



Zap-X Radiosurgery System Treatment Planning Manual

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

Preface



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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.

EU Authorized Representative	Notified Body
MedPass SAS 95 bis Boulevard Pereire, 75017 Paris, France	BSI Group The Netherlands Say Building John M. Keynesplein 9, 1066 EP Amsterdam. The Netherlands

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

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.



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



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.

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 a Zap product 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.

Maintenance

No user maintenance is required on the TPS computer. Please see the Treatment Delivery Manual (p/n E0920-00004) for maintenance of that part of the system.

Regulatory Classification

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

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

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 Radiosurgery System.

Treatment Planning Manual: The Treatment Planning Manual (this document) 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: The Treatment Delivery Manual (p/n E0920-00004) 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.

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 Zap-X Radiosurgery 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.

Specific Warnings, Cautions, and Notes



Warning: The quality of the output depends critically on the quality of the input data, and any irregularities or uncertainties about input data units, identification, or quality of any other nature shall be thoroughly investigated before the data are used.



Warning: Do not alter the software or any of the components in the Zap-X Radiosurgery System. Do not attempt to access Zap files except through the Zap user interface.



Warning: Do not attempt to obtain connection to the internet unless directed to by Zap personnel.

Caution: Do not modify Treatment Planning system code or data.

Note: Customer is responsible for providing a secure connection to their network.

Note: Safe and effective exchange of information between Zap-X radiosurgery System and customer network-based devices is the responsibility of the customer.

Note: Customer is also responsible for the archive of patient data to a separate medium.

Note: The software has limits on numeric values and text that can be entered. In the event that an invalid value is entered, an error message will appear before returning to the previous page.

Note: The Treatment Planning system includes a check to ensure all files used by the software application and the application itself have not been modified. In the event that either is modified, the system will not start and it will display an error. If this occurs, contact Zap-X Customer Support for assistance.

Note: Failure of the diagnostic checks result in orderly termination of the Treatment Planning process.

Known side effects

Caution: Prevalence and intensity of side effects experienced by patients during radiotherapy vary based on the type of cancer, 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. Common side effects include fatigue, drowsiness, sleep, pain, feeling upset, memory difficulties, skin problems, lack of appetite, shortness of breath, nausea, urination difficulties, and vomiting.

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1. Overview

This section gives an overview of the planning workflow. Each section in this overview is a page or two, and generally references a chapter where more detailed information can be found.

1.1. Overview of Patient Selection

This overview assumes that:

- You have an account and are logged in. (see Chapter 11)
- The patient is in the Zap-X database and DICOM images are available. (see Chapter 12)

Please see Chapter 3 for detailed information related to this overview.

Home page: Selecting a Patient

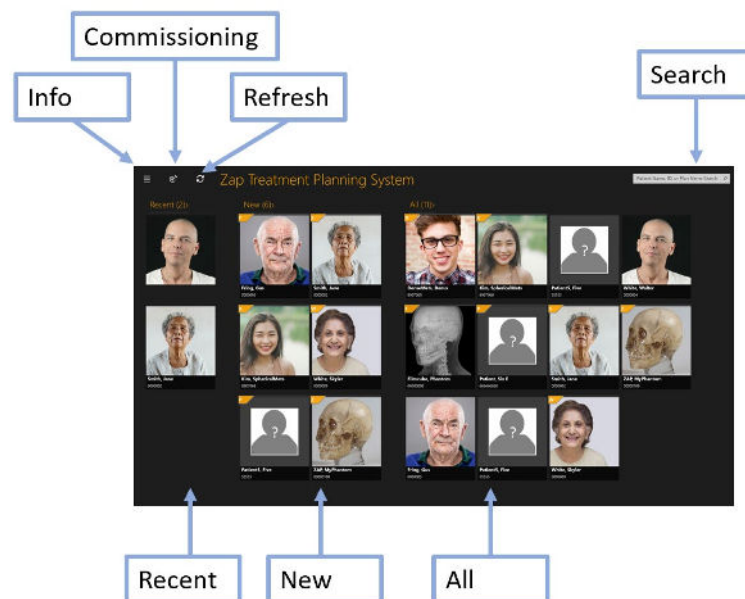


Figure 1.1.1: The home screen.

The Home Screen is the initial screen displayed when the planning software is invoked. This page shows the list of patients that are available for planning:

- **Recent Patients:** The next section shows the most recent five patients that have had some planning done. The plans may or may not have been completed.
- **New Patients:** The left side of the screen shows patients that do not have a plan.
- **All Patients:** Shows all patients currently in the planning database.

- **Search:** Type the patient name, ID, or plan name to filter the list of patients that are displayed.

Starting a Plan

Once a patient is selected the patient page is displayed, and you can start a new plan or re-open an existing plan. If there are existing plans the next screen shows a display of those plans. Tabs at the top of the screen let you pick between re-opening an existing plan or starting a new one.

If you are starting a new plan, you will see a display of the MR and CT series that have been loaded for that patient. A CT series must be selected as the primary image series. The primary image will be used during treatment to align the patient to the plan. A second series, either CT or MR, can be included in the planning process.

Once the image series are selected, click on the “Create New Plan” button in the upper right of the screen. You will be asked to confirm the images that will be used, and the system will confirm that the images meet the Zap-X criteria. After that, the planning process is started.

1.2. Overview of the User Interface

The Workflow Wheel

Figure 1.2.1 shows an example of the Workflow Wheel, which is the main UI interaction on the Zap-X system.



Figure 1.2.1: The Workflow Wheel

There are three concentric parts to the wheel:

- **Inner Wheel:** This progresses through the main workflow of the planning session. See table 1.2.1 for a description of the items on this wheel.
- **Outer Wheel:** This shows options related to the currently selected inner wheel option.

- **Zap ‘Z’:** Depending on the state, this can either hide the wheel or provide access to advanced functionality. When performing a lengthy calculation, such as Fuse, a spinning Z indicates that the system is working.







Function	Icon	Description
Fuse		This workflow aligns the CT and MR series when multiple series have been included in the plan. See chapter 4 for details.
Contour		This workflow draws the contour of the target(s) and, if appropriate, any critical structures. See chapter 5 for details.
Plan		The next step is to plan the isocenters and dosing to be used during treatment. See chapter 6 for details.
Approve Plan		The plan can be approved for delivery once planning is complete. See chapter 7 for details.
General Controls		General controls such as reset, measure, settings, etc. See chapter 9 for details.
Patient Info		Shows the patient name, ID, and picture.

Table 1.2.1: Contents of the Inner Workflow Wheel

Image manipulation

During the course of planning you will be editing contours to define targets and critical structures. You will also be editing isocenters to define the treatment. While doing this, you may also want to manipulate the underlying CT or MR image. In general, pressing the Control (“Ctrl”) key means the next action applies to the contour or isocenter. The details are described below. If Ctrl is not pressed it generally means the action applies to the image.

Function	Access
Image pan	Click/drag on the image.
Image Brightness	Right click on the image and move left/right.
Image Windowing	Right click on the image and move up/down. The value of the window and level will be displayed while you do so.
Scroll series	Scroll the Mouse Wheel. One click per image.

Zoom image	Shift + Scroll the Mouse Wheel.
Switch between CT/MR	Click on the “A” icon in the lower left of each view to switch to the other series “B”. A/B is also available to show both at once.
Focus Point	Click/drag on the small triangle on each edge of each view to move the intersection between views. Or double-click on a point in the image to set the focus.

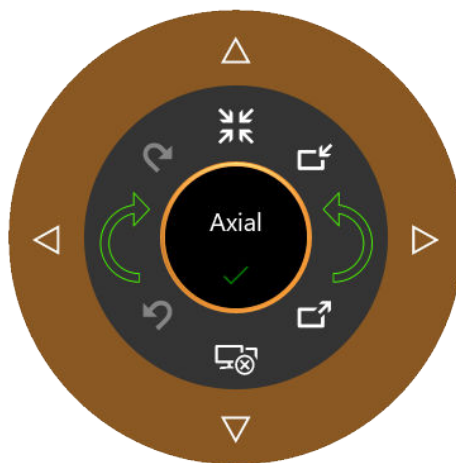
Table 1.2.2: Image manipulation controls


1.3. Overview of Image Fuse

See Chapter 4 for details of features described in this overview.

A CT series is required as the primary image for every plan. The primary image is what Zap-X uses to align with the patient head during treatment delivery. However, a second series can be used during planning to help visualize the target while planning. The second series can be an MR series or another CT series. This section will assume it is an MR series.

When a planning session includes two series the first step is to fuse them together so that the anatomy aligns between the two. Figure 1.3.1 shows the Workflow Wheel when fusing image series.

**Figure 1.3.1. The Fuse Workflow Wheel**

Function	Icon	Description
Typical Workflow These two steps are often all you need to do.		
Start Fuse		Clicking this will automatically fuse the two series based off the currently selected algorithm. This will take several seconds.









Approve		If you are satisfied with the results of Auto Fuse, press this control to end the Fuse workflow. A confirmation dialog is displayed to confirm keeping the current fuse.
Fuse Mode		Toggles between three different fuse algorithms. The default (icon shown) is for the system to automatically select a sub-volume to fuse.
Manual Workflow Use these controls if you are not satisfied with the Auto-Fuse results.		
Reset		Resets both series to the original location, undoing any fuse operations that had occurred.
Import/Export		Imports or exports fuse parameters.
Undo/Redo		Allows you to undo or redo a rotate or nudge command.
Rotate Left/Right		These icons rotate the MR series a small amount clockwise or counter-clockwise. The rotation amount will be larger if Ctrl is pressed while using these icons.
Nudge		These 4 icons on the outer wheel will nudge the MR series a small amount in the indicated direction. The nudge distance will be larger if Ctrl is pressed while using these icons.
Active quadrant		Clicking this cycle between Axial, Coronal, and Sagittal. The nudge and rotate controls apply to the active quadrant.

Table 1.3.1: Fuse controls

1.4. Overview of Contouring

See Chapter 5 for details of features described in this overview.

Once image series are fused, the next step is to add contours. There are two types of contours:





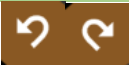
- **Targets:** These are the lesions you want to treat.
- **Critical Structure:** Areas where you want to particularly minimize radiation.

All contour editing is done on the Axial view.

Figure 1.4.1 shows the Workflow Wheel for adding contours. When this wheel is first displayed the only icon that is displayed is the “Add Contour” icon at the top. Other controls become available after you enter the name and the type of the first contour.



Figure 1.4.1. Workflow Wheel for adding contours

Function	Icon	Description
Contour Management Tools		
These tools manage the number/type/etc. of the contours		
Add Contour		Add a new contour. Displays a dialog to select from target, critical structure, or water equivalent. This dialog also provides pre-selected names for targets and critical structures, or allows you to enter custom labels.
Cycle Contours		The editing tools apply to one contour at a time. This control cycles between the current contours.
Change Layout		Toggles between the default quad screen layout and one that shows a large axial slice and 8 small adjacent slices.
Contour List		Displays a table of all contours.
Editing Tools		
These tools edit the currently active contour. All of these are used by pressing the Ctrl key while the tool is active.		
Undo/Redo		Undo or Redo the last edit to the contours.







Pen		Ctrl+click+drag will draw a line as the mouse is moved.
Polygon		A series of Ctrl+click will put down a series of dots connected by straight lines. A double-click ends the series.
Circle		Ctrl+click+drag creates the diameter of a contour.
Bumper		Ctrl+click+drag will move the borders of a contour. If the bumper is inside a contour this will extend it. If the bumper is outside a contour this will push it in.
Cut		Ctrl+click will delete the contour from the current image.
Copy/ Paste		Clicking this on one image will copy the contour from that image. Scrolling to another image and clicking again will paste that contour on the new image.

Table 1.4.1. The Add Contour Workflow Wheel

A few helpful hints:

- The system will automatically interpolate between image slices to fill out a contour. For example, you can skip multiple image slices when creating an initial contour, and then go back and edit each slice with the bumper to correct the interpolated contour on each slice.
- The bumper has a fixed size in pixels. Use Zoom (shift+mouse wheel) to change the image scale and thus change how much anatomy is affected by the bumper.

1.5. Overview of Isocenters and Dosing







See Chapter 6 for details of features described in this overview.

Once the target(s) and any critical structures are contoured, the next step is to add isocenters and determine the dose prescription. Click the “Plan” icon on the inner Workflow Wheel to access this phase. Figure 1.5.1 shows an example of the planning Workflow Wheel.



Figure 1.5.1: The Workflow Wheel while adding isocenters

Function	Icon	Description
Cycle Isocenter		When multiple Isocenters have been created, this will cycle between them. Each isocenter in turn becomes active. The axial plane may shift as needed to display the active isocenter.
Beam Reduction		Reduces the number of beams, and thus increases the dose per beam. A dialog will ask you to set how many beams are skipped.
Auto-Fill		Fills the current target contours with automatically calculated isocenters. A dialog will ask you to set the algorithm to use.
Dose Calculation		Calculates a dose distribution for all isocenters, assuming a nominal dose.
Prescribe		Defines the actual dose. A dialog will ask you to set the dose for a given isodose level, along with the number of fractions to use. Calculating the dose can take some time, during which a transition dialog is displayed.
Plan Summary		Shows a DVH curve for the current contours. You cannot approve the plan from this display (See “Approving the Plan”, below).
Isocenter List		Shows a list of isocenters, including information such as scaling, MU, beams, etc.

Hide/Show		Clicking this icon will toggle the display of the non-active isocenters on/off. (Non-active isocenters are normally minimized.)
Undo/Redo		Undo the last isocenter edit, or redo what had just been undone.
Scale		Sets the scaling for the currently selected isocenter. The scale value of each isocenter will determine the dose delivered relative to other isocenters.
Add Isocenter		Adds a new isocenter at the current point of focus. A new isocenter can also be added anywhere by using CTRL+left-click.
Delete Isocenter		Deletes the currently selected isocenter.
Isocenter Control		This displays the advanced Workflow Wheel. In this state clicking the center of the wheel cycles the outer wheel between: Buttons for each collimator size. Arrow keys to nudge the isocenter in 3 axes.

Clicking on an isocenter makes it active. Normally only the active isocenter is shown in full size, while non-active isocenters are minimized. Note, “non-active” refers to the UI state; these isocenters are still part of the plan and impact the isodose curves.

Most of the interactions with Isocenters involve pressing the Control key. While the Control key is pressed:

- Scrolling the mouse wheel changes the collimator size.
- Clicking on the image will place a new isocenter at that point.
- Click and drag on an existing isocenter will move it around on the image.

1.6. Overview of Approving and Reporting

See Chapters 7 and 8 for details of features described in this overview.

Once you are satisfied with the planning process it is time to approve a plan.

Pressing the Plan Approval icon on the inner wheel will display a screen similar to figure 1.6.1. This is the same screen that is displayed in the plan summary function of the isocenter outer wheel except that here it has a save icon.

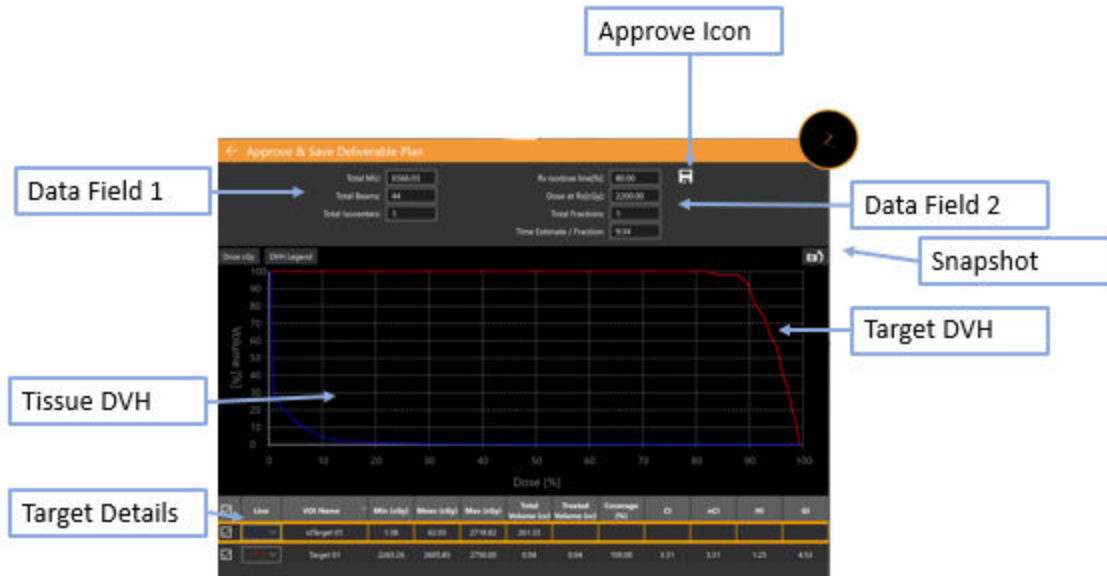


Figure 1.6.1. Approving the Plan

Approve Icon: Clicking this will save the plan as deliverable. A dialog will appear asking you to name the plan and who is the approver. (The approve icon does not show in the plan preview UI).

Data Field 1: Shows the Total MU, Total Beams, and the number of isocenters.

Data Field 2: Shows the prescribed isodose line, the dose to be delivered at that line, and the number of fractions to be used. These can be set in the “Prescribe” interaction (see section 6). Also shown is an estimate of the delivery time per fraction.

Snapshot: This toggles a picture of the DVH curve into or out of the preliminary report.

Target DVH: The Dose Volume Histogram shows a DVH curve for each contour, target (red) or critical structure (green). Buttons on the upper left toggle between Dose and Dose% for the X-axis, and to hide/show the legend of each target.

Tissue DVH: Blue lines on the DVH curve show the DVH curve for the tissue immediately surrounding target contours.

Target Details: There is one line here for each DVH curve shown: targets, critical areas, and tissue. Clicking on a line will highlight it. Note that clicking anywhere on the DVH curves will show the volume and dose for the highlighted row.

You can generate a preliminary report based on an approved plan. See chapter 9, General Controls, for details.

2. CT and MR Images

This chapter describes the requirements for acquiring CT and optional MR image series for use during planning and treatment. Please refer to the user manual of your CT or MR system for the proper operation of that equipment.

2.1. Introduction

Every plan must have a primary image series that is a CT. The primary image is used for:

- Delineating structures during planning
- Defining anatomical features for tracking
- Dose calculation
- During treatment delivery to align the patient with the plan

In addition, plans can optionally have a secondary image series that is either a CT or an MR. For example, a secondary image series may be used to better visualize anatomy during the planning process. During the planning process this secondary image is fused to the primary image so the anatomy aligns between them.

2.2. CT Acquisition

CT Set-up

Zap strongly recommends that you use the CT head support that is provided with the Zap-X system (p/n E0040-00237). Using this head support, along with a compatible headrest such as Civco Silverman, will help ensure that the patient position relative to the table is the same for image acquisition and treatment delivery.



Warning: Verify that the Treatment Planning System displays patient orientation labels as intended by the manufacturer of the scanner. Use of incorrectly labeled images could result in patient mistreatment.



Warning: Prior to import, review the images to verify that the patient did not move during image acquisition.

Basic Parameters for CT Imaging

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

- Head First Supine (HFS)
- 512x512 pixels per slice
- Slice thickness: $\leq 1.25\text{mm}$; 1.00mm is ideal
- Constant slice thickness throughout the series
- Air gap surrounding patient silhouette:

- 10mm anterior
 - 10mm posterior, from bottom of table to edge of CT in posterior direction
 - 1mm superior
 - none inferior
 - left/right centered
- Yaw/Pitch/Roll = Approximately 0 deg.
- Use the same immobilization device as will be used during treatment delivery.
- No imaging device specific CT to density curves are applied to specific devices. A nominal CT to density conversion is applied for all imaging devices covering the range of available densities.
- Please refer to Chapter 12 (DICOM) for required DICOM parameters.

Patient Immobilization

Proper patient alignment during image acquisition should replicate as closely as possible the patient position during treatment.

Use the same head immobilization device as will be used during treatment. Zap-X supports any FDA cleared mask with Type-S interface.

Adjust the orientation of the treatment table so that the alignment is the same as that recorded during the primary CT scan.

➤ To provide head and neck immobilization

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.

2.3. MR Imaging Guidelines

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

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

2.4. The Image Display During Planning

During planning the typical display is a quad screen layout. Counter-clockwise from the upper left it shows Axial, Coronal, Sagittal, 3D views. Figure 2.4.1 shows an example of the Axial quadrant, showing some of the detailed information that is displayed.

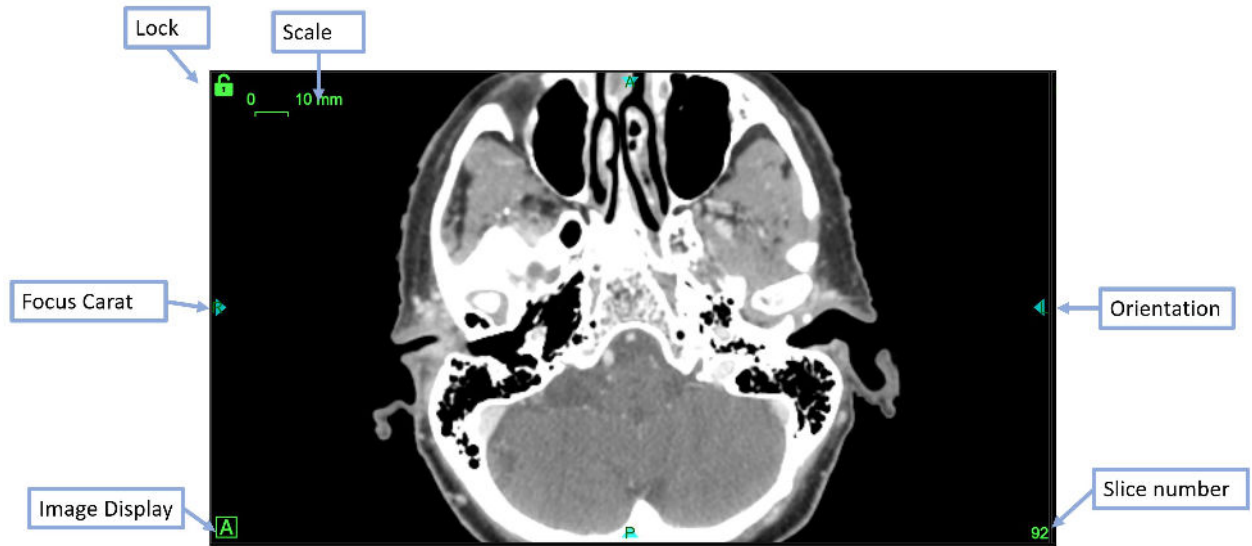


Figure 2.4.1. Example Axial quadrant display

The information includes:

- **Scale:** A line segment showing 10mm in length. The size of this segment changes as the image is zoomed (using shift+scroll).
- **Lock:** The green lock icon in the upper left corner of each image pane allows you to keep that pane still when scrolling through slices of the CT images.
- **Focus Carat:** The focal point is where the Axial/Coronal/Sagittal quadrants intersect. The focus carat always appears to indicate where this is.
- **Image Display:** Clicking on this icon cycles the quadrants between the primary image series ('A'), the secondary image series ('B'), or a checkerboard display of both.
- **Orientation:** Located in the center of each side, the orientation labels indicate the patient orientation imported with the image series. This includes L (left), R (right), P (posterior), A (anterior), S (superior), and I (inferior).
- **Slice Number:** The current slice which is displayed.

Hovering on a focus carat will show the focus lines on all quadrants. (see Figure 2.4.2). When the lines are displayed, they can be dragged to move the focus point anywhere on that quadrant. Unless the other quadrants are locked, they will scroll images as needed to show the focus point on that quadrant.

While the focus lines are displayed the lower left corner of each quadrant will display the X, Y, Z location of the focus. Once dose levels are calculated it will also show the point dose at the focus point.

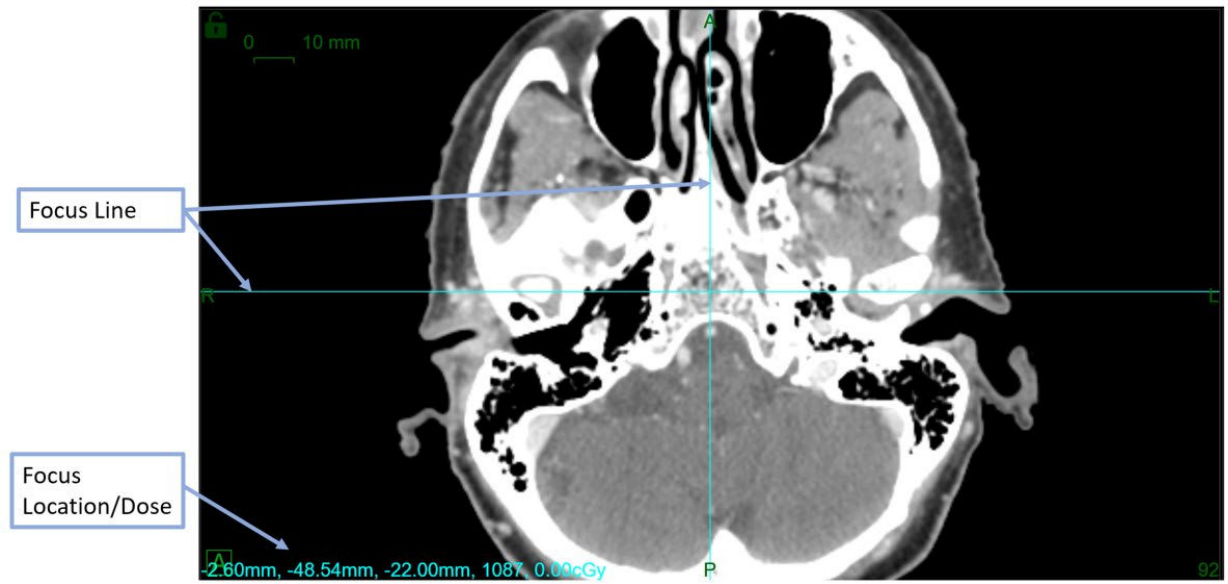


Figure 2.4.2. An example of the focus lines.

3. Starting a Planning Session

This chapter covers logging into the TPS software, selecting patient, and either creating a new plan or editing an existing plan.

3.1. Logging In



Warning: Only authorized users can log into the system.

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.

The Treatment Planning Computer has been configured by Zap surgical to connect to the database of patient information and plans. Please see your system administrator for user name or password issues.

➤ To log into the Treatment Planning System

1. Power up and log into the Treatment Planning computer, then double-click on the TPS desktop icon.
2. Enter the username in the User Name textbox.
3. Enter the password in the Password textbox.

As information is entered, black dots will be displayed. To make corrections, press the DELETE or BACKSPACE key.

4. Click the **Login** button.



Figure 3.1. The TPS login screen

Note that at the bottom of the login screen there is confirmation that the system has sufficient memory, disk space, and display settings. You will not be able to login if any of these criteria do not pass. Please see Chapter 11 (System Administration) in that case.

3.2. The Home Page

The Home Page is displayed when the TPS software is first invoked. It is also displayed after a planning session is completed. It shows a list of all patients that are available for planning.

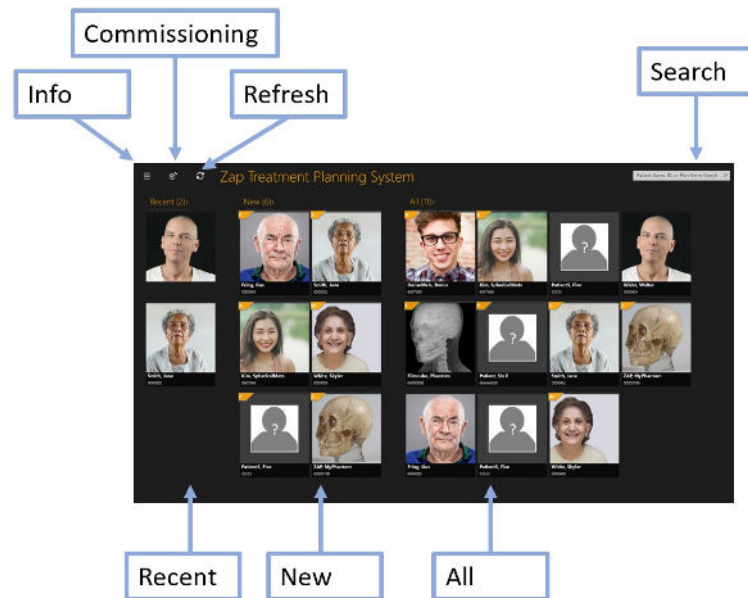


Figure 3.2.1. The Patient Page.

- **Recent Patients:** The next section shows the most recent five patients that have had some planning done. The plans may or may not have been completed.
- **New Patients:** The left side of the screen shows patients that do not have a plan.
- **All Patients:** Shows all patients currently in the planning database. Patients are sorted alphabetically by last name.
- **Search:** Type the patient name, ID, or plan name to filter the list of patients that are displayed.

Note, figure 3.2.1 shows an example that has pictures for each patient. The system can be configured to not show these pictures, if so desired.

Additional information is shown when the cursor is hovering over a patient. A single click on any patient brings you to the interaction where you are working with patient data. See section 3.3 for details.

The Patient Page also has some utility controls:

- **Application Settings:** The main use for this control is to exit the application, log out, or to switch users. See figure 3.2.2 for an example. It also has version and the database IP settings, which may be useful for DICOM administrators (see Chapter 12). Also in this menu is an option to hide/show patient pictures from the main patient page.
- **Commissioning:** Displays the current commissioning data and allows you to import new data. See Chapter 10 (Beam Data) for details.
- **Refresh:** Updates the display of patients. This ensures the display is up to date with the database contents.

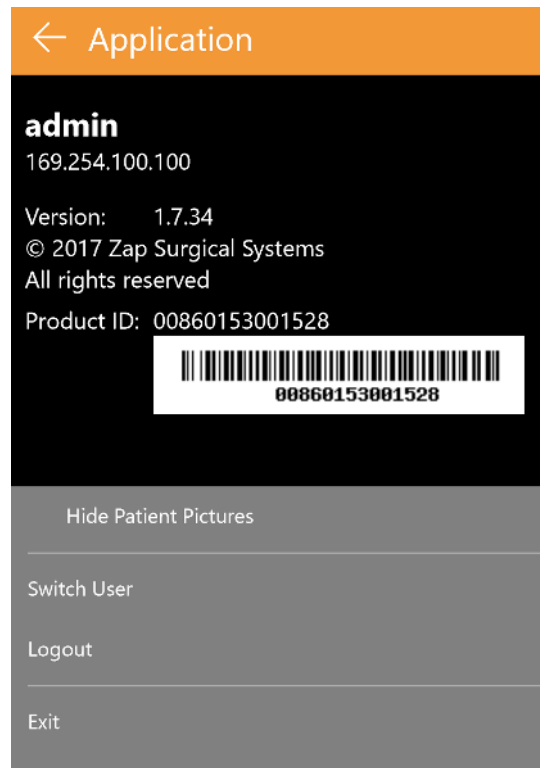


Figure 3.2.2. The Application Settings Dialog.

3.3. Patients and Plans

The Patient page is displayed when a patient is selected from the Home page. See figure 3.3.1 for an example.

If there are existing plans for this patient, then there are tabs along the top of the screen for “New Plan” and “Existing Plan”. The tab for Existing Plan is active by default.

To Create a new plan

When the “New Plan” tab is active TPS displays the CT and MR series that are available for the current patient.

- The first CT series you select will default to be the primary CT series. If you select another CT series, you can decide which is the primary by selecting the “Primary CT” radio button on the image thumbnail.
- If you want a second image series to be included in the plan, simply select it as well. The second series can be either CT or MR.
- Once the image series are selected, press the “Create New Plan” button in the upper right of the screen.



Warning: Verify that the Treatment Planning System displays patient orientation labels as intended by the manufacturer of the scanner. Use of incorrectly labeled images could result in patient mistreatment.



Warning: Verify that for each DICOM image series selected, that all slices are listed and meet the image acquisition guidelines. Refer to the pretreatment scanning guidelines.

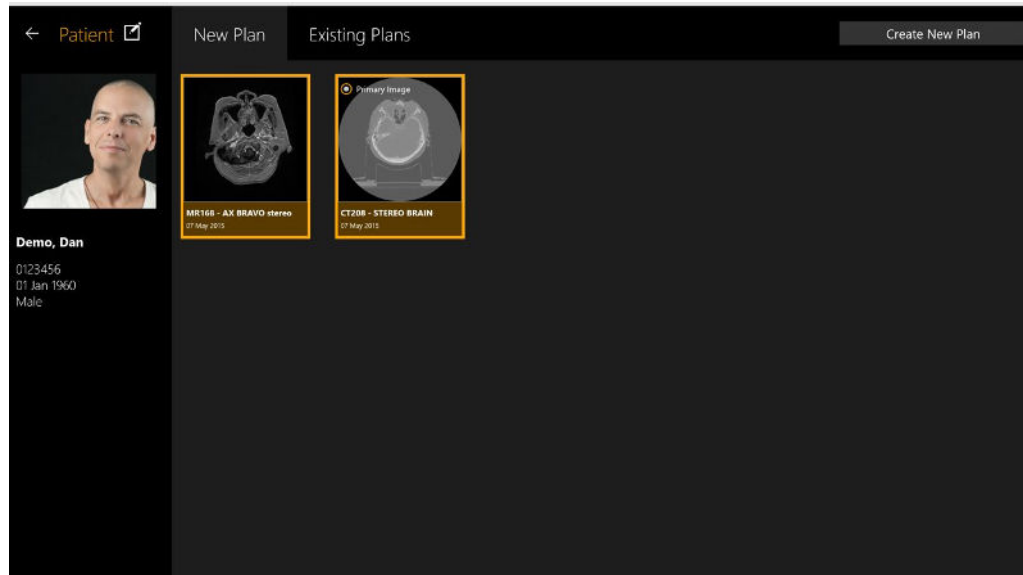


Figure 3.3.2: The Patient page with 2 images series selected.

To Open an existing plan

With the “Existing Plans” tab active the system displays the plans that are available. Select the plan you want to work on and press the “Open Plan” button in the upper right of the screen. Figure 3.3.2 shows an example of the existing plan display.

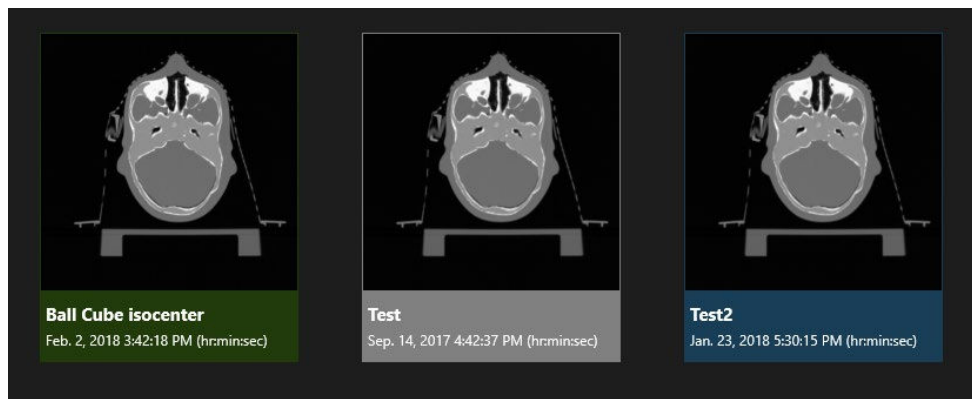


Figure 3.3.2. Existing Plan Display

Plans show up in one of 3 colors:

- Blue plans are in process of planning.

- Green plans are approved for delivery. It is still possible to edit and re-save these.
- Grey plans are ones that are already delivered (either partially or completely).

Deleting a Plan

A plan cannot be deleted if:

- Treatment of the plan has begun.
- Another user is using the same plan.
- The plan is being loaded.
- The plan is currently locked by another application.
- It is already delivered.

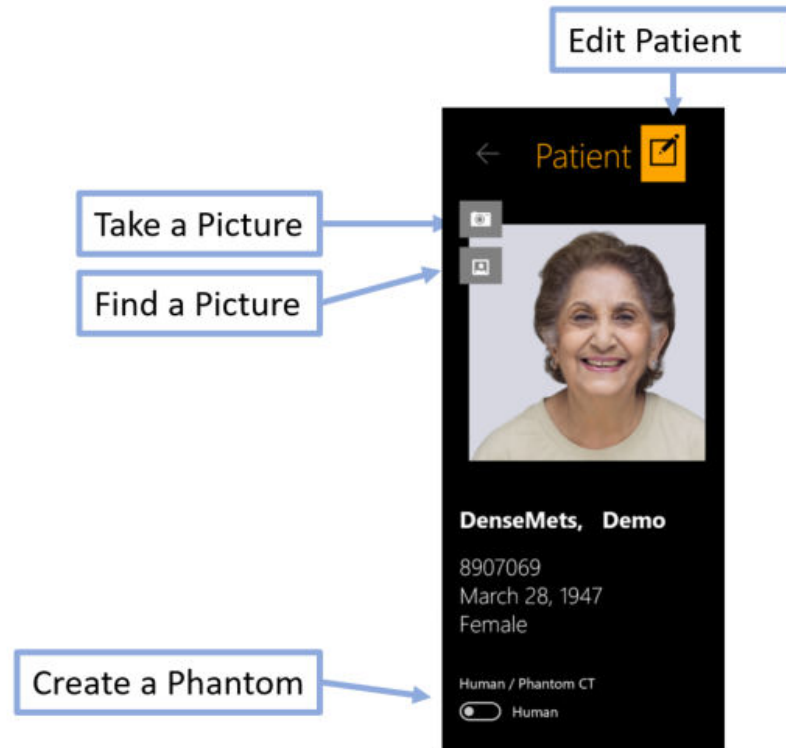
➤ **To delete a plan from a patient's profile:**

1. Select the correct patient from the home page to access their profile.
2. Select the correct plan.
3. Click the Delete Plan button in the upper righthand corner.

3.4. Editing Patient Information

The “Edit Patient” button is an icon right above the patient picture. It supports the following actions:

- **Take a Picture:** If you have a supported camera on your computer this will invoke that camera to take a picture of the patient.
- **Find a Picture:** Brings up a file browser to find a picture of the patient on your computer.
- **Create a Phantom:** If you have a CT for a phantom it is imported into the system as if it was a patient. This control lets you tell the system that this ‘Patient’ is really a phantom (see “Simulated Plans” below)



3.5. Simulated Plan

A simulated plan is one that is developed on a real patient, and then remapped to a phantom. This allows you to measure the actual dose to be delivered as a QA step before the treatment. To create a simulated plan, you must first import images for the phantom that will be used to measure the delivered dose, and then convert that 'Patient' to a phantom by editing the patient information (see above). Once that is done:

- Develop and save a plan for the intended patient using the images of that patient.
- Select that plan on the patient page, and then right-click. You will see three options:
 - **Simulate plan:** Creates a simulated plan while keeping the contours and isocenters in the same position as the original plan.
 - **Simulate plan using Rx centroid:** Moves the peak dose of the plan to the centroid of the phantom. Not all Linac positions are available for all isocenter locations, so this may reduce the number of beams delivered, but it won't change the overall dose.
 - **Simulate plan to ion chamber target center:** This moves the peak dose of the plan to a pre-defined location. Please contact your service representative if you want to set up this pre-defined location.
- Once the type of simulation is selected the system will display all CT images that have been designated as phantoms. Select one of these and press the "Add Simulation Plan" button in the upper right of the screen
- TPS will open the new plan so you can confirm that it is correct. Once it is saved it will be displayed as a new plan, with "_Simulation" appended to the plan name and a "Simulation" watermark over the patient picture.

3.6. Merging Plans

As currently implemented each plan has one prescription level at one isodose line, no matter how many isocenters are used (see chapter 6 for more information). If a clinical situation calls for different targets to have different prescriptions the following steps may be used:

- Create separate plans for each prescription level needed. Save each plan.
- On the patient page for that patient, select the first of the saved plans with a single click. Ctrl+click on each of the remaining plans you want to combine. This will select them as well.
- Right-click on any of the selected plans. Select the “Merge plans” option on the right-click menu.
- The system will open a new plan, with the isocenters and doses of each of the plans combined into one.
- Save the new merged plan as a new, separate plan.

Note, a merged plan is a simple combination of the beams of the input plans. It is your responsibility to review the merged plan and correct for the effects of the combined beams.

Note: the displayed prescription level in the merged plan does not reflect the separate prescriptions of the input plans. The displayed isodose lines and point doses will be correct.

3.7. Auto-saved Plans

TPS will regularly auto-save a plan as it is being worked on. If a plan was not saved properly or if TPS terminates unexpectedly, Treatment Planning System will give the user the option to load an auto save plan if it is detected or start a new plan from scratch. Select **Restore Auto Saved Plan** to return to the plan you were previously working on. Select **Delete Auto Saved Plan** to delete the previous plan and start a new one. This option will lead you to the Home Page.



Warning: Confirm a restored plan is correct before re-saving it.

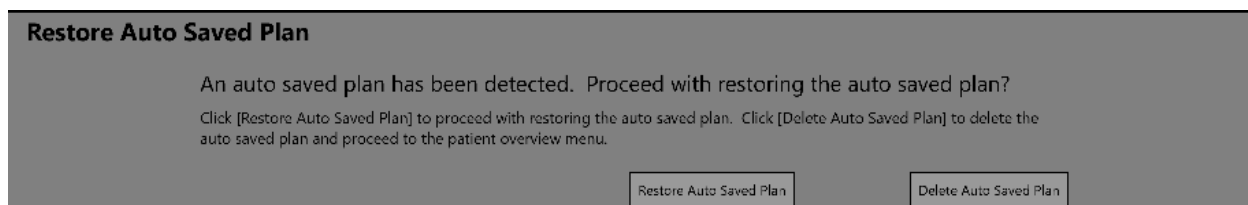


Figure 3.7.1. Recover Auto Saved Plan

4. Fusing Image Series



Warning: If images are registered from two different patients, it could result in serious injury to the patient during treatment delivery. Be certain that the images being registered are for the same patient.



Warning: When registering images, verify that the images being registered contain sufficient anatomic features to ensure proper registration.



Warning: Always confirm registration correctness visually before proceeding.

A CT series is required as the primary image for every plan. The primary image is what Zap-X uses to align with the patient head during treatment delivery. However, a second series can be used during planning to help visualize the target while planning. The second series can be an MR series or another CT series.

When a planning session includes two series the first step is to fuse them together so that the anatomy aligns between the two. To invoke the Fuse interaction, press the Fuse icon at the top of the inner Workflow Wheel.

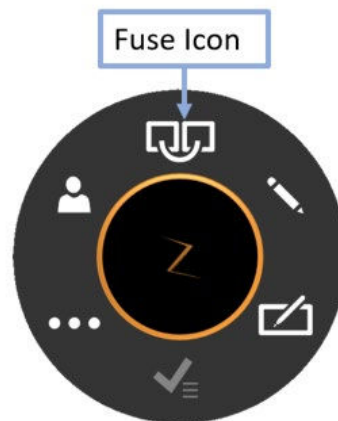


Figure 4.1 The Fuse Icon.

When the Fuse interaction is invoked the Workflow Wheel will move out of the center of the screen and into the lower-right sagittal display to fully show the axial image. You can move the wheel anywhere at any time simply by dragging it.

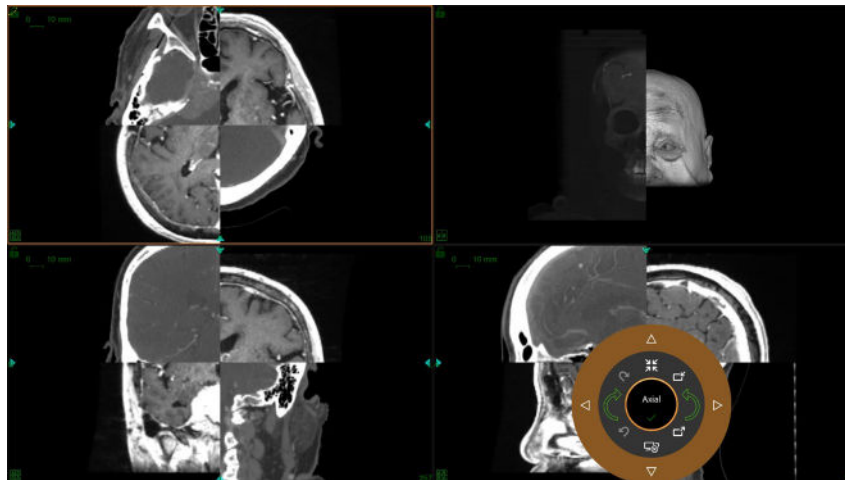


Figure 4.2. The Fuse screen

The initial display will show both the primary and secondary series in a checkerboard display. Typically, the two series are not aligned to start, so landmarks that cross the checkerboard border are often not aligned to start.

Figure 4.3 shows the Workflow Wheel during fuse. The fuse workflow can be separated between the Auto Fuse and the manual fuse, described separately below.

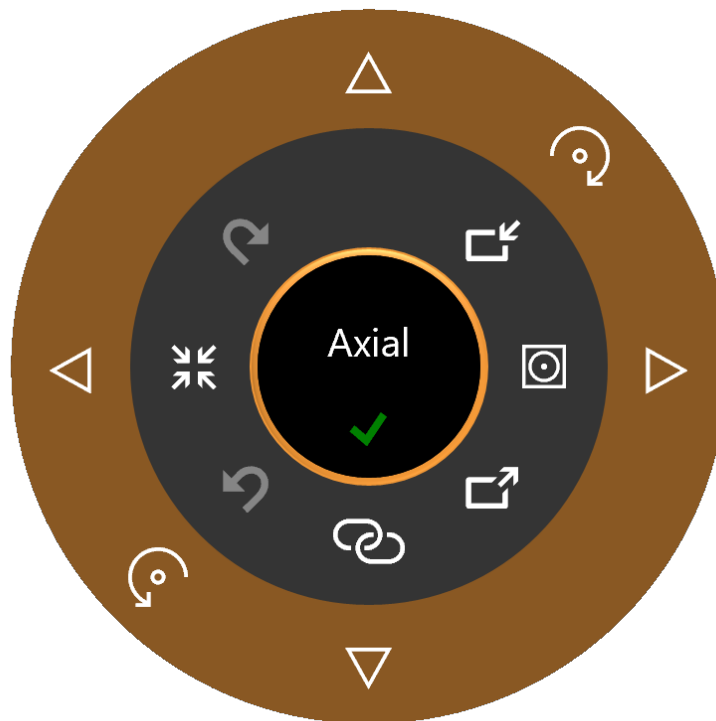




Figure 4.3: The Workflow Wheel during Fuse

4.1. Automated Fuse

The Auto Fuse is often the only step needed to fuse the two series. It is invoked by clicking the Start Fuse button at the bottom of the inner wheel. When this is clicked the system will do an intensity-based registration between the two series. The secondary series is rotated and translated as needed to optimize the fuse.

There are 2 versions of the fuse algorithm supported. You can switch between them by clicking on the fuse mode button on the right side of the inner wheel. As you click, the icon switches between the following 2 states:

Function	Icon	Description
Sub-Volume		The system optimizes the fuse based on a sub-volume automatically selected to focus on anatomy. This is the default setting.
Manual		A manually selected sub-volume is used to optimize the fuse. This is shown as a green rectangle on each plane. Each rectangle shows 8 grab points around the edge. Ctrl+click+drag on a handle allows you to change the sub-volume to optimize.










Once the Auto Fuse algorithm is complete the images should appear aligned. The system will display a similarity measure for the Auto-Fuse, as shown in figure 4.4. The higher the number the better the fusion. It ranges from 0 to 1. Since the two series are by their nature different you should not expect the final number to be 1. The real criterion for a good fusion is your clinical judgement about how well the two series are aligned.



Figure 4.4: Results of the Auto Fuse

4.2. Manual Fuse

If the Auto Fuse is not sufficient you may decide to do a manual fusion between the two series. The following table shows the complete list of tools available to fuse the images.

Function	Icon	Description
Start Fuse		Starts the automated fuse described in section 4.1.
Approve		This will approve the Fuse and return to the main workflow. It completes and accepts the current Fuse results, whether manual or auto.
Fuse Mode		Toggles between three different fuse methods. The icon will change depending on the method. See section 4.1 for details.
Reset		Resets both series to the original location, undoing any fuse operations that had occurred.
Export/Import		These exports and import the correlation matrix.
Undo/Redo		If you are making manual changes to the fuse, these will undo or redo recent changes.
Rotate Left/Right		These icons rotate the secondary series a small amount clockwise or counter-clockwise. The rotation amount will be larger if Ctrl is pressed while using these icons.
Nudge		These 4 icons on the outer wheel will nudge the secondary series a small amount in the indicated direction. The nudge distance will be larger if Ctrl is pressed while using these icons.
Active View		Clicking these cycles between Axial, Coronal, and Sagittal. The nudge and rotate controls apply to the active quadrant.

5. Adding Contours

Contours define the boundaries of clinically relevant structures for the plan. There are three kinds of contours:

- **Targets:** The tumor or other clinically relevant structures that will be treated.
- **Critical Structure:** A sensitive area where radiation should be particularly minimized.

- **Water Replace:** The dose absorbance of this volume will be assumed to be water equivalent. This can be used, for example, if there is a lot of artifact in the CT image.

Contouring is started by clicking the Contour icon in the inner workflow ring:



When Contouring is first invoked the Workflow Wheel looks as shown on the left in figure 5.1. At this point there are no contour controls because there is no target to contour. Click the plus icon on the outer workflow ring to add a contour.

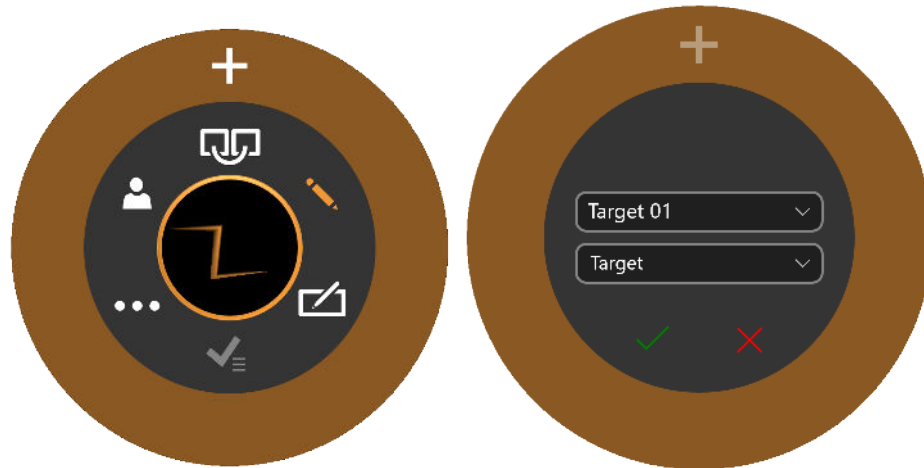


Figure 5.1: Initializing the contour workflow

When you click the plus icon you will see the workflow ring shown on the right of figure 5.1. The lower dropdown (“Target” in 5.1) will define if the new contour is for a Target, a Critical structure, or Water Replace. The upper dropdown (“Target 01” in 5.1) defines the name of the contour. You can accept the default, or type in your own name, or pick a name from the pull-down menu.



Figure 5.2: The contour workflow

All contour editing is done on the Axial view.

Figure 5.2 shows the Workflow Wheel for editing contours once they have been added.












Function	Icon	Description
Contour Management Tools		
These tools manage the number/type/etc. of the contours		
Add Contour		Add a new contour. This displays the dialog shown on the right in figure 5.1. This displays a dialog to select from target, critical structure, or water equivalent. This dialog also provides pre-selected names for targets and critical structures, or allows you to enter custom labels.
Cycle Contours		The editing tools apply to one contour at a time. This control cycles between the current contours. The name of the current contour is displayed.
Change Layout		Toggles between the default quad screen layout and one that shows a large axial slice and 8 small adjacent slices.
Contour List		Displays a table of all contours. See below for details.
Editing Tools		
These tools edit the currently active contour.		
Undo/Redo		Undo or Redo the last edit to the contours.
Pen		Ctrl+click+drag will draw a line as the mouse is moved.
Polygon		A series of Ctrl+click will put down a series of dots connected by straight lines. A double-click ends the series.
Circle		Ctrl+click+drag creates the diameter of a contour.
Bumper		Ctrl+click+drag will move the borders of a contour. If the bumper is inside a contour this will extend it. If the bumper is outside a contour this will push it in. Ctrl+scroll wheel will change the size of the bumper
Cut		Ctrl+click will delete the contour from the current image.
Copy/Paste		Once a contour is drawn on a given image slice, clicking this button will copy that contour to a clipboard. Moving to another slice and clicking it again will paste that contour in the new slice.

Table 5.1. The Contour Workflow Wheel.

The edit tools apply to the active contour only. The active contour is shown in brighter colors than any inactive contours.

A few helpful hints:

- The system will automatically interpolate between image slices to fill out a contour. For example, you can skip multiple image slices when creating an initial contour, and then go back and edit each slice with the bumper to correct the interpolated contour on each slice.
- The bumper has a fixed size in pixels. Use Zoom (shift+scroll wheel) to change the image scale and thus change how much anatomy is affected by the bumper.

Contour list

Clicking on the contour list icon will display a list of current contours, as seen in figure 5.3.

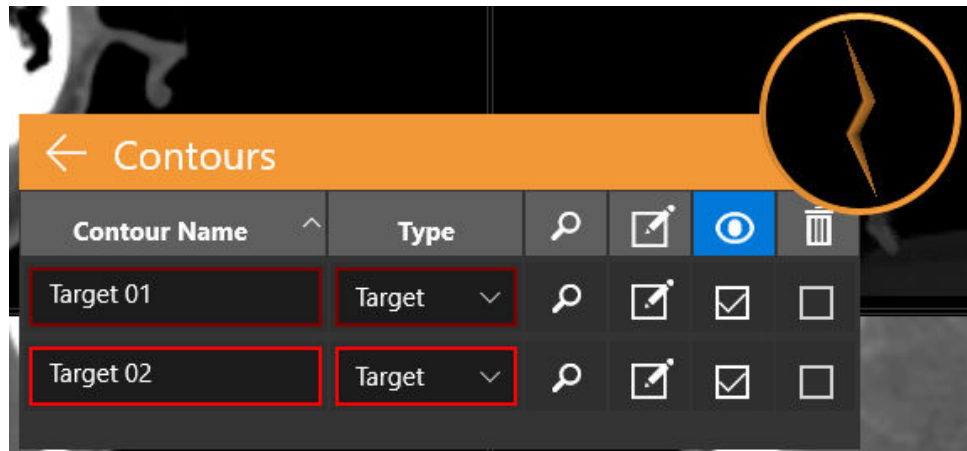


Figure 5.3. The contour list

Contour Name: The name that was typed in when the contour was created. You can also edit the name here. Do not use more than 30 characters. Use alphanumeric characters, underscore, or single dash.

Type: Shows whether this is a target or a critical structure. This is a drop-down interaction. If a mistake was made when the contour was created, you can switch between a target and a critical structure here.

Find: Click on the magnifying glass icon to move the Axial, Coronal, and Sagittal images to the center of the selected contour.

Edit: The checkbox icon both moves the Axial, Coronal, and Sagittal images to the center, and it invokes the editing tools for that contour.

Visible: The checkboxes under the eye icon will hide/show the selected contour. Clicking on the column header will hide/show all contours.

Delete: The checkboxes under the trashcan icon will delete the selected contour after a confirmation dialog. Clicking on the column header will delete all contours.

6. Isocenters and Dosing




6.1. Introduction












TPS supports Forward Planning (also known as “Ray Trace Planning”).

In Forward Planning, you add the isocenters, fix their size and scale, and then define a dose for a given isodose line. The system will display the isodose lines for your confirmation.



Figure 6.1: The Workflow Wheel while adding isocenters

Function	Icon	Description
Cycle Isocenter		When multiple isocenters have been created, this will cycle between them. Each isocenter in turn becomes active. The axial plane may shift as needed to display the active isocenter.
Beam Reduction		Reduces the number of beams, and thus increases the dose per beam. See section 6.2 for details.
Auto-Fill		Fills the current target contours with automatically calculated isocenters. See section 6.3 for details.

Dose Optimization		Dose Optimization invokes the Inverse Planning function. In Inverse Planning, you define the constraints of the dose distribution and the system tries to find a collection of beams that meet those constraints. See Section 6.4 for details.
Dose Calculation		Calculates a dose distribution for the current isocenters, assuming a nominal dose.
Prescribe		Defines the actual dose. A dialog will ask you to set the dose for a given isodose level, along with the number of fractions to use. Calculating the dose can take some time, during which a transition dialog is displayed.
Plan Summary		Shows a DVH curve for the current contours. You cannot approve the plan from this display (See “Approving the Plan”, below).
Isocenter List		Shows a list of isocenters, including information such as scaling, MU, beams, etc.
Hide/Show		Clicking this icon will make all isocenters full size. (Non-active isocenters are normally minimized.)
Undo/Redo		Undo the last isocenter edit, or redo what had just been undone.
Isocenter Control		This displays the advanced Workflow Wheel. In this state clicking the center of the wheel cycles the outer wheel between: Buttons for each collimator size. Arrow keys to nudge the isocenter in 3 axes.
Scale		Sets the scaling for the currently selected isocenter. The scale value of each isocenter will determine the dose delivered relative to other isocenters.
Add Isocenter		Adds a new isocenter at the current point of focus. A new isocenter can also be added anywhere by using Ctrl+left-click.
Delete Isocenter		Deletes the currently selected isocenter.

Clicking on an isocenter makes it active. Normally only the active isocenter is shown in full size, while non-active isocenters are minimized. Note: “non-active” refers to the UI state; these isocenters are still part of the plan and impact the isodose curves.

Most of the interactions with Isocenters involve pressing the Control key. While the Control key is pressed:

- Scrolling the mouse wheel changes the collimator size.
- Ctrl+Clicking on the image will place a new isocenter at that point.
- Click and drag on an existing isocenter will move it around on the image.

6.2. Beam Reduction

Clicking on the Beam Reduction icon will display the following dialog:

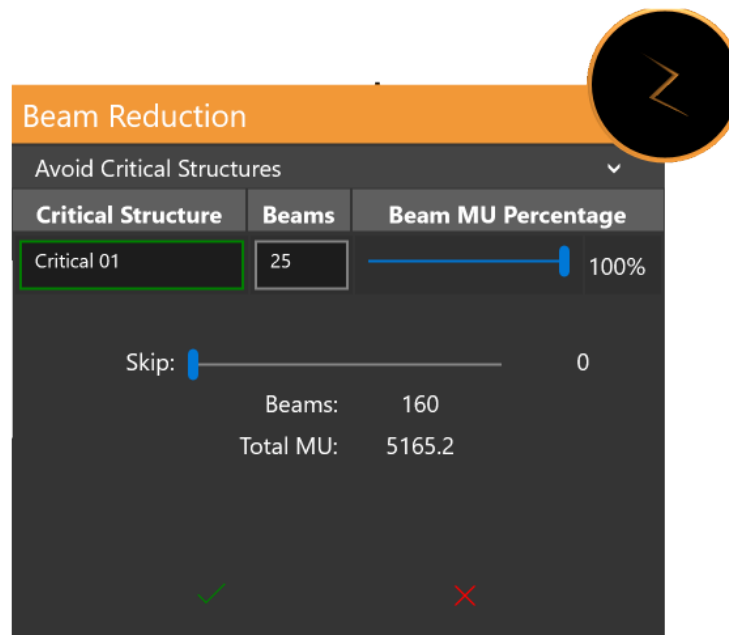


Figure 6.2: The Beam Reduction dialog

The top section only appears if there is a critical structure defined. It provides a list of critical structures and the number of beams that will go through each critical structure with the current plan definition. The slider on the right can be used to further reduce those beams.

The bottom section can be used to reduce the number of overall beams in the plan. A slider allows you to pick the number of beams that will be skipped in between each active beam. For example, a beam-skip of 1 will skip 1 beam in between each delivered beam, resulting in half as many beams. The remaining beams then get a larger dose to keep the overall MU unchanged.

6.3. Auto-Sphere Packing

The Auto-fill, or auto-sphere packing, UI is shown in figure 6.3.1.



Figure 6.3.1: Auto-sphere packing

The auto-sphere packing function will automatically size and place isocenters in the contours you have defined. It includes the following interactions:

- **Collimator selection:** The outer ring shows all available collimator sizes. By toggling these on/off you can limit which collimators are used for the auto-fill function. Generally, smaller collimators will result in more isocenters with finer coverage.
The system will automatically select the collimators it thinks are appropriate when the 'Bullseye' icon in the inner ring is pressed.
- **Max beams:** This allows you to set the maximum number of beams that are used, summed across all isocenters.
- **Path:** All isocenters used for the auto-fill function must use the same gantry path for beam delivery.
- **Existing isocenters:** You can keep or discard the existing isocenters with the checkbox shown.

Clicking the green check box will start the auto-sphere packing algorithm. Clicking the red 'x' will cancel the interaction. Auto-sphere packing will take some time, during which a transition dialog is displayed.

6.4. Inverse Planning

The inverse planning interaction is invoked by clicking on the Dose Optimization icon from the Planning Workflow Wheel. In Inverse Planning, you define constraints on the dose distribution and the system attempts to create a beam set that satisfies those constraints. See figure 6.4 for an example of the inverse planning interaction.

Depending on the system configuration, default constraints may or may not be present when the interaction is invoked.

Each row in the interaction defines one constraint. Each constraint has the following items:

Function	Description
Constraint Order	The order in which the constraints are shown. Note, this is not the priority of each constraint.
Constraint Source	<p>This provides 3 types of choices for the source of this constraint:</p> <ul style="list-style-type: none"> • A list of all contours, target or critical structure • The total number of beams in the plan • Creation of one or more sets of points defined by the user. The Constraint applies to those points.
Distance	<p>Available only if the constraint source is a contour. Applies this constraint to one of:</p> <ul style="list-style-type: none"> • The interior of the contour • The border of the contour • A shell 5mm outside the border • A shell 10mm outside the border
Condition	For contour or point-set constraints you can specify \geq or \leq . For beam-count constraints this is always \leq .
Value	The target value of this constraint.
Weight	The weight of this constraint. A larger value in this field will give this constraint a higher priority than other constraints.
Solution	This field will show the solution after the plan has been optimized. If the solution is different than the target value, then it is shown in yellow.
Locate Constraint Source	For each constraint this will show the contour or point-set that is used for that constraint.
Add Constraint	Adds a new constraint in the line below the current constraint.
Delete Constraint	Deletes the current constraint.

Three buttons along the bottom of the interaction allow you to reset the constraints, optimize the constraints, or solve given the current optimizations.

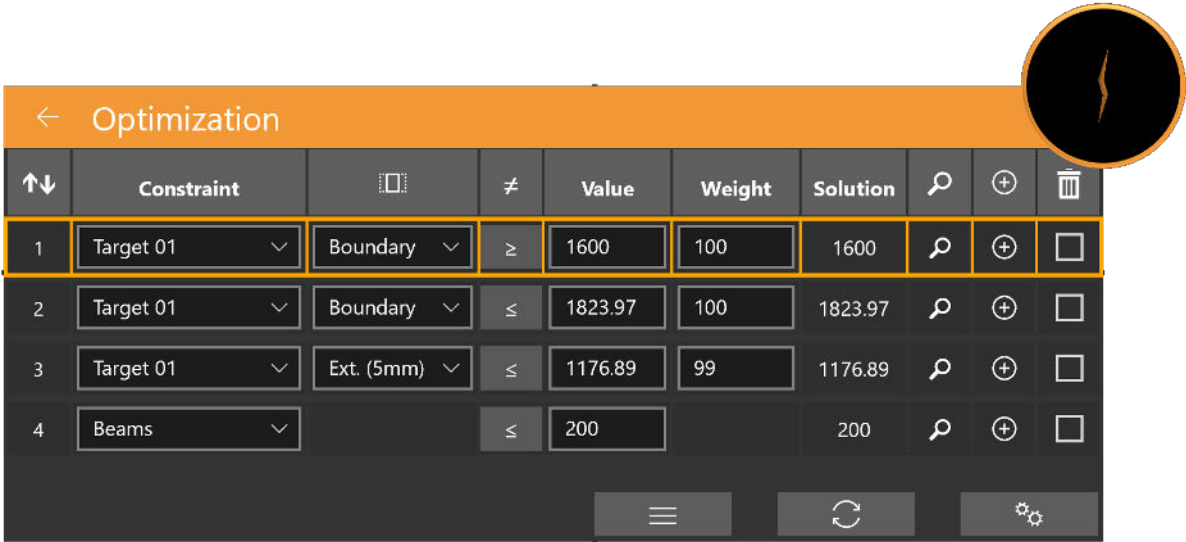


Figure 6.4: Inverse Planning Interaction

7. Saving and Approving the Plan

Once you are satisfied with the planning process you may approve the plan.

7.1. Plan Review

Pressing the Plan Approval icon on the inner wheel will display a screen similar to figure 7.1. This is the same screen that is displayed in the plan summary function of the isocenter outer wheel except that here it has a save icon.

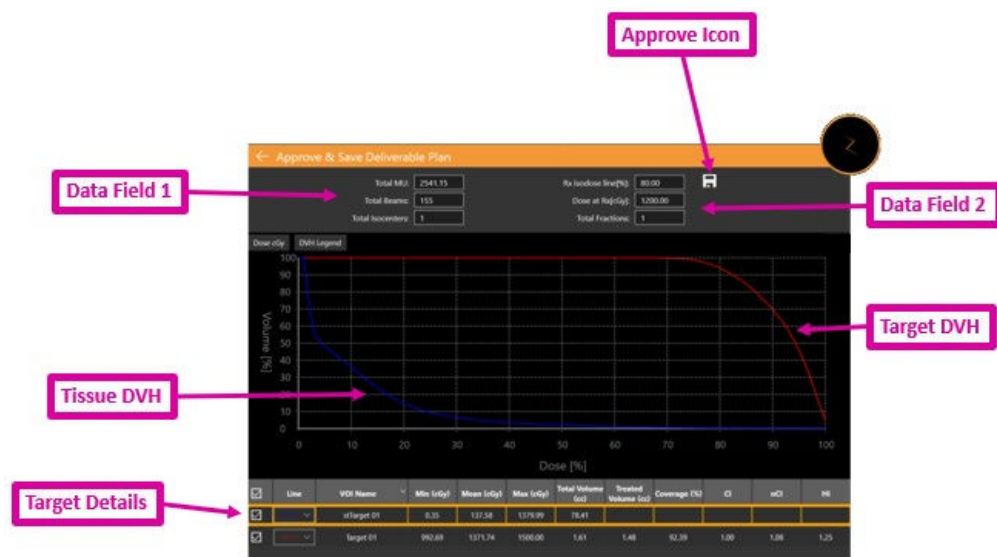


Figure 7.1: Approving the Plan

Approve Icon: Clicking this will save the plan as deliverable. A dialog will appear asking you to name the plan and who is the approver. (The approve icon does not show in the plan preview UI). See section 7.2 for details.

Data Field 1: Shows the Total MU, Total Beams, and the number of isocenters.

Data Field 2: Shows the prescribed isodose line, the dose to be delivered at that line, and the number of fractions to be used. These can be set in the “Prescribe” interaction (see chapter 6). Also shown is an estimate of the delivery time per fraction.

Target DVH: The Dose Volume Histogram shows a DVH curve for each contour, target (red) or critical structure (green). Buttons on the upper left toggle between Dose and Dose% for the X-axis, and to hide/show the legend of each target.

Tissue DVH: Blue lines on the DVH curve show the DVH curve for the tissue immediately surrounding target contours.

Target Details: There is one line here for each DVH curve shown: targets, critical areas, and tissue. Clicking on a line will highlight it. Note that clicking anywhere on the DVH curves will show the volume and dose for the highlighted row.

You can generate a preliminary report based on an approved plan. See chapter 9, General Controls, for details.

7.2. Plan Approval

To approve a plan, click on the Plan Approval icon on the inner Workflow Wheel. You will see the display shown in figure 7.1. At the top of that display there is a save icon. When you click on that icon you will see a dialog similar to figure 7.2



The dialog is a dark gray circle with an orange border. At the top center is a white floppy disk icon. Below it is the label "Plan Name" above a text input field containing "Demo Plan". Underneath the input field is a checked checkbox followed by the text "save as deliverable". Below this is the label "Approver Name" above a text input field containing "Dr. Smith". At the bottom of the dialog are two icons: a green checkmark on the left and a red X on the right.

Figure 7.2: The Plan Approval Dialog

The dialog has fields to enter the plan name, the name of the approver, and a checkbox to confirm that the plan is ready for delivery.



Warning: All treatment plans must be approved by a qualified person before the information in them is used for radiotherapy treatment purposes.

8. Reporting

8.1. Report overview

Treatment planning reports provide information related to treatment planning and beam data. The plan overview provides information for a selected patient and their treatment plan, which includes an overview, the image series used, plan details, authorization details, and DVH data.

The Report consists of the following sections:

Patient Data: Includes patient information such as the patient's name, medical ID, sex, and date of birth

Plan Summary: Provides detailed information for a selected patient and treatment plan. Details include an overview, plan details (including treatment parameters, prescription, dose calculation, and VOI list). Once all data has been reviewed and verified, the physician and physicist can sign and enter the date of approval on the signature page.

Beams Table: Provides a list of the beams and their associated geometric parameters.

Dose Volume Histogram: The Dose Volume Histogram (DVH) will be included in the Planning Report if you clicked the screenshot icon during the review phase

➤ **To generate plan report:**

1. Go to **General Controls**.
2. Click the **Generate Plan Report** button on the Workflow Wheel.
 - The system displays the **Report Options** dialog box.

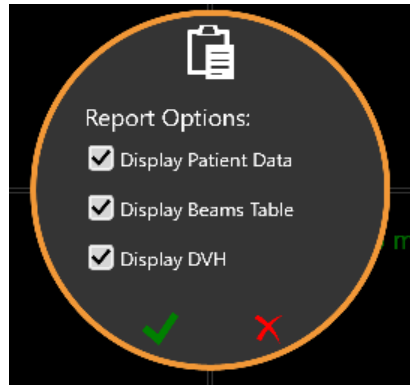


Figure 8-1. Report Options Dialog Box


3. Select the desired options for the plan report from the **Report Options** dialog box.
 - **Display Patient Data:** Displays patient name, sex, and date of birth. Medical ID will be displayed when the option to display patient data is selected ([see Figure 8-2](#)).
 - **Display Beams Table:** Displays the list of beam details including the Isocenter ID, Node ID, and Plan MU ([see Figure 8-3](#)).

Reports may still be generated if neither option is selected. If the plan is not saved, the plan name and plan data and time will be blank.

4. Click the check to proceed with generating the report.

Figure 8.2 shows an example of the patient information section. If the plan has been approved this also includes the name of the approver.

Demo, Dan (0123456)
 DemoDanPlan1



Treatment Planning Report

Patient Information

Name:	Demo, Dan
Medical ID:	0123456
Sex:	M
DOB:	01 Jan 1960

System Information

System:	System1
Operator:	admin
Plan:	DemoDanPlan1
Plan Date & Time:	22 Oct 2019 14:02:25 (hr:min:sec)
Plan Version:	1.7.41
LINAC Energy Level:	3MV
Commissioning Time:	17 May 2019 15:43:06 (hr:min:sec)
Approver:	Dr. Smith



Figure 8-2. Patient Data Report

Figure 8.3 shows the plan summary.

Plan Summary						
Fractions		Max Dose (cGy)		Prescription %	Prescription Dose (cGy)	DV Spacing (mm)
5		2500		80	2000	1
Contours						
Name		Volume (mm³)		Min Dose (cGy)		Max Dose (cGy)
Target 02		1253.33		1516.47		2500
Target 01		2680.67		1519.65		2443.24
Isocenters						
ID	Coll Size (mm)	X (mm)	Y (mm)	Z (mm)	Dose (cGy)	Beams
1	20	-27.33	216.79	163.93	2183.39	36
2	15	23.78	212.48	166.93	2183.39	36
Total Isocenters			Total Non-Zero Beams		Total Plan MU	
2			72		7602.28	

Figure 8.3. The Plan summary

Figure 8.4 shows an example page of the beams table. This section can be several pages long, depending on the number of treatment nodes that are part of this plan.

Plan Details			
Beams			
Isocenter ID	Node Index	Plan MU	Fraction MU
1	1	144.23	28.85
1	2	74.49	14.9
1	3	79.48	15.9
1	4	83.85	16.77
1	5	86.91	17.38
1	6	91.67	18.33
1	7	101.72	20.34
1	8	123.68	24.74
1	9	141.31	28.26
1	10	144.24	28.85
1	11	128.91	25.78
1	12	151.48	30.3
1	13	145.34	29.07
1	14	128.41	25.68
1	15	124.04	24.81

Figure 8.4. Example beam table.

8.2. Reports Viewer

When displaying a report in TPS the following controls appear at the bottom of the screen:





Icon	Tool Tip	Description
	Back Page	Goes to the preceding page.
	Next Page	Proceeds to the following page.
	Save As	Saves the planning report to the user's computer, enabling the user to print the report.
	Close	Exits the treatment planning reports viewer.

Table 8.2. The report controls.

➤ **To save a plan report:**

1. Click the **Save As** button on the Reports action bar.
2. Follow your operating systems directions on how to save the document.
3. Once the report has been saved, it may be printed from your computer.

9. General Controls

9.1. Overview





General controls are accessed by clicking on the icon on the inner Workflow wheel:









When clicked, the Workflow Wheel shown in figure 9.1 appears.



Figure 9.1: The General Controls Workflow Wheel

Function	Icon	Description
Home		Exits the plan and returns to either the patient page or the home page.
Reset Display		Returns the image to the center of the display and restores the original size.
CT Setup		See Section 9.2.
Ruler		Activates the measure function. When this is active, Ctrl+click+drag will measure the distance in mm between any two points.

Auto-Place		Automatically place an isocenter at the geometric center of the ball-cube.
Plan Settings		See section 9.3.
Report		Displays the report. See Chapter 8.
Save		Saves the current plan. See Chapter 7.
Export		Presents a dialog to export any combination of Plans, Isocenters, Contours, and Dose Volumes. Exported files are in .csv format. Also in this dialog you can chose to anonymize the plan data that is exported.
Import		Present a dialog to select a DICOM RT file from the file system. Supports importing a set of contours from the same image series.

9.2. CT Setting

The system will automatically generate a treatment path that is based on the location of the target with respect to the nominal head center. If the Zap table insert is used with a compatible head support, then the default value for the head center should be acceptable. Use the CT Settings control only if these defaults need to be changed.

Note: the nominal head center may or may not be the actual center of each patient's head. Rather, it is a nominal value that corresponds to where the isocenter of the system will be when the patient is first inserted.

When the CT Setting icon is clicked the sagittal view changes to what is shown in figure 9.2.

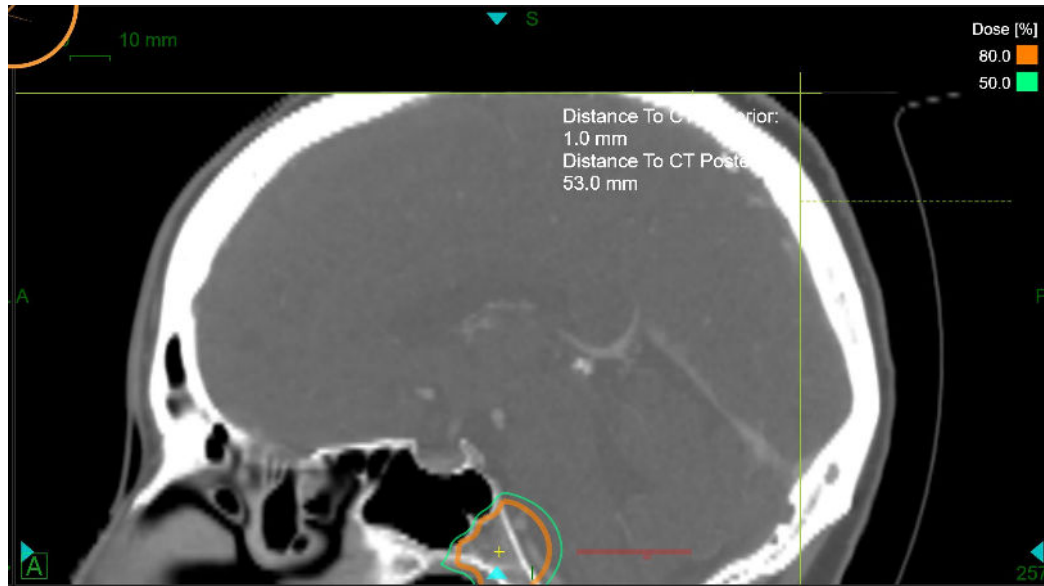


Figure 9.2: The CT setting interaction.

When this is displayed the system will also display the current head center location on the axial and coronal views. You can adjust the reference point in the Sagittal view by holding the CTRL key and dragging the mouse until the reference lines are touching the edge of the headrest. Once you release the mouse, the distance to CT superior and distance to CT posterior values will be updated and the Head Center (x,y,z) values will be updated automatically. The nominal head center is displayed as a green crosshair in each of the 3 views. If moving the reference line is not enough, you can also move the head center directly in any view.

Note: the nominal head center is always fixed with respect to the reference lines in the Sagittal view. If the reference lines are set to the table edge, then the head center is correct in that view. Moving the head center in Axial or Coronal view may be rarely needed if the patient was not centered on the table during imaging.

9.3. Plan Settings

When the Plan Settings icon is pressed, the dialog shown in figure 9.3 is shown.

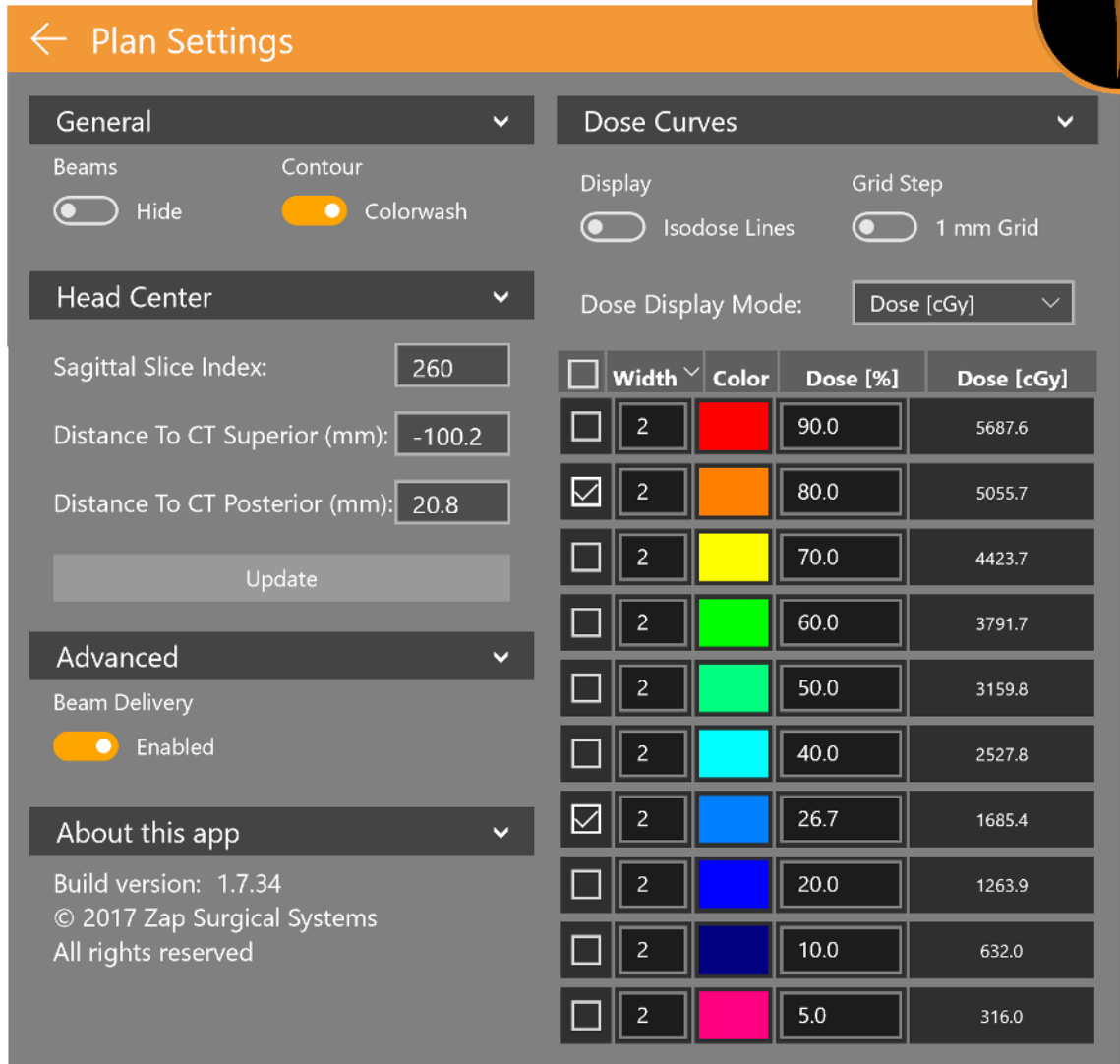


Figure 9.3: The Plan Settings dialog

It contains the following interactions:

Orthogonal View: Contains the following choices for display on the 3D reconstruction:

- **Beam Hide/Show:** Toggles the display of beams.
- **Contours:** Toggles the display of the targets and critical areas.
- **Isocenters:** Toggles the display of the Isocenters.
- **Rx Dose Cloud:** Toggles the display of the region that will receive at least the prescribed dose.

Head Center: Displays the current head center parameters and allow you to edit them. See section 9.2.

Advanced: Contains the Beam Delivery option. Saving a copy of a plan with beams disabled will create a “dry-run” plan that, for example, could be used to test gantry movement before the actual plan is delivered.

About this app: Shows the version number of the TPS software.

Dose Curves:

- **Isodose lines:** Toggles between showing Isodose lines and Isodose wash.
- **Grid Step:** Toggles the fine dose calculation between 1mm and 0.5mm. (see below for details*)
- **Dose Display Mode:** Toggles between displaying the isodose lines as a percent of maximum or as absolute dose. You can also toggle between these two displays by double clicking on the isodose legend on the image.

Dose Display Options: Contains the following columns:

- **Check box:** The system can display up to 10 isodose lines. These checkboxes determine which lines are displayed.
- **Width:** The thickness of the displayed line.
- **Dose(%):** The dose at each line as a percent. This is an editable field. You can customize the value of the displayed lines.
- **Dose(cGy):** The dose at each line as an absolute value.

***Dose Grid:** Around each target or critical structure, the dose is calculated on a tightly spaced grid within a cube of 64x64x64mm³ centered on the volume of interest. You can choose whether that grid has 0.5mm or 1.0mm spacing. Tighter spacing may improve precision. The 1mm spacing will improve calculation time. Away from targets and critical structures the dose is calculated on a 5mm grid, with linear interpolation into the tighter spacing. You can drive more detailed calculations in any area by adding a critical structure into that area.

Caution: It is important that you understand these trade-offs and make appropriate dose grid choices.

10. Beam Data

Beam acquisition data tasks are performed by a medical physicist. Use the beam data tools described in this chapter to acquire beam data for the treatment planning system. Before using the beam data tools, you must perform the procedures described in the *Beam Data Manual* for beam data acquisition and import.



Warning: Errors in beam data may not be easily detected and can result in patient injury or death. A qualified person must enter and confirm accuracy of all beam data prior to treatment planning and delivery.

The following beam data must be acquired, properly formatted, and imported to Zap-X System prior to accepting the dose calculation algorithm:

- Tissue Phantom Ratio (TPR)
- Off Center Ratio (OCR)
- Output Factor (OF)

The TPR, OCR, and OF files should be in plain text. Refer to *Beam Data Manual* for the file format.

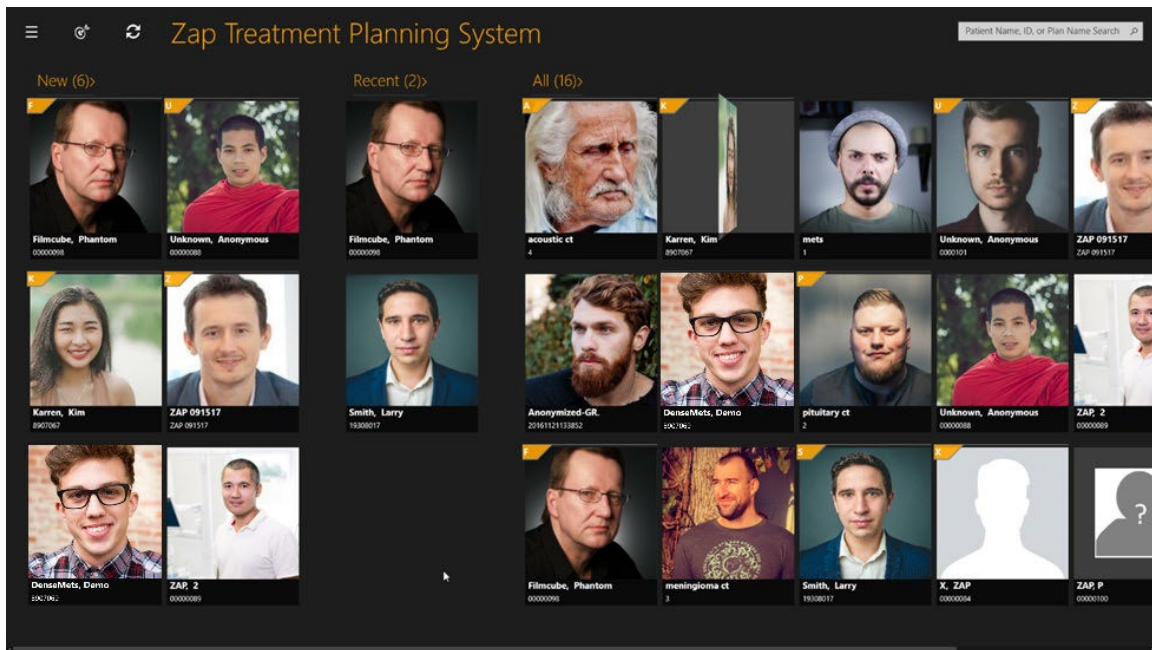


Figure 10.1: TPS Home Page

➤ **To access beam data functions:**

1. Click on the **Beam Data Icon** in the upper left corner of the home page (see Figure 10.2)



Figure 10-2. Beam Data Icon

Note: Warning message in red indicates that TPS uses template beam data. Zap-X Planning System comes with set of template beam data for TPR, OCR, and OF. Before the user acquires actual beam data, the template data is loaded for the Treatment Planning System.

2. Beam data page will appear (see Figure 10.3)

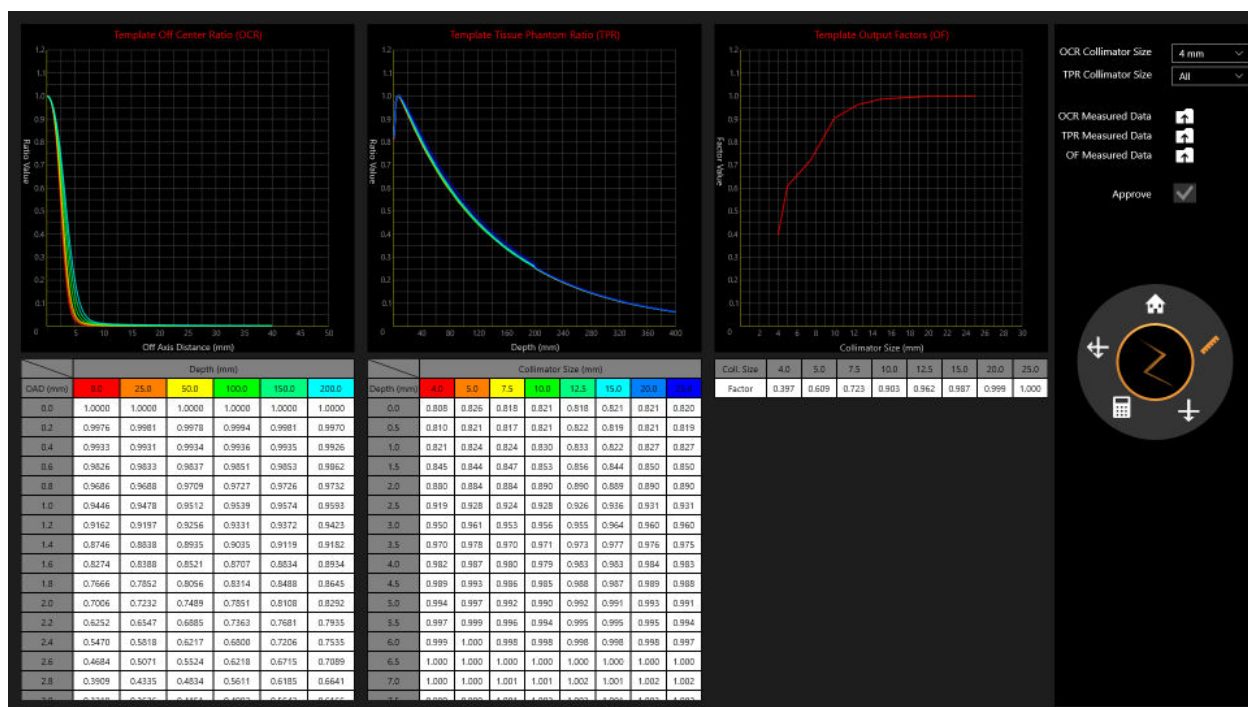


Figure 10.3: Beam Data Page

10.1. Workflow Wheel, Beam Data Primary Ring

Procedures are displayed on the Workflow Wheel on the right side. Each task displays one or more steps (see Figure 10.4 and Table 10-1).



Figure 10.4: Beam Data Primary Ring






Icon	Task	Description
	Measured Beam Data	Uploads measured data for Tissue Phantom Ratio (TPR), Off-Center Ratio (OCR), and Output Factor (OF). Adjust the collimator size for OCR and TPR and approve the data.
	One Beam	Calculates dose value for one beam.
	Calculated Beam Data	Adjusts collimator size for Calculated Off-Center Ratio (OCR) and Calculated Percent Depth Dose (PDD). Import or Export PDD as calculated PDD, measured PDD, or difference.
	Two Beams	Calculates dose value for two beams.
	Home	Return to the home page.

Table 10.1: Beam Data Primary Ring Tools

10.2. Reviewing and Approving Beam Data

During beam data acquisition, review the measured beam data, compare it with beam data calculated by Treatment Planning System, and approve the calculated beam data and/or algorithms. The approved beam data are saved in the system database. Treatment Planning then uses the approved data for dose calculation.

The displayed graphs allow you to review the Measured OCR and TPR beam data at different depths for different collimator sizes, and OF beam data for different collimator sizes. Observe any abnormalities in the curves on the graph, for instance, bumps, discontinuities, etc. If the results are acceptable, you can then approve the beam data.

The positions of applied Radiation Beams are listed in the beam list with coordinates related to patient coordinate system.

➤ To review beam data:

- Load measured **OCR**, **TPR**, and **OF** data by clicking on corresponding icons.
 - The **Measured Beam Data** is chosen by default on the Beam Data Primary Wheel.
 - Click the icon to the right of **OCR/TPR/OF Measured Data** (see Figure 10.5).

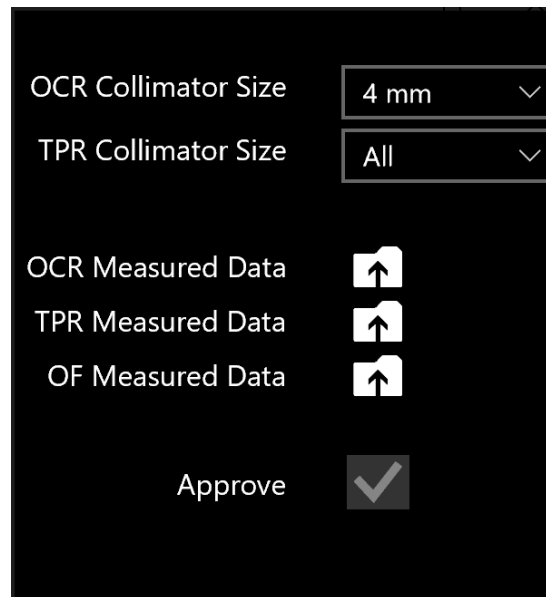


Figure 10.5: Uploading Measured Data

2. Change collimator size by clicking on the dropdown menu next to **OCR/TPR Collimator Size**.
3. Review the acquired beam data associated with the selected collimator by looking at graphs and scrolling through the tables below the graphs.
4. Review all collimators and the corresponding data (see Figure 10.6).
5. Approve the measured beam data by clicking the checkbox next to **Approve**.

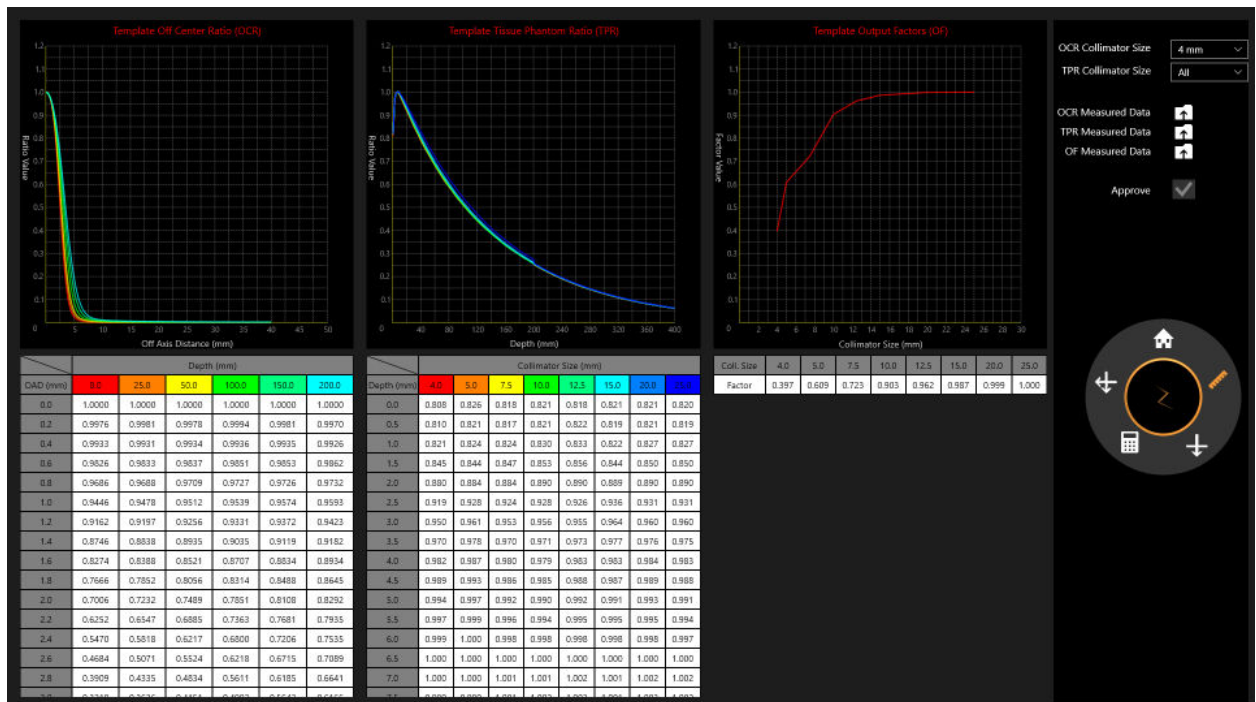


Figure 10.6: Review of Measured Beam Data

10.3. Dose Calculation

Note: A system generated water phantom with a volume of 300 mm x 300 mm x 300 mm is used for dose calculation.

The Zap-X System uses a dose calculation algorithm as follows:

$$Dose(x) = 1 \left(\frac{cGy}{MU} \right) * \left(\frac{450}{SAD} \right)^2 * OCR(coll, OAD, Deff) * TPR(coll, Deff) * OF(coll)$$

Each item in the formula is depicted in the following figure (see Figure 10-7) .

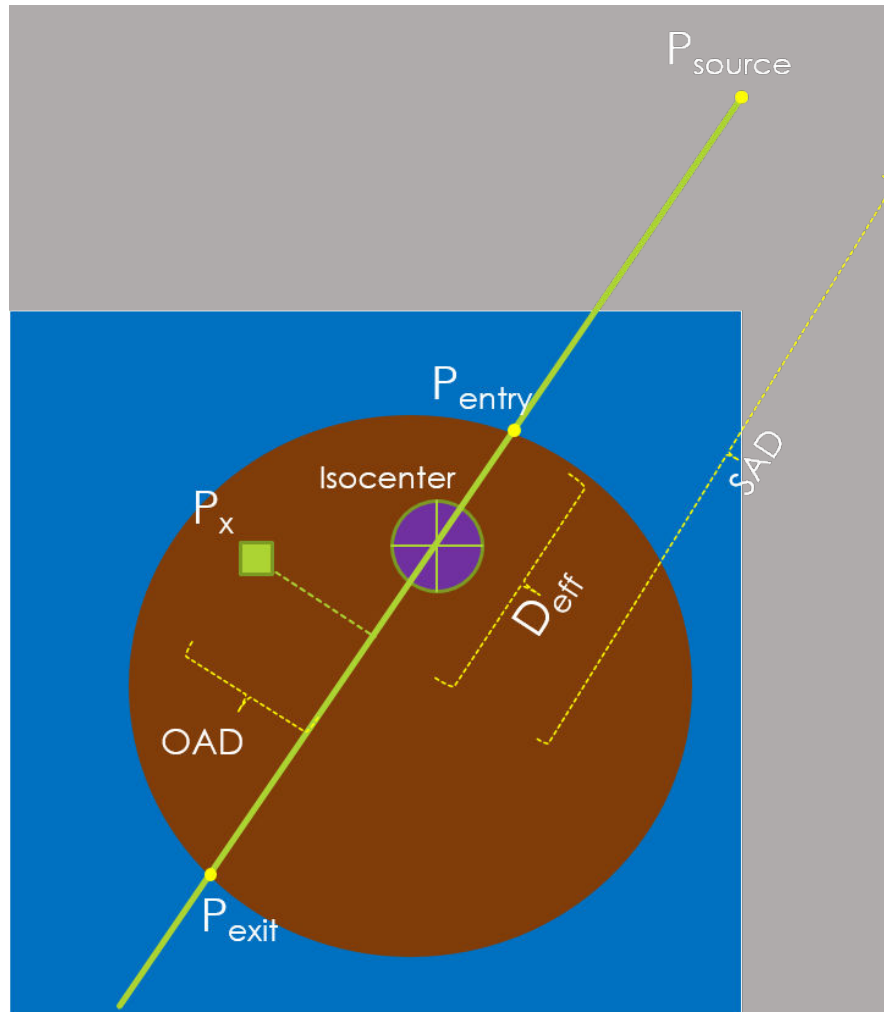


Figure 10.7: Dose Calculation Algorithm Depiction

System design does not support bulk density assignment or applying density overrides to contours.

System test procedures are included in the technical description that will allow the Responsible Organization to verify the accuracy of the dose calculation algorithm.

Note: If dose is being calculated for a depth outside the range of the acquired TPR or OCR beam data, the last beam data value is used.

10.4. Dose Calculation, 1 Beam

➤ To calculate dose value for 1 beam:

1. Click the **One Beam** icon from the beam data primary wheel.
2. Change the value of **SSD** to reflect the measurement setup by clicking on its dropdown menu.
3. Change the **Collimator Size** by clicking on its dropdown menu.
4. Dose calculation will occur automatically.
5. Use Ctrl + Click to display single point dose value.

The screen will display Depth, Off-Axis Distance, and SSD (Source to Surface Distance) for each point in the bottom left corner (see Figure 10-8).



Figure 10.8: Depth, Off-Axis Distance, and SSD

6. Use Ctrl + Right Click and Drag to display the measured distance between two crosshairs (see Figure 10-9).

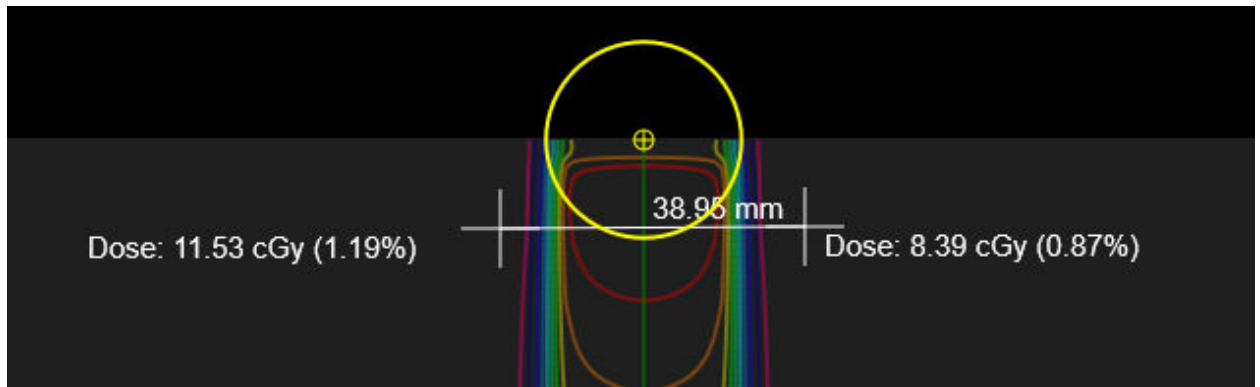


Figure 10.9: Distance Between Crosshairs

➤ **To review the calculated dose:**

1. Click the **Calculated Beam** button from the primary wheel.
2. Change collimator size by clicking on the dropdown menu next to **OCR/TPR Collimator Size**.
3. Review the Calculated Percent Depth Dose (PDD) data (see Figure 10-10).
 - Click **Import** to import the Measured PDD data.
 - Once the data has been imported, the three Display Options are available to display the Measured and Calculated PDD data, as well as the Absolute Difference between these two.
4. Review the Calculated Off-Center Ratio (OCR) (see Figure 10-11).

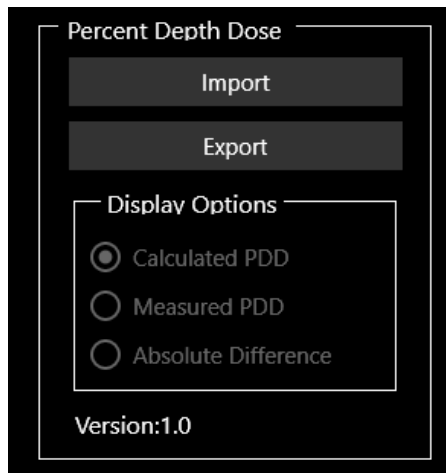


Figure 10.10: PDD Dialog Box

- Click **Export** to save the Calculated PDD.

Note: For OCR and TPR, the Zap TPS performs linear interpolations at depths other than the measured beam data at 7mm (d_{max}), 50mm, 100mm, 200mm, and 250mm. These linear interpolations are 2D for OCR (depth and OAD), and 1D for TPR (depth). For depths beyond 250mm the values for 250mm are used

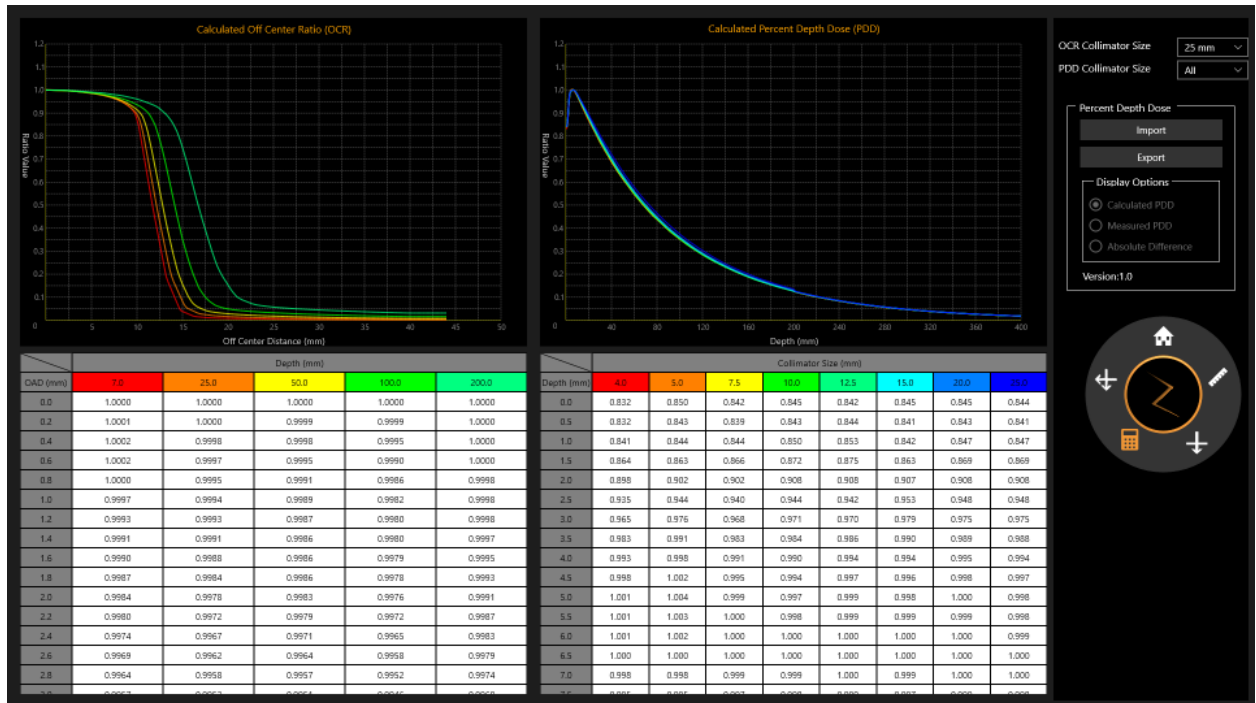


Figure 10.11: 1-Beam Review

10.5. Dose Calculation, 2 Beams

➤ To calculate dose value for two beams:

1. Click the **Two Beams** button on the primary wheel.
2. Change the **Collimator Size** by clicking on its dropdown menu.
3. Dose calculation will occur automatically.
4. Use Ctrl + Click to display single point dose value.

The screen will display Beam 1 and Beam 2 data for Depth, Off-Axis Distance, and SSD (Source to Surface Distance) for each point in the bottom left corner to display (see Figure 10-12).

5. Use Ctrl + Click and Drag to display the measured distance between two crosshairs.

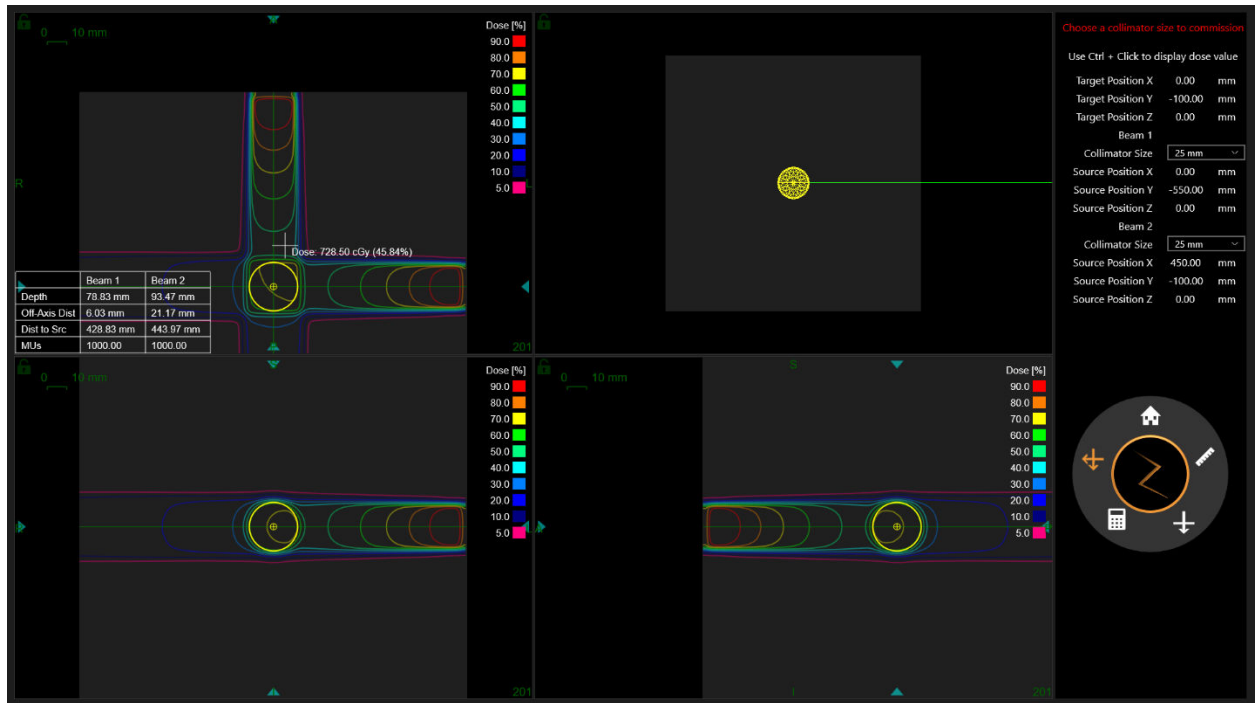


Figure 10.12: Depth, Off-Axis Distance, and SSD for 2 Beams

10.6. Return Home

Click on the **Home** button from the primary wheel to return to the TPS home page.

11. System Administration

Note that at the bottom of the login screen there is confirmation that the system has sufficient memory, disk space, and display settings.

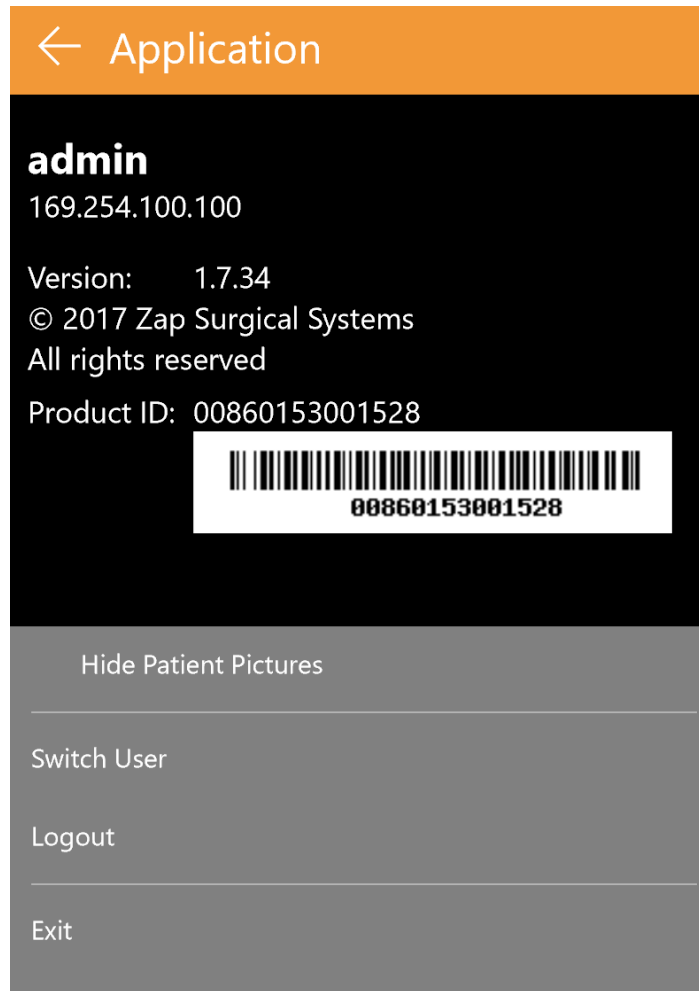


Figure 11.2: Server IP Address

11.1. Disabled Login

When the Treatment Planning System is launched, it will immediately check that available memory is at least 10GB and available disk space is at least 2GB. Since these criteria were met at install these tests should pass every time. Please contact your Zap service representative if this is not true.

12.Cybersecurity

Network:

The Zap-X System operates on its own network that is segregated from the hospital network through a configurable firewall (Dell SonicWALL). All Zap Surgical provided equipment is behind the firewall and only communicates with entities outside the Zap-X network via the SonicWALL. The default configuration provides open ports for Zap-X inbound DICOM traffic and Zap-X outbound connectivity to Zap Surgical for remote support.

Malware Protection:

All traffic to and from the Zap-X network is configured to pass through the firewall. The firewall configuration can be customized according to customer IT policies and access can be restricted to permit only authorized traffic. Although the default configuration has specific ports open it can be configured to be as restrictive as required. Protocol filtering protects the network entities in case of malware infection on either side.

Accounts & Passwords

The Zap-X system provides two workstations, one for the Planning System and one for the Delivery System, to users and they both have local system user accounts to access the respective computers and resources on them. A single local administrator account is created on each of the computers. The passwords used for local accounts meet typical minimum complexity requirements. Both Planning and Delivery workstations come preinstalled with the respective applications and each application requires additional authentication in order to use the system. The database and application servers are also protected by dual authentication and only accessible to the designated support staff.

Operating System Updates:

The system is updated at the time of deployment with all the relevant operating system patches that have been thoroughly tested for system reliability and security. The rate at which new patches are released does not allow for proper testing to ensure that new reliability or security issues have not been introduced by the patches themselves. Zap-X system is closed to automatic windows update and no patches can be applied without proper controls. This mitigates the risk and allows Zap-X to roll out patches on a schedule that allows for proper testing prior to installation.

Backup and Disaster Recovery:

The Zap-X system is not designed for long term storage of patient information. Upon completion of a plan or treatment, Zap Surgical recommends that you save and export a paper or electronic copy of the report for the patient record.

Documentation:

Per Regulations, a comprehensive Device History Record is maintained for all systems. The DHR is a compilation of all records pertaining to the production of a finished medical device. It entails extensive documentation that includes dates of manufacture, quantity manufactured and when they were released, and acceptance records to show that the device was produced according to device master records (DMR).

13.DICOM

13.1. Required fields

Images imported into Zap require the following DICOM fields:

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

13.2. Data Import

The image data are imported to the Treatment Planning System via a DICOM server that is on the same network as the CT and MR scanners. The image scans are sent to the DICOM server after they are acquired. The Treatment Planning System can access the DICOM server and display on the Home Page all the images stored on the server.

It is advisable that the operator confirms the patient information and image data are correct before proceeding to the next part of planning. For example, the image series can be corrupted or can have missing slices.

14. Glossary

Numerics

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.

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.

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.

DVH: Dose Volume Histogram

E

F

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

H

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

I

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

J

K

L

M

MR: (or MRI). Magnetic Resonance Imaging

MU: Monitor Unit

N

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

O

OAR: Organ At Risk.

OCR: Off-Center Ratio

OF: Output Factor.

P

PDD Percent Depth Dose

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.

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 primary user interface when working with TPS.

X

Y

Z

Zap-X: The Zap-X Radiosurgery System.

Contact Information

ZAP Surgical Systems
590 Taylor Way
San Carlos, CA 94070, USA

