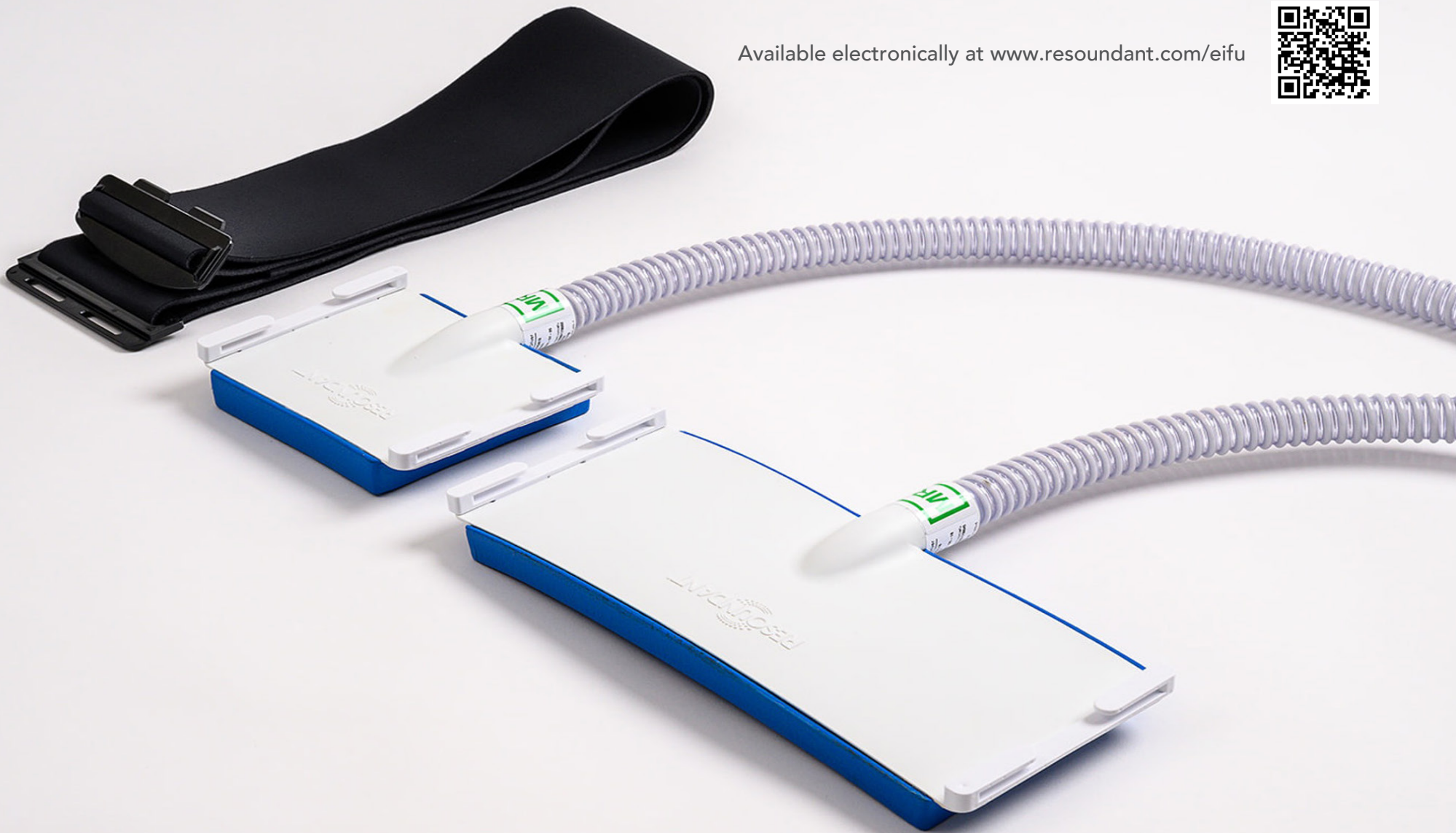


Available electronically at www.resondant.com/eifu



FLEX PASSIVE DRIVER

INSTRUCTIONS FOR USE



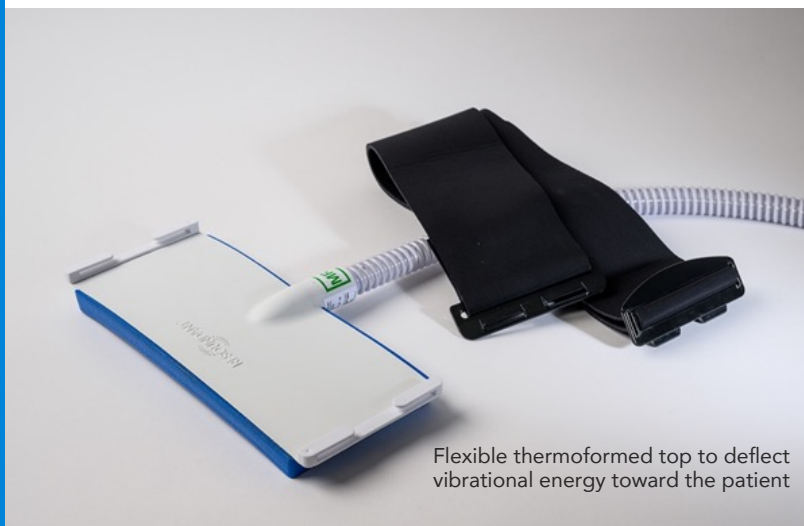
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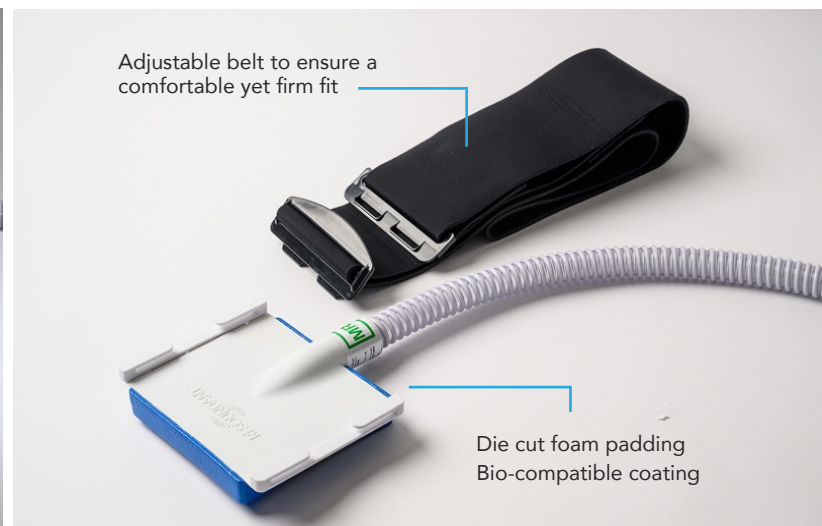
Introduction

Resoundant's MR Elastography (MRE) Flex Passive Driver and Flex Passive Driver Small are constructed with soft foam material that provides a superior level of comfort while delivering consistent, high-quality MRE results. The Flex Passive Drivers come with a 10 cm-wide belt assembly that slips through the driver guides and clips to itself for an adjustable custom fit. Additional belt assemblies are available separately should a belt need to be replaced.

This User Guide will illustrate how to correctly position and firmly secure the Flex Drivers to ensure an enhanced patient experience, improve usability, and promote technical success.



Flex Passive Driver



Flex Passive Driver - Small

Each size available and ordered separately.

Flex Driver Setup



Place the belt flat on the MR scanner table at the level of the diaphragm, smooth side up with the non-adjustable clip on the patient's right side.

Place the patient on the scanner table in the supine position.

The Passive Driver should be placed over the patient gown, centered over the area of interest. For the liver, place the edge of the Passive Driver where the patient's right side meets the table (see picture), centered at the level of the xiphoid process. Tubing may extend toward the head or feet, whichever is best supported by the installation.

Place the belt through the belt guides on each end of the Passive Driver. Connect the belt clips.



1.

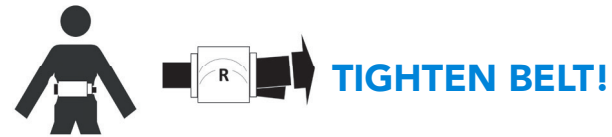


2.

3.



Tighten the Driver by pulling firmly on the belt ensuring the Driver is firmly secured and patient can breathe normally.



4.



Final Setup position for the Flex Driver - Large

5.



Note: Final setup position for the Flex Driver – Small.





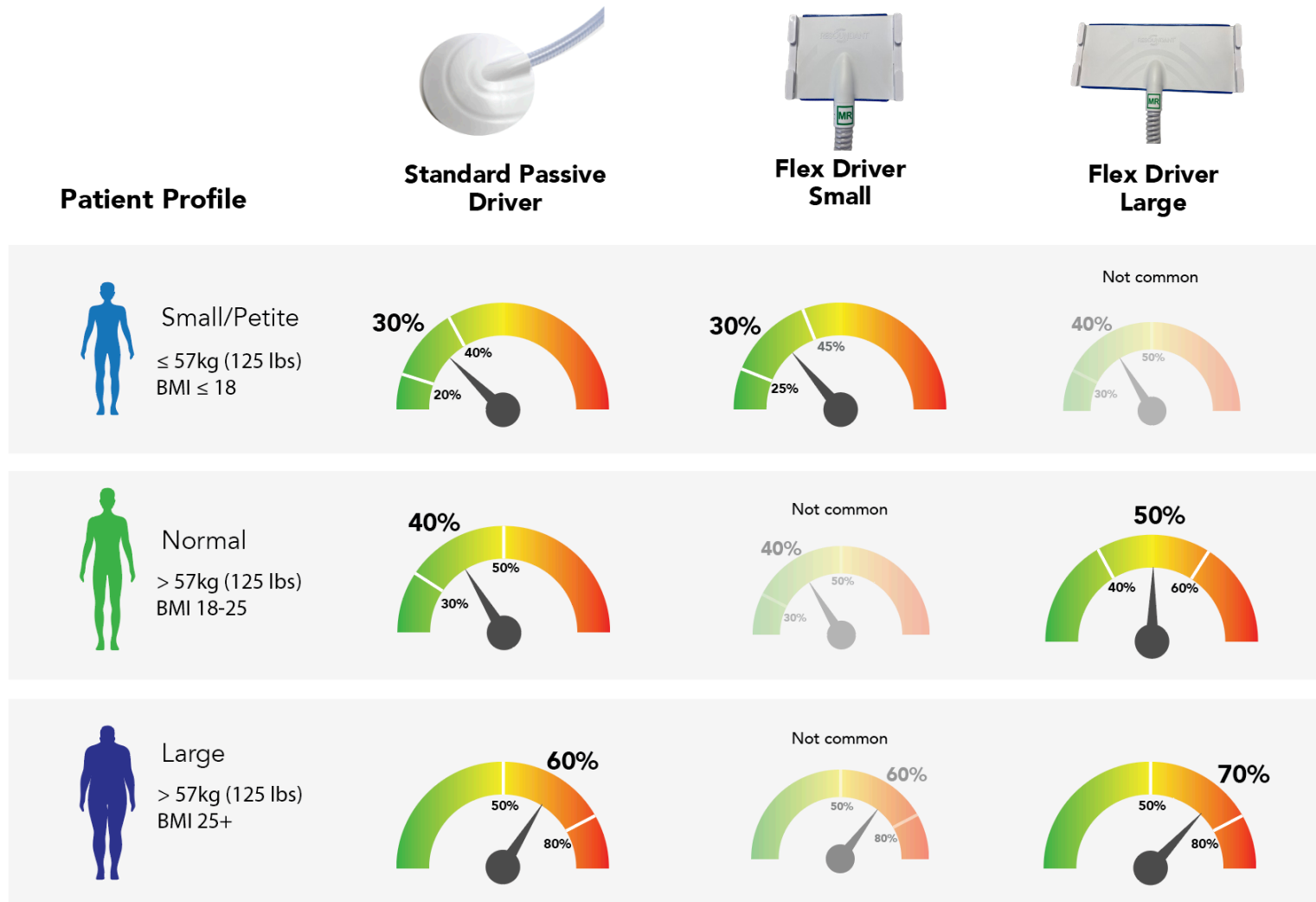
To ensure a successful MRE exam, the Flex Driver must be properly positioned and firmly secured to the patient by tightening the attached belt.



Confirm Amplitude Settings

Selection of correct passive driver and corresponding active driver amplitude will help ensure adequate vibrations while optimizing patient comfort.

















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 patient profile and/or Body Mass Index (BMI).



*Vibration from smaller drivers may be perceived to be less comfortable than larger drivers when supplied with equal amplitudes.

Regulatory Information

Use of Symbols

 Manufacturer	 Batch Code	 Not for general waste	 CE mark for Europe
 MR Safe	 Caution	 Medical device	 Authorized representative in European Community/European Union
 Type B Applied Part	 Tighten Belt	 Consult Instructions for Use	 Swiss authorized representative
 Catalog Number	 Date of Manufacture	 Unique Device Identifier	 Caution: Federal Law Restricts this Device to Sale By or on the Order of a Physician

Contents

1 (Large or Small) Flex Passive Driver; 1 Belt; 1 User Guide/Instructions for Use

Weight / Dimensions

Flex Passive Driver Large: Weight. 500 grams; Dimensions: 29.7 cm x 13 cm x 3 cm, Tube 40 cm length, Belt 10 cm x 140 cm

Flex Passive Driver Small: Weight. 400 grams; Dimensions: 15.5 cm x 13 cm x 3 cm, Tube 40 cm length, Belt 10 cm x 140 cm




Indications for Use

The Flex Passive Driver is an accessory for use with the Resoundant MR Elastography (MRE) 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 a Magnetic Resonance Imaging (MRI) exam to assess tissue elasticity for diagnostic purposes as part of MRE. When interpreted by a trained physician, this information can be useful in determining a diagnosis.

Contraindications: None.

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 Flex Passive Driver if it appears damaged or cracked.
-  If any part of the Flex Passive Driver has become contaminated by human body fluids, dispose of in accordance with local regulations.

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 Flex Passive Driver, follow the MRE System setup instructions from the MRI Scanner Original Equipment Manufacturer (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 MRE 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: United States 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:

Hydrogen Peroxide 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 Flex Passive Driver flat on a shelf.

Disposal: For disposal of the Flex Passive Driver at the end of useful life, please dispose of in accordance with local regulations, or contact Resoundant Inc. at phone +1 507.322.0011, 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 Flex Passive Driver. If an accident occurs as a result of Flex Passive Driver use, discontinue use until an authorized investigation is conducted.

Standards

IEC 60601-1

ISO 15223-1

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