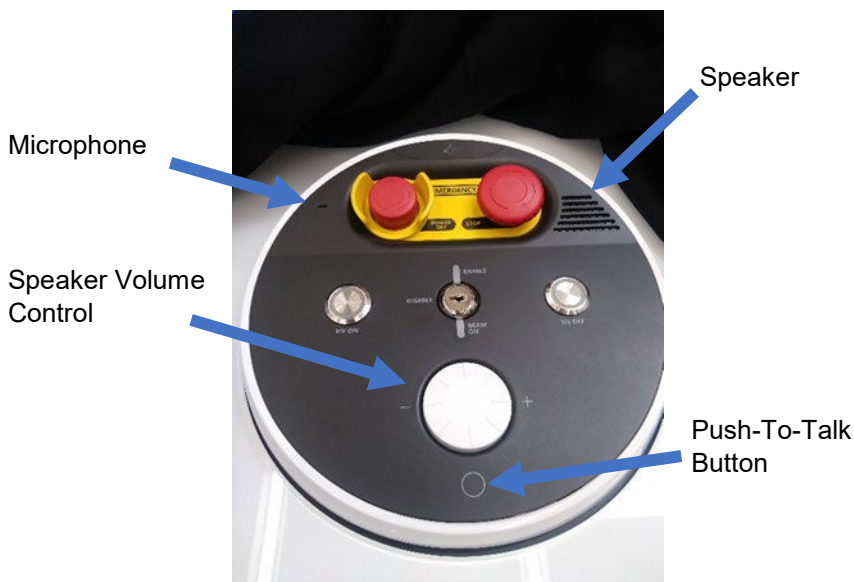


Figure 2-6 Audio communication interface at the Operator Console.

2.3 Suggested Test Procedures

2.3.1 Safety Feature Tests

In general, each safety feature of the Zap-X System may be tested by intentionally activating a given feature and verifying that system operation has been inhibited.

- To test E-Stops:
 1. Press one of the E-stop buttons.
 2. Verify that an E-stop message is displayed on the screen and that operation is disabled.
 3. Verify that the patient table can be moved by hand.
- To test Emergency Power Off (E-off):

Note: The sudden removal of power from the system does create stress on some of the system components. As such, it is suggested that this procedure be limited in frequency as much as possible.

 1. Press the E-off switch.
 2. Verify that all system power is lost.

This may be an excellent opportunity to review and practice procedures for an emergency power loss. Please refer to the Power Failure section of Chapter 1 in the Treatment Delivery User Manual.
- To test key:
 1. Either remove the key from the console or place it in the OFF position.
 2. Load a non-patient treatment plan or enter the Daily QA tab and attempt to deliver a beam.

3. Verify that the High Voltage is not activated and that no beam is delivered.
- To test proximity sensors:
 1. Clear all active system interlocks.
 2. Place an object in the protected area.
 3. Verify that an E-Stop is activated and that system operation is inhibited.
- To test collimator collision detection:
 1. Place a large, soft object on the headrest (e.g. pillow).
 2. Move the machine to the Home position by clicking on the Initialize button on the Dashboard.
 3. Carefully push the patient table into the machine until the soft object is nearly touching the collimator.
 4. Verify that the collision indicator on the screen changes color from green to yellow as seen in Figure 2-7.



Figure 2-7 Collision detection indication on the User Interface.

5. Click on the Daily QA button, and then click on the Move button and verify that the system does not begin motion.
 6. Carefully pull the patient table out of the machine and remove the soft object from the headrest.
- To test A/V monitoring:
 1. Verify that the cameras and audio feed are functional.

Chapter 3: Linear Accelerator

3.1 Introduction

This chapter describes the tools and methods developed by Zap Surgical Systems that are made available to the Medical Physicist to assist them in performing the measurements needed to assess the performance of the Linear Accelerator Subsystem within the Zap-X Radiosurgery System. We emphasize that the responsible Medical Physicist must consult with applicable local and national guidelines in order to determine the tests, frequency and tolerances to be used.

The remainder of the chapter is divided into two sections. First, a brief overview of the tools provided with the Zap-X System will be given. This is followed by a set of suggested procedures that may be used to accomplish some common QA tasks.

3.2 Description of Zap LINAC QA Tools

3.2.1 F-Bracket

This tool attaches to the Zap-X System collimator and enables the placement of various devices at specific locations along the central beam axis. Included the bracket are several inserts that may be used for various tasks.

- Laser Alignment: Inserts with a 3 mm hole are placed at two levels along the beam central axis.

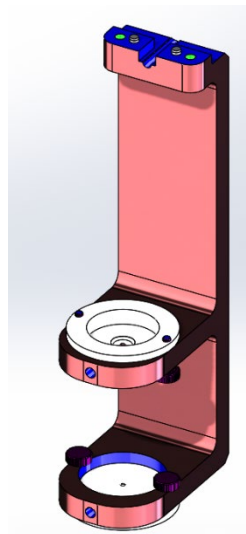


Figure 3-1 Zap-X F-Bracket with in Laser Alignment configuration.

- **Film Measurement:** An insert that holds a piece of radiochromic film with 6.5 mm of buildup and 15.5 mm of backscatter placed at 450 mm SAD along the central beam axis.

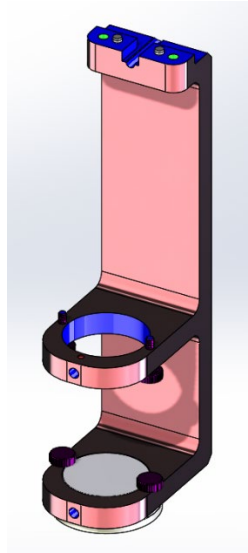


Figure 3-2 Zap-X F-Bracket in the Film Exposure configuration.

- **D10/D20:** A solid column of acrylic plastic with ionization chamber holders placed at a depth of 10 cm and 20 cm (SSD 450 mm) along the beam central axis.

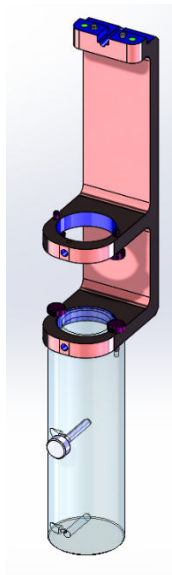


Figure 3-3 Zap-X F-Bracket in the D10/D20 configuration.

- Dmax/D10: A solid column of acrylic plastic with an ionization chamber holder placed at SAD 450 mm with 6.5 mm buildup. A second ionization chamber holder is placed at a depth of 10 cm.

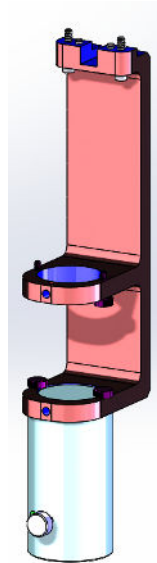


Figure 3-4 Zap-X F-Bracket in the Dm

- Output Measurement: A solid hemisphere with an ionization chamber holder placed at SAD 450 mm with 6.5 mm of buildup. The hemisphere was designed to provide sufficient buildup, side and backscatter to enable accurate output measurements.

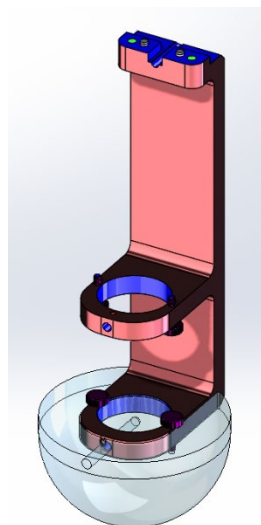


Figure 3-5 Zap-X F-Bracket with the hemisphere attached.

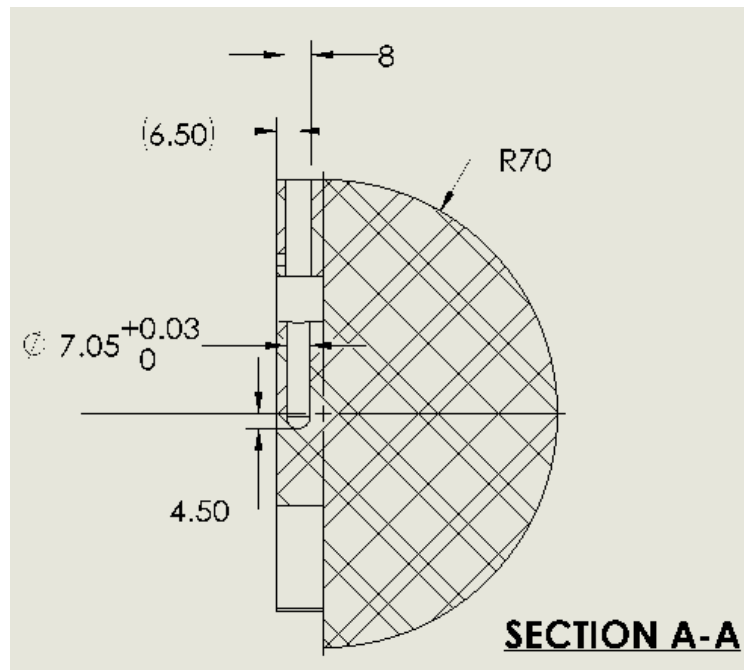


Figure 3-6 Schematic of the Zap-X F-Bracket hemisphere showing dimensions for the ion chamber cavity.

- Output Measurement at 500 mm SAD: A solid sphere with an ionization chamber holder placed at SAD 500 mm with 50 mm of water equivalent buildup (44 mm acrylic) and 50 mm of acrylic side and backscatter.

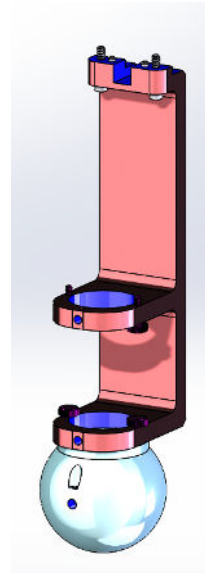


Figure 3-7 Zap-X F-Bracket with the 500 mm SAD sphere attached.

3.2.2 Patient Table Isocenter Fixture

This tool attaches to the Zap-X System patient table and enables the placement of various devices at or near the system isocenter.

The tool includes a 19 mm steel ball that is placed at isocenter when the patient table is moved to the designated isocenter location. The steel ball may be removed and replaced by an ion chamber, if desired.

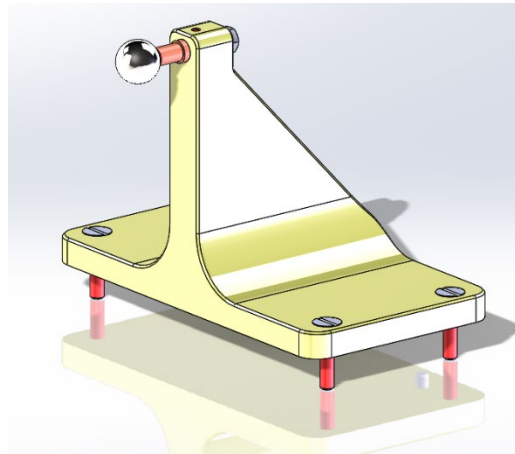


Figure 3-8 Zap-X Patient Table Isocenter Fixture.

The isocenter is placed at a distance of 24.5 mm from the front face of the tool.

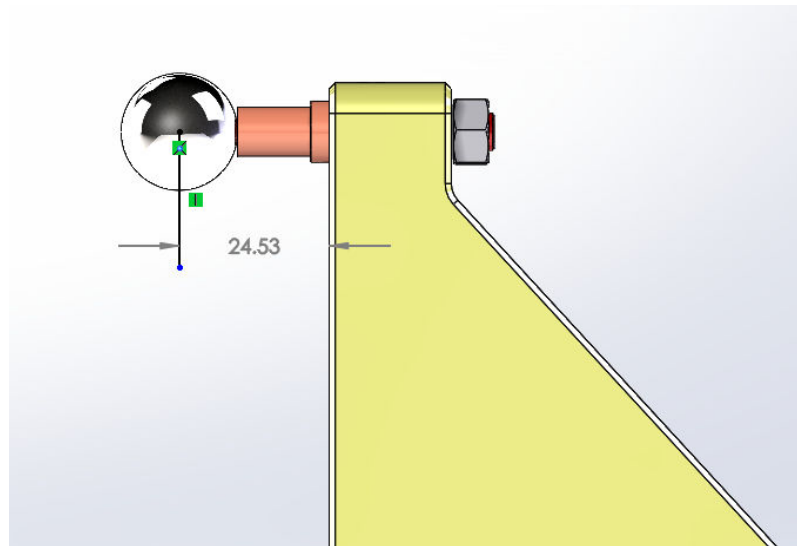


Figure 3-9 Schematic showing the distance from the front face of the fixture to the idealized isocenter location.

In addition, a Starshot Fixture is provided that can be attached in place of the steel ball. This fixture can be used to hold a piece of radiochromic film in the plane of the isocenter. It has a rotational axis that passes through the isocenter such that it can be adjusted to perform starshot measurements in various planes, typically corresponding to the two gantry axes of the Zap-X System.

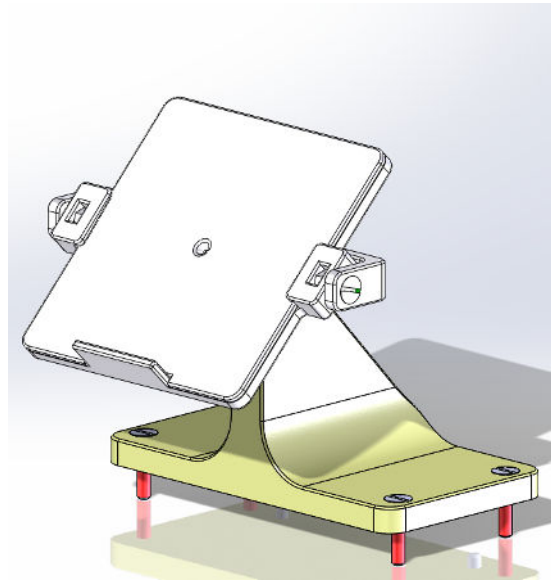


Figure 3-10 Zap-X Patient Table Isocenter Fixture with Starshot Fixture attached.

3.3 Suggested Test Procedures

3.3.1 Warm up

The LINAC shall be run for 6000 MU before additional tests are performed.

➤ **To Warm up the Zap-X System:**

1. Log in to the treatment console.
2. If the machine has not been powered on and initialized, perform these two operations.
3. Click on the **Daily QA** icon.



Figure 3-11 System dashboard showing the Daily QA icon.

4. Select the **Daily QA** page and the **Table and Gantry** Tab. Click on the **Move to Iso** button to move the patient table into the machine. Then click on the **Close Shell** and **Close Door** buttons to close the door and shell.

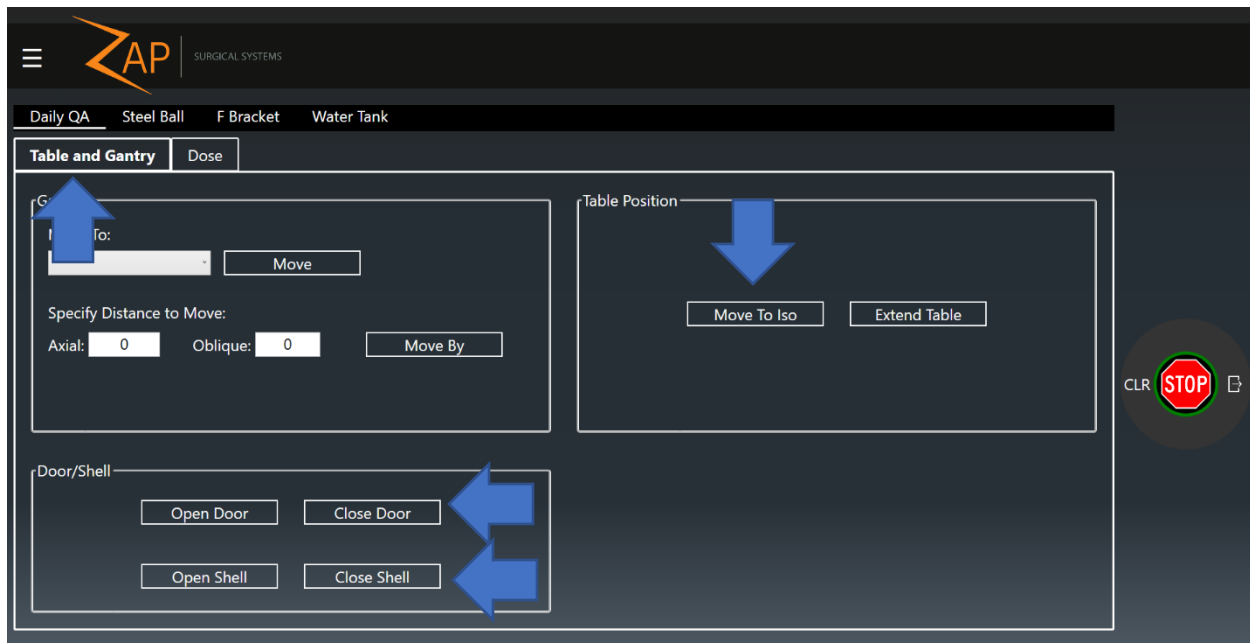


Figure 3-12. Daily QA page, Table and Gantry tab. Arrows highlight buttons to move table into the machine and close the shell and door.

- Click on the **Dose** tab of the Daily QA page.

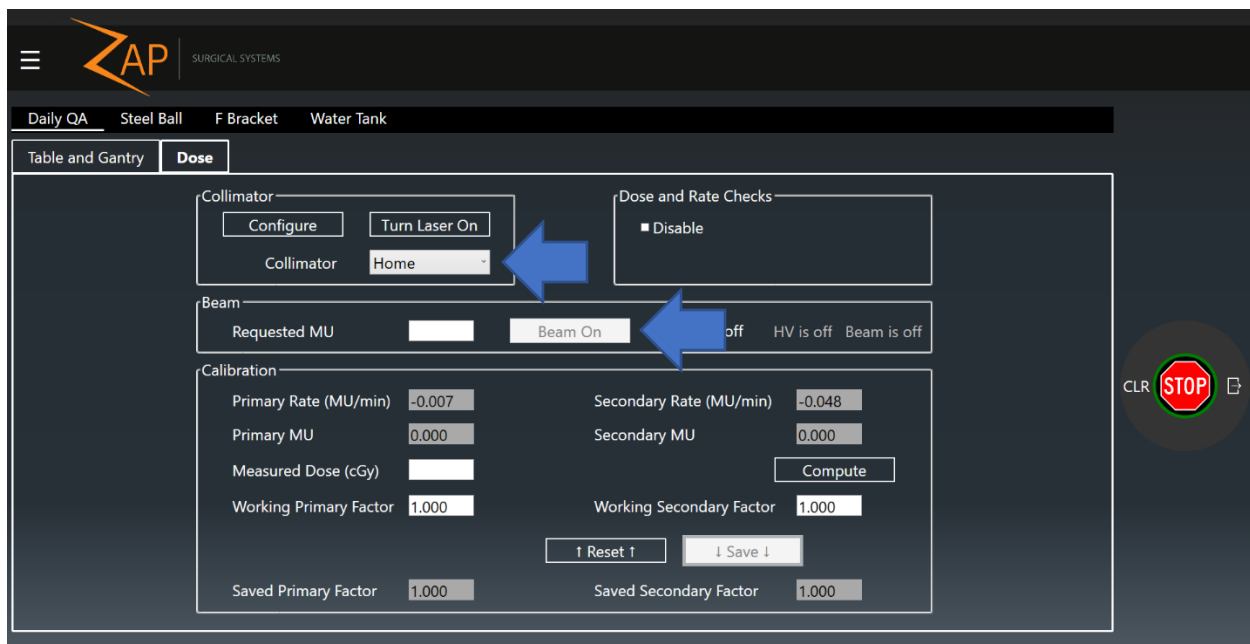


Figure 3-13 Daily QA page, Dose tab. Arrows highlight input for collimator selection and the setting of exposure.

- Select the Home options in the Collimator Selection Tab.
- Enter 6000 in the **Requested MU** box.
- Press the **HV ON** button on the console.
- Click the **Beam On** button.

10. Wait for the delivery to complete.

3.3.2 Output and Dose Rate

The Zap-X F-Bracket and Output Measurement attachment were designed to simplify performing output and dose rate measurements on the Zap-X Radiosurgery System. This fixture places the ion chamber at 450 mm SAD with 6.5 mm of buildup and adequate side and backscatter. As an alternative the 500 mm SAD sphere may be used in place of the Output Measurement attachment.

Note: Correction factors for the acrylic phantom material are required for absolute measurements. This setup is therefore most appropriate as a constancy or abbreviated measurement and is not recommended for absolute calibration.

➤ **To Measure the Output or Dose Rate of the Zap-X System:**

1. Log in to the treatment console.
2. If the machine has not been powered on and initialized, perform these two operations.
3. Verify that the system is at the Home position, if not, click on the **Daily QA** Icon. Then select the **F Bracket** page and the **Table and Gantry** tab. In the dropdown box for **Gantry, Move To:** select Home and then click **Move** (see Figure 3-14).

Caution: Once the F-Bracket is installed the gantry and table will not operate unless the internal collision scanner is turned off. In this state, system motion speed will be significantly reduced, and it is operator's sole responsibility to ensure no collisions occur. It is therefore suggested that the system be placed in its desired position prior to installing the F-Bracket.

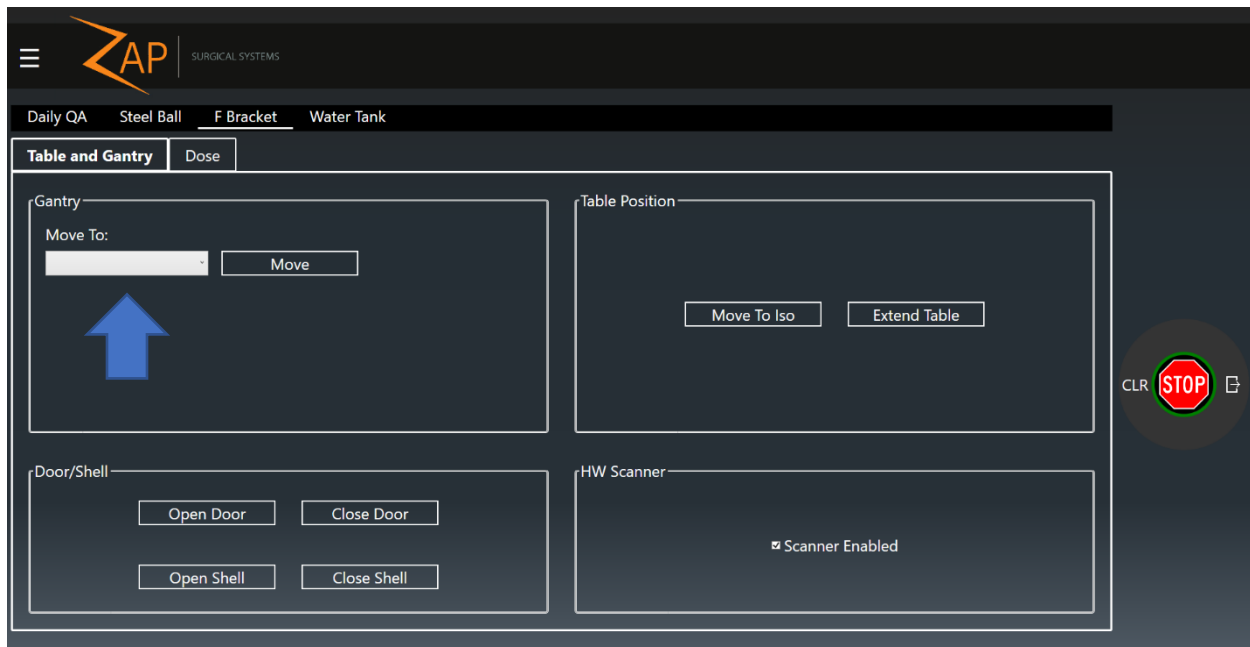


Figure 3-14 F Bracket page, Table and Gantry tab. Arrow highlights selection of desired gantry position.

4. Press the **E-Stop** button at the user console.
5. Install the F-Bracket on the collimator of the Zap-X system by aligning the F-bracket with the mounting features on the collimator housing and tightening the two screws (see Figure 3-15 and Figure 3-16).

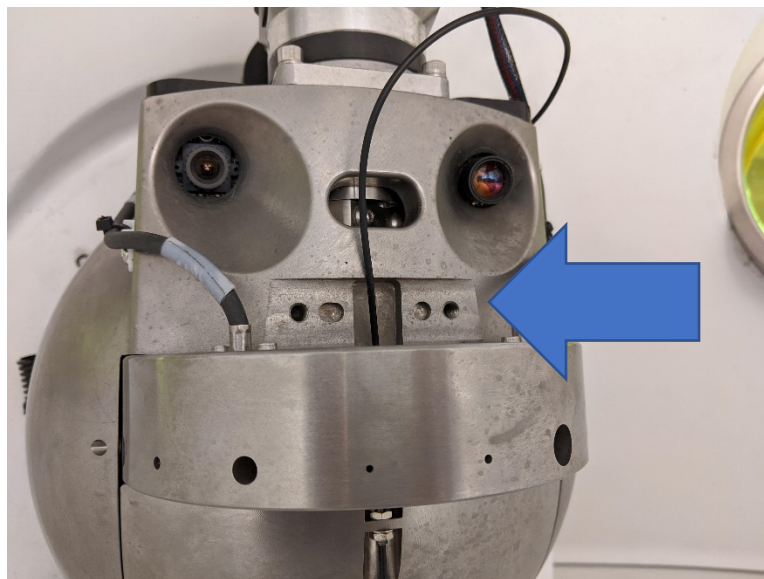


Figure 3-15 Photo of the Zap-X collimator and collimator housing. Arrow highlights area of the house to which the F-Bracket mounts.



Figure 3-16 Photos of the Zap-X collimator and collimator housing with the F-Bracket installed.

6. Install the Output Measurement or Output Measurement at 500 mm SAD attachment on the F-Bracket by placing it on the lower level of the F-bracket and tightening the two thumb screws.

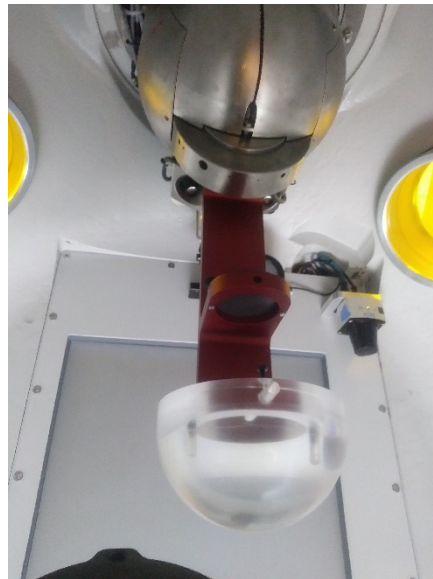


Figure 3-17 Photo showing the Output Measurement attachment on the F-Bracket.

7. Carefully pass the ion chamber into the machine through the cable access hole near the door, being sure to provide enough cable to ensure proper operation (see Figure 3-18).

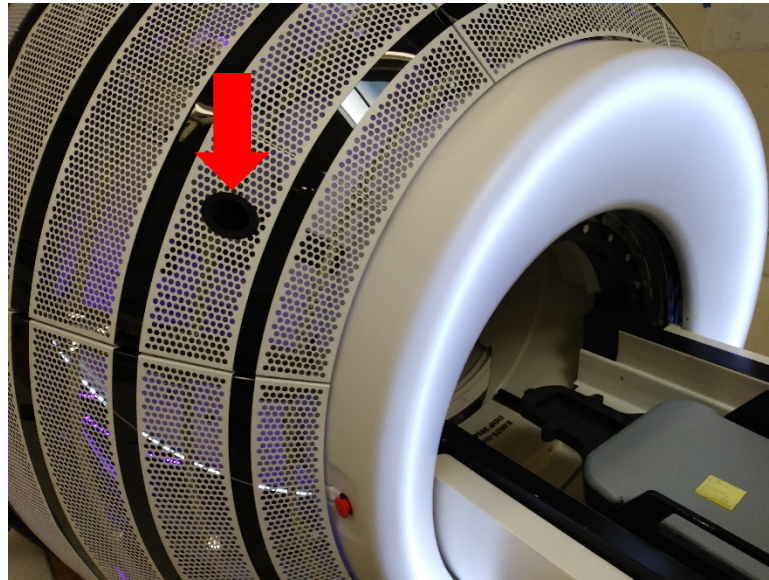


Figure 3-18 Location port for passing cables into the Zap-X System.

8. Insert an appropriately sized Ion Chamber into the holder (0.125 cm³ thimble chamber with reference point 4.5 mm from tip, reference PTW 31010).
9. Ensure the chamber is properly located within the holder and secure by tightening the set screw.
10. Manually push the table into the machine until all parts of the table are clear of the door.
11. Release the **E-stop** button, clear the E-stop and use the pendant to move the patient table into the machine and close the door and shell.
12. Click on the **Daily QA** icon on the dashboard (see Figure 3-11). Select the **F Bracket** page.
13. Select the **Table and Gantry** tab. Click the **Close Door** and **Close Shell** buttons to close the machine.

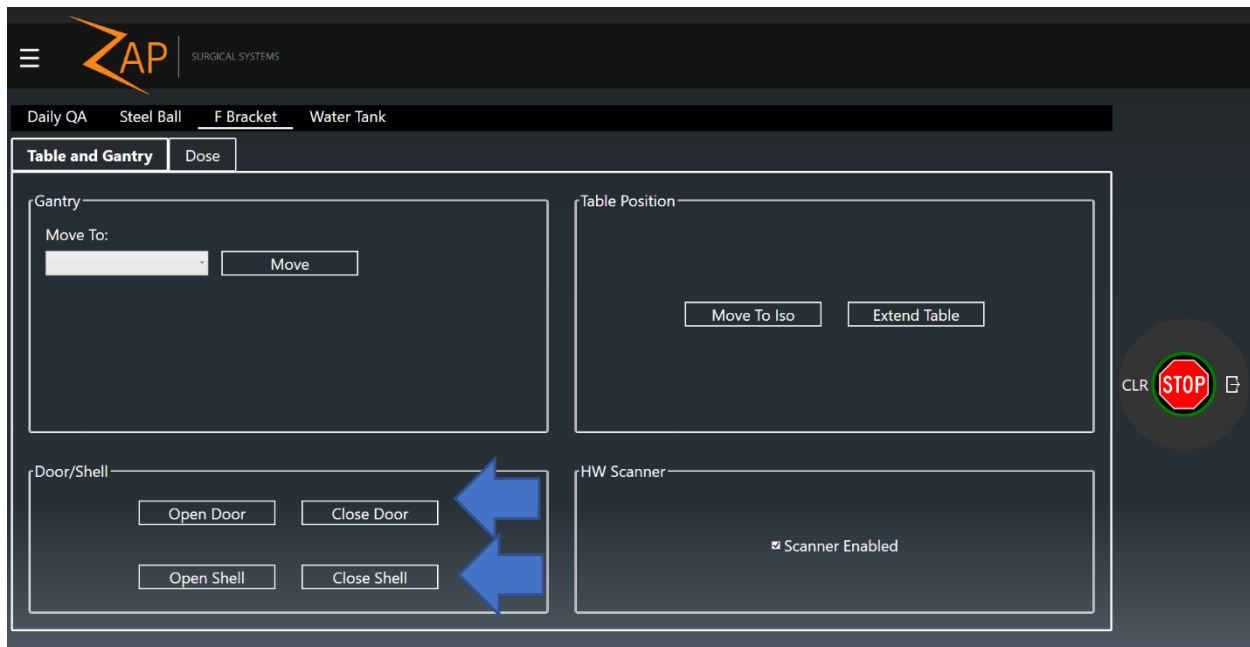


Figure 3-19 F Bracket page, Table and Gantry tab. Arrows highlight buttons close the door and shell.

14. Now, select the **Dose** tab.
15. Select the desired collimator from the collimator selection box.
16. Enter the desired number of MUs in the **Requested MU** box.
17. Press the **HV ON** button on the console.
18. Click the **Beam On** button.

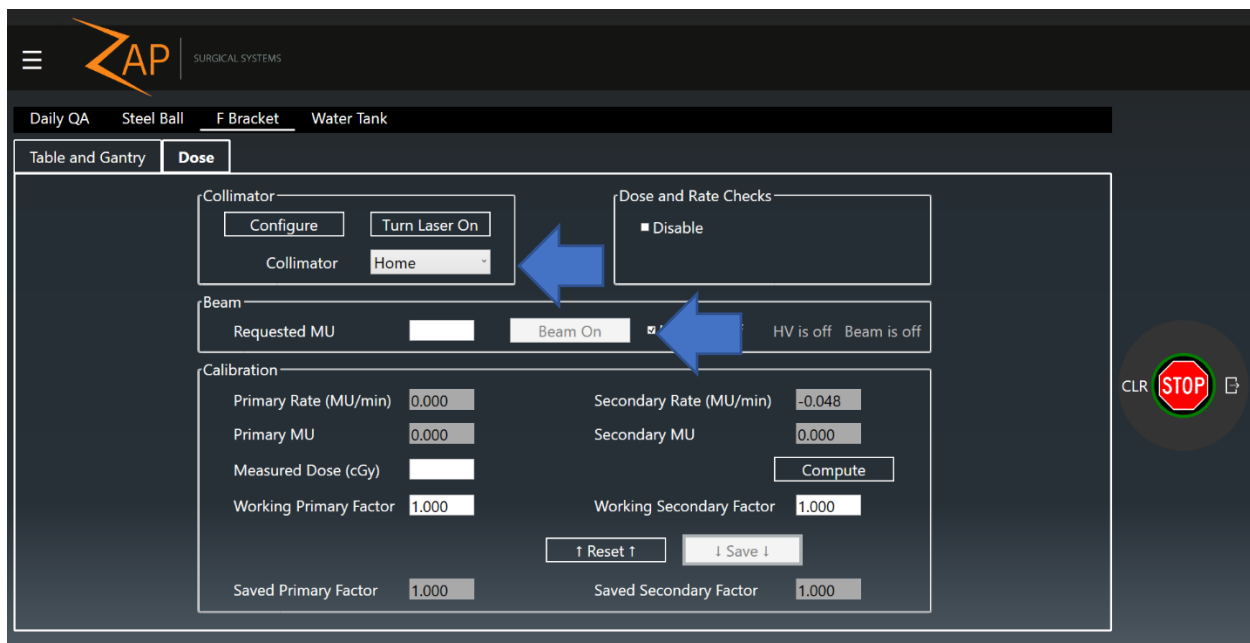


Figure 3-20 F Bracket page, Dose tab. Arrows highlight input for collimator selection and the setting of exposure.

19. Wait for the delivery to complete. If the **HV Auto-off** box is checked, HV will be turned off at the completion of the beam. If you prefer to keep HV on during repeated exposures, clear this box.
20. Make note of any desired measurements and repeat steps 13-17 as necessary.
21. If high voltage has not been turned off automatically, turn off high voltage by press the **HV OFF** button on the console.
22. Open the door and shell by returning to the **Table and Gantry** tab and clicking the **Open Door** and **Open Shell** buttons.
23. The Table may be removed from the machine manually or by clicking the **Extend Table** button.
24. Press the **E-stop** button.
25. Carefully remove the ion chamber from the F-bracket and from the machine.
26. Carefully remove the F-bracket.

3.3.3 Output Constancy

The Zap-X Table Isocenter Fixture may be used to perform output consistency measurements when the ball is replaced with an ion chamber. A qualified Medical Physicist should carefully evaluate how such data is collected and analyzed, but the hardware provides a simple method for positioning a chamber within the system.

➤ **To Measure the Output Constancy of the Zap-X System:**

1. Log in to the treatment console.
2. If the machine has not been powered on or initialized, perform these two operations
3. Place the Zap-X Table Isocenter Fixture on the patient table.
4. Secure an appropriate ion chamber within the fixture.
5. Carefully pass the necessary cables through the appropriate ports on the system (see Figure 3-18).
6. Connect the cable to the ion chamber.
7. Use the Pendant to move the couch to the iso-center position and close the door and shell. Alternatively, click on the **Daily QA** icon on the Dashboard (see Figure 3-11), then click on the **Daily QA** page and the **Table and Gantry** tab (see Figure 3-12). Click on the **Move to Iso**, **Close Door** and **Close Shell** buttons.
8. If desired, select a gantry position from the dropdown box and click the **Move** button to position the gantry at the desired position.
9. Click on the **Dose** tab (see Figure 3-13).
10. Enter an appropriate number of MU in the MU box.
11. Press the **HV ON** button on the console.
12. Click the **Beam On** button.
13. Wait for the delivery to complete. If the **HV Auto-off** box is checked, HV will be turned off at the completion of the beam. If you prefer to keep HV on during repeated exposures, clear this box.
14. Make note of any desired measurements and repeat steps 10-13 as necessary.

15. If high voltage has not been turned off automatically, turn off high voltage by press the **HV OFF** button on the console.
16. Open the door and shell by returning to the **Table and Gantry** tab and clicking the **Open Door** and **Open Shell** buttons.
17. Remove the ion chamber form the Table Isocenter Fixture.
18. Remove the Table Isocenter Fixture from the patient table.

3.3.4 Beam Energy

The Zap-X F-bracket and the Dmax/D10 or the D10/D20 attachment may be used to evaluate the beam energy of the Zap-X Radiosurgery system without requiring the installation of a water phantom. The Dmax/D10 attachment places an ion chamber at an SAD of 450 mm with 6.5 mm of acrylic buildup and a second chamber at a depth of 10 cm. The D10/D20 attachment places a column of acrylic plastic at 450 SSD with ion chamber holders located at a depth of 10 cm and 20 cm. The ratio of the dose delivered to these two locations may be used to assess the energy of the radiation beam.

NOTE: As with any phantom made from a material other than water, care should be made to correct for the phantom material if an absolute measurement is necessary. It is therefore suggested that these tools be used to measure constancy over time rather and are not appropriate for machine calibration or commissioning.

➤ **To Measure the Beam Energy of the Zap-X System:**

1. Log in to the treatment console.
2. If the machine has not been powered on or initialized, perform these two operations
3. Verify that the system is at the North Pole position, if not, click on the **Daily QA** icon. Then select the **F Bracket** page and the **Table and Gantry** tab. In the dropdown box for **Gantry, Move To:** select **North Pole** and then click **Move** (see Figure 3-14).

Caution: Once the F-Bracket is installed the gantry and table will not operate unless the internal collision scanner is turned off. In this state, system motion speed will be significantly reduced, and it is operator's sole responsibility to ensure no collisions occur. It is therefore suggested that the system be placed in its desired position prior to installing the F-Bracket.

4. Press the **E-Stop** button on the user console.
5. Install the F-Bracket on the collimator of the Zap-X system by aligning the F-bracket with the mounting features on the collimator housing and tightening the two screws (see Figure 3-15 and Figure 3-16).
6. Install the Dmax/D10 or D10/D20 attachment on the F-Bracket.
7. Carefully pass the ion chamber into the machine through the cable access hole near the door, being sure to provide enough cable to ensure proper operation (see Figure 3-18).
8. Insert an appropriately sized Ion Chamber into the one of the holders (0.125 cm³ thimble chamber with reference point 4.5 mm from tip, reference PTW 31010). Place the plug in the other holder.

9. Ensure the chamber is properly located within the holder and secure by tightening the set screw.
10. Carefully move the patient table back into the machine ensuring it does not collide with the F-Bracket.
11. Release the **E-Stop** button and clear the E-stop on the console PC.
12. Click on the **Close Door** and **Close Shell** buttons to close the door and shell.
13. Click on the **Dose** tab.
14. Select the desired collimator from the collimator selection box.
15. Enter the desired number of MUs in the **Requested MU** box.
16. Press the **HV ON** button on the console.
17. Click the **Beam On** button.
18. Wait for the delivery to complete. If the **HV Auto-off** box is checked, HV will be turned off at the completion of the beam. If you prefer to keep HV on during repeated exposures, clear this box.
19. Make note of any desired measurements and repeat steps 14-18 as necessary.
20. If high voltage has not been turned off automatically, turn off high voltage by pressing the **HV OFF** button on the console.
21. Open the door and shell by returning to the **Table and Gantry** tab and clicking the **Open Door** and **Open Shell** buttons.
22. Press the **E-stop** button.
23. Carefully remove the ion chamber and plug from the holders and place the ion chamber in the other hole and the plug in the D10 hole.
24. Repeat steps 9-21.
25. Carefully remove the ion chamber from the F-bracket and from the machine.
26. Carefully remove the F-bracket.

3.3.5 Symmetry and Beam Shape

The Zap-X F-bracket may be used with the film holder attachment to measure beam symmetry and beam shape. The bracket is placed in the machine, and a piece of radiochromic film is placed in the holder. The holder will position the film at 450 mm SAD with 6.5 mm of buildup and 15 mm of backscatter.

➤ **To obtain Symmetry and Beam Shape data:**

1. Log in to the treatment console.
2. If the machine has not been powered on and initialized, perform these two operations.
3. Verify that the system is at the desired position, if not, click on the **Daily QA** Icon. Then select the **F Bracket** page and the **Table and Gantry** tab. In the dropdown box for Gantry, Move To: select the desired location and then click Move (see Figure 3-14).

Caution: Once the F-Bracket is installed the gantry and table will not operate unless the internal collision scanner is turned off. In this state, system motion speed will be significantly reduced, and it is operator's sole responsibility to ensure no collisions occur. It is therefore suggested that the system be placed

- in its desired position prior to installing the F-Bracket. Press the **E-Stop** button on the user console.
4. Install the F-Bracket on the collimator of the Zap-X system by aligning the F-bracket with the mounting features on the collimator housing and tightening the two screws (see Figure 3-15 and Figure 3-16).
 5. Place a piece of pre-cut radiochromic film in the holder.
 6. Install the film holder attachment on the F-Bracket.
 7. Release the **E-stop** button, clear the E-stop and use the pendant to move the patient table into the machine and close the door and shell.
 8. Click on the **Dose** tab.
 9. Select the desired collimator from the collimator selection box.
 10. Enter the desired number of MUs in the MU box.
 11. Press the **HV ON** button on the console.
 12. Click the **Beam On** button.
 13. Wait for the delivery to complete. If the **HV Auto-off** box is checked, HV will be turned off at the completion of the beam. If you prefer to keep HV on during repeated exposures, clear this box.
 14. If high voltage has not been turned off automatically, turn off high voltage by press the **HV OFF** button on the console.
 15. Click on the **Gantry and Table** tab and open the door and shell by clicking the corresponding buttons.
 16. Press the **E-stop** button.
 17. Carefully remove the film from the holder.
 18. If necessary, place a new film in the holder and repeat steps 8-17 as needed.
 19. Remove the F-bracket and from the machine.
 20. Carefully remove the F-bracket.
 21. Use an appropriate scanner and software to scan the exposed films and measure the values of interest.

3.3.6 Collimator Verification

➤ **To test collimator selection:**

1. Log in to the treatment console.
2. Click on the Daily QA tab.
3. Use the Collimator Selection box to select a collimator.
4. Enter a number of MU in the box.
5. Enable High voltage and press the beam on button.
6. Confirm that the desired collimator can be selected and dose can be delivered.

3.3.7 Test Laser Alignment

The Zap-X F-bracket may also be used to evaluate the alignment of the system laser. Two discs are inserted into the bracket. Each one has a small hole in the center that is 3 mm in diameter. This allows both the location of the laser, and its co-linearity with the central beam axis to be evaluated.

- **To test laser alignment with isocenter pointer:**
1. Click on the Daily QA button on the dashboard.
 2. Select the 4.0 mm collimator from the **Collimator Selection** dropdown menu.
 3. Click the **Move** box to move the collimator to a position directly above machine isocenter.
 4. Mount the F-bracket equipped with Laser Beam Centering discs to the collimator (see Figure 3-1). Each disc contains a small hole at the center. Place a piece of colored tape blocking the center hole on the bottom disc so the laser position can be seen within the hole.
 5. Click the **Turn Laser On** button.
 6. Evaluate the location of the laser relative to the 3 mm hole.

3.3.8 Starshot

The Zap-X starshot fixture may be used to perform a measurement of the deviation of the beam central axis from the mechanical isocenter as the gantry rotates in a single plane. Note that while Zap provides a fixture for performing this measurement, the procurement and analysis of the film is the responsibility of the site physicist.

- **To perform a starshot measurement:**
1. Click on the **Daily QA** button on the dashboard.
 2. Select the **Daily QA** page and the **Table and Gantry** Tab
 3. Click on the **Move To Iso** button. Wait for table motion to complete.
 4. Manually pull the table out of the machine.
 5. Secure the starshot fixture to the couch.
 6. Use a level to adjust the angle of the film holder to be vertical for an axial axis measurement, or 45 degrees for an oblique axis measurement.

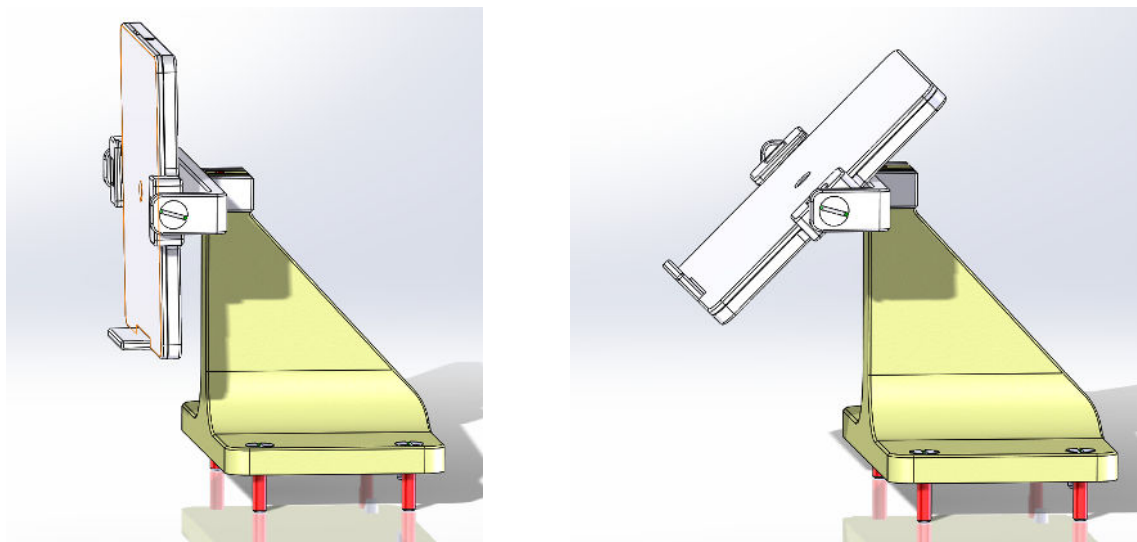


Figure 3-21 Starshot fixture configured for an axial gantry measurement (left) and an oblique gantry measurement (right).

7. Move the table into the machine by clicking on the **Move To Iso** button. Close the shell and door using the corresponding buttons.

8. For an axial gantry measurement, move the gantry to axial 270, oblique 90.
For an oblique gantry measurement. Move the gantry to axial: 0, oblique 180.
9. Click on the **Dose** tab. Select the desired collimator from the dropdown box.
10. Input the Requested MU, press the **HV ON** button on the console and then click **Beam On**.
11. Once the exposure is complete, return to the **Table and Gantry** tab and move the gantry to the next desired position. Repeat steps 9-10 to expose the film from this new angle. Repeat as desired.
12. Extract the table from the machine and remove the starshot fixture from the table.

Chapter 4: Imaging Subsystem

The Zap-X System contains a flat panel kV detector and kV x-ray source. Please consult with an authorized Zap Surgical Service Engineer to obtain images necessary for evaluating these systems.

Chapter 5: Treatment Planning

The Zap-X System also includes Treatment Planning capabilities. It is essential that the functionality of these tools is regularly evaluated. A qualified Medical Physicist should consult with appropriate guidelines to determine what, how and when to test these functions.

Chapter 6: System Level Tests

6.1 Steel Ball Workflow

This section describes a simplified positioning and isocentricity test that can be performed quickly and easily on the Zap-X System.

6.1.1 Phantom Insert, 4 mm Ball

The Phantom Insert, 4 mm Ball is a cube of plastic that contains a single 4 mm Tungsten ball at its center. This cube is intended to be inserted into an anthropomorphic phantom. This phantom may then be positioned within the system. Beams are then delivered and the shadow of the ball on the MV Imager is used to determine the position of the ball relative to the machine isocenter as well as the deviation of the beam central axis from the machine isocenter.

6.1.2 Prerequisites

➤ **To prepare the system to perform the Steel Ball Workflow:**

1. Place the Phantom Insert into an anthropomorphic phantom. Ensure that the insert is rigidly fixed to the phantom. Any relative motion between the insert and the phantom will contribute to errors in the data provided by the workflow. Ideally the insert should be left permanently with in the phantom. If this is not possible, efforts should be made to ensure that the insert may be repeatably placed within the phantom.
2. Obtain a CT of the phantom using immobilization and settings that mirror, as closely as possible, those of the standard clinical workflow.
3. Import the CT into the Zap planning system.
4. Carefully place a single isocenter at the center the 4 mm ball.
5. Save the plan.
6. Consult with a Zap Service Engineer to configure your system to utilize the prepared plan for the Steel Ball Workflow.

6.1.3 Suggested Test Procedure

➤ **To execute the Steel Ball Workflow:**

1. Place the Phantom Insert into the anthropomorphic phantom that was used to acquire the CT and set the phantom up on the machine using the same immobilization that was used during CT.
2. Navigate to the **Daily QA** logo, **Steel Ball** page, **Table and Gantry** tab.
3. Move the table into the machine by clicking **Move To Iso** and close the shell and door by clicking **Close Shell** and **Close Door**.

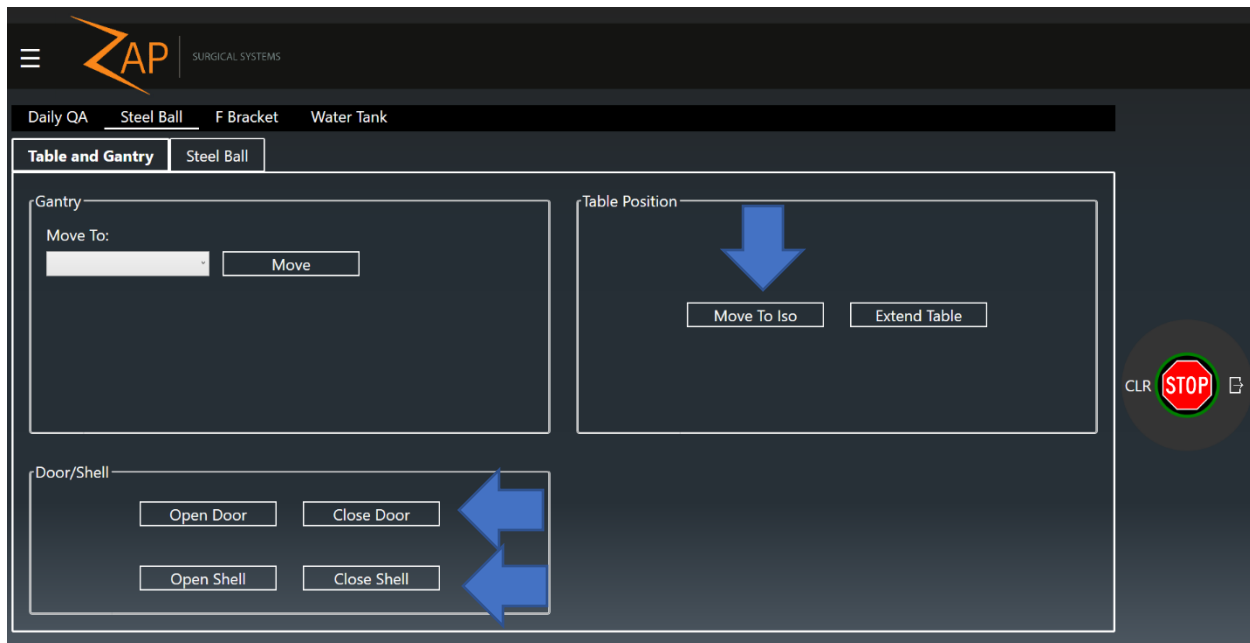


Figure 6-1 Steel Ball page, Table and Gantry tab. Arrows highlight steps to move the table into the machine and close the shell and door.

- Click on the **Steel Ball** tab and click the **Start** button. The system will perform the same auto align sequence used during treatment delivery. Then the system will deliver beams from the following locations: Home, AP, left lateral, PA, right lateral. For each beam an MV Image is captured and analyzed to determine the offset between the center of the field and the center of the shadow of the 4 mm ball.

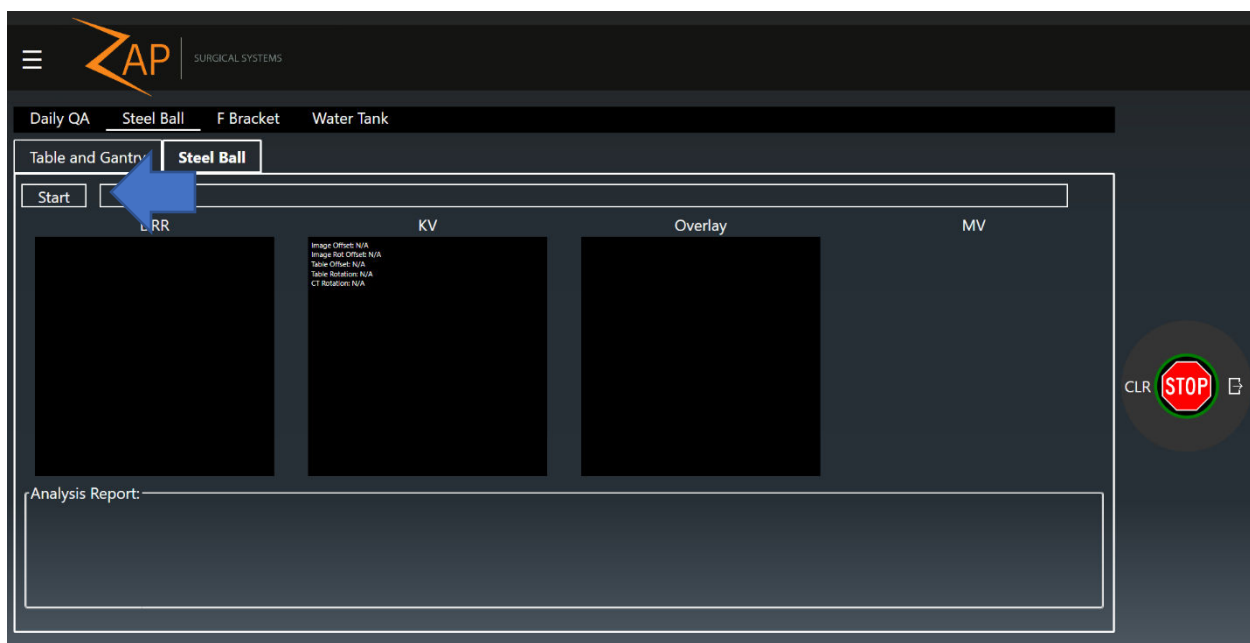


Figure 6-2 Steel Ball page, Steel Ball tab. Arrow highlights button to initiate the Steel Ball workflow.

5. Once all five exposures are complete an analysis is presented. The analysis includes the following items:
 - DoseLab 3D Target Offset: Calculation of the location of the ball relative to the machine mechanical isocenter calculated using equations from a traditional C-Arm gantry geometry.
 - Zap 3D Target Offset: Calculation of the location of the ball relative to the machine mechanical isocenter calculated using equations unique to the Zap-X system geometry.
 - Zap 2D Beam Offset: Calculation of the deviation of the beam central axis from the mechanical isocenter calculated using equations unique to the Zap-X system geometry.

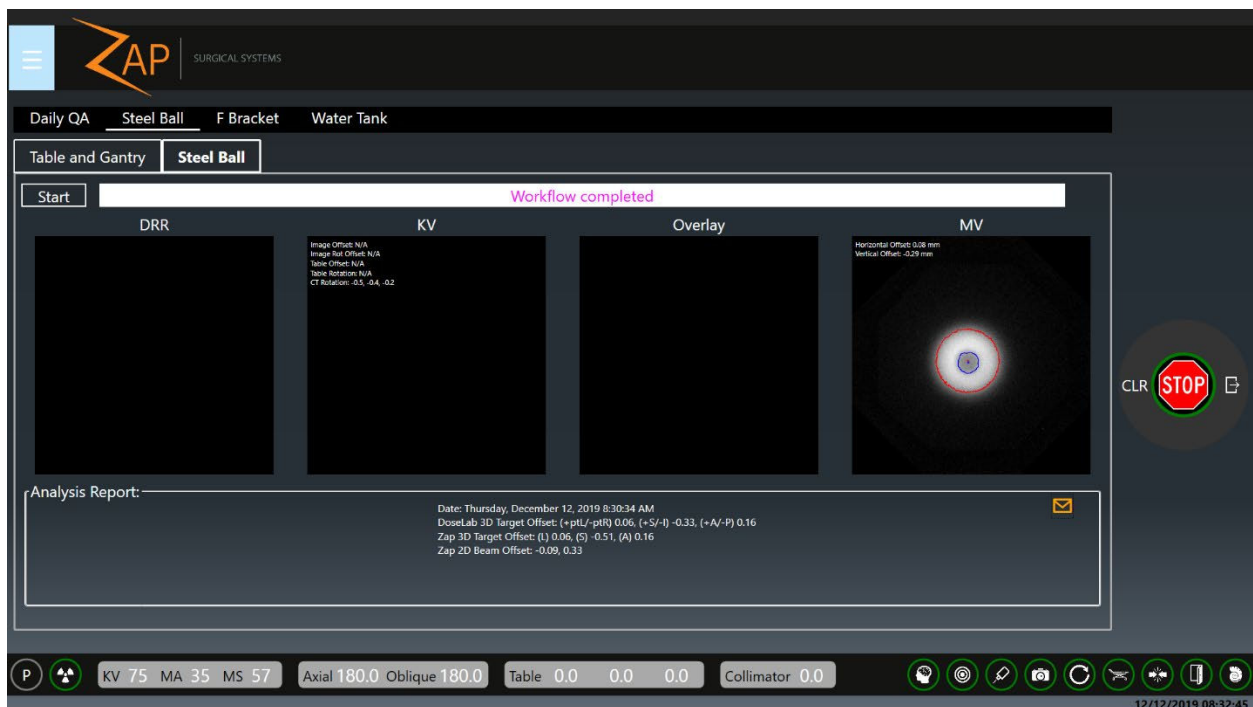


Figure 6-3 Steel Ball page, Steel Ball tab. Example of workflow completion with results populated in the Analysis Report section of the screen.

6. If desired, click the **Envelope** icon to email a report of the collected data to a predefined recipient (consult with a service engineer to set up this email).

6.2 End-to-End Testing

Please reference Chapter 7: End-to-End test for details on a suggested end-to-end testing procedure.

Chapter 7: End-to-End test

7.1 Introduction

This chapter describes procedures for performing End-to-End (E2E) tests on the Zap-X System.

Contents

This chapter contains the following topics:

- 7.2 Equipment and Materials for E2E Tests
- 7.3 Using the Ball-cube in E2E Tests
- 7.4 Treatment Plans for E2E Tests
- 7.5 E2E Dose Delivery
- 7.6 Film Analysis

7.2 Equipment and Materials for E2E Tests

This section describes the equipment and materials used to perform E2E tests.

7.2.1 Ball-cube and Films

This procedure makes use of a ball-cube phantom and radiochromic film. The ball cube is a cube that enables two pieces of radiochromic film to be placed repeatably in the sagittal and coronal planes within an anthropomorphic head phantom. The center of the cube contains a high-density ball that can aid in repeatable isocenter placement during treatment planning.

7.2.2 Film Scanner

Zap suggests the use of an Epson V600 or equivalent scanner.

7.2.3 E2E Test Procedure Overview

The complete E2E test procedure includes the following general steps:

1. Perform a CT scan of the phantom(s) with Ball-cube that will be used in the E2E test. Phantoms should be loaded with films during CT scans. Follow the CT scanning guidelines listed in the Treatment Planning Manual.
2. Import the CT image studies.
3. In the Treatment Planning System, identify the treatment target (i.e. center of the Ball-cube). Then design a treatment plan and save it as deliverable.
4. Load films into the Ball-cube and deliver the treatment plan.
5. After the plan is delivered, perform film analysis. The film analysis software determines the film size and performs the appropriate analysis based on the size of the scanned film. The centroid of the actual delivered dose distribution on the exposed film is compared with the centroid of the planned dose distribution.

The E2E test is used to determine the total positional error for the Zap-X System.

7.3 Using the Ball-cube in E2E Tests

7.3.1 Using the Ball-cube

This section describes how to insert film into the Ball-Cube.

➤ **To insert films into the Ball-cube:**

1. Label the film reference edges (A-L for Anterior-Left and A-S for Anterior-Superior) with a fine tip permanent marker (see Figure 7-1). The labels should stay away from the center of the films. The writing will be preserved in the scanned image of the exposed films for identification purposes.

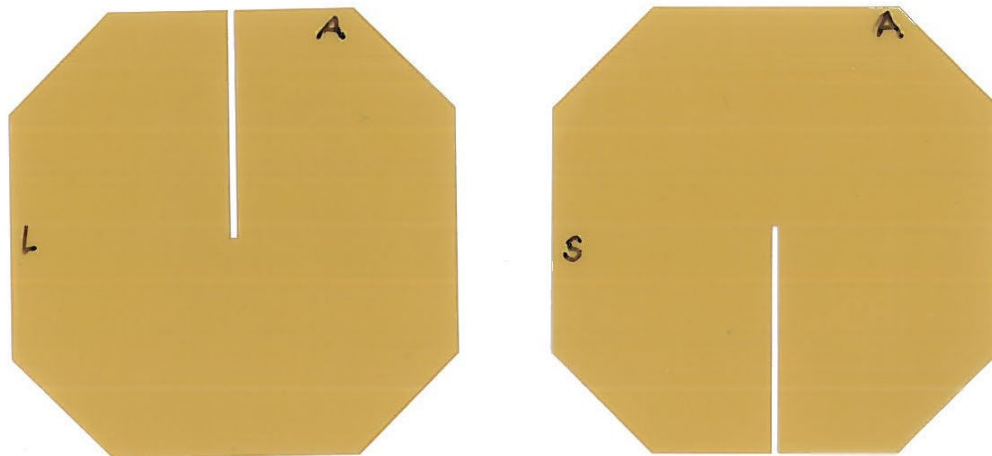


Figure 7-1 Axial (left) and Sagittal (right) Films.

2. Join the 2 pieces of film at the slits such that the two films are perpendicular to each other.
3. Open the Ball-cube, then insert the joined films into the open slots.
Use the following alignment guidelines for the joined films:
 - Axial film: Aligned with the anterior and left edges of the Ball-cube.
 - Sagittal film: Aligned with the anterior and superior edges of the Ball-cube.
4. Press each face of the Ball-cube against a flat surface so that the film edges are flush with the cube faces. If the film becomes stuck, push the film from the opposite side using a stiff piece of paper.
5. Confirm that the films are aligned flush with the anterior, superior, and left faces of the assembled Ball-cube.
To determine this, look at the reference edges from a 45-degree angle with respect to the surface of the Ball-cube. The film edges should appear as black lines. If the film is below the surface, a black line is not visible. If the film is sticking out too far, you can see it sticking out and/or can feel it with your fingers.
6. When the films are aligned flush with the faces of the Ball-cube, tighten the nuts to secure the films.
7. Put the Ball-cube with films into the head phantom.
8. Perform CT scan of the head phantom and import the CT scan to Treatment Planning System software.

7.4 Treatment Plans for E2E Tests

This section provides details on treatment planning for E2E tests using Ball-cube with films.

7.4.1 New Plan

1. Open the Treatment Planning System.
2. Login.

3. Click on the desired patient from the home page.
4. Click on the **New Plan** tab.
5. Select the desired CT image.
6. Click **Create New Plan** on the top right corner.
 - There will be four quadrants with Axial, Coronal, Sagittal, and 3D views of the selected CT and a wheel in the middle on the following screen.
7. Click on the floating wheel to access your tools
 - This wheel provides the tools necessary to create a new plan. Each icon reveals a second ring with more tools for the user. Hover the mouse over any icon to see the name of the tool.

7.4.2 Ball-cube Step

Note: This option is only applicable for phantom CT with Ball-cube.

In this step, you contour the spherical target for the ball inside the Ball-cube.

➤ **To create a volume of interest (VOI):**

1. Click on the **Contour** icon to start a new contour.
2. Click on the plus sign to name the new contour and select the VOI type from the dropdown menu (Target or OAR).

After the contour is named, the remaining tools are activated.

3. Use the contour tools such as pen, lines, circle, cut and bumper to delineate contour of the Ball. Activate these tools using the Ctrl key as described in the Treatment Planning Manual.
4. Scroll through the **AXIAL** slices to delineate the complete contour of the Ball throughout the CT volume.

After you have delineated a contour for the Ball, you may proceed to adding an isocenter.

➤ **To automatically place an isocenter at ball center:**

1. Click on the **Plan** icon to add an isocenter (see Figure 7-2).
2. Click **Manually Add/Edit Isocenters** to create an isocenter inside the ball region of the phantom CT image.
 - a. Choose 25mm collimator.

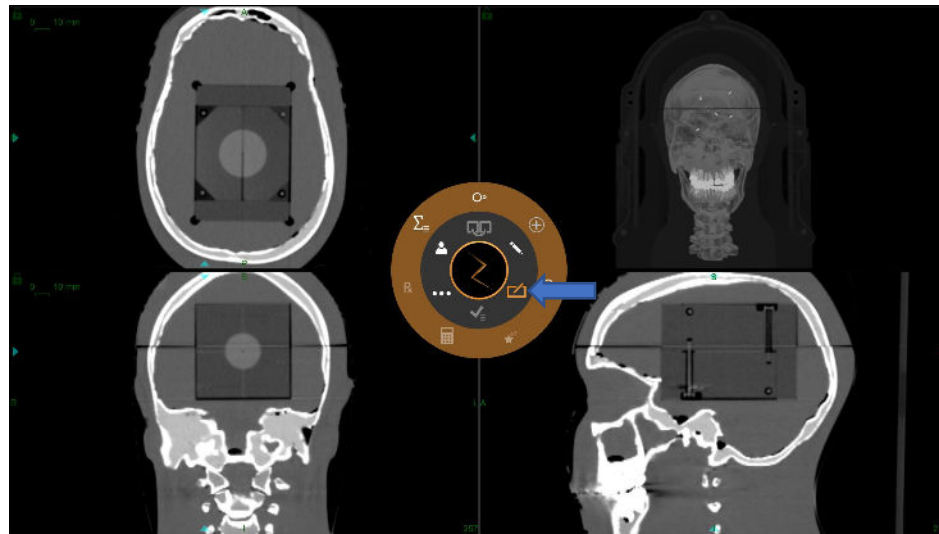


Figure 7-2 Plan icon.

3. Click **Auto ball center detection** to place the isocenter to the ball center (see Figure 7-3).



Figure 7-3 Ball-cube step.

- **To plan:**
 1. Move the isocenter as needed so that its center matches the center of the ball target.
 - Choose the collimator to be 25mm.
 2. Calculate dose.
 3. Prescribe 420 cGy to the 70% isodose line *per fraction*.
 4. Save as a deliverable plan.

7.5 E2E Dose Delivery

- **To perform E2E dose delivery:**

1. Place the Ball-cube loaded with films into the head phantom. Be sure to correctly orient the Ball-cube.

The orientation of the Ball-cube when loaded into the phantom for dose delivery should correspond to its orientation during a CT scan.

2. Place the phantom head on the treatment table in the same orientation used for the CT scan.
3. On the treatment delivery computer, deliver the E2E treatment plan to the phantom containing the Ball-cube as per the procedure described in the Treatment Delivery Manual.
4. When treatment is completed, remove the Ball-cube from the phantom.

When you dismantle the Ball-cube, evaluate the position of the Ball-cube in the phantom and the position of the films in the Ball-cube. Double check the correct orientation of the Ball-cube and confirm that the films are labeled properly.

5. Remove the films from the Ball-cube and scan the films with film scanner for analysis.

7.6 Film Analysis

Users can choose commercially available film analysis software for the End-to-End test results analysis. The optional film analysis software provided by Zap can be used to calculate End-to-End targeting errors (see Figure 7-4). The steps needed to complete film analysis for are as follows:

- Setup
- Processing
- Analysis

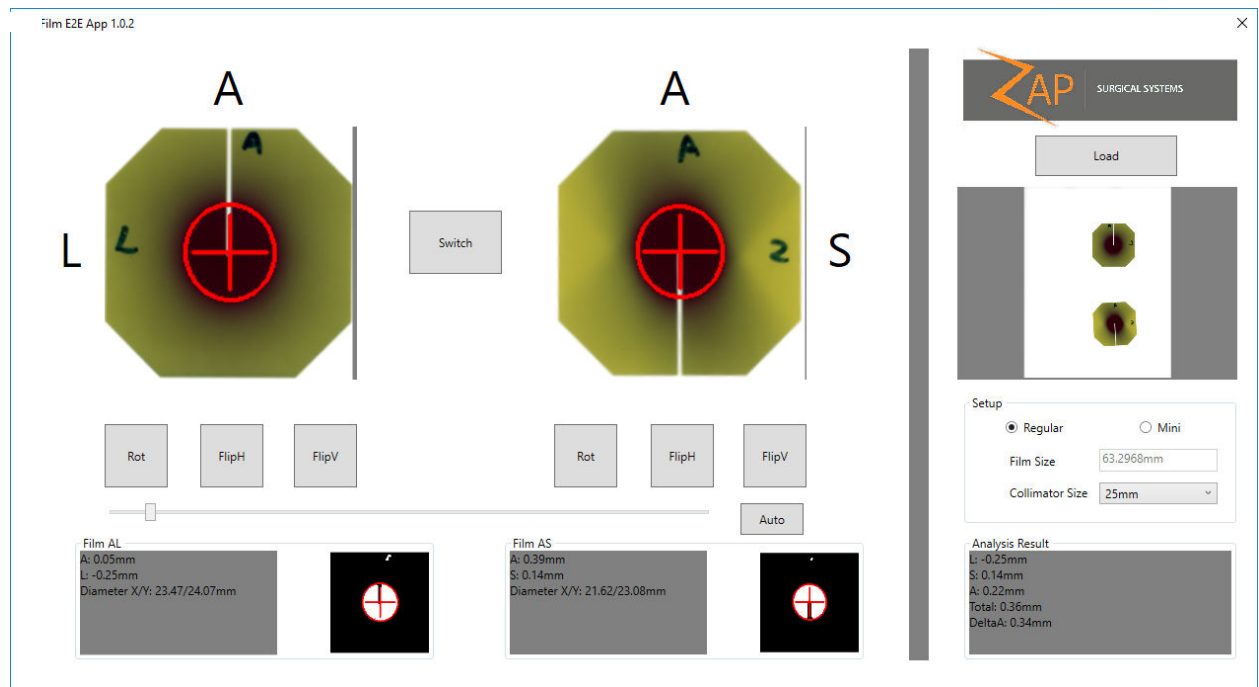


Figure 7-4 Film analysis software.

7.6.1 Setup

1. Launch the Film Analysis Software Tool by double clicking the “FilmAnalysisApp” executable file located at C:\Program Files\Zap Surgical Systems\Treatment Application.
2. Load the films into the Film Analysis Software by clicking the **Load** button (see Figure 7-5).

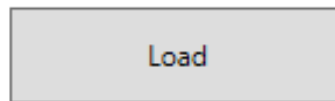


Figure 7-5 Load Button.

- Select the desired image by clicking on it and clicking **Open** (see Figure 7-6).
- All images must contain two films in order to be loadable.

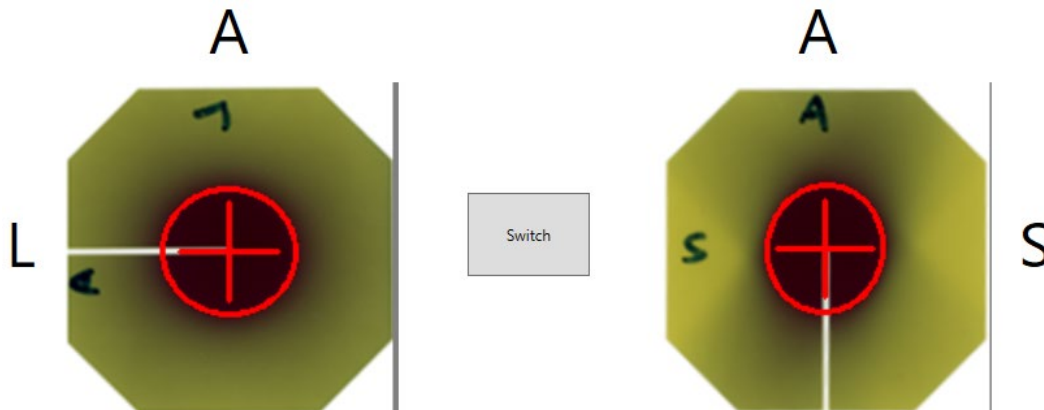


Figure 7-6 Initial orientation of films after image loading.

3. Select the size of the Ball-cube (see Figure 7-7).
 - Select Regular.

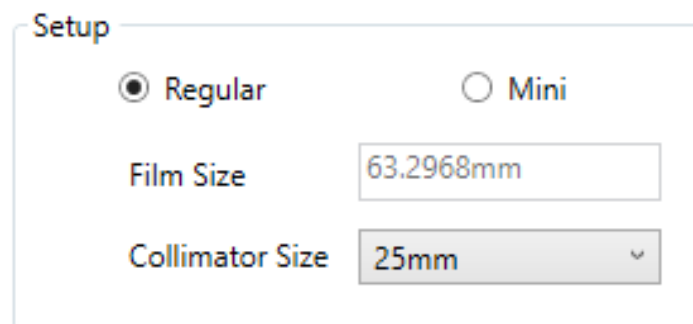


Figure 7-7 Setup ball-cube size.

4. Select the collimator size based on the size of the Ball-cube in the Collimator Size dropdown menu.

- Select 25mm.

7.6.2 Processing

Film processing, or segmentation and alignment, is done automatically in the background. The Anterior (A) and Superior/Left (S/L) edges must align. If they do not, there are various movement options for both the A/L and A/S Films that will enable the user to align them (see Figure 7-8).

- To transform the image:
1. Click **Switch** to switch the films with each other.
 2. Click **Rot** to rotate the film clockwise.
 3. Click **FlipH** to flip the film horizontally.
 4. Click **FlipV** to flip the film vertically.

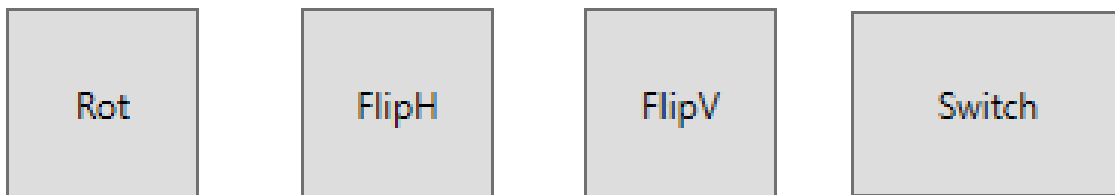


Figure 7-8 Movement buttons.

Continue to adjust the images until the (A/L) and the (A/S) align with the labels of the software (see Figure 7-9).

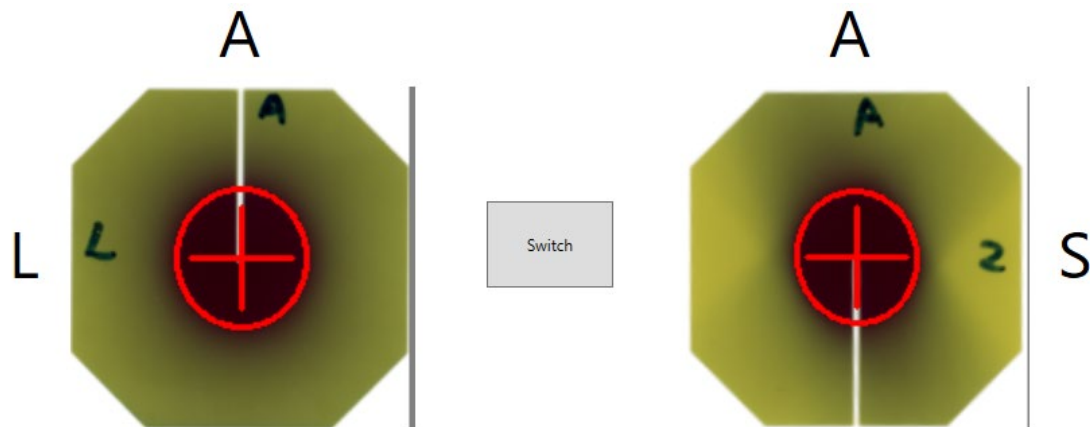


Figure 7-9 Correctly oriented films.

Note: It is extremely important to verify the correct orientation using these buttons. Failure to do so may result in incorrect and/or inconsistent results.

7.6.3 Analysis

Analysis results indicate the End-to-End error which equals the distance between the centroid of the dose profile and the center of the films (see Figure 7-10).

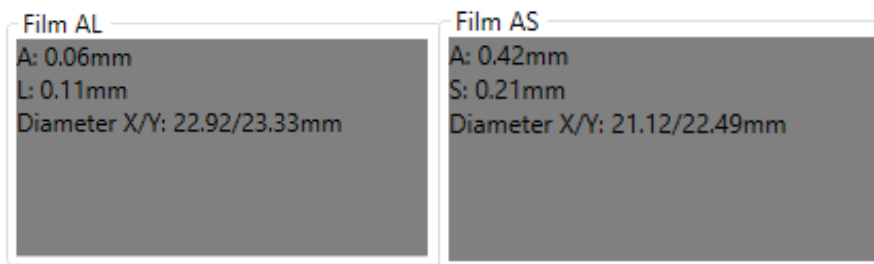


Figure 7-10 Individual film results.

- **A:** Error between the distance from the anterior edge and the distance from the target ball.
 - **L:** Error between the distance from the left edge and the distance from the target ball.
 - **S:** Error between the distance from the superior edge and the distance from the target ball.
 - **Diameter X/Y:** The ratio between the diameters in X and Y directions.
- **To get optimal analysis results:**
1. Click **Auto** to detect the dose contour.
 2. Reach the absolute smallest value of the dose contour by dragging along the slider bar to the left of the **Auto** button (see Figure 7-4). The contour is smallest on the left side and largest on the right side.

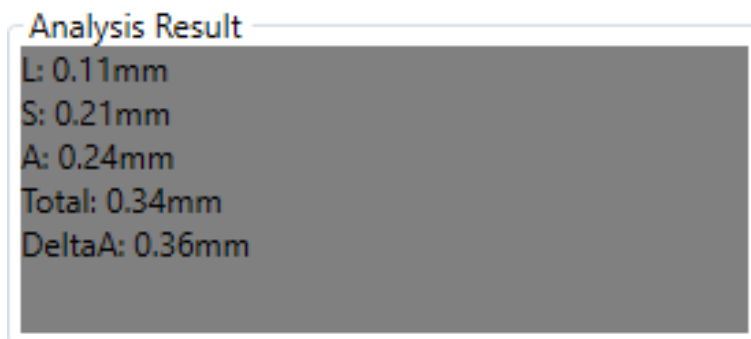


Figure 7-11 Optimal analysis results

- **L:** Error between the distance from the left edge and the distance from the target ball.
- **S:** Error between the distance from the superior edge and the distance from the target ball.
- **A:** The average of the anterior error from both films.
- **Total:** End-to-End Error which equals the square root of the sum of the squares of the results of the left error, superior error, and anterior error.
- **DeltaA:** The difference of the results for Anterior from both films.