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RESYS4001-RESYSAB

# MR ELASTOGRAPHY SYSTEM

## INSTRUCTIONS FOR USE



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# Section 1 - Introduction

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

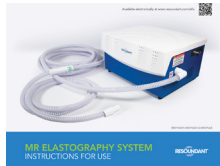
If you have any questions or need assistance with the use of the product, please contact the Magnetic Resonance Imaging (MRI) scanner Original Equipment Manufacturer (OEM) service representative.

# 1-1 Shipping Contents

## 1-1-1 Active Driver Box (RESYS4001) - quantity 1 each



**Active Driver**



**Instructions for Use**  
(in box or provided  
digitally via QR code)



**US Power Line Cable**  
20 ft. (6.09m)



**European Power Line Cable**  
20 ft. (6.09m)



**China Power Line Cable**  
20 ft. (6.09m)

## 1-1-2 Installation Accessories (RESYSAB) ) - quantity 1 each



**Passive Drivers and  
Belt**



**Tubing**  
30 ft. (9.14m)



**Tubing**  
9 ft. (2.74m)



**Ethernet Cable**  
50 ft. (15.24m)



**BNC Cable**  
20 ft. (15.24m)



**Fiber Optic Cable**  
32.8 ft. (10m)



**Passive Drivers:**  
Instructions for Use



**MRE Phantom Kit:**  
Phantom, Friction Pad,  
Instructions for Use

## 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 MRE System is composed of an Active Driver, Passive Driver(s), supporting cabling and tubing components, and MRE Phantom.

The Active Driver creates pneumatic pressure. When connected to a Passive Driver via tubing, it can impart motion to subjects necessary for acquiring MRE. The Passive Driver is a Type B applied part.

While the Resoundant system may be used in conjunction with imaging systems, it does not control the imaging system in any way. No patient information is transmitted to the Active Driver.

For additional descriptions, refer to the operator and service documentation of the MRI scanner.














## 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:

-  On (power)
-  Off (power)
-  General Warning
-  Refer to Instruction Documentation/ 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
-  ETH
-  Network port (100Mbps, RJ-45)
-  TRIGGER IN Trigger input, electrical, TTL (0-5V), BNC connector
-  IN Trigger input, optical, Versatile Link (VL) connector

-  Reset Switch Hold 0-4s to Wake Hold 5 – 9s to Reset Network Hold >10s to Factory Reset
-  UL Compliance for US
-  Alternating Current
-  MR Safe
-  MR Unsafe
-  Manufacturer
-  Protective Earth; Protective Ground
-  EC REP Authorized Representative in the European Community
-  CH REP Swiss Authorized Representative
-  Caution: Federal Law Restricts this Device to Sale By or on the Order of a Physician
-  MD Medical Device
-  Tighten Belt
-  OUT Trigger output, optical, Versatile Link (VL) connector. Follows optical input.

-  Power Status (Green LED)
-  ? System status (Blue LED) lit (steady) = Awake; Unlit = Sleep, low power

## 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 documentation of the MRI scanner.

### 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 side 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.



Green (power) and blue (awake) indicator lights








### 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 documentation of the MRI scanner.

### 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 documentation of the MRI scanner 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 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 documentation of the MRI scanner .

## 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.

 **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 China regions. If replacement is required, only use a **Power Line Cable** that is approved by a regional Authority Having Jurisdiction.

**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.

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

## 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 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

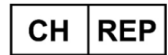


Resoundant, Inc.  
421 First Avenue SW STE204W  
Rochester, Minnesota 55902 USA  
Phone: +1 507.322.0011  
Email: mreinfo@resoundant.com

## 1-5-9 Authorized Representatives



VISAMED GmbH  
Kastellstrasse 8  
D-76227 Karlsruhe  
GERMANY  
URL: [www.visamed.com](http://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

## 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 environmentally controlled equipment room or room other than the scan room.

## 1-6-1 Environmental Specifications

### Operating Ranges

- Operating temperature range: 10°C to 33°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 95% 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 service representative. Please refer to the service documentation of the MRI scanner for installation and configuration information.

Technical support for the Resoundant MR Elastography System may be obtained by utilizing the following sources:

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

Please have the following information ready when contacting Resoundant:

- Serial Number of Resoundant **Active Driver** component
- Indication of MRI scanner
- 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:

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

### 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. 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.

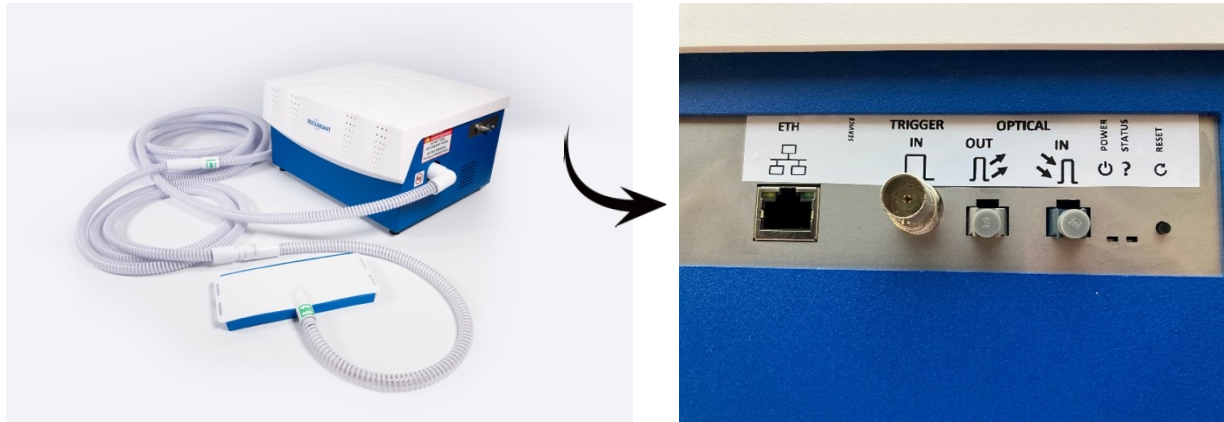
Caution: (US) Federal law restricts this device to sale by or on the order of a physician.

## 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 documentation of the MRI scanner for configuration and setup of the Resoundant **Active Driver** component.



Active Driver Dimensions & Weight:

- 20" (51cm) wide
- 11" (28cm) tall
- 17" (44cm) deep Weight: 33lbs (16kg)



## 2-3 Passive Driver Setup

For Positioning and Use, visit [www.resoundant.com/eifu](http://www.resoundant.com/eifu) and look for the relevant **passive driver** IFU.



### Passive Driver Options:



**Round Rigid Passive Driver**



**Flex Passive Drivers**



**Pillow Passive Driver**

## 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 to numbing. The most common fault condition results in no acoustic pressure. The unlikely fault condition of high pressure may be perceived as uncomfortable.



**ADVISORY:** Incorrect acquisition or post-processing can lead to incorrect MRE results.

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

## Section 3 - Maintenance

Patient contact or detachable 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:

- 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.

#### 3-1-2 Cleaning Instruction - Belt

- Handwash with cool water and mild soap
- Air dry

### 3-1-3 Maintenance instruction – Active Driver

Active Driver is expected to last for the lifetime of the MRI scanner with no maintenance or calibration. There are no serviceable parts inside of the driver system.

Degradation or loss of performance can be corrected through replacement of the unit. Contact your MR service team for options.

External surfaces may be cleaned with damp cloth and mild soap and water. The Active Driver is IPX-0 rated, and therefore is not sealed against ingress of water. DISCONNECT AC POWER BEFORE CLEANING. Allow to dry before completely before use.

### 3-1-4 Storage

Install the Resoundant MR Elastography System components in their environmentally controlled equipment room. (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 +1 507.322.0011, via email mreinfo@resoundant.com or dispose of in accordance with local regulations.

RESYS4001-RESYSAB

# MR ELASTOGRAPHY SYSTEM INSTRUCTIONS FOR USE

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