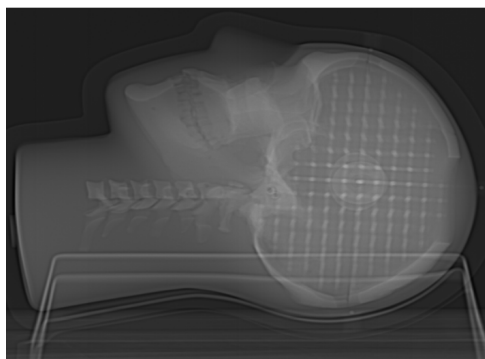


MR Distortion & Image Fusion Head Phantom

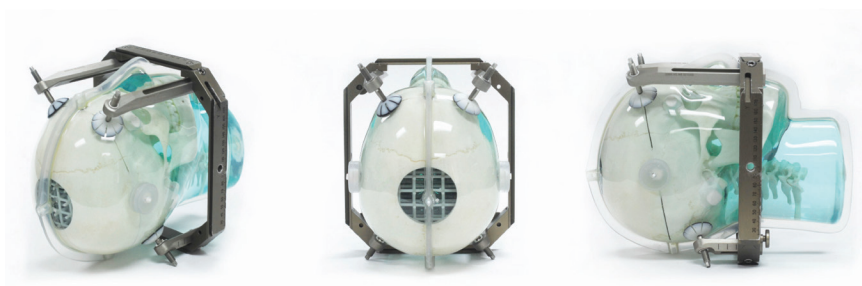
Model 603-GS



USER GUIDE

CIRS

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SPECIFICATIONS

OVERALL DIMENSIONS	32 cm x 24 cm x 18 cm
WEIGHT	12 lbs (5.5 kg)
MATERIALS	Skull: Plastic-based bone substitute Interstitial/ Soft tissues: Water-base polymer Grid: Reinforced nylon

MODEL 603-GS INCLUDES

MODEL	QTY	COMPONENT DESCRIPTION
-	1	MR Distortion & Image Fusion Head Phantom
-	1	ABS Cradle
-	-	Unlimited scans using MRI Distortion Check Software for initial 2 year period. For instructions on how to create your account, go to https://www.cirsinc.com/software/distortion-check/
-	1	Custom Carry Case
-	1	User Guide
-	-	60-Month Warranty
038-20	1	SRS Frame Support Cups (set of 4)

HANDLING PRECAUTIONS AND END OF LIFE DISPOSAL

With proper care, the Model 603-GS will withstand years of normal use. Below are some guidelines to follow:

The phantom may be cleaned with mild soap and water **ONLY**. Avoid solvent-based, alcohol-based, or abrasive cleaning agents.

For longest life, the phantom should be stored at room temperature. The phantom **SHOULD NOT** be subjected to freezing or boiling conditions such as those encountered in the trunk of a car during a South Dakota winter or Arizona summer. The most accurate measurements will be made with the phantom $22^{\circ}\text{C} \pm 1^{\circ}\text{C}$ ($70^{\circ}\text{F} - 73^{\circ}\text{F}$).

Always store the phantom in the air-tight carry case provided to maximize life expectancy.

Zerdine® will desiccate over time if the phantom is not stored properly. If there is a noticeable change in the phantom the phantom should be returned **IMMEDIATELY** for repair or replacement.

Inspect your phantom regularly for signs of damage.



This product contains Zerdine, a non-flowing water-based, poly-acrylamide material which is fully sealed within the phantom housing. Zerdine contains trace amounts of residual monomer acrylamide CAS#79-06-1. There are no known hazards when the phantom is used and stored as intended. Zerdine is fully cured and will not leak from the housing. Damage to the integrity of the housing may expose the user to Zerdine containing trace monomer acrylamide below levels necessary to cause adverse health effects. None the less, it is advised to wear protective gloves if handling exposed Zerdine gel. It is also advisable to wash hands and all surfaces with soap and water after handling exposed Zerdine gel.



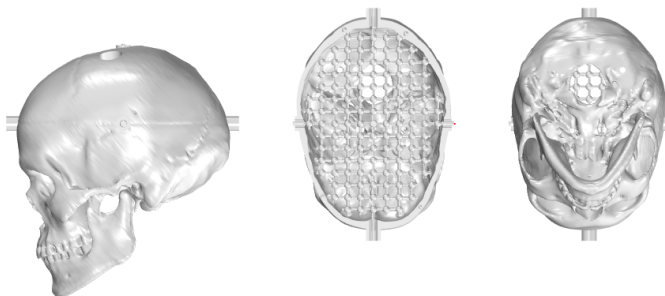
Regulations regarding disposal of materials with trace acrylamide monomer vary by locality. Contact your local authority for instructions. If assistance is desired in the proper disposal of this product, including accessories and components, after its useful life, please return to CIRS.

PHANTOM DESCRIPTION

The CIRS 3D Anthropomorphic Skull Phantom is made from materials that can be imaged using X-ray, Computed Tomography and Magnetic Resonance Imaging. It images well with all MRI sequences tested to date, including T1 weighted, T2 weighted, MPRAGE and CISS sequences. The skull is manufactured from a plastic-based trabecular bone substitute. The interstitial and surrounding soft tissues are made from a proprietary water-based polymer. The entire phantom is encased in a clear vacuum-formed plastic shell to protect the gel from desiccation.

The entire cranial portion of the skull volume is filled with a 3D grid of 2.5mm diameter cross-like shaped rods spaced 10mm (I-S), 10.5mm (AP) and 11mm (L-R). Five extended axis-rods intersect at the reference origin of the grid. The end of each extended axis is fitted with CT and MR markers allowing for accurate alignment with laser-light as well as CT/MR image co-registration.

The model 603-GS 3D grid has 859 control points. The model 603-GS is used in conjunction with CIRS MRI Distortion Check Software. The 603-GS comes with



unlimited scans using MRI Distortion Check Software for initial 2 year period. For instructions on how to create your account, go to <https://www.cirsinc.com/software/distortion-check/>. The phantom includes two 6.35 mm diameter acrylic rods with air voids of 3 mm in diameter and 17 mm long to simulate each ear canal.



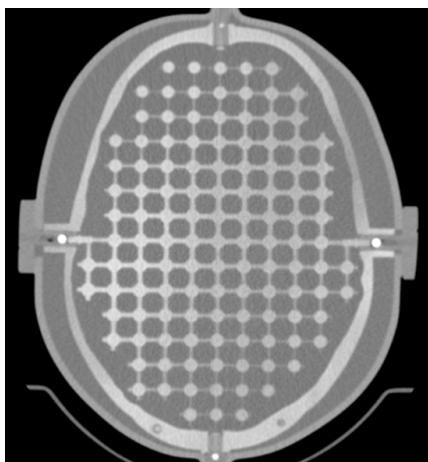
Skull in Stereotactic Frame
capital portion of the skull.

USE OF THE PHANTOM

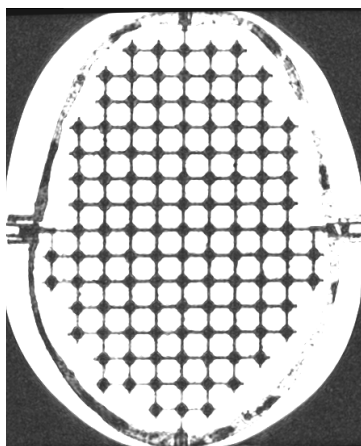
The phantom was designed for end to end testing and comes with special pads that allow it to be fixated with most stereotactic frames such as the Leksell Model G, Radionics CRW or BRW, Leibinger or BrainLab. The stereotactic frame screws should be affixed to the pads, which can be placed on the orbital ridges and oc-

Note: It is strongly recommended that the pads be used otherwise the sharp points on the frame may puncture the plastic shell and compromise the integrity of the airtight shell, which protects the gel. If the pads are too slippery once the frame is mounted, they can be glued to the phantom shell using a plastic compatible glue. For temporary adhesion, put textured tape on the shell and apply the pads to the tape. A torque of no more than 7 inch pounds is recommended for tightening the frame fixation screws.

After positioning the skull in the stereotactic frame, it can be imaged in any CT or MRI scanner. The images may be imported into DICOM software programs and analyzed as a patient file. The point and line tools in the stereotactic program can then be used to measure the (known) spacing between rod intersections. The measurement sheets in the Appendix may be useful in either on-line (MRI or CT console) or off-line (stereotactic workstation) fiducial measurements.



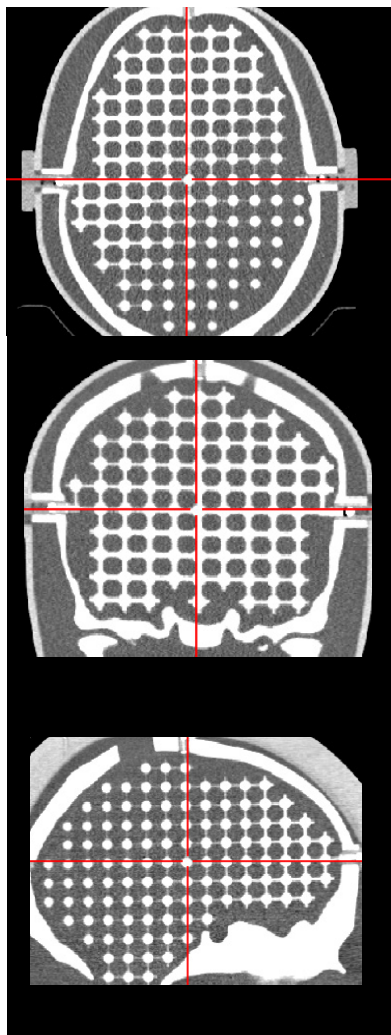
CT



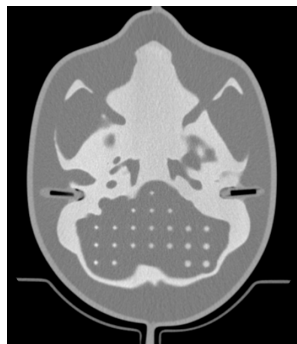
MRI

MRI scanners have the minimum amount of distortion at the isocenter of the unit, so it is best if the phantom is placed so that the center of the phantom is positioned at the isocenter for the beginning of the study. It is useful to assess image distortion in the center-most axial slice of the study (in both lateral and anterior-posterior directions) and then work up to the most superior slice and back to the most inferior slice. Typically, the image distortion will increase as the scan reaches the most superior and most inferior slices.

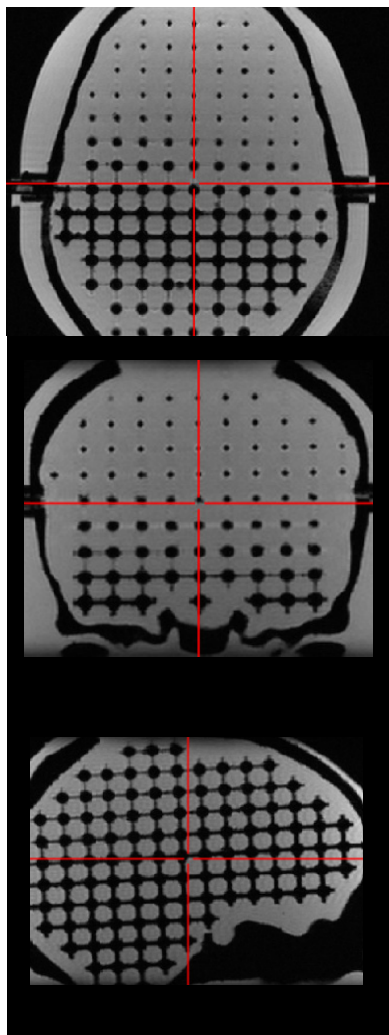
Some stereotactic imaging programs allow the user to import multiple data sets and either compare them with a common point, or to use some form of "Image Fusion" to intermingle one data set with the other. Appendix 4 provides a format for the user to take a rod intersection and compare its center point stereotactic coordinates with those of the same rod intersection in a different imaging set. The displacement of one data set relative to the other can thus be compared.



CT Reconstruction



CT showing ear canal void



MRI Reconstruction

APPENDIX 1

CIRS MRI Phantom

Data Acquisition Sheet

Scan Date: _____

CT Scanner: _____

Manufacturer: _____

Model: _____

Slice Thickness: _____

APPENDIX 2

Axial Scan Report:

Central Slice: _____ Axial Slice: _____

Lateral distance, Most Anterior rod intersections: _____

Lateral distance, Central rod intersections: _____

Lateral distance, Most Posterior rod intersections: _____

Central Slice: _____ Axial Slice: _____

Ant-Post distance, Right Most rod intersections: _____

Ant-Post distance, Central rod intersections: _____

Ant-Post distance, Left Most rod intersections: _____

Most Superior Slice: _____ Axial Slice: _____

Lateral distance, Most Anterior rod intersections: _____

Lateral distance, Central rod intersections: _____

Lateral distance, Most Posterior rod intersections: _____

Most Superior Slice: _____ Axial Slice: _____

Ant-Post distance, Right Most rod intersections: _____

Ant-Post distance, Central rod intersections: _____

Ant-Post distance, Left Most rod intersections: _____

Most Inferior Slice: _____ Axial Slice: _____

Lateral distance, Most Anterior rod intersections: _____

Lateral distance, Central rod intersections: _____

Lateral distance, Most Posterior rod intersections: _____

Most Inferior Slice: _____ Axial Slice: _____

Ant-Post distance, Right Most rod intersections: _____

Ant-Post distance, Central rod intersections: _____

Ant-Post distance, Left Most rod intersections: _____

APPENDIX 3

Coronal Scan Report:

Central Slice: _____ Ant-Post Coordinate: _____

Lateral distance, Most Anterior rod intersections: _____

Lateral distance, Central rod intersections: _____

Lateral distance, Most Posterior rod intersections: _____

Central Slice: _____ Ant-Post Coordinate: _____

Axial distance, Most Anterior rod intersections: _____

Axial distance, Central rod intersections: _____

Axial distance, Most Posterior rod intersections: _____

Most Anterior Slice: _____ Ant-Post Coordinate: _____

Lateral distance, Most Anterior rod intersections: _____

Lateral distance, Central rod intersections: _____

Lateral distance, Most Posterior rod intersections: _____

Most Posterior Slice: _____ Ant-Post Coordinate: _____

Axial distance, Most Anterior rod intersections: _____

Axial distance, Central rod intersections: _____

Axial distance, Most Posterior rod intersections: _____

APPENDIX 4

CIRS Phantom Measurement

CT vs. MRI Report Form

CT slice thickness: _____mm

MRI slice thickness: _____mm

Central Slice:

MRI Displacement:

Lateral: _____mm

Ant-Post: _____mm

Most Superior Slice:

MRI Displacement:

Lateral: _____mm

Ant-Post: _____mm

Most Inferior Slice:

MRI Displacement:

Lateral: _____mm

Ant-Post: _____mm

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 or your local distributor prior to returning the product. Visit <https://www.cirsinc.com/distributors/> to find your local distributor. 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,

PRODUCT	WARRANTY PERIOD
Model 603- GS - MR Distortion & Image Fusion Head Phantom	60 Months



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