Operator's Manual

SureWave™ Elastography

For Siemens Healthineers 1.5T and 3T MRI Systems

www.qualityelectrodynamics.com

QED REF	Siemens
Q7000225	11787935

Warranty and Liability

The responsibility for maintenance and management of the product after delivery resides with the customer who has purchased the product. The warranty does not cover the following items, even during the warranty period:

- Damage or loss due to misuse or abuse.
- Damage or loss caused by Acts of God such as fires, earthquakes, floods, lightning, etc.
- Damage or loss caused by failure to meet the specified conditions for this equipment, such as inadequate power supply, improper installation, or unacceptable environmental conditions.
- Damage due to changes or modifications made to the product.

In no event shall QED be liable for the following:

- Damage, loss, or problems caused by relocation, modification, or repair performed by personnel not explicitly authorized by QED.
- Damage or loss that results from negligence or from ignoring the precautions and operating instructions contained in this operation manual.

Transportation and Storage Conditions

This equipment shall be transported and stored under the following conditions:

	Temperature	-20°C to +60°C
	Relative humidity	10% to 90%

Shock indicators for monitoring transport are affixed to the packaging. If the shock indicator is activated as shown by a red color inside the glass tube, the device was not handled with the required care. However, an activated shock indicator does not necessarily indicate damage to the device.

CAUTION

If the device packaging is exposed to environmental conditions outside of the transportation and storage conditions, the packaging is damaged, the packaging is opened prior to delivery, or the shock indicator is activated, complete Quality Assurance testing prior to actual use. If the device passes QA testing, it may be used normally.

United States Federal Law

Caution: Federal law restricts this device to sale, distribution, and use by or on the order of a physician. The device is limited by Federal Law to investigational use for indications not in the Indications Statement.

About This Manual

This manual contains detailed information on the safety precautions, use, and care of the SureWave™ Elastography device.

CAUTION	For safety and accuracy in using the product, read this manual as well as the MRI coil and system operation manuals carefully prior to operation of the product. This manual does not include instructions or safety information on equipment not provided by QED, such as the MRI coil and system. Please consult the MRI system manufacturer for information regarding non-QED equipment.

The operator's manual is available online as a PDF file at www.qualityelectrodynamics.com. To request a paper copy of the operator's manual, please email info@qualedyn.com or complete the contact form at www.qualityelectrodynamics.com.

Legend

In this manual, the following symbols are used to indicate safety and other important instructions. The signal words and their meanings are defined below.

WARNING

WARNING must be heeded to avoid a hazardous situation that could result in death or serious injury.

CAUTION

CAUTION is necessary to avoid a hazardous situation, which, if not avoided, could result in minor or moderate injury.

INFORMATION

Emphasizes important details or provides information on how to avoid operating errors or other potentially hazardous situations, which, if not observed, may result in property damage.

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Chapter 1 – Introduction

1.1 Description

SureWave™ Elastography is an accessory to be used in conjunction with a compatible Magnetic Resonance Imaging (MRI) system for Magnetic Resonance Elastography (MRE) to produce visual maps (elastograms) of the liver, indicative of tissue stiffness of the imaged anatomy.

1.2 Operating Principle

SureWave™ Elastography is composed of both hardware and software. The hardware, which includes a tower, axes, and transducer, induces shear wave vibrations in tissue during the MRI scan. The hardware is IP X-0 rated and is a Type B applied part. The software transforms the data acquired with a suitable motion-encoded MRI sequence into elastograms that indicate the stiffness of the tissue.

1.3 Operating Environment and Compatibility

SureWave™ Elastography is intended to be used in conjunction with Siemens Healthineers 1.5T or 3T MRI system in a specialized healthcare facility. SureWave™ Elastography is compatible with Siemens MRI system software version syngo MR XA60 or above.

1.4 User Profile

Operator – Radiologic technologists, laboratory technologists, physicians (all applicable laws in the relevant country must be followed).

User training – Training is available through Siemens Healthineers Applications Specialists.

1.5 Patient Information

Age, health, condition – SureWave™ Elastography is intended for adult patients.

Weight - SureWave™ Elastography has no specific weight limitations. Consult the MRI system operation manual for system weight restrictions.

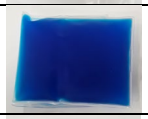
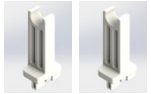
1.6 Clinical Benefits

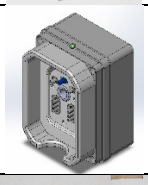
Magnetic Resonance Elastography can be used to evaluate the elasticity (or stiffness) of the organs of the body, particularly the liver. The use of MRE can help health care providers diagnose and determine the stage of certain conditions, such as liver fibrosis.

Chapter 2 – SureWave™ Elastography Components

SureWave™ Elastography is shipped with the parts shown below. Upon receipt, please ensure that all parts are included in the shipment.

2.1 SureWave™ Elastography Starter Kit

Box #	Item #	Description	Quantity	Siemens Part #	QED Part #	Illustration
1	1	MRE Tower	1	11.852.014	MAC000153	
	2	MRE Axis Hanger	1	11.852.033	MAC000160	
2	3	MRE Axis	3*	11.852.024	MAC000167	
3	4	MRE Transducer	1	11.852.023	MAC000166	
	5	MRE Gel Pad	2*	11.852.021	MAC000164	
	6	MRE Transducer Fabric Cover	2*	11.852.022	MAC000169	
	7	MRE Gel Phantom†	1	11.852.026	MAC000168	
	8	MRE Strap M MRE Strap XXL	1 1	11.852.027 11.852.028	MAC000172 MAC000165	
	9	MRE Axis Clips	2 2	11.852.029 11.852.030	MAC000170 (DaGama) MAC000171 (DaVinci)	

Box #	Item #	Description	Quantity	Siemens Part #	QED Part #	Illustration
	10	MRE Power Supply Box	1	11.852.016	MAC000155	
4	11	MRE Wall Socket System Connector	1	11.852.025	MAC000157	
	12	MRE Filter Panel	1	11.852.017	MAC000161	
	13	MRE Optical Cable Set	1	None	2004050	
	14	Floor Marking Tape 2" Blue	1	None	3009331	

*Spare component included in kit; store spare MRE Axis in straight orientation.

† Discard dispenser and product insert; these are not used with SureWave™ Elastography.

2.2 SureWave™ Elastography Installation Hardware Kits

> **i** The following SureWave™ Elastography Installation Kits are necessary to enable use in multiple MR scan room(s).

SureWave™ Elastography Installation Kit #1 (Part Number MAC000161)

Item #	Description	Quantity	QED Part #
1	MRE Filter Panel Assembly	1	2003828
2	MRE Optical Cable Set	1	2004050
3	Screw M5x35mm Long Hex, 316 Stainless	16	3009313
4	Screw M4x25MM Long Hex, 316 Stainless	16	3009318

SureWave™ Elastography Installation Kit #2 (Part Number MAC000162)

Item #	Description	Quantity	QED Part #
1	Scan Room Wall Socket	1	2003755
2	Female Drilling Anchor #6	5	3009332
3	Screw Number 6x1in SS	5	3009333
4	Floor Marking Tape	1	3009331

SureWave™ Elastography Installation Kit #3 (Part Number MAC000163)

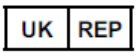
Item #	Description	Quantity	QED Part #
1	MRE Power Supply Box	1	2003615
2	Power Supply Cable Kit	1	3009057 (US) 3009152 (UK) 3009153 (EU)

Chapter 3 – Safety

This section describes the general precautions and safety information that must be observed during SureWave™ Elastography use.

CAUTION	Before using the SureWave™ Elastography, review the safety information in the MRI system operation manual for a full list of safety considerations.

3.1 Symbols

Symbol	Number	Standard	Title, Meaning
	1641	ISO 7000 IEC 60417	Operator's manual; Consult operating instructions before operating the device
	5172	ISO 7000 IEC 60417	Class II equipment
	5333	ISO 7000 IEC 60417	Type BF applied part
	1321A	ISO 7000	Equipment Mass / Safe Working Load
	5032	IEC 60601-1 IEC 60417	Alternating Current
	5019	IEC 60601-1 IEC 60417	Protective Earth (Ground)
	3082	ISO 7000 IEC 60417	Manufacturer and Date of Manufacture
	N/A	IEC 60601-2-33 IEC 62570	MR Safe
	N/A	IEC 60601-2-33 IEC 62570	MR Conditional
	N/A	IEC 60601-2-33 IEC 62570	MR Unsafe
	5041	IEC 60878	Caution, Hot Surface
	W007	ISO 7010	Warning; Floor-level obstacle (Do Not Trip)
	P024	ISO 7010	Warning: Do Not Walk or Stand (Do Not Step)
	5.1.2	ISO 15223-1	Indicates the Authorized Representative in EU
	5.1.2	ISO 20417 ISO 15223-1	Indicates the UK Responsible Person

Symbol	Number	Standard	Title, Meaning
CH REP	5.1.2	SwissMedic ISO 15223-1	Indicates the authorized representative in Switzerland
REF	2493	ISO 7000 IEC 60417	Catalog Number
SN	2498	ISO 7000 IEC 60417	Serial Number
	0632	ISO 7000 IEC 60417	Temperature limit
	2620	ISO 7000 IEC 60417	Humidity limitation
MD	5.7.7	ISO 15223-1	Medical Device
UDI	5.7.10	ISO 15223-1	Unique Device Identifier
	5.1.8	ISO 15223-1	Importer
	5.1.9	ISO 15223-1	Distributor
	N/A	EN50419 EU2012/18/EU	The use of this symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. For more detailed information concerning the return and recycling of this product, please consult the supplier from whom you purchased the product.

3.2 Indications

The SureWave™ Elastography device is intended for use with Siemens 1.5T and 3T MRI systems to generate shear wave vibrations in the body of adult patients during an MRI examination that are translated into images representing tissue stiffness. The images may be used for diagnostic purposes when interpreted by a trained physician.

3.3 Contraindications

None.

3.4 Precautions

- Patients with increased likelihood of seizures or claustrophobia
- Patients who are unconscious, heavily sedated, or in a confused mental state
- Patients with an inability to maintain reliable communications

3.5 Cautions

- Do not use a defective or damaged SureWave™ Elastography device, stop using immediately and contact your Service representative.
- Do not use an MRE Gel Pad that is leaking; discard and replace with a new MRE Gel Pad.
- Do not use the SureWave™ Elastography device if an unusual noise or excessive vibration is detected from the MRE subsystem or component.
- Do not bend the flexible MRE Axis excessively during operation or setup.

Acceptable bending

Excessive bending

- Do not open or alter the MRE Gel Phantom in any way; this could affect the integrity of the QA scan.
- Do not attempt to change or modify the SureWave™ Elastography device.
- Stop the scan immediately if the patient complains of excessive vibration, pain, or similar sensations. Contact a physician before continuing with the scan.
- Use only the accessories described in this manual with the SureWave™ Elastography device. Use of accessories, transducers, or cables other than those provided as specified in this manual could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Ensure that the MRE Axes are stored straight. Excessive or continued bending during storage could result in damage to the device.
- Power supply cables are provided for US, UK, EU and compatible regions. If replacement is required, only use a power supply cable that is approved by a regional Authority Having Jurisdiction.

3.6 MRI Safety Information

SureWave™ Elastography device components are labeled according to appropriate MRI safety labeling below.

Labelling	Component	Conditions for Safe Use
 MR Safe	MRE Strap MRE Gel Phantom MRE Gel Pad MRE Transducer MRE Transducer Fabric Cover MRE Axes	None, may be located anywhere in MRI scan room
 MR Conditional	MRE Tower	Do not use SureWave™ Elastography with MRI systems greater than 3T
 MR Unsafe	MRE Power Supply	Installed outside of the MRI scan room; not to enter MRI scan room

3.7 Cybersecurity

The SureWave™ Elastography software operates entirely within Siemens Open Recon which is protected by Siemens access control. Cybersecurity protections are provided through Open Recon. Additionally, the Motor Controller Computer (MCC) located in the MRE Tower software is pre-installed by the manufacturer. Any required updates to the MCC software are performed by Siemens service personnel. No additional actions or controls are required by the user.

If a cybersecurity event occurs, report it to your Siemens Healthineers representative and to the SureWave Elastography Manufacturer.

3.8 Residual Risks and Undesirable Side-Effects

All known risks associated with SureWave™ Elastography have been controlled as far as possible. The benefit of the device has been determined to far outweigh the risk and residual risks are low. Residual risks are communicated through cautionary statements within this manual.

SureWave™ Elastography has no known undesirable side-effects aside from those attributed to the MRI examination. Refer to the MRI system operation manual.

3.9 Emergency Procedures and Incident Reporting

In case of an emergency during the scan, stop the scan immediately, remove the SureWave™ Elastography components from the patient and remove patient from the room, and obtain medical assistance, if necessary.

If a serious incident occurs, it should be reported to the manufacturer and the Competent Authority of the Member State in which the user facility is established.

Chapter 4 – Installation

Installation activities must be completed by a Siemens Healthineers representative prior to using the SureWave™ Elastography device. A separate installation manual is provided which details installation activities.

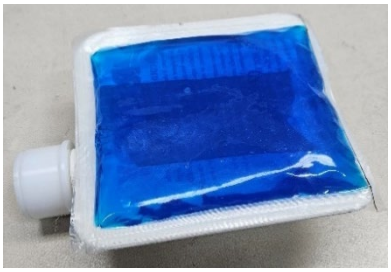
WARNING

Only properly trained and qualified personnel are authorized to install SureWave Elastography.

Chapter 5 - MRE Transducer Assembly

The MRE Transducer requires initial assembly prior to first use. Please collect the MRE Transducer, MRE Gel Pad, and MRE Transducer Fabric Cover and follow the instructions below to complete initial assembly.

1. Secure the Gel Pad to the Transducer by removing the backing of the double-sided on the Gel Pad and place the Pad centered on the concaved side of the Transducer.



2. Ensure that the MRE Gel Pad is securely adhered to the MRE Transducer by gently pulling on the pad.

3. Slide the MRE Transducer Fabric Cover over the MRE Gel Pad and MRE Transducer.

4. Secure with the hook and loop fasteners.

The MRE Transducer is now ready for use.

5. Connect one MRE Axis to the MRE Transducer.

CAUTION	➢ Use caution when connecting the MRE Axis to the MRE Transducer. The user could be pinched between the two pieces. ➢ The MRE Gel Pad is intended for use at room temperature; do not heat or cool prior to use.

If the MRE Transducer Fabric Cover or MRE Gel Pad detach or the MRE Gel Pad requires replacement, repeat the steps above.

Chapter 6 – SureWave™ Elastography Hardware Setup and Use

6.1 SureWave™ Elastography Hardware Setup

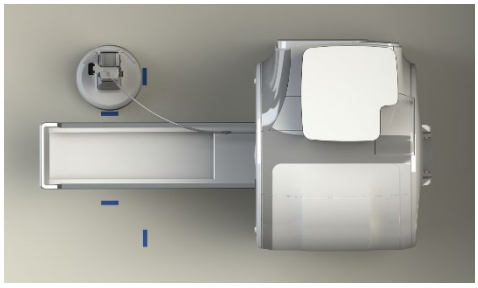
WARNING	The MRE Power Supply is MR Unsafe and should NEVER be brought into the magnet room.

CAUTION	The MRE Tower cannot be used with MRI systems greater than 3T.

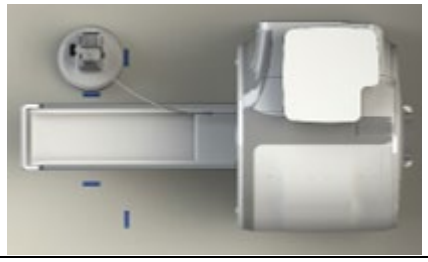
1. Transport the MRE hardware components into the MRI Examination Room. The device should be moved by one user at a time and moved only by the handle. The brakes of the device are engaged by default. In order to move the device, lift the lower handle up toward the fixed handle while being careful not to place hands between the two handles.

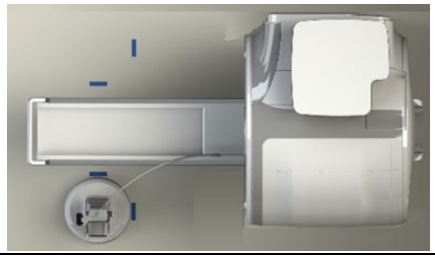
CAUTION	Use caution when operating the brakes and moving the MRE Tower. The patient or user could be pinched by the brake handle or between the MRE Tower and the wall or MRI system during movement. Improperly stored MRE System Cables could be damaged during MRE Tower movement, potentially exposing live wires.

2. Position the MRE Tower at the defined location as noted on the examination room floor by the blue marking tape (adjacent to the MRI Patient Couch). Note that the MRE Tower can be located on either side of the MR Scanner patient table; however, during normal use, the location may be limited to one side based on the site's magnet room design and layout.



The MRE Tower may be positioned on either side of the MRI Patient Couch depending on the use case.





i	Only power on the MRE Tower in the marked location; if the MRE tower is powered on outside of the marked location, then equipment operation may be affected.

⚠ CAUTION	Position the MRE Tower in such a way that the power cord is accessible for disconnection.

3. Place the MRE Strap across the MRI Patient Tabletop with the hook & loop fastener facing up.

6.2 Patient Positioning and Scanning

⚠ CAUTION

Only operate SureWave™ Elastography with two MRE Axis sections connected without excessive bending and in the marked location or equipment damage could result.

Acceptable bending

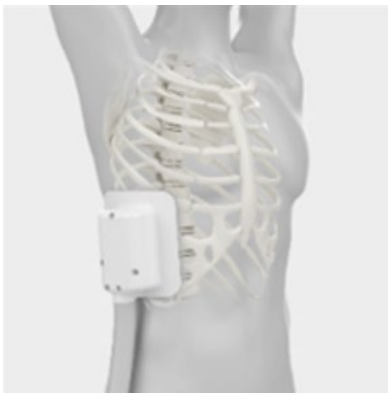
Excessive bending

1. Ensure the MRE Transducer has been assembled per the MRE Transducer Assembly section.

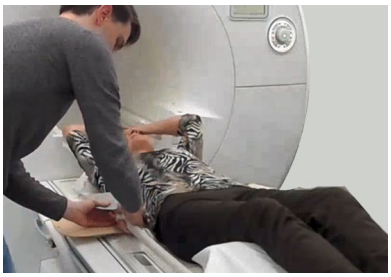
2. Position the patient on the MR Patient Table, on top of the MRE Strap, per the MRI system operator manual. Patients may be positioned in either the head-first or feet-first position.

3. Lay the MRE Transducer and MRE Axis on the MRI Patient Couch Table next to the patient.

4. Align the MRE Transducer with the location of the liver.



5. Center the MRE Transducer over the target anatomy on top of the patient's clothing or gown, at the anatomical position indicated.

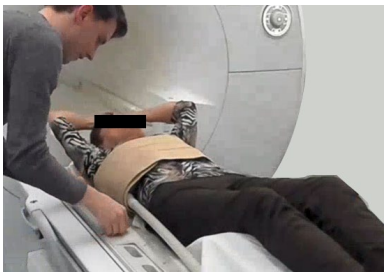


⚠ CAUTION	Be sure to prevent the hook-and-loop fastener strap from coming into direct contact with the patient's skin. Scraping the hook surface of the strap against the patient's skin may result in injury to the patient.

⚠ CAUTION	Ensure that the fabric of clothing or gown lies flat beneath transducer. Bunched fabric could result in discomfort to the patient

6. Wrap the MRE Strap around the patient and MRE Transducer and tighten sufficiently so that the MRE Transducer remains in place during scan session.

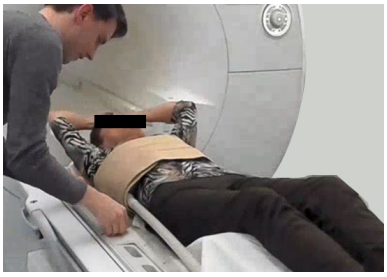
7. Secure the MRE Strap to itself and wrap any excess next to the MRE Transducer.



⚠ CAUTION	➢ Avoid positioning MRE Transducer under the non-stretch area of the MRE Strap; transducer could move and possibly diminish elastogram quality. ➢ Tighten the MRE Strap so that the MRE Transducer is held in position and patient can breathe easily. Overtightening could result in patient discomfort. Undertightening could result in poor elastography results.

8. Using an MRE Axis Clip compatible with the patient support table, press the clip into the Patient Table Accessory Rail.

9. Secure the MRE Strap to itself and wrap any excess next to the MRE Transducer.



10. Snap the MRE Axis into the MRE Axis Clip to ensure the MRE Axis remains in place and will not interfere with patient or couch movement into the gantry.

11. Position any RF Coils over the MRE Transducer and patient as directed by the RF coil operator manual.

12. Attach the second MRE Axis Section to the MRE Tower.

13. Connect the two MRE Axis sections together.

14 Connect the MRE System Connector to the MRE Socket in the MRI Exam Room.

15. Rotate the locking mechanism clockwise to secure.

16 The indicator will be green when the locking mechanism is in the operational position.

17. Press the power button on the MRE Tower to turn the power on.

    Note: the light ring around the button will illuminate when the power is on.

⚠ CAUTION	Position the MRE System Cable away from patient/operator pathways to avoid creating a tripping hazard.

18. Raise/lower the MR Patient Couch Table per MRI system operator manual.

19. Plan the acquisition using the isocenter reference using the laser and move the patient support to magnet isocenter as directed by the MRI system operation manual.

⚠ CAUTION	Guide the MRE Axis and MRE Transducer during couch movement to avoid patient discomfort or damage to the device.

20. Proceed to the MR Control Room to begin the scan session.

Chapter 7 - Quality Assurance

The Quality Assurance procedure confirms that SureWave™ Elastography is working properly.

> CAUTION
> Perform system quality assurance as required by the MRI system operator manual prior to using the SureWave™ Elastography.

7.1 SureWave™ Elastography System and Phantom Setup

1. Record the serial number of the SureWaveTM Elastography device and coil(s) being used, as well as software build version (from test record).
2. Remove any other surface coils (if present) from the table.
3. Position the MRE Tower at the defined location as noted by the blue tape on the exam room floor (adjacent to MRI Patient table).

> Only power on the MRE Tower in the marked location; if the MRE tower is powered on outside of the marked location, then equipment operation may be affected.

> CAUTION
> Position the MRE Tower in such a way that the power cord is accessible for disconnection.

4. Place the MRE Strap in position across the Patient Tabletop.

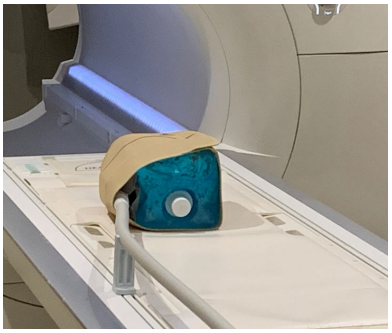
5. Attach the MRE Axis Clip to the Patient Accessory Rail.

6. Position the MRE Gel Phantom and MRE Strap for a phantom scan per normal scan setup procedure.

⚠ CAUTION	Do not open or alter the MRE Gel Phantom in any way; this could compromise the integrity of the QA scan.

7. Press the foam jacket of the Axis Section that is attached to the transsducer into the top of the clips and place the MRE Transducer and MRE Gel Pad on the MRE Phantom.

8. Using the belt strap the Transducer to the phantom with one MRE Axis Section attached to the transducer.



9. Position the MRE Transducer, MRE Gel Phantom and MRE Strap combination into an RF coil appropriate for abdominal imaging.

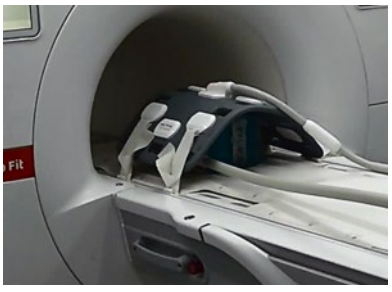
10. Attach the second MRE Axis Section to the MRE Tower.

11. Connect the two MRE Axis Sections together.

CAUTION

Use caution when connecting the MRE Axis Sections; skin may be pinched between the two pieces.

12. Plan the acquisition with the center of the RF Coil as the isocenter reference using the laser and move the setup to magnet isocenter.



13. Ensure that both MRE Axis Sections are straight when the MRE test object is positioned at isocenter.

Note: the two MRE Axis Sections should be mostly straight without tension.

CAUTION

Only operate SureWave™ Elastography with two MRE Axis sections connected without excessive bending and in the marked location or equipment damage could result.

Acceptable bending

Excessive bending

14. Attach the MRE Power / Signal Cable Plug end to the MRE Wall Socket.

15. Rotate the locking mechanism clockwise to secure.

16. The indicator will be green when the locking mechanism is in the operational position.

17. Turn on the power to the MRE Tower by pressing the power button on the side of the MRE Tower.

    Note: The light ring around the button will illuminate when the power is on.

Power is off (light is off).

Power is on (light is on).

7.2 Quality Assurance Scan

1. Select the SureWaveTM Elastography 3D clinical scan from SIEMENS→ abdomen → library → Elastography → SureWave

2. It is highly recommended to use the following acquisition parameters:
   - Slice Thickness = 4 mm
   - FOV Read = 300 mm
   - FOV Phase ≥ 85 %
   - Base Resolution = 128
   - Phase Resolution = 100 %
   - TR = use mininum TR [suggested range: TR min to 112.0 ms]
   - TE = 8.0 ms [suggested range: 7.5 to 9.8 ms]
   - Bandwidth = 450 Hz/px [suggested range: 400 to 800 Hz/px]

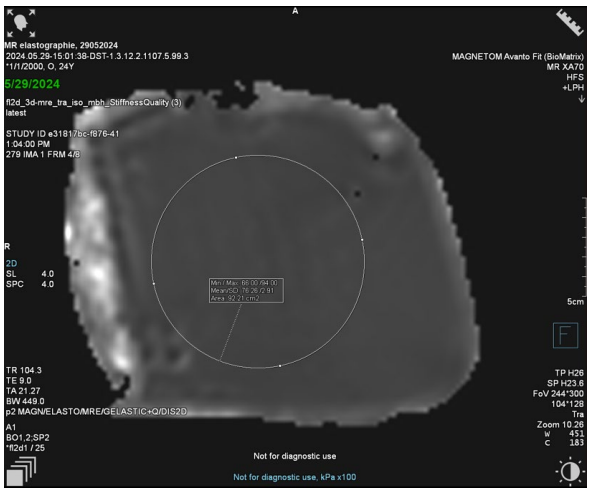
3. The following seven image types will be generated by the acquisition:

Acquisition Images	**SureWaveTM Elastography Images**
Magnitude Image Phase Image	Stiffness Image Stiffness with Quality Threshold Wave-X Wave-Y Wave-Z

4. For the Quality measurement, analyze only the Stiffness with Quality Threshold image.

5. Select a single central slice (i.e., Slice 4 or 5), draw a ROI on the US Gel Phantom using a DICOM measurement tool. Position the ROI in the middle of the phantom with half of the phantom diameter on the Stiffness + Quality Image (per QIBA).

   Note: The central region of the Stiffness with Quality Threshold image should be free of zero-valued pixels. If you cannot draw a ROI that occupies approximately half of the phantom cross-section without including several zero-valued pixels then contact your Siemens Healthineers representative.



Circular ROI drawn on slice 4 of an 8-slice 3D MRE acquisition

In this example, the phantom stiffness measured from the ROI has
Mean = 0.76 kPa
Std dev = 0.03 kPa

6. Record the mean and Standard Deviation within the ROI of the Stiffness with Quality Threshold image.

Note: The instruction and Table 1 below is an excerpt from QIBA Profile 2022_02.docx to aid in the process to develop a method for recording MRE QA.

Record the date and the Phantom Mean Stiffness and Phantom SD Stiffness for each assessment in a table such as Table 1.

Compute and record the Stiffness Measurement Difference between the current (E_current) and previous (E_previous) measurements as: 2 × abs (E_current-E_previous)/(E_current + E_previous).

Table 1: MRE QA Record

Date	Phantom Mean Stiffness (kPa)	Phantom SD Stiffness (kPa)	Stiffness Measurement Difference	Pass Criteria (Expected Stiffness Measurement Difference)
First Scan	E0	SD0	NA	NA
6 months	E1	SD1	2 × abs (E1-E0)/(E1+E0)	≤ 10%
Next 6 months	E2	SD2	2 × abs (E2-E1)/(E2+E1)	≤ 10%
⋮	⋮	⋮	⋮	⋮

Chapter 8 – Image Sequence and Image Reconstruction on Siemens Healthineers Systems

- The MRE gel pad will be visible outside the anatomy on most clinical scans.
  - The signal from the MRE gel pad can be helpful to ensure proper positioning of the transducer for MRE acquisitions.
- The MRE belt may cause fold-in artifacts. In case of unclear lesions it is recommended to use additional imaging sequences with additional weightings or orientations to verify the lesions.
  - The MRE Strap may be visible at the perimeter of the patient on scans with fat suppression.
- MRE acquisitions should always be run with the orientation set to transversal.
- Phase encoding direction considerations:
  - Transversal abdominal scans should always be acquired with the phase encoding direction set to A >> P (or P >> A) when the MRE transducer, MRE gel pad, and MRE belt are positioned on the patient.
  - For coronal abdominal scans with the phase encoding direction set to L >> R (or R >> L), make sure the FOV phase covers the full extent of the MRE transducer gel pad and MRE transducer. Consider using phase oversampling of at least 25% to prevent aliasing in the phase encoding direction if the phase FOV needs to be sized close to the patient.
- For 3D sagittal scans, make sure the slice coverage and slice oversampling prevent aliasing of the signal from the MRE transducer and MRE gel pad.
- EPI scans may have ghosting artifacts from the MRE gel pad along the phase encoding direction.
  - For transversal EPI diffusion scans with phase encoding direction set to A >> P (or P >> A), the artifact signal will be outside of the anatomy and will not interfere with clinical interpretation.
- The MRE acquisition must be run with the B0 shim enabled.
  - This will not affect typical abdominal scanning workflow because B0 shim will be enabled for abdominal scans with fat suppression or for acquisition that are sensitivity to field homogeneity, such as those that use Dixon techniques. When available, higher order shims should be used to correct the B0 disturbances caused by the MRE transducer and MRE gel pad.

8.1 SureWave™ Elastography Imaging Protocols

1. Choose the SureWave™ MRE imaging protocol for 2D or 3D from the Siemens Healthineers protocol tree.
2. Confirm that the SureWave™ Open Recon reconstruction container (MRecon) is configured under the Open Recon tab card (Inline >> Open Recon) of the Siemens Healthineers imaging protocols.
3. In the Open Recon tab card, select the appropriate reconstruction mode under “Preset”:

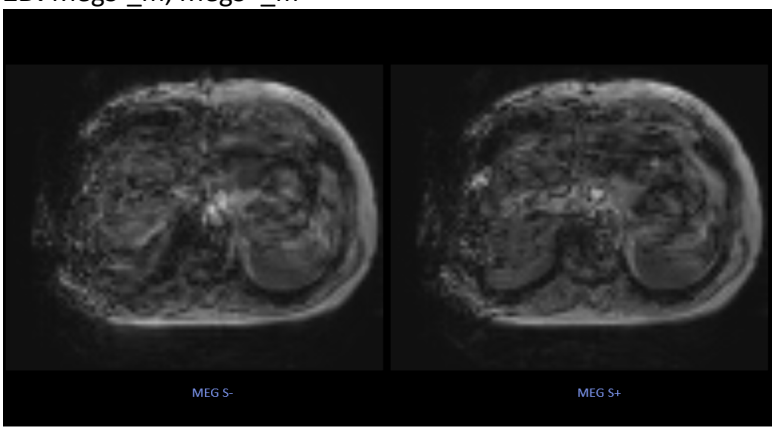
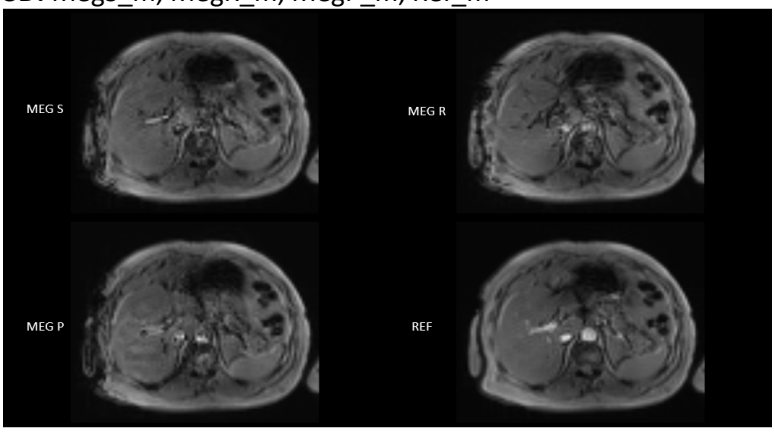
a. Standard Mode: Generates the following outputs: Magnitude and Phase images, Stiffness and Stiffness with Quality Threshold and Wave maps. This mode is recommended for routine clinical use.
b. Advanced Mode: Generates the following outputs: Magnitude and Phase images, Stiffness and Stiffness with Quality Threshold maps, Wave images, Atot, Non-linearity and CurlOverDivergence (3D MRE only) maps. Use Advanced Mode for QA Scan test (see Chapter 7) or detailed troubleshooting in cases of error.

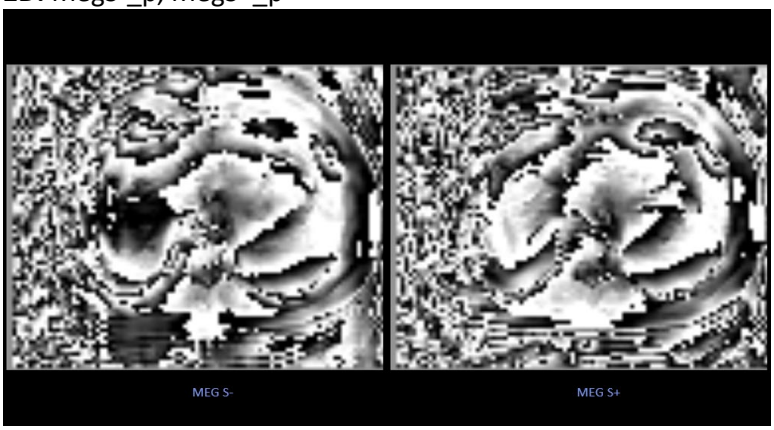
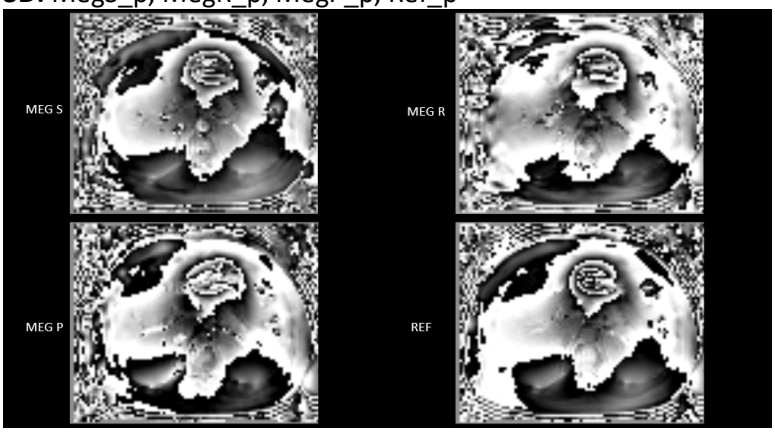
i	Ensure that the patient follows breath hold instructions as described in the MRI system operator manual.

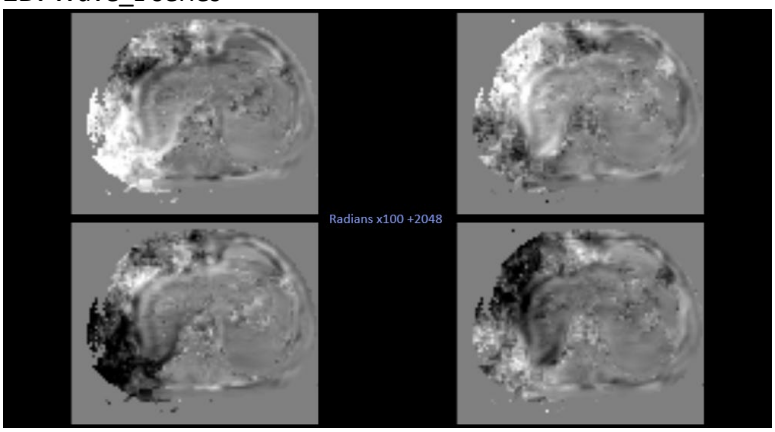
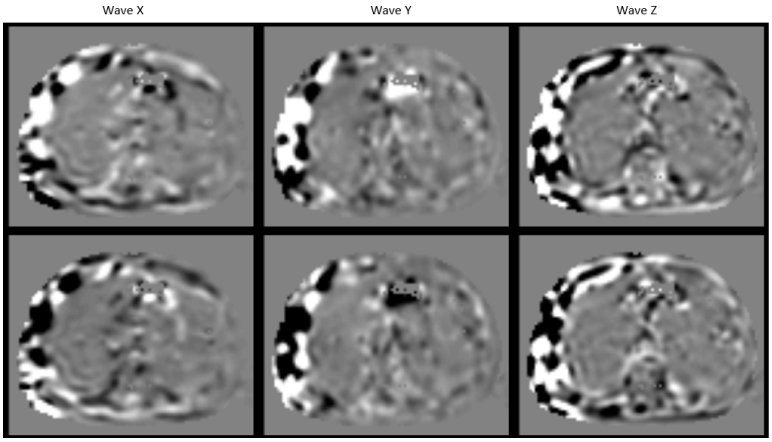
8.2 Viewing the Results

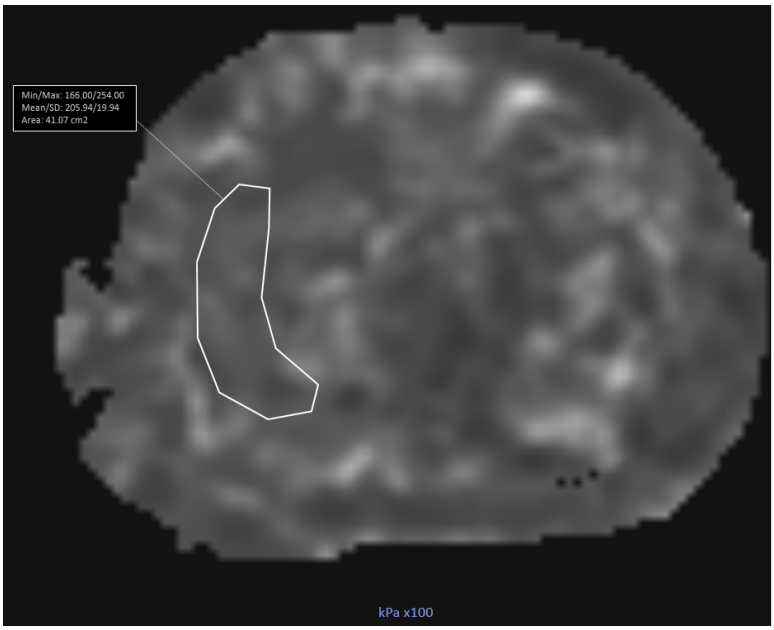
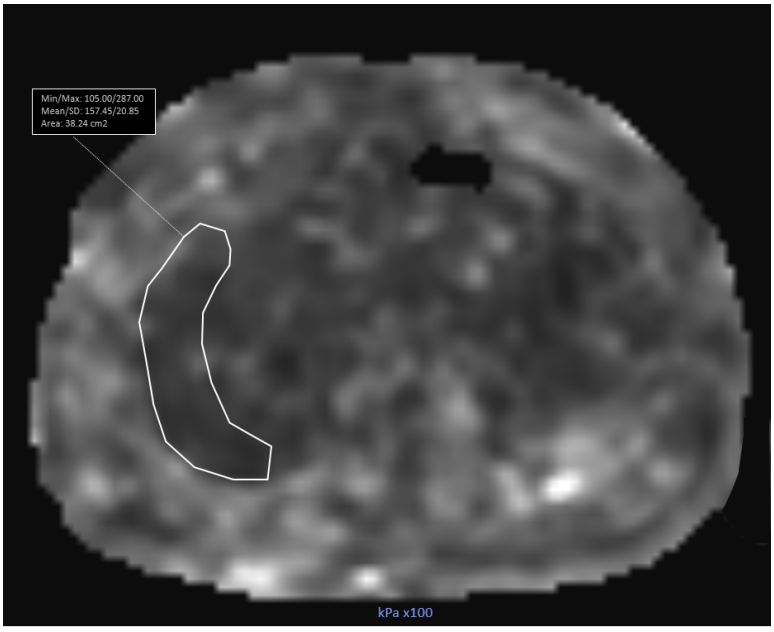
⚠ CAUTION	➢ Do not directly compare stiffness values from SureWave™ Elastography to stiffness values obtained from other devices; differences in device technologies may cause differences in measured stiffness values. ➢ Do not directly compare 2D and 3D stiffness values; SureWave™ Elastography 3D results read approximately 15% lower on average than SureWave™ Elastography 2D results.

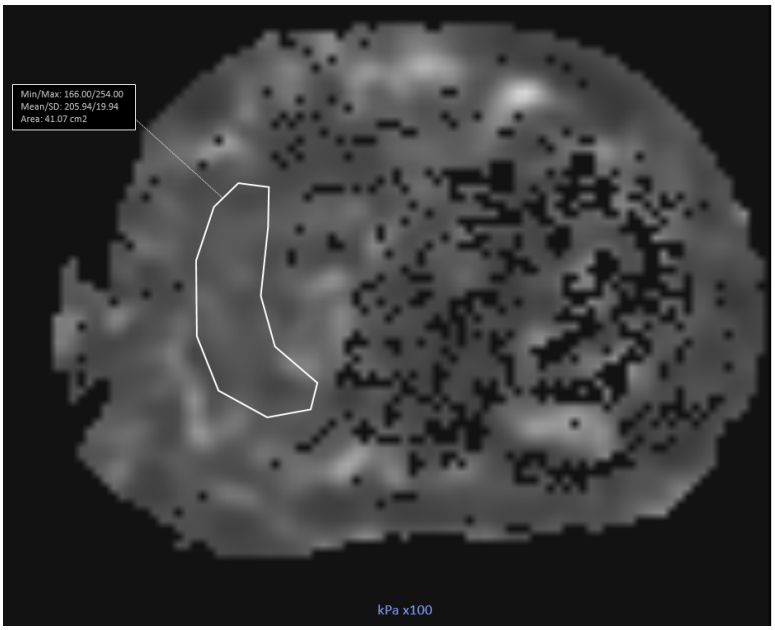
The imaging results are automatically loaded into the viewer.

Output Images	
2D: MegS-_m, MegS+_m  **3D:** MegS_m, MegR_m, MegP_m, Ref_m  	**Magnitude Images** Standard anatomical image and magnitude component of the acquisition. This output is available in Standard and Advanced mode for 2D and 3D MRE.

Output Images	
2D: MegS-_p, MegS+_p  **3D:** MegS_p, MegR_p, MegP_p, Ref_p  	**Phase Images** Phase component of the acquisition. This output is available in Standard and Advanced mode for 2D and 3D MRE.

Output Images	
2D: Wave_z series  **3D:** Wave_x, Wave_y, and Wave_z series 	**Wave Images** These image series display the unwrapped wave displacement as encoded by the MRE sequence. This output is available in Standard and Advanced mode for 2D and 3D MRE.

Output Images	
2D  **3D**  	**Stiffness Maps** The stiffness map displays the magnitude of the complex shear modulus. Divided the reported values by 100 to convert the pixel values to the stiffness in kilopascals (kPa). This output is available in Standard and Advanced mode for 2D and 3D MRE.

Output Images	
2D  	**Stiffness with Quality Maps** The stiffness quality map displays the stiffness map merged with a quality index for each pixel. If the quality index of a pixel is below the threshold, then the stiffness value for the pixel is set to zero in the stiffness with quality map to indicate that the pixel should not be used for stiffness measurements**. Avoiding pixel with a stiffness value of zero will ensure that only high quality pixels are used for the assessment of the liver stiffness. Divided the reported values by 100 to convert the pixel values to the stiffness in kilopascals (kPa). This output is available in Standard and Advanced mode for SureWave 2D and SureWave 3D.

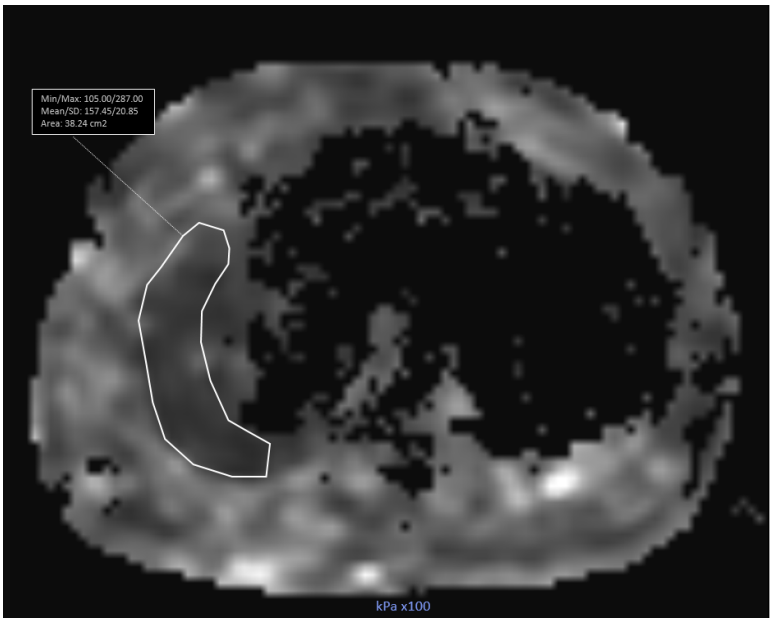
**The quality index is a measure of the confidence of the stiffness computation for that pixel.

For 2D SureWave Elastography:

$$QI_{2D} = log_{10}\left(\frac{amplitude\ total}{nonlinearity}\right)$$

If $QI_{2D} \geq 1.0$ for a pixel then the computed stiffness is presented in the stiffness with quality map.

If $QI_{2D} < 1.0$ for a pixel then the pixel value is set to 0 in the stiffness with quality map.

Output Images	
3D  	**Stiffness with Quality Maps** The stiffness quality map displays the stiffness map merged with a quality index for each pixel. If the quality index of a pixel is below the threshold, then the stiffness value for the pixel is set to zero in the stiffness with quality map to indicate that the pixel should not be used for stiffness measurements**. Avoiding pixel with a stiffness value of zero will ensure that only high quality pixels are used for the assessment of the liver stiffness. Divided the reported values by 100 to convert the pixel values to the stiffness in kilopascals (kPa). This output is available in Standard and Advanced mode for SureWave 2D and SureWave 3D.

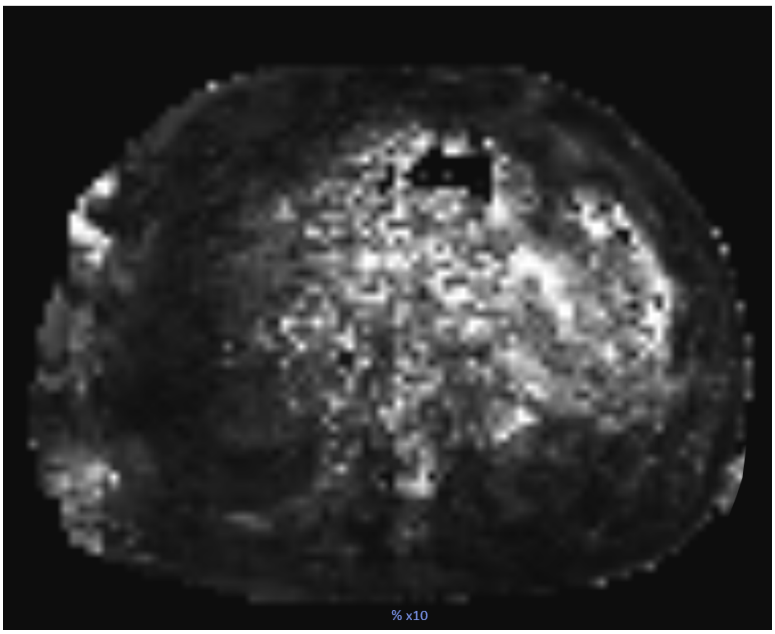
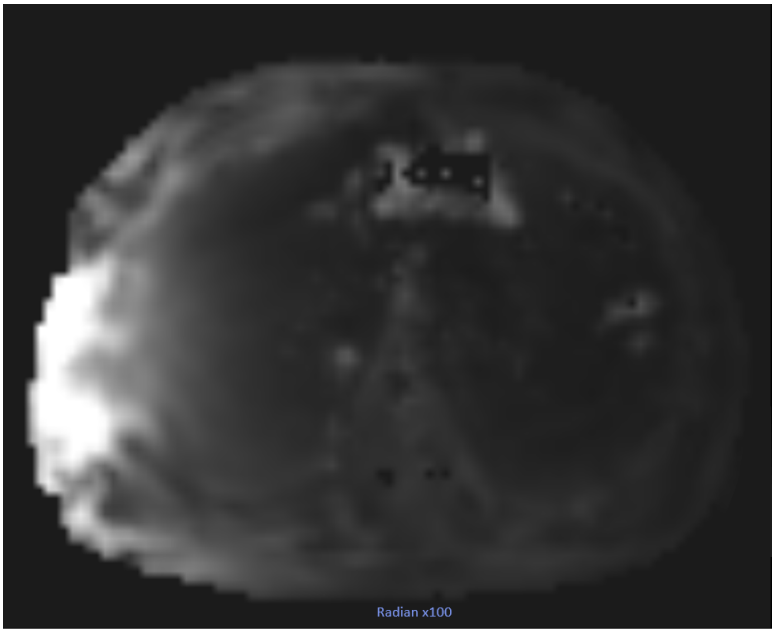
**The quality index is a measure of the confidence of the stiffness computation for that pixel.

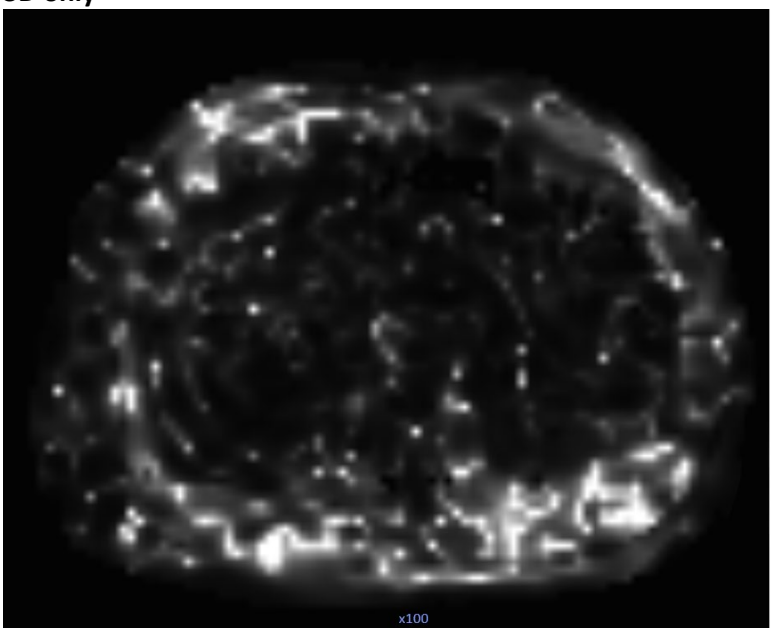
For 3D SureWave Elastography:

$$QI_{3D} = log_{10}\left(\frac{amplitude\ total}{nonlinearity} * \frac{|curl|}{|divergence|}\right)$$

If $QI_{3D} \geq 1.0$ for a pixel then the computed stiffness is presented in the stiffness with quality map.

If $QI_{3D} < 1.0$ for a pixel then the pixel value is set to 0 in the stiffness with quality map.

Output Images	
2D or 3D  	**Nonlinearity Maps** The nonlinearity map displays the nonlinearity of the mechanical vibrations in each pixel. Nonlinearity describes the deviation of the estimated oscillatory motion from a perfect sinusoidal displacement. A nonlinearity of 0% is indicative of perfect sinusoidal motion. Good nonlinearity ≤ 40% for in-vivo scans and ≤ 20% for phantom scans in the ROI. Divide the reported values by 10 to convert the presented pixel values for nonlinearity to a percentage. This output is only available in Advanced mode.
2D or 3D  	**Total Amplitude Maps (Atot)** The total amplitude of the measurement displacement field describes the intensity of the vibrations within the body. Divide the reported values by 100 to convert the presented pixel values for total amplitude to radians. The amplitude in radians can be converted to µm from the strength of the motion encoding gradients. This output is only available in Advanced mode.

Output Images	
3D only  	**Curl over Divergence Maps** The signal to noise of the shear wave can be quantified by the ratio of its curl to its divergence. The ratio is dimensionless. Good quality in-vivo data will have curl/divergence > 4. Phantom data easily attain much higher values. Divide the reported values by 100 to convert the presented pixel values to ratio of curl over divergence. This output is only available in Advanced mode for 3D MRE.

Chapter 9 – Shutdown and Storage

1. Move the patient table out of the bore per MRI system operation manual; monitor/guide the MRE Axis during movement.
2. Remove the patient from the patient table.
3. Disconnect and store the RF Coil.
4. Disconnect the Axis section from the MRE Tower by pulling the collar on the Axis section connector.

5. Store it on the MRE Axis Hanger by pushing the foam outer jacket through the clip and then dropping the connector into the hole.

5. Disconnect the two MRE Axis sections by pulling the collar for the MRE Axis Section connector end.

6. Remove the MRE Axis section with MRE Transducer attached.
7. Store it on the MRE Axis Hanger by pushing the foam outer jacket through the clip and then dropping the connector into the hole.

7. Remove the MRE Axis Clip, MRE Phantom, and MRE Strap from the MRI patient table and store on the MRE Tower shelving.

   Note: Place the MRE Phantom on the bottom self.
8. Press the power button on the MRE Tower to turn power off.

9. Unlock the locking mechanism on the MRE System Connector.

10. Disconnect the MRE System Connector from the MRE Socket in the MRI Exam Room.

11. Store the MRE System Connector Cable on the MRE Tower.

⚠ CAUTION	Be sure to store the MRE System Connector Cable securely on the MRE Tower. Unsecure cables could be damaged during movement of the MRE Tower and could expose live wires.

⚠ CAUTION	Do not store non-MRE components on the MRE Tower shelving.

	• Mass including safe working load is 35kg + 9kg for MRE components stored on MRE Tower shelving.

ℹ	• Ensure that the MRE Axes are stored straight. Excessive or continued bending during storage could result in damage to the device. • The MRE Transducer may be stored connected to the MRE Axis or separately. • The MRE device may be stored in the MRI suite but not directly next to the MRI system.

Chapter 10 – Cleaning, Maintenance, Service, and Disposal

10.1 Cleaning

10.1.1 Cleaning the MRE Transducer, MRE Transducer Fabric Cover, MRE Axes, and MRE Tower

Surfaces that could have contacted the patient, personnel, or bodily fluids, such as the MRE Transducer, MRE Transducer Fabric Cover, and MRE Axes, should be cleaned and disinfected after each use. The MRE Tower may be cleaned as needed.

Use a peroxide-based disinfectant with proven cleaning efficacy that is certified by relevant national authorities (EPA, VAH) for cleaning and disinfection. The cleaning and disinfection instructions below were validated using the following product:

- Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant Wipes

Cleaning and Disinfection Precautions

⚠ Do not pour or spray cleaning fluids onto surfaces; equipment is not protected against liquid ingress.

⚠ Do not immerse objects in water or cleaning fluids.

⚠ Do not place into any type of sterilizer.

⚠ Ensure that no liquids seep into the openings of the product, for example, gaps between covers.

⚠ Do not use hard or sharp objects (for example, knives or tweezers) to remove residue.

⚠ Do not insert any objects into areas that are hard to reach.

⚠ Do not wipe electrical contacts or outlets. Cover electrical contacts before cleaning, if possible.

⚠ Avoid wiping affixed hook and loop surfaces; detachment may occur.

⚠ Wear appropriate personal protective equipment per the cleaner or disinfectant manufacturer's instructions.

⚠ Use only commercially available cleaning and disinfectant solutions. Follow the instructions provided by the manufacturer of the cleaning or disinfectant agent.

⚠ Use only the recommended cleaning agents; incompatible cleaning agents may cause surface damage or discoloration.

Preparation

1. Disconnect device before coil cleaning.
2. If any parts of the device are detachable, detach them and clean and disinfect separately.
3. Wipe off any dirt on the surface using a dry cloth. If dirt is difficult to remove, clean it according to the procedures below.

Cleaning

1. Thoroughly wipe all surfaces with sufficiently saturated cleaner disinfectant wipes until completely wet and visible contamination is removed.
    a. Use as many wipes as necessary to remove visible signs of contamination.
    b. Pay attention to hard-to-clean areas, such as crevices and mated surfaces. Use extra wipes as needed for hard-to-clean areas. Use a sterile cotton swab to push the wipe into crevices.
2. Check all surfaces for cleanliness. If soiling is still visible, repeat the cleaning steps above.
3. To remove cleaner residue, moisten at least one lint-free cloth with water and thoroughly wipe the cleaned surfaces.
4. Allow surfaces to air dry completely before use.
5. Dispose of cleaning materials according to federal, state, and local regulations.

Disinfection

1. Thoroughly wipe all surfaces with sufficiently saturated cleaner disinfectant wipes until completely wet.
    a. Use as many wipes as necessary to wet surface.
    b. Pay attention to hard-to-clean areas, such as crevices and mated surfaces. Use extra wipes as needed for hard-to-clean areas. Use a sterile cotton swab to push the wipe into crevices.
2. Ensure that the areas to be disinfected remain visibly wet for at least **two (2) minutes**.
    a. Additional wipes may be used to keep surfaces wetted with the disinfectant.
3. To remove disinfectant residue, moisten at least one lint-free cloth with water and thoroughly wipe the disinfected surfaces.
4. Allow surfaces to air dry completely before use.
5. Dispose of disinfection materials according to federal, state, and local regulations.

10.1.2 Cleaning the MRE Strap

Hand wash the MRE strap in cold water with mild soap. Air-dry away from heat and sunlight. Do not bleach, iron, dry clean, or tumble dry.

10.1.3 Cleaning the MRE Gel Pad

Under normal use, the MRE Gel Pad should not require cleaning because it is used under the MRE Transducer Fabric Cover.

10.2 Maintenance

Under normal use, the MRE Tower brakes may accumulate dust. The MRE Tower brakes should be cleaned as needed with a soft cloth.

10.3 Service

Please contact your Siemens Healthineers representative with questions regarding service of the SureWave™ Elastography device.

10.4 Disposal

Please follow local regulations for the disposal of electrical equipment.

Recycle components that bear recycling symbols. Dispose of the remainder in accordance with local, regional, or national laws and regulations.

Dispose of the MRE Strap and MRE Gel Pad if they become contaminated by human body fluids.

Contact your Siemens Healthineers representative with questions regarding the return or disposal of the SureWave™ Elastography device.

10.5 Expected Service Life

The SureWave™ Elastography MRE Tower and MRE Power Supply are designed for an expected service life of at least 6 years under normal usage conditions. Other SureWave™ Elastography components may be replaced as needed. The device is safe to use beyond the expected service life as long as information in the Safety section is followed and Quality Assurance tests pass.

10.6 Consumable Parts

The table below lists the Consumable Parts that can be ordered by the SureWave MRE end-user.

Description	QED Part Number	Siemens Material Number	Replacement Time
MRE Gel Pad	MAC000164	11.852.021	5 minutes
MRE Transducer Fabric Cover	MAC000169	11.852.022	5 minutes
MRE Strap, XXL	MAC000165	11.852.028	5 minutes
MRE Strap, M	MAC000172	11.852.027	5 minutes
MRE Transducer	MAC000166	11.852.023	5 minutes
MRE Axis Section	MAC000167	11.852.024	5 minutes
MRE Gel Phantom	MAC000168	11.852.026	5 minutes
MRE Axis Clip (DaGama)	MAC000170	11.852.029	5 minutes
MRE Axis Clip (DaVinci)	MAC000171	11.852.030	5 minutes

Chapter 11 – SureWave™ Elastography Troubleshooting

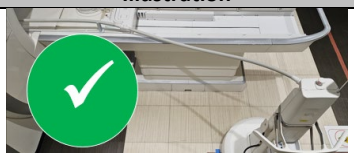
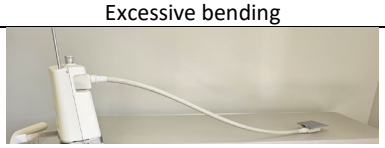
11.1 SureWave™ Elastography Software Issues

In the event of an acquisition or processing error, SureWave™ Elastography software will produce an informational message in the form of an image. The following table provides a list of error codes and troubleshooting steps to resolve the error.

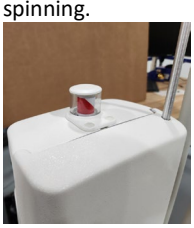
Code	Description	Troubleshooting Steps
-1	ERROR_IMAGE: Unexpected message in data stream	Check that the sequence is a compatible MRE sequence. Check that the acquisition ran to completion.
-2	ERROR_MRE_MODE: Unsupported value for the 'set' parameter.	Check that the sequence is a compatible MRE sequence.
-3	ERROR_INPUT_DIMS: Unsupported value for a scan parameter.	Check the scan parameters. The MRecon algorithm supports compatible MRE acquisitions with the following scan parameters: 64 x 64 up to 128 x 128 reconstructed image size 1 partition 1 average 1 repetition 1 segment 1 contrast 4 phases **2D MRE** may have 1 – 256 slices **3D MRE** may have 8 – 256 image slices
-4	ERROR_INPUT_PAIRWISE: Images not received in pairs as expected.	Check that the sequence is a compatible MRE sequence.
-5	ERROR_RESOLUTION: Better resolution required.	Reduce the acquisition voxel size. The MRE algorithm requires the voxel size to be smaller than 4.17 mm x 4.17 mm. Decrease the voxel size by making one or more of the following adjustments: • Decreasing the FOV read • Decreasing the FOV phase • Increasing the Base resolution • Increasing the Phase resolution
-6	ERROR_EQUIDISTANT: Distance between slices is not constant.	Check that distance between slices is constant. This error will not occur for acquisitions with a single slice group because the Distance factor will be constant.
-7	ERROR_ORIENTATION: Orientation is not the same for all slices.	Check that all slices have the same orientation. This error will not occur for acquisitions with a single slice group because the orientation will be same for all slices.

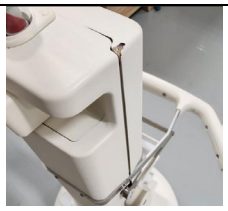
Code	Description	Troubleshooting Steps
-8	ERROR_FREQUENCY: Calculated frequency is not in allowed range.	Check that the sequence is a compatible MRE sequence. The sequence adjustment code will set the TR to be compatible with the allowed frequency range. This error will not occur for a released compatible MRE acquisition.
-9	ERROR_INVERSION_CORE: Unexpected error from inversion.	Check that the sequence is a compatible MRE sequence. Check that parameter settings are in the range of the recommended values. Use default scan parameter settings. If the problem persists then contact Siemens service.
-10	ERROR_TIMESERIES: Error in time series computation.	Check that the sequence is a compatible MRE sequence.
-11	ERROR_IMAGE_NUMBER_RECEIVED: Received incomplete image data.	This error is expected if the acquisition is aborted or paused before completion.

11.2 MRE Tower – Operational Issues

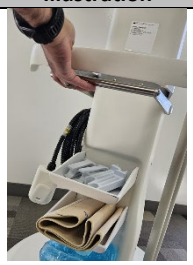
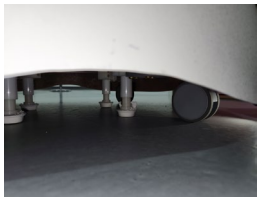
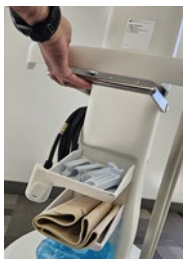
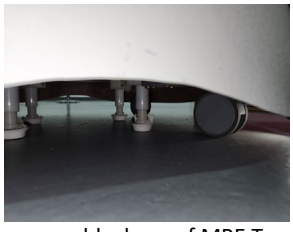
Problem	Troubleshooting Steps	Illustration
Tower makes strange audible sound.	1. Confirm that the MRE Tower connections and setup are correct. a. Do not bend the MRE Axis sections excessively. If the MRE Axis was bending too much, straighten axis and initiate a scan. b. Check for noise.	 Acceptable bending  Excessive bending
	2. If noise is present: a. Test each axis section one at a time with one end attached to the MRE Tower and the other to the MRE Transducer. b. Initiate a scan and check for noise. c. If one axis section is faulty, the MRE Axis section requires replacement.	 Single axis attached to transducer
	3. If noise is still present with only one MRE Axis sections attached: a. Disconnect both axis sections from MRE Tower. b. Initiate a scan and check for noise. c. If noise is present, call Siemens Healthineers Service. MRE Tower may require replacement.	 Both axes removed from MRE Tower

Problem	Troubleshooting Steps	Illustration
The MRE Tower does not have power	1. Confirm that the MRE Tower power switch is in the ON position and that the white power LED on the MRE Tower Unit is illuminated.	
	a. Confirm that the tower cable connection at the socket is secure.	 
	b. Confirm that the green power indicator on the MRE Socket is ON. ○ If NOT ON, go to Step 2 ○ If ON, call Siemens Healthineers Service. The Tower Cable may require replacement.	 MRE Socket power ON
	2. If the green power indicator on the MRE Socket is OFF.	 MRE Socket Power OFF

<table>
<tr><th>Problem</th><th>Troubleshooting Steps</th><th>Illustration</th></tr>
<tr><td></td><td>a. Check if the green power indicator on the MRE Power Supply is ON (located in the equipment room).
b. If the power indicator on the MRE Power Supply is ON, call Siemens Healthineers Service. The connection between the MRE Power Supply and MRE Socket (through RF Filter) may be compromised.
c. If the green power indicator on the MRE Power Supply is OFF. Go to Step 3.</td><td> 
MRE Power Supply power ON
 
Power Supply OFF</td></tr>
<tr><td></td><td colspan="2">3. Check if the power switch on the MRE Power Supply is in the ON position.
4. If the power switch on the MRE Power Supply is in the OFF position, switch on and check if the green power indicator on the back of the MRE Power Supply is illuminated.
5. If not illuminated, check if the AC power cord is plugged into an outlet and other end is plugged into the MRE Power Supply. If plugged in, then call Siemens Healthineers Service.
If power is ON at the System Mains Power Supply in the equipment room and the MRE Power Supply indicator remains OFF, call Siemens Healthineers Service. The Equipment Room Power Supply may require replacement.</td></tr>
<tr><td rowspan="4">The Main Vertical Axis (Spin Indicator) on the MRE Tower is not spinning.
  </td><td>1. Confirm that the white power LED on the MRE Tower is ON (illuminated).</td><td> 
MRE Tower power ON</td></tr>
<tr><td>2. If light is OFF, go to section ‘MRE Tower does not have power’ to troubleshoot a power related issue.</td><td> 
MRE Tower power OFF</td></tr>
<tr><td>3. If the LED is ON, check the following:</td><td></td></tr>
<tr><td>a. Turn off the MRE Tower. Wait 10 seconds. Turn on the MRE Tower. Try to trigger the MRE Tower to spin again.
b. Confirm that the MRE Axis sections are not bent excessively.</td><td> 
Acceptable bending
 
Excessive bending</td></tr>
</table>

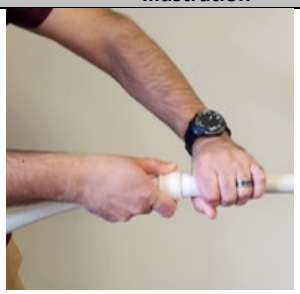
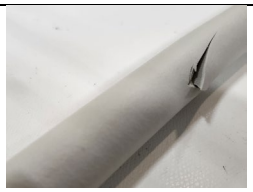
Problem	Troubleshooting Steps	Illustration
	c. Disconnect MRE Transducer, then initiate scan. If the Spin Indicator is spinning, replace the MRE Transducer.	
	d. Disconnect one MRE Axis section at a time and initiate scan to determine if one of the axes is faulty. If one axis section is faulty, replace that MRE Axis section.	 Single axis attached to transducer
	e. Disconnect both MRE Axis sections from the MRE Tower and initiate a scan. If the Spin Indicator still does not spin, call Siemens Healthineers Service. MRE Tower may require replacement.	 Both Axes removed from MRE Tower
MRE Tower Cable has torn cable jacket or damage to connector housing	Call Siemens Healthineers Service; the MRE Tower Cable must be replaced.	
Cracked Cover(s) on MRE Tower	Call Siemens Healthineers Service; the MRE Tower must be replaced.	 Cracked cover on MRE Tower
MRE Tower Cable not attaching to MRE Socket properly	1. Inspect for debris in the MRE Tower Cable connector or MRE Socket. Remove any debris. 2. Inspect for damage to the MRE Tower Cable connector or MRE Socket. If damage is found, call Siemens Healthineers Service; the MRE Tower Cable or MRE Socket may require replacement.	 Mating sides of the socket fixtures

11.3 MRE Tower – Handling Issues

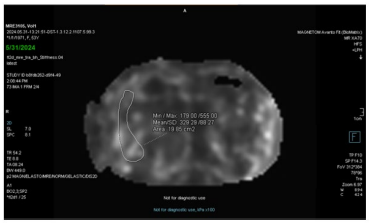
Problem	Troubleshooting Steps	Illustration
Unable to unlock braking on MRE Tower. Unable to move MRE Tower.	1. Confirm that the brake handle moves upward.	 Lift handle upward to unlock
	2. Confirm that the brake plungers have lifted from the floor with the brake handle engaged. 3. Check that the MRE Tower wheels are not restricted by any objects. 4. Check for debris in or near the MRE Tower skirt. 5. Contact Siemens Healthineers Service.	 Ensure brake plungers have lifted and no blockage of MRE Tower skirt or wheels
Unable to lock MRE Tower wheels. MRE Tower moves freely.	1. Engage and release the brake handle to see if locking is restored. 2. Check under the MRE Tower skirt and ensure no foreign objects are blocking the brake plungers from moving downward. 3. If the brake plungers are dirty, clean the plungers per Section 10.2 Maintenance. 4. Contact Siemens Healthineers Service.	 Lift handle upward to release brake
Difficulty in moving tower across floor.	1. Ensure the brake handle is fully engaged. 2. Check around the MRE Tower base; confirm no objects are blocking the wheels or skirt. 3. Call Siemens Healthineers Service	 Lift handle upward to release brake  Ensure no blockage of MRE Tower skirt or wheels

11.4 MRE Axis and Transducer Issues

Problem	Troubleshooting Steps	Illustration
Unable or difficult to connect MRE Axis to MRE Tower	1. Turn off power to the MRE Tower. 2. Check for any debris or obstruction between the tower axis port and axis connector port. 3. Connect a different MRE Axis to determine if a proper connection can be made. 4. If proper a connection cannot be made, the MRE Axis section is faulty. Replace the MRE Axis section.	
Unable or difficult to connect Axis Section to Axis Section	1. Turn off power to the MRE Tower. 2. Check for any debris or obstruction between the axis connectors or connector port. 3. Connect a different MRE Axis section to determine if a proper connection can be made. 4. If proper a connection cannot be made, the MRE Axis section is faulty. Replace the MRE Axis section.	
Unable or difficult to connect Axis to the Transducer	1. Turn off power to the MRE Tower. 2. Check for any debris or obstruction between the axis and transducer connector ports. 3. Connect a different MRE Axis section to determine if a proper connection can be made. 4. If proper connection cannot be made, the MRE Axis section is faulty. Replace the MRE Axis section.	
MRE Transducer is warm or hot to touch	1. Stop scanning patients immediately! 2. Call Siemens Healthineers service.	
MRE Axis is warm or hot to touch	1. Stop scanning patients immediately! 2. Call Siemens Healthineers service.	

Problem	Troubleshooting Steps	Illustration
The MRE Axis emergency disconnect does not release	1. Ensure the patient table is stopped. 2. Check the connection between the two MRE Axis Sections, between the MRE Axis section and MRE Tower, and between the other MRE Axis section and MRE Transducer. 3. If connections are made properly and emergency disconnect still does not release, call Siemens Healthineers service. Replacements are needed.	
Damage or Tear in axis jacket	Call Siemens Healthineers service. The MRE Axis section must be replaced.	

11.5 MRE Image Quality Issues

Problem	Troubleshooting Steps	Illustration
Stiffness with quality threshold map has many zero values where anatomy is located. The corresponding stiffness map reports high values.	1. Confirm that the MRE device is connected and powered on. 2. Confirm that the MRE Axis sections are connected properly. 3. Confirm that the MRE Transducer is properly positioned and that the MRE Strap is holding the MRE Transducer in place. 4. Call Siemens Healthineers service.	 Quality threshold map  Stiffness map

Chapter 12 – Performance Characteristics

12.1 Technical Specifications

Field Strength	1.5T or 3T
Siemens MRI System Software Version	VA60/XA60 or greater
Input Power	100-240 V
Rated Frequency Range	50-60 Hz
Input Power Rating	5.8-3.2 A
Duty Cycle	3 minutes ON, 27 minutes OFF
Safe Working Load	35 kg + 9 kg
Conformance	IEC 60601-1, IEC 60601-1-2, ISO 14971
Comparison to phantoms with known stiffness	

Expected Value (kPa)*	Measured Value (kPa)	
	SureWave 2D**	SureWave 3D**
0.82	0.76 ± 0.01	0.73 ± 0.01
2.02	2.53 ± 0.94	2.01 ± 0.07
2.77	3.83 ± 0.44	3.27 ± 0.32
5.80	5.80 ± 0.67	5.20 ± 0.08

* The expected stiffness values of 2.02 kPa, 2.77 kPa, and 5.80 kPa were established using mechanical techniques.

** 95% confidence interval

12.2 Electromagnetic Compatibility (EMC) - Guidance and Manufacturer's Declaration

SureWave™ Elastography hardware requires special attention regarding EMC and must be installed and used in accordance with the EMC guidelines provided in this manual. Only use the device in the environment specified below; electromagnetic compatibility is not ensured in environments other than those specified.

Essential Performance of the device: SureWave™ Elastography does not have any essential performance.

12.2.1 Classification

This device is classified as Class A per CISPR 11 when it is used in combination with an MRI system.

> 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 a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

12.2.2 Environment and Compatibility

The MRE Tower is intended to be used in an RF-shielded scan room within a specialized healthcare facility. The MRE Power Supply is intended to be used in a professional healthcare facility environment. All cables and accessories are part of the device and cannot be removed or replaced by the user.

RF Shielded Scan Room Specifications:

The required attenuation of the RF-shielded scan room is 90 dB in the frequency range of 15 – 128 MHz.

The testing shall be performed in accordance with the following test specification:
Title: IEEE 299 – 2006, Standard Method for Measuring the Effectiveness of Electromagnetic Shielding Enclosures the Institute of Electrical and Electronics Engineers, Inc.

All equipment used in the MRI Room should be designed and labeled in accordance with the ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment as well as the Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment Guidance for Industry and Food and Drug Administration Staff issued on May 20, 2021 and the updated references from the documents released on October 10, 2023.

WARNING

1. WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
2. WARNING: Use of accessories, transducers and cables other than those specified or provided in this manual could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
3. WARNING: 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 MRE System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

CAUTION

Failure to use this equipment in the specified type of shielded location could result in degradation of the performance of this equipment, interference with other equipment or interference with radio services.

12.2.3 Electromagnetic Emission – MRE Tower

The device is used only within an RF-shielded environment. Therefore, IEC 60601-1-2 clause 7 regarding electromagnetic emission does not apply.

12.2.4 Electromagnetic Immunity – MRE Tower

This device complies with IEC 60601-1-2 clause 8 when used in the specified electromagnetic environment.

Immunity Test	Test and Compliance Level
Electrostatic discharge (ESD), contact discharge	IEC 61000-4-2 ±2kV, ±4kV, ±6kV, ?8 kV
Electrostatic discharge (ESD), air discharge	IEC 61000-4-2 ±2kV, ±4kV, ±8kV, ±15kV
Radiated RF EM fields	IEC 61000-4-3 3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3 See Clause 8.10.
Immunity to proximity magnetic fields in the frequency range 9kHz to 13.56 MHz	IEC 61000-4-39 See Clause 8.11.

12.2.5 Electromagnetic Compliance – Power Supply

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2-2014 4th edition. These limits and test levels are intended to provide reasonable safety with regard to electromagnetic disturbances when the device is used in a typical medical installation.

12.2.6 Deviations

The MRE Tower is utilized in a special environment alongside an MRI system. Due to the location used and the use of filters in line with the MRE Power Supply, testing has been limited to performing limited scope of testing on the MRE Tower.

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