

Magphan® 100 & 170 Product Guide

Copyright © 2021

WARNING

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.

To prevent damage to your Magphan® do not let it freeze when filled with a solution. The Maphan® should always be emptied with a plug removed when shipped by air to prevent damage from low pressure.

When inserting the SMR170 tank end, follow the instructions listed in this manual. Do not use the support post screws to set in lid.

When handling MRI solutions be sure to follow safe work practices as outlined in the chemical manufacturers' material safety data sheets.

Note: Our manuals are occasionally updated. For the most recent version, please check our website: www.phantomlab.com.

SMR100
SMR170

Medical device labeling

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

EU Representative: Raförninn ehf
Suðurhíð 35
IS-105 Reykjavík ICELAND

Product: Magphan® 100 and 170

Model: SMR100

UDI: 
(01)00812266030895

Model: SMR170

UDI: 
(01)00812266030918

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 The Phantom Laboratory, Incorporated.

T h e P h a n t o m L a b o r a t o r y

Magphan® 100 and 170 Product Guide

Contents

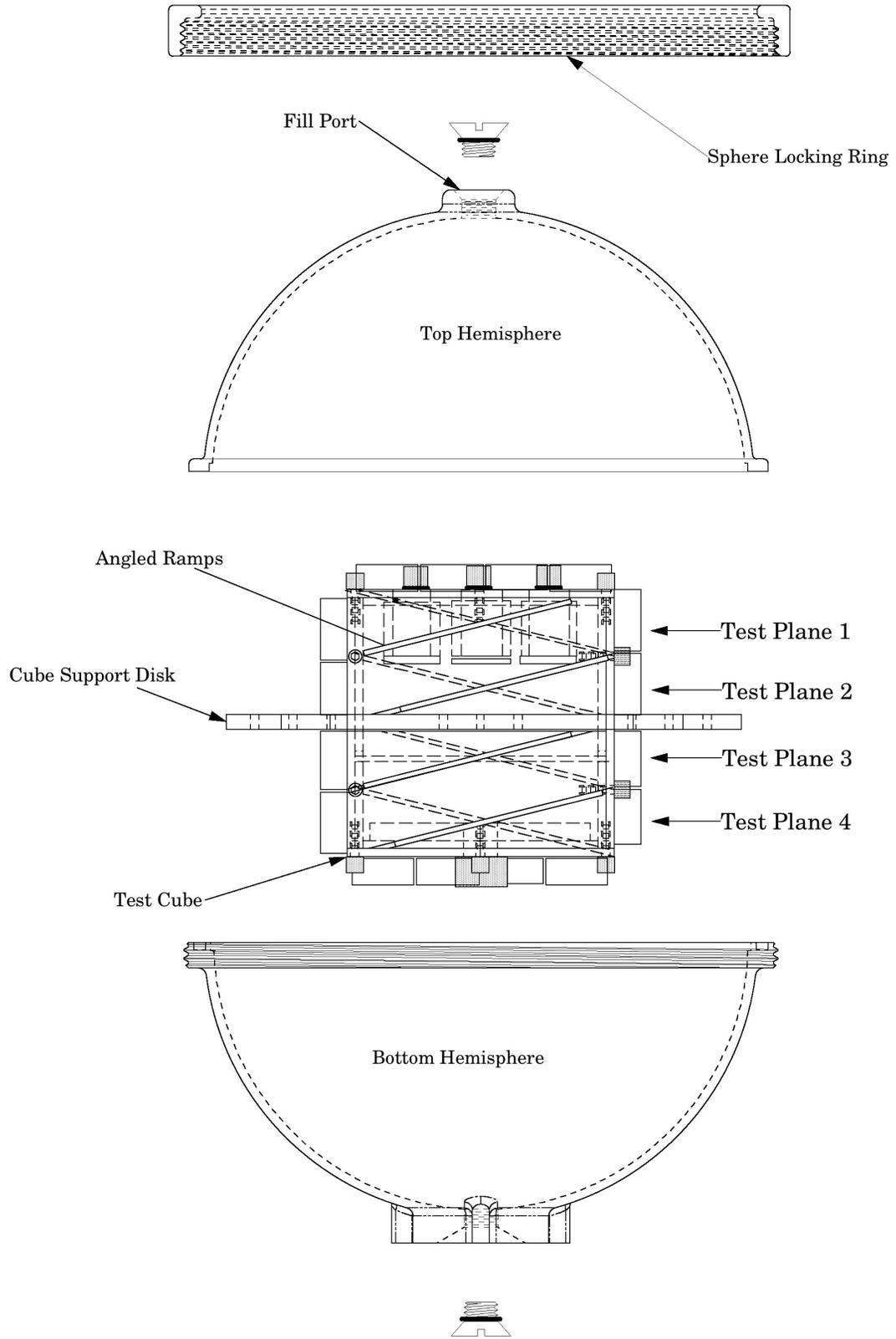
Warnings	1
Introduction	4
Exploded view of the Magphan® SMR100	5
Exploded view of the Magphan® SMR170	6
Prescan	7
Installation and Removal of the test cube in the Magphan® sphere	7
Installation and Removal of the test cube in the Magphan® cylinder	7
Test cube configurations	8
Initial Phantom Positioning of the Magphan®	9
Positioning of the Magphan® sphere	9
Positioning of the Magphan® cylinder	10
Phantom Position Verification	11
Patient Alignment System Check	12
Circular Symmetry	13
Scan Slice Geometry (Slice Width)	13
Scan Slice Selection	15
Test cube plane 1	16
Sensitometry (MRI numbers)	16
Test cube plane 2 or phantom without test cube	17
Uniformity tests	17
Test cube plane 3	18
High Resolution Gauge	18
Geometric Distortion (spatial linearity)	19
Test cube support disk	19
Test cube plane 4	20
Low Contrast Sensitivity	20
Liquid Bath Research	21
Dynamic Scanning	21
10cm Sphere	22
A Sample Quality Assurance Program	23
Bibliography	24
Warranty	25

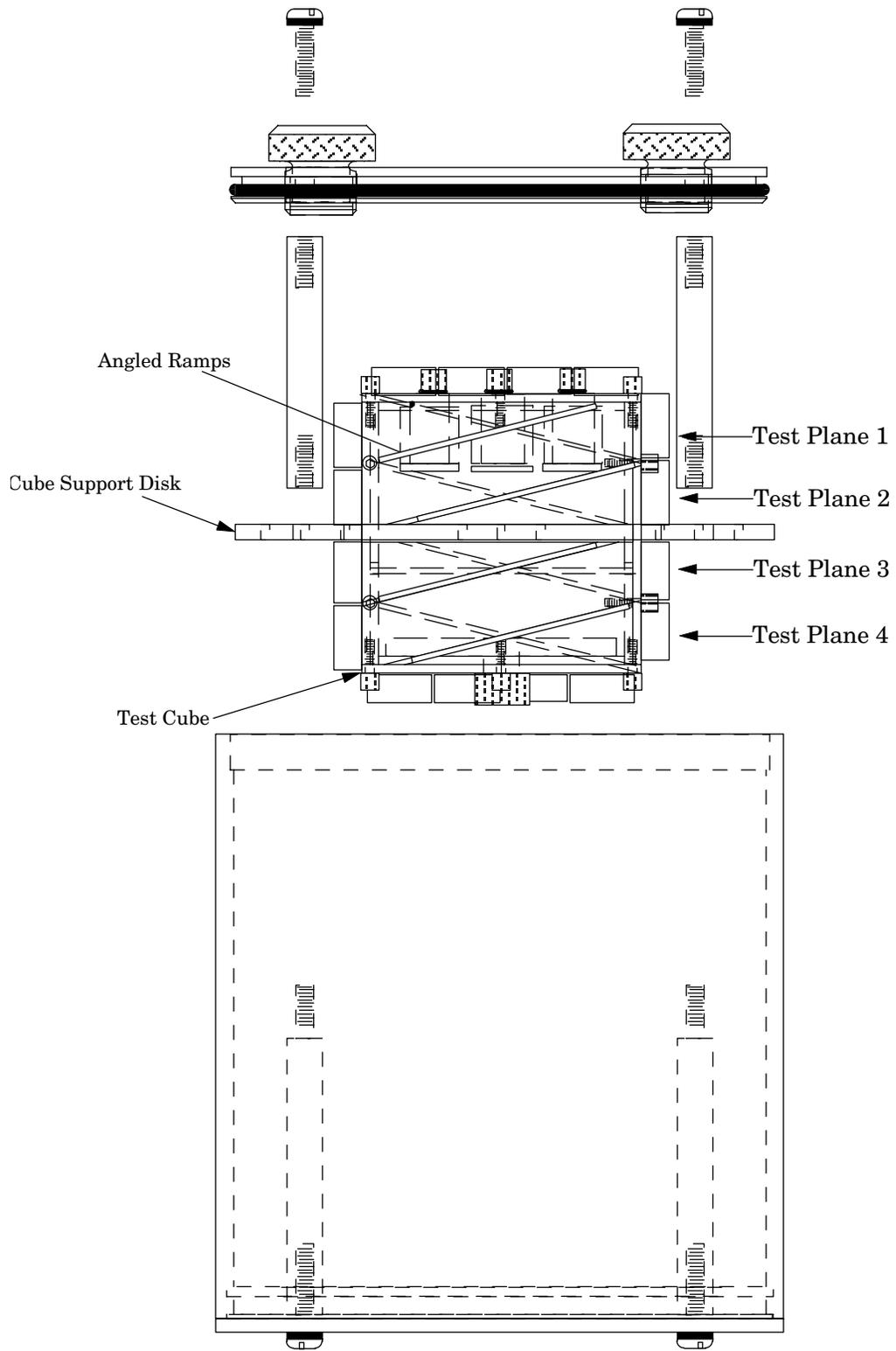
Introduction

The Phantom Laboratory and physicist, David J. Goodenough, Ph.D., are continually developing and researching new tests and modifications for the Magphan® phantoms. The test objects that make up the current Magphan® models embody more than a decade of scientific evaluation and field experience. This manual outlines the applications of each test contained in the current Magphan® phantoms.

We do not make specific recommendations on the content of your quality assurance program, because each medical imaging facility has its own unique set of requirements. A sample program is provided to give you ideas for possible program content. We suggest a review of local governing regulations, manufacturer's specifications and the needs of your radiologists and physicists before developing your MR quality assurance program.

If you have any additional questions please contact The Phantom Laboratory at:
Phone: 800-525-1190 or 518-692-1190
Fax: 518-692-3329
email: sales@phantomlab.com





Prescan

Installation and Removal of the test cube in the Magphan® sphere

Empty liquid from the Magphan® sphere by removing the 1/2" fill port at either end of the phantom. After draining the Magphan®, place the bottom end of the sphere into the 3 pointed cut out in the top of the case. Looking down on the phantom turn the locking ring counterclockwise to loosen and remove the ring. The top and bottom hemispheres can now be separated.

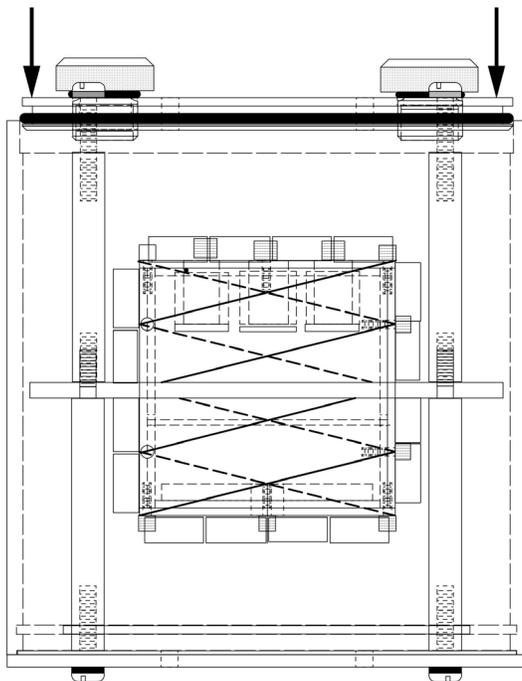
Once the top hemisphere has been removed, the test cube and two piece support disk can be lifted from the lower sphere. Note the orientation of the support disk halves in relation to the test cube and be careful not to drop the support disk halves which are fitted loosely into slots in the test cube.

To assemble, place the test cube with support disk installed so the notch of the support disk aligns with the key in the lower hemisphere. If it does not fit, check the alignment of the support disk halves with the test cube notches and each other. Align the notch in the top hemisphere with the support disk before tightening the lock ring. Apply a minimal amount of lubricating gel, such as K Y Jelly, to the flange where it contacts the lock ring and to the o-ring. This will make it easier to turn the lock ring and for the o-ring to seal, preventing leaks.

Installation and Removal of the test cube in the Magphan® cylinder

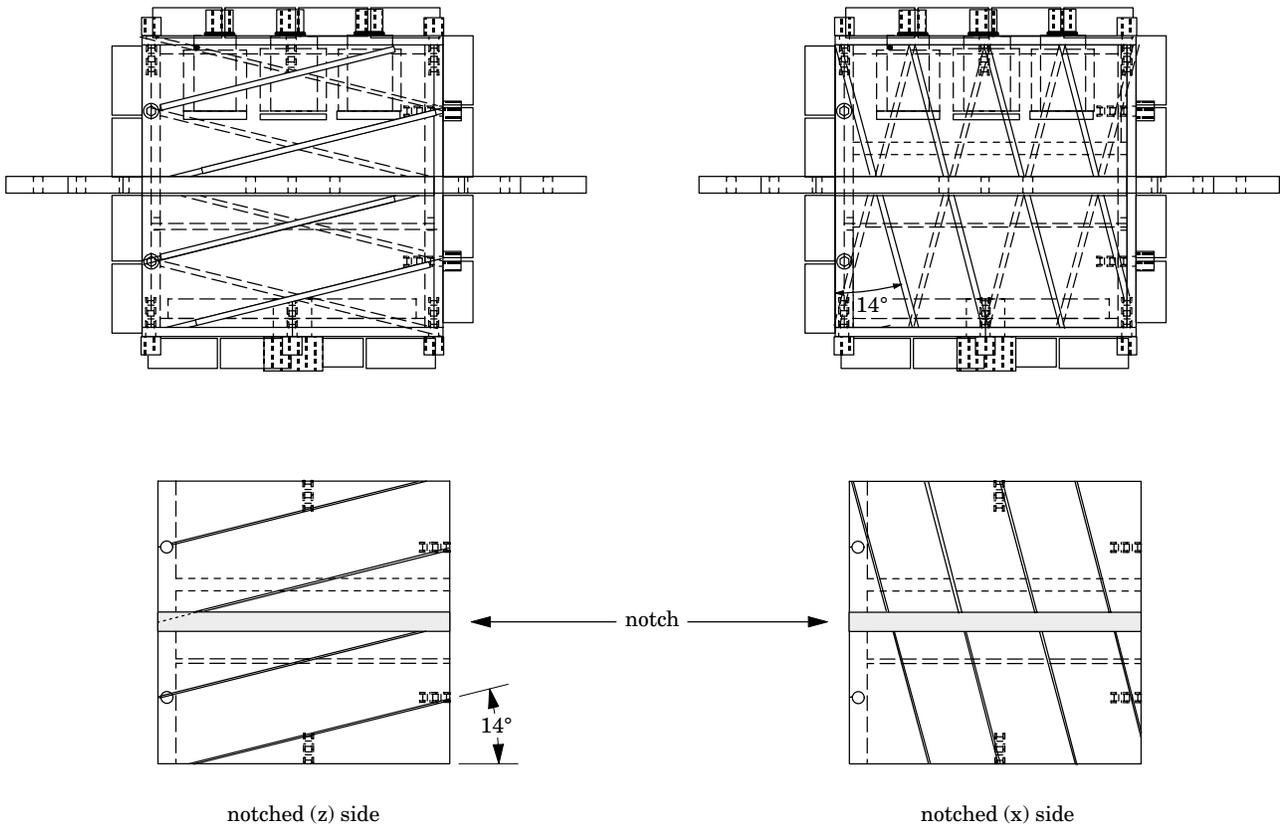
Empty liquid from the Magphan® cylinder by removing the fill ports at the end of the phantom. The cylinder end plate can be removed after draining the liquid. Remove the 4 nylon screws that go through the end plate. Hook your fingers through the plug holes in the end plate and work it out of the Magphan® cylinder. The use of a lubricating gel, such as K Y Jelly, will make it easier to open and close the o-ring seal and help to prevent leaks.

Once the end plate has been removed, unthread the 4 posts which hold the two piece support disk. The disk and cube can now be lifted from the phantom. The support disk halves are held together by the 2 retaining disks.



To install the test cube and support disk, the two pieces of the support disk need to be oriented so the wide flanges correspond to the notches in the test cube. Then attach the retaining disks. The cube and disk assembly should then be lowered onto the support posts in the phantom.

Install the upper support posts and lubricate the o-ring. Loosely place the end plate on the phantom and loosely thread the 4, 1/4-20" nylon screws into the phantom (do not tighten these screws). Evenly press the end plate with your hands into the phantom (do not use the screws). Once the end plate is seated, tighten the 4 nylon screws.



Standard test cube configuration

3-D x, y, z, measurement configuration

Test cube configurations

Your Magphan® comes equipped with an extra pair of cube sides which enables you to measure x, y, and z slice widths from a single three dimensional (3-D) data acquisition. If you would like to use these sides, remove the pair of notched (z) sides from the test cube and replace them with the pair of notched (x) sides. The 6 bolts which secure each side can be removed with the hex key wrench supplied.

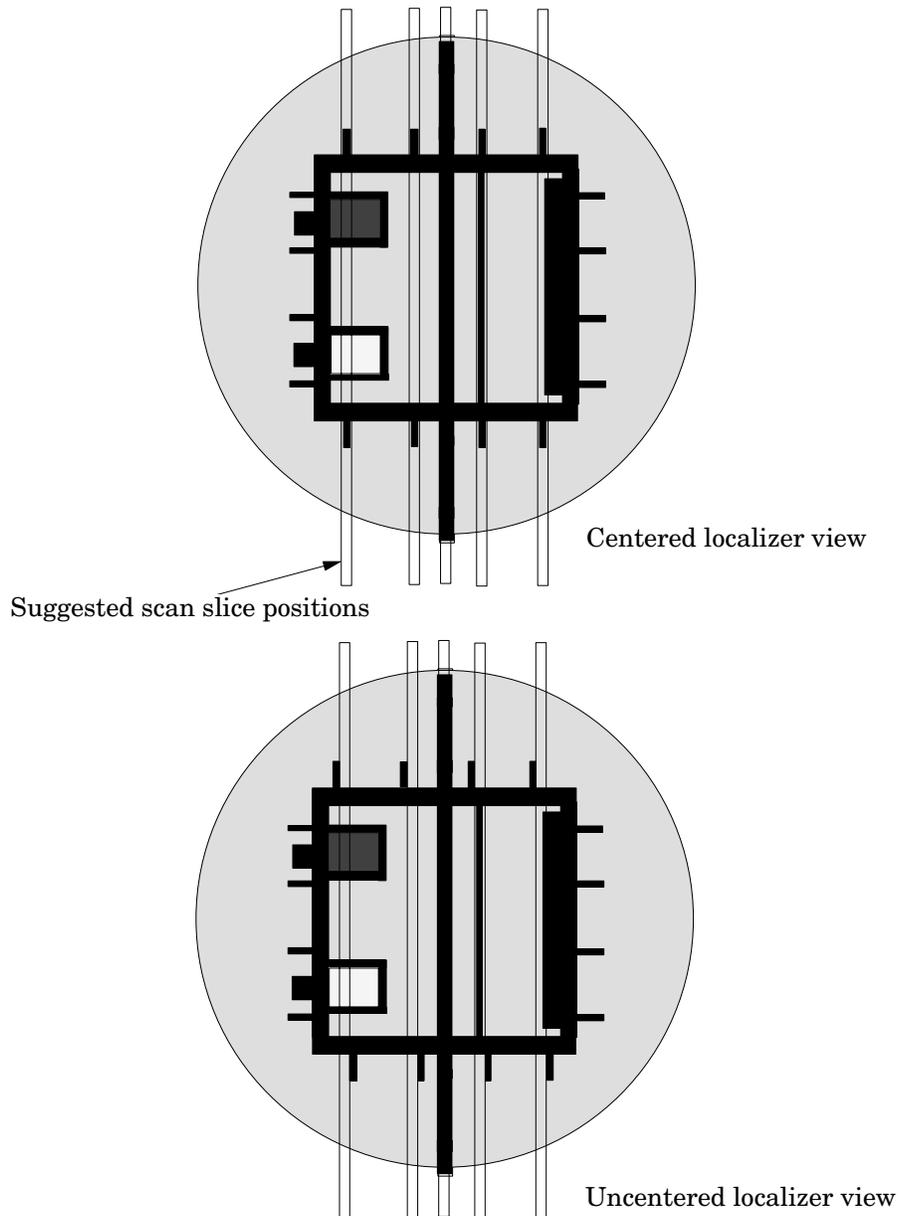
The standard test cube configuration encompasses two sets of opposed ramps oriented in the x and y direction. The advantage of this (the standard) configuration is the easy visual recognition of phantom alignment from the scan images.

Initial Phantom Positioning of the Magphan®

Positioning of the Magphan® sphere

Select the orientation you wish to use (sagittal, coronal, axial or oblique). Orient the phantom with its z axis perpendicular to the selected scan plane using the plastic level supplied and the scanner alignment lights as a guide. The edge of the coupling ring can be used to orient the sphere to the scan plane.

After the phantom has been manually positioned, make a localizer image of the phantom. In the localizer image you will see cross sections of the slice width ramps protruding from the test cube. If the phantom is centered the ramp protrusions will be opposite each other.



Set up the scan slices so they run through the center of the opposed ramp protrusions for each plane that you would like to view. All the test planes within the cube are spaced in 2.5cm increments. Once you have located the center of any test plane, you can locate the other test planes by indexing 2.5cm.

Positioning of the Magphan® cylinder

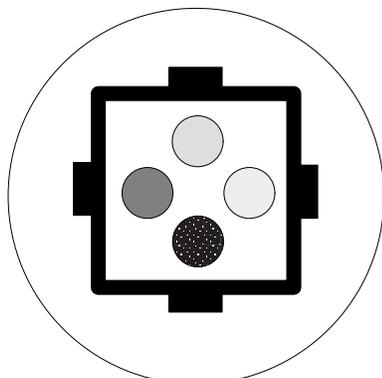
Orient the phantom with its z axis using the plastic level supplied and the scanner alignment lights as a guide.

After the phantom has been manually positioned, make a localizer image of the phantom. In the localizer image you will see cross sections of the slice width ramps protruding from the test cube (see the illustration on the previous page). If the phantom is centered the ramp protrusions will be opposite each other.

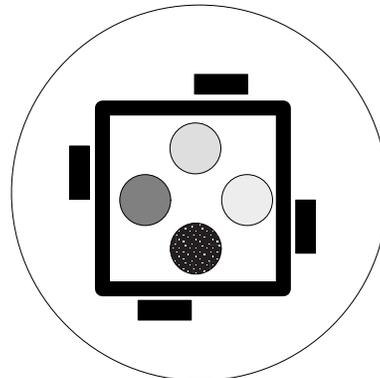
Set up the scan slices so they run through the center of the opposed ramp protrusions for each plane that you would like to view. All the test planes within the cube are spaced in 2.5cm increments. Once you have located the center of any test plane, you can locate the other test planes by indexing 2.5cm.

Phantom Position Verification

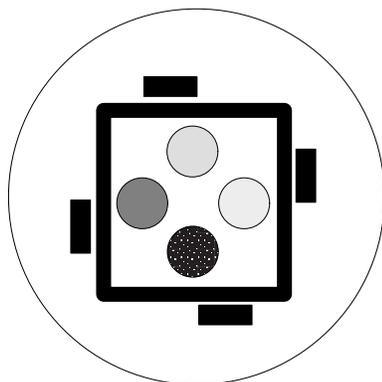
Scan through the first (sensitometry) test plane to verify that the Magphan® is centered and correctly positioned. The lines created on the image by the four ramps (two ramps if the cube is set up for 3 dimensional slice thickness measurements) should be directly across from each other and centered on the x and y axis. The four ramps run at a 14° angle from the scan plane. The ramps are positioned so they all rise from one end of the cube to the other in a counter clockwise pattern. As the section is moved into the scanner the lines created by the ramps will skew from a clockwise to a counter-clockwise orientation in relation to the x and y axis. There is a set of ramps for each imaging plane in the test cube.



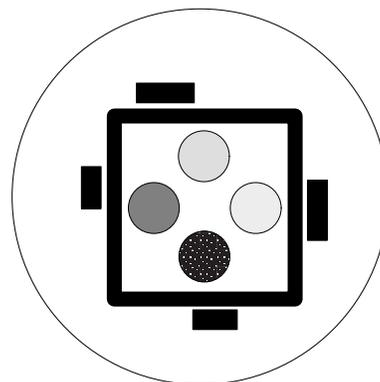
Correct alignment



Clockwise skew (too high)



Counterclockwise skew (too low)

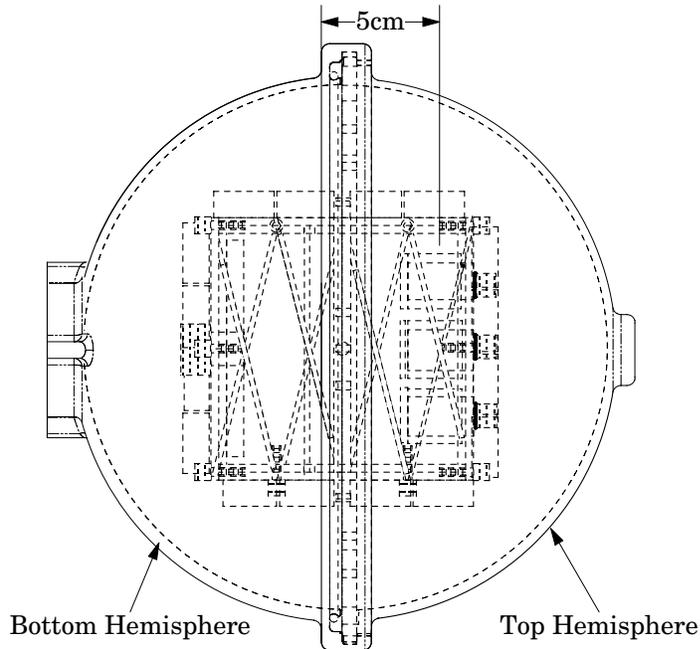


Phantom misalignment (angulation)

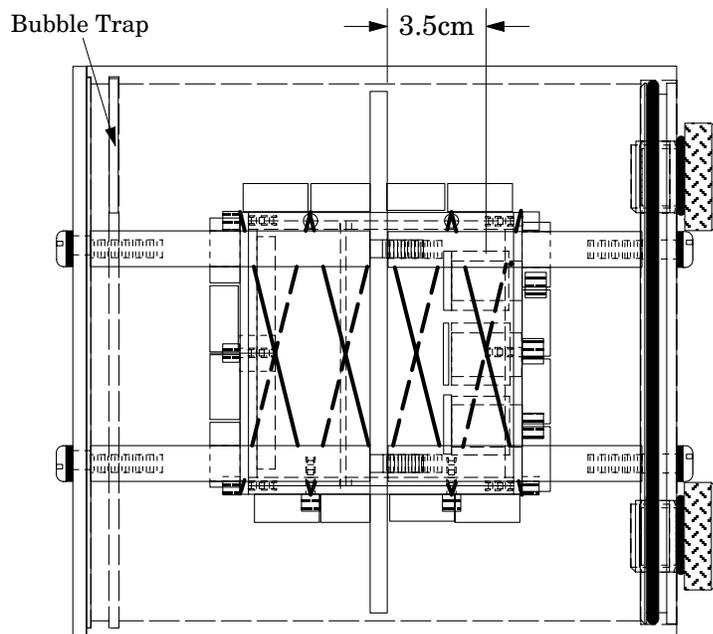
Misalignment of the phantom with the scanner axis is indicated when the lines created by the ramps are not symmetrical, as illustrated above. In this situation the phantom should be re-positioned to obtain proper alignment.

Patient Alignment System Check

To check the optical, and mechanical patient alignment system, position the Magphan® so the alignment light aligns with the outer edge of the lower coupling ring. The image plane should then be indexed 5cm up the phantom to the center of the first test plane as illustrated below. The scanned image should show good alignment as shown on the previous page, left top.



With the Magphan® cylinder, align the light with the top side of the support disk and index the scanner up 3.5cm to the center of the first test plane and check the image as discussed above.



Notify your service engineer if the image shows clockwise or counter-clockwise skew, because this may indicate misalignment of the scan plane and patient alignment lights.

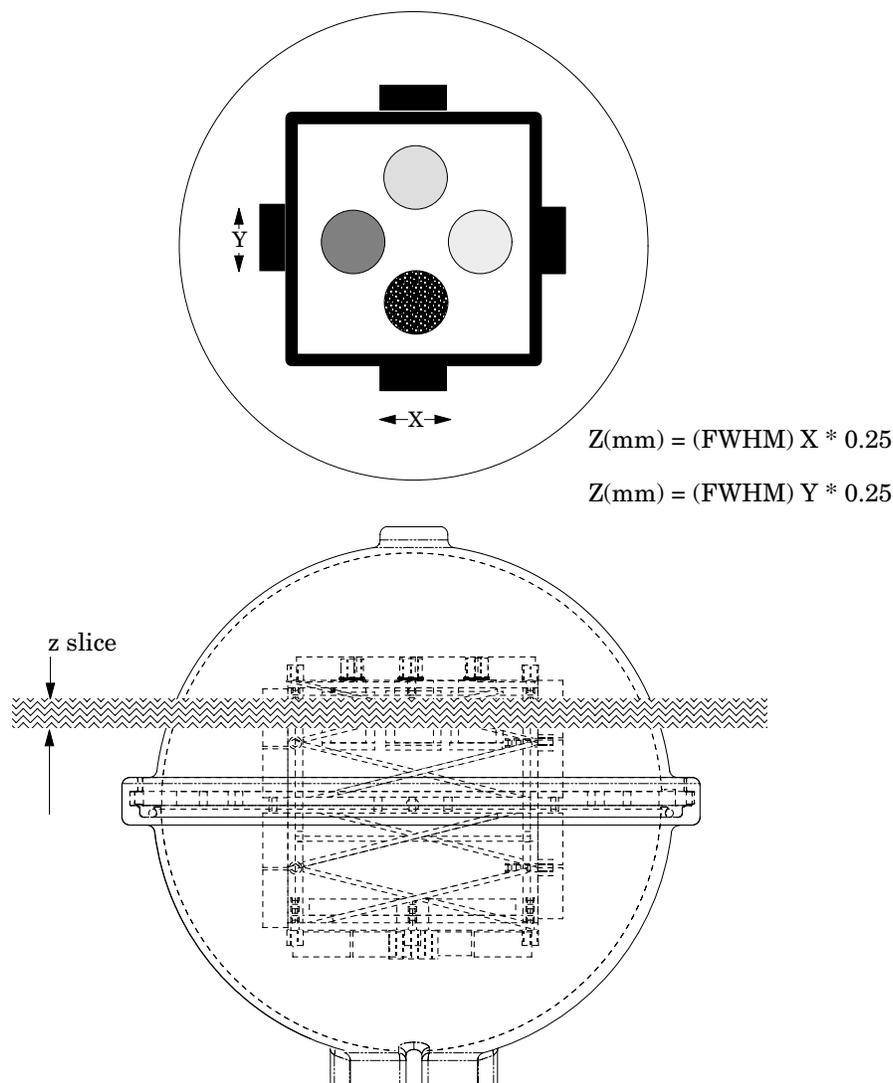
Circular Symmetry

The circular and cylindrical phantom housings are used to test for circular symmetry of the MRI image, including calibration of the CRT display system. If an elliptical image is produced and the x and y distance measurements are the same, the x-y balance of the image display system should be adjusted.

Scan Slice Geometry (Slice Width)

At each of the 4 test planes in the test cube there are two pairs of opposed 14° ramps: one pair is oriented to the x axis, the other pair to the y axis (two ramps if you have set the test cube up for 3 dimensional slice thickness measurements; see test cube configuration section). The ramps are made of 2mm thick acrylic strips 10mm wide mounted at 14° angles to the imaging plane. These ramps are used to estimate slice width.

To estimate the slice width z (mm), multiply the Full Width Half Maximum (FWHM) of



any of the four angled ramps by 0.25:

$$z(\text{mm}) = (\text{FWHM})_x * 0.25$$

$$z(\text{mm}) = (\text{FWHM})_y * 0.25$$

To find the FWHM of the ramp from the scan image you need to determine the values for the peak of the ramp, and for the background.

To calculate the value for the peak of the ramp, close down your window width. Move the MRI scanner window level to the point where the ramp disappears. Note the number of the level at this occurrence as your peak.

To calculate the value for the background, use the region of interest indicator to identify the mean value of the area adjacent to the ramp.

Using the above values determine the Half Maximum:

First calculate the net peak...
 $\text{peak} - \text{background} = \text{net peak}$

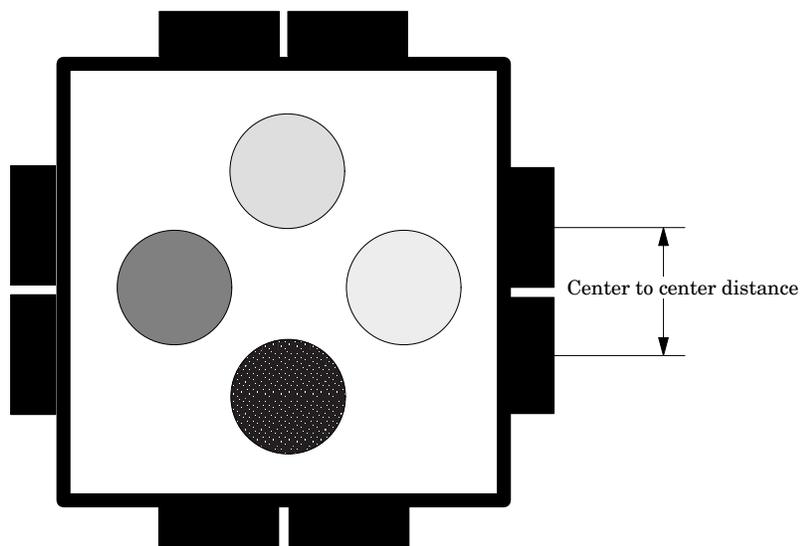
Calculate the 50% net peak...
 $\text{net peak} \div 2 = 50\% \text{ net peak}$

Calculate the half maximum setting...
 $50\% \text{ net peak} + \text{background} = \text{half maximum}$

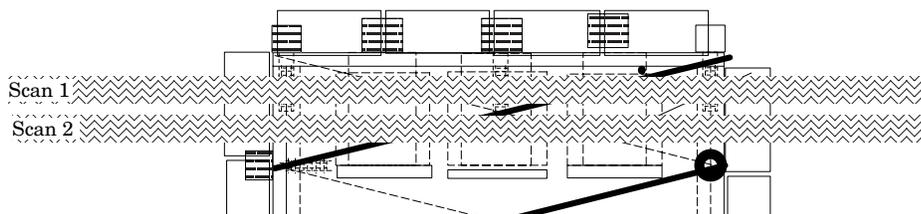
Now that you have the half maximum setting you can measure the full width of the ramp. Set the MRI scanner window level at the half maximum value maintaining a narrow window opening. Measure the length of the ramp image to determine the FWHM.

Scan Slice Selection

Use the angled ramps to test for proper scanner selection among and between slices, and for table movement.

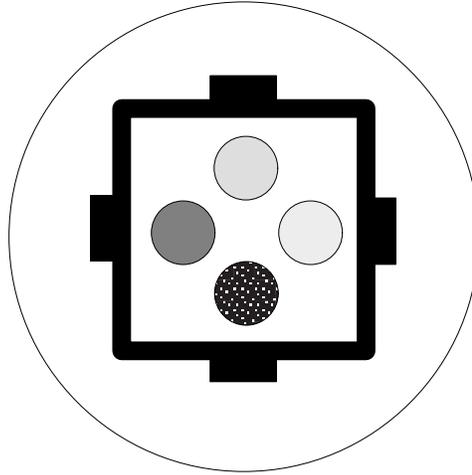


Schematic illustration of 2 superimposed scans used to test the indexing accuracy between slices on MRI systems.



The ramps can be used to test the indexing between slices within a multislice sequence. Set a multislice sequence with an inter scan gap of 0. The sequence should be positioned so the end of the first slice will be even with the center of a test plane. Measure from the center of the first ramp to the center of the second ramp and multiply it by .25 (the 14° scaling factor) to determine the scan index between scans.

The ramps can be used to test table increment accuracy. Scan a test plane and increment the table 30mm in and out of the gantry and scan again. The ramp position should be identical in the two films.

Test cube plane 1**Sensitometry (MRI numbers)**

Four sensitometric target vials are found in the top scan plane of the Magphan® test cube. These targets can be filled with your choice of MRI test solutions or gels. For example, four solutions with known systematical varied concentrations can be used. To fill the vials remove the screw plugs on top of the test cube using the hex wrench provided. Do not over tighten the screws after filling the vials.

vial 1 _____

vial 2 _____

vial 3 _____

vial 4 _____

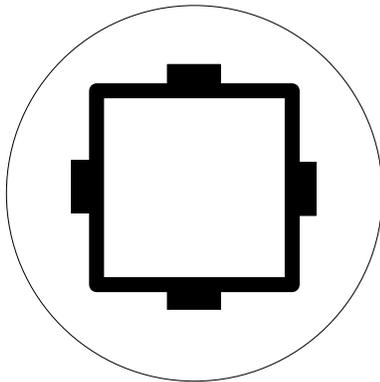
By recording each vial daily, a log of MRI number reproducibility can be established.

Test cube plane 2 or phantom without test cube

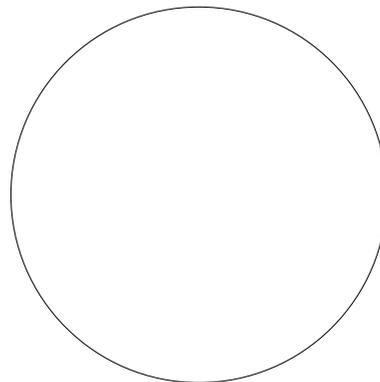
Uniformity tests

Most MRI scanners allow the measurement of the mean value and the corresponding standard deviations (SD) in MRI numbers within a region of interest (ROI). These measurements are taken from different locations within the scan field.

Two liquid bath options are available, test cube plane 2 and the Magphan® housing without the test cube and support disk. For the most accurate measurements, it is recommended that you use the Magphan® housing without the test cube, however for daily use, plane 2 can be utilized.



Test cube plane 2



Magphan® housing

Spatial (non)Uniformity

(non)Uniformity can be defined as :
$$\frac{\text{MRI\# max} - \text{MRI\#min}}{\text{MRI\#max} + \text{MRI\#min}}$$

Measure spatial uniformity by scanning either of the above. The max and min MRI numbers are measured within the signal producing regions. The phenomenon of severe hot or cold non uniform regions or banding may indicate the need for recalibration.

Signal to noise ratio of MRI Systems

Signal to noise can be defined as:
$$\frac{\text{net MRI signal}}{\text{SD of central region}}$$

 Net MRI signal = central region MRI # - background (air) MRI #

The mean and standard deviation of a large number of points, say 1000 for example, is determined for central and peripheral locations within the scan field (and perhaps in the air region outside the scan) for each type of scanning protocol. Inspect the data for changes from previous scans and for correlation between dual slices.

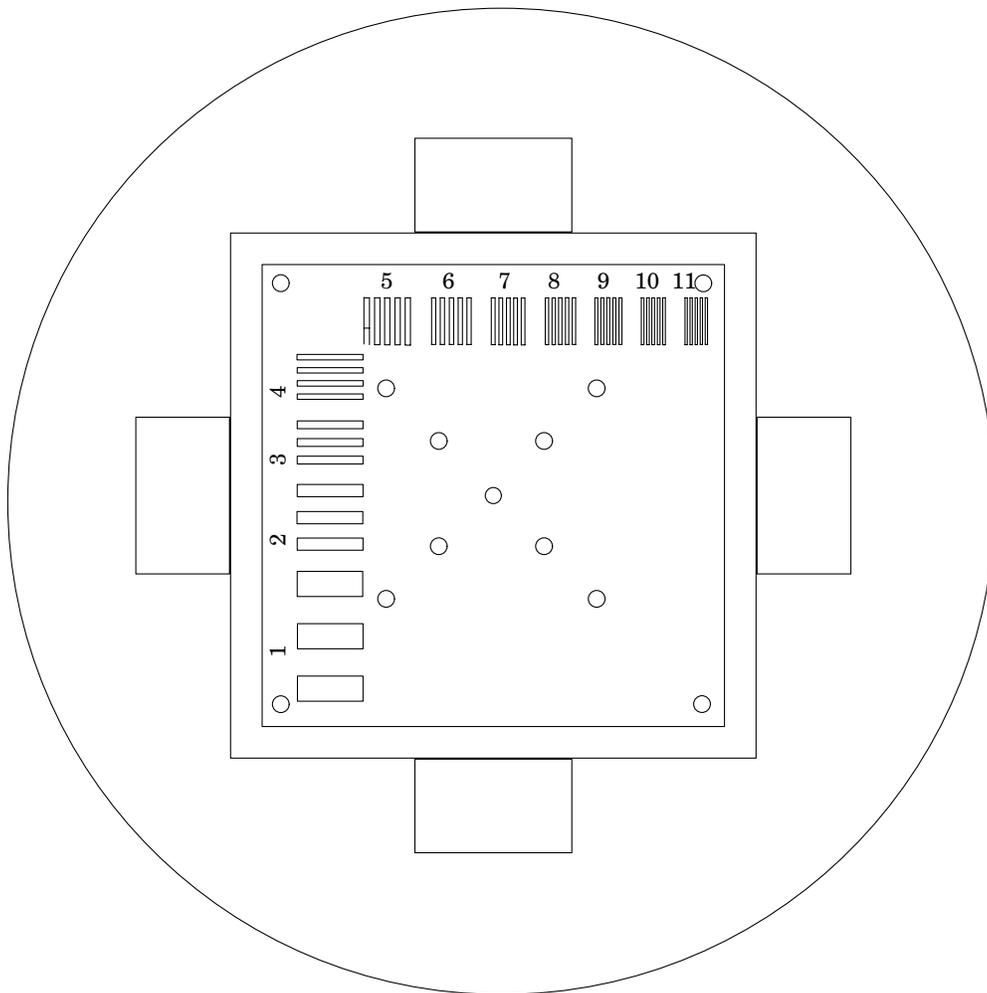
Test cube plane 3

High Resolution Gauge

Index the scanner to the resolution section. This section has a 1 to 11 line pair/cm, high resolution test pattern. The targets are 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, and 11 line pair/cm.

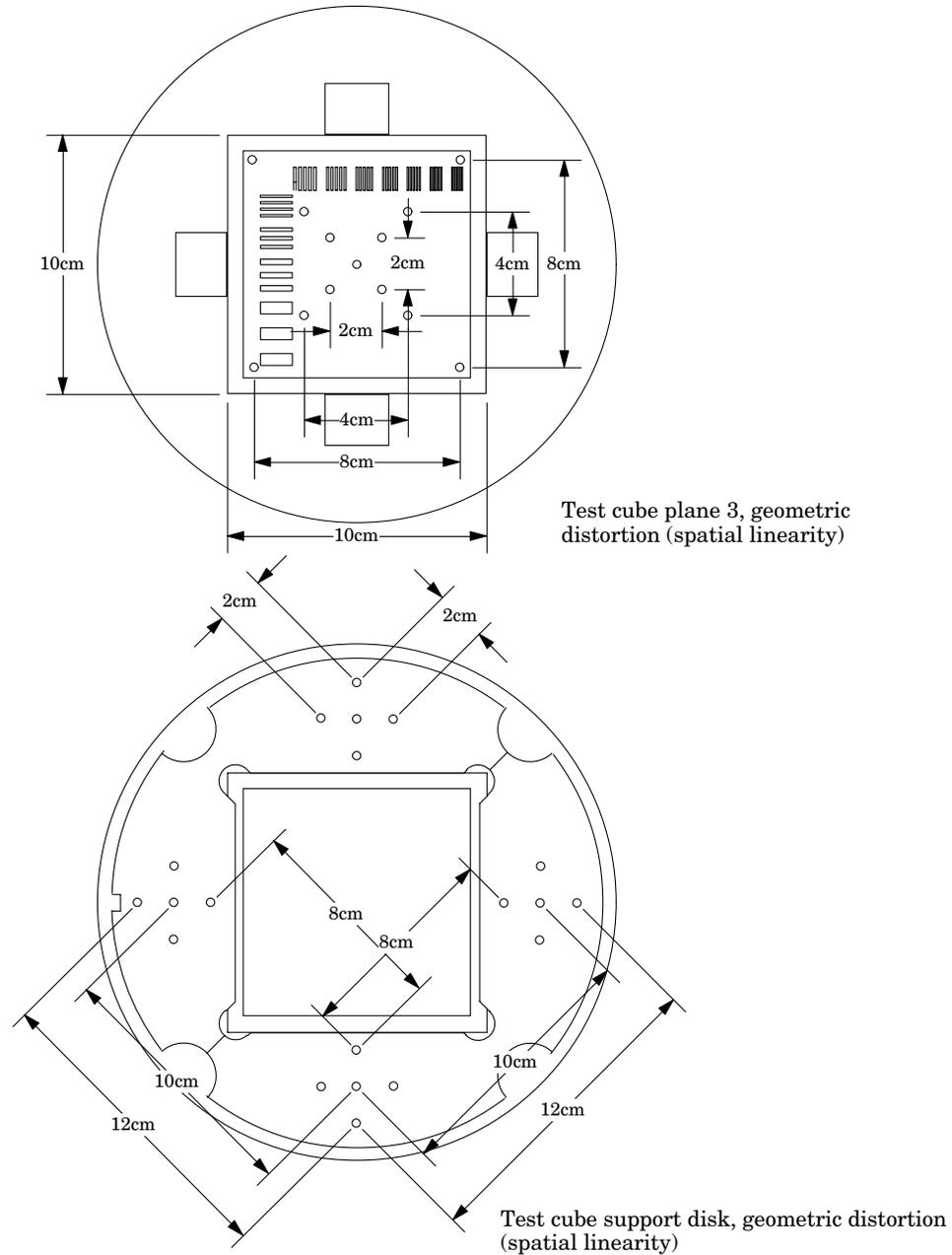
Depending on the choice of slice thickness, the contrast levels will vary due to volume averaging. The actual contrast numbers are determined at the slice width you are using by taking the MRI numbers from the surrounding material inside the test cube and from the gauge lines themselves.

The high resolution gauge provides a square wave test object that can be used to determine the MTF. The procedure for CT scanners is outlined in the Japanese CT Phantom Standards. An English translation is available from The Phantom Laboratory.



Geometric Distortion (spatial linearity)

Geometric distortion can be measured in test plane 3 by measuring between the 3mm holes which are spaced in a pattern forming 2cm, 4cm, and 8cm squares. To measure for distortion, measure the distance between the center of these holes with the MR cursor and the “distance” function.



For larger field measurements of geometric distortion use the test cube support disk which is positioned 1.25cm above this test plane.

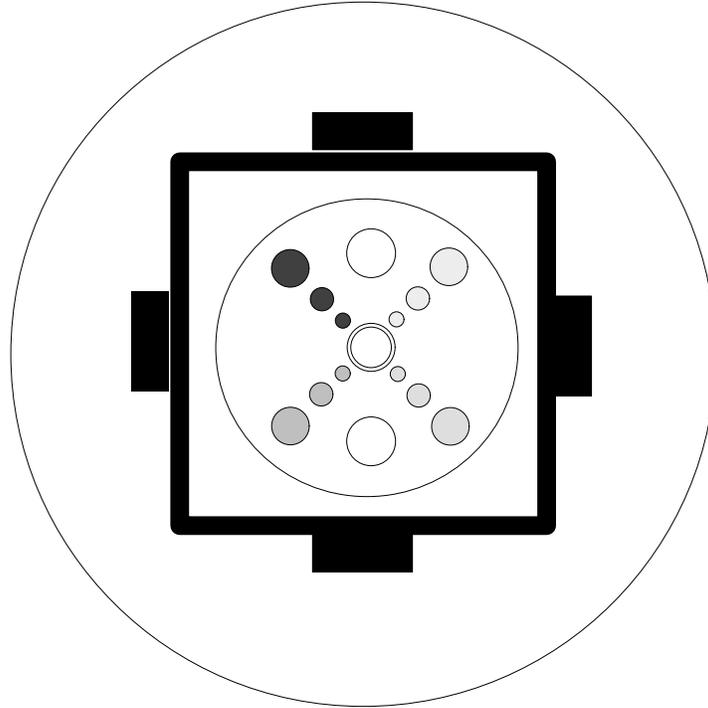
Test cube support disk

The test cube support disk has 3mm holes positioned in a pattern forming 8cm, 10cm, and 12cm squares centered around the phantom's axis and 4 sets of 2cm squares at the corners of the larger squares. This design allows both measurements of the overall geometric distortion along with localized distortion.

Test cube plane 4

Low Contrast Sensitivity

Move the table to Section 4. Refer to figure 7. The low contrast targets have the following diameters and contrasts:



Target diameters

4.0mm

6.0mm

10.0mm

Nominal target contrast levels are achieved by volume averaging of the following four hole depths:

0.5mm

0.75mm

1.0mm

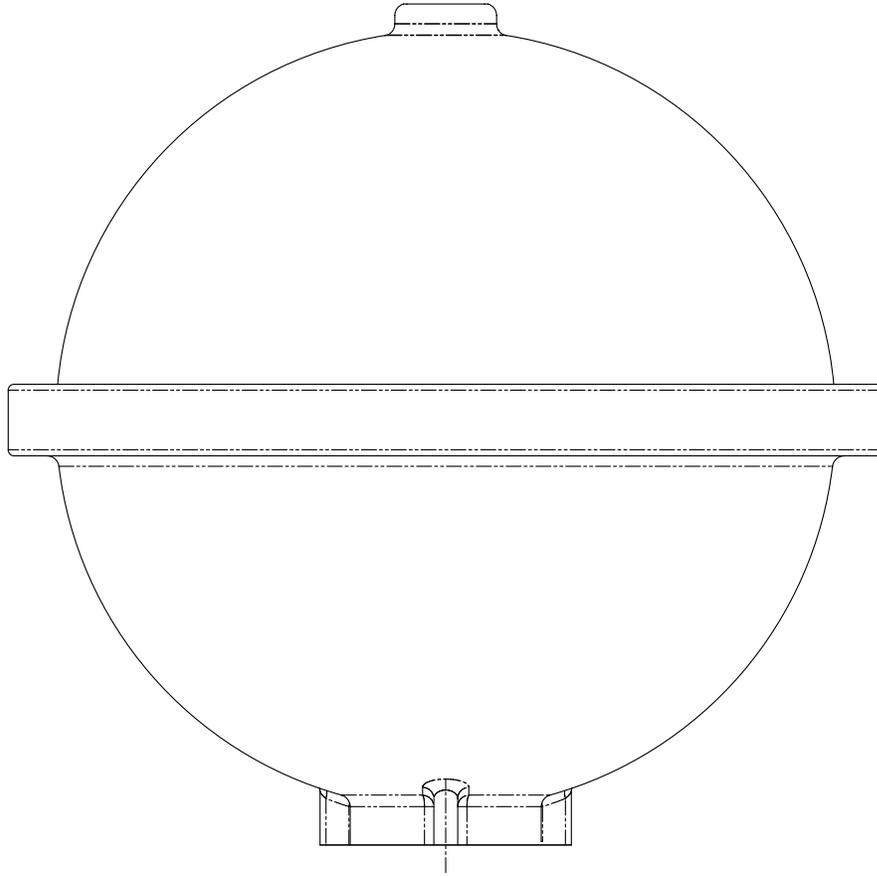
2.0mm

To determine the actual contrast levels of your phantom, calculate the average of the measurements from several scans of your low contrast section.

The actual contrast levels are measured by making two region of interest measurements; one over the target, and another over the local background area. It is important to measure the background area adjacent to the target because non-uniformity effects cause variation of MR numbers from one scan region to another. Position the region of interest to avoid the target edges. The region of interest should be at least 4 x 4 pixels in diameter. Because low contrast measurements are “noisy” it is advisable to calculate the average of the multiple measurements made from several scans. Carefully monitor the techniques setting because the signal to noise ratio will improve with increased slice width and pixel sizes. Use the size of the targets visualized under various noise levels to estimate information on contrast detail curves.

Liquid Bath Research

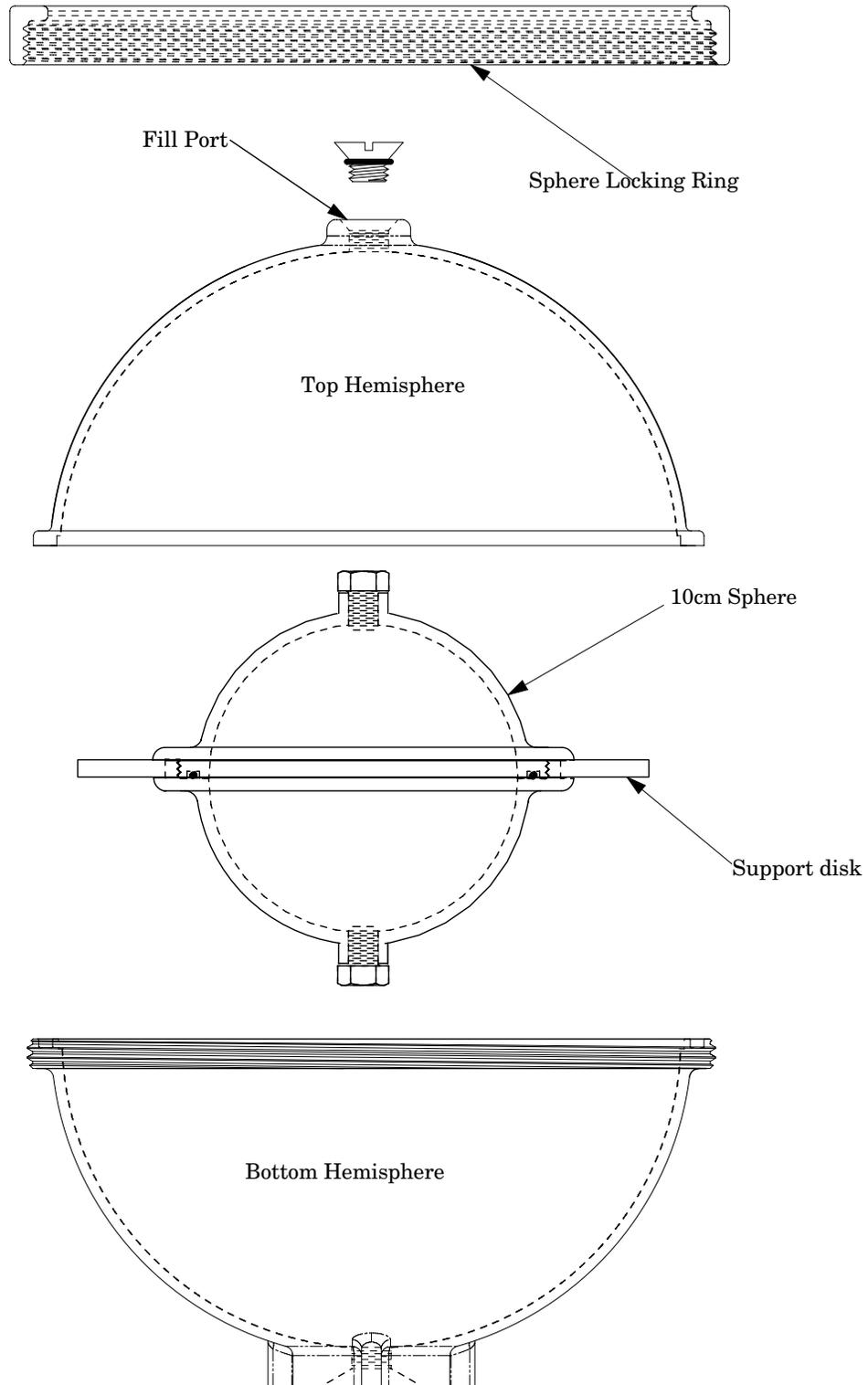
The Magphan® phantom is equipped with two ports and coupling rings to separate the hemispheres to facilitate insertion of your own test objects, specimens or fluids.

**Dynamic Scanning**

The dual ports in the Magphan® allow skilled researchers to set up the Magphan® with additional valves and basins to study dynamic flow. Note: special caution to prevent spilling of fill solution must be taken to prevent personal injuries and equipment damage.

10cm Sphere

The Magphan® phantom is available with an optional 10cm diameter sphere for small field tests. Additionally, it can be mounted within the 20cm sphere for evaluations using different contrast solutions or dynamic studies.



A Sample Quality Assurance Program

The following shows a sample QA program. Review the manufacturer's recommendations, local governing requirements, and the needs of your physicians and physicists when developing a QA program for your institution. We recommend this program be utilized only as a sample to demonstrate program content used in the past.

Each test to be conducted at initial acceptance testing and following any preventative maintenance:

Test	Daily	Weekly	Monthly
Positional verification	*		
Circular symmetry and linearity		*	
Scan slice geometry / slice width		*	
Sensitometry (MRI number scale)	*		
Resolution	*		
Low contrast			*
Uniformity and signal to noise characteristics	*		

Bibliography

AAPM committee on Nuclear Magnetic Resonance. Price (Chairman), Task Group #1
NMR Phantom Descriptions and Quality Assurance Procedures
Available from AAPM, 335 E. 45th Street, New York, NY 10017

Deluca, Maraviglia and Mercurio
Biological tissue simulation and standard testing material for MRI
Magnetic Resonance in Medicine 4, 189-192, 1987

Durney
Radiofrequency Radiation Dosimetry Handbook
United States Airforce School of Aerospace Medicine, ed, 2, 1978

Dyer and Goodenough
MRI Acceptance Testing: Theoretical and Practical Aspects
(Abstract) Magnetic Resonance in Medicine, Vol 8, Sup 1, 161, 1990

FDA, 21 CFR-Part 1020.33
Computed Tomography Equipment
Department of Health and Human Services, Food and Drug Administration, August, 31
1984

Goodenough
Psychophysical Perception of CT Images, in Newton and Potts Eds.: Radiology of the
skull and Brain: Technical Aspects of Computed Tomography Vol. V, 3993-4021 St.
Louis, MO,
1981

Goodenough, Atkins and Dyer
Automated Techniques for Quality Assurance of Radiological Image Modalities
(In Press) SPIE, Proceedings Vol. 1444, February 1991.

Goodenough and Weaver
Phantoms for Specifications and Quality assurance of MRI Scanners
computerized Medical Imaging and Graphics. Vol 1-4, 193-209, 1988

Goodenough, Weaver, and Davis
Development of a Phantom for Evaluation and Assurance of Image Quality in CT
Scanning
The Proceedings of the Application of Optical Instrumentation in Medicine V meeting
sponsored by The Society of Photo-Optical Instrumentation in Medicine V meeting spon-
sored by The Society of Photo-Optical Instrumentation Engineers, Washington DC; and,
Optical Engineering, January 1977

Madsen and Fullerton
Prospective tissue-mimicking materials for use in NMR imaging phantoms
Magnetic Resonance Imaging Vol. 1, 135-142, 1982

NEMA(National Electrical Manufacturers Association)
Determination of SNR in Diagnostic MR Images #MSI-1988
2101 L. St. N.W. Washington, DC 20037

Runge, Johnson and Smith
NMR phantom design: Evaluation of performance parameters
Noninvasive Medical Imaging Vol.1, 135-142, 1982

WARRANTY

THE PHANTOM LABORATORY INCORPORATED ("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:

The Phantom Laboratory Incorporated
2727 State Route 29
Greenwich, NY 12834
or
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.