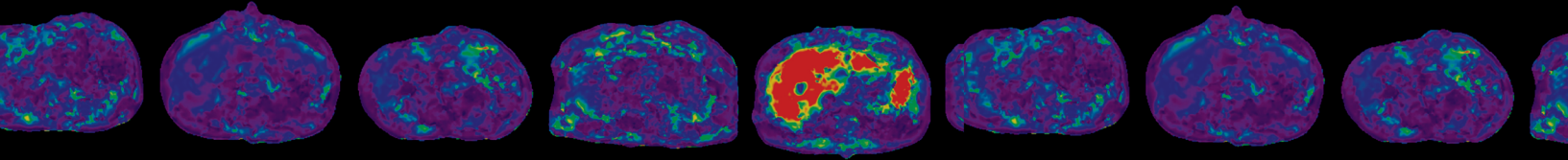




MR ELASTOGRAPHY PHANTOM

INSTRUCTIONS FOR USE



Available electronically at www.resoundant.com/eifu

REMREP15

CONTENTS

Introduction	2
Setup Procedure	4
Web Resources	6
Product Safety	11

INTRODUCTION

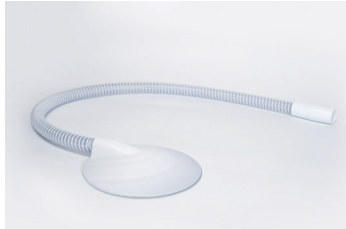
Resoundant's MR Elastography (MRE) Phantom is made from a homogeneous elastic material permanently sealed in a high impact container. The Phantom is ready to set up and scan.

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.

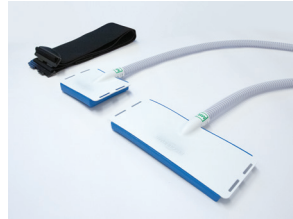
Use the following procedures to position the Phantom in a standard Torso or Head coil. The setup procedure will be similar for systems and head coils from all MR manufacturers.

The MRE Phantom can be scanned with the following Passive Drivers.



Passive Driver (round-rigid)

Page 4



Flex Passive Drivers

Page 7

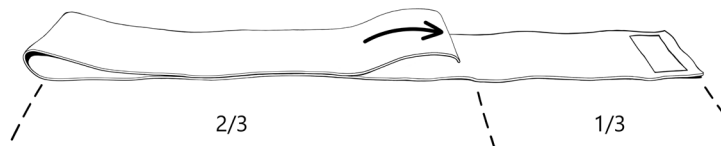


Pillow Passive Driver

Page 9

MRE Phantom

Setup procedure with the round rigid passive Driver



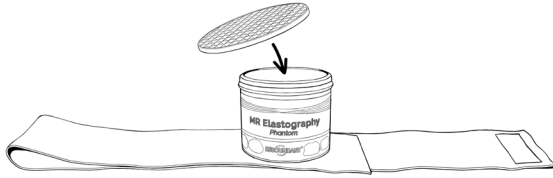
Fold the Resoundant Belt so approximately 2/3 is overlapped.



Place the Phantom in the center of the folded belt.

Care and Handling

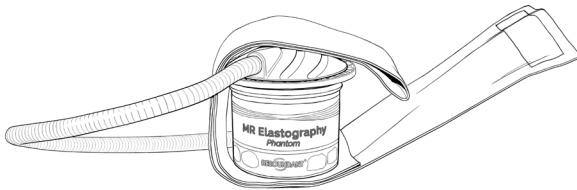
Do not remove seal or lid from the MRE Phantom. For longest life, store the MRE Phantom upright at room temperature, away from heat, moisture and direct sunlight. Please dispose of the MRE Phantom in accordance with local regulations or contact Resoundant via email at mreinfo@resoundant.com for instructions.



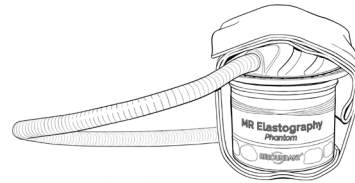
Place the silicone friction pad on top of the Phantom.



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



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

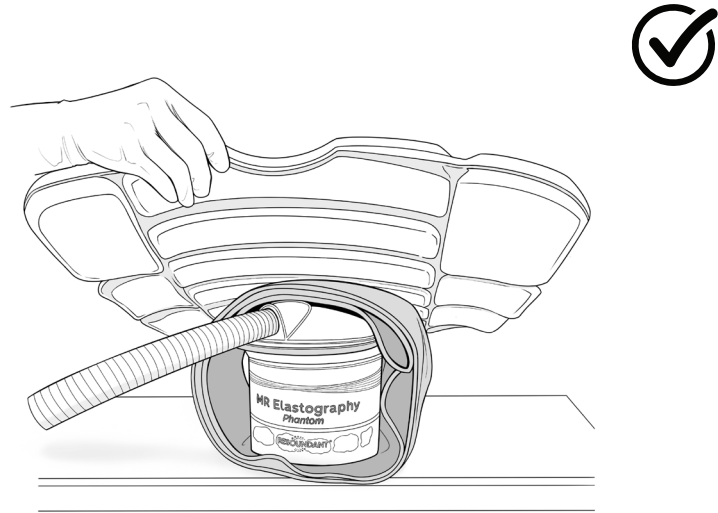


Firmly secure the belt around the phantom bundle.

Place the phantom bundle on the scanner table. Position the torso coil on top of the Phantom bundle.

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

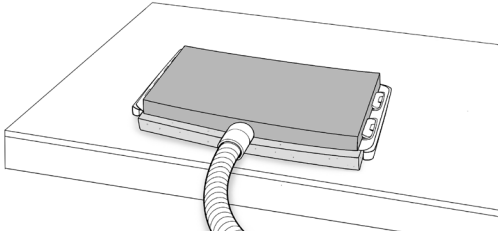
Note: Set up the small Flex Passive Driver same as the round Rigid Passive Driver, with the small Flex Driver on top of the phantom, firmly secured with the 4 in. belt.



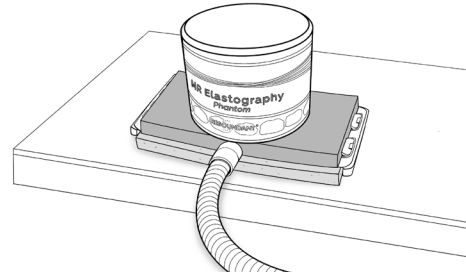
Go to resoundant.com/phantom-guide to access the most up to date phantom scanning protocols for various MRI systems.

MRE Phantom

Setup procedure with the Flex Passive Driver



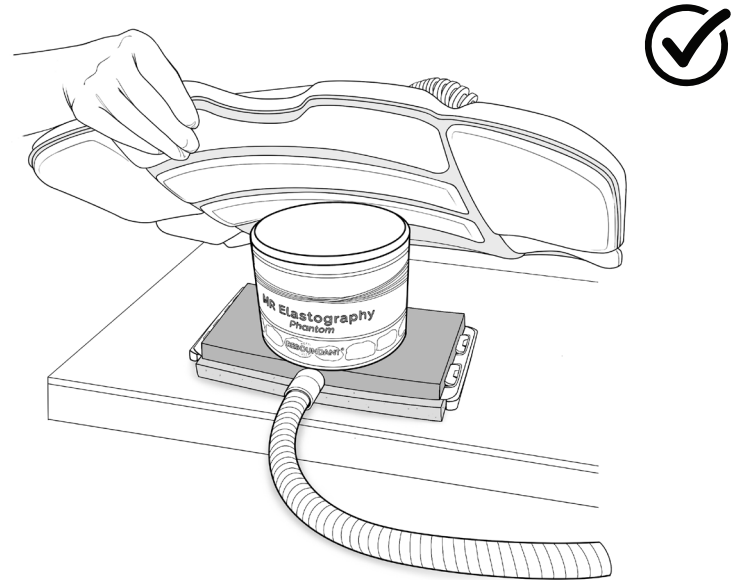
Place the Flex Passive Driver on the scanner table with the blue, soft side up with a sponge pad between the table and the Flex Passive Driver.



Place the MRE Phantom on top of the Flex Passive Driver.

Position the torso coil on top of the Phantom.

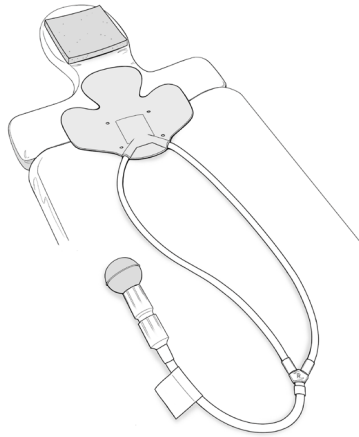
The Phantom is now ready to scan.



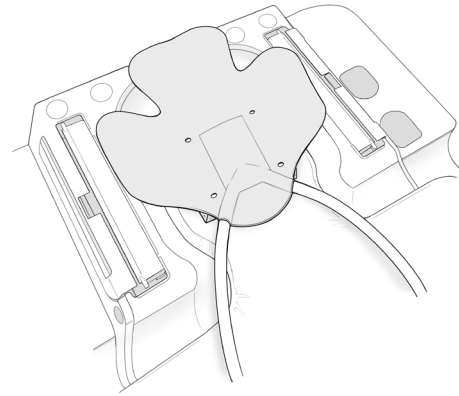
Go to resoundant.com/phantom-guide to access the most up to date phantom scanning protocols for various MRI systems.

MRE Phantom

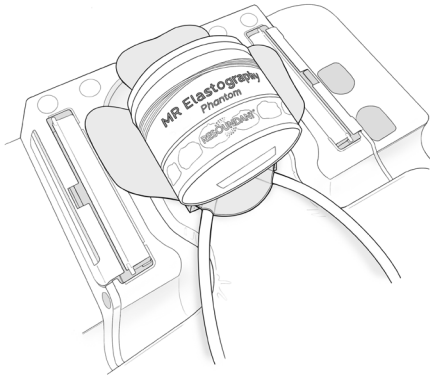
Setup procedure with the Pillow Passive Driver



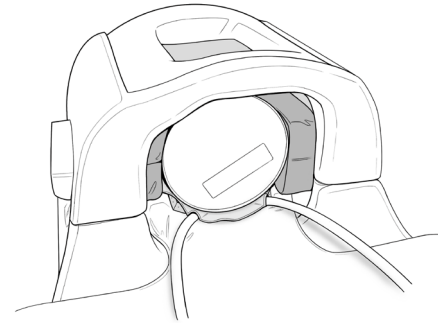
Place the square sponge in the base of the head coil.



Position Pillow Passive Driver on top of the sponge centered in the head coil.



Position the MRE Phantom on its side, centered on the Pillow Passive Driver.



Place the top of the head coil in position and add sponges on each side of the Phantom to keep it centered in the coil.

The Phantom is now ready to scan.



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



Authorized Representative
in Europe



MR Safe



Medical device



CE mark for Europe



Swiss Authorized
Representative



General warning

Contents

- 1 Phantom
- 1 Friction Pad
- 1 User Guide

Weight / Dimensions

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



Conditions of Normal Use

Warning: DO NOT use the Phantom if it appears to be damaged or cracked. For additional warnings please check with the operation 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 4)

Disposal

(see Care and Handling – page 4)



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
Email: mreinfo@resoundant.com
URL: www.resoundant.com

**Authorized European Representative:**

VISAMED GmbH
Kastellstrasse 8
D-76227 Karlsruhe
Germany
URL: www.visamed.com

**Swiss Authorized Representative:**

AJW Technology
Consulting GmbH
Kreuzplatz 2, CH-8032
Zurich, Switzerland

UK Authorized Representative:

UK-REP: AJW Technology
Consulting Ltd.
4/4a Bloomsbury Square, London,
United Kingdom, WC1A 2RP

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RESOUNDANT, INC.
421 1ST AVE SW STE 204W
ROCHESTER, MN 55902 USA
+1 507 322 0011
MREINFO@RESOUNDANT.COM
RESOUNDANT.COM

