Phantom Patient for Stereotactic End-to-End Verification





MACHINE QA • PATIENT QA • ALIGNMENT QA



Phantom Capabilities

Perform End-to-End testing for commissioning as directed by AAPM TG-101

Verify patient positioning using frame/frameless systems, head and shoulder masks or other positioning fixation devices

Verify patient treatment plan in critical regions

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 multimodality imaging capabilities (CT, MRI, and PET)

Confirm TPS deformable image registration algorithm accuracy



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, verifying patient-specific treatment plans, or performing daily radiation alignment systems checks, intense attention to detail is required. The Stereotactic End-to-End Verification Phantom "STEEV", CIRS Model 038, is the only phantom that provides a means to perform machine, patient and radiation alignment QA with system checks as challenging as a real patient.

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.

"...cumulative system accuracy for the procedure can be significant and needs to be characterized through an end-to-end test using phantoms with measurement detectors and imaging"

AAPM TG-101 report Stereotactic Body Radiation Therapy

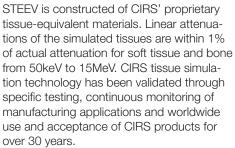


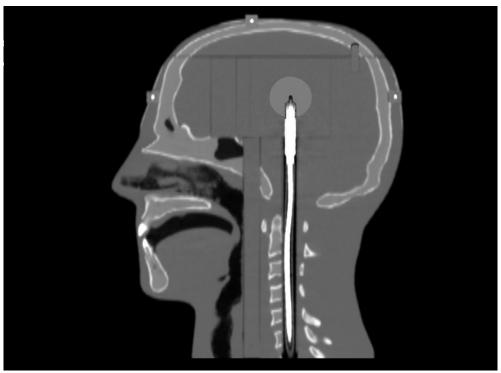
Computerized Imaging Reference Systems, Inc is recognized world wide for tissue simulation technology and is the leader in the manufacture of phantoms and simulators for medical imaging and radiotherapy.

www.cirsinc.com

Proven Tissue-Equivalent Technology







Linear Attenuation Coefficients To Reference Tissues (1) (2)							
	Trabecular Bone	Soft Tissue	Brain	Spinal Cord	Cortical Bone		
En, MeV	Ratio, %	Ratio, %	Ratio, %	Ratio, %	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

Verify TPS corrections for heterogeneities

Intuitive patient positioning means no special set-up required

Measure dose at high-dose gradient areas and within critical structures

Compatible with any framebased, 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

High-Fidelity Simulation

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.



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 while interchanging inserts.

Intuitive Setup

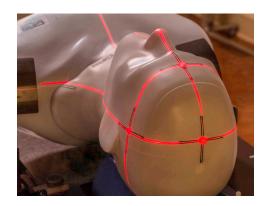
ALIGNMENT

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

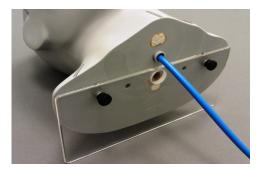
STEEV's anthropomorphic exterior allows for use of multiple positioning and fixation devices as used in clinical applications, including intuitive patient positioning with stereotactic frames, frameless systems, and head and neck masks. STEEV does not require any additional mechanical interfaces between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

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 shoulderes 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 three essential QA applications for SRS systems: End-to-end machine QA, patient QA and radiation alignment QA. In order to facilitate required system checks for each of these applications, STEEV accommodates twelve interchangeable inserts. Cubic brain equivalent inserts enable measurement of

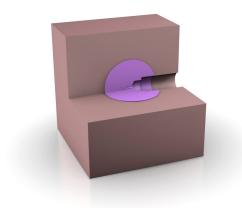
dose delivered at ISO center and off-ISO center positions using micro- and pinpoint ion chambers, film, MOSFET, TLD, OSL (nanoDOT) and 3D gel. When used in concert with the various imaging inserts for CT, MRI and PET, STEEV provides the most comprehensive endto-end testing and QA solution for SRS systems.

ION CHAMBER TARGET DOSIMETRY KIT

MODEL 038-03-CVXX-XX*

The Ion Chamber Dosimetry Kit includes a brain-equivalent cube containing a tissueequivalent, 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.



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.

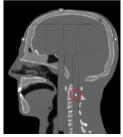
*When ordering, specifiy cavity code. For complete list of ion chamber cavity codes, please refer to www.cirsinc.com/support.

VARIABLE POSITION ION CHAMBER DOSIMETRY KIT

MODEL 038-04-CVXX-XX*

Kit allows for measurements at variable locations in the brain and neck. Incremental SI positioning is achieved by stacking brainequivalent cylindrical spacers in either parallel neck channel. Channels are spaced 30mm apart in the AP direction for axis and off-axis measurements. Their locations provide the capability to measure dose within critical structures of the spinal cord and at highdose gradient regions between the spine and trachea. Spacers and two tissue-equivalent sleeves minimize air gaps around the ion chamber and stem for measurements outside the brain. An additional tissue-equivalent plug with a ceramic BB at ISO center allows for chamber localization during treatment planning.

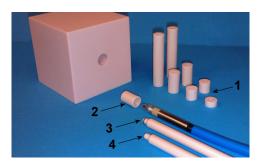






- · Incremental ion chamber positioning through trachea and spinal cord
- · Accomodates small-volume ion chambers
- May be used with 038-03 for simul taneous dose measurements within brain and neck

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



Included with 038-04-CVXX-xx:

- 1. Spacer Plugs, 2. Drilled cavity spacer,
- 3. Cavity plug with BB, 4. Solid Cavity plug.

Interchangeable Inserts

GEL CASSETTE INSERT

MODEL 605-GC



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

The Gel Cassette Insert comprises a brainequivalent cube that receives a disposable gel container (CIRS Model B6) desiged for small volume dose distributions. The container is approximately 5cm diameter x 5cm long.

ELECTRON DENSITY CUBE WITH REMOVABLE VIAL

MODEL 038-09



Features:

- Perform CT number to electron density 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 Ø5MM 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.

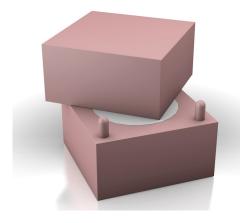
SINGLE FILM TARGET DOSIMETRY INSERT

MODEL 038-05

The brain-equivalent cubic insert includes a 30 mm diameter spherical target with +5% contrast. It receives a single piece of radio-chromic film through the center plane of the

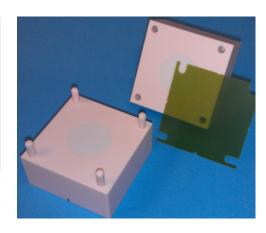
sphere. The film can be positioned in the axial, sagittal or coronal orientation and allows for the presence of a target volume through all stages of the treatment process. The cube is

assembled using four pinholes with an offset arrangement that allows for consistent assembly and film orientation. External marks on both halves make it easy to align and close.



Features:

- Ø30 mm Spherical target with +5% contrast
- Receives a single film through center plane
- Orient film in axial, sagittal or cornal planes



FILM STACK DOSIMETRY INSERT

MODEL 605-FC

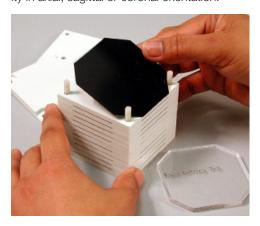
The Film Stack Insert is a brain-equivalent cube for use in small-volume dose mapping with film. The Film stack accommodates 13

layers of radiochromic film with 4mm thick brain-equivalent spacers in between each film. Film edges may be scored to enables x, y, and z orientation when viewing films. The film stack may be placed within the brain cavity in axial, sagittal or coronal orientation.



Features:

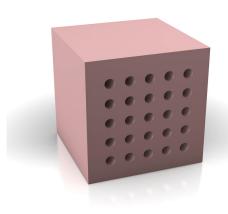
- Provides small volume dose mapping in axial, sagittal and coronal planes
- Accomodates 13 films with 4 mm spacing
- Designed to allow x,y, and z orientation when viewing individual films



TLD DOSIMETRY INSERT

MODEL 038-06

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

Features:

- · Provides 2D or 3D dose verification
- Receives TLD chips, rods, bars cubes and disks
- Ø5 mm through holes ina 1cm x 1cm grid pattern

with TLDs. 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 avialable separately.

Interchangeable Inserts

MRI/PET/CT SPHERICAL TARGET INSERT

MODEL 038-11

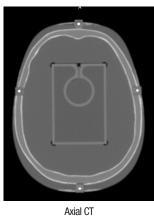
The insert facilitates multi-modality image reconstruction tests. Its 30 mm diameter spherical tumor volume allows for assessment of image and reconstruction integrity when images are moved among different imaging systems. This insert is designed to work together with the "matching target" in the lon 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.

Features:

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









Axial MRI TSE-T1

Axial MRI TSE-T2

MRI/PET/CT ORGANIC TARGET INSERTS

MODEL 038-12 & 038-13

Two MRI/PET/CT Organic Target Inserts are available for experimental testing of TPS deformable registration algorithms. Each insert contains an organically shaped target within a rectangular insert. The organically shaped



target volumes and rectangular volumes can be filled individually through separate fill ports using MRI or PET compatible liquids. The Model 038-12 contains an organic shaped target of 25cc internal volume. The Model 038-13 contains the same organic target shape isotropically reduced to a 12.5cc internal volume. Both targets contain the same central position relative to the phantom's external MRI/ CT fiducials.



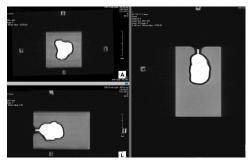
25cc Organic Target C



12.5cc Organic Target C

Features:

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

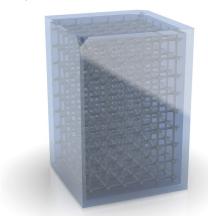


12.5 cc- MRI TSE T1 Organic Target

MRI/PET/CT SPATIAL 3D DISTORTION INSERT

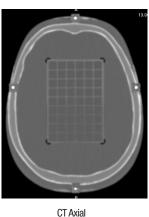
MODEL 038-14

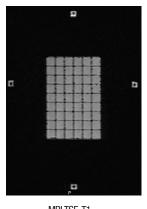
The MRI/PET/CT Spatial 3D Distortion insert contains a 3D grid (10 mm x 10 mm spacing) of Ø 1 mm high contrast wire (~600HU). It can be filled with MRI or PET compatible liquids. Grid is aligned with MRI/CT fiducials. It provides a single, precise tool to check image fusion and image distortion across multiple modalities.

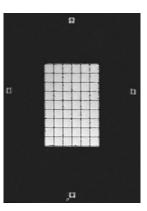


Features:

- Ø30 mm spherical tumor internal volume
- · Can be used in tandem with lon Chamber Target Dosimetry Kit







MRITSE-T1

MRITSE-T2

MRI/PET/CT ISO CENTER INSERT

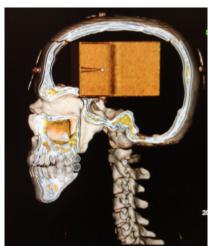
MODEL 038-15

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 fusion functions of treatment planning systems.

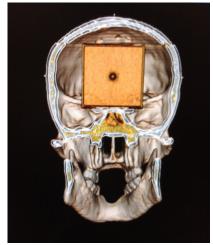
Features:

- 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









CT Coronal Recon.

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), one MRI/CT Iso Center Insert
- · Neck alignment plate
- · Foam-lined carry case
- · User guide and warranty.



Optional Insert Configurations

SRS MACHINE QA

- · Ion Chamber Target Dosimetry Kit
- · Single Film Target Dosimetry Insert
- MRI/PET/CT Spherical Target Rectangular Insert
- · MRI/PET/CT Spatial 3D Distortion Insert
- MRI/PET/CT Organic Target Rectangular Inserts
- Electron Density Cube with Removable Vial

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/PET/CT 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.

PATIENT-SPECIFIC QA

- Variable Position Ion Chamber Dosimetry Kit
- · Film Stack Dosimetry Kit
- · TLD Dosimetry Kit
- · Gel Cassette Dosimetry Insert

To evaluate patient specific QA, STEEV accommodates inserts without targets so that users can validate dose delivery to unique patient 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 patient QA protocol using dosimeters they already own.

RADIATION ALIGNMENT QA

 Winston Lutz Cube with 5mm diameter Centroid and Off-Center Target

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

Model 038 Includes

PART NO.	DESCRIPTION
038	Stereotactic End-to-End Verification Phantom Patient
605-SS1	Brain Equivalent Spacer (63.4 x 63.4 x 10 mm)
605-SS2	Brain Equivalent Spacer (63.4 x 63.4 x 20 mm)
605-SS4	Brain Equivalent Spacer (63.4 x 63.4 x 63.4 mm)
038-15	MRI/CT ISO Center rectangular insert
-	Solid Ø 12.5 mm posterior chamber access plug
-	Solid Ø 12.5 mm anterior chamber access plug with MRI/CT fiducial
-	Neck Alignment Plate
-	Foam-lined case
-	User Guide
-	48 Month Warranty

Optional Accessories

PART NO.	DESCRIPTION		
038-01	Shoulders (additional 100 mm width)		
038-02	ABS Vacuum formed cradle		
038-03- CvXX-XX	Ion Chamber Dosimetry Kit: (1) 63.5 mm Cube with Ø30 mm Spherical Target Cavity, (1) Ø12.7mm Sleeve for adapting Ion cavity, ((1) Solid plug with Ø 2.5 mm aluminum oxide BB in ISO center, (1) Solid plug		
038-04- CvXX-XX	Variable Ion Chamber Position Dosimetry Kit: (1) 63.5 mm Cube with cavity thru hole, (2) \emptyset 12.5 mm Sleeves for adapting Ion cavity, (1) Solid cavity plug with \emptyset 2.5 mm aluminum oxide BB in ISO center, (1) Solid cavity plug, (1) Spacer plug set to accommodate cavity at different positions		
605-FC	Film Stack		
038-05	Film Cube for Single Film Dosimetry with Ø30 mm target		
038-06	TLD Dosimetry Cube		
605-GC	Gel Cassette (includes B6 Gel Container)		
038-09	Electron Density Cube with Real Water Electron Density plug (Water Equivalent Material Surrounding Removable Ø 1" Vial)		
038-10	Cube 63.5mm with Centroid & Offset Ø5mm targets		
038-11	MRI/CT/PET Target Cube with Ø30mm target		
038-12	MRI/CT/PET Target Cube with 25 cc Organic target		
038-13	MRI/CT/PET Target Cube with 12.5 cc Organic target		
038-14	MRI/CT/PET Spatial 3D Distortion rectangular insert		

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
2428 Almeda Avenue Suite 218,
Norfolk, Virginia, 23513 USA

PRODUCT	WARRANTY PERIOD
Model 038- STEEV Stereotactic End-to-End Verification Phantom Patient	48 Months

Model 038 Features

Tissue-equivalent within 1% actual attenuation of water and bone from 25 kV to 15 MV

11 optional Interchangeable cubic inserts

Suitable for use with MRI, CT, and PET

Optional shoulder attachments

Foam-lined Case



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