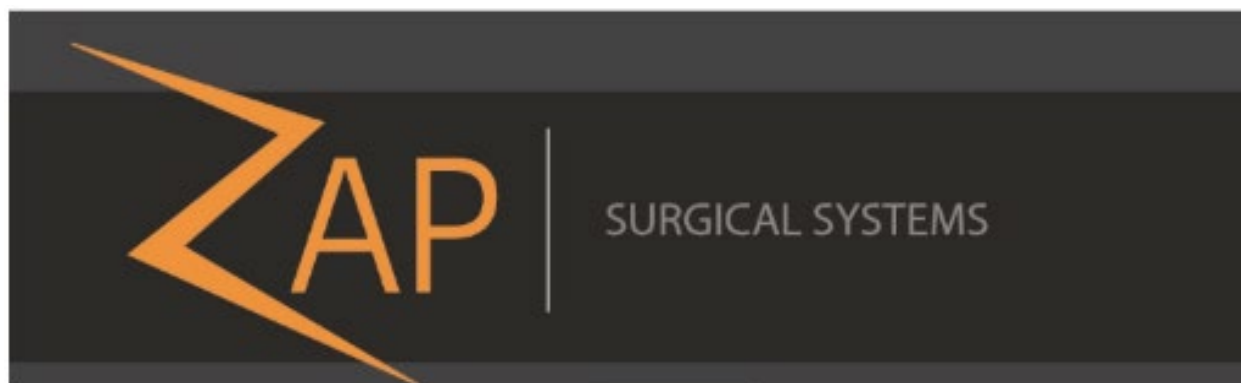


USER MANUAL BEAM DATA ZAP-X SYSTEM

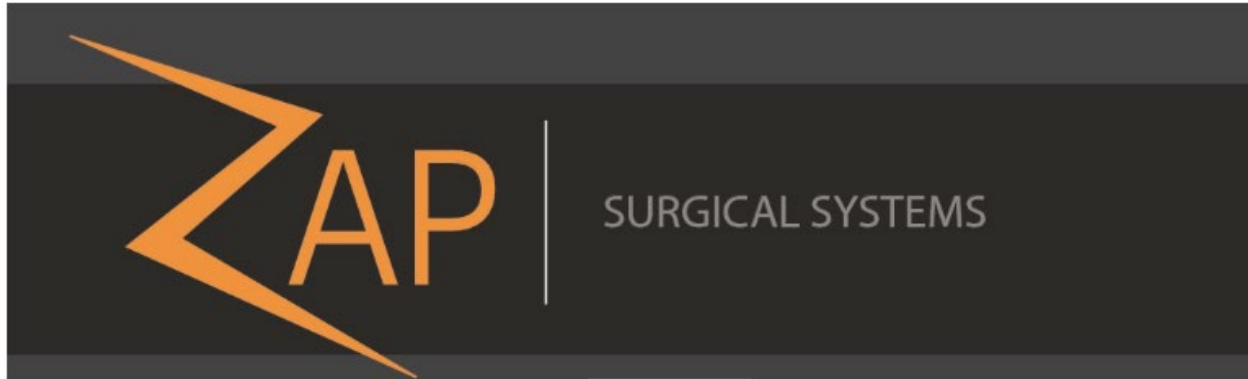
REV. 013



Zap-X Radiosurgery System Beam Data Manual E0920-00002

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Preface



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

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

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

This manual applies to the Zap-X Radiosurgery System.

Intended Use

This manual describes the beam data acquisition procedure.

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

System Information



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

Notice:

The user manual contains instructions for multiple features of the Zap-X Radiosurgery System. Since some features of the Radiosurgery System are optional, some of the instructions in this manual may not apply to your system.

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

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

Device Description

The Zap-X Radiosurgery System ("Zap-X System") is a computer controlled system for performing non-invasive stereotactic radiosurgery that is self-shielded for ionizing radiation and uses a linear accelerator mounted on a gantry along with an imaging system (kV imaging system) to accurately locate the treatment target. The system uses patient skeletal anatomy to align the treatment target with respect to the system isocenter. The Zap-X System uses the kV imaging system to track patient movement and adjust the table precisely to compensate for such movement during treatment.

Indications for Use

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 brain, head and neck when radiation treatment is indicated.

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.

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



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

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.

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.

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.

Conventions

The conventions described below are used in this manual. Familiarize yourself with these conventions before using the Zap-X Radiosurgery Device.

Numeric Display Format

The Zap-X Radiosurgery System software and the Treatment Planning System use the following notation conventions to display numerals:

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



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

Computer Terminology

This manual uses standard personal computer terminology. Zap Surgical Systems assumes the system operator knows how to use a standard personal computer to navigate through windows and files on the computer workstation. See the documentation that came with the computer. The following conventions are used in this manual.

Click	Press the left mouse button.
Right-click	Press the right mouse button.
Double-Click	Press the left mouse two times in rapid succession.
CTRL-click	Hold down the CTRL key and press the left mouse button.
SHIFT-click	Hold down the SHIFT key and press the left mouse button.
Scroll	Rotate the scroll wheel on the mouse. A <i>backward scroll</i> rotates the scroll wheel with the finger moving away from the hand. A <i>forward scroll</i> rotates the scroll wheel with the finger moving toward the hand.
Hold	Press the mouse button and hold it down while you perform another function.
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.
Select	Place the cursor over a name button and click once, or place the cursor at the beginning of the name, click, hold, and drag across the name until it is highlighted (changes colors).
Open	Double-click the name of a window to open it.

Warning, Caution, and Note Symbols

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



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

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

Note: Provides more information about a subject.

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Chapter 1: Beam Data Acquisition

Introduction

This chapter describes Zap-X Radiosurgery (“Zap-X”) System beam data acquisition procedures.

This chapter contains the following topics:

- Equipment & Materials
- Beam Data Acquisition Setup
 - Zap System Preparation
 - Determine Absolute & Relative Dosimetry
 - PTW Tank Setup
- Beam Data Acquisition Procedure
- Beam Data Acquisition for Dose Calculation Algorithm



Warning: The examples or data included in this manual are for demonstration only. They are not for clinical use.

Equipment & Materials

This section describes the equipment and materials used to perform Beam Data Acquisition

1. Inclinometers: Mitutoya Digital Protractor Pro 3600 or equivalent
2. PTW MP3-XS Water Phantom
3. PTW model 31022 ionization chamber 0.016 cc (for output factor measurement)
4. PTW Dosimetry Diode SRS Type 60018 (for beam profile measurement)
5. Computer/Laptop & USB to R232 adapter
6. R232 cable connecting PC and PTW Controller (including electrometer)
7. Reference chamber T-REF 34091 (for beam profile and PDD measurement)
8. E0010-00320 Patient table supporting bracket for water Phantom
9. E0023-00121(J-C), E023-00122(J-Z) Centering jigs
10. E0021-00373 Front pointer
11. E0040-00126 Revolve alignment bracket
12. Distilled water

Beam Data Acquisition Setup

Properly preparing for Beam Data Acquisition is necessary to ensure a safe, accurate, and repeatable dose delivery for the Zap-X System.

Zap-X System Preparation

1. Open shell and door and extract table via pendant app.
2. Open Treatment Delivery System (TDS), perform system initialization then start Linac Calibration window (under the QA tab) and move the Gantries to the calibrated North Pole position.
3. Tape tarps inside the treatment chamber to protect from accidental water spill.

Note: No more axial movement until you remove the tarps

4. Configure collimator as described in the TDS manual.
5. Set the collimator to 25 mm.

PTW Tank Setup

Note: Zap-X system can only use the PTW MP3-XS water phantom.

1. Remove the head rest on the patient table and replace it with PTW supporting bracket.
2. Place an empty PTW tank in the bracket and center the tank with 2 centering jigs ([see Figure 1-1](#)).

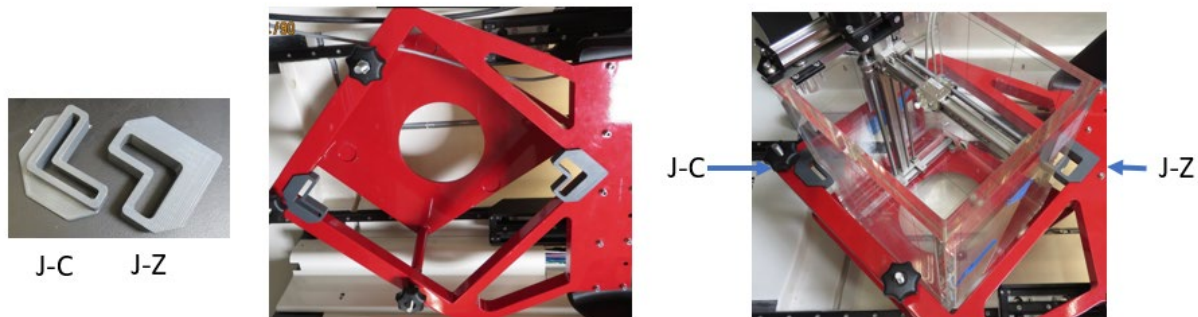


Figure 1-1. PTW Tank

3. Place the **PTW TBA** control unit and Tandem on other end of the patient table and away from the collimator to minimize radiation exposure (see Figure 1-2).



Figure 1-2. Control Unit on Patient Table

4. Cable connections:
 - a. Connect all the cables between water tank and control unit and Tandem.
 - b. Insert **R232** and **power cable** through the side hole of the system near the patient entry (see Figure 1-3).



Figure 1-3. Cables Insertion

- c. Connect **R232 cable** between the computer and **PTW TBA** control unit.
- d. Connect the power cable to the control unit.
- e. Connect the **Pendant Controller** to the water tank and connect PTW Pendant to the Pendant Controller.
5. Perform a rough tank leveling visually to ensure the bracket is within a reasonable range and is not hitting any part of the system.
6. PTW tank leveling using Water tank supporting bracket:
 - a. Verify the distance as shown in drawing below, making sure Z is close to 174 ± 5 mm (see Figure 1-4). If not, adjust Z by turning the nuts.

Note: If Z is outside the range, tank will not be able to achieve zero level.

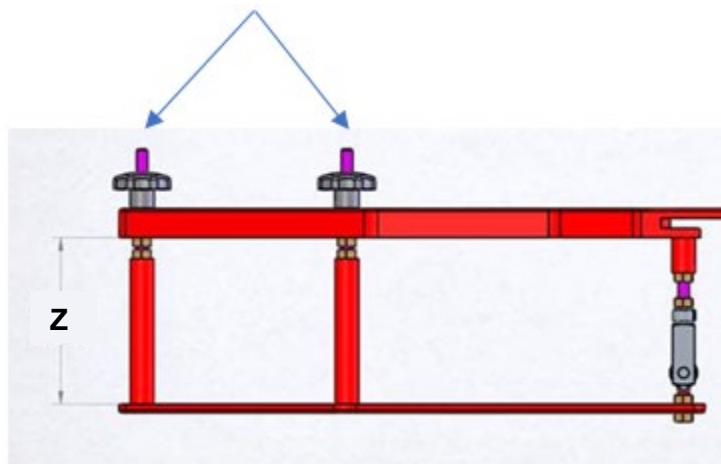


Figure 1-4. Water Tank Adjustment

- b. Before leveling, move all three knobs to the top (see Figure 1-5).

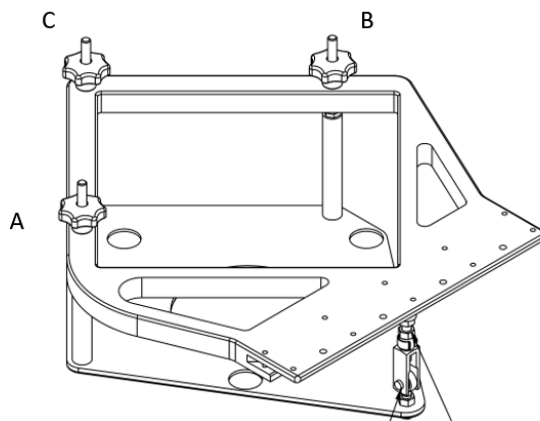


Figure 1-5. Adjustment Knobs

- c. First level tank across the axis of the patient table using knob A & B
d. Place the Inclinator at the corner of the tank facing you. Achieve an angle of zero using A & B knobs, then use C to level the tank along the axis of the patient table (see Figure 1-6).

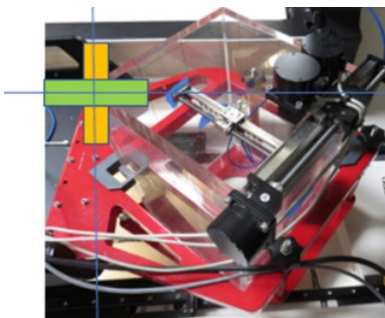


Figure 1-6. Inclinator

7. Install **PTW T4316/U341 Universal Adapter** following with **T4316/U361 pointing device** for water leveling adjustment (see Figure 1-7).

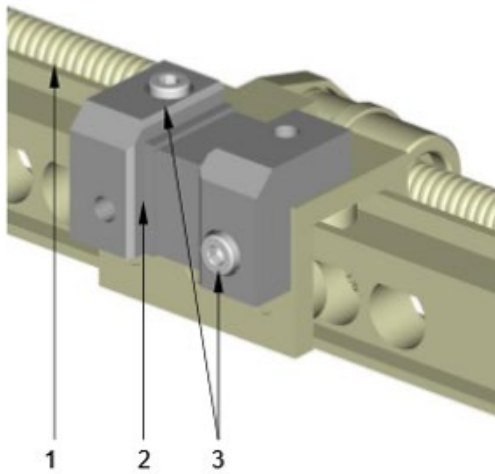


Figure 1: Universal adapter T4316/U341 (installed on the C-axis)

- 1 C-axis of the moving mechanism
- 2 Universal adapter
- 3 Cylinder bolts M4x10 for universal adapter

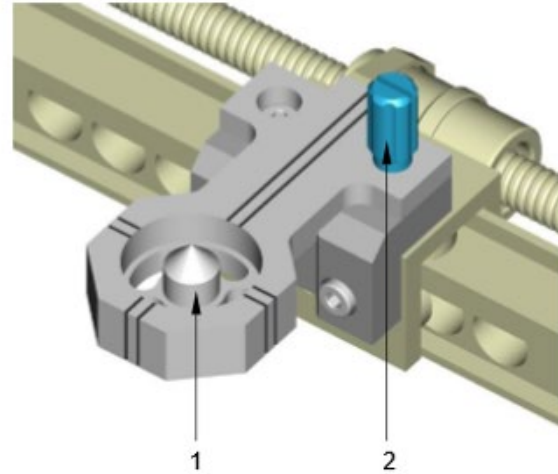


Figure 2: Pointing device T4316/U361 (installed on the universal adapter T4316/U341)

- 1 Pointing device
- 2 Fastening bolt for pointing device

Figure 1-7. Universal Adapter

8. Use PTW Pendant to move the pointing device close to the center of the scanning area, where the arrow point to crossline (see Figure 1-8). Lower the pointing device in +B direction to below 1/3 from the top of the tank. Then set it to a new zero position on Pendant.

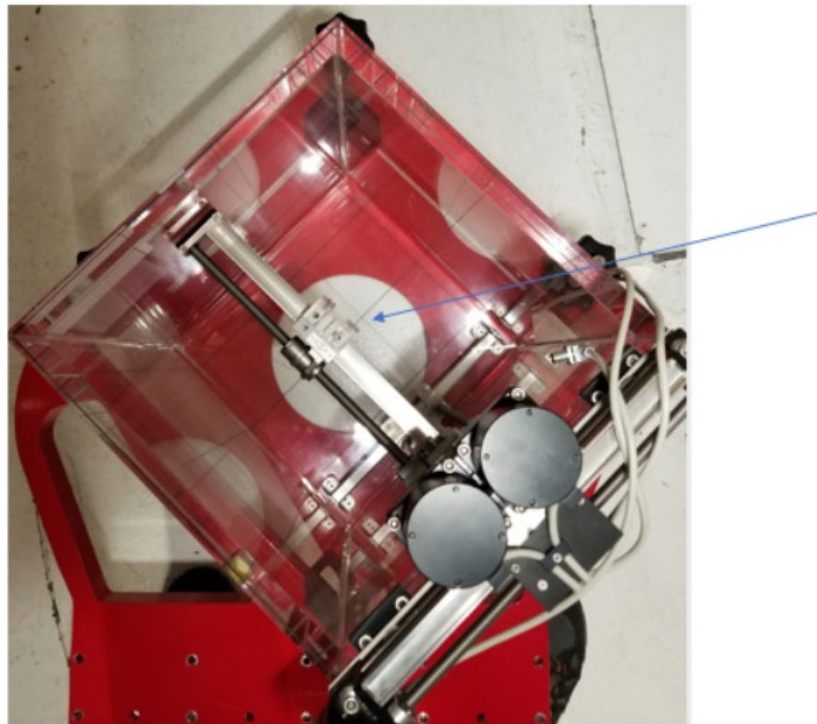


Figure 1-8. Center of the Scanning Area

9. Lie on the table with the front pointer and alignment bracket.
10. Slowly move the tank into the Zap system manually until the tank is below the collimator (see Figure 1-9).



Figure 1-9. Tank Inside System

11. Install alignment bracket.
12. Insert front pointer to collimator on 25 mm hole through the revolve alignment bracket and secure the pointer by finger- tightening it with the Nylon screw on the side (see Figure 1-10).

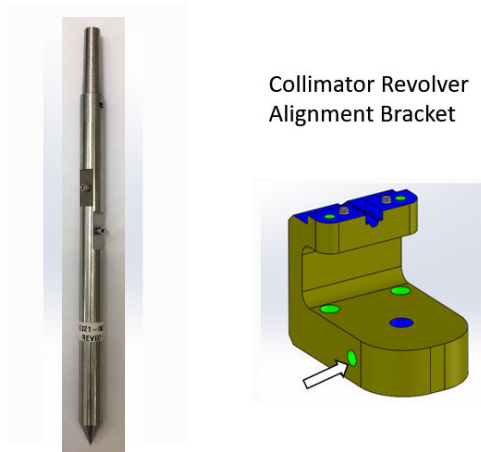


Figure 1-10. Front Pointer and Revolve Alignment Bracket

13. Move table and align the PTW pointing device to the tip of the front pointer. When the pointing device touches the tip of the front pointer (see Figure 1-11), the pointing device will be at the ISO center position. Record the table position shown on Linac Calibration software.



Figure 1-11. PTW Pointing Device

14. Lower the pointing device in +B direction to 1/3 from the top of the tank. Then remove the front pointer and alignment bracket.
15. Move the Patient table out of the Gantry completely and use PTW Pendant to move the PTW pointing device back to zero position.
16. Fill the tank with distilled water until the water level same as the tip of the PTW pointing device.
17. Verify the leveling of the tank with Inclinator to ensure that it is at zero degree of water level. Adjust Tank or water leveling if needed.
18. Water tank setup is completed.
19. Ready to use PTW water phantom for Beam Data acquisition. Replace the pointing device with the PTW 60018 diode for PDD and OCR measurements ([see Figure 1-12](#)). Move the water phantom into the treatment chamber to match the recorded table position from **step 13**.

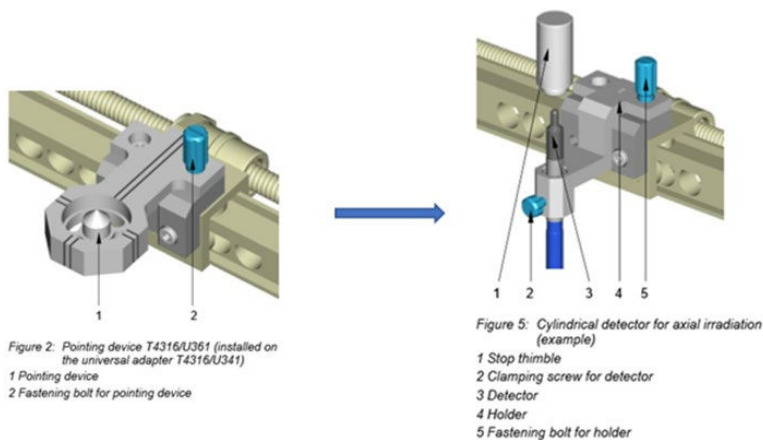


Figure 1-12. PTW 60018 Diode

20. Attach the T-REF reference chamber to the water phantom and center it above PTW 60018 diode, parallel to the surface of water, and at least 20cm above the water surface (see Figure 1-13).



Figure 1-13. T-REF Chamber Setup

Beam Data Acquisition Procedure

This section covers the following topics:

- Required Beam Data Overview
- Beam Data Acquisition
- Beam Data Files

Required Beam Data Overview

The following types of measurements are required for beam data acquisition of the dose calculation algorithm:

- Percentage depth Dose (PDD) Measurements
- Off Center Ratio (OCR) Measurements
- Output Factor (OF) Measurements

All the data can be obtained by a water phantom with ionization chambers as described in the previous section. All measurements are relative, and all files are ASCII and follow the format as described below.

Ensure that PTW origin is on the central axis of the beam by performing centering scans at d-max for 25mm collimator.

Percentage Depth Dose (PDD) Measurements:

- a. The Percentage Depth Dose Measurement can be converted to Tissue Phantom Ratio values with reference at constant SAD of 450 mm. The reference depth for the Zap System is 7 mm for all collimator sizes.
- b. Go to PTW Mephysto for Relative Dosimetry, select **Relative Dosimetry**, **3D** and **Water Tank Scan** (see Figure 1-14).



Figure 1-14. PTW Mephysto

- c. Click **OK** and proceed to input the information as shown on the Linac tab using 25mm cone as an example. The display shows 2.5 cm x 2.5 cm (see Figure 1-15).

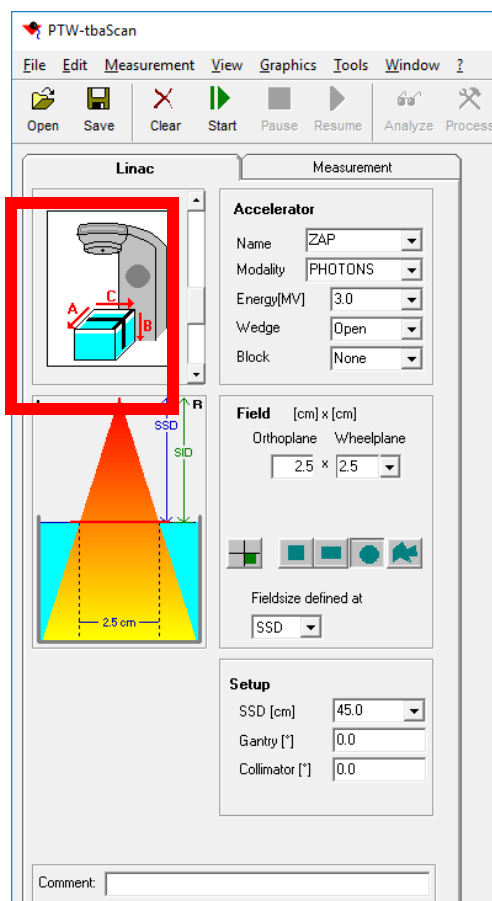


Figure 1-15. Linac Tab

- d. Turn on PTW Tandem controller and select 0 on the High Voltage with + HV polarity for the field and reference to 400v (see Figure 1-16).



Figure 1-16. PTW Tandem Controller

- e. In the Measurement tab, input the information as shown below. Ensure that only PDD is selected and arrow points upward (see Figure 1-17).

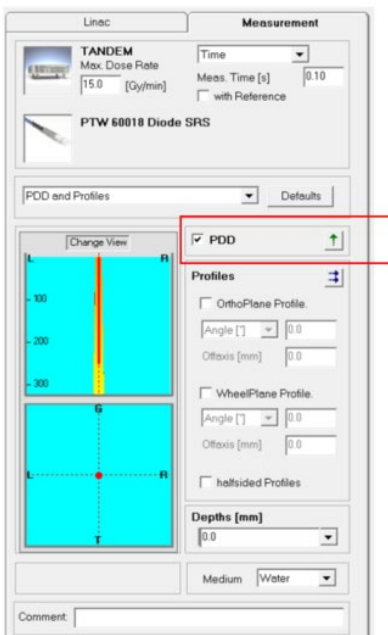


Figure 1-17. PDD Selection

- f. Input 0.0 mm as the maximum scanning depth in the Depths Section.
- g. Go to TDS Linac Calibration, select 25 mm Collimator and input Dose of 5000 MU. After turning on the beam, immediately go to PTW Mephysto and press **Start** to begin scanning. Typical Plot for PDD is shown below (see Figure 1-18).

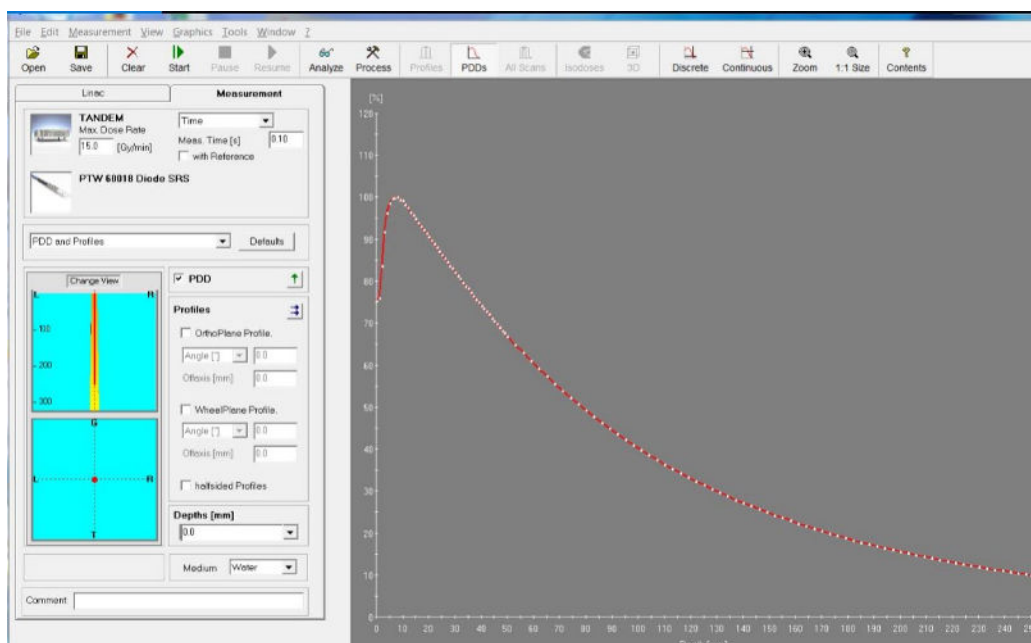


Figure 1-18. PDD Plot

When scanning completed, select **Analyze** to find "D100[%]" as indicated below (see Figure 1-19).

	R100 [mm]	R80 [mm]	R50 [mm]	Ds [%]	D100 [%]	OI	NAP [MV]	SSD [cm]	Field Size [cm x cm]	Curve Type
	7.98	32.62	78.52	75.68	40.29	0.4307	2.56	45.0	2.5 x 2.5	PDD


Figure 1-19. PDD Analysis

If D100[%] is $40 \pm 2\%$, beam Percentage Depth Dose is satisfied. System is ready to perform next measurement. If D100[%] < 38 % or > 42 %, system troubleshoot is required until D100[%] meets this acceptance requirement. Save the PDD file for current collimator size.

- h. Repeat **steps c - g** for the PDD measurement using different collimators including 4, 5, 7.5, 10, 12.5, 15 and 20 mm.

Note: Sizes 12.5mm and 7.5mm will be displayed 1.3 cm x 1.3 cm and 0.8 cm x 0.8 cm respectively.

Off-Center Ratio: (OCR)

1. The Off-Center Ratio (OCR) is the ratio of absorbed dose at a given off-axis point to the CAX dose at the same depth using a constant SSD of 450 mm.
2. In Linac tab, set field size to 2.5 cm x 2.5 cm (see example in [Figure 1-15](#)).
3. OCR data must be taken for each collimator at different depths such as D_{\max} (7.0 mm), 50, 100, 200, and 250 mm or maximum allowable.
4. At 25 mm collimator, go to PTW Mephysto, deselect PDD and select **OthoPlane /WheelPlane** on **Profile**. Make changes on the scanning direction with the icon  and make changes on the Depths to D_{\max} (7.0 mm), 50, 100, 200, and 250 mm. Turn on the beam for 50,000 MU from the TDS Linac Calibration and start PTW scan right after beam on. Typical setup and plots are shown as below ([see Figures 1-20 and 1-21](#)).

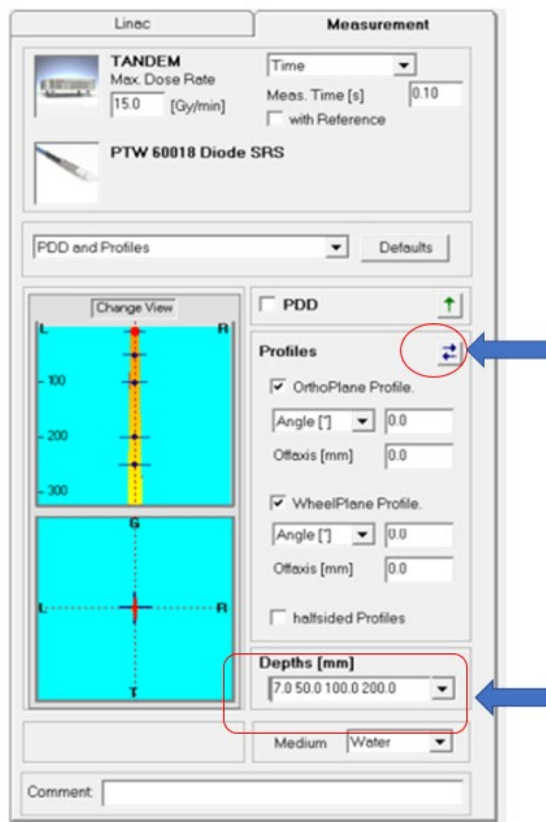


Figure 1-20. OCR Measurement

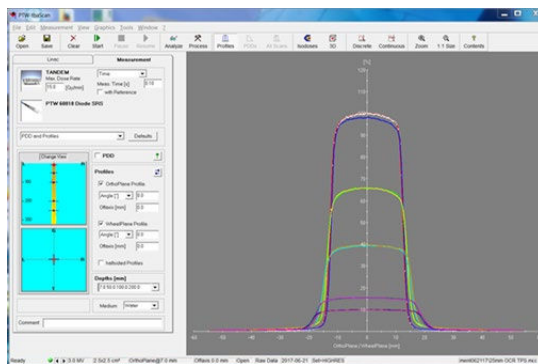


Figure 1-21. OCR Plot

5. Save current OCR file.
6. After completing 25 mm collimator, repeat **steps 2 – 5** to measure other collimator sizes including 20, 15, 12.5, 10, 7.5, 5, and 4 mm.

Note: For each collimator, all scans must be normalized to the CAX value of D_{\max} (7.0 mm) depth scan.

Output Factor: (OF)

1. Output Factors measured at SSD=443 mm, SAD 450 mm, at $D_{\max} = 7.0$ mm for all collimators.
2. Move the PTW Tank outside the Gantries to adjust the PTW tank water level.
3. Remove the PTW 60018 diode by loosening the fastening Bolt for holder without changing or touching the Ionization Chamber.
4. Replace it with the pointing device (see Figure 1-22).

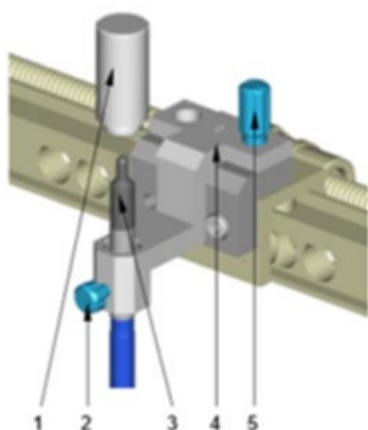


Figure 5: Cylindrical detector for axial irradiation (example)

- 1 Stop thimble
- 2 Clamping screw for detector
- 3 Detector
- 4 Holder
- 5 Fastening bolt for holder

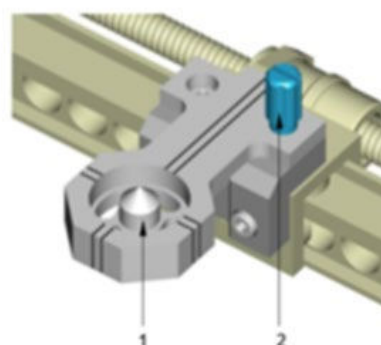


Figure 2: Pointing device T4316/U361 (installed on the universal adapter T4316/U341)

- 1 Pointing device
- 2 Fastening bolt for pointing device

Figure 1-22. Pointing Device

5. Use the PTW Pendant to move the pointing device to zero position.
6. At zero position, move the pointing device in -B direction by D_{\max} (7.0 mm) so the SSD is set at $(450 - 7) \text{ mm} = 443 \text{ mm}$.
7. Adjust the water level until it reaches the tip of the pointing device.
8. Replace the pointing device with PTW 31022 ionization chamber (see Figure 1-23).

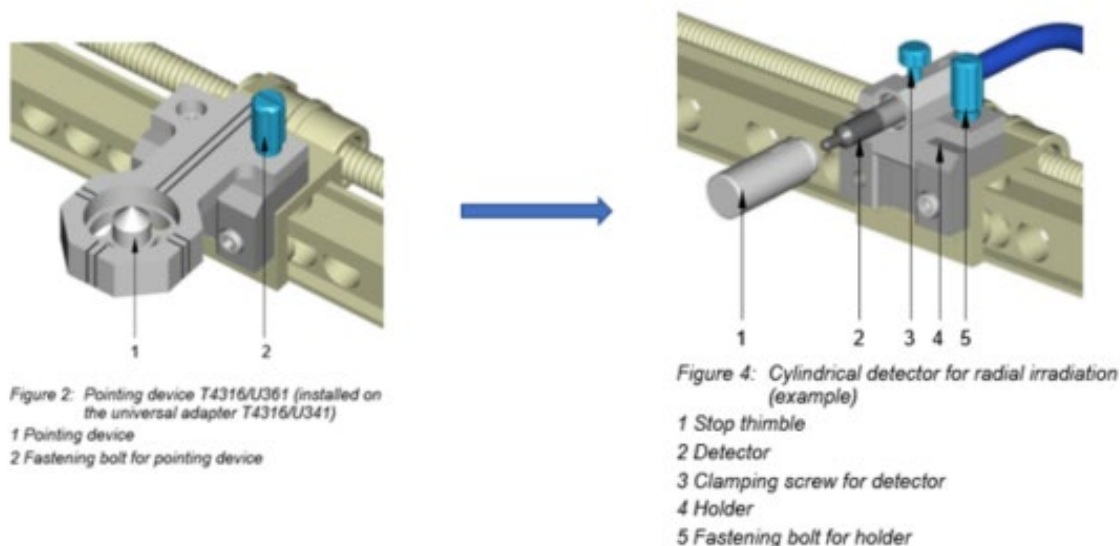


Figure 1-23. PTW 31022 Ionization Chamber

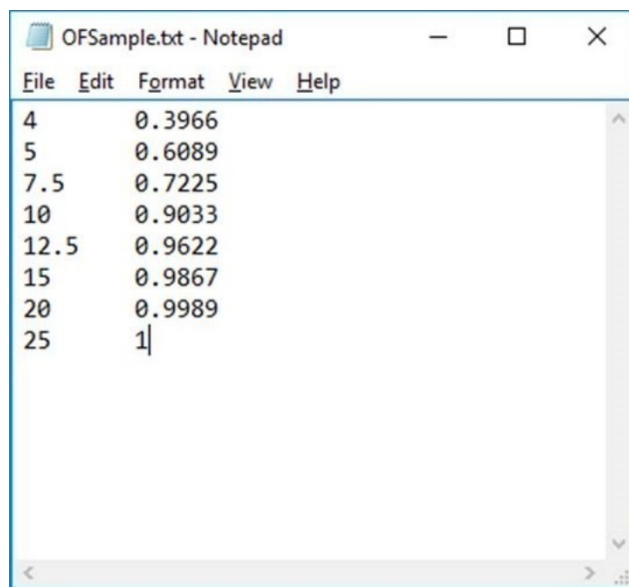
9. Verify the ionization chamber position to ensure that it is set correctly.
10. Run three consecutive runs for each collimator at 500 MU. Record the values from PTW. The average value of the three runs will be used for determining output factor per collimator. Output Factor values are normalized to the value from the 25 mm Collimator.

Beam Data File Format

Plain text (ASCII) beam data files must be generated in accordance with the specific formatting procedures as described further in this section.

Output Factor – 1 File

The Output Factor file contains two columns and eight lines. The left column is the collimator sizes. The right column is the output factor values which correspond with the individual collimator size to the left (see Figure 1-22 for an example).



The screenshot shows a Notepad window titled 'OFSample.txt - Notepad'. The window contains a table with two columns: collimator sizes and output factor values. The data is as follows:

Collimator Size	Output Factor
4	0.3966
5	0.6089
7.5	0.7225
10	0.9033
12.5	0.9622
15	0.9867
20	0.9989
25	1

Figure 1-22 Output Factor File

MCC Files

The data generated by the PTW measuring and analysis modules are saved in ASCII files with the file extension *.mcc.

Each line of such a file consists of a keyword and note, one or several data values. Only the data values essential for describing the task are included in the file. See Appendix A of *PTW User Manual* for more information.

For Zap-X Radiosurgery System, the following files need to be generated based on the PTW measurement data described in previous sections as input for the Treatment Planning System (TPS):

- Tissue Phantom Ratio (TPR) – 1 File
- Off Center Ratio (OCR) – 1 File

Where TPR data are converted from PDD data. Please consult with Zap personnel on how to convert the PTW measurement data to the proper data format for TPS.

Beam Data Acquisition for Dose Calculation Algorithm

The beam data acquisition procedure, see Chapter 9, “Beam Data Acquisition” in the *Manual, Treatment Planning*.

Glossary

Acronyms and Abbreviations

Definitions

A

B

C

D

E

F

Field Size

The size of the radiation field. Usually defined at a reference SAD. Zap-X field sizes are defined at 450mm SAD.

G

H

I

J

K

L

M

N

O

OCR – Off Center Ratio

The ratio of absorbed dose at a given off-axis point to the dose at the central axis at the same depth.

OF – Output Factor

The ratio of the absorbed dose of a particular field size to the dose at a reference field size. For the Zap-X System, the reference field size is 25 mm.

P

PDD – Percent Depth Dose

The ratio of the absorbed dose at any depth to the absorbed dose at a fixed reference depth using a constant SSD. Specified as percentage.

Q

R

S

SAD – Source to Axis Distance

The distance from the radiation source to the axis of rotation for the radiation source. The Zap-X nominal SAD is 450 mm.

SSD – Source to Surface Distance

The distance from the radiation source (X-ray target) to the surface of the phantom.

T

TPR – Tissue Phantom Ratio

The ratio of absorbed dose at a given point to the dose at a fixed reference depth using constant SAD. Zap-X's reference depth is 7.0 mm.

U

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