RESOUNDANT®

Instructions for Use

for the Resoundant MR Elastography System

RESYS4001- RESYSAB

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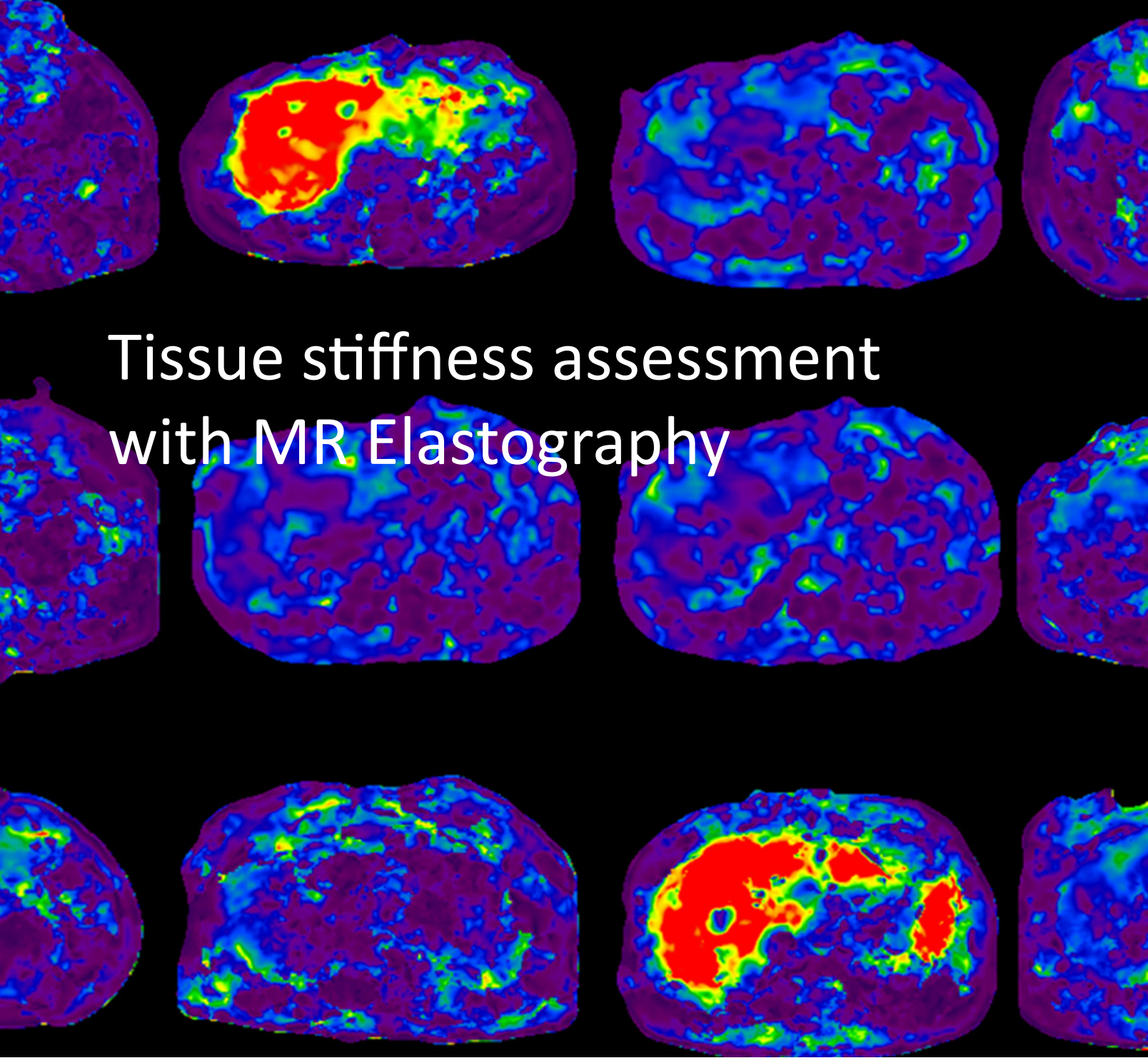

Tissue stiffness assessment with MR Elastography

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Section 1 - Introduction

This manual describes the features, use, safety precautions and care of the Resoundant MR Elastography System (RESYS4001-RESYSAB). Please review this manual thoroughly before using the **Active Driver** and **Passive Driver** components.

If you have any questions or need assistance with the use of the product, please contact the Magnetic Resonance Imaging (MRI) scanner Original Equipment Manufacturer (OEM) service representative.

1-1 Shipping Contents

1-1-1 Active Driver Box

DESCRIPTION	QUANTITY
A. ACTIVE DRIVER	1
B. EUROPEAN POWER LINE CABLE (25 ft; 7.62 m)	1
C. US POWER LINE CABLE (20 ft; 6.09 m)	1
D. INSTRUCTIONS FOR USE	1

1-1-2 New Installation Accessories

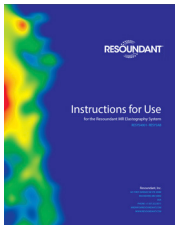
DESCRIPTION	QUANTITY
E. PASSIVE DRIVER	2
F. BELT	1
G. TUBING - LONG (30 ft; 9.14 m); OD: 1 in (25 mm)	1
H. TUBING - SHORT (9 ft; 2.74 m); OD: 1 in (25 mm)	1
I. BNC CABLE (50 ft; 15.24 m)	1
J. ETHERNET CABLE (50 ft; 15.24 m)	1
K. MRE PHANTOM KIT (MRE PHANTOM, FRICTION PAD AND USER GUIDE)	1

A

B

C

D



E

F

G

H

I

J

K

1-2 System Description

The Resoundant MR Elastography System is an accessory to be used in conjunction with the hardware and software of compatible MRI systems. The device is rated as IPX-0 and is a Type B Applied Part. The system consists of an **Active Driver**, **Passive Driver** and supporting components. While the Resoundant system may be used in conjunction with imaging systems, it does not control the imaging system in any way. For additional descriptions, refer to the operator and service manual of the MRI scanner OEM.

1-3 Instructions for Use Information

These Instructions for Use provide information on the specifications, operation and maintenance of the Resoundant MR Elastography System. All users should read these Instructions for Use before using the **Active Driver** and **Passive Driver** components.

1-4 Use of Symbols

Operator should understand the following symbols:

On (power)


Off (power)


General Warning


Refer to Instruction Manual/Booklet


WEEE (Waste Electrical and Electronic Equipment)

Humidity Limitation

Temperature Limitation


Keep Dry


Fragile, Handle with Care


This Side Up


Type B Applied Part


CE Mark for Europe

UL Compliance for US


Alternating Current

MR Safe

MR Unsafe


Manufacturer


Protective Earth; Protective Ground

Authorized Representative in the European Community

Swiss Authorized Representative

Caution: Federal Law Restricts this Device to Sale By or on the Order of a Physician

Medical Device

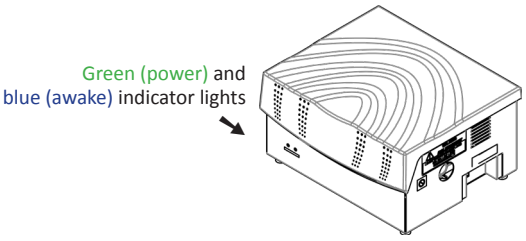

Tighten Belt

1-5 Safety

These Instructions for Use contain information on the positioning and use of the Resoundant MR Elastography System. **The instructions should be read carefully and thoroughly before using this system.** For further details, review the warnings in the operator and service manual of the MRI scanner OEM.

1-5-1 System Operating Safety

Always follow proper safety, operating and maintenance procedures to prevent exposure to electrical or mechanical hazards that may cause injury.



NOTE - INDICATOR LEDs: The **Active Driver** front panel includes a **green indicator** light for **Power** and **blue indicator** light to indicate **Awake** (ready to output acoustic energy). Both lights should be illuminated prior to and during an MRE exam. If the Awake light is not illuminated, turn the **Active Driver** off for five (5) seconds and then back on, or input a UDP command over the Ethernet channel in order to reset the **Active Driver** to an Awake state.

1-5-2 Patient Safety

Patient safety and comfort should be the primary concern during use of the Resoundant MR Elastography System. Risks for an MRE exam are similar to those for any MRI exam. For further details, review the warnings in the operator and service manual of the MRI scanner OEM.

1-5-3 Equipment Safety

All personnel using the Resoundant MR Elastography System should be instructed in the proper connection, use and handling of the System. This System is a component and to be used in conjunction with the software of compatible MRI systems. Please refer to the operator manual of the MRI scanner OEM for installation and setup instructions.

NEVER PLACE THE ACTIVE DRIVER COMPONENT OF THE SYSTEM IN THE MAGNET/SCAN ROOM.

⚠ Personnel should observe all warnings and cautions that appear in this **Instructions for Use**.

⚠ The Active Driver is not suitable for use in the presence of flammable anesthetics in combination with air or other combustible gases.

⚠ All boxes are MR Unsafe and should NEVER be brought into the magnet/scan room.

⚠ This equipment is not protected against ingress of liquids.

⚠ Multiple components in this device are designated MR UNSAFE and are only intended for installation where the field strength is less than five (5) gauss (0.5 millitesla).

⚠ Use of this equipment adjacent to or stacked with other equipment should be avoided as it may result in improper operation. If such use is required, all equipment should be monitored to verify normal operation.

⚠ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the **Active Driver**. Otherwise, degradation of the performance of this equipment could result.

- Before each use, visually check the components (**Passive Driver**, tubing connections, belt, etc.) for any external damage. DO NOT use the components if there is any visual damage.
- ALL components must be used with care.
- For additional warnings please check with the operator and service manual of the MRI scanner OEM.

1-5-4 Electrical and Mechanical Safety

The Resoundant MR Elastography System consists of both electrical and mechanical components. Service personnel must have specialized training to ensure the safe operating condition of the components.

UL CLASSIFIED DEVICE:
MEDICAL - GENERAL MEDICAL EQUIPMENT
TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH ANSI/AAMI ES60601-1:2005/(R)2012 AND A1:2012, C1:2009/(R)2012 AND A2:2010/(R)2012, CAN/CSA C22.2 NO. 60601-1:14
CONTROL NO. E474010

TO AVOID RISK OF ELECTRIC SHOCK, THIS EQUIPMENT MUST ONLY BE CONNECTED TO A MAINS POWER WITH PROTECTIVE EARTH.

⚠ Only properly trained and qualified personnel should be authorized to install and service the Resoundant MR Elastography System.

⚠ Position the equipment in such a way that the power cord is accessible for disconnection.

⚠ Use of accessories or cables other than those specified or provided by Resoundant could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment, resulting in improper operation.

⚠ Remove **Power Line Cable** (US or European) before connecting or disconnecting **Ethernet** or **BNC Cable**, or before attaching or detaching **Tubing** to the **Active Driver**.

⚠ Connect **Ethernet** and **BNC Cable** only to ISO 60601 or IEC 60950 certified devices.

- **Power Line Cables** are provided for EU, US and compatible regions. If replacement is required, only use a **Power Line Cable** that is approved by a regional Authority Having Jurisdiction.

Electrical input:
100-240 V~
50/60Hz
250VA

NOTE - EMISSIONS: the emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in an environment for which CISPR 11 class B is normally required, this equipment may

not offer adequate protection to radio-frequency communication services. The user may need to take mitigation measures, such as relocating or re-orienting the equipment.

1-5-5 Modifications

Any changes or modifications to the components must be approved by Resoundant or its designee prior to installation.

NOTE - FUSE: Replace fuse(s) with M 4A H 250V, Medium-blow, 4 Ampere, High Breaking Current (200A minimum), 250V rated, 5 x 20mm cartridge.

NOTE - DO NOT DISABLE SLEEP TIMER: Disabling Sleep Timer may reduce system life.

1-5-6 Residual Risks

- Appropriate control measures have been applied to all known risks associated with the Resoundant MR Elastography System. 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.

1-5-7 Reporting of Incidents

- Users should contact their local MRI scanner OEM field representative immediately to report an incident and/or injury to an individual, operator or maintenance employee that occurred as a result of system operation.
- If an accident occurs as a result of system operation, do not operate the equipment until an authorized investigation is conducted.

1-5-8 Manufacturer

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

1-5-9 Authorized Representatives

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

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

CH REP

Swiss Authorized Representative:
AJW Technology
Consulting GmbH,
Kreuzplatz 2, CH-8032
Zurich, Switzerland

1-6 Environmental Requirements

NEVER PLACE THE ACTIVE DRIVER COMPONENT OF THE SYSTEM IN THE MAGNET/SCAN ROOM.

Install the **Active Driver** component of the System in an air-conditioned equipment room or room other than the scan room.

1-6-1 Environmental Specifications

Operating Ranges

- Operating temperature range: 10.0°C to 33.3°C (50°F to 92°F)
- Operating and nonoperating humidity range: 10% to 85% 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)
- Shipping/storage humidity range: 10% to 90% RH, noncondensing

1-7 Installation and Troubleshooting of System Components

Installation and configuration of the **Active Driver** and **Passive Driver** components require the services of a trained MRI scanner OEM service representative. 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:

- **Contact MRI scanner OEM Technical Support**: Refer to your MRI scanner OEM technical support documentation.
- **Worldwide Web**: MRI scanner OEM trained service representatives may access troubleshooting procedures at: resoundant.com/support
- **Email**: mreinfo@resoundant.com

Please have the following information ready when contacting Resoundant:

- Serial Number of Resoundant **Active Driver** component
- Indication of MRI scanner OEM
- Clear description of the problem
- Contact details

1-8 External Standards

1-8-1 IEC 60601-1, IEC 60601-1-2

This product conforms to the requirements of IEC 60601-1 2nd edition, 3rd edition, and 3.1 edition and IEC 60601-1-2 4th edition standards.

1-8-2 EMC Table

Refer to MRI manufacturer.

1-8-3 ISO 13485:2016

This product conforms to the requirements of ISO 13485:2016.

1-9 Quality Assurance

Prior to using the Resoundant MR Elastography System on an individual, follow system installation and setup instructions from the MRI scanner OEM. Once installed, power on and check all parts and connections to make sure the system is functioning properly prior to use.

Section 2 - Indications for Use and Setup

2-1 Indications for Use

The Resoundant MR Elastography System is intended for use with magnetic resonance diagnostic devices (MRDD) that include legally marketed MR elastography capabilities. It is indicated for generating acoustic vibrations in the body during an MRI exam in order 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.

2-1-1 Contraindications

None.

2-1-2 Intended Users

Installation and Maintenance by Trained Service Personnel: Installation and maintenance of the Resoundant MR Elastography System should only be performed by trained service personnel familiar with the specific MRDD and capable of safe and effective integration into the target system.

Acquisition by Trained MR Technologists: MRE acquisitions should only be performed by trained MR Technologists, to ensure comfort and safety of the patient and collection of diagnostically useful data.

Review by certified Radiologists: Analysis and diagnosis/reporting on acquired MRE data should only be performed by board certified medical professionals.

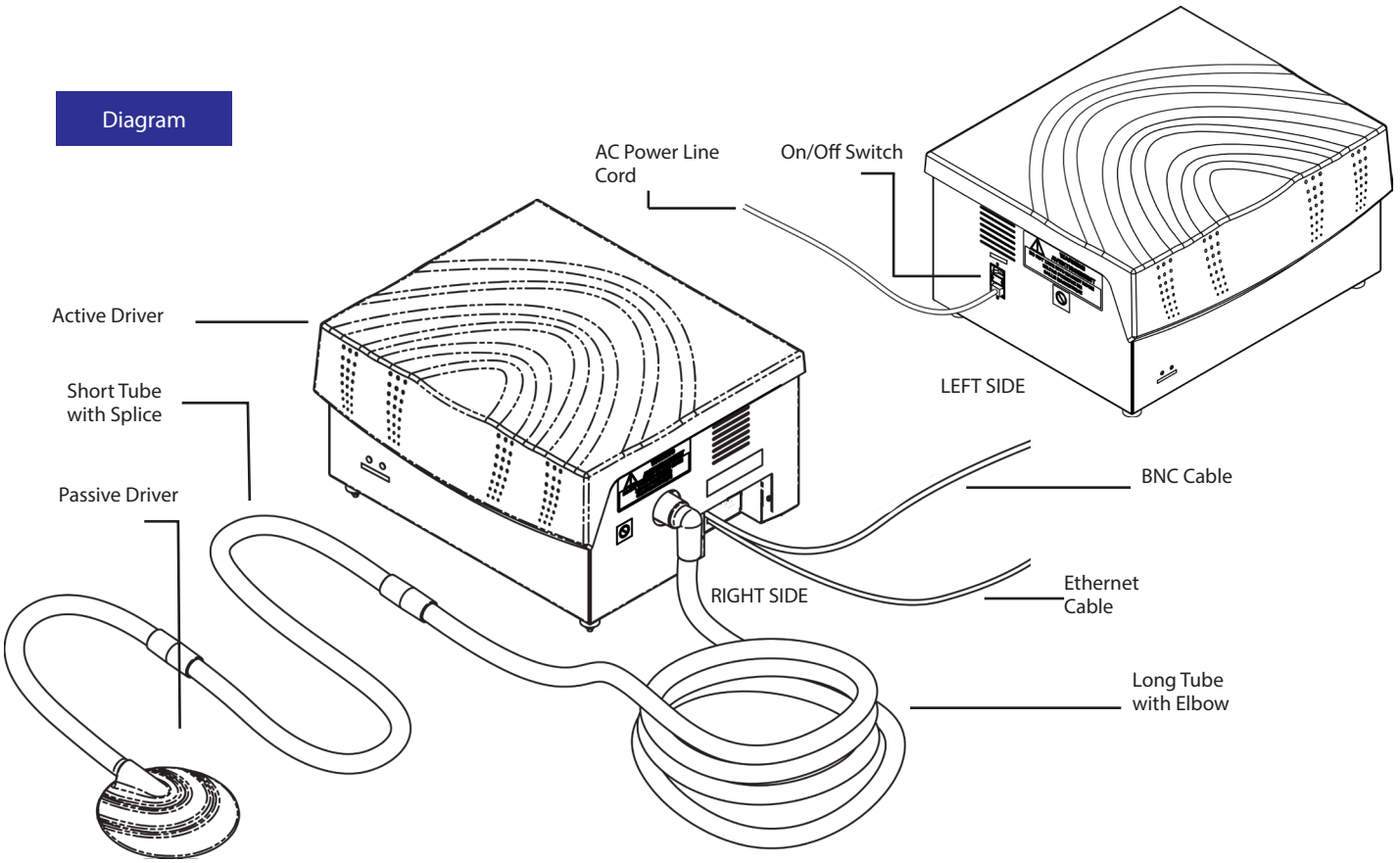
Caution: (US) Federal law restricts this device to sale by or on the order of a physician.

2-2 Active Driver Setup

NEVER PLACE THE ACTIVE DRIVER COMPONENT OF THE SYSTEM IN THE MAGNET/SCAN ROOM.

Please refer to the operator and service manual of the MRI scanner OEM for configuration and setup of the Resoundant **Active Driver** component.

Diagram



Active Driver Dimensions & Weight
21” (53cm) wide
15” (38cm) tall
19” (48cm) deep
Weight: 35lbs (16kg)

2-3 Passive Driver Setup

Positioning and use of the **Passive Driver** is as follows:

1. Prior to patient's arrival in the MRI suite, place the belt on the MR table at the approximate location of the patient's area of interest.

2. The **Passive Driver** should be placed over the patient's clothing or gown, centered over the area of interest.

3. Secure the belt tightly around the patient to hold the **Passive Driver** in position.

Tighten belt!

4. Push and twist to connect the plastic tubing to the **Passive Driver** with the connector shown in photo.

2-4 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 being enjoyable (massage) to numbing. The most common fault condition results in no acoustic pressure. The unlikely fault condition of high pressure may be perceived as uncomfortable.

Section 3 - Maintenance

Durability: The MRE system is expected to last for the lifetime of the MR scanner. The active driver can provide one thousand MRE exams per year with no maintenance. Patient contact parts may become worn or damaged and can be easily replaced.

3-1 System Care

3-1-1 Cleaning Instruction - 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.

3-1-2 Cleaning Instruction - Belt

- Handwash with cool water and mild soap
- Air dry

3-1-3 Cleaning Instruction - Active Driver

DO NOT ATTEMPT TO CLEAN THE RESOUNDANT ACTIVE DRIVER SYSTEM WHILE ATTACHED TO AC POWER SUPPLY.

Unplug the **Active Driver** from the mains power before attempting to clean. Wait for all components to dry completely before next use. Having the **Active Driver** plugged into mains power during cleaning or when it is wet may results in electrical shock.

- Clean the components with a damp cloth containing a mixture of mild soap and water. Cloth should not be so wet as to result in excess liquid run off during component cleaning.
- Any excess liquids which migrate into **MR Elastography System** components may cause shock and/or component failure.
- Wipe with a clean, dry cloth.
- Allow all components to air dry completely before next use.

3-1-4 Storage

Install the Resoundant MR Elastography System components in their designated air-conditioned scan room or equipment room environments. (Refer to Section 1-6 Environmental Requirements).

Store the **Passive Driver** flat on a shelf.

3-1-5 Disposal

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

For the disposal of the system at the end of its useful life, please contact a Resoundant service representative or its designee at Phone 507.322.0011, via email mreinfo@resoundant.com or dispose of in accordance with local regulations.

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