

phantomlab

Magphan® S162 Phantom Product Guide

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WARNING

To avoid phantom damage:

- This phantom should be stored at room temperature. Do not allow this phantom to be frozen or subjected to high heat. If this phantom is frozen the housing and spheres will be damaged beyond repair.
- This phantom is not intended to be shipped from site to site. If you have to ship the phantom you must remove 40 cc of fill solution from the phantom before replacing the fill plug. If the phantom is shipped without removing fill solution, expansion of the fill solution could result in phantom damage.

To avoid fire:

- This product has an FH3-4 mm/min flame rating and is considered to be flammable. It is advised not to expose this product to open flame or high temperature (over 125° Celsius or 250° Fahrenheit) heating elements.

Disregarding these warnings will nullify the Warranty.

EMR162

15-March-2024

Medical device labeling

Manufactured by: Phantom Laboratory
2727 State Route 29
Greenwich, NY 12834 USA



EU Representative: Hoff & Lowendahl AB
Eudamed Actor ID: SE-AR-000001888
Address: Högåsvägen , 125 74141 Knivsta
Telephone number: +46 (0) 722313355
Email: info@lowendahl.eu



Product: Magphan® S162



Model: EMR162



UDI:



(01)00812266030833

Basic UDI: B-EMR162CL

Device Class: 1



This device is intended for use under direction of a trained medical physicist. Please refer to your machine manufacturer documentation and regulatory guidance for information on intended use.

A sample of this product has been assessed against the Essential Requirements of the EU Medical Device Regulation (MDR). The above mentioned product is deemed in compliance with MDR 2017/745 EU.

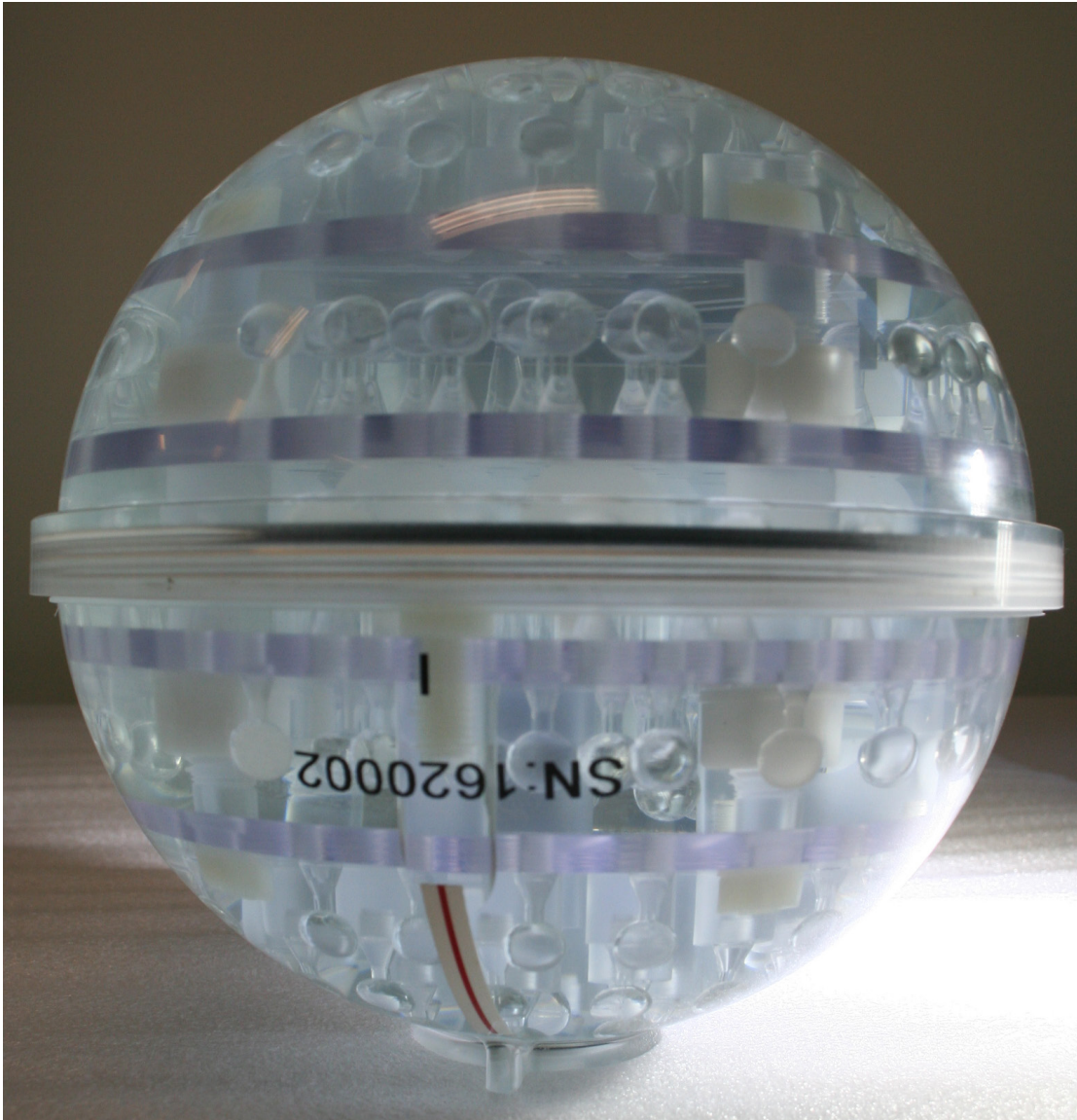
A risk assessment was conducted to the following standard: EN ISO14971
This declaration of conformity is the result of testing and evaluation performed by Phantom Laboratory.

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Magphan® S162 Phantom Manual

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Magphan® EMR162

For handling the phantom it should be positioned with the 3 pointed base down. When the phantom is scanned the round end is usually placed down sitting in the concave base of the head coil.

Introduction

Richard Mallozzi, Ph.D., led Phantom Laboratory's development of the Magphan® S162, a comprehensive MR system phantom that addresses the needs of quantitative MR imaging. It is ideal for medical physicists that use MR in their treatment planning and/or position verification for radiation therapy, surgery or modeling applications. The S162 is designed to fit in most advanced head coils; for body imaging the Magphan® RT covers a large field.

The phantom is designed to be used with the Smári analysis service. The first two years of the service are included with the phantom purchase.

We do not make specific recommendations on the content of your quality assurance program because each organization has its own unique set of requirements.

If you have any additional questions on the phantom please contact Phantom Laboratory at:

Phone: 800-525-1190 or 518-692-1190

Email: sales@phantomlab.com

Additional product and Smári service information is available at: phantomlab.com

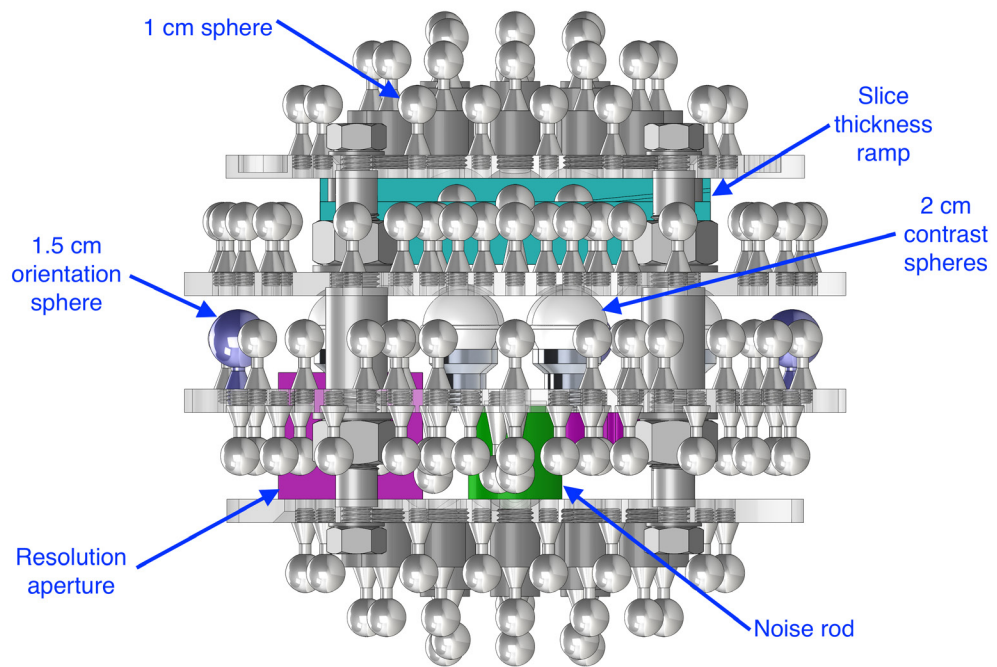
Schematic view of phantom:

Illustration of phantom test objects with housing removed

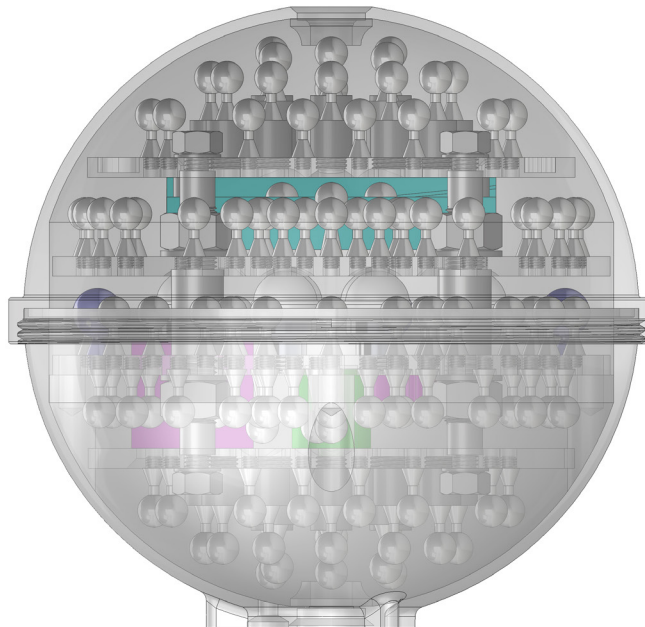


Illustration of phantom with housing

Phantom fill solution

The Magphan® S162 contains approximately 3 liters of solution.

The water based solution has the following materials:

Distilled water

1.6 [g/l] Potassium Sorbate (prevents bacterial growth, used in beer and milk)

0.68 [g/l] Copper Sulfate

9.0 [g/l] Sodium Chloride

25.0 [g/l] PVP

Safety Data Sheet (SDS) links

The fill solutions in this phantom are made by dissolving powders into distilled water. The SDS sheets for the materials that were used at the time this product guide was assembled are available from their respective suppliers:

Copper (II) Sulfate Pentahydrate, 99%

<https://www.alfa.com/en/content/msds/USA/A11262.pdf>

Potassium Sorbate, 99%

<https://www.alfa.com/en/content/msds/USA/A12844.pdf>

Manganese(II) Chloride Tetrahydrate

<https://www.sigmaaldrich.com/MSDS/MSDS/DisplayMSDSPage.do?country=US&language=en&productNumber=221279&brand=SIGALD&PageToGoToURL=https%3A%2F%2Fwww.sigmaaldrich.com%2Fcatalog%2Fsearch%3Fterm%3D221279%26interface%3DAll%26N%3D0%26mode%3Dmatch%2520partialmax%26lang%3Den%26region%3DUS%26focus%3Dproduct>

PVP (Polyvinylprrolidone)

<https://www.sigmaaldrich.com/MSDS/MSDS/DisplayMSDSPage.do?country=US&language=en&productNumber=PVP40&brand=SIAL&PageToGoToURL=https%3A%2F%2Fwww.sigmaaldrich.com%2Fcatalog%2Fproduct%2Fsial%2Fpvp40%3Flang%3Den>

Sodium Chloride

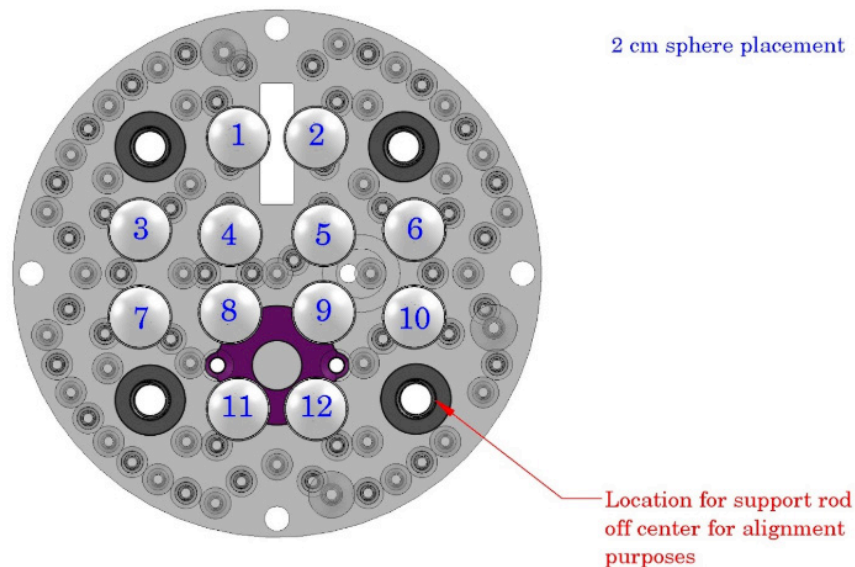
<https://www.sigmaaldrich.com/MSDS/MSDS/DisplayMSDSPage.do?country=US&language=en&productNumber=S7653&brand=SIAL&PageToGoToURL=https%3A%2F%2Fwww.sigmaaldrich.com%2Fcatalog%2Fsearch%3Fterm%3DSodium%2Bchloride%26interface%3DProduct%2520Name%26N%3D0%2B%26mode%3Dmode%2520matchpartialmax%26lang%3Den%26region%3DUS%26focus%3DproductN%3D0%2520220003048%2520219853286%2520219853269>

Please note that the Manganese Chloride is only used in the contrast solutions used in the 2 cm spheres.

Contrast solutions

The Magphan® S162 contains 12 contrast spheres with a 2 cm diameter. The “Sphere Location Number” in the chart below refers to the locations in the phantom shown in the following sketch. These solutions are being characterized; the target information may be updated in the future. The target numbers are for a field strength of 1.5T.

Sphere Location Number	T1 Target [ms]	T2 Target [ms]	ADC target [1000mm ² /s]	CuSO4 5H20 Concentration [g/L]	MnCl2 4H20 Concentration [g/L]	PVP Mass Pct. Concentration [% by weight]
1	220	22	2.50	0.044	0.12	0
12	265	29	2.50	0.12	0.093	0
7	320	38	2.50	0.15	0.070	0
6	385	49	2.50	0.15	0.053	0
3	464	111	1.00	0.041	0.015	39
2	560	65	2.50	0.029	0.041	0
11	675	85	2.50	0.036	0.030	0
5	813	146	2.00	0.048	0.013	7
8	981	191	2.50	0.080	0.012	0
9	1182	675	1.50	0.022	0.0009	17
10	265	111	0.75	0.44	0.012	61
4	2350	2000	2.50	0.00	0.00	0



Unpacking and topping off the phantom

The Magphan® S162 is shipped in a maple storage case. As soon as the phantom is received it should be placed in a room temperature location. Inspect the interior of the plastic bag containing the phantom and the aluminum foil it is wrapped in to make sure there was not any leakage during the shipment. If there is liquid in the bag, contact Phantom Laboratory at info@phantomlab.com or 518-692-1190. The aluminum foil and plastic bag may be discarded. The foil is used to reduce heating and cooling impacts when the phantom is shipped.

The phantom is purposely shipped with approximately 40 ml of fill solution removed. A bottle with fill solution is located in the phantom case. Position the phantom with the 3 pointed base on top. Remove the smaller screw plug and top off the phantom with the extra fill solution provided. Then insert the flat head screw plug and o-ring to seal the phantom.



If additional air appears, the phantom may need to be topped off again. However, if the phantom leaks fluid, contact Phantom Laboratory. Once the phantom is filled you are ready to scan. The remaining refill fluid should be saved to top-off the phantom in the future if air bubbles should develop.

Phantom test components

The phantom consists of a uniform background fill with solid test components that appear dark in MR images. Below is a list of test components in the phantom:

Fiducial spheres for distortion measurement

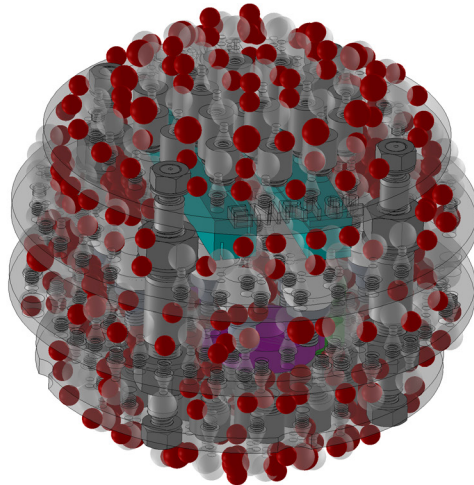
Two slice thickness ramp pairs -- for measurement of axial, and coronal slices (sagittal with rotation)

Two resolution apertures for measuring the Point Spread Function (PSF) / Edge Spread Function (ESF) -- for measurements in axial, and coronal slices (sagittal with rotation)

One noise rod for measuring noise

Twelve contrast solution spheres for T1 and T2 measurements

Identified virtual uniformity spheres within background region



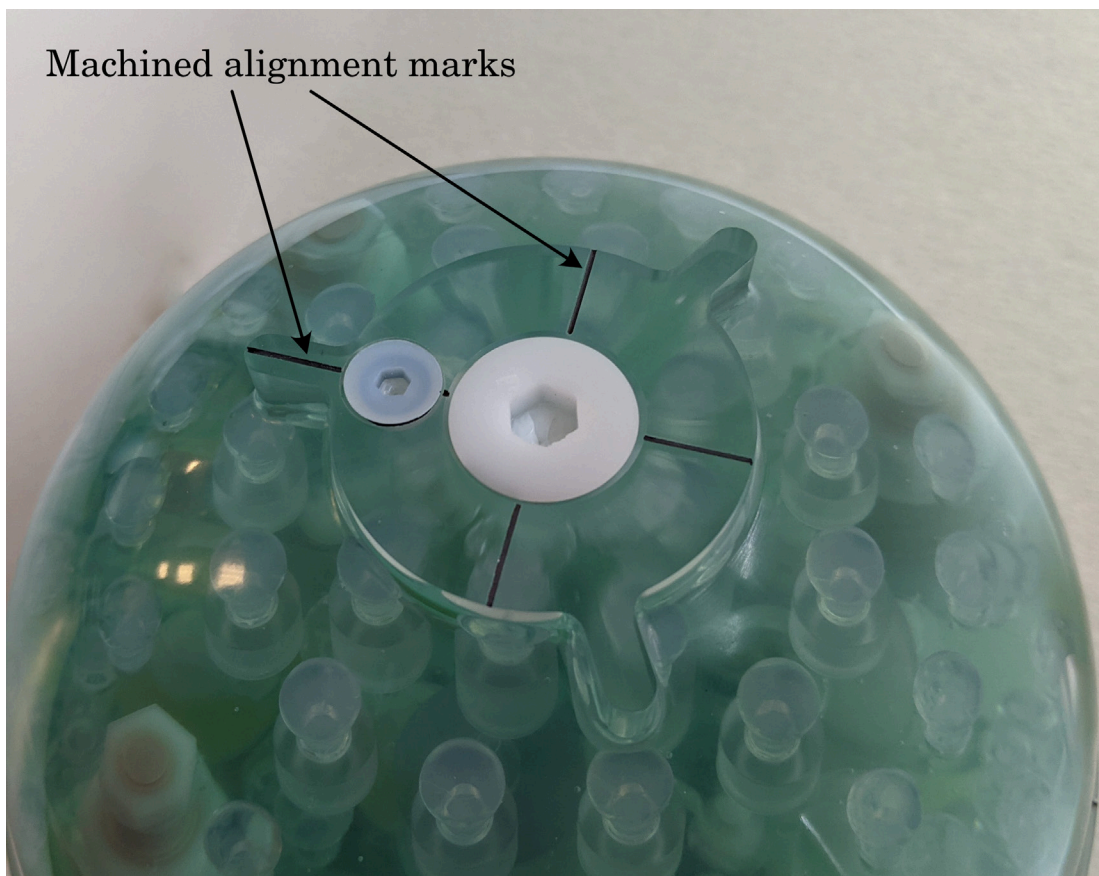
Red spheres in photo above indicate virtual spherical regions in fill solution that are used for uniformity measurements

Positioning the phantom

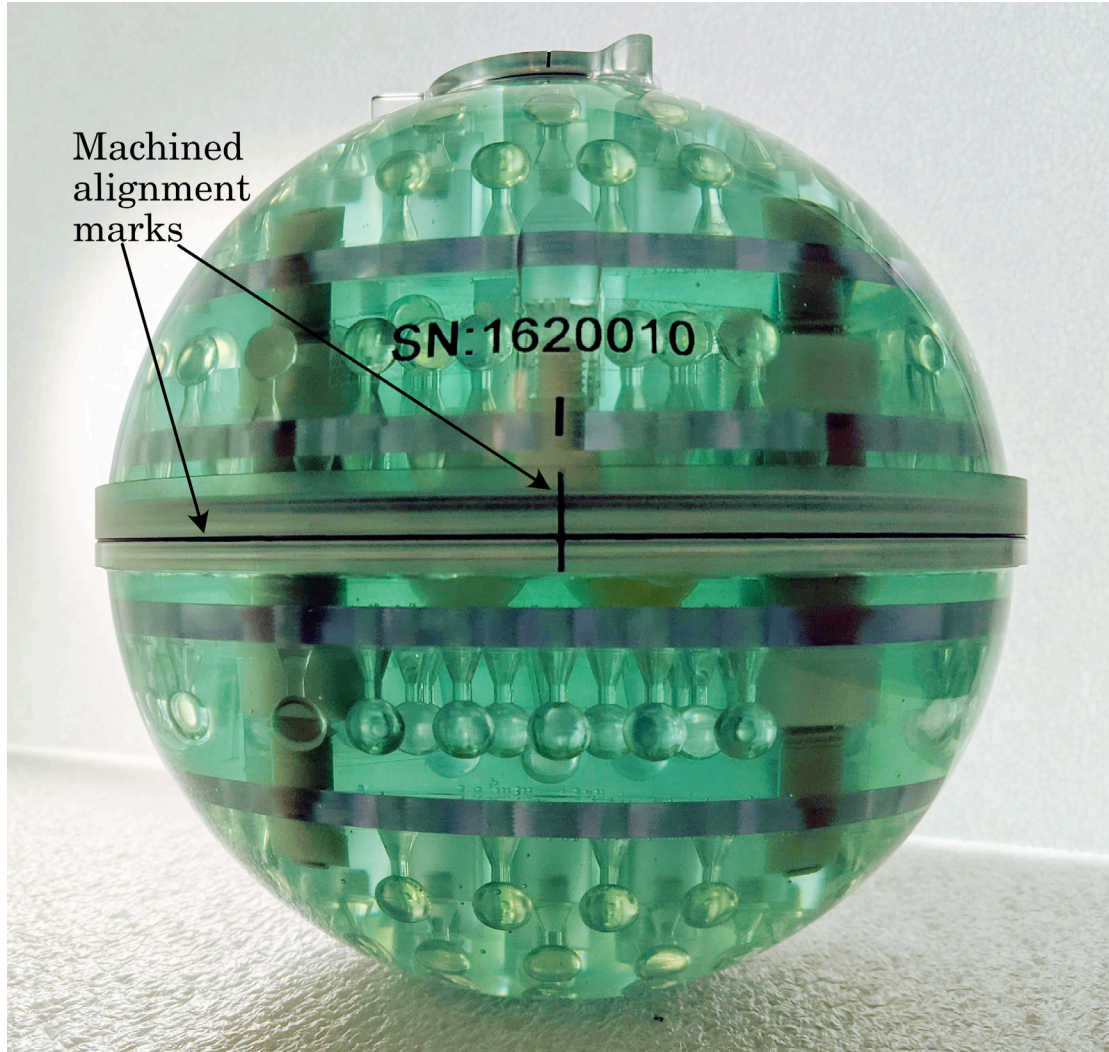
The phantom is marked with alignment lines and Superior, Inferior, Right, Left (S, I, R, L) labels to assist in orienting the phantom so the resolution and slice thickness tests are aligned with the axial and coronal planes.

The phantom should be scanned in its entirety with contiguous slices. The distortion and signal-to-noise analysis will run with the phantom placed in any orientation or location within the field of view. Distortion measurements, however, will only be performed in the region encompassed by the sphere fiducials within the phantom.

The phantom placement analysis will also be performed regardless of orientation and location, but to be useful for testing the laser alignment system, the phantom must be positioned and oriented within the scanner using the alignment lights, so that the phantom is scanned at the isocenter of the MRI system.



Precise marks are machined into the phantom top (scanning position) and center ring. By aligning these marks with the alignment lights, the phantom can be precisely oriented in the scanner. As a check of the alignment lights the Smári report will provide information regarding the phantom's alignment within the MR scanner.



By raising phantom (typically done by placing padding under the phantom), the machined marks on the center ring can be aligned with the height laser line.

The slice thickness and resolution measurements require that the scan plane be aligned with their corresponding measurement features. Hence, the phantom must be aligned properly within two degrees of the intended scan plane in order for these analyses to be performed. There are two slice thickness features and two resolution features, oriented such that axial and coronal scan planes each have a feature designed to perform the corresponding measurements. If it is desired to perform resolution and slice thickness measurements on a sagittal scan, then the phantom can be rotated by 90 degrees so that the S/I and R/L axes are switched, and the features normally used to measure axial slice orientations now line up with the sagittal scan plane.

Scanning the phantom

The phantom is designed to support a wide range of scanning protocols, and is meant to provide information on the specific protocols being used clinically, rather than a predefined set of test protocols. For the analysis to function properly some prerequisites need to be met. The Signal-to-Noise ratio must be sufficiently high for the slice thickness and resolution measurements to process (approximately 20:1 or higher for mean/standard deviation). This requirement is assessed automatically during the Smári analysis processing. The images must also have relatively low artifacts.

Most conventional MR images meet these requirements, but some advanced sequences such as Echo Planar Imaging can have high sensitivity to magnetic field inhomogeneities that can introduce strong artifacts into the images. Artifacts have potential to render the analysis unable to properly locate the phantom features within the images. If artifacts appear to be a problem, possible recourses are to consult an MRI physicist or the manufacturer of the equipment to understand if the artifacts are expected from the particular set of acquisition parameters, or if there is a service issue that needs to be addressed.

Analyzing the phantom images with the Smári service

After the phantom is scanned, log into your Smári account and upload the DICOM images. A report will be automatically generated.

To get set up with an account go to the Smári page on the phantomlab.com site.

To register for the service, go to the Smári page at our website: phantomlab.com
You will need your phantom serial number to register, which is located on the phantom.

Once we receive your information, Phantom Laboratory support will contact you and set up your account.

Phone: 518-692-1190

Email: support@phantomlab.com

WARRANTY

PHANTOM LABORATORY ("Seller") warrants that this product shall remain in good working order and free of all material defects for a period of one (1) year following the date of purchase. If, prior to the expiration of the one (1) year warranty period, the product becomes defective, Buyer shall return the product to the Seller at:

By Truck

Phantom Laboratory
2727 State Route 29
Greenwich, NY 12834

By Mail

Phantom Laboratory
PO Box 511
Salem, NY 12865-0511

Seller shall, at Seller's sole option, repair or replace the defective product. The Warranty does not cover damage to the product resulting from accident or misuse.

IF THE PRODUCT IS NOT IN GOOD WORKING ORDER AS WARRANTED, THE SOLE AND EXCLUSIVE REMEDY SHALL BE REPAIR OR REPLACEMENT, AT SELLER'S OPTION. IN NO EVENT SHALL SELLER BE LIABLE FOR ANY DAMAGES IN EXCESS OF THE PURCHASE PRICE OF THE PRODUCT. THIS LIMITATION APPLIES TO DAMAGES OF ANY KIND, INCLUDING, BUT NOT LIMITED TO, DIRECT OR INDIRECT DAMAGES, LOST PROFITS, OR OTHER SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, WHETHER FOR BREACH OF CONTRACT, TORT OR OTHERWISE, OR WHETHER ARISING OUT OF THE USE OF OR INABILITY TO USE THE PRODUCT. ALL OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTY OF MERCHANT ABILITY AND FITNESS FOR PARTICULAR PURPOSE, ARE HEREBY DISCLAIMED.

