Technical Specification for a Stereotactic Radiosurgery (SRS) & Stereotactic Body Radiation Therapy (SBRT) device

This specification document outlines the minimum requirements for a computerized system being able to treat intracranial and extracranial lesions using three and four dimensional planning of stereotactic beam technologies. The system shall be able to deliver treatments in hypo-fractionated mode (typically maximum of five fractions).

The target(s) should be localized by stereotactic methods and treatment delivered using multiple beam directions. Lesions that are difficult or impossible to approach surgically may be treated with critical structures and other normal tissue spared as the technology allows high-precision dose specifications.

Listed in this document are the required and desirable technical specifications for the SRS/SBRT system.

Chapters:

1. Treatment Delivery

1.1. Beam type & energy

1.1.1. The LINAC should be able to deliver photon beams with a nominal energy of 6MV. Please indicate maximum and minimum nominal X-ray energies available with your system.

1.1.2. Specify the beam characteristics

1.2. Beam field size

1.2.1. Field size must be variable. Specify the available field sizes at isocenter.

1.2.2. The system must feature a multileaf collimator 2.5mm thick leaves across the entire Field Size (or 2.5mm on a 10 by 12 cm field size minimum). Give the MLC specifications.

1.3. Dose rates

1.3.1. The system shall support a dose rate of 1000MU/min at 80cm SAD, for a 60mm diameter field size at Dmax.

1.3.2. The machine output shall be calibrated to maintain a constant dose-rate at all times

1.4. Cooling system

1.4.1. A cooling system must be supplied by manufacturer. If a chiller is required, it must be supplied; installation/connection, testing, and warranty must be included.

1.5. Collimation

1.5.1. State the type of beam collimation.

1.5.2. The radiotherapist shall not need to enter the room to switch between collimators, the system shall be able to do it on its own automatically when following the treatment plan.

1.6. Beam delivery

1.6.1. The system shall be able to deliver non coplanar and non isocentric beams independently of the collimation chosen without moving the couch

2. Mechanical Systems

2.1. Mechanical accuracy and beam positioning

2.1.1. The mechanical positioning accuracy of the linac gantry or equivalent shall be less than 0.25 mm.

2.1.2. Describe the method of measurement from which this figure is derived.

2.1.3. The combined targeting error, including imaging system, couch and linac accuracy should be in a sub-millimeter range.

2.1.4. Describe what is accounted for in this figure.

2.1.5. The machine must not be limited to 2D gantry positioning if the treatment couch is not moved (IMRT is not considered as an additional plane).

2.1.6. The system shall follow an isocentric and a non-isocentric approach.

3. Treatment Couch

3.1. Automatic patient positioning

3.1.1. The system must be IGRT capable and the Treatment Couch must be integrated with the imaging system. Describe any user interaction necessary to align the Treatment Couch to the alignment corrections given by the imaging system.

3.1.2. Couch motion ranges

3.1.2.1. Describe the range of translational and rotational corrections that can be applied by the automatic patient couch.

3.1.2.2. The couch shall be able to go as low as 64 or 45 cm – depends on what the customer targets (first value is for Standard Couch, second for RoboCouch) - to ease the patient positioning. Specify the lowest possible height of the couch top above the floor for all available configurations.

3.1.2.3. The couch shall be able to support at least 158/ 226 kg – depends on what the customer targets (first value is for Standard Couch, second for RoboCouch).

4. Control System

4.1. Treatment console and keyboard

4.1.1. A treatment console and keyboard must be provided for control of the system from outside of the treatment room. Please give details on treatment console.

4.1.2. The system must be capable of being disabled by the removal of a security key while still allowing the accelerator electronics, electron gun, microwave sources etc. to be powered. Please provide details on the security arrangements. All described items must be included.

5. Image Guidance System

5.1. Method

5.1.1. An X-ray image guidance system must be provided that is capable of monitoring the patient/beam alignment. Please describe the system used.

5.1.2. The provided image guidance system shall be able to be used for intra-fractional imaging.

5.1.3. The system should allow intra-fractional imaging. State its frequency.

5.1.4. The system should automatically correct (without manual interaction) the beam delivery if changes in the target position have been detected.

5.2. Imaging system details

5.2.1. Describe the X-ray imaging system.

5.2.2. State the dose required for image collection for a typical intracranial and a typical extracranial treatment fraction.

5.3. Image Analysis

5.3.1. The system shall offer several algorithms used to compare treatment images with pre-treatment images in order to align tumour and beam including time from image collection to alignment being performed.

5.3.2. The system shall require minimal user interaction to support the tracking process.

6. Treatment Planning System

6.1. A dedicated treatment planning system (workflow management, image fusion, automated planning and contouring, optimization and dose calculation plan review and editing) should be supplied.

6.1.1. The system shall offer multi-modality fusion options (e.g. CT/MR, CT/PET).

6.1.2. The system shall support Dynamic Contrast Enhanced MRI as secondary image.

6.1.3. Describe the algorithm used for image fusion.

6.1.4. State in particular any manual interaction needed to support the fusion process.

6.1.5. The system shall offer several contouring tools.

6.1.6. State the image orientations on which contouring is possible.

6.1.7. Describe the inverse planning algorithm(s) available with your system.

6.1.8. What is the maximum number of beams allowable per plan?

6.1.9. Give details on the treatment planning system hardware and operating system.

6.1.10. If a separate system is available to perform functions such as image fusion, contouring or plan review, please provide details.

6.1.11. Describe the dose calculation algorithms available on the system.

6.1.12. The system should allow the visualization of several plans on the same monitor *– this is optional for FI and FM configuration*

6.1.13. The system should offer a feature that allows easy contouring of specific structures. *– Brain AutoSegmentation included in all versions but Males Pelvis AutoSegmentation is optional for FI and FM configuration,in Prostate package*

6.1.14. The system shall provide a tool for physicians to decrease treatment time

7. Data Management

7.1. State the DICOM RT import and export options and provide the DICOM conformance statement as an attachment.

7.2. The system shall assist in the integration of radiotherapy patient data throughout the entire department which includes linear accelerators by connecting to the Oncology Information System

7.3. An archiving system must be included, as well as any necessary computers, computer servers and components. This system must allow archiving of patient records online, as well as the capability of later restoring patient records back into the system patient database for possible follow-up treatment. Please explain in full detail.

7.4. The system shall have the option to create reports about the utilization of the device and print it via the internet,

8. Special Treatment Modes / Clinical Applications

8.1. Treating tumors moving with respiration

8.1.1. The system must include a model for lung lesions and other soft tissue lesions that move relative to the breathing cycle. A special treatment mode must be available. Please describe the treatment mode (for example gating, breath-hold, real-time tracking) and provide details.
Note: Synchrony, Xsight(R) Lung Tracking and Lung Optimized Treatment optional with some configuration, part of the Lung Package and Spine Prone + Lung Package

8.1.2. The described treatment mode shall not require abdominal pressure devices or equivalent.

8.1.3. This method shall be integrated to the system.

8.1.4. State the overall treatment accuracy and the method to measure this accuracy.
radiochromic film implanted in a phantom that simulates respiratory motion.

8.1.5. The system shall give the user an opportunity to determine the best tracking method for lung tumors prior to creating the treatment plan
Optional with the Lung Package and Spine Prone and Lung Package

8.2. A special target motion tracking method should be integrated to the system. So that the imaging frequency should automatically increase when target motion becomes erratic.*- this is an option part of the Prostate Package*

8.3. Treating spine tumors

8.3.1. Describe the method used for alignment of spinal tumors or lesions to the beam including any need for fiducials, immobilization devices or equivalent auxiliary material.

8.3.2. State the frequency of alignment correction during the treatment.

8.3.3. State the overall treatment accuracy and the method to measure this accuracy (spine lesions).

8.3.4. The System should offer an option to treat patients in the prone position
Part of Spine Prone Package and Spine Prone + Lung Package

8.3.5. 4D CT image data integration – this is an option part of the Lung Package and Spine Prone + Lung Package

8.3.5.1. The system shall be able to integrate 4D CT image data into the treatment planning process.

8.3.5.2. Describe how the 4D CT data is used and its influence on the treatment.

8.4. The system shall offer a method which automatically creates a treatment plan with minimal user input. It shall fuse the images, contour structures, and proceed to the optimization and dose calculation, presenting the user with a plan which needs to be authorized before delivery. *– this is an option for FI and FM configurations*

9. Clinical Usage

9.1. The system should have FDA clearance to provide treatment planning and image-guided radiosurgery for tumors anywhere in the body.

9.2. State if the system can also be used for non-stereotactic treatments.

10. Miscellaneous

10.1. Give a complete list of the number of individual workstations required to operate the system (including TPS, beam collimation, imaging system, etc.).

10.2. All system user documentation, training guides, release notes, etc. must be provided.

10.3. Describe the system's service agreement including any material (spare parts, included updates and upgrades).

10.4 The system shall fit in an existing vault.

10.5 Adequate training shall be given to end users. It shall include theoretical as well as hands on training and be delivered in several session allowing time for the user to digest the information.