Zap-X Radiosurgery System

Technical Specification

Information to the User

E0920-00013

Zap Surgical Systems
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1. Purpose

Provide technical specifications for the Zap-X^R Radiosurgery system in the format described in Annex A of IEC 60976.

2. References

- IEC60976 Edition2.0 2007-10
- IEC60601-2-1
- Treatment Delivery User Manual E0920-00004 (“TDS Manual”)

Note, the Zap-X system meets all requirements of GB 15213-2016 and GB 9706.5-2008.

3. Definitions

The specifications presented in Sections 5 – 17 of this document are defined in IEC 60976.

4. Document Organization

Sections 5-16 of this document have section numbering that is aligned with IEC60976. Where a section number is skipped in this document it means that no relevant information to the user is called for in that section of the standard.

Section 17 of this document has information relevant to IEC60601-2-1.

5. General Information to the User

5.1 Available nominal energies and absorbed dose rates

Nominal Energy is: 3.0 MeV.
Nominal absorbed dose rate is 1500cGy/min.

5.2 Available Radiation Fields

Possible sizes of the collimator in cm are: 2.5, 2, 1.5, 1.25, 1, 0.75, 0.5, 0.4 cm. All collimators are circular. There is also a ‘Home’ position which blocks beam delivery.

5.3 Normal Treatment Distance

The normal treatment distance is 45cm.

5.4 Available Wedge Fields

None

5.5 Available flattening filters

None

5.6 Availability

The Zap-X requires 30 minutes form power on to being prepared for full operation.

5.7 Influencing quantities

Continuous delivery of beam in excess of 30 minutes may affect the performance of the characteristics of the Zap-X. Intermittent delivery of beam, as is common during patient treatment, should be considered normal use.

5.8 Maintenance

No user maintenance of the System is required. The system will undergo periodic maintenance carried out by Zap personnel every 3 months. Zap recommends, and local regulation generally requires, the user to employ a robust quality assurance program in accordance with local laws and national and international guidelines.

5.9 Dimensions, clearances, within the radiation head

The Zap-X does not have a multi-element beam limiting device.

5.10 IMRT

The Zap-X does not offer IMRT.

6. Dose monitoring system

6.1 Dose Monitoring System

Dose monitoring System Type: The Zap-X is equipped with a Primary-Secondary Dose Monitoring System. Therefore, only the performance of the primary dose monitoring system is reported. The Dose Monitoring system complies with this standard at the nominal dose rate of 1500 cGy/min and for absorbed doses of 0.1 Gy to 10 Gy

6.2 Reproducibility

Maximum coefficients of variation of ratio R of the number of dose monitor units and absorbed dose for X-Radiation: 0.5%

6.3 Proportionality

Maximum deviation of the measured absorbed dose from the value given by multiplying the measured value U of Dose Monitor Units by the proportionality factor S: 2%.

6.4 Dependence on angular positions

Maximum difference between the maximum and minimum value of R over the full angular ranges of the gantry and beam limiting system.

Declared maximum difference: 3%

6.5 Dependence on gantry rotation

Not Applicable. Zap-X does not deliver radiation while the gantry is in motion.

6.6 Dependence on the shape of the radiation field

Not Applicable. The Zap-X radiation field is always circular.

6.7 Stability after high dose delivered

Maximum difference of R between beginning and end of a period of irradiation of 100 Gy at normal treatment distance: 2%

6.8 Stability throughout the day

Maximum difference of R between beginning and end of 8h of successive 4Gy irradiations followed by 10min without irradiation: 2%

6.9 Stability throughout the week

Maximum difference between the highest and lowest values of R measured immediately following switch-on on 5 consecutive days: 2%

6.10 Stability in moving beam radiotherapy

Not Applicable. Zap-X does not support moving beam radiotherapy.

7. Depth absorbed dose characteristics

7.1 X-Radiation

Nominal X-ray energy (of electrons striking the X-ray target): 3.0 MeV

7.1.1 Depth dose characteristics

See Appendix A for PDD charts.

25 mm: Depth of dose max: 0.7 cm, Penetrative Quality: 3.2 cm, max deviation 2 mm, Quality Index: 0.37

10 mm: Depth of dose max: 0.65 cm, Penetrative quality: 3.0 cm, max deviation 2 mm, Quality Index: 0.37

7.1.2 Surface Dose

25mm: 61% (typical)

10mm: 62% (typical)

7.1.3 Isodose Charts

See Appendix A for Isodose Charts.

8. Uniformity of radiation field

8.1.1 Flatness of square X-ray fields

Not Applicable. Zap-X does not provide flattened fields.

8.1.2 Deviation of close distribution of square X-ray fields

Maximum variation in the ration of absorbed dose at a point in the flattened area to absorbed dose on the radiation beam axis both at standard measurement depth for all angular positions of the gantry and beam limiting system.

Deviation with angular position: 3%

8.1.3 Symmetry of square x-ray fields

Maximum ratio of absorbed doses at points symmetrically displaced from the axis of the beam and within the flattened area at standard measurement depth: Symmetry: 103%

8.1.4 Maximum ratio of absorbed dose

Nominal energy

Maximum ratio of absorbed dose in the radiation field to absorbed dose on the radiation beam axis in the plane at the depth of dose maximum.

Maximum ratio of absorbed dose: 107%

8.1.5 Wedge X-Ray Fields

NA not supported.

8.1.6 IMRT

NA. Not supported.

8.2 Electron Radiation

NA. Not supported

8.3 Penumbra of Radiation Fields

Maximum distance along major axes between points of 80% and 20% of the absorbed dose on the radiation beam axis, all measurement being in the plane at standard measurement depth:

Penumbra: 25mm: 5mm, 10mm: 5mm

9. Indication of Radiation Fields

9.1.1 Numerical Field-indication

Maximum difference between the numerical radiation field-indication and the dimensions of the radiation field and normal treatment distance:

Deviation from indicated field size: 3 mm

9.1.2 Light Field Indicator

Not Applicable. The Zap-X Radiosurgery system is not equipped with a light field. Field placement is verified using image guidance.

9.1.3 Reproducibility

Variation of Field Size: 2mm

Note: The Zap-X Radiosurgery system is equipped with fixed collimators. No variation is expected.

9.1.4 Alignment of an SRS frame of reference

Along the longitudinal axis of patient support assembly: 0.5mm

Along the lateral axis of patient support assembly: 0.5mm

Along the vertical axis of patient support assembly: 0.5mm

Method: The Zap-X Radiosurgery system utilizes image guidance to align the target to the machine isocenter. This is accomplished by matching kV images to digitally reconstructed radiographs generated from the planning CT.

9.1.5 SRS X-ray Beam Guidance

Maximum distance between central axis of SRS X-ray beam from the isocenter:

Smallest SRS X-ray field: 0.5mm

Largest SRS X-ray field: Same as smallest

Method: The Zap-X Radiosurgery system always directly the beam at isocenter. The target is aligned to the machine isocenter as described in 10.1.4.

10. Indication of Radiation Beam Axis

10.2 Indication on entry to the patient: 0.5mm

The Zap-X Radiosurgery system is not equipped with any device that indicates the entry of the beam on a patient. A mechanical front pointer and laser are provided for convenience in positioning detectors during measurements but are not for use with patients.

10.3 Indication on exit from the patient

Not Applicable. the Zap-X does not provide an indication of beam exit.

11. Isocenter

11.1 Displacement of the radiation beam axis from Isocenter

Maximum displacement of the radiation beam axis from the isocenter: 0.5mm

11.2 Indication of the Isocenter

Indication of isocenter: None

12. Indication of Dist. along Beam Axis

12.1 Indicating device

The Zap-X Radiosurgery system is not equipped with any device that indicates the distance along the beam axis for a patient. A mechanical front pointer is provided for convenience in positioning detectors during measurements but is not for use with patients.

Maximum difference between the indicated distance and the actual distance from isocenter: 2mm.

12.2 Additional indicating device

No additional indicating devices are provided.

13. Zero Position of Rotational Scales

For a description of the coordinate system employed by the Zap-X Radiosurgery System, please refer to the Treatment Delivery Manual Section 11.1 and 11.2.

13.1 Maximum difference between the zero-position indicated

Rotation of Axial axis: 0.5°

Pitch of the Radiation Head: 0.1°

Roll of the Radiation Head: 0.1°

Rotation of the Table: 0.5°

Pitch of the Table: 0.5°

Roll of the Table: 0.5°

14. Congruence of the opposed Fields

Congruence of opposed fields: 1mm

15. Movements of the Patient Table

15.1 Longitudinal stability of the patient table

Maximum difference in the table height near isocenter between 30 kg load at retracted condition and 135 kg load at extended condition: 5 mm

16. Additional information

16.1. Gantry, Radiation Head, and Patient Support

Some moving parts of the system, including the door and shell, are not designed with sensors to detect collision. Please see Chapter 2: Safety, in the TDS user manual (p/n E0920-00004)

16.2. Attachment of Accessories

The MV imager is a user-replaceable accessory that is replaced as needed. Please see the TDS User Manual (p/n E0920-00004) section 11.3

16.3. Verification of Data Coherence

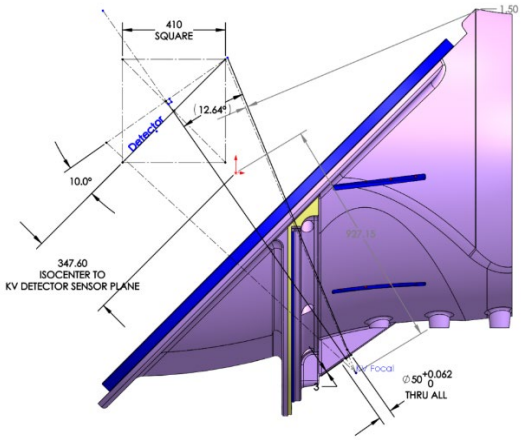
Treatment delivery on the Zap-X system requires a plan created on the Zap planning system.

16.4. X-Radiation

The average ABSORBED DOSE D_{LX}, due to LEAKAGE RADIATION through the collimator does not exceed 0.75 % of the maximum ABSORBED DOSE.

16.5. Image Field of View and Alignment

Positioning of Reference Axis: Figure 18.1 shows the position of the reference angle in normal use.


410
SQUARE
(12.64°)
Detector
10.0°
347.60
ISOCENTER TO
KV DETECTOR SENSOR PLANE
927.15
1.50
Focal
⌀50 +0.062 0
THRU ALL

Appendix A

Charts for depth absorbed dose characteristics

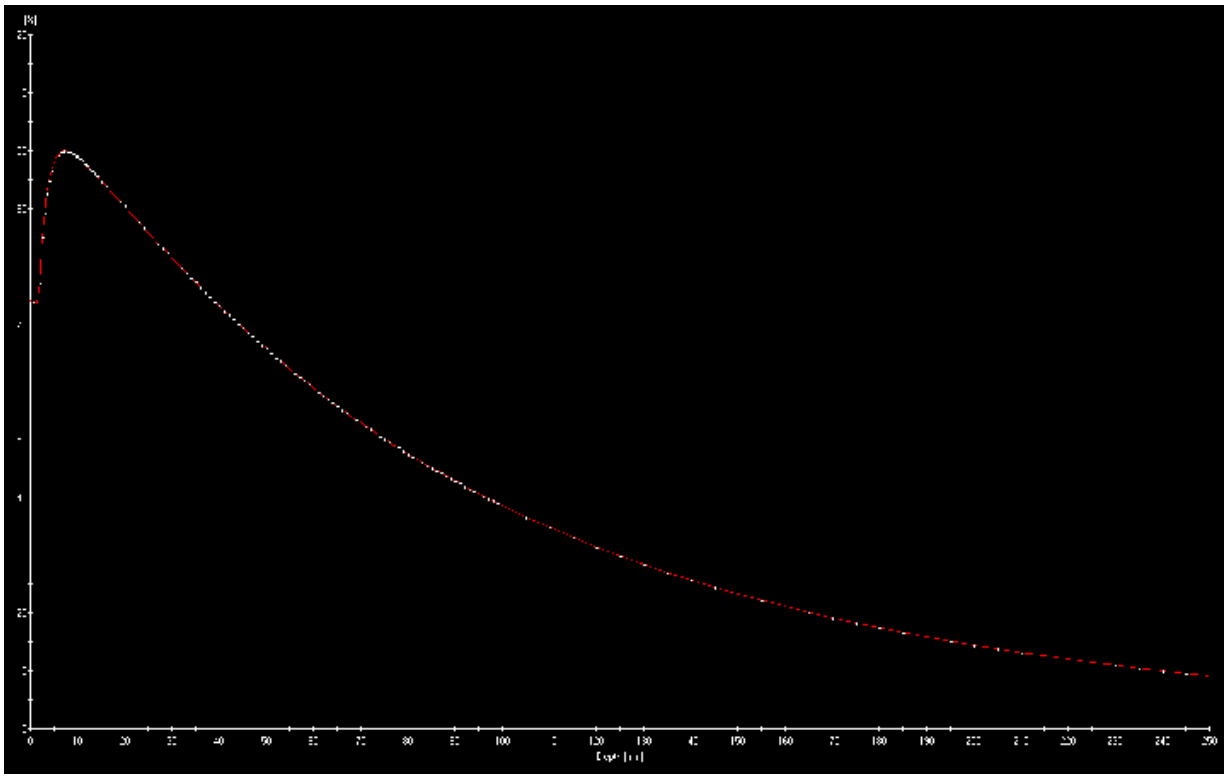


Figure 1. Percent Depth Dose Chart for 25 mm field size.

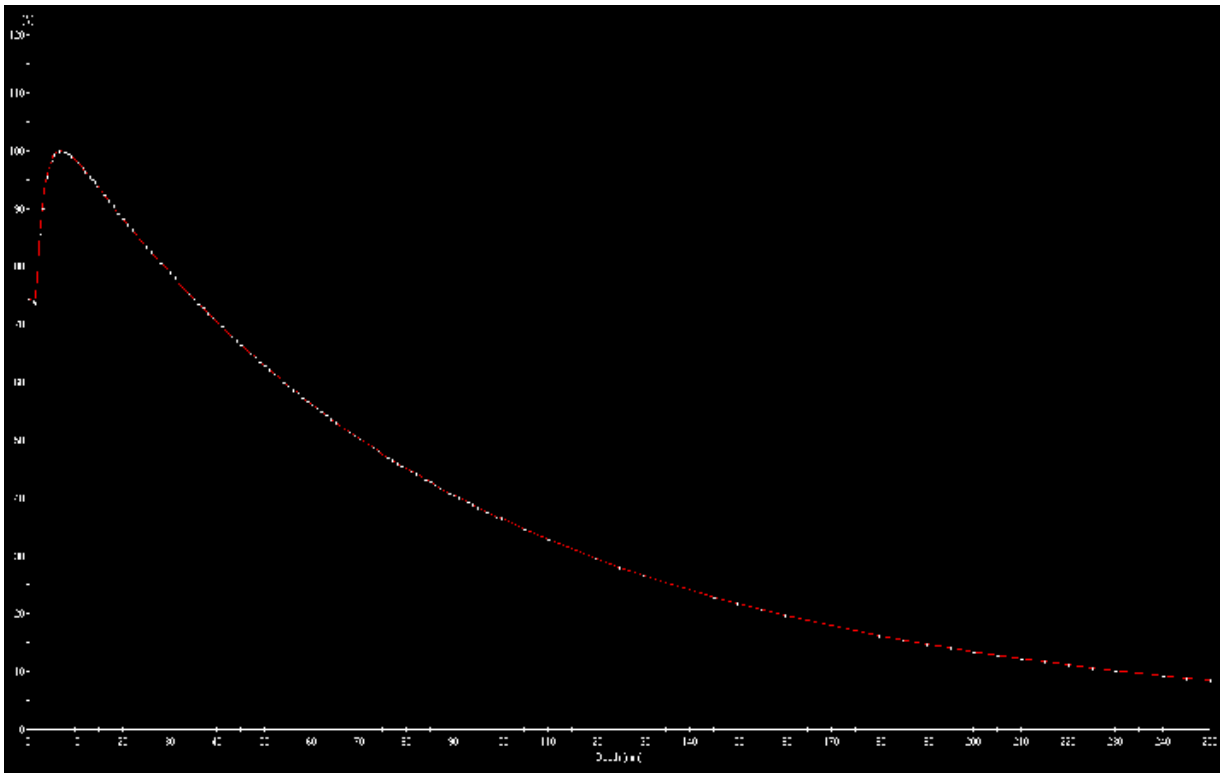


Figure 2. Percent Depth Dose Chart for 10 mm field.

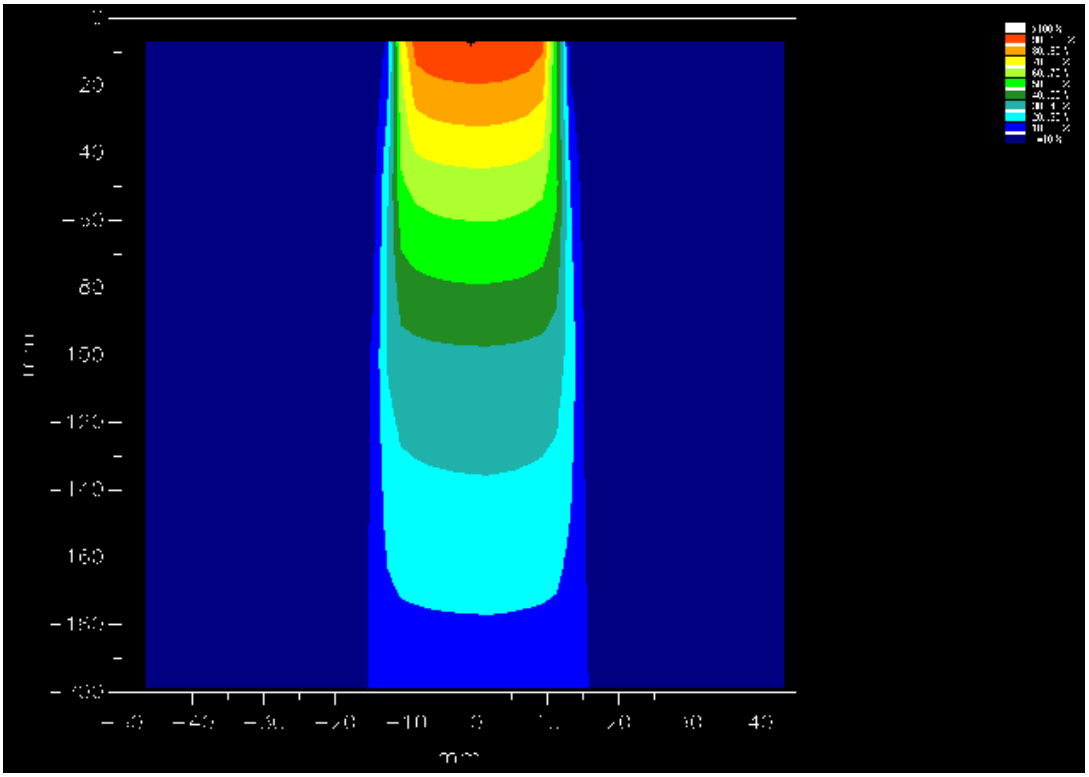


Figure 3. Isodose chart for 25 mm field size.

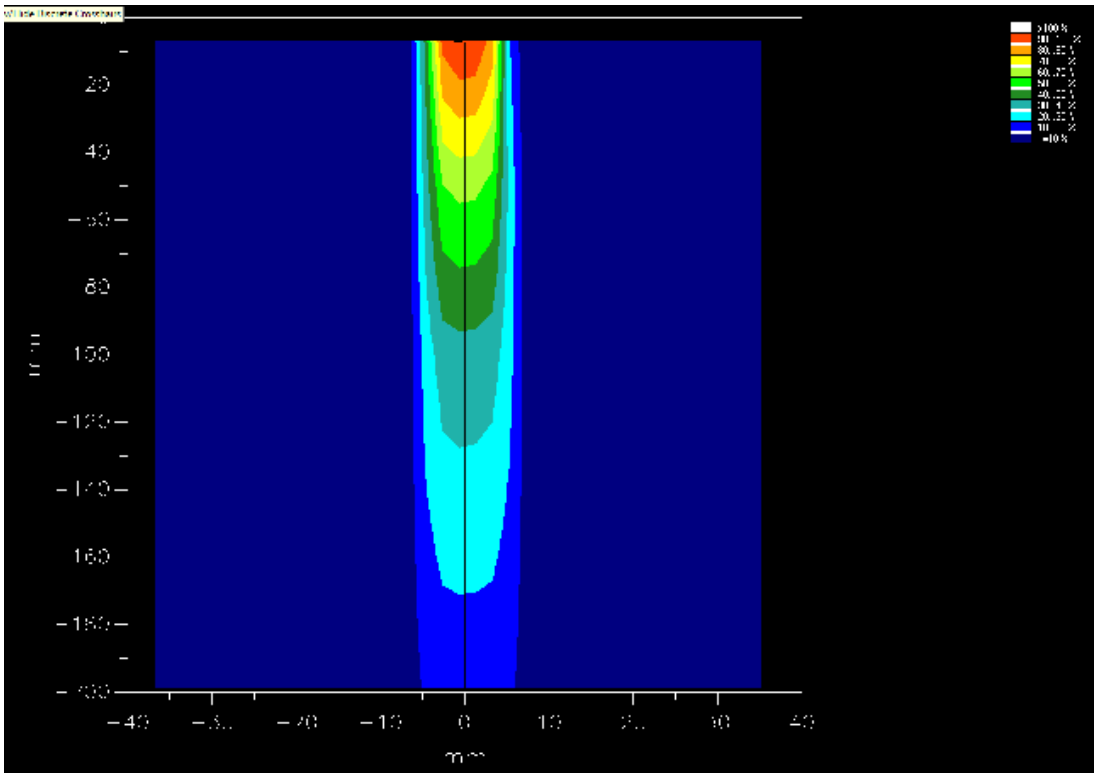


Figure 4. Isodose chart for 10 mm field size.