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PILLOW PASSIVE DRIVER KIT
INSTRUCTIONS FOR USE

RESOUNDANT®

CONTENTS

Introduction

Resoundant's MR Elastography Pillow Passive Driver is constructed with a soft flexible material that provides consistent, high-quality MRE results. The Pillow Passive Driver is designed for brain MRE, with a head coil. It can also be used for other body areas as indicated. The Pillow Passive Driver comes with a 10 cm-wide belt for applying to other body areas.

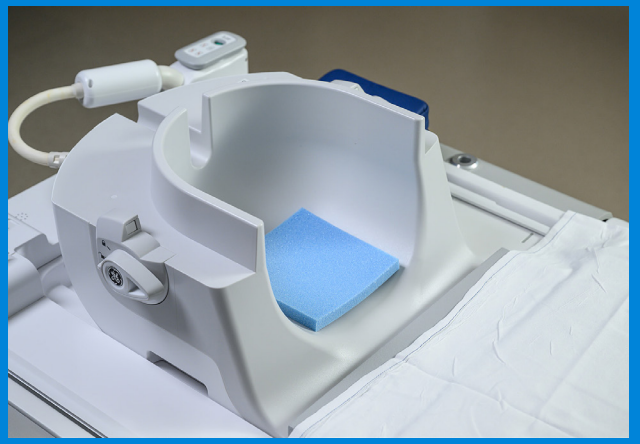
The Instructions for Use will illustrate how to correctly position and secure the Pillow Passive Driver in a Head coil for the brain, or for use in other areas of the body.

Pillow Passive Driver Kit

Pillow Passive Driver Setup

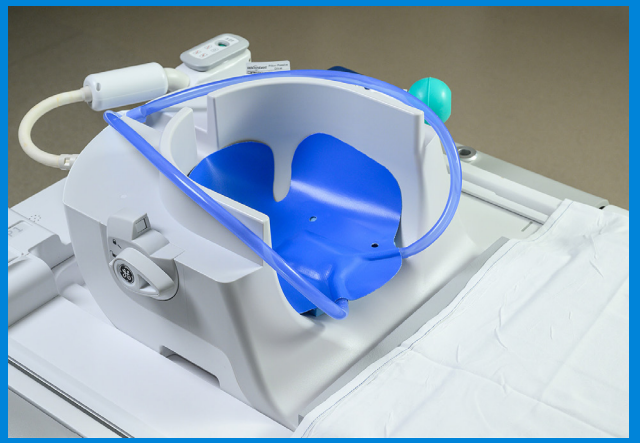
Brain applications

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



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

Place the supply tubes over the top of the head coil base.



Place the patient in the head coil centered over the Pillow Passive Driver and move the supply tubes to the patient's chest. Use the squeeze bulb to ensure the patients head is centered on the driver and moves straight up and down as the bulb is squeezed. Stabilize the patients head position with a sponge on each side of the patient's head.

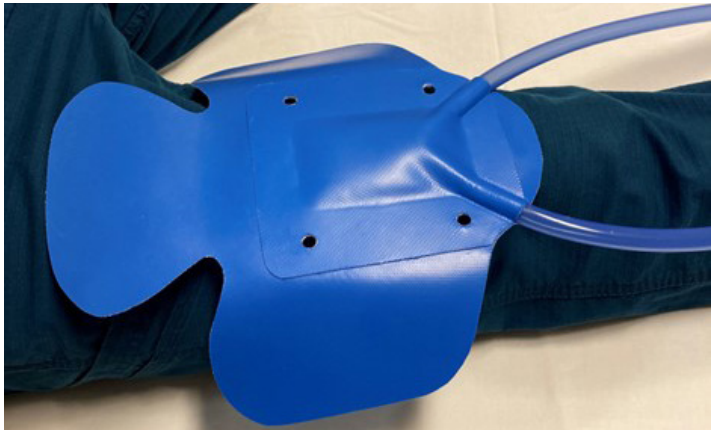
An optional pillowcase may be placed between the Pillow Passive Driver and the patient's head.

Place the top section of the head coil in position. Remove the squeeze bulb and connect the driver to the main supply tube.

The Patient is now ready to scan.

Other Body Areas

The Pillow Passive Driver can be applied to other body areas of interest with the aid of the included belt assembly.

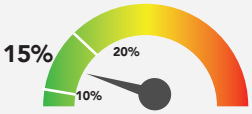
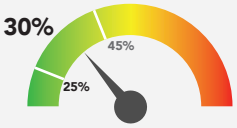


Position the Pillow Passive Driver and secure firmly with the adjustable belt assembly.

Confirm Amplitude Settings

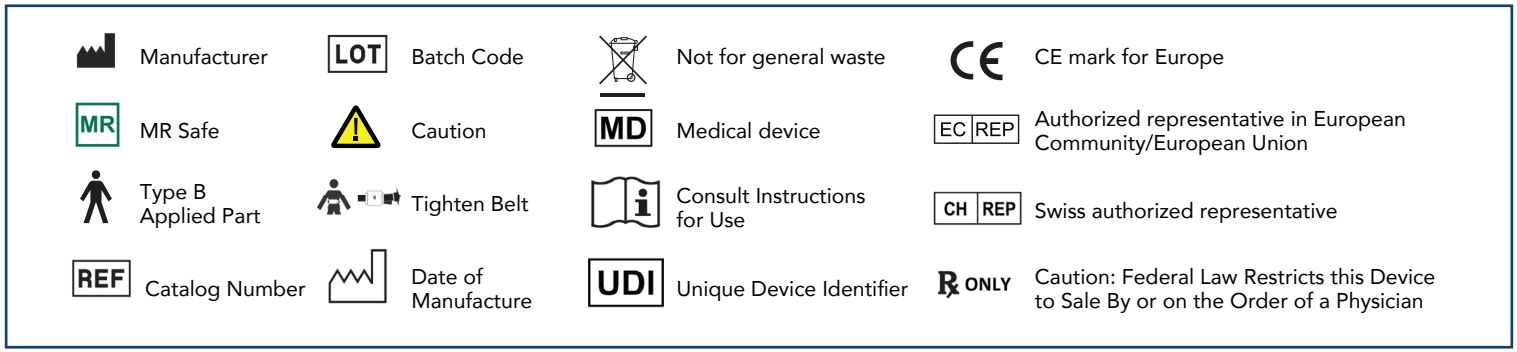
Selection of the Passive Driver and amplitude settings for the Active Driver will help ensure adequate vibrations throughout the body area of interest while optimizing patient comfort.The Passive Driver selection and amplitude is at the discretion of the MR technologist to achieve diagnostically viable images.

The following recommendations serve as guidelines based on body area and patient profile.

Patient Body Areas	Pillow Passive Driver	Comments
 Avg size		⚠ For brain MRE, do **not** exceed 20% amplitude setting
 Normal BMI		Amplitude settings based on body part size.

Regulatory Information

Use of Symbols



Contents
1 Pillow Passive Driver; 1 Foam Pad, 1 Belt, 1 Squeeze Bulb Positioner tool, reference to Electronic User Guide/Instructions for Use

Weight / Dimensions
Pillow Passive Driver, Wt. 253 g. Dim: 29cm x 28.2cm., Tube 88cm length, Belt 10 cm x 140 cm

Indications for Use
The Pillow Passive Driver is an optional accessory for use with the Resoundant MR Elastography System. It is intended for use with magnetic resonance diagnostic device (MRDD) that include legally marketed MR elastography capabilities. It is indicated for generating acoustic vibrations in the body during an MRI exam to assess tissue elasticity for diagnostic purposes as part of magnetic resonance elastography (MRE). When interpreted by a trained physician, this information can be useful in determining a diagnosis.

Contraindications: Consistent with contraindication to MRI including but not limited to cardiac pacemakers, intraocular or intracranial metal, or other MRI incompatible devices. Aneurysm clips, even if MR safe, are contraindicated for brain MRE..

Residual risks: Appropriate control measures have been applied to all known risks associated with the Flex Passive Driver. 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.

General warnings:

- See MAINTENANCE section for compatible cleaning agents.
- DO NOT use the Pillow Passive Driver if it appears damaged or cracked.
- If any part of the Pillow Passive Driver has become contaminated by human body fluids, dispose of in accordance with local regulations.
- Excessive amplitude can result in patient discomfort

Precaution: Read and understand this document.

Special Patient Populations: None - see guidelines for setting amplitude based on patient size

Adverse Reactions: None

Quality Assurance: Prior to using the Resoundant Pillow Passive Driver, follow the MR Elastography System setup instructions from the MRI Scanner OEM. Once installed, check all the parts and connections to ensure that the system is functioning properly.

Conditions of Normal Use: In normal use, the acoustic pressure is detectable by the user with no discomfort to the patient. The normal patient experience ranges from mild to moderate vibration sensations. The most common fault condition results in no acoustic pressure or vibrations. The unlikely fault condition of high pressure may be perceived as uncomfortable.

Intended Users: Installation and maintenance of the Resoundant MR Elastography System should only be performed by trained service personnel familiar with the specific MRDD. MRE acquisitions should only be performed by trained MR Technologists, to ensure comfort and safety of the patient and collection of diagnostically useful data. Analysis diagnosis/reporting on the acquired data should be performed by board certified medical professionals. CAUTION: (US) Federal law restricts this device to sale by or on the order of a physician.

Environmental Specifications:
Operating Temperature Range: 10.0°C to 33.3°C (50°F to 92°F)
Non-operating Temperature Range: -20°C to 60°C (-4°F to 140°F)
Operating humidity range: 10% to 85% RH, non-condensing
Non-operating humidity range: 10% to 95% RH, non-condensing
Operating and non-operating atmospheric pressure range: 700 - 1060 mbar

Installation and Troubleshooting of the System components: Please refer to the service manual of the MRI scanner OEM for installation and configuration information. Technical support for the Resoundant MR Elastography system may be obtained by utilizing the following sources:

OEM Technical Support - Refer to your MRI scanner OEM technical support documentation.
Worldwide Web - MRI scanner OEM trained service representatives may access trouble shooting procedures at: www.resoundant.com/support

Maintenance:

Cleaning Instructions, Passive driver:
- Never place the components into any type of sterilizer;
- Do not use alcohol-based cleaners on the passive driver.

Clean the components with:
- Hydroxide solution of 0.5% concentration by volume;
- A damp cloth containing a mixture of mild soap and water;
- Avoid allowing excess liquids on the interior of the Passive Driver;
- Allow components to dry completely before next use.

Storage: Store the Pillow Passive Driver flat on a shelf.

Disposal: For disposal of the Pillow Passive Driver at the end of useful life, please dispose of in accordance with local regulations, or contact Resoundant Inc. at phone 507.322.0011, via email, MREinfo@resoundant.com

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 Pillow Passive Driver. If an accident occurs as a result of Pillow Passive Driver use, discontinue use until an authorized investigation is conducted.

Standards
IEC 60601-1
ISO 15223-1

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