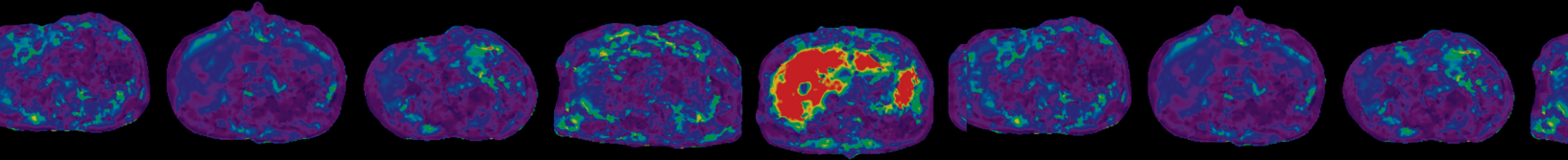
A series of thin, white, wavy lines that sweep across the top of the page, creating a sense of motion and depth.

MRE PHANTOM
USER GUIDE
MAGNETIC RESONANCE ELASTOGRAPHY



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INTRODUCTION

Resoundant's MR Elastography (MRE) Phantom is made from a homogeneous elastic material permanently sealed in a high impact container. The Phantom is ready to set up and scan.

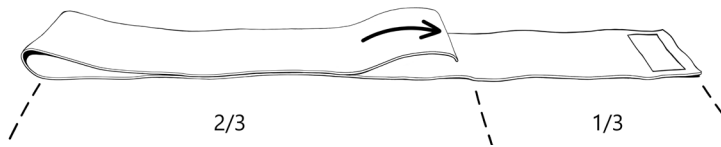
The MRE Phantom serves several purposes including verification that all MRE system elements are functioning properly: confirming that shear waves are generated, wave images and elastogram images are created, and a stiffness value is being calculated and displayed. The stiffness value for this phantom should be between 2.0kPa and 4.0kPa and may increase slightly (5%-10%) per year as the elastic material continues to cure. This is normal and has no impact on its function.

The MRE Phantom is a valuable aid to allow the installation engineers to easily verify the MRE system is installed properly and functioning correctly and can assist the service engineer or scientist in trouble shooting should there be any concern regarding the operational status of the MRE system. This verification can be done periodically by the MRE operators should they choose to do so. Additionally, the phantom is a convenient device to scan as part of a training exercise for new users.

Use the following procedure to position the phantom in a standard head coil. The setup procedure will be similar for systems and head coils from all MR manufacturers.

MRE PHANTOM SET UP PROCEDURE

1a



Fold the Resoundant Belt so approximately 2/3 is overlapped.

1b



Place the Phantom in the center of the folded belt.

Care and Handling

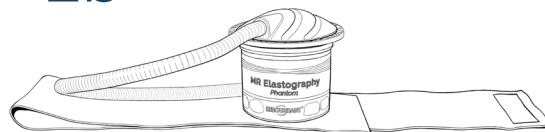
Do not remove seal or lid from the MRE Phantom. For longest life, store the MRE Phantom at room temperature, away from heat, moisture and direct sunlight. Please dispose of the MRE Phantom in accordance with local regulations or contact Resoundant via email at mreinfo@resoundant.com for instructions.

2a



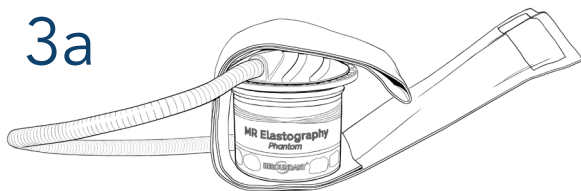
Place the silicone friction pad on top of the Phantom.

2b



Place the Passive Driver on top of the silicone friction pad.

3a



Fold the Resoundant belt over the Phantom, Friction pad, and Passive Driver.

3b



Firmly secure the belt around the phantom bundle.



Place the phantom bundle in the head coil. Use a simple sponge to level the bottom of the head coil as needed.

The Phantom is now ready to scan according to the vendor-specific instructions below.



Go to resoundant.com/phantom-guide to access the most up to date phantom scanning protocols for various MRI systems.

Use of Symbols



Manufacturer



Refer to instruction manual



Not for general waste



CE mark for Europe



MR Safe



General warning



Medical device



Authorized representative
in Europe

Contents

- 1 Phantom
- 1 Friction Pad
- 1 User Guide

Weight / Dimensions

Wt. 2.2 Kg, Cylinder shape, 13 cm high, 16 cm dia.



Warning: DO NOT use the Phantom if it appears to be damaged or cracked. For additional warnings please check with the operator and service manual of the MRI scanner OEM.

Intended Purpose

The intended purpose of the MRE Phantom is to verify that all necessary system elements are installed and are functioning properly.

Indication: N/A

Contra-indications: N/A

Patient Target Group: N/A

Intended Users

- Clinician
- Scientist
- Service engineer
- Radiologist

Operating Ranges

Operating temperature range: 10.0°C to 33.3°C (50°F to 92°F)
 Operating and nonoperating humidity range: 10% to 90% RH, noncondensing
 Operating and nonoperating atmospheric pressure range: 700 - 1060 mbar

Nonoperating, Shipping and Storage Ranges

Shipping/storage/nonoperating temperature range: -20°C to +60°C (-4°F to 140°F)

Residual Risks

Appropriate control measures have been applied to all known risks associated with the MRE Phantom. The benefit/risk comparison is overwhelmingly favorable and residual risks are defined to be low. Residual risks are further communicated and addressed within general warnings and cautionary statements.

Maintenance

Cleaning Instructions: Clean the components with a damp cloth containing a mixture of mild soap and water as needed. Disinfect with peroxide solution 0.5% by volume

Handling Storage:

(see Care and Handling – page 3)

Disposal

(see Care and Handling – page 3)



CONTAMINATION: If any part of the components becomes contaminated by human body fluids, dispose of in accordance with local regulations.

Reporting of Incidents

Users should contact the manufacturer immediately to report an incident and/or injury to an individual, operator or maintenance employee that may be associated with use of the MRE Phantom.

If an accident occurs as a result of MRE Phantom use, discontinue use until an authorized investigation is conducted.

Manufacturer:

Resoundant, Inc.
 421 First Avenue SW STE204W
 Rochester, Minnesota 55902 USA
 Phone: 507.322.0011
 Email: mreinfo@resoundant.com
 URL: www.resoundant.com

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