Phantom Patient for Stereotactic End-to-End Verification User Guide

Model 038

SUN NUCLEAR
A MIRION MEDICAL COMPANY

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CIRS
900 Asbury Ave
Norfolk, VA 23513
Phone +(757) 855-2765

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Contents

1 Introduction

Phantom Capabilities

- Perform end-to-end testing for commissioning as directed by AAPM TG-101
- Verify positioning accuracy using frame/frameless systems, head and shoulder masks or other positioning fixation devices
- Perform geometric machine QA- Winston-Lutz isocenter verification tests and localization/repositioning with couch shift
- Perform IGRT QA procedures for X-ray onboard kV and MV imagers including CBCT
- Assess image fusion, image transfer QA, accuracy verification, TPS testing with multi-modality imaging capabilities (CT, MRI, and PET)
- Confirm TPS deformable image registration algorithm accuracy

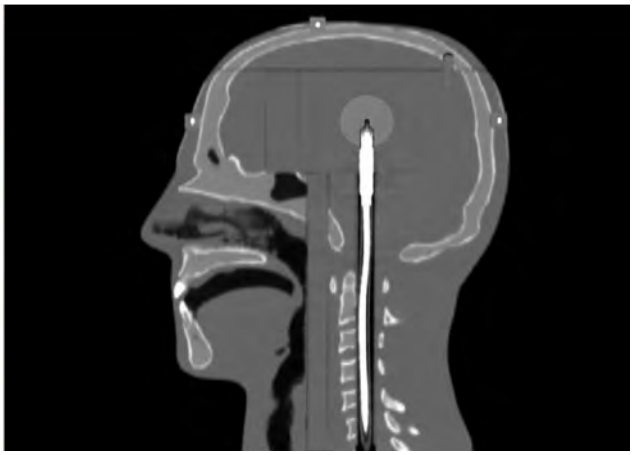
Phantom Description

Stereotactic Radiosurgery (SRS) necessitates a high degree of accuracy in target localization and dose delivery. Small errors can result in significant under treatment of portions of the tumor volume or overdose of nearby healthy tissues. Whether commissioning a new system, or performing daily radiation alignment systems checks, intense attention to detail is required. Internal details of the Stereotactic End-to-End Verification Phantom “STEEV”, CIRS Model 038, provide a most realistic clinical simulation to perform end-to-end testing of SRS systems in most challenging anatomical regions.

With STEEV, users can commission SRS systems following AAPM TG-101. After commissioning, STEEV is suitable for use in diagnostic energy ranges for treatment planning in single or multiple modalities. Its anthropomorphic, tissue-equivalent design makes it the only phantom available to account for the challenging effects of tissue heterogeneity. Geometric and organic target inserts allow for comprehensive image QA, geometric machine QA, and TPS QA for increased confidence in system performance.

STEEV accommodates a multitude of dosimeters for dose verification. When used in concert with the various imaging inserts, STEEV provides our most comprehensive end-to-end testing and QA solution for SRS systems.

Proven tissue-Equivalent Technology



STEEV is constructed of CIRS' proprietary tissue-equivalent materials. Linear attenuations of the

Linear Attenuation Coefficients To Reference Tissues (1) (2)

En, MeV	Trabecular Bone Ratio, %	Soft Tissue Ratio, %	Brain Ratio, %	Spinal Cord Ratio, %	Cortical Bone Ratio, %
0.04	99.8	100.0	100.0	100.0	99.3
0.06	100.1	100.2	100.1	100.0	99.7
0.08	100.3	100.3	100.3	100.0	99.8
0.10	100.3	100.3	100.3	99.9	100.0
0.20	100.5	100.4	100.3	99.9	99.8
0.40	100.5	100.4	100.4	100.0	100.0
0.60	100.5	100.3	100.3	100.0	100.1
0.80	100.4	100.4	100.4	99.9	100.1
1.00	100.5	100.3	100.4	99.9	100.1
2.00	100.5	100.4	100.4	100.0	100.1
4.00	100.5	100.3	100.0	99.7	99.7
6.00	100.3	100.0	100.0	100.0	99.6
8.00	100.0	100.0	99.6	100.0	99.6
10.0	100.0	100.0	99.6	100.0	99.3
20.0	99.5	99.5	99.5	100.0	98.5
30.0	99.5	99.4	98.9	100.0	98.2
Density, g/cc	1.20	1.06	1.07	1.07	1.93
Electron Density x 10^{23}, per cc	3.863	3.434	3.470	3.488	5.956

1. ICRP 23, Report of the Task Group on Reference Man (1975).
2. Woodard, H.Q., White, D.R., The Composition of Body Tissues, The British Journal of Radiology (1986) 59: 1209-1219

simulated tissues are within 1% of actual attenuation for soft tissue and bone from 50keV to 15MeV. CIRS tissue simulation technology has been validated through specific testing, continuous monitoring of manufacturing applications and worldwide use and acceptance of CIRS products for over 30 years.

The Model 038 approximates the average male human head in both size and structure. STEEV includes detailed 3D anthropomorphic anatomy such as: skull, brain, vertebrae, larynx, trachea, sinus, nasal and oral cavities, spinal cord and teeth. The bones feature cortical and trabecular separation. C1-C7 vertebrae are present and include spinal disks. The teeth include distinct dentine, enamel and root structure. The maxillary and mandibular nerves are present. The sinus cavities are fully open and include sphenoid, frontal, and maxillary sinuses.

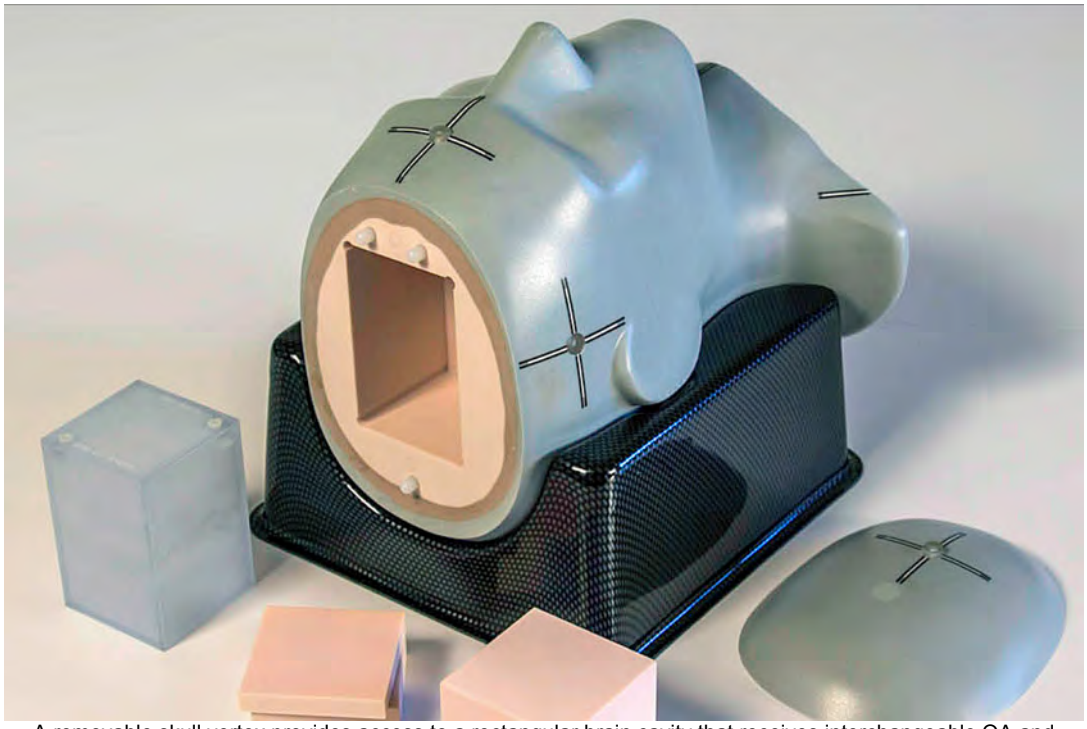
These internal details provide a most realistic clinical simulation to evaluate the challenging effects of complex intra- and extra-cranial anatomies. Two cylindrical holes in the neck provide ion chamber access to the rectangular brain cavity. The detailed internal structure and location of these access holes enable users to verify dose within critical structures and high dose-gradient regions of interest, such as the bone/soft tissue interface.

Intuitive Setup

Phantom Features

- Verify TPS corrections for heterogeneities
- Intuitive positioning means no special set-up required
- Measure dose at high-dose gradient areas and within critical structures
- Compatible with any frame-based, head-and-shoulder mask or frameless positioning system

- True End-to-End testing along entire treatment chain from Diagnostic Scanning and Treatment Planning to Dose Delivery

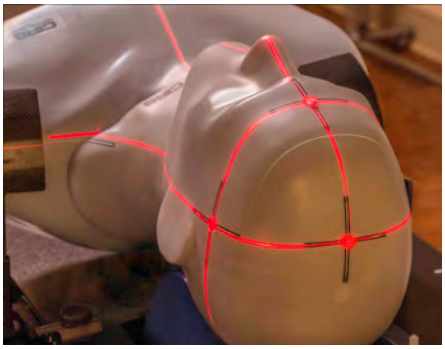


A removable skull vertex provides access to a rectangular brain cavity that receives interchangeable QA and dosimetry inserts. The phantom may remain set up on the treatment couch in either the positioning cradle or any patient fixation device while interchanging inserts (above: STEEV shown with positioning cradle)

Model 038-29, Adapter for Model 038 STEEV and Leksell® Frame G shown above. Model 038-29 is compatible with all optional components of the Leksell Coordinate Frame G, including MRI Indicators and various adapters including the Gamma Knife Adapter.

*Leksell® Coordinate Frame G is a registered trademark of Elekta (Stockholm, SE)

Alignment

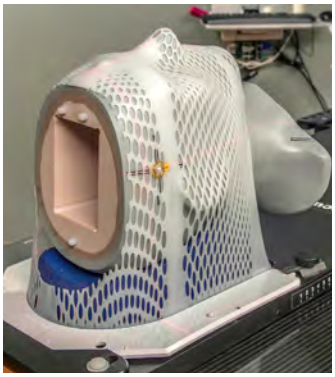


Both the head and neck have laser alignment marks to position the isocenter of the rectangular brain cavity with the system lasers, including when the Model 038 is used with an SRS mask. Additionally, there are four MRI/CT fiducials positioned at cross-hair centers in an axial plane and one at the vertex of the head. Another fiducial is embedded in a rod insert that aligns with the vertex fiducial when positioned in one of two access holes. Together all six fiducials create an orthogonal, three-axis system of coordinates with the coordinate origin matching a target location in the rectangular brain cavity.

MRI/ CT fiducials contain ceramic BB encapsulated in proprietary gel that provides MRI signal for any sequence, including fat saturated.

The rectangular brain cavity is positioned parallel to the clinically relevant Frankfort Plane (FP). When STEEV is aligned with the machine lasers, the FP matches with the axial plane inside the gantry.

Fixation without Extraneous Interfaces

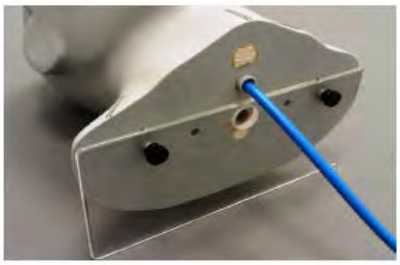


STEEV's anthropomorphic exterior allows for use of multiple positioning and fixation devices as used in clinical applications, including intuitive patient positioning with stereotactic frames, frameless systems, and head and neck masks. STEEV does not require any additional mechanical interfaces between the phantom and the positioning.

An Alignment Plate is included with every phantom to stablize phantom on the treatment couch for easy of positioning and alignment with lasers independent of any immobilization devices.systems that would not be used in a clinical setting.

The removable skull vertex provides access to the rectangular brain cavity that receives interchangeable QA and dosimetry inserts. The phantom may remain set up on the treatment couch while interchanging inserts.

Optional shoulders allow use of various masks and shoulder brackets. They attach via nylon rods and allow for inferior insertion of ion chambers. The shoulders are made of homogeneous, soft-tissue equivalent material and do not include internal anatomy.



An Alignment Plate is included with every phantom to stablize phantom on the treatment couch for easy of positioning and alignment with lasers independent of any immobilization devices.

An optional cradle allows easy access to the brain cavity for exchanging inserts without compromising phantom set-up.

Interchangeable Inserts

STEEV allows users to perform essential QA applications for SRS systems. In order to facilitate required system checks for each application, STEEV accommodates fourteen interchangeable inserts. Cubic brain equivalent inserts enable measurement of dose delivered at ISO center and off-ISO center positions using micro- and pinpoint ion chambers, film, MOSFET, TLD, OSL (nanoDOT) and 3D gel. When used in concert with the various imaging inserts for CT, MRI and PET, STEEV provides the most comprehensive end-to-end testing and QA solution for SRS systems.

Ion Chamber Target Dosimetry Kit

MODEL 038-03-CVXX-XX*

The Ion Chamber Dosimetry Kit includes a brain-equivalent insert containing a tissue-equivalent, 30 mm diameter spherical target. The insert is machined to receive an ion chamber at the center of the target for final dosimetry measurements during end-to-end testing. The Model 038-03 allows ion chamber dosimetry in a tissue-equivalent spherical target that matches the MRI/PET/CT Spherical Target Insert (038-11) both in location and dimension. This insert may be used in two positions within the brain cavity that space the target isocenter 30mm in the anterior-posterior direction. A solid cavity plug with ceramic BB at ISO center allows for chamber localization during treatment planning. A soft-tissue equivalent sleeve helps minimize air gaps around the ion chamber stem.

*When ordering, specify cavity code. For complete list of ion chamber cavity codes, refer to www.cirsinc.com/support.

Features

- Ø30 mm Spherical target with +5% contrast
- Receives user selected small-volume ion chambers
- Includes brain-equivalent cavity plug with Ø2.5 mm point fiducial

CT of ion chamber in anterior position

Variable Position Ion Chamber Dosimetry Kit

MODEL 038-04-CVXX-XX*

Kit allows for dosimetry measurements at different locations through the brain and neck during patient treatment plan QA. This can be achieved using two parallel channels that are drilled through the phantom 30mm apart in the Inferior-Superior direction. The Posterior channel runs through the spinal cord and anterior hole is drilled in the challenging, heterogeneous, high dose-gradient region

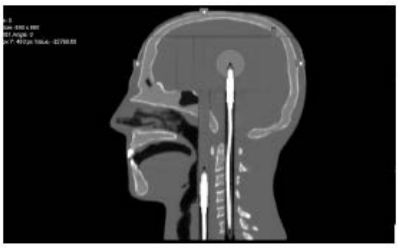
between the spine and trachea. The central hole in the included brain-equivalent cube can be aligned with anterior or posterior channels by positioning accordingly in the brain cavity. Dosimeters can be placed in one channel through the neck and brain and inside the other channel through the neck only. In this configuration, two dosimeters could be used simultaneously for tumor and organ-at-risk dosimetry. A set of the brain-equivalent spacers, designed to fit through the channels, helps to minimize air influence during the dosimetry measurements. Spacers measure between 50mm and 5mm long to allows 5mm incremental detector positioning. The set of spacers includes one spacer with tip drilled for customer-specified chamber to provide the best measurements conditions around detector's sensitive volume. Two dosimeters could be used simultaneously for tumor and spare organ dosimetry. See CT reconstruction picture.

A cavity plug with a ceramic BB in ISO center, which can be identified by a black ring around the tip of the plug, allows for chamber localization during treatment planning. Two soft-tissue-equivalent sleeves also help to minimize air gaps around the ion chamber stem and cable for measurements outside the brain. A solid cavity plug can be used to fill the cavity if BB in the ISO center not needed.

*When ordering, specify cavity code. For complete list of ion chamber cavity codes, refer to www.cirsinc.com/support.

Features

- Incremental ion chamber positioning through trachea and spinal cord
- Accommodates small-volume ion chambers
- May be used with 038-03 for simultaneous dose measurements



Included with 038-04-CVXX-xx:1. Spacer Plugs, 2. Drilled cavity spacer, 3. Cavity plug with BB, 4. Solid Cavity

TLD Dosimetry Insert

MODEL 038-06

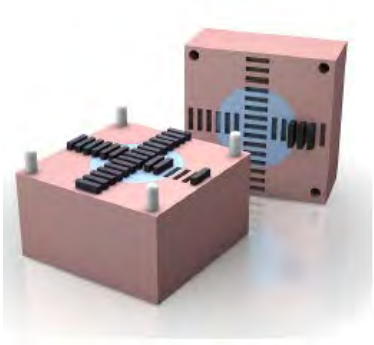
Features

- Provides 2D or 3D dose verification
- • Receives TLD chips, rods, bars cubes and disks
- • Ø5 mm through holes in a 1cm x 1cm grid pattern within brain and neck

The TLD Dosimetry Insert allows 2D and 3D dose verification using TLDs. The insert consists of a brain-equivalent cube drilled in a 1 cm X 1cm grid pattern of 5mm diameter through holes. Each hole is filled with a 5mm diameter brain-equivalent solid plug for use for TLDs placement . TLD can be positioned between plugs at the desired depth within each hole. Tissue-equivalent plugs cast to precisely receive TLD chips, rods, bars and cubes are available separately.

Multiple OSL Dosimetry Target Insert

MODEL 038-08



Features

- Drilled for nanoDot™ OSL spaced 4.1 mm apart in two orthognal directions
- Allows 3D measurements by rotating
- Measurements in embedded soft-tissue
- target and penumbra
- Easy insertion and removal of nanoDot™

The Multiple-OSL Dosimetry Target Insert enables 2D point-to-point dosimetry in two orthogonal directions both inside the target and penumbra using Landauer nanoDots™. By rotating the insert in 3 orthogonal directions, it also enables 3D dosimetry.

Model 038-08 consists of a brain-equivalent cubic insert with a 30 mm diameter spherical target with +5% contrast. The insert receives 27 OSL dosimeters through the center plane of the sphere. Cube is assembled using four pinholes with an off-set arrangement that allows for consistent assembly. External marks machined outside both halves make it easy to align when assembled.

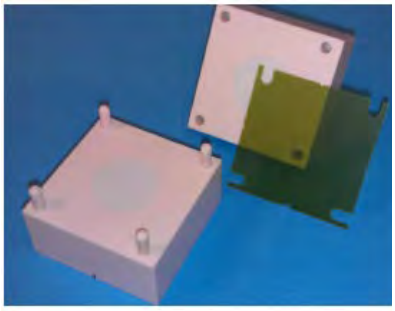
Single Film Dosimetry Target Insert

MODEL 038-05

The brain-equivalent cubic insert includes a 30 mm diameter spherical target with +5% contrast. It receives a single piece of radiochromic film through the center plane of the sphere. Refer to page 14 for CIRS Precision Cut EBT3 Film options. The film can be positioned in the axial, sagittal or coronal orientation and allows for the presence of a target volume through all stages of the treatment process. Cube is assembled using four pinholes with an off-set arrangement that allows for consistent assembly. External grooves machined outside both halves make it easy to mark film for accurate image registration. This also helps for easy assembly.

Features

- Ø30 mm Spherical target with +5% contrast
- • Receives a single film through center plane
- • Orient film in axial, sagittal or cornal planes
- OSL Dosimeters with no air gaps



Film Stack Dosimetry Insert

MODEL 038-021

Film Stack Insert is a brain-equivalent cube for use in small-volume dose mapping with film. The Film Stack can be used for treatment plan verification of targets in different shapes and sizes, including multi-metastasis targets. The Film Stack accommodates 13 layers of radiochromic film with 4 mm dimensional integrity, the Film Stack comes with replacement plastic sheets. To optimize use of film, it is recommended plastic sheets be replaced with film only where necessary.

Refer to page 14 for CIRS Precision Cut EBT3 Film options. External grooves allow for film edge markings to enable x, y, and z image registration for dose analysis. The Film Stack may be placed within the brain cavity in axial, sagittal or coronal orientation.

Features

- Provides small volume dose mapping in axial, sagittal and coronal planes
- Verifies multi-lesion, single ISO center treatment plans
- Accommodates 13 films with 4 mm spacing
- Designed to allow x,y, and z registration when viewing individual films

Single Slice Film Insert with Fiducials

MODEL 038-27-CVXX-XX

Features

- Ø30 mm Spherical target with +5% contrast
- Receives a single film through center plane
- Receives pin-point ion chamber in one half of the sphere
- Steel fiducials allow for accurate film registration OSL Dosimeters with no air gaps

The brain-equivalent cubic insert includes a 30 mm diameter spherical target with +5% contrast. It receives a single piece of radiochromic film through the center plane of the sphere. A pin-point ion chamber cavity is machined into half of the target sphere allowing simultaneous measurements of absolute dose & dose distribution inside the target. Film can be positioned inside the 5mm deep pocket which contains 6 stainless steel fiducials symmetrically placed. Fiducials provide a means for easy treatment plan registration.

Electron Density Cube with Removable Vial

MODEL 038-09

Features

- Perform CT number to electron den- sity calibrations
- Comes standard with 1” diameter vial for real water measurements
- Compatible with all Model 062M Electron Density reference plugs

The brain-equivalent cubic insert includes a water-equivalent electron density plug surrounding a removable 1” diameter vial for water or other liquids. The insert can accommodate any of the standard electron density plugs offered with CIRS Electron Density Phantom (Model 062M). Additional plugs, including high-density options, can be purchased separately. The Electron Density Cube is useful for refining CT number to electron density calibrations.

Winston Lutz Cube with Ø50 mm Centroid and Off-Center Targets

MODEL 038-10

Features

- Ø5 mm tungsten BB fiducial at the centroid
- Ø5 mm target offset from center

The brain-equivalent cubic insert contains a 5 mm diameter tungsten BB at the centroid and an additional 5 mm BB that is offset from center in three orthogonal planes at x-y-z distances of 15 mm, 20 mm, and 25 mm respectively. The insert facilitates isocenter verification (Winston Lutz) and couch shift localization/ repositioning. The insert can be used by itself or inside the head for “blind” Winston Lutz tests.

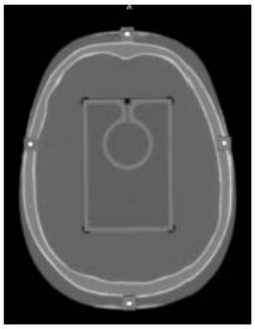
MRI/PET CT Spherical Target Insert

MODEL 038-11

Features

- Use in tandem with other spherical target inserts
- Target volume and surrounding region can be filled separately.

The insert facilitates multi-modality image reconstruction tests. Its 30 mm diameter spherical tumor volume allows for assessment of image and reconstruction integrity when images are moved among different imaging systems. This insert is designed to work together with the “matching target” in the Ion Chamber Target Dosimetry Kit (038-06-CVXX-xx) and Single Film Target Dosimetry Insert (Model 038-05). The series of interchangeable inserts enables enhanced end-to-end testing of image acquisition, planning and delivery. Spherical target volume and rectangular insert volume can be individually filled through separate fill ports using MRI or PET compatible liquids. Cube is aligned with external MRI/CT fiducials.



Axial CT

Axial MRI TSE-T1

Axial MRI TSE-T2

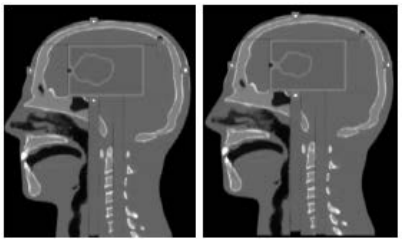
MRI/PET CT Organic Target Inserts for Deformable Image Registration

MODEL 038-12 & 038-13

Features

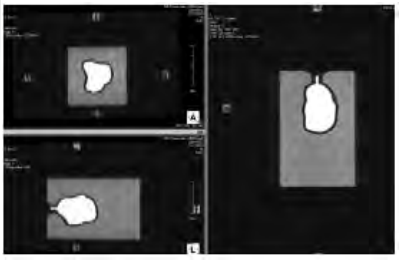
- 25cc organic target and isotropically reduced 12.5 cc targets in two inter- changeable inserts
- Assess TPS deformable image registration and transformation algorithms
- Target and volume each fillable with MRI or PET compatible liquids

Two MRI/PET/CT Organic Target Inserts are available for experimental testing of TPS deformable image registration and transformation algorithms. The Model 038-12 contains an organic shaped target of 25cc internal volume. In Model 038-13 the same organic target shape is isotropically reduced to a 12.5cc internal volume. Both targets contain the same central position relative to the phantom's external MRI/ CT fiducials. The target volumes and rectangular volumes can be filled individually through separate fill ports using MRI or PET compatible liquids.



25cc Organic Target CT

12cc Organic Target CT



12.5 cc- MRI TSE T1 Organic Target

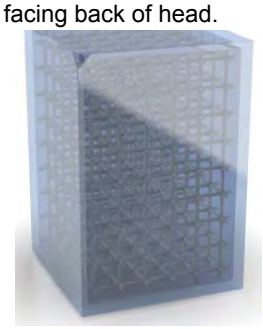
MRI/PET/CT Spatial 3D Distortion Insert

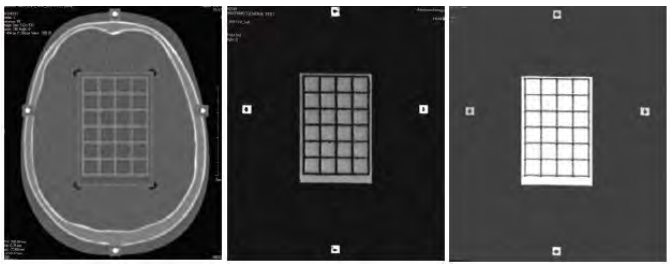
MODEL 038-14

Features

- Quick and intuitive image fusion algorithm verification
- Can be used in tandem with external fiducials for 3D distortion assessment

The MRI/PET/CT Spatial 3D Distortion insert contains a 3D grid (13 x 13 mm spacing) of Ø 1.6 mm high contrast wire (more than 200HU). The insert can be filled with MRI or PET compatible liquids. It provides a single, precise tool to check image fusion and image distortion across multiple modalities. To align internal grid with external MRI/CT fiducials, please position insert with fill ports facing back of head.





CT Axial MRI TESE-T1 MRI TESE-T2

MRI/PET/CT ISO Center Insert

MODEL 038-15

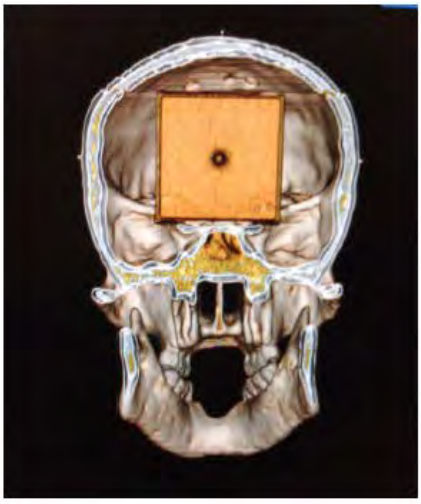
Features

Assess isocenter alignment accuracy during image fusion

- Fillable with MRI or PET compatible liquids
- Contains ceramic fiducial at ISO center when aligned to phantom's external MRI/CT fiducials

This rectangular insert features a 3.2 mm diameter ceramic BB at ISO center aligned to the phantom's external MRI/CT fiducials. The insert can be filled with MRI or PET compatible liquids. Insert can be used alone or in combination with other imaging inserts to evaluate image fusion functions of treatment planning systems.

CT Sagittal Recon



CT Coronal Recon

2 The Standard Model 038

The Standard Model 038 Includes

- Phantom head and neck with external fiducials and markings
- Three brain equivalent spacers to fill rectangular intercranial cavity
- Two tissue-equivalent rods to fill cylindrical channels (one includes MRI/CT fiducial)
- MRI/CT/PET ISO Center Insert
- Neck alignment plate
- Foam-lined carry case
- User guide and warranty

Optional Configuration

SRS Machine QA

- Ion Chamber Target Dosimetry Kit
- Single Film Target Dosimetry Insert
- MRI/CT/PET Spherical Target Rectangular Insert
- MRI/CT/PET Spatial 3D Distortion Insert
- MRI/CT/PET Organic Target Rectangular Inserts
- Electron Density Cube with Removable Vial
- Adapter for Model 038 STEEV and Leksell® Frame G

During the commissioning process, SRS systems require QA testing of the entire treatment chain to include positioning and fixation, diagnostic imaging in CT, MRI and/or PET, treatment planning, and dose delivery verification. STEEV's uniquely anthropomorphic design allows for easy transition throughout this process. Users can easily change between dosimetry, image fusion, TPS deformable image registration, and electron density inserts while STEEV remains in position. A series of inserts with identical 30 mm diameter spherical targets allow for target consistency during dose measurements and MRI/CT/PET image-fusion making them ideal for end-to-end testing. Geometric and organic target inserts provide means for comprehensive image QA, geometric machine QA and TPS QA for increased confidence in system performance.

Dose Verification

- Variable Position Ion Chamber Dosimetry Kit
- Film Stack Dosimetry Kit

- TLD Dosimetry Kit
- Adapter for Model 038 STEEV and Leksell® Frame G

To evaluate dose, STEEV accommodates inserts without targets so that users can validate dose to unique target volumes. Inserts facilitate dosimeter placement at multiple locations within the brain, other critical structures such as the spine and within challenging high-dose gradient regions in the neck. Inserts are compatible with a wide range of dosimeters so users can implement dose QA protocol using dosimeters they already own.

Radiation Alignment QA

- Winston Lutz Cube with 5mm diameter Centroid and Off-Center Target
- Adapter for Model 038 STEEV and Leksell® Frame G

STEEV's radiation alignment QA inserts allow users to assess optical and geometric isocenter alignment to verify geometric accuracy

Multi-Lesion TP QA

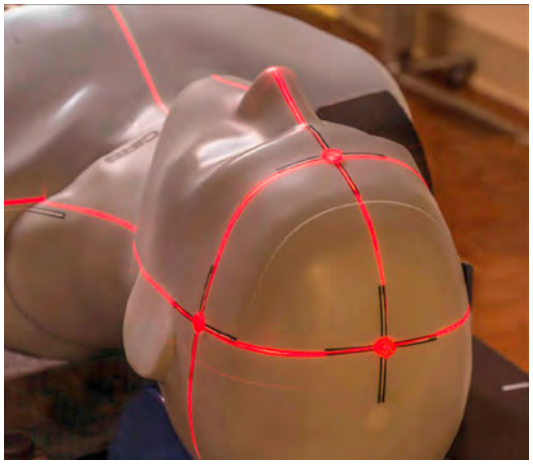
- Film Stack Dosimetry Kit

Deformable Image Registration QA

MRI/PET/CT Inserts with 25 cc & 12.5 cc Organic Target

3 Using the Phantom

Phantom Setup

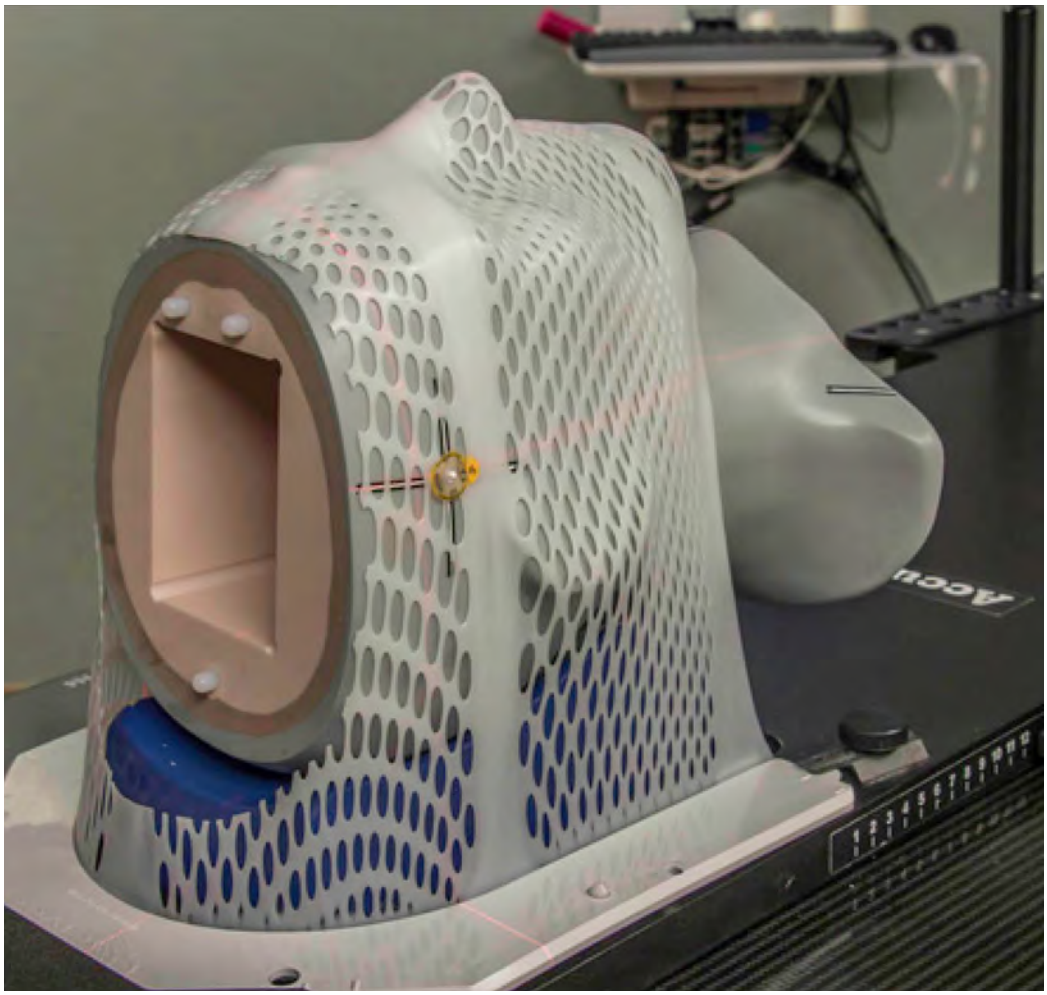


STEEV comes standard with a number of features that facilitate fast and easy set up. Both the head and neck have black cross hairs with white filling for better phantom alignment to lasers, including when the Model 038 is positioned in an SRS mask. Additionally, there are four MRI/CT fiducials positioned at the cross-hair centers in an axial plane and one at the vertex of the head. Another fiducial is embedded into the anterior rod and aligned with the vertex fiducial when it is plugged to the anterior hole. Together all six fiducials create an orthogonal three-axis system of coordinates with the coordinate origin matching the targets' anterior location in the rectangular cavity. MRI/CT fiducials are 10 mm in length and hold 3.2 mm BB at the center surrounded by MRI signal generating gel.

STEEV contains a rectangular cavity positioned inside of the brain and parallel to the clinically relevant Frankfort Plane (FP). When aligned with lasers, the FP matches with the axial plane inside the gantry.

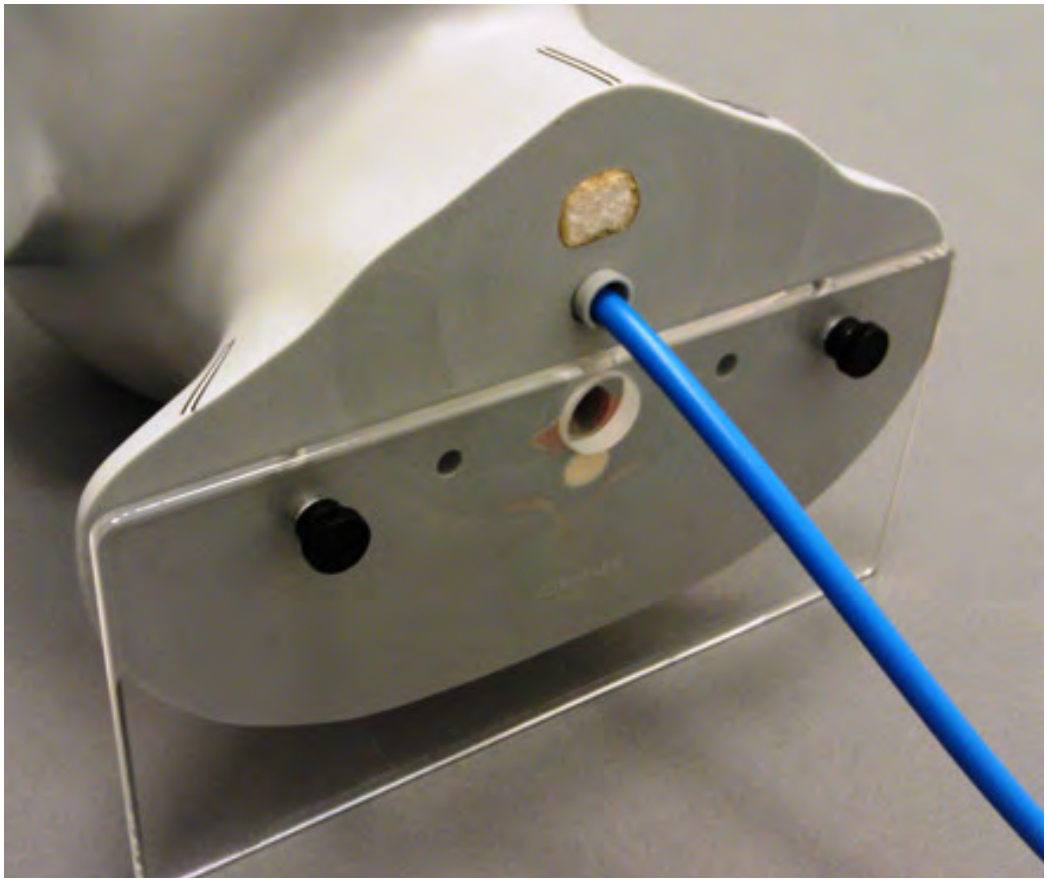
Setup Configuration

STEEV's anthropomorphic exterior allows for intuitive positioning with any frame, mask, or frameless fixation device used in SRS. Removable skull vertex allows for the phantom to remain positioned on the treatment couch while interchanging inserts.



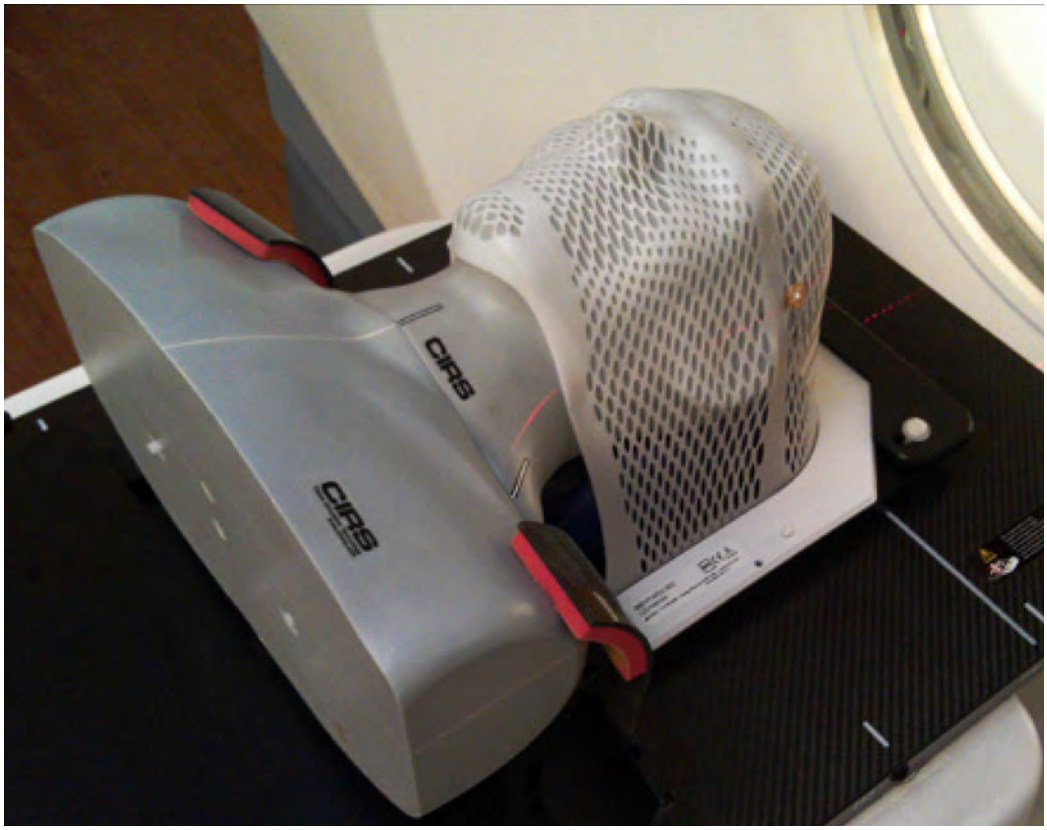
Neck Alignment Plate

The Neck Alignment Plate comes standard with the phantom and allows for phantom positioning and alignment with the lasers, on a hard couch top. It is attached to the neck with two nylon thumb screws.



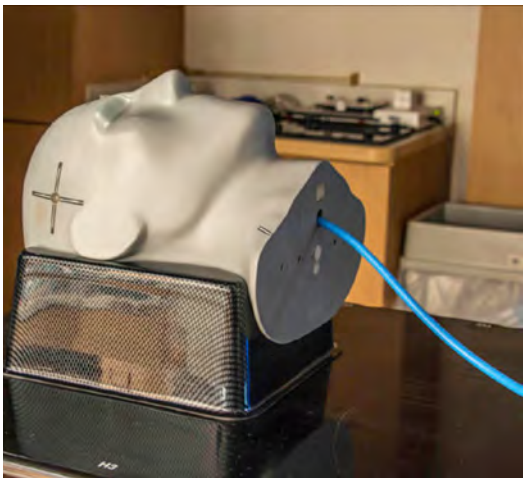
Shoulders

The optional Shoulders are made of homogeneous, soft-tissue-equivalent material. They are anthropomorphic and contain external anatomical landmarks such as clavicles. The shoulders allow use of different fixation devices including shoulder masks and shoulder brackets. Shoulders are attached to the neck using nylon threaded rods and nuts and have two cylindrical holes that match with the holes in the neck for the ion chamber access.



Positioning Cradle

The optional Positioning Cradle allows for phantom position and storage. Additional alignment shims might be required for proper head alignment with the equipment lasers. The positioning cradle allows users to gain access to the brain cavity to interchange inserts without compromising phantom set-up.



Your phantom is manufactured from epoxy resin. Various other chemicals and fillers have been added to the resin using proprietary CIRS tissue simulation technology. See appendix for simulation data. As with most other epoxy plastics, your phantom may discolor slightly over time. This process can be accelerated by direct exposure to sunlight or extreme temperatures. It is recommended that when not in use, the phantom be stored in a dark, fully climatized storage area. Epoxy is quite durable, but can still be damaged if it is dropped on a hard surface so handle with care! Most phantoms can be easily repaired. If damaged, contact CIRS. It is recommended that the phantom only be cleaned with mild detergent and water. Avoid solvent based or abrasive cleaning agents.

Note: Two rubber bands are included with the phantom's accessories. They can be used to prevent the top cap of the head from falling off when the phantom is not in its storage case like in the image shown to the right.

Engineers and physicists at CIRS are available to answer specific questions regarding the materials, design and technical specifications of the phantom. Specific questions regarding quality assurance protocols should be directed toward the appropriate equipment manufacturers and experts in the field.

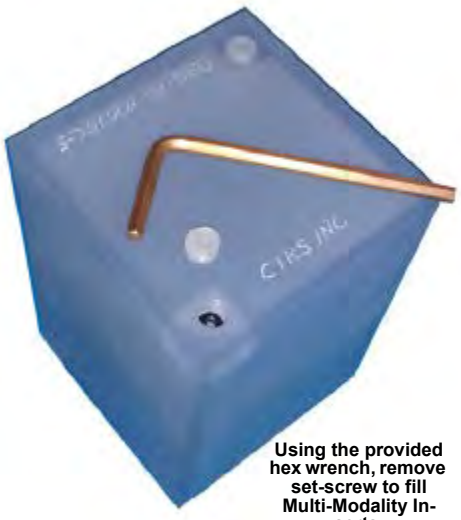
Interchanging Inserts

The phantom cavity can be opened and inserts can be interchanged in the vertical position or on the treatment couch. Use the provided suction cups to open the phantom cavity and remove interchangeable inserts. Use both hands to avoid dropping and damaging the phantom.

- Clean the suction cup and phantom surface of dust and debris.
- Place the suction cup toward the back of the removable skull vertex and pull up slowly.
- Once skull portion has been removed, use the suction cup to remove insert. If the insert is too tight to remove with the suction cup alone, use the tissue-equivalent rod to gently push from the neck side.
- TO MINIMIZE AIR GAPS, TOLERANCES BETWEEN INSERTS AND PHANTOM ARE INTENTIONALLY TIGHT. TO MAINTAIN PRECISE FIT, IT IS RECOMMENDED THAT USERS STORE PHANTOM AND INSERTS IN THE SAME AMBIENT ROOM TEMPERATURE.

Filing and Multi-Modality Inserts

- Each Multi-Modality Insert is fillable with the user's liquid of choice. CIRS recommends distilled water and its solutions to avoid organic growth inside. Do not use alcohol or other solvents for filling or cleaning the inserts.
- If the insert contains a hollow target, this target may also be filled.
- CIRS recommends user fill the inserts using a syringe and needle no larger than 14 gauge.
- During filling process, use one filling port for a needle insertion and a second port to release air. Tilting the insert during filling may help to drain almost all residual air.
- Care must be taken during filling and draining processes to avoid damaging insert interior. Damage caused by needle insertion is not covered by warranty.



Using the provided hex wrench, remove set-screw to fill Multi-Modality Inserts.

- After filling the insert, seal with provided screws and gaskets using the 1/8" hex wrench. Do not over-tighten. Over-tightening could result with lock of the screw inside the threaded.

4 Support and Maintenance

Handling and Care

For best results the phantom should be kept clean at all times and stored at room temperature. Phantom can be cleaned with mild soap and water. Avoid solvent based or abrasive cleaning agents.

Repair

Model 038 and the parts provided with the Model 038 cannot be repaired by the user. If there are problems with any of the devices, contact Sun Nuclear Support.

Contacting Sun Nuclear Support

You can 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, Option 3
  - Netherlands: +31 20 399 90 41, Option 1
  - Germany: +49 61 02 50 49 500, Option 2

Support Website

1. Open an internet browser and navigate to www.sunnuclear.com/support.
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

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
Model 038 - STEEV Stereotactic End-to-End Verification Phantom Patient	60 Months
Inserts 038-11, 038-12, 038-13, 038-14, 038-15 and MRI/CT Fiducials	12 Months

Appendix A: Regulatory Supplement

Symbols

The following symbols are used in this guide and in our product labels.

WARNING: This symbol indicates a risk of electric shock. (EN ISO 7010, W012)

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

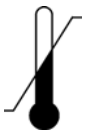
CAUTION: This symbol indicates a potential hazard that could result in minor injury or equipment damage. (EN ISO 15223-1, 5.4.4)

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)

This symbol indicates a general mandatory action. (EN ISO 7010, M001)

Fragile. Handle with care (EN ISO 15223-1, 5.3.1)

Operator Responsibility

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

Reporting Health or Safety Related Issues or Concerns

Should the need arise to report any safety or health related issues or concerns regarding the use of Sun Nuclear products, contact Sun Nuclear directly.

CIRS
900 Asbury Ave
Norfolk, VA 23513
Phone +(757) 855-2765

Modifications to Equipment

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

+1 321 259 6862 // **sunnuclear.com**
Sun Nuclear Corporation, 3275 Suntree Boulevard, Melbourne, FL 32940 USA

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