Multi-Lesion Brain QA Phantom User Guide

Model 037



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1 Overview

The Multi-Lesion Brain QA Phantom for SRS, Model 037, provides an efficient method for comprehensive QA of single-isocenter, multi-lesion SRS treatment plans using radiochromic film in multiple locations. Unlike diode or ion chamber array devices, this method provides the high spatial resolution needed to fully evaluate the quality of SRS deliveries for every lesion at a single dose delivery. The size and composition of the Model 037 phantom result in QA dose distributions that closely mimic the actual dose distributions in patient plans providing a means for comprehensive treatment planning system (TPS) QA with increased confidence in the system performance. The high spatial resolution and true dose distributions offered by this phantom provide QA analysis that is superior to other currently available techniques.

The phantom features 4 mounting rods of different materials optimized for kV image based setups and thus may be used to perform complete end-to-end testing for validation of single-isocenter multi-lesion techniques on different systems.

With its precisely machined geometry, the Multi-Lesion phantom receives film in up to 29 planes with consecutive film planes centered precisely 5 mm apart. This empowers the user to acquire film measurements through high dose regions of each PTV in a multi-lesion plan with a single delivery. The pre-loaded polyester sheets exhibit the same thickness as radiochromic film, preserving the sensitive geometry re- quired for this procedure. This allows to optimize film use by replacing the polyester sheets only where required. External laser marks provide the means for precise and repeatable phantom positioning on the treatment table. The ceramic BB positioned at the phantom's ISO center (split between two spacers) helps locating treatment plan with minimal efforts or shifting if needed. External grooves that are visible on TPS screen allow for convenient film loading and marking for easy and accurate film for treatment plan registration.

Handling and Care

It is recommended that the phantom only be cleaned with mild detergent and water.

Specifications

Dimensions

Film Dimensions

150 mm (W) X 190 mm (H) x 170 cm (L)167 mm x 150 mm Weight: 5 kg/ 11 lbs Materials

Brain Equivalent Epoxy Resin Slab Thickness

Top & Bottom slabs: 15 mm Spacers: 4.7 mm

Polyester Sheets (PET)

29 pcs, 0.3 mm thick Accessories

60-Month Warranty User Guide Case



2 Phantom Features

- 1 Phantom slabs (spacers) are 4.7 mm thick to accommodate radiochromic film or replacement polyester sheets with a thickness of 0.3 mm each. This allows consistent 5.0 mm spacing between films.
- 2 The ISO center of the phantom is located at the central film plane and is easy to identify by a ceramic BB that is split between corresponding slabs.
- 3 The external laser marks match with the ISO center and BB location.



- 4 Slabs are marked on two surfaces with a distance between pointed film plane to the central film in mm.
- 5 All slabs are precisely assembled together using 4 pin holes.



- 6 Mounting rods must be used to quickly and easily secure phantom assembly using locations that are labeled on the top of phantom surface. This ensures phantom integrity while using x-ray imaging for setup.
- 7 There are grooves on the external surfaces of the phantom. They are visible on the TPS screen and help to identify proper film positions for optimized QA. The grooves can also be used for film marking using permanent marker for precise film to treatment plan registration during QA analysis. Vertical grooves in the middle identify the film center, offset grooves prevent mis-positioning and a diagonal groove at the 45° angle helps to identify desired film plane in respect to the central plane by simply measuring the distance between diagonal and vertical grooves that match to the distance from the central plane.



ID	Material	Density
ABS	ABS	1.05 g/cc
PA6	Nylon	1.14 g/cc
POM	Delrin	1.41 g/cc
PVC	PVC	1.42 g/cc

3 Use of the Phantom

Creating a Phantom Patient



- 1 To create a Phantom Patient acquire a computed tomography (CT) image of the phantom. This may be done using your normal kV and mAs CT acquisition settings for your SRS brain protocol, as the size and composition of the phantom are comparable. It is advisable to use a slice thickness and spacing of 0.5 or 1 mm to correspond precisely with the geometry of the phantom. Image and store your phantom with all 29 polyester sheets in the phantom. Each polyester sheet is 0.3 mm thick. Small variations in geometry due to variable numbers of loaded sheets/films would complicate the QA procedure and have dramatic effects on the QA results. Ensure that the phantom is leveled and orientated as you use it for QA measurements.
- Prior to removing the phantom from the CT table, import the CT image into your treatment planning system (TPS) according to the procedure specified by the TPS vendor. Check that the film planes are precisely centered in CT slices. If they are not, fine tune the CT table height and acquire and import a new CT image into your TPS.
- 3 Create any necessary body and/or table structures.
- 4 It is helpful to set an origin at the central slice of the phantom, that holds a ceramic BB, and create reference points corresponding to the locations of each of the film planes. These points should be set with high accuracy, and doing this properly in a QA phantom greatly improves the efficiency of the routine QA procedure. Verify the accuracy of the film plane reference point placements by comparing physical measurements of the grooves on the phantom with measurements made in the TPS.

Setting Up a Workflow

1 It is helpful to set up a spreadsheet to assist in efficiently locating appropriate film planes for each planning target volume (PTV). This process varies, depending on how image origins and treatment isocenters are set during the planning process.

(A) If the normal practice for patient planning is to set both the image origin and treatment isocenter approximately at the center of the patient's brain, then the

coordinates of the PTVs in the patient's plan matches the coordinates of the PTV dose distributions in the Phantom Patient.

(B) If the normal practice for patient planning is to have a shift from the image origin to the isocenter, then it is necessary to calculate PTV coordinates in the QA plan. The following is an example of a spreadsheet created to perform these calculations. The physicist performing the QA procedure would record the isocenter shifts for the patient plan, and the spreadsheet computes the corresponding coordinates and Plane #'s for the QA plan. This spreadsheet includes space for the physicist to denote the location in the plan. This can be helpful in identifying individual PTV dose distributions in the case when there are multiple high dose PTV regions in a single film plan.

Patient Name:								
Patient Plan	x	У	z					
Isocenter Shifts								
	PTV Center in Plan		PTV Center in QA plan		PTV	PTV		
	Х	Y	Z	Х	Y	Z	Plane #	Loc in Plane
PTV1				0	0	0		
PTV2				0	0	0		
PTV3				0	0	0		
PTV4				0	0	0		
PTV5				0	0	0		
PTV6				0	0	0		
PTV7				0	0	0		
PTV8				0	0	0		
PTV9				0	0	0		
PTV10				0	0	0		

Note: It is helpful to adopt a clinical practice of setting the patient treatment isocenter at the approximate center of the patient's brain, rather than at the center of the PTVs. If this is not practical or possible, it is necessary to factor the appropriate shifts into your spreadsheet.

- 2 Prepare film to use for TPS QA procedures. Any radiochromic film suitable for SRS measurements works, though it must be cut to fit the phantom. Precision Cut EBT3 Film is available for purchase to reduce effort and film waste: Part No. 158200-07 (10 film inserts plus 30 calibration strips).
- 3 If not already implemented, set up an appropriate radiochromic film protocol according to instructions provided by your film and software vendor(s).

Performing QA Using the Phantom Patient

- 1 Compute a QA plan using your Phantom Patient.
- 2 Review the QA plan to ensure that the high dose PTV regions are all within the phantom. Perform shifts and re-calculate your QA plan if necessary.

- 3 Review QA plan to ensure that none of your PTV dose distributions intersect film planes only high dose gradient regions. This may occur if you plan to very small PTVs. If it does occur, add a small shift, re-calculate your QA plan and make a note to perform this shift prior to the QA delivery.
- 4 Identify PTV coordinates and Plane #'s in the QA plan for each PTV, according to the workflow set up in the previous section.
- 5 Remove polyester sheets from appropriate film planes, and replace with pre-cut films. Use grooves on the phantom edges for convenience. Keep films at the same orientation. Mark film orientation, as appropriate. Carefully mark edges of each film using phantom grooves for film to treatment plan registration during QA analysis.
- 6 Deliver the plan to the phantom. A good setup is critical. It is possible to achieve excellent QA results following a careful setup based only on crosshairs for machines with highly tuned crosshair and table parameters. The phantom also contains rods of various materials, which enables an imaging based setup. While not necessary, image based setup corrections per couch angle provide the most accuracy in the QA process.
- 7 Remove and mark films. Analyze according to instructions provided by the film and film software vendor(s).

4 Support and Maintenance

Care and Handling

It is advisable not to clean the product surface with solvent based cleaners. Use mild soap and water and dry with a clean towel. Store the phantom in the carry case or on a flat surface when not in use.

Contacting Sun Nuclear Support

You may request support in two ways:

- Submit a support request using our online form. See *Support Website* below.
- Contact the Sun Nuclear Support team by telephone:
 - U.S.A.: +1 321-259-6862
 - Netherlands: +31 20 399 90 41
 - Germany: +49 61 02 50 49 500

Support Website

- 1 Open an internet browser and navigate to <u>sunnuclear.com/support</u>.
- 2 Enter your email address and password and then click **Login**.
 - To download product information, click **Products and Devices**, select the product, and then select the download type.
 - To open a Support request, click **Open New Case**, complete the form, and then click **Create Case**.

Warranty Information

All standard CIRS products and accessories are warranted by CIRS against defects in material and workmanship for a period as specified below. During the warranty period, the manufacturer will repair or, at its option, replace, at no charge, a product containing such defect provided it is returned, transportation prepaid, to the manufacturer. Products repaired in warranty will be returned transportation prepaid.

There are no warranties, expressed or implied, including without limitation any implied warranty of merchantability or fitness, which extend beyond the description on the face hereof. This expressed warranty excludes coverage of, and does not provide relief for, incidental or consequential damages of any kind or nature, including but not limited to loss of use, loss of sales or inconvenience. The exclusive remedy of the purchaser is limited to repair, recalibration, or replacement of the product at manufacturer's option.

This warranty does not apply if the product, as determined by the manufacturer, is defective because of normal wear, accident, misuse, or modification.

Non-Warranty Service

If repairs or replacement not covered by this warranty are required, a repair estimate will be submitted for approval before proceeding with said repair or replacement.

Returns

If you are not satisfied with your purchase for any reason, please contact Customer Service prior to returning the product. Call 800-617-1177, email rma@cirsinc.com, or fax an RMA request form to 757-857-0523. CIRS staff will attempt to remedy the issue via phone or email as soon as possible. If unable to correct the problem, a return material authorization (RMA) number will be issued. Non-standard or "customized" products may not be returned for refund or exchange unless such product is deemed by CIRS not to comply with documented order specifications. You must return the product to CIRS within 30 calendar days of the issuance of the RMA. All returns should be packed in the original cases and or packaging and must include any accessories, manuals and documentation that shipped with the product. The RMA number must be clearly indicated on the outside of each returned package. CIRS recommends that you use a carrier that offers shipment tracking for all returns and insure the full value of your package so that you are completely protected if the shipment is lost or damaged in transit. If you choose not to use a carrier that offers tracking or insure the product, you will be responsible for any loss or damage to the product during shipping. CIRS will not be responsible for lost or damaged return shipments. Return freight and insurance is to be pre-paid.

With RMA number, items may be returned to:

CIRS Receiving 900 Asbury Ave, Norfolk, Virginia, 23513 USA

Product	Warranty Period			
Multi-Lesion Brain QA Phantom	4 years			

Appendix A: Regulatory Supplement

In addition to the regulatory information contained in the body of this manual, the following supplemental regulatory information is provided.

Sun Nuclear Corporation Symbols

The following symbols are used in this guide and in Sun Nuclear Corporation's product labels.



WARNING: This symbol indicates a hazard that could result in major injury or equipment damage. (EN ISO 7010, W001)



CAUTION: This symbol indicates a potential hazard that could result in minor injury or equipment damage. (EN ISO 15223-1, 5.4.4)



CAUTION: This symbol indicates a pinch hazard. (EN ISO 7010, W024)



Note: Important or supporting information.



Manufacturer's Identification (name and address). (EN ISO 15223-1, 5.1.1)



Date of Manufacture. (EN ISO 15223-1, 5.1.3)



Temperature limitation. (EN ISO 15223-1, 5.3.7)



Humidity limitation. (EN ISO 15223-1, 5.3.8)



Atmospheric pressure limitation. (EN ISO 15223-1, 5.3.9)



Serial Number. (EN ISO 15223-1, 5.1.7)



Catalog Number. (EN ISO 15223-1, 5.1.6)



Consult instructions for use. This equipment must be used in accordance with the instructions in this manual. Read all instructions and safety labels before use. (EN ISO 15223-1, 5.4.3)



Do not throw in trash; dispose of in an environmentally friendly way. (EN 50419) $\,$

Operator Responsibility

The instructions in this manual are intended for trained clinical personnel. The operator is solely responsible for the accurate setup and use of the phantom.

Reporting Health or Safety Related Issues or Concerns

A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

To report any safety or health related issues or concerns regarding the use of Sun Nuclear products, contact Sun Nuclear directly.

Modifications to Equipment

Any changes or modifications to the device that are not expressly approved by Sun Nuclear Corporation could void your warranty.



