

## **Magphan® EMR128 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.

**EMR128**

**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® 128



Model: EMR128



UDI:



(01)00812266031199

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.

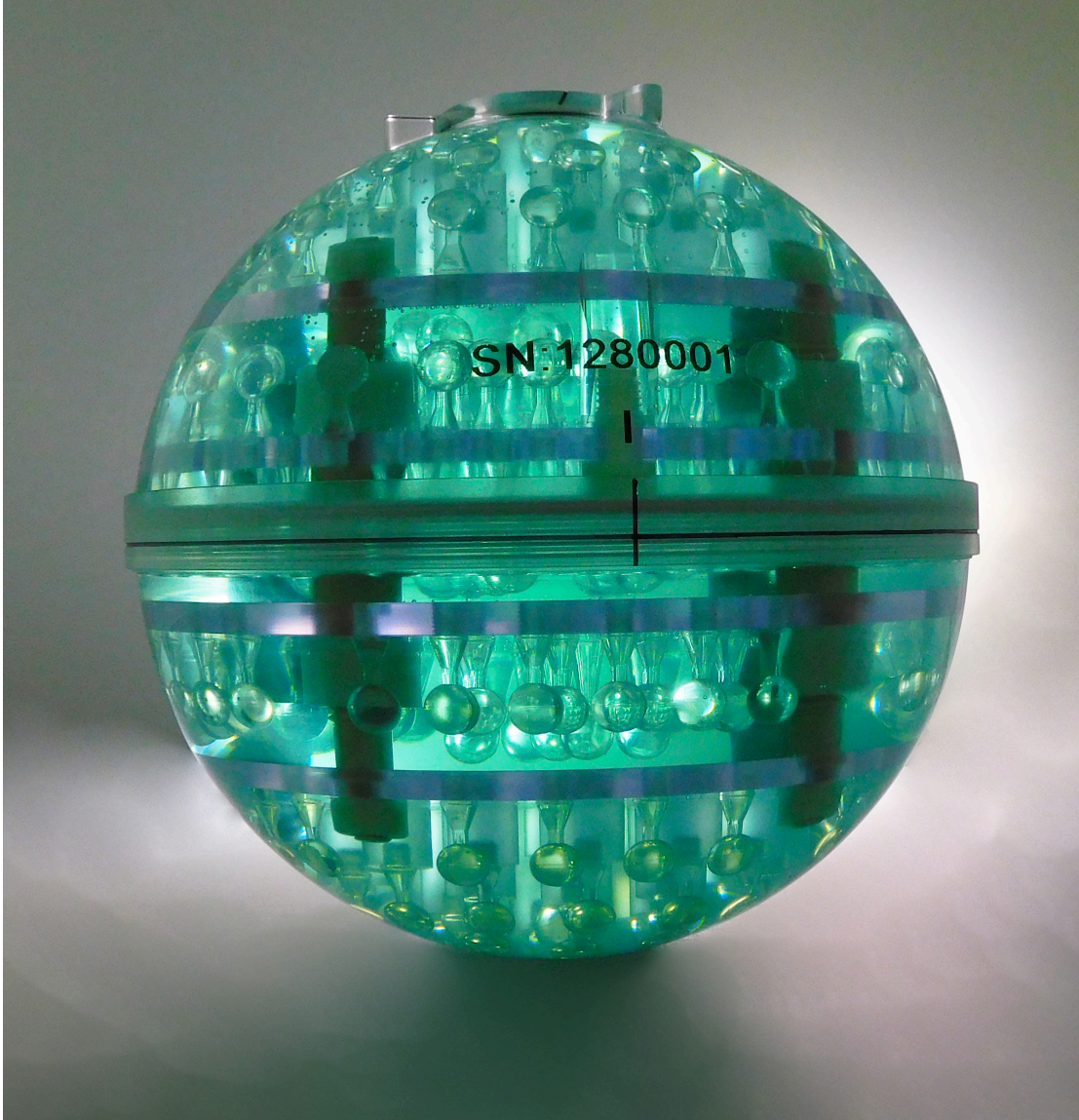
A risk assessment was conducted to the following standard: EN ISO14971  
 This declaration of conformity is the result of testing and evaluation performed by The Phantom Laboratory, Incorporated.

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

## **Magphan® EMR128 Phantom Product Guide**

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Magphan® EMR128

When not in a head coil, the phantom 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 The Phantom Laboratory's development of the Magphan® EMR128 phantom. This phantom is design to accurately measure and map distortion in MR scanners. The phantom's 18cm diameter is designed to fit into most modern head coils.

If you need a comprehensive evaluation of your MR image quality along with distortion measurements, we recommend the Magphan® S162. If you need to perform quantitative evaluations for MR body imaging, the Magphan® RT models are designed to cover large fields.

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 The Phantom Laboratory at:

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

Fax: 518-692-3329

Email: [info@phantomlab.com](mailto:info@phantomlab.com)

Additional product and Smári service information is available at: [phantomlab.com](http://phantomlab.com)

**Schematic view of phantom:**

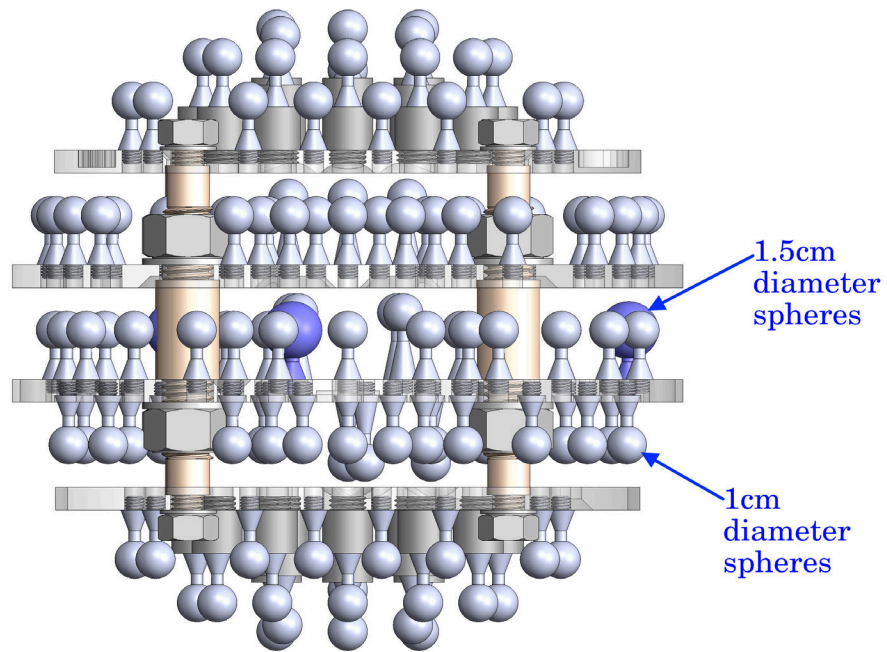


Illustration of phantom test objects with housing removed



Illustration of phantom with housing

## Phantom fill solution

The Magphan® S128 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 manual 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>

PVP (Polyvinylpyrrolidone)

<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>

### Unpacking and topping off the phantom

The Magphan® S128 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 The Phantom Laboratory at [info@phantomlab.com](mailto: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 The 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 EMR128 is a dedicated distortion measurement phantom. The phantom is filled with a uniform background solution and 221 spheres that appear dark in the MR images. The phantom contains 3 position identification reference spheres with a 1.5cm diameter along with 218 spheres with a 1cm diameter.

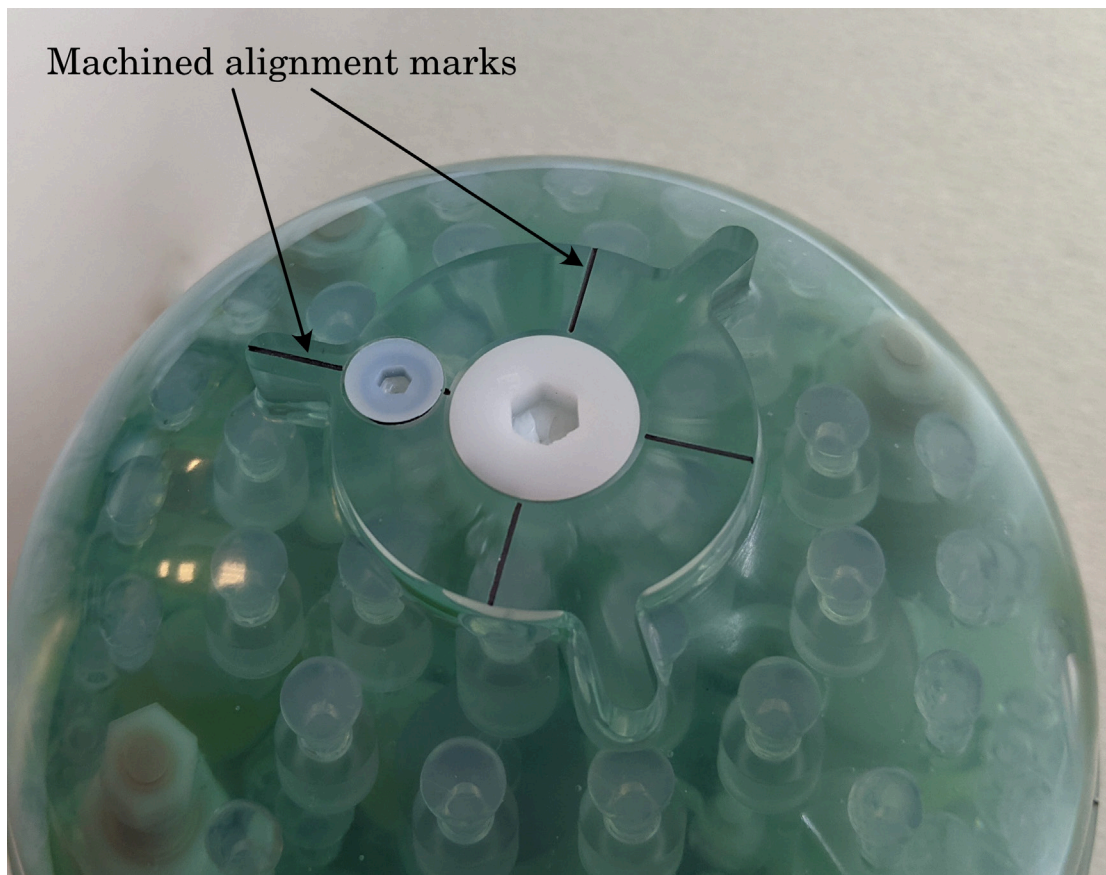
The Smári Analysis Service precisely identifies the center of each sphere and then uses the measured location information to generate distortion measurements.

## Positioning the phantom

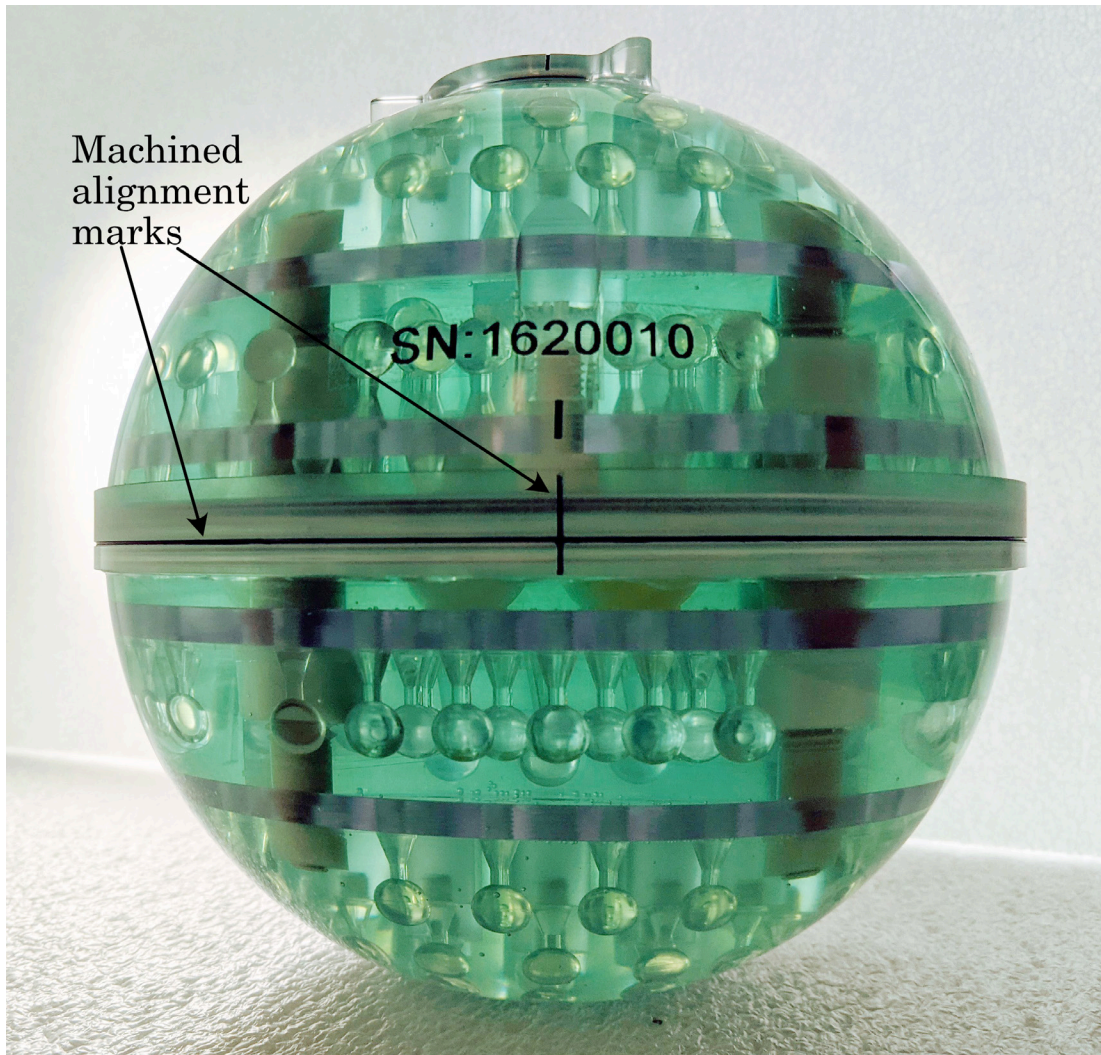
The phantom is marked with alignment lines and Superior, Inferior, Right, Left (S, I, R, L) labels to assist in orienting the phantom so the resolution and slice thickness tests are aligned with the axial and coronal planes.

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.



The machined marks on the center ring can be aligned with the laser alignment marks.

**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. 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, it may still be possible to perform a distortion measurement using the reduced set of fiducials that are able to be identified. Consult the software help pages for more information on adjusting analysis parameters for such situations.

**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](http://phantomlab.com) site.

To register for the service, go to the Smári page at our website: [phantomlab.com](http://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](mailto:support@phantomlab.com)

**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:

By Truck

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

By Mail

The Phantom Laboratory, Incorporated  
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.