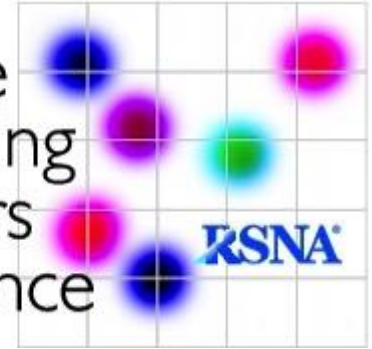


Quantitative
Imaging
Biomarkers
Alliance



QIBA Profile:

Magnetic Resonance Elastography of the Liver

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Stage: 2. Consensus Profile.
May 2, 2018

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Maintenance Release: June 22, 2021

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When referencing this document, please use the following format:

QIBA MR Biomarker Committee. MR Elastography of the Liver, Quantitative Imaging Biomarkers Alliance. Profile Stage: Consensus. June 22, 2021. Available from: <http://qibawiki.rsna.org/index.php/Profiles>

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Change Log:

This table is a best-effort of the authors to summarize significant changes to the Profile.

Date	Sections Affected	Summary of Change
12/2/2016	All	Added References
12/7/2016	4	Added details on proposed test-retest study for sites to demonstrate conformance with profile.
12/23/2016	All	Changed profile claim to a 19% change (revised from a 22% change)
12/23/2016	3.3	Added brief discussion on comparison of MRE and materials testing in phantoms and tissue to highlight complexity and explain the role of the volunteer test-retest conformance validation as opposed to a phantom study.
1/9/2017	2/3.3	Moved discussion of MRE phantom measurements and DMA testing to from the Periodic QA section to the end of the Claims discussion section.
1/9/2017	3.5.1	Changed fasting time from 3 to 4 hours.
5/5/2017	4.2	Revised wording regarding demonstration of conformance with the profile.
7/28/2017	4.2	Additional discussion was added to clarify the specific situations in which it would be necessary to demonstrate conformance to the profile.
1/10/2018	Appendix D	Changes made to Phillips protocols to reflect current parameters
1/10/2018	All	Suggested formatting change to meet profile requirements including changes to bold font.
1/10/2018	Multiple	Requirements were reformatted as QIBA Shall Tables, assigning the requirements to specific actors.
1/10/2018	2	Wording of the Claim adjusted to remove the words “in this patient”
1/10/2018	3.1, 3.4, 3.9	Sections dropped due to no substantive content
1/10/2018	2	Requirements of using the same scanner, driver hardware, parameters, and software were moved to section 3.5.1 and 3.6.1 per QIBA profile guidance that the “holds when” section should be used for clinically relevant limitations and not profile requirements.
11/14/2018	Appendices	Updates were made to the appendices to more accurately reflect the current imaging acquisition protocols and to clarify imaging procedures.
3/14/2019	All	Grammar and text clarifications provided.
3/14/2019	Appendices	Added Appendices A, B, and C, updated Appendix D
6/9/2020	All	Updated language throughout the profile to better conform with QIBA guidelines.

6/9/2020	Appendix D	Updated image acquisition parameters.
6/9/2020	3.11	Revised requirement to calculate the weighted mean for the reported liver stiffness values to the mean across the slices.
6/9/2020	3.2	Removed section 3.2 as there are no profile specific requirements for Installation.
6/9/2020	Appendix F	Added Checklist to profile.
4/12/2021	3.10	Updated minimum ROI size to 500 pixels (12.8 cm ³).
4/12/2021	3.6.1	Added text to recommend the use of EPI-MRE sequences at 3T due to the higher technical success rate.
4/12/2021	Appendix F	Updated checklist with revised text.

45 Open Issues:

The following issues are provided here to capture associated discussion, to focus the attention of reviewers on topics needing feedback, and to track them so they are ultimately resolved. In particular, comments on these issues are highly encouraged during the Public Comment stage.

50 Closed Issues:

The following issues have been considered closed by the biomarker committee. They are provided here to forestall discussion of issues that have already been raised and resolved, and to provide a record of the rationale behind the resolution.

Q. The longitudinal claim presented in this profile requires that the MRE stiffness measurements (magnitude of the complex shear modulus) have a linear relationship with true stiffness. Can this be confirmed with phantom testing?

A. The working group noted that existing technology does not provide a way to fabricate elastography phantoms with stiffness values that are precisely defined in advance by the composition and process. Existing dynamic mechanical testing devices used in laboratories have significant limitations for estimating the complex shear modulus of semi-solid materials. Therefore, no currently-accepted test procedure can be recommended to confirm the assumption of linearity. However, based on the physical principles of the MRE measurement process and published comparisons with benchtop mechanical testing (refs), the working group concludes that linearity is a reasonable assumption at this time.

Q. Should the profile attempt to identify commercial suppliers of MRE phantoms in this first edition?

A. At this time, commercial products are limited, have not been widely tested, and may only be available from some of the MRI OEM's. The draft profile describes the use of an MRE phantom to aid training and as an optional tool for generally confirming proper system operation (not to test accuracy). Accordingly, it may be appropriate to defer

<p>attempting identify commercial MRE phantoms to the second edition of the profile, when there may be more experience to confirm availability and usability.</p>
<p>Q. References/Citations A. References were added</p>
<p>Q. “The wCV value is really your fundamental technical performance claim. Essentially, if actors follow the profile they will achieve measurements of a wCV of 7%. Move this into an additional claim.” – From Public Comments A. Chose to leave this as informative text but not move to an additional claim.</p>
<p>Q. Related to section 4.2 “It’s not clear from the text above and here whether the requirement is on the wCV or the RC%. Admittedly they’re ‘equivalent’ but it’s simpler to pick one.” A. As these are equivalent, the wCV and RC% will be left in the text.</p>
<p>Q. The statement below conflicts with section 4.1.3. Should the profile contain a requirement that patients need to be scanned on the same MRI scanner with the same hardware for follow-up exams?</p> <p>Section 3.5.1: For follow-up exams, confirm that the subject will be scanned on the same MRI scanner and passive driver hardware as the baseline liver MRE.</p> <p>Section 4.1.3 states: Image analysis software for liver MRE is standardized across vendors. Therefore, the quantitative elastograms or stiffness maps are highly reproducible across sites and vendors. For the determination of ROIs, training and procedures should be followed as outlined in Section 3.10.</p> <p>A. Wording in Section 3.5.1 was updated, adding the wording “in order to satisfy the specific requirements for the claim” to provide clarification.</p>
<p>Q. In section 3.5.2 (Figure 1), the profile states: <(links on MR tech training – to be added)></p> <p>Will this training be made available, or should this statement be removed from the profile?</p> <p>A. This was removed.</p>
<p>Q: There is a new proposed limit of 500 pixels per exam (rather than 500 pixels per slice) based on a simulation study performed by members of the biomarker committee. Should this limit be adopted into the profile?</p> <p>A. The limit of 500 pixels was updated in Section 3.10. Language was added on the ROI volume and number of pixels for cases where the image acquisition parameters may be different from the protocol.</p>

55 **1. Executive Summary**

The goal of a QIBA Profile is to help achieve a useful level of performance for a given biomarker.

The **Claim** (Section 2) describes the biomarker performance.

The **Activities** (Section 3) contribute to generating the biomarker. Requirements are placed on the **Actors** that participate in those activities as necessary to achieve the Claim.

60 **Assessment Procedures** (Section 4) for evaluating specific requirements are defined as needed.

This QIBA Profile (**Magnetic Resonance Elastography of the Liver**) addresses the **application of Magnetic Resonance Elastography (MRE) for the quantification of liver stiffness, which is often used as a biomarker of liver fibrosis**. It places requirements on **Acquisition Devices, Technologists, Radiologists, Reconstruction Software and Image Analysis Tools** involved in **Subject Handling, Image Data Acquisition, Image Data Reconstruction, Image QA and Image Analysis**.

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The requirements are focused on **achieving sufficient accuracy and avoiding unnecessary variability of the measurement of hepatic stiffness**.

The clinical performance target is **to achieve a 95% confidence interval for a true change in stiffness has occurred when there is a measured change in hepatic stiffness of 19% or larger**.

70 This document is intended to help clinicians basing decisions on this biomarker, imaging staff generating this biomarker, vendor staff developing related products, purchasers of such products and investigators designing trials with imaging endpoints.

Note that this document only states requirements to achieve the claim, not “requirements on standard of care.” Conformance to this Profile is secondary to properly caring for the patient.

75 QIBA Profiles addressing other imaging biomarkers using CT, MRI, PET and Ultrasound can be found at qibawiki.rsna.org.

2. Clinical Context and Claims

Clinical Context

80 Chronic liver disease (CLD) is a major health burden in the United States. CLD, regardless of etiology, when untreated may lead to liver fibrosis and if progressive to cirrhosis and its complications. Effective treatment methods for some forms of CLD are available and can prevent progression, or even result in regression, of fibrosis [1,2]. A reliable non-invasive technique is needed for detection, staging and assessment of treatment response in liver fibrosis. Measurement of *liver stiffness* (defined in this document as the magnitude of the complex shear modulus) with MR Elastography (MRE) has been shown to be useful for non-invasive detection and staging of liver fibrosis [3,4]. Published evidence has established that MRE is an accurate and reproducible technique and promising for use in clinical trials [5-7].

90 **Conformance to this Profile by all relevant staff and equipment supports the following claim(s):**

Claim: A measured change in hepatic stiffness of 19% or larger indicates that a true change in stiffness has occurred with 95% confidence.

Discussion

95 This claim is based on estimates of the normal liver stiffness within-subject coefficient of variation (wCV) which we have estimated as 7% [8]. The Repeatability Coefficient is then $2.77 \times \text{wCV}$, or 19%. If Y1 and Y2 are the stiffness values (in kPa) at the two time points, then the 95% confidence interval for the true change is $(Y2-Y1) \pm 1.96 \times \sqrt{[Y1 \times 0.07]^2 + [Y2 \times 0.07]^2}$ kPa.

100 Clinical interpretation with respect to the magnitude of true stiffness change:
The magnitude of the true change is defined by the measured change and the error bars. For example, if 3.5 kPa and 2.5 kPa are the stiffness values at time points 1 and 2, respectively, then $(3.5-2.5)/3.5$ represents a 40% decrease. Since $40\% > 19\%$, we are 95% confident that a true change in hepatic stiffness has occurred. The 95% confidence interval for the true change is 1.0 ± 0.49 kPa.

105 Multiple studies have demonstrated good agreement in mechanical stiffness of phantom materials assessed using MRE, and of the same phantom materials assessed using dynamic mechanical analyzer (DMA) instruments [9-11]. These studies provide confidence in the validity of MRE-based stiffness measurements. However, routine comparisons of MRE and DMA measurements for tissue and tissue-like materials are of limited use for MRE QA due to the technical limitations of DMA testing, including the difficulty of defining the geometry of semi-solid test specimens.

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3. Profile Activities

The Profile is documented in terms of “Actors” performing “Activities”. Equipment, software, staff or sites may claim conformance to this Profile as one or more of the “Actors” in the following table.

120 Conformant Actors shall support the listed Activities by conforming to all requirements in the referenced Section.

Table 1: Actors and Required Activities

Actor	Activity	Section
MR Physicist	Periodic QA	3.3.
	Assessment procedures	4.1
Technologist	Subject Handling	3.5.
	Image Data Acquisition	3.6.
	Image Data Reconstruction	3.7.
Radiologist	Image QA	3.8.
	Image Analysis	3.10.

125 The requirements in this Profile do not codify a Standard of Care; they only provide guidance intended to achieve the stated Claim. Failing to conform to a “shall” in this Profile is a protocol deviation. Although deviations invalidate the Profile Claim, such deviations may be reasonable and unavoidable and the radiologist or supervising physician is expected to do so when required by the best interest of the patient or research subject. How study sponsors and others decide to handle deviations for their own purposes is entirely up to them.

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3.3. Periodic QA

Parameter	Actor	Requirement
Required QA	Physicist	Measurements of liver stiffness (magnitude of the complex shear modulus) obtained with MRE depends on the spatial fidelity of the acquired phase images. Therefore, the validity of the field of view and image linearity shall be assessed and confirmed on an ongoing basis, using manufacturer-recommended procedures.
	Physicist	While other instrumental causes of drift in stiffness measurements have not been documented in the literature, technical failures such as faulty synchronization of the driver system or incorrect driver frequency settings can cause incorrect measurements. The physicist shall confirm correct driver frequency settings as outlined in Appendix D.
Optional QA	Physicist	Shall confirm correct user set-up and proper functioning of the MRE system using a phantom with previously-measured stiffness properties. These usually consist of a uniform, tissue-simulating material with known stability over time and storage conditions. An MRE phantom can be used to confirm proper functioning of the MRE system after initial installation and as a periodic test of correct functioning. There is as of yet, no consensus on recommendations for the frequency of phantom testing. Optional QA testing with a phantom should employ a protocol recommended by the phantom manufacturer. Appendix 2 describes a sample protocol for a currently available phantom.

Optional QA.

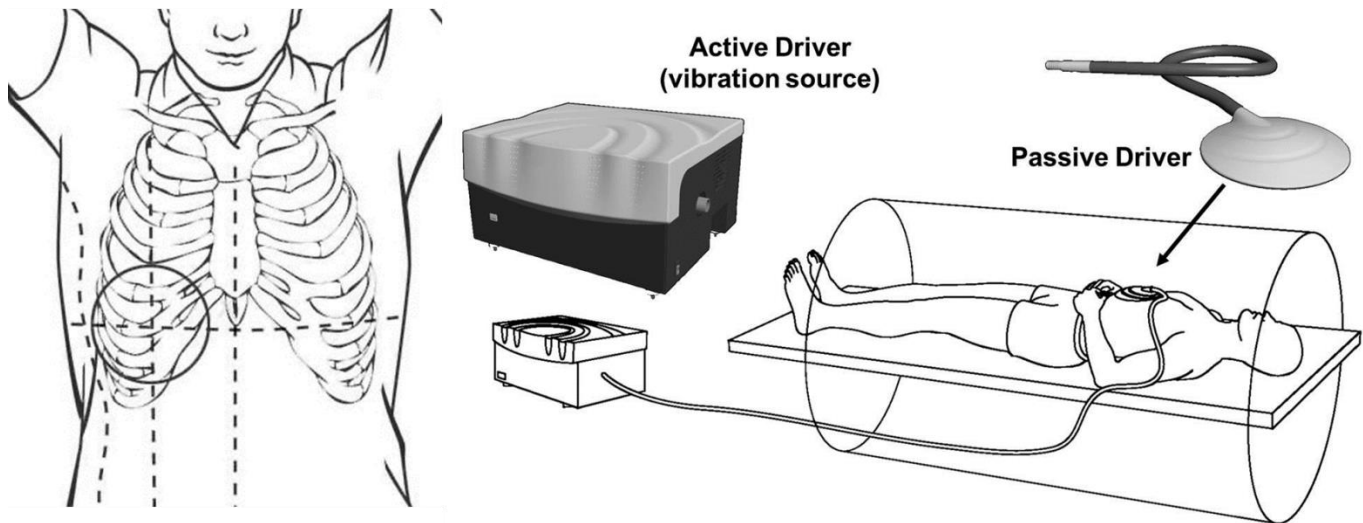
135 3.5. Subject Handling

3.5.1 Subject preparation

Parameter	Actor	Requirement
Fasting state	Technologist	Shall confirm that the subject is fasting for at least 4 hours before the scheduled time of imaging [12,13].
MR scanner and MRE device selection	Technologist	For follow-up exams, the technologist shall confirm that the subject will be scanned on the same MRI scanner and passive driver hardware as the baseline liver MRE in order to satisfy the specific requirements for the claim.

3.5.2 Subject positioning

Parameter	Actor	Requirement
Subject positioning	Technologist	Shall scan the subject in supine position.
	Technologist	Shall place the passive driver over the right lower chest wall at the level of xiphisternum in midclavicular line. (Can be placed in the right mid-axillary line if colon is present between the anterior body wall and the liver) [14,15].
	Technologist	Shall ensure the passive driver is held in firm contact with the body wall using an elastic band.
	Technologist	Shall ensure connection of the plastic tube between the passive & active driver, which is located outside the scan room.



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Figure 1: The passive driver should be placed over the right lower anterior chest wall at the level of the xiphisternum, centered on the mid-clavicular line. Once positioned, the passive driver should be held firmly against the chest wall by a wide elastic band, placed around the torso. Check to ensure that the band is stretched sufficiently so that the driver is not loose during full expiration. Note that the passive driver is connected via a plastic tube to the active driver (vibration source), which is located outside the scan room.

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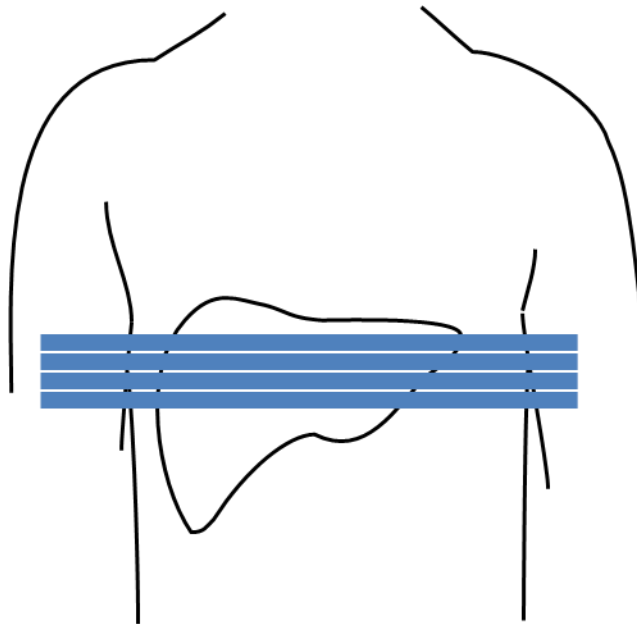
3.6. Image Data Acquisition

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3.6.1 MRE Sequence (GRE and EPI)

Parameter	Actor	Requirement
Image Acquisition	Technologist	Shall acquire image data during suspended expiration in a natural end-expiratory position.
Slice Selection	Technologist	Shall acquire sections for MRE positioned at the level of the widest transverse extent of the liver, avoiding the lungs, liver dome and inferior tip of the right lobe, prescribed in a coronal image in relaxed end-expiration. (Figure 2)
Image Acquisition	Technologist	Shall use an EPI-MRE sequence at 3T if available due to the higher technical success rate. Note, GRE MRE sequences are susceptible to T_2^* effects resulting in poor SNR or failures in tissue with short T_2^* relaxation times, particularly at 3T.[16]
Image acquisition	Technologist	For follow-up exams, technologist shall confirm that subjects are scanned with the same parameters and software as the baseline liver MRE.

Sequences discussed are commercially available 2D MRE acquisition techniques. See Appendix D for detailed vendor specific and scanner specific protocol parameters.



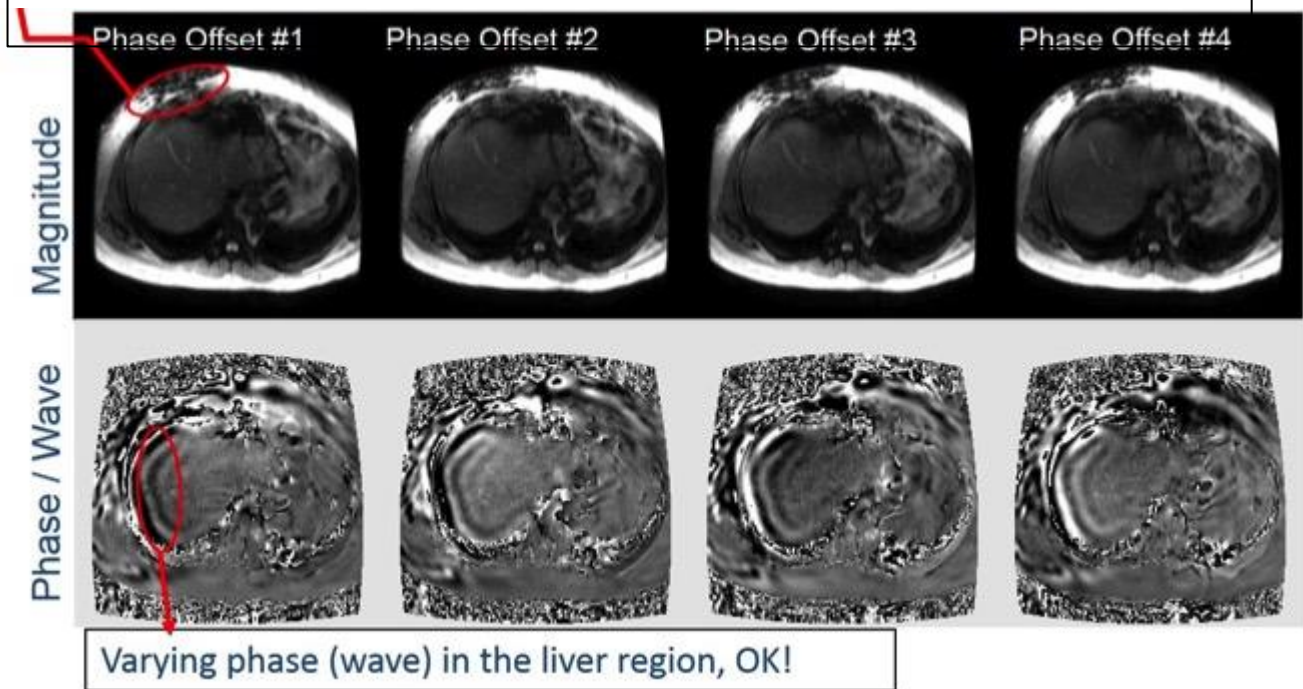
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Figure 2: Acquired sections for MRE are positioned at the level of the widest transverse extent of the liver, avoiding the lung, liver dome and inferior tip of the right lobe. Sections should be prescribed in a coronal image in relaxed end-expiration.

3.6.2 Technical success

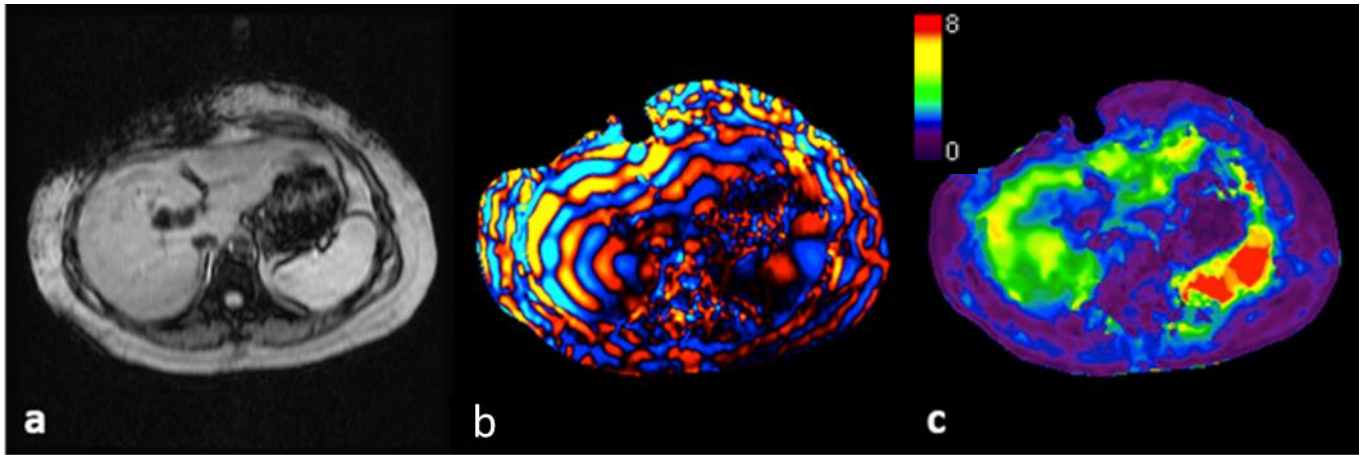
Parameter	Actor	Requirement
Image Acquisition	Technologist	Shall review the raw magnitude and phase images obtained from the MRE acquisition on the scanner console at the time of the exam.
Technical success	Technologist	The technologist shall confirm that the magnitude images show signal loss in the subcutaneous fat just below the passive driver placement, confirming that mechanical waves are being applied. The phase images (also known as wave images) should demonstrate shear waves in the liver. (Figure 3)
Technical success	Technologist	If no waves are imaged in the liver, then the technologist shall check driver system.

Loss of signal in subcutaneous fat → adequate motion from the passive driver.

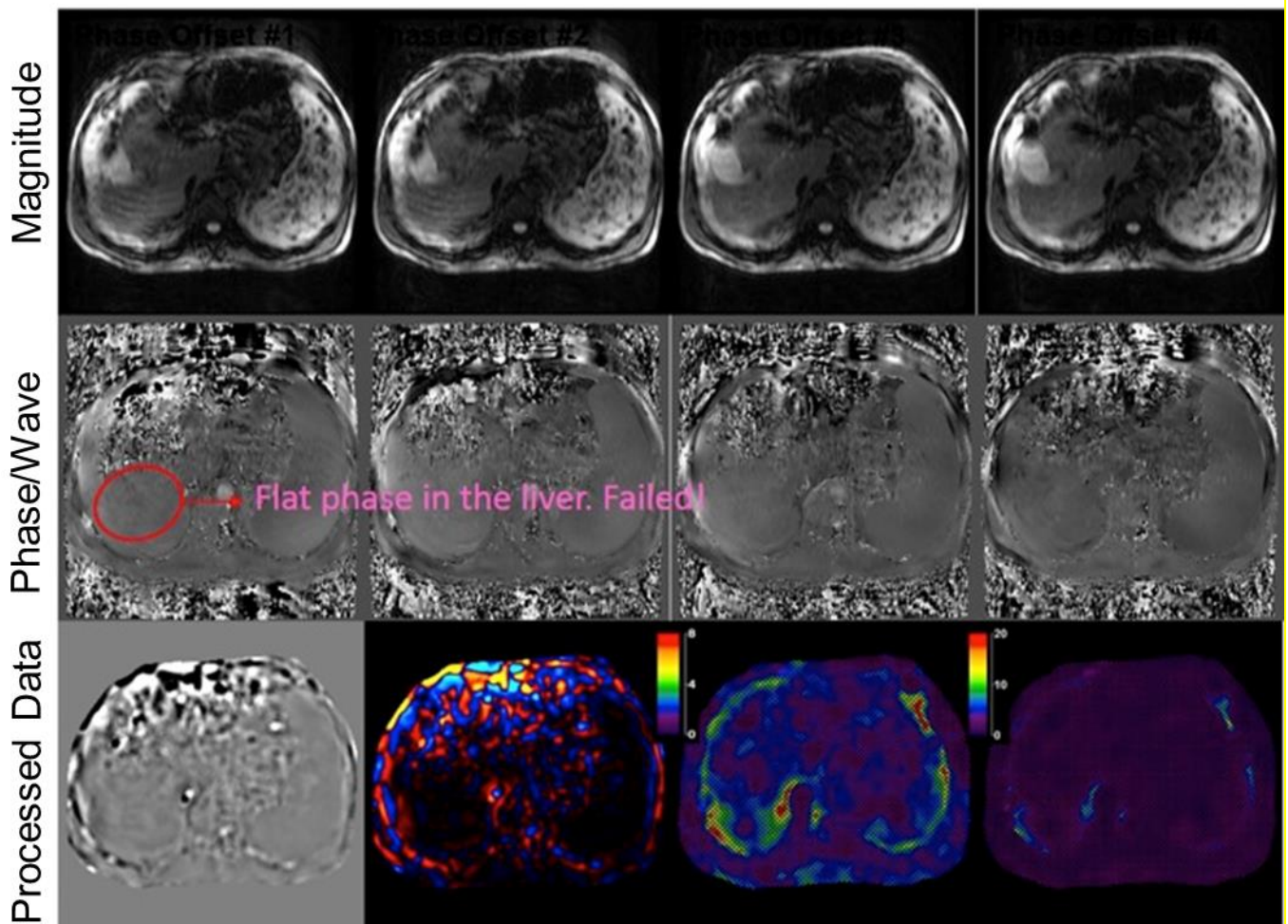


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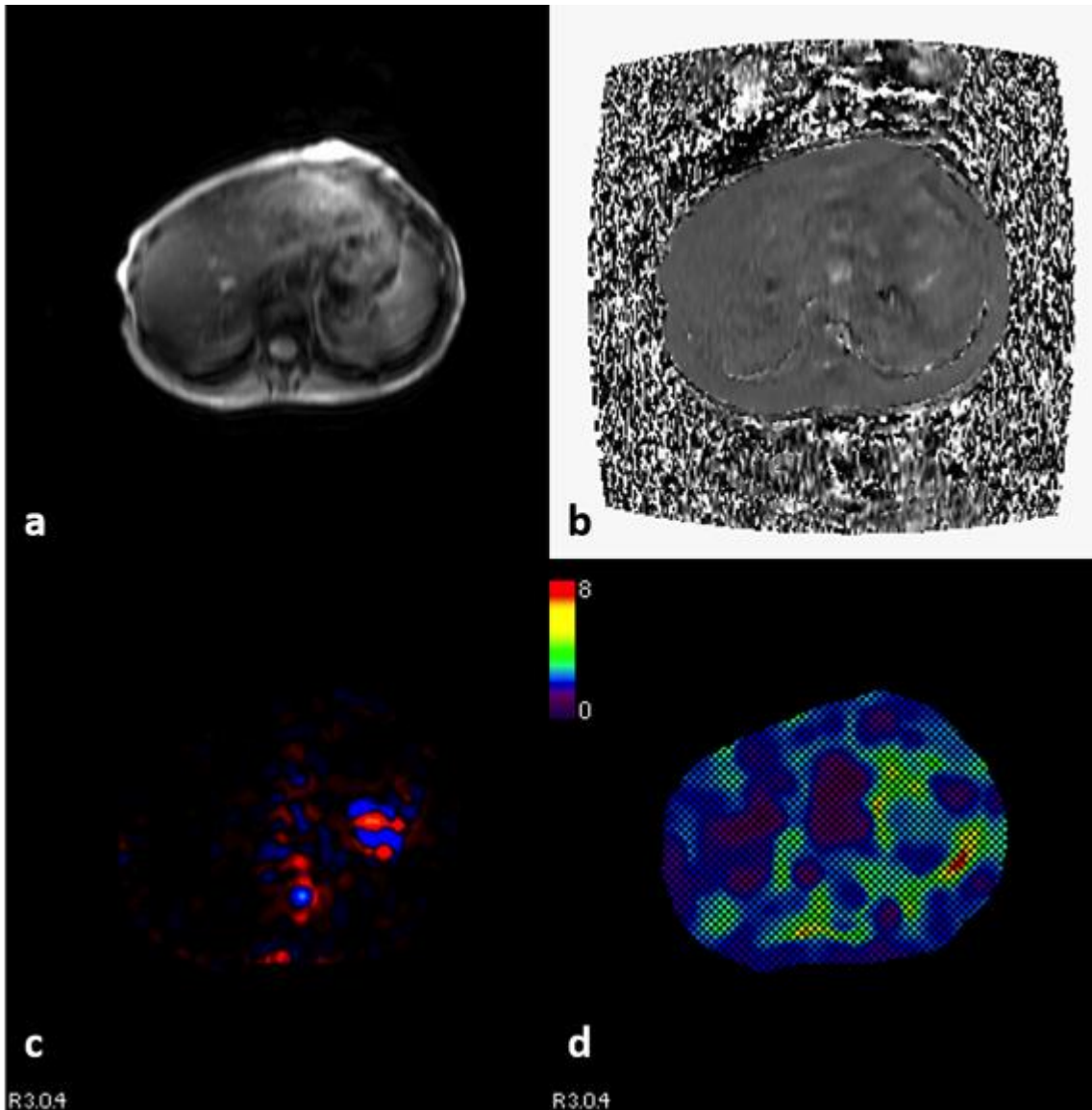
Figure 3: Valid MRE. Top row shows the magnitude images of four time offsets and bottom row shows the phase (wave) images. The four time offsets belong to a single slice location.



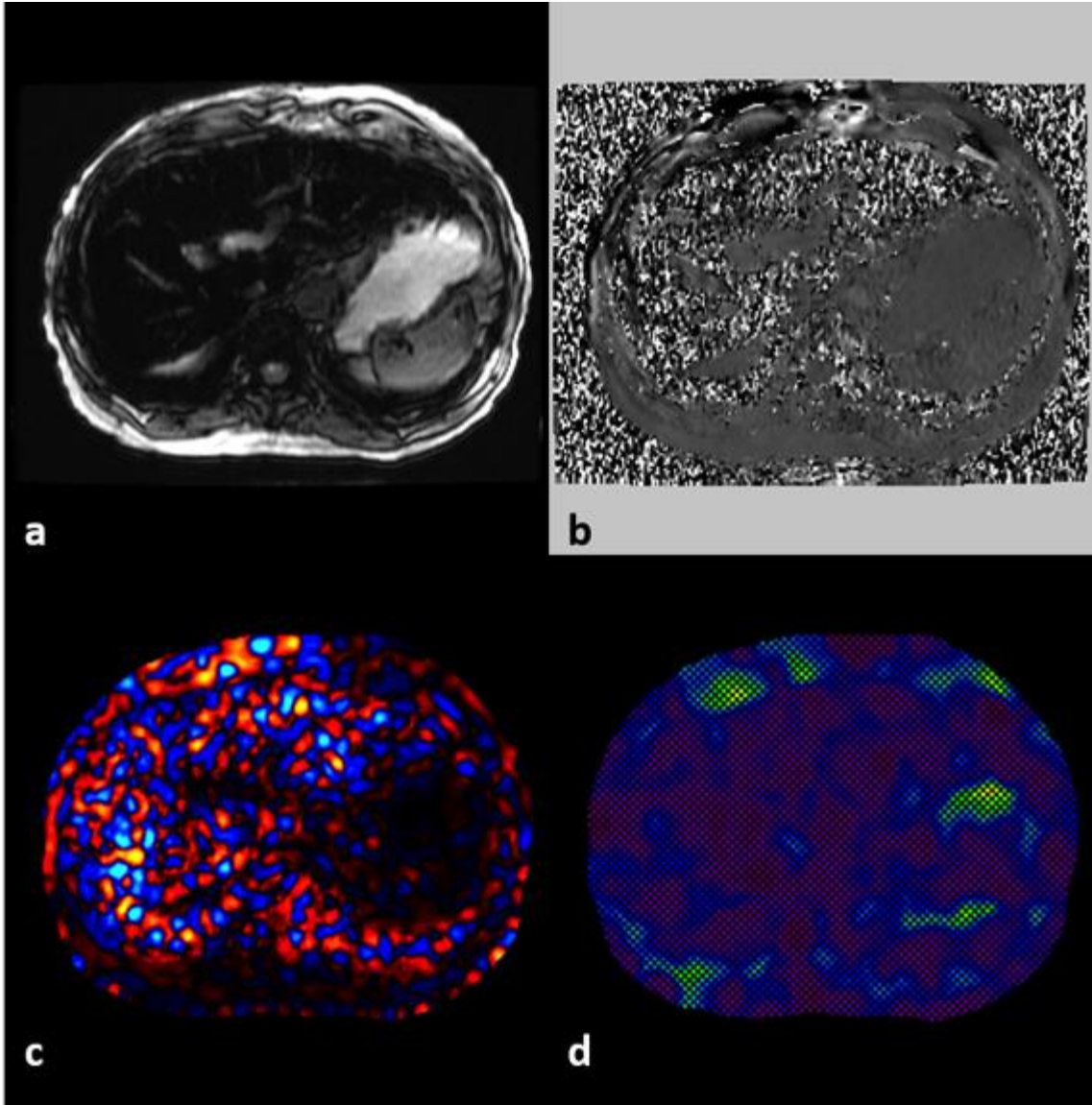
165 **Figure 4:** Magnitude (a) and color-coded wave (b) images of a successful MRE showing excellent illumination of waves through the liver. Stiffness map (c) shows elevated liver stiffness consistent with significant fibrosis.



170 **Figure 5:** Failed MRE exam – Representative images of failed MRE exam due to colonic interposition between the passive driver and the liver.



175 **Figure 6:** Failed MRE exam – Representative images of failed MRE exam due to a disconnection of the plastic tube between the passive and active drivers. Magnitude (a), phase (b), and color-coded wave (c) images show no waves traversing the liver. Stiffness map (d) has no valid data.



180 **Figure 7:** Failed MRE exam – Representative images of failed MRE exam due to hepatic iron overload. Magnitude (a) shows a lack of liver signal while the phase (b) and color-coded wave (c) images show no waves traversing the liver. Stiffness map (d) has no valid data (represented with the hashed-out area). Lack of signal in the liver from T2* effects confound the MRE processing.

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3.7. Image Data Reconstruction

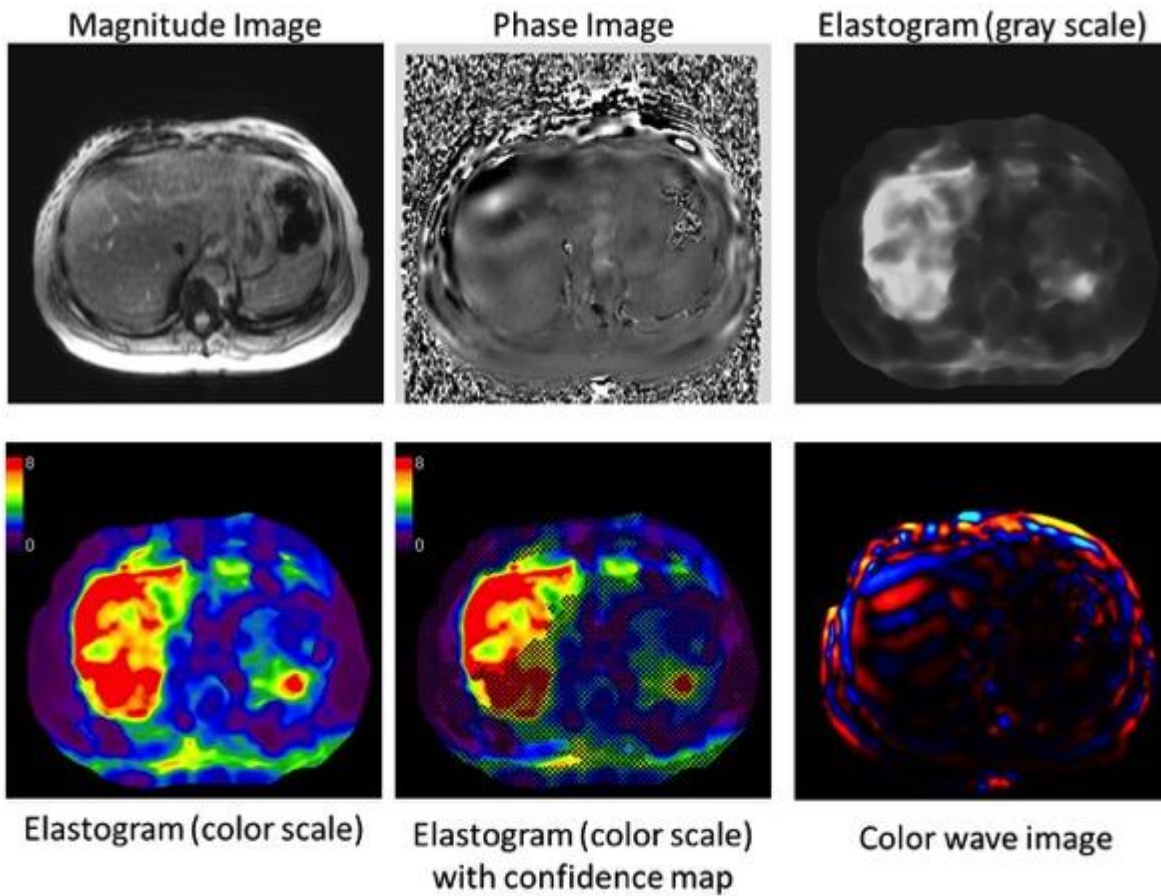
3.7.1 DISCUSSION

190 Post-processing of the acquired magnitude and phase (wave) images is performed to create quantitative maps of liver stiffness, or elastograms. This post-processing technique is standardized across vendors.

3.7.2 QUANTITATIVE ELASTOGRAMS

Parameter	Actor	Requirement
Image Reconstruction	Technologist	The technologist shall confirm that the scanner computer automatically processes the information to generate the following images on the scanner console: quantitative stiffness maps, confidence maps, and unwrapped phase images. (Figure 8)

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1. Quantitative stiffness maps (elastograms), depicting the magnitude of the complex shear modulus in a gray or color scale. The most appropriate default scale is 0-8 kPa.
 2. Confidence maps: quantitative elastograms in which areas where the estimated stiffness values have reduced reliability due to low wave amplitude are indicated with cross-hatching or other means.
- 200
3. Unwrapped wave images, providing a clear depiction of the observed waves. Phase wrapping occurs when the shear wave motion is large. Since MRE is a phase-based technique, the displacement data typically must be unwrapped before subsequent processing is performed.



205 **Figure 8:** Representation of images generated in a MRE study. Additional post-processed images may be available depending on the software version installed on the scanner.

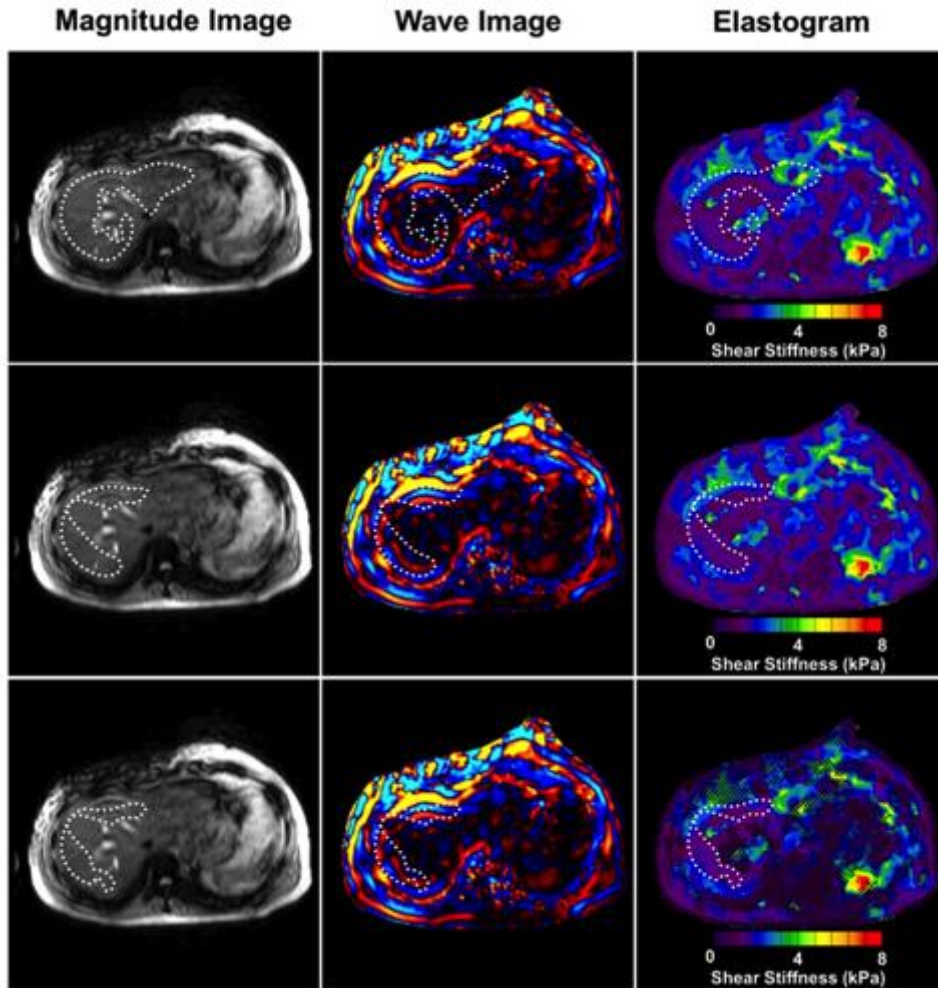
3.8. Image QA

Parameter	Actor	Requirement
Image QA	Radiologist	At the time of image review, the suitability of the data shall be checked again by confirming the presence of signal loss in subcutaneous fat under the driver in the magnitude images, and the presence of visible waves in the liver in the phase and wave images (Figure 3).

210 The quantitative elastograms of successful exams should demonstrate areas of valid stiffness data within the liver in the confidence maps (see figures 3 to 8 as representative examples of a successful and failed MRE studies).

3.10. Image Analysis

Parameter	Actor	Requirement
Mean shear stiffness of the liver	Radiologist	Mean shear stiffness of the liver shall be calculated using manually specified regions of interest (ROIs). The ROIs are drawn manually in the largest possible area of liver parenchyma in which coherent shear waves are visible, while excluding major blood vessels seen on the MRE magnitude images.
	Radiologist	To avoid areas of incoherent waves, the radiologist shall avoid regions immediately under the passive driver and stay ~1 cm inside the liver boundary and contain a minimum of 500 pixels for an acquisition with a 420 mm FOV and reconstruction matrix of 256x256 total, corresponding to approximately 12.8 cm ³ [17,3].
	Radiologist	ROIs shall be placed in individual slices and in the right lobe whenever possible. MRE magnitude and phase/wave images should be used to guide the placement of the ROIs. (Figure 9)
	Radiologist	Image shall be rejected if the acquisition failed due to hepatic iron overload. (Figure 7)
	Radiologist	Image shall be rejected if colonic interposition between the passive driver and liver is present. (Figure 5)



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Figure 9: Regions of interest (ROIs) should be drawn with reference to the magnitude, wave, and elastogram images. The ROI should be within the contour of the liver, excluding areas near the margins and major vessels (top row). The ROI should be modified to exclude areas with low wave amplitude as well as incoherent waves (due to wave interference from waves propagating through the region from different directions or due to other disruptions to the wave field such as those caused by adjacent blood vessels, fissures, and other organs), as observed in the wave images (middle row). The ROI should also exclude areas of low confidence, as seen by the checkerboard pattern in the masked elastogram images (lower row). In practice, the ROIs may be drawn in a single step, keeping these principles in mind. Generally the ROI should be confined to the right lobe of the liver.

3.11. Image Interpretation

Parameter	Actor	Requirement
Liver stiffness	Radiologist	Overall mean stiffness of liver shall be reported by calculating the mean stiffness value of each ROI and then reporting the mean value across all slices.

Example: Slice 1: mean liver stiffness = 2.32 kPa ; Slice 2: mean liver stiffness = 2.25 kPa; Slice 3: mean liver stiffness = 2.52 kPa; and Slice 4: mean liver stiffness = 2.22 kPa; then the overall mean = $(2.32+2.25+2.52 + 2.22)/(4) = 2.33$ kPa.

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4. Assessment Procedures

To conform to this Profile, participating staff (“Actors”) and equipment shall support each activity assigned to them in Table 1.

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To support an activity, the actor shall conform to the requirements (indicated by “shall language”) listed in the specifications table of the activity subsection in Section 3.

Although most of the requirements described in Section 3 can be assessed for conformance by direct observation, some of the performance-oriented requirements cannot, in which case the requirement will reference an assessment procedure in a subsection here in Section 4.

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Formal claims of conformance by the organization responsible for an Actor shall be in the form of a published QIBA Conformance Statement. Vendors publishing a QIBA Conformance Statement shall provide a set of “Model-specific Parameters” (as shown in Appendix D) describing how their product was configured to achieve conformance. Vendors shall also provide access or describe the characteristics of the test set used for conformance testing.

4.1. Assessment Procedure: Stiffness Measurement in the liver

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This procedure can be used by a vendor, physicist, or an imaging site to assess the stiffness measurement made with MRE. For MRE use as a quantitative imaging biomarker of liver stiffness, it is essential to ensure quality assurance of the acquisition and image processing methodology.

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For an MRE image acquisition, it is important to consider the availability of:

- Appropriate imaging equipment
- Experienced MR technologists for the imaging procedure
- Procedures to ensure standardized image analysis techniques

4.1.1 IMAGING EQUIPMENT

Parameter	Actor	Requirement
Imaging Equipment	Physicist	As outlined in Section 3.2, installation and initial functional validation shall be performed according to manufacturer-defined procedures and specifications. This includes specific guidelines on the MRI scanner and MRE driver system. The scanner must be under quality assurance and quality control processes as outlined by local institution and vendor requirements. The scanner software version should be identified and tracked across time.

Parameter	Actor	Requirement

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4.1.2 IMAGING PROCEDURE

Parameter	Actor	Requirement
Imaging Procedure	Technologist	Currently, there is not a standard imaging phantom for standardized image acquisition and processing procedures. The technologist shall follow Appendix E for phantom imaging protocols.

4.1.3 IMAGE ANALYSIS

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Image analysis software for liver MRE is standardized across vendors. Therefore, the quantitative elastograms or stiffness maps are highly reproducible across sites and vendors. For the determination of ROIs, training and procedures should be followed as outlined in Section 3.10.

4.2. Test-Retest Conformance Study

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Actors may demonstrate conformance to the profile through a test-retest repeatability study which may be performed in a group of healthy volunteers. The specific situations in which it would be advisable to prove conformity are currently the subject of study, but there is a consensus that assessment of conformity would typically be appropriate when a new version of MRE is introduced, such as by a new vendor. An important assumption underlying the claim is that the image analysis software has a within-subject test-retest coefficient of variation (wCV) of <0.07 (7%) (or RC of <19%). In order to test this assumption, N=40 normal subjects will be imaged, with each subject imaged twice on the same day (and additionally, some of these subjects may return for a third scan within one week). Subject selection should be performed as outlined in Section 3.4. The same scanner, driver hardware, parameters, and software should be used following the guidelines outlined in Section 3.5 for subject preparation and positioning. Following the liver MRE acquisition on day 1, subjects will be asked to stand and are repositioned for a second MRE exam. A third MRE exam should be performed within 7 days. The data is reconstructed and analyzed using the techniques outlined in Section 3.7 and 3.10 respectively.

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Let Y_{i1} denote the liver stiffness measurement from the first scan 1, Y_{i2} denote the liver stiffness measurement from the second scan, and, as available, Y_{i3} denote the liver stiffness measurement from the third scan on the i -th subject. For each subject, calculate the mean of the J measurements (where $J=2$ or 3) and the wSD :

$$\bar{Y}_i = \sum(Y_{ij})/J \text{ and } wSD_i^2 = \sum(Y_{ij} - \bar{Y}_i)^2 / (J - 1).$$

Then estimate the wCV:

285

$$wCV = \sqrt{\sum_{i=1}^{N=40} (wSD_i^2 / \bar{Y}_i^2) / N}.$$

The percent repeatability coefficient is then calculated as follows: $\%RC = 1.96 \times \sqrt{2 \times \%wCV^2}$.

290 To demonstrate conformance with the profile claim, this estimated %RC from the test-retest study must be $\leq 19\%$.

References

- 295 1. Ellis EL, Mann DA (2012) Clinical evidence for the regression of liver fibrosis. *Journal of Hepatology* 56 (5):1171-1180. doi:<http://dx.doi.org/10.1016/j.jhep.2011.09.024>
2. Snowdon VK, Fallowfield JA (2011) Models and mechanisms of fibrosis resolution. *Alcohol Clin Exp Res* 35 (5):794-799. doi:10.1111/j.1530-0277.2010.01400.x
3. Yin M, Glaser KJ, Talwalkar JA, Chen J, Manduca A, Ehman RL (2016) Hepatic MR Elastography: Clinical Performance in a Series of 1377 Consecutive Examinations. *Radiology* 278 (1):114-124. doi:10.1148/radiol.2015142141
- 300 4. Yin M, Woollard J, Wang X, Torres VE, Harris PC, Ward CJ, Glaser KJ, Manduca A, Ehman RL (2007) Quantitative assessment of hepatic fibrosis in an animal model with magnetic resonance elastography. *Magn Reson Med* 58 (2):346-353. doi:10.1002/mrm.21286
- 305 5. Shire NJ, Yin M, Chen J, Raikar RA, Fox-Bosetti S, Johnson SM, Beals CR, Dardzinski BJ, Sanderson SO, Talwalkar JA, Ehman RL (2011) Test-retest repeatability of MR elastography for noninvasive liver fibrosis assessment in Hepatitis C. *Journal of Magnetic Resonance Imaging* 34:947-955
6. Yasar TK, Wagner M, Bane O, Besa C, Babb JS, Kannengiesser S, Fung M, Ehman RL, Taouli B (2016) Interplatform reproducibility of liver and spleen stiffness measured with MR elastography. *J Magn Reson Imaging* 43 (5):1064-1072. doi:10.1002/jmri.25077
- 310 7. Hines CDG, Bley TA, Lindstrom MJ, Reeder SB (2010) Repeatability of magnetic resonance elastography for quantification of hepatic stiffness. *Journal of Magnetic Resonance Imaging* 31:725-731
8. Repeatability of Magnetic Resonance Elastography of Liver - A Meta-Analysis. *Radiology* (In Review)
9. Arunachalam SP, Rossman PJ, Arani A, Lake DS, Glaser KJ, Trzasko JD, Manduca A, McGee KP, Ehman RL, Araoz PA (2016) Quantitative 3D magnetic resonance elastography: Comparison with dynamic mechanical analysis. *Magnet Reson Med*. doi:10.1002/mrm.26207
- 315 10. Chen Q, Ringleb SI, Hulshizer T, An KN (2005) Identification of the testing parameters in high frequency dynamic shear measurement on agarose gels. *J Biomech* 38 (4):959-963. doi:10.1016/j.jbiomech.2004.05.015
- 320 11. Okamoto RJ, Clayton EH, Bayly PV (2011) Viscoelastic properties of soft gels: comparison of magnetic resonance elastography and dynamic shear testing in the shear wave regime. *Phys Med Biol* 56 (19):6379-6400. doi:10.1088/0031-9155/56/19/014
12. Mederacke I, Wursthorn K, Kirschner J, Rifai K, Manns MP, Wedemeyer H, Bahr MJ (2009) Food

intake increases liver stiffness in patients with chronic or resolved hepatitis C virus infection. *Liver Int* 29 (10):1500-1506. doi:10.1111/j.1478-3231.2009.02100.x

- 325 13. Yin M, Talwalkar JA, Glaser KJ, Venkatesh SK, Chen J, Manduca A, Ehman RL (2011) Dynamic postprandial hepatic stiffness augmentation assessed with MR elastography in patients with chronic liver disease. *American Journal of Roentgenology* 197:64-70
14. Venkatesh SK, Ehman RL (2015) Magnetic Resonance Elastography of Abdomen. *Abdom Imaging* 40 (4):745-759
- 330 15. Venkatesh SK, Yin M, Ehman RL (2013) Magnetic resonance elastography of liver: technique, analysis, and clinical applications. *J Magn Reson Imaging* 37 (3):544-555. doi:10.1002/jmri.23731
16. Kim DW, Kim SY, Yoon HM, Kim KW, Byun JH (2019) Comparison of technical failure of MR elastography for measuring liver stiffness between gradient-recalled echo and spin-echo echo-planar imaging: a systematic review and meta-analysis. *Journal of Magnetic Resonance Imaging*
- 335 17. Dzyubak B, Venkatesh SK, Manduca A, Glaser KJ, Ehman RL (2016) Automated liver elasticity calculation for MR elastography. *Journal of Magnetic Resonance Imaging* 43 (5):1055-1063. doi:10.1002/jmri.25072

Appendices

340 **Appendix A: Acknowledgements and Attributions**

This document is proffered by the Radiological Society of North America (RSNA) Quantitative Imaging Biomarker Alliance (QIBA) MR Elastography Biomarker Committee. The MR Elastography Biomarker Committee is composed of physicians, scientists, engineers and statisticians representing academic institutions, professional societies, developers, imaging device manufacturers, biopharmaceutical companies, government research organizations and regulatory agencies that utilize MRE.

345

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Appendix B: Background Information

350 A number of publications report the repeatability of liver stiffness measurements with MRE. Ten articles were included based on fulfillment of four or more categories of the QUADAS-2 tool (Quality Assessment of Diagnostic Accuracy Studies). For the purpose of this profile, 10 studies were included in the RC calculation of RC=18.4% with 95% CI of [14.2, 22.2]. Table 1 lists the publications used for the determination of the claim.

355 **Table 1: Selected repeatability parameters extracted from literature publications.**

Publication	Sample Size	Field Strength (T)	Freq (Hz)	Time Interval	CV Reported (%)	RC (%)	RC 95% CI
Wang 2011 [1]	5	1.5	60	2 weeks	9-12	23	14.3, 56.4
Venkatesh 2014 [2]	41	1.5	60	4-6 weeks	8.4	18.8	13.5, 31.0
Shire 2011 [3]	9	1.5	60	1-2 weeks	6-11	17	12.2, 28.0
Shinagawa 2014 [4]	10	3.0	60	1 week	NA	10	7.0, 17.5
Shin 2014 [5]	15	1.5	60	2 weeks	NA	14	10.3, 21.7

Shi 2014 [6]	22	3.0	60	1 week	5.75	15.9	12.7, 21.4
Lee 2014 [7]	47	1.5	60	8-10 mins	13	25.3	21.0, 31.7
Jajamovich 2014 [8]	30	3.0	60	20 mins	3.8	10.5	8.6, 13.4
Bohte 2013 [9]	30	3.0	50	1-4 weeks	10.1	22.2	17.7, 29.7
Trout 2016 [10]	24	1.5, 3.0	60	same day	10.7	16.6	13.3, 23.1

Note, CV = coefficient of variation, NA = not applicable, RC = repeatability coefficient, CI = confidence interval. All publications reported values for the complex shear modulus (G^*).

References

- 360 [1] Wang Y, Ganger DR, Levitsky J, et al. Assessment of chronic hepatitis and fibrosis: comparison of MR elastography and diffusion-weighted imaging. *AJR Am J Roentgenol* 2011; 196(3):553-561.
- [2] Venkatesh SK, Wang G, Teo LL, Ang BW. Magnetic resonance elastography of liver in healthy Asians: normal liver stiffness quantification and reproducibility assessment. *J Magn Reson Imaging* 2014; 39(1):1-8.
- 365 [3] Shire NJ, Yin M, Chen J, et al. Test-retest repeatability of MR elastography for noninvasive liver fibrosis assessment in hepatitis C. *J Magn Reson Imaging* 2011; 34(4):947-955.
- [4] Shinagawa Y, Mitsufuji T, Morimoto S, et al. Optimization of scanning parameters for MR elastography at 3.0 T clinical unit: volunteer study. *Jpn J Radiol* 2014; 32(7):441-446.
- [5] Shin SU, Lee JM, Yu MH, et al. Prediction of esophageal varices in patients with cirrhosis: usefulness of three-dimensional MR elastography with echo-planar imaging technique. *Radiology* 2014; 370 272(1):143-153.
- [6] Shi Y, Guo Q, Xia F, Sun J, Gao Y. Short- and midterm repeatability of magnetic resonance elastography in healthy volunteers at 3.0 T. *Magn Reson Imaging* 2014; 32(6):665-670.
- [7] Lee YJ, Lee JM, Lee JE, et al. MR elastography for noninvasive assessment of hepatic fibrosis: reproducibility of the examination and reproducibility and repeatability of the liver stiffness value measurement. *J Magn Reson Imaging* 2014; 39(2):326-331.
- 375 [8] Jajamovich GII, Dyvorne II, Donnerhack C, Taouli B. Quantitative liver MRI combining phase contrast imaging, elastography, and DWI: assessment of reproducibility and postprandial effect at 3.0 T. *PLoS One* 2014; 9(5):e97355.
- [9] Bohte AE, Garteiser P, De Niet A, et al. MR elastography of the liver: defining thresholds for detecting viscoelastic changes. *Radiology* 2013;269(3):768-776.
- 380 [10] Trout AT, Serai S, Mahley AD, et al. Liver stiffness measurements with MR elastography: agreement and repeatability across imaging systems, field strengths, and pulse sequences. *Radiology* 2016; 281(3):793-804.

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Appendix C: Conventions and Definitions

Definitions/Abbreviations

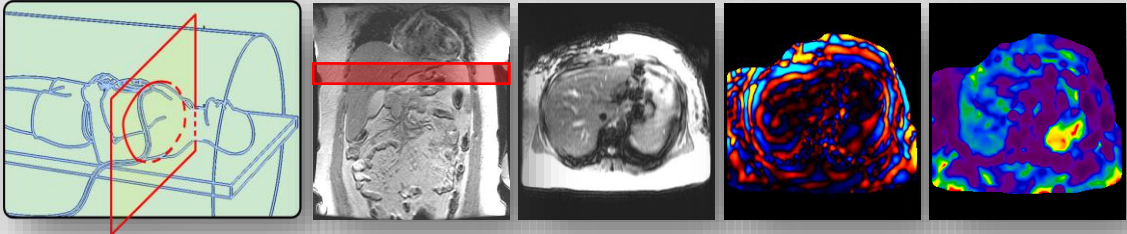
- DMA: dynamic mechanical analyzer
- CLD: chronic liver disease
- 390 • CT: computed tomography
- MRE: magnetic resonance elastography
- MRI: magnetic resonance imaging
- PET: positron emission tomography
- QA: quality assurance
- 395 • QIBA: Quantitative Imaging Biomarkers Alliance
- RC: repeatability coefficient
- ROI: region of interest
- RSNA: Radiological Society of North America
- wCV: within-subject coefficient of variation
- 400 • wSD: within-subject standard deviation

Appendix D: Detailed MRE Protocols

For acquisition modalities, reconstruction software and software analysis tools, profile conformance requires meeting the activity specifications above in Sections 2, 3, and 4.

405 This Appendix provides, as an informative tool, some specific acquisition parameters, reconstruction parameters and analysis software parameters that are expected to be compatible with meeting the profile requirements.

GE 1.5T - Hepatic MRE Protocols - June 2020

Scanners and Sequences	Scanner	Artist, Creator, Explorer, HDx, Optima MR450w, Voyager		
	Software versions	HD16 and ≥DV22.1	HD16 and ≥DV22.1	≥DV22.1
	Pulse sequence	fgremre (Resoundant-GE)	epimre (Resoundant-GE)	MR-Touch (GRE)
	Mode	2D, zoom gradient	2D, zoom gradient	2D
	Options	Fast, ASSET, MultiPhase	FC, ASSET, MultiPhase	Fast, ASSET, MultiPhase
Patient Cooperation	<p>(1) Patients shall fast at least 4-6 hours prior to the exams (2) Patients hold their breath at the end of expiration during all MRE scans, as well as during the scout scans and parallel imaging calibration scans. (3) Make sure the elastic belt is tightly secured on the driver and the patient for optimized energy transfer, while patient can breathe comfortably. For patients with thick subcutaneous fat, this is very important.</p>			
Slice Positioning	 <p style="text-align: center;">Place 4 axial slices at the largest portion of the liver in coronal view avoiding the heart, the liver dome and the liver bottom tip.</p>			
Patient Information Input	Position	feet-first, supine	feet-first, supine	feet-first, supine
	Weight	Actual Weight	Actual Weight	Actual Weight
	Height			
Coil (note 1)	Coil	Torso	Torso	Torso
Imaging Parameters	Imaging Plane	Axial	Axial	Axial
	No. of slices	4	4	4

GE 1.5T - Hepatic MRE Protocols - June 2020

Slice thickness (mm)/gap	10 mm / 0 mm	8 mm / 2 mm	10 mm / 0 mm
FOV (mm) / Phase FOV (100%)	420(required)x420(or less) (note 4)	420(required)x(420 or less) (note 4)	420(required) x 420 (or less) (note 4)
Matrix	256 x 64	80 x 80	256 x 64
TE (msec)	in-phase TE (about 18.2)	min full (around 55.4) (note 1)	min TE (type a value close to 18.2 if possible)
TR (msec)	50	1000	50
Flip Angle (degree)	25	default (90)	25
NEX, EPI shots	1	1, 1shot	1
Bandwidth (kHz)	31.25	250 (hard coded)	31.25
Freq Encoding Dir	right - left	right - left	right - left
Phases per Location	4	3	
Phase Acq. Order	Interleaved	Interleaved	
Delay After Acq.	Minimum	Minimum	
Acceleration	ASSET (Note 1)	ASSET (Note 1)	ASSET (Note 1)
Acceleration factor	2	2	2
No. of breath holds	4 (note 2)	1	4 (note 2)
Shimming Volume	Cover the whole body	Cover the whole body	Cover the whole body
Spectrum Peaks	Water Peak	Water Peak	Water Peak
Saturation Band	SI	SI	SI

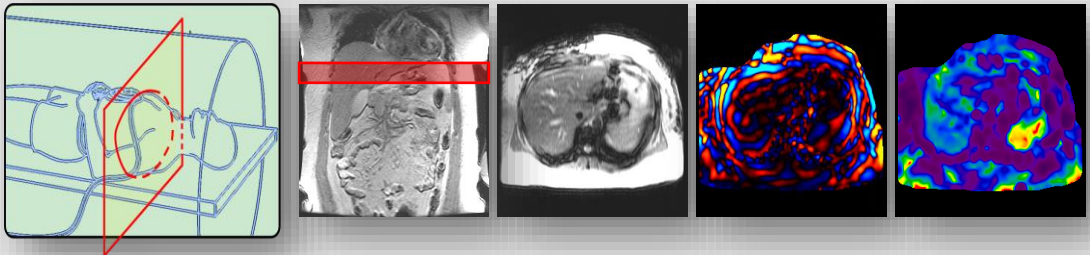
GE 1.5T - Hepatic MRE Protocols - June 2020				
	scan time	55 s (note 2)	11 sec	55 sec (note 2)
Driver Parameters (Generic) (note 5)	Driver Power (%)	50	50	50
	Driver frequency (Hz)	60	60	60
	Driver cycles/ trigger (Duration)	3 (auto-calculated)	Auto-calculated	Auto-calculated
Motion Encoding Gradients (Generic) (note 5)	MEG frequency (Hz) (or Period Mismatch)	75 Hz (0.8)	80	75
	MENC (1/motion sensitivity)	~30 μm / (π radian) (note 3)	~30 μm / (π radian) (note 3)	~30 μm / (π radian)
	Axis of MEG	4 (Z)	4 (Z)	4 (Z)
User CV or Advanced Table (Specific: epimre - DV16 and DV24) (note 5)	CV0 -Ramp Sampling (1=on, 0=off)		1	
	CV5 -Scale for RF2 Crusher Area		1	
	CV6 -Split MEG (0=L, 1/2/3 = L-R in/half/min)		2	
	CV7 -Flow Comp. Type for MEG		0	
	CV8 -Driver Frequency Percent Increase		0	
	CV9 -Time from Start of MEG1 to MEG2 (-1 = opt, 0=min)		0	
	CV10 -Number of Gradient Pairs		1	
	CV11 -Soft-start Ramp-up Time (sec)		0	
	CV12 -Fraction of Max Gradient Amplitude		1	
	CV13 -Desired MEG Frequency (Hz)		80	
	CV14 -Driver Amp. % (-1 = not V3)		50	

GE 1.5T - Hepatic MRE Protocols - June 2020				
	CV15 -Recon (Def-1912;3D ver =1914;Brain=1915;2D MMDI = 1916)		1916	
	CV16 -Trigger Loc # of Cycles Pre-MEG		4	
	CV17 -MEG Direction (F/P/S=1/2/4, Tetra=8)		4	
	CV18 -Vibration Mode (0=Burst, 1 or 2 = Contin.)		1	
	CV19 - MENC (um per radians)		Don't edit	
	CV20 -# of Motion Periods for Offsets		1	
	CV21 -Frequency of Applied Motion (Hz)		60	
	CV23 -Burst Mode Burst Count		1	
	CV24 -Do High-Resolution Recon.?		1	
User CV (Specific: fgremre - DV16) (note 5)	CV 12 -use version3 driver	1		
	CV 13 -Motion Encoding Gradient (MEG) pairs	1		
	CV 14 Motion Frequency - Hz	60		
	CV 15 Scale Max Gradient Amplitude	0.75		
	CV 17 freq=1, phase=2, slice=4	4		
	CV 21 period mismatch	0.8		
	CV 24 driver amplitude	50		
MR-Touch Tab	Temporal Phases	4		

GE 1.5T - Hepatic MRE Protocols - June 2020

(Specific fgremre-DV22.1, DV24) (note 5)	MEG Frequency (Hz)	75		
	Driver Amplitude (%) (note 6)	50		
	Driver Cycle Per Trigger	3		
	MEG Direction	4 (Z)		
Advanced Tab (Specific fgremre-DV22.1, DV24) (note 5)	CV12 use Resoundant	1.00		
MR-Touch Tab (Specific MR-Touch sequence - DV22.1, DV24) (note 5)	Temporal Phases			4
	MEG Frequency (Hz)			75
	Driver Amplitude (%) (note 6)			50
	Driver Cycle Per Trigger			3
	MEG Direction			4 (Z)

NOTE: (1) Use the body coil instead of the torso if the patient cannot fit into the bore with the torso coil; if the body coil is used then the ASSET is turned off automatically, increasing the scan time (gre) or TE (epi). (2) For GREMRE, scan time can vary depending on the FOV (in phase dir) - decreasing the phase FOV can slightly decrease the scan time and breath-hold time. (3) Depending on your gradient hardware performance, the absolute gradient strength could be different. (4) FOV is recommended to be a fixed value (420 mm) for consistency, even for small patients; **if a different FOV is prescribed for a study, it is recommended that the same FOV is applied to every patient and every time point.** (5) The specific tab and parameters can be different for different software versions and MRE sequences; the generic MRE parameters for driver and motion encoding gradients are the guideline to those specific tab and parameters (MRE-related); overall, this recommendation is conservative so that it can be successfully performed at all software versions and scanners. (6) Driver Frequency is 60Hz (default).

GE 3T - Hepatic MRE Protocols - June 2020				
Scanners and Sequences	Scanner	Architect, Discovery MR750w, PET/MR, Pioneer, Premier		
	Software versions	HD16 and ≥DV22.1	HD16 and ≥DV22.1	≥DV22.1
	Pulse sequence	fgremre (Resoundant-GE)	epimre (Resoundant-GE)	MR-Touch (EPI)
	Mode	2D, zoom gradient	2D, zoom gradient	2D
	Options	Fast, ASSET, MultiPhase	FC, ASSET, MultiPhase	FC, ASSET, MultiPhase
Patient Cooperation	<p>(1) Patients shall fast at least 4-6 hours prior to the exams (2) Patients hold their breath at the end of expiration during all MRE scans, as well as during the scout scans and parallel imaging calibration scans. (3) Make sure the elastic belt is tightly secured on the driver and the patient for optimized energy transfer, while patient can breathe comfortably. For patients with thick subcutaneous fat, this is very important.</p>			
Slice Positioning	 <p>Place 4 axial slices at the largest portion of the liver in coronal view, and avoid the heart, the liver dome and the liver bottom tip.</p>			
Patient Information Input	Position	feet-first, supine	feet-first, supine	feet-first, supine
	Weight	Actual Weight	Actual Weight	Actual Weight
	Height			
Coil (note 1)	Coil	Torso	Torso	Torso
Imaging Parameters	Imaging Plane	Axial	Axial	Axial
	No. of slices	4	4	4
	Slice thickness (mm)/gap	10 mm / 0 mm	8 mm / 2 mm	8 mm / 2 mm

GE 3T - Hepatic MRE Protocols - June 2020

FOV (mm) / Phase FOV (100%)	420(required)x420(or less) (note 4)	420(required)x420(or less) (note 4)	420(required)x420(or less) (note 4)
Matrix	256 x 64	96 x 96	96 x 96
TE (msec)	min full (around 15.9, this is close to in-phase TE)	min full(around 55.4) (note 1)	min full(around 55.4) (note 1)
TR (msec)	50	1000	1000
Flip Angle (degree)	20	default (90)	default (90)
NEX, EPI shots	1	1, 1shot	1, 1shot
Bandwidth (kHz)	31.25	250 (hard coded)	250 (hard coded)
Freq Encoding Dir	right - left	right - left	right - left
Phases per Location	4	3	
Phase Acq. Order	Interleaved	Interleaved	
Delay After Acq.	Minimum	Minimum	
Acceleration	ASSET (Note 1)	ASSET (Note 1)	ASSET (Note 1)
Acceleration factor	2	2	2
No. of breath holds	4 (note 2)	1	1
Shimming Volume	Cover the whole body	Cover the whole body	Cover the whole body
Spectrum Peaks	Water Peak	Water Peak	Water Peak
Saturation Band	SI	SI	SI
scan time (note 7)	about 55 s (note 2)	about 11 sec	about 16 sec

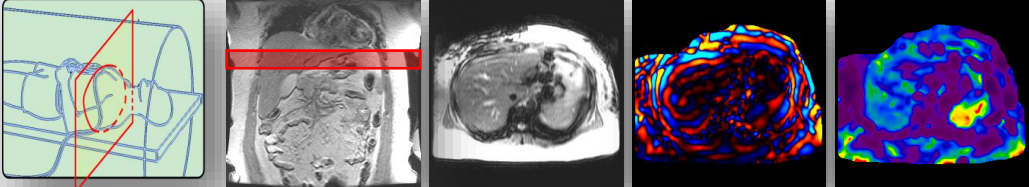
GE 3T - Hepatic MRE Protocols - June 2020				
Driver Parameters (Generic) (note 5)	Driver Power (%)		50	50
	Driver frequency (Hz)	60	60	60
	Driver cycles/trigger (Duration)	3 (auto-calculated)	Auto-calculated	Auto-calculated
Motion Encoding Gradients (Generic) (note 5)	MEG frequency (Hz) (or Period Mismatch)	80 Hz (0.75)	80	80
	MENC (1/motion sensitivity)	~30 $\mu\text{m}/(\pi \text{ radian})$ (note 3)	~30 $\mu\text{m}/(\pi \text{ radian})$ (note 3)	~30 $\mu\text{m}/(\pi \text{ radian})$ (note 3)
	Axis of MEG	4 (Z)	4 (Z)	4 (Z)
User CV or Advanced Table (Specific: epimre - HD16 and \geqDV24) (note 5)	CV0 -Ramp Sampling (1=on, 0=off)		1	
	CV5 -Scale for RF2 Crusher Area		1	
	CV6 -Split MEG (0=L, 1/2/3 = L-R in/half/min)		2	
	CV7 -Flow Comp. Type for MEG		0	
	CV8 -Driver Frequency Percent Increase		0.5	
	CV9 -Time from Start of MEG1 to MEG2 (-1 = opt, 0=min)		0	
	CV10 -Number of Gradient Pairs		1	
	CV11 -Soft-start Ramp-up Time (sec)		0	
	CV12 -Fraction of Max Gradient Amplitude		1	
	CV13 -Desired MEG Frequency (Hz)		80	
	CV14 -Driver Amp. % (-1 = not V3)		50	

GE 3T - Hepatic MRE Protocols - June 2020				
	CV15 -Recon (Def-1912;3D ver =1914;Brain=1915; 2D MMDI = 1916)		1916	
	CV16 -Trigger Loc # of Cycles Pre-MEG		4	
	CV17 -MEG Direction (F/P/S=1/2/4, Tetra=8)		4	
	CV18 -Vibration Mode (0=Burst, 1 or 2 = Contin.)		1	
	CV19 - MENC (um per radians)		Don't edit	
	CV20 -# of Motion Periods for Offsets		1	
	CV21 -Frequency of Applied Motion (Hz)		60	
	CV23 -Burst Mode Burst Count		1	
	CV24 -Do High-Resolution Recon.?		1	
User CV (Specific: fgremre - HD16) (note 5)	CV 12 -use version3 driver	1		
	CV 13 -Motion Encoding Gradient (MEG) pairs	1		
	CV 14 Motion Frequency - Hz	60		
	CV 15 Scale Max Gradient Amplitude	0.75		
	CV 17 freq=1, phase=2, slice=4	4		
	CV 21 period mismatch	0.75		
	CV 24 driver amplitude	50		
MR-Touch Tab	Temporal Phases	4		

GE 3T - Hepatic MRE Protocols - June 2020				
(Specific fgremre- ≥DV22.1)(note 5)	MEG Frequency (Hz)	80		
	Driver Amplitude (%) (note 6)	50		
	Driver Cycle Per Trigger	3		
	MEG Direction	4 (Z)		
Advanced Tab (Specific fgremre- ≥DV22.1) (note 5)	CV12 use Resoundant	1.00		
MR-Touch Tab (Specific MR-Touch sequence - ≥DV22.1) (note 5)	Temporal Phases			4
	MEG Frequency (Hz)			90
	Driver frequency (Hz)			60
	Driver Amplitude (%)			50
	MEG Direction			Z
	Driver Cycle Per Trigger			15 (Not for edit)
	MENC um/rad			28.5 (Not for edit)

NOTE: (1) Use body coil instead of torso if patients cannot fit into the bore with the torso coil; if body coil is used then the ASSET is turned off automatically, scan time is longer (gre) or TE is longer (epi). (2) For GREMRE, scan time can vary depending on the FOV (in phase dir) setup - decreasing phase FOV can slightly decrease scan time and breath-hold time. (3) Depending on your gradient hardware performance, the absolute gradient strength could be different. (4) FOV is recommended to be a fixed value (420 mm), even for small patients for consistency; **if a different FOV is determined for a study, it is recommended the same FOV is applied to every patient and every time point.** (5) The specific tab and parameters can be different for different software versions and MRE sequences; the generic MRE parameters for driver and motion encoding gradients are the guideline to those specific tab and parameters (MRE-related); overall, this recommendation is conservative so that it can be successfully performed at all software versions and scanners.(6) Driver Frequency is 60Hz (default). (7) scan time can be slightly different for different scanners

Siemens 1.5T - Hepatic MRE Protocols - June 2020

Scanners and Sequences	Scanner	MAGNETOM Tim 3G or Tim 4G	
	Software versions	N4 VE11C SP01 and above	
	Pulse sequence	greMRE	epseMRE (WIP)
	Mode	2D	2D
Patient Cooperation	<p>(1) Patients shall fast at least 4-6 hours prior to the exams</p> <p>(2) Patients hold their breath at the end of expiration during all MRE scans, as well as during the scout scans and parallel imaging calibration scans.</p> <p>(3) Make sure the elastic belt is tightly secured on the driver and the patient for optimized energy transfer, while patient can breathe comfortably. For patients with thick subcutaneous fat, this is very important.</p>		
Slice Positioning	 <p>Place 4 axial slices at the largest portion of the liver in coronal view, and avoid the heart, the liver dome and the liver bottom tip.</p>		
Patient Information Input	Position	head-first, supine	head-first, supine
	Weight	Actual Weight	Actual Weight
	Height	Actual Height	Actual Height
Coil (note 1)	Coil	Torso	Torso
Imaging Parameters	Imaging Plane	Transversal	Transversal
	No. of slices	4	4
	Slice thickness (mm)/dist. Factor	10 mm / 0% (0)	8 mm / 25% (2mm)
	FOV (mm) / Phase FOV (100%)	420/1 (note 4)	420/1 (note 4)

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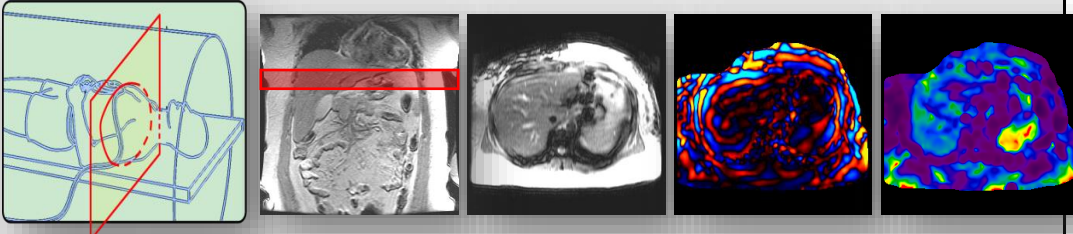
	Matrix (Base x Phase)	256 x 25% (64)	98 x 100% (128)
	TE (msec)	min (about ~20 with flow comp off)	min (about 40 with flow comp on)
	TR (msec)	50	1000
	Flip Angle (degree)	20	default (90)
	NEX, EPI shots	1	1, 1shot
	Bandwidth (Hz/Pixel)	260 Hz/pixel	2000 Hz/pixel
	Phase enc.dir.	Anterior-Posterior	Anterior-Posterior
	Acceleration	GRAPPA (note 1)	GRAPPA (note 1)
	Acceleration factor	2	2
	No. of breath holds	4 (each 17sec) (note 2)	1 (each 11 sec)
	Shimming Volume	auto	auto
	Spectrum Peaks	Water Peak	Water Peak
	Saturation Band	SI	SI
	Fat Suppression		SPAIR
	Fat Sat. mode		Strong
	scan time	4 x 17 sec	11 sec
Driver Parameters (Generic) (note 5)	Driver Power (%)	50 (default) (note 6)	50 (default) (note 6)
	Driver frequency (Hz)	60 (default) (note 6)	60 (default) (note 6)

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	Driver cycles/ trigger (Duration)	3 (default) (note 6)	3 (default) (note 6)
Motion Encoding Gradients (Generic) (note 5)	MEG fractional encoding	85%	80%
	MEG frequency (Hz)	60 Hz (Hard Coded)	60 Hz (Hard Coded)
	MEG Amplitude	(Hard coded)	30 mT/m (Hard coded)
	Axis of MEG	Slice (Hard Coded)	Slice
	Number of phase	4 (Hard coded)	3
Specific Parameters (note 5)	Sequence - Part 1 - Flow Comp	NO	YES
	Sequence - Special - MEG Amplitude (mT/m)	Not available	30
	Sequence - Special - MEG Frequency (mT/m)	Not available	60.0
	Sequence - Special - MEG Waveform	Not available	1-2-1
	Sequence - Special - MEG Direction	Not available	Slice
	System - Tx/Rx - Img. Scale Cor.	2	2
	Resolution - Filter Image - Prescan Normalize	Check	Check

NOTE: (1) Use body coil instead of torso if patients cannot fit into the bore with the torso coil; if body coil is used then the ASSET is turned off automatically, scan time is longer. (2) For GREMRE, scan time can vary depending on the FOV (in phase dir) setup - decreasing phase FOV can slightly decrease scan time and breath-hold time. (3) Depending on your gradient hardware performance, the absolute gradient strength could be different. (4) FOV is recommended to be a fixed value (420 mm), even for small patients for consistency; **if a different FOV is determined for a study, it is recommended the same FOV is applied to every patient and every time point.** (5) The specific tab and parameters can be different for different software versions and MRE sequences; the generic MRE parameters for driver and motion encoding gradients are the guideline to those specific tab and parameters (MRE-related); overall, this recommendation is conservative so that it can be successfully performed at all software versions and scanners. (6) The current implementation of Siemens MRE does not access the active driver, those values are default values and can be changed by using a separate web connection to the active driver (Syngo or Laptop); epseMRE sequences delivers one trigger every 50ms.

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Scanners and Sequences	Scanner	MAGNETOM Tim 3G or Tim 4G	
	Software versions	N4 VE11C SP01 and above	
	Pulse sequence	greMRE	epseMRE
	Mode	2D	2D
Patient Cooperation	<p>(1) Patients shall fast at least 4-6 hours prior to the exams (2) Patients hold their breath at the end of expiration during all MRE scans, as well as during the scout scans and parallel imaging calibration scans. (3) Make sure the elastic belt is tightly secured on the driver and the patient for optimized energy transfer, while patient can breathe comfortably. For patients with thick subcutaneous fat, this is very important.</p>		
Slice Positing	 <p>Place 4 axial slices at the largest portion of the liver in coronal view, and avoid the heart, the liver dome and the liver bottom tip.</p>		
Patient Information Input	Position	head-first, supine	head-first, supine
	Weight	Actual Weight	Actual Weight
	Height	Actual Height	Actual Height
Coil (note 1)	Coil	Torso	Torso
Imaging Parameters	Imaging Plane	Transversal	Transversal
	No. of slices	4	4
	Slice thickness (mm)/dist. Factor	10 mm / 0% (0)	8 mm / 25% (2mm)

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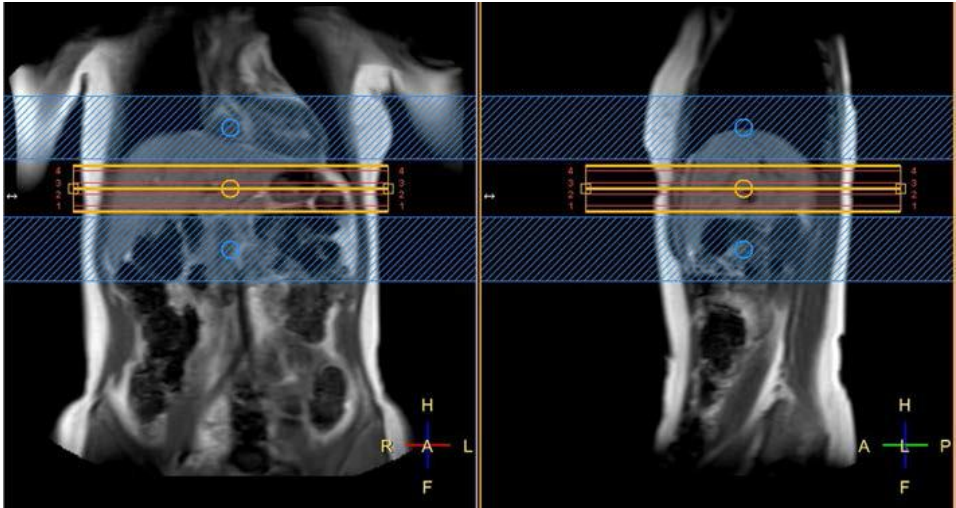
	FOV (mm) / Phase FOV (100%)	420/1 (note 4)	420/1 (note 4)
	Matrix (Base x Phase)	256 x 25%(64)	98 x 100%(128)
	TE (msec)	min (about 20 with flow comp off)	min (about 40 with flow comp on)
	TR (msec)	50	1000
	Flip Angle (degree)	20	default (90)
	NEX, EPI shots	1	1, 1shot
	Bandwidth (Hz/Pixel)	260 Hz/pixel	2380 Hz/pixel
	Phase enc.dir.	Anterior-Posterior	Anterior-Posterior
	Acceleration	GRAPPA (note 1)	GRAPPA (note 1)
	Acceleration factor	2	2
	No. of breath holds	4 (each 17sec) (note 2)	1 (each 11 sec)
	Shimming Volume	auto	auto
	Spectrum Peaks	Water Peak	Water Peak
	Saturation Band	SI	SI
	scan time	4 x 17 sec	11 sec
Driver Parameters (Generic) (note 5)	Driver Power (%)	50 (default) (note 6)	50 (default) (note 6)
	Driver frequency (Hz)	60 (default) (note 6)	60 (default) (note 6)
	Driver cycles/ trigger (Duration)	3 (default) (note 6)	3 (default) (note 6)

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Motion Encoding Gradients (Generic) (note 5)	MEG fractional encoding	85%	80%
	MEG frequency (Hz)	60 Hz (Hard Coded)	60 Hz (Hard Coded)
	MEG Amplitude	(Hard coded)	30 mT/m (Hard coded)
	Axis of MEG	Slice (Hard Coded)	Slice
	Number of phase	4 (Hard coded)	3
Specific Parameters (note 5)	Sequence - Part 1 - Flow Comp	NO	YES
	Sequence - Special - MEG Amplitude (mT/m)	Not available	30
	Sequence - Special - MEG Frequency (mT/m)	Not available	60.0
	Sequence - Special - MEG Waveform	Not available	1-2-1
	Sequence - Special - MEG Direction	Not available	Slice
	System - Tx/Rx - Img. Scale Cor.	2	2
	Resolution - Filter Image - Prescan Normalize	Check	Check

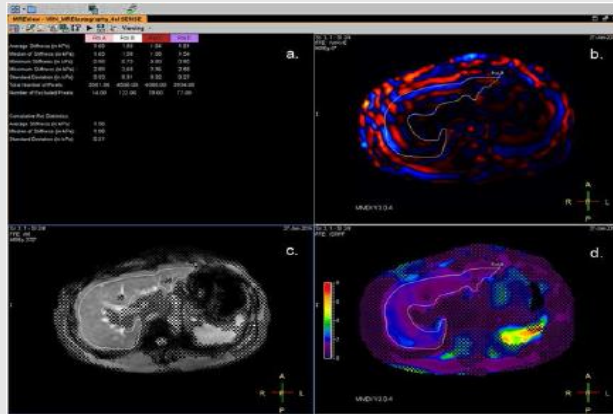
NOTE: (1) Use body coil instead of torso if patients cannot fit into the bore with the torso coil; if body coil is used then the ASSET is turned off automatically, scan time is longer. (2) For GREMRE, scan time can vary depending on the FOV (in phase dir) setup - decreasing phase FOV can slightly decrease scan time and breath-hold time. (3) Depending on your gradient hardware performance, the absolute gradient strength could be different. (4) FOV is recommended to be a fixed value (420 mm), even for small patients for consistency; **if a different FOV is determined for a study, it is recommended the same FOV is applied to every patient and every time point.** (5) The specific tab and parameters can be different for different software versions and MRE sequences; the generic MRE parameters for driver and motion encoding gradients are the guideline to those specific tab and parameters (MRE-related); overall, this recommendation is conservative so that it can be successfully performed at all software versions and scanners. (6) The current implementation of Siemens MRE does not access active driver, those values are default values and can be changed by using a separate web connection to the active driver (Syngo or Laptop); epseMRE sequences delivers one trigger every 50ms.

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Scanners and Sequences	Scanner	Achieva, Ambition, Ingenia	
	Software versions	MR R5.1.7 SP2 (or later)	
	Pulse sequence	FFE MRE	SE-EPI MRE
	Mode	2D	2D
Patient Cooperation	<p>(1) Patients shall fast at least 4-6 hours prior to the exams</p> <p>(2) Patients hold their breath at the end of expiration during all MRE scans, as well as during the scout scans and parallel imaging calibration scans.</p> <p>(3) Make sure the elastic belt is tightly secured on the driver and the patient for optimized energy transfer, while patient can breathe comfortably. For patients with thick subcutaneous fat, this is very important.</p>		
Slice Positioning			

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Place 4 axial slices at the largest portion of the liver in coronal view, and avoid the heart, the liver dome and the liver bottom tip.



Patient Information Input	Position	head-first, supine	head-first, supine
	Weight	Actual Weight	Actual Weight
	Height		
Coil	Coil	Torso	Torso
Imaging Parameters	Imaging Plane	Axial	Axial
	No. of slices	4	4
	Slice thickness (mm)/gap	10 mm / 1 mm	8 mm / 2 mm
	FOV (mm) / Phase FOV (mm)	420(required)x420(or less) (Note 2)	420(required)x420(or less) (Note 2)
	Matrix	300 x 85	100 x 100
	TE (msec)	20	58 (note 4)
	TR (msec)	50	1000
	Flip Angle (degree)	30	90
NSA, EPI shots	1	1, 1shot	

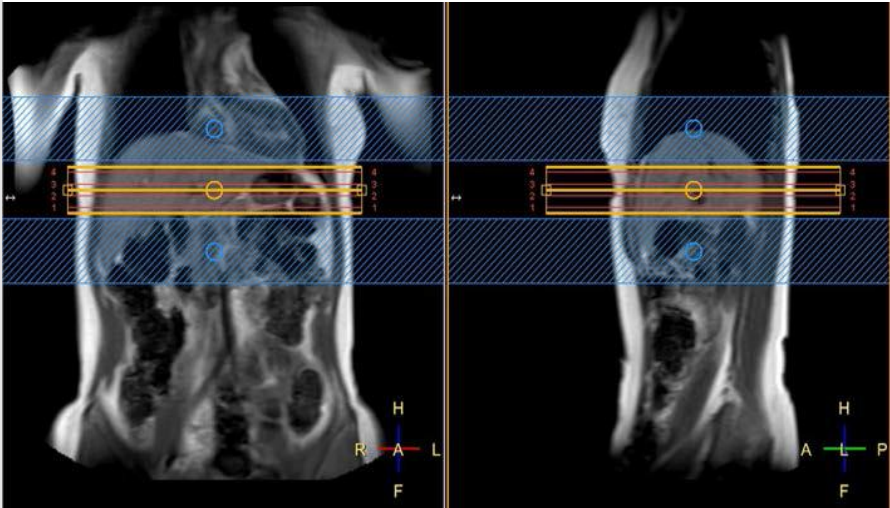
Philips 1.5T - Hepatic MRE Protocols – June 2020

	Bandwidth (Hz/Pixel)	~288 Hz/pixel	~2000 Hz/pixel
	Freq Encoding Dir	right - left	right - left
	Acceleration	SENSE	SENSE
	Acceleration factor	2	2
	No. of breath holds	4	1
	Shimming Volume	Auto	Auto
	REST slabs	2 parallel	2 parallel
	scan time	71 s (note 1)	9 sec
Driver Parameters (Generic)	Driver Power	Moderate (50%)	Low (25%) (note 4)
	Driver frequency (Hz)	60	60
	Driver cycles/ trigger (Duration)	3 (auto-calculated)	Auto-calculated
Motion Encoding Gradients (Generic)	MEG frequency (Hz) (or Period Mismatch)	60 Hz (note3)	60 Hz (note3) (note 4)
	MENC (1/motion sensitivity)	~30 $\mu\text{m}/(\pi \text{ radian})$ (note 6)	~30 $\mu\text{m}/(\pi \text{ radian})$ (note 6)
	Axis of MEG	FH	FH
	Number of phase	4	4
Specific Parameters (To be specified)			

NOTE: (1) For FFE MRE, scan time can vary depending on the FOV (in phase dir) setup - decreasing phase FOV can slightly decrease scan time and breath-hold time. (2) FOV is recommended to be a fixed value (420 mm), even for small patients for consistency; **if a different FOV is determined for a study, it is recommended the same FOV is applied to every patient and every time point.** (3) In current sequences, MEG frequency is the same as the driver frequency; in future versions, there will be a separate MEG frequency input, the recommended value is higher

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than 60Hz, usually 70Hz (period fraction 85%), or 75Hz (period fraction 80%). (4) future SE EPI version will have flexible MEG number, as well as fractional MEGs so the TE can be reduced, which is important for liver applications. (4) future SE EPI version will have option of one MEG instead of current two MEGs, as well as fractional MEGs so the TE can be reduced, which is important for liver applications; because the motion sensitivity will be lower by a factor of two, the driver power should be at 50% instead of 25%.

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Scanners and Sequences	Scanner	Achieva, Elition, Ingenia	
	Software versions	MR R5.1.7 SP2	
	Pulse sequence	FFE MRE	SE-EPI MRE
	Mode	2D	2D
Patient Cooperation	<p>(1) Patients shall fast at least 4-6 hours prior to the exams</p> <p>(2) Patients hold their breath at the end of expiration during all MRE scans, as well as during the scout scans and parallel imaging calibration scans.</p> <p>(3) Make sure the elastic belt is tightly secured on the driver and the patient for optimized energy transfer, while patient can breathe comfortably. For patients with thick subcutaneous fat, this is very important.</p>		
Slice Positing	<div style="display: flex; justify-content: space-around;">  </div> <p>Place 4 axial slices at the largest portion of the liver in coronal view, and avoid the heart, the liver dome and the liver bottom tip.</p>		
	Position	head-first, supine	head-first, supine

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Patient Information Input	Weight	Actual Weight	Actual Weight
	Height		
Coil	Coil	Torso	Torso
Imaging Parameters	Imaging Plane	Axial	Axial
	No. of slices	4	4
	Slice thickness (mm)/gap	10 mm / 1 mm	8 mm / 2 mm
	FOV (mm) / Phase FOV (mm)	420(required)x420(or less) (Note 2)	420(required)x420(or less) (Note 2)
	Matrix	300 × 85	100 x 100
	TE (msec)	20	58 (note 4)
	TR (msec)	50	1000
	Flip Angle (degree)	30	90
	NSA, EPI shots	1	1, 1shot
	Bandwidth (Hz/Pixel)	~288 Hz/pixel	~2000 Hz/pixel
	Freq Encoding Dir	right - left	right - left
	Acceleration	SENSE	SENSE
	Acceleration factor	2	2
	No. of breath holds	4	1
	Shimming Volume	Auto	Auto
REST slabs	2 parallel	2 parallel	

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	scan time	71 s (note 1)	9 sec
Driver Parameters (Generic)	Driver Power	Moderate (50%)	Low (25%) (note 4)
	Driver frequency (Hz)	60	60
	Driver cycles/ trigger (Duration)	3 (auto-calculated)	Auto-calculated
Motion Encoding Gradients (Generic)	MEG frequency (Hz) (or Period Mismatch)	60 Hz (note 3)	60 Hz (note 3) (note 4)
	MEG Amplitude (mT/m)	18.4	18.4
	Axis of MEG	FH	FH
	Number of phase	3	3
Specific Parameters (To be specified)			
<p>NOTE: (1) For FFE MRE, scan time can vary depending on the FOV (in phase dir) setup - decreasing phase FOV can slightly decrease scan time and breath-hold time. (2) FOV is recommended to be a fixed value (450 mm), even for small patients for consistency; if a different FOV is determined for a study, it is recommended the same FOV is applied to every patient and every time point. (3) In current sequences, MEG frequency is same as the driver frequency; with research patches, there would be separate MEG frequency input, the recommended value is higher than 60Hz, usually 70Hz (period fraction 85%), or 75Hz (period fraction 80%).(4) future SE EPI research patch will have option of one MEG instead of current two MEGs, as well as fractional MEGs so the TE can be reduced, which is important for liver applications; because the motion sensitivity will be twice lower, the driver power should be at 50% instead of 25%.</p>			

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Phantom Parameter Recommendations

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Scanners and Sequences	Scanner	HDx	HDx	MR450w (Tentative)
	Software versions	DV16 and DV22.1 and 24	DV16 and DV22.1 and 24	DV22.1 and 24
	Pulse sequence	fgremre (Resoundant-GE)	epimre (Resoundant-GE)	MR-Touch (GRE)
	Mode	2D, zoom gradient	2D, zoom gradient	2D
	Options	Fast, ASSET, MultiPhase	ASSET, MultiPhase	Fast, ASSET, MultiPhase
Phantom Setup	Place the 16-cm diameter cylinder phantom vertically in the torso coil, place the liver driver (facing down) on the top of the phantom and secure them with the liver MRE elastic belt tightly.			
Slice Positioning	Place one coronal slice at the center of the height of the phantom, with a fixed squared FOV (200 mm). 			
Information Input (Pretent Patient)	Position	feet-first, supine	feet-first, supine	feet-first, supine
	Weight	150 Lbs	150 Lbs	150 Lbs
	Height			
Coil (note 1)	Coil	Torso	Torso	Torso
Imaging Parameters	Imaging Plane	coronal	coronal	coronal
	No. of slices	4	4	4
	Slice thickness (mm)/gap	10 mm / 0 mm	8 mm / 2 mm	10 mm / 0 mm
	FOV (mm) / Phase FOV (100%)	20cm/1 (note 4)	20cm/1 (note 4)	20cm/1 (note 4)
	Matrix	256 x 64	64 x 64	256 x 64
	TE (msec)	in-phase TE (about 18.2) (note 7)	min full TE (note 1)	min full TE (type a value close to 18.2 if possible)
	TR (msec)	50	250	50
	Flip Angle (degree)	25	default (90)	25
	NEX, EPI shots	1	8, 4shot	1
	Bandwidth (kHz)	31.25	250 (hard coded)	31.25
	Freq Encoding Dir	Superior-Inferior	Superior-Inferior	Superior-Inferior
	Phases per Location	4	4	
	Phase Acq. Order	Interleaved	Interleaved	
	Delay After Acq.	Minimum	Minimum	
Acceleration	ASSET (Note 1)	ASSET (Note 1)	ASSET (Note 1)	

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	Acceleration factor	1	1	1
	No. of breath holds			
	Shimming Volume	Cover the whole phantom	Cover the whole phantom	Cover the whole phantom
	Spectrum Peaks	Peak with middle freq (there are 3 peaks)	Peak with middle freq (there are 3 peaks)	Peak with middle freq (there are 3 peaks)
	Saturation Band	SI	SI	SI
	scan time	about 28 s (note 2)	about 1 min 13 sec	about 28 sec (note 2)
Driver Parameters (Generic) (note 5)	Driver Power (%)	10	10	10
	Driver frequency (Hz)	60	60	60
Motion Encoding Gradients (Generic) (note 5)	Driver cycles/ trigger (Duration)	3 (auto-calculated)	Auto-calculated	Auto-calculated
	MEG frequency (Hz) (or Period Mismatch)	75 Hz (0.8)	155	75
	MEG Amplitude (G/cm)	About 3 G/cm with Zoom gradient (75%) (note 3)	Full Scale (note 3)	
	Axis of MEG	4 (Z)	4 (Z)	4 (Z)
User CV or Advanced Table (Specific: epimre -DV16 and DV24) (note 5)	CV0 -Ramp Sampling (1=on, 0=off)		1	
	CV1			
	CV2			
	CV3			
	CV4			
	CV5 -Scale for RF2 Crusher Area		1	
	CV6 -Split MEG (0=L, 1/2/3 = L-R in/half/min)		2	
	CV7 -Flow Comp. Type for MEG		0	
	CV8 -Driver Frequency Percent Increase		0.5	
	CV9 -Time from Start of MEG1 to MEG2 (-1 = opt, 0=min)		0	
	CV10 -Number of Gradient Pairs		1	
	CV11 -Soft-start Ramp-up Time (sec)		0	
	CV12 -Fraction of Max Gradient Amplitude		1	
	CV13 -Desired MEG Frequency (Hz)		155	
	CV14 -Driver Amp. % (-1 = not V3)		10	
	CV15 -Recon (Def=1912;3D ver =1914;Brain=1915;2D MMDI = 1916)		1916	
	CV16 -Trigger Loc # of Cycles Pre-MEG		4	
CV17 -MEG Direction (F/P/S=1/2/4, Tetra=8)		4		

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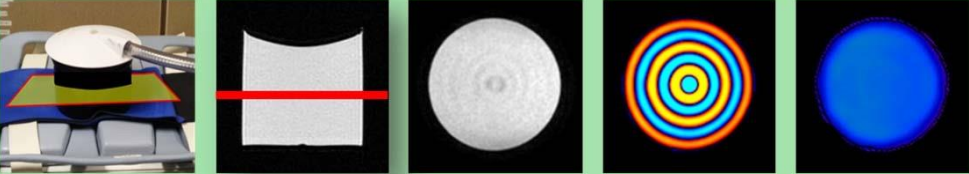
	CV18 -Vibration Mode (0=Burst, 1 or 2 = Contin.)		2	
	CV19 - MENC (um per radians)		Don't edit	
	CV20 -# of Motion Periods for Offsets		1	
	CV21 -Frequency of Applied Motion (Hz)		60	
	CV22			
	CV23 -Burst Mode Burst Count		1	
	CV24 -Do High-Resolution Recon.?		1	
	CV 12 -use version3 driver	1		
	CV 13 -Motion Encoding Gradient (MEG) pairs	1		
	CV 14 Motion Frequency - Hz	60		
User CV (Specific: fgremre DV16) (note 5)	CV 15 Scale Max Gradient Amplitude	0.75		
	CV 17 freq=1, phase=2, slice=4	4		
	CV 21 period mismatch	0.8		
	CV 24 driver amplitude	10		
MR-Touch Tab (Specific fgremre-DV22.1, DV24) (note 5)	Temporal Phases	4		
	MEG Frequency (Hz)	75		
	Driver Amplitude (%) (note 6)	10		
	Driver Cycle Per Trigger	3		
	MEG Direction	4 (Z)		
Advanced Tab (Specific fgremre-DV22.1, DV24) (note 5)	CV12 use resoundant	1.00		
MR-Touch Tab (Specific MR-Touch sequence -DV22.1, DV24) (note 5)	Temporal Phases			4
	MEG Frequency (Hz)			75
	Driver Amplitude (%) (note 6)			10
	Driver Cycle Per Trigger			3
	MEG Direction			4 (Z)

NOTE: (1) Always use torso coil (multi-channel), add pads around the phantom to support the top part of the torso coil, which should not contact the phantom; if other coils that do not support parallel imaging is used, then the ASSET is turned off automatically, scan time is longer. (2) For GREMRE, scan time can vary depending on the FOV (in phase dir) setup - decreasing phase FOV can slightly decrease scan time; however, do not do this for the phantom. (3) Depending on your gradient hardware performance, the absolute gradient strength could be different. (4) FOV is recommended to be a fixed value (200 mm), even for this 16-cm diameter cylinder phantom. (5) The specific tab and parameters can be different for different software versions and MRE sequences; the generic parameters for driver and motion encoding gradients are the guideline to those specific tab and parameters; overall, this recommendation is conservative so that it can be successfully performed at all software versions and scanners.(6) Driver Frequency is 60Hz (default). (7) FC is not supported with F/W in phase TE, FC should be turned off; if this causes trouble, then Try min full TE.

GE 3T - Phantom 2DMRE Parameter Recommendations – June 2020					
Scanners and Sequences	Scanner	HDx	HDx	MR750w	3T (MR750W)
	Software versions	DV16 and DV22.1 and 24	DV16 and DV22.1 and 24	DV22.1 and 24	DV22.1 and 24
	Pulse sequence	fgremre (Resoundant-GE)	epimre (Resoundant-GE)	MR-Touch (EPI) - Clinical Mode	MR-Touch (EPI) - Research Mode
	Mode	2D, zoom gradient	2D, zoom gradient	2D	2D
	Options	Fast, ASSET, MultiPhase	ASSET, MultiPhase	ASSET, FC	ASSET, FC
Phantom Setup	Place the 16-cm diameter cylinder phantom vertically in the torso coil, place the liver driver (facing down) on the top of the phantom and secure them with the liver MRE elastic belt tightly.				
Slice Positing	Place one coronal slice at the center of the height of the phantom, with a fixed squared FOV (200 mm). 				
Information Input (Pretent Patient)	Position	feet-first, supine	feet-first, supine	feet-first, supine	feet-first, supine
	Weight	150 Lbs	150 Lbs	150 Lbs	150 Lbs
	Height				
Coil (note 1)	Coil	Torso	Torso	Torso	Torso
Imaging Prameters	Imaging Plane	coronal	coronal	coronal	coronal
	No. of slices	4	4	4	4
	Slice thickness (mm)/gap	10 mm / 0 mm	8 mm / 2 mm	8 mm / 2 mm	8 mm / 2 mm
	FOV (cm) / Phase FOV (100%)	20cm/1 (note 4)	20cm/1 (note 4)	20cm/1 (note 4)	20cm/1 (note 4)
	Matrix	256 x 64	96 x 96	96 x 96	96 x 96
	TE (msec)	min full (around 15.9, this is close to inphase TE)	min full(around 31 msec) (note 1)	min full(around 57.6 msec) (note 1)	min full (note 1)
	TR (msec)	50	250	250	248 (display CV -> act_tr = 248000)
	Flip Angle (degree)	20	default (90)	default (90)	default (90)
	NEX, EPI shots	1	8, 4shot	1, 1shot	1, 8-shot (display CV -> touch_maxshots = 8))
	Bandwidth (kHz)	31.25	250 (hard coded)	250 (hard coded)	250 (hard coded)
	Freq Encoding Dir	Superior-Inferior	Superior-Inferior	Superior-Inferior	Superior-Inferior
	Phases per Location	4	4		
	Phase Acq. Order	Interleaved	Interleaved		
	Delay After Acq.	Minimum	Minimum		
	Acceleration	ASSET (Note 1)	ASSET (Note 1)	ASSET (Note 1) (Note 2)	ASSET
	Acceleration factor	1	1	2	1
	No. of breath holds				
Shimming Volume	Cover the whole phantom	Cover the whole phantom	Cover the whole phantom	Cover the whole phantom	
Spectrum Peaks	Peak with middle freq (there are 3 peaks)	Peak with middle freq (there are 3 peaks)	Peak with middle freq (there are 3 peaks)	Peak with middle freq (there are 3 peaks)	
Saturation Band					

GE 3T - Phantom 2DMRE Parameter Recommendations – June 2020					
	scan time	28 s (note 2)	1 min 13 sec	10 sec	24 sec
Driver Parameters (Generic) (note 5)	Driver Power (%)	10	10	10	10
	Driver frequency (Hz)	60	60	60	60
	Driver cycles/ trigger (Duration)	3 (auto-calculated)	Auto-calculated	Auto-calculated	Auto-calculated
Motion Encoding Gradients (Generic) (note 5)	MEG frequency (Hz) (or Period Mismatch)	80 Hz (0.75)	155	90	90
	MEG Amplitude (G/cm)	About 1.7 G/cm with whole gradient (75%) (note 3)	Full Scale (note 3)		
	Axis of MEG	4 (Z)	4 (Z)	4 (Z)	4 (Z)
User CV or Advanced Table (Specific: epimre –DV1 and DV24) (note 5)	CV0 -Ramp Sampling (1=on, 0=off)		1		
	CV1				
	CV2				
	CV3				
	CV4				
	CV5 – Scale for RF2 Crusher Area		1		
	CV6 – Split MEG (0=L, 1/2/3 = L-R in/half/min)		2		
	CV7 – Flow Comp. Type for MEG		0		
	CV8 – Driver Frequency Percent Increase		0.5		
	CV9 – Time from Start of MEG to MEG2 (-1 = opt, 0 = min)		0		
	CV10 – Number of gradient pairs		1		
	CV11 – Soft start Ramp-up time (sec)		0		
	CV12 – Fraction of Max Gradient Amplitude		1		
	CV13 – Desired MEG Frequency (Hz)		155		
	CV14 – Driver Amp %(-1 = not V3)		10		
	CV15 = Recon (Def – 1912; 3D ver = 1914; Brain = 1915; 2D MMDI = 1916)		1916		
	CV16 – Trigger Loc # of Cycles Pre-MEG		4		
	CV17 – MEG Direction (F/P/S = 1/2/4, Tetra = 8)		4		
	CV18 – Vibration Mode (0 = Burst, 1 or 2 = Continuous)		2		
	CV19 – MENC (um per radians)		Don't edit		
	CV20 - # of Motion Periods for Offsets		1		
	CV21 – Frequency of Applied Motion (Hz)		60		
	CV22				
	CV23 – Burst Mode Count		1		
CV24 – Do High Resolution Recon?		1			
User CV (Specific: fgremre – DV16) (note 5)	CV 12 – use version 3 driver	1			
	CV 13 – Motion Encoding Gradient (MEG) pairs	1			

GE 3T - Phantom 2DMRE Parameter Recommendations – June 2020					
	CV 14 Motion Frequency (Hz)	60			
	CV 15 Scale Max Gradient Amplitude	0.75			
	CV 17 freq = 1, phase = 2, slice = 4	4			
	CV 21 period mismatch	0.75			
	CV24 driver amplitude	10			
MR-Touch Tab (Specific fgremre – DV22.1, DV24) (note 5)	Temporal phase	4			
	MEG Frequency (Hz)	80			
	Driver Amplitude (%) (note 6)	10			
	Driver cycle per trigger	3			
	MEG Direction	4 (Z)			
Advanced Tab (Specific fgremre – DV22.1, DV24) (note 5)	CV12 use resoundant	1.00			
MR-Touch Tab (Specific MR-Touch sequence – DV22.1, DV24) (note 5)	MEG Frequency (Hz)			90	90
	Driver frequency (Hz)			60	60
	Driver amplitude (%)			10	10
	MEG Direction			Z	Z
	Driver Cycle per Trigger			15 (not for edit)	15 (not for edit)
	MENC um/rad			28.5 (not for edit)	28.5 (not for edit)
<p>NOTE: (1) Always use torso coil (multi-channel), add pads around the phantom to support the top part of the torso coil, which should not contact the phantom; if other coils that do not support parallel imaging is used, then the ASSET is turned off automatically, scan time is longer. (2) For GREMRE, scan time can vary depending on the FOV (in phase dir) setup – decreasing phase FOV can slightly decrease scan time; however do not do this for the phantom. (3) Depending on your gradient hardware performance, the absolute gradient strength could be different. (4) FOV is recommended to be a fixed value (200 mm), even for this 16-cm diameter cylinder phantom. (5) The specific tab and parameters can be different for different software versions and MRE sequences; the generic parameters for driver and motion-encoding gradients are the guideline to those specific tab and parameters; overall, this recommendation is conservative so that it can be successfully performed at all software versions and scanners. (6) Driver Frequency is 60 Hz (default).</p>					

Siemens 1.5T - Phantom 2DMRE Parameter Recommendations – June 2020			
Scanners and Sequences	Scanner	MAGNETOM (Tim 3G, Tim 4G)	
	Software versions	N4 VE11C SP01 and above	
	Pulse sequence	greMRE	epseMRE
	Mode	2D	2D
Phantom Setup	Place the 16-cm diameter cylinder phantom vertically in the torso coil, place the liver driver (facing down) on the top of the phantom and secure them with the liver MRE elastic belt tightly.		
Slice Positing	Place one coronal slice at the center of the height of the phantom, with a fixed squared FOV (200 mm). 		
Information Input	Position	head-first, supine	head-first, supine
	Weight	150 Lbs	150 Lbs
	Height	5 ft	5 ft
Coil (note 1)	Coil	Torso	Torso
Imaging Parameters	Imaging Plane	Coronal	Coronal
	No. of slices	4	4
	Slice thickness (mm)/dist. Factor	10 mm / 0% (0)	8 mm / 25% (2mm)
	FOV (mm) / Phase FOV (100%)	200mm/1 (note 4)	200mm/1 (note 4)
	Matrix (Base x Phase)	256 x 25%(64)	128 x 100%(128)
	TE (msec)	min (about ~20 with flow comp off)	min

	TR (msec)	50	1000
	Flip Angle (degree)	25	default (90)
	NEX, EPI shots	1	1, 1shot
	Bandwidth (Hz/Pixel)	260 Hz/pixel	1502 Hz/pixel
	Phase enc.dir.	Right-Left	Right-Left
	Acceleration	GRAPPA (note 1)	GRAPPA (note 1)
	Acceleration factor	1	1
	No. of breath holds	NA	NA

	Shimming Volume	auto	auto
	Spectrum Peaks	Peak with middle freq (there are 3 peaks)	Peak with middle freq (there are 3 peaks)
	Saturation Band		
	scan time	34 sec	11 sec
Driver Parameters (Generic) (note 5)	Driver Power (%)	10 (default) (note 6)	10 (default) (note 6)
	Driver frequency (Hz)	60 (default) (note 6)	60 (default) (note 6)
	Driver cycles/ trigger (Duration)	3 (default) (note 6)	3 (default) (note 6)
Motion Encoding Gradients (Generic) (note 5)	MEG frequency (Hz)	60 Hz (Hard Coded)	60 Hz (Hard Coded)
	MEG Amplitude	(Hard coded)	30 mT/m (Hard coded)
	Axis of MEG	Slice (Hard Coded)	Slice
	Number of phase	4 (Hard coded)	4 (Hard coded)
Specific Parameters (note 5)	Sequence - Part 1 - Flow Comp	NO	YES
	Sequence - Special - MEG Amplitude (mT/m)	Not available	30
	Sequence - Special - MEG Frequency (Hz)	Not available	60.0
	Sequence - Special - MEG Waveform	Not available	1-2-1
	Sequence - Special - MEG Direction	Not available	Slice

	System - Tx/Rx - Img. Scale Cor.	1	1
	Resolution - Filter Image - Prescan Normalize	Check	Check

NOTE: (1) Always use torso coil (multi-channel), add pads around the phantom to support the top part of the torso coil, which should not contact the phantom; if other coils that do not support parallel imaging is used, then the ASSET is turned off automatically, scan time is longer. (2) For GREMRE, scan time can vary depending on the FOV (in phase dir) setup - decreasing phase FOV can slightly decrease scan time; however, do not do this for the phantom. (3) Depending on your gradient hardware performance, the absolute gradient strength could be different. (4) FOV is recommended to be a fixed value (200 mm), even for this 16-cm diameter cylinder phantom. (5) The specific tab and parameters can be different for different software versions and MRE sequences; the generic MRE parameters for driver and motion encoding gradients are the guideline to those specific tab and parameters (MRE-related); overall, this recommendation is conservative so that it can be successfully performed at all software versions and scanners. (6) The current implementation of Siemens MRE does not access active driver, those values are default values and can be changed by using a separate web connection to the active driver (Syngo or Laptop); epseMRE sequences delivers one trigger every 50ms.

Siemens 3T - Phantom 2DMRE Parameter Recommendations - June 2020

Scanners and Sequences	Scanner	MAGNETOM (Tim 3G, Tim 4G)	
	Software versions	N4 VE11C SP01 and above	
	Pulse sequence	greMRE	epseMRE
	Mode	2D	2D
Phantom Setup	Place the 16-cm diameter cylinder phantom vertically in the torso coil, place the liver driver (facing down) on the top of the phantom and secure them with the liver MRE elastic belt tightly.		
Slice Positioning	Place one coronal slice at the center of the height of the phantom, with a fixed squared FOV (200 mm). 		
Information Input (Patient)	Position	head-first, supine	head-first, supine
	Weight	150 Lbs	150 Lbs
	Height	5 ft	5 ft
Coil (note 1)	Coil	Torso	Torso
Imaging Parameters	Imaging Plane	Coronal	Coronal

	No. of slices	4	4
	Slice thickness (mm)/dist. Factor	10 mm / 0% (0)	8 mm / 25% (2mm)
	FOV (mm) / Phase FOV (100%)	200mm/1 (note 4)	200mm/1 (note 4)
	Matrix (Base x Phase)	256 x 25%(64)	128 x 100%(128)
	TE (msec)	min (about ~20 with flow comp off)	min
	TR (msec)	50	1000
	Flip Angle (degree)	20	default (90)
	NEX, EPI shots	1	1, 1shot
	Bandwidth (Hz/Pixel)	260 Hz/pixel	1502 Hz/pixel
	Phase enc.dir.	Right-Left	Right-Left
	Acceleration	GRAPPA (note 1)	GRAPPA (note 1)
	Acceleration factor	1	1
	No. of breath holds	NA	NA

	Shimming Volume	auto	auto
	Spectrum Peaks	Peak with middle freq (there are 3 peaks)	Peak with middle freq (there are 3 peaks)
	Saturation Band		
	scan time	34 sec	11 sec
Driver Parameters (Generic) (note 5)	Driver Power (%)	10 (default) (note 6)	10 (default) (note 6)
	Driver frequency (Hz)	60 (default) (note 6)	60 (default) (note 6)
	Driver cycles/ trigger (Duration)	3 (default) (note 6)	3 (default) (note 6)
Motion Encoding Gradients (Generic) (note 5)	MEG frequency (Hz)	60 Hz (Hard Coded)	60 Hz (Hard Coded)
	MEG Amplitude	(Hard coded)	30 mT/m (Hard coded)
	Axis of MEG	Slice (Hard Coded)	Slice

	Number of phase	4 (Hard coded)	4 (Hard coded)
Specific Parameters (note 5)	Sequence - Part 1 - Flow Comp	NO	YES
	Sequence - Special - MEG Amplitude (mT/m)	Not available	30
	Sequence - Special - MEG Frequency (Hz)	Not available	60.0
	Sequence - Special - MEG Waveform	Not available	1-2-1
	Sequence - Special - MEG Direction	Not available	Slice
	System - Tx/Rx - Img. Scale Cor.	1	1
	Resolution - Filter Image - Prescan Normalize	Check	Check

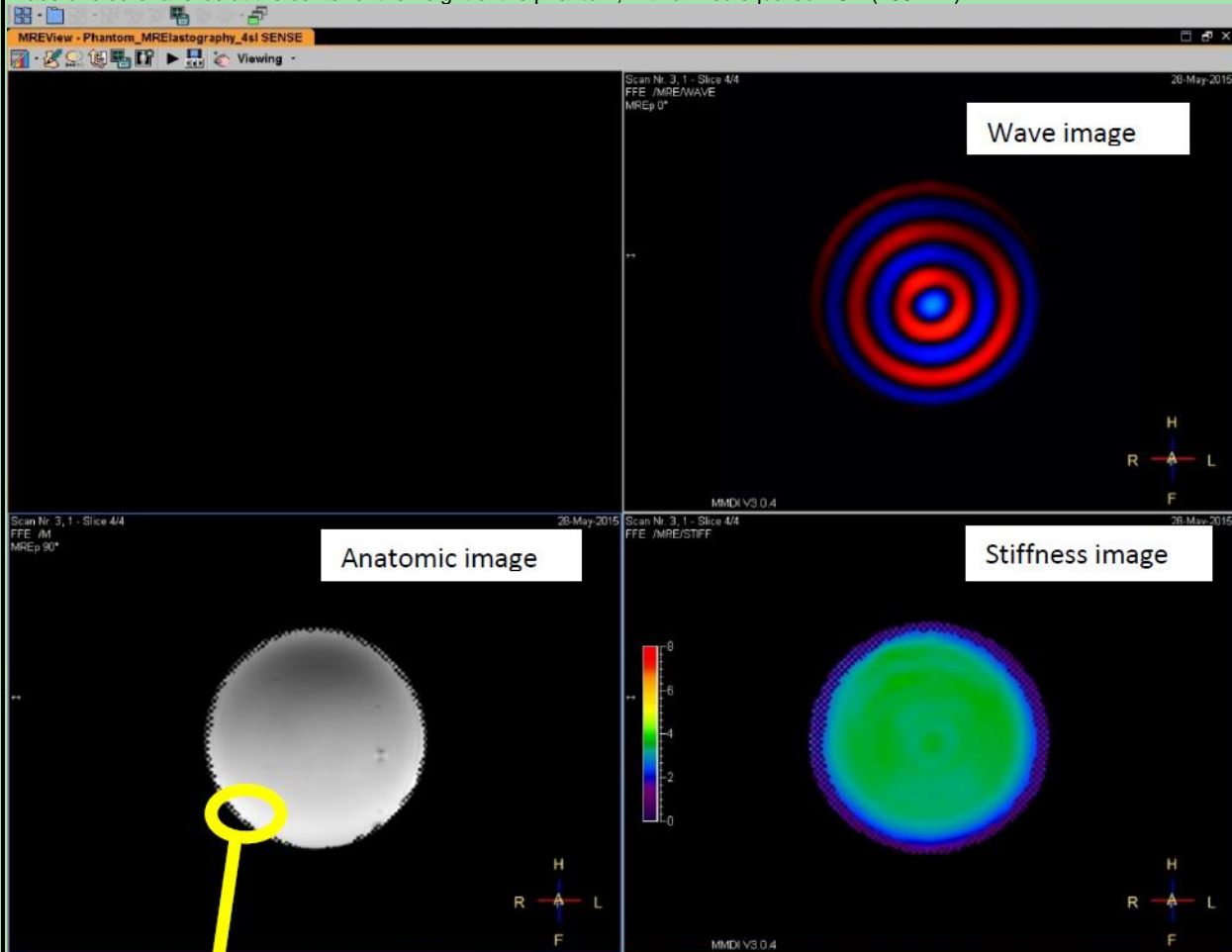
NOTE: (1) Always use torso coil (multi-channel), add pads around the phantom to support the top part of the torso coil, which should not contact the phantom; if other coils that do not support parallel imaging is used, then the ASSET is turned off automatically, scan time is longer. (2) For GREMRE, scan time can vary depending on the FOV (in phase dir) setup - decreasing phase FOV can slightly decrease scan time; however, do not do this for the phantom. (3) Depending on your gradient hardware performance, the absolute gradient strength could be different. (4) FOV is recommended to be a fixed value (200 mm), even for this 16-cm diameter cylinder phantom. (5) The specific tab and parameters can be different for different software versions and MRE sequences; the generic MRE parameters for driver and motion encoding gradients are the guideline to those specific tab and parameters (MRE-related); overall, this recommendation is conservative so that it can be successfully performed at all software versions and scanners. (6) The current implementation of Siemens MRE does not access active driver, those values are default values and can be changed by using a separate web connection to the active driver (Syngo or Laptop); epseMRE sequences delivers one trigger every 50ms.

Philips 1.5T - Phantom 2DMRE Parameter Recommendations - June 2020

Scanners and Sequences	Scanner	Achieva, Ambition, Ingenia	
	Software versions	MR R5.1.7 SP2 (or later)	
	Pulse sequence	FFE MRE	2D SE-EPI MRE (WIP)
	Mode	2D	2D
Phantom Setup	Place the 16-cm diameter cylinder phantom vertically in the head coil, place the liver driver (facing down) on the top of the phantom and secure them with the liver MRE elastic belt tightly.		



Place one coronal slice at the center of the height of the phantom, with a fixed squared FOV (200 mm).



Slice
Positing

Information
Input
(Patient)

Position	head-first, supine	head-first, supine
Weight		

	Height		
Coil (note 1)	Coil	Head	Head
Imaging Parameters	Imaging Plane	Coronal	Coronal
	No. of slices	4	4
	Slice thickness (mm)/gap	10 mm / 1 mm	8 mm / 2 mm
	FOV (mm) / Phase FOV (100%)	300/300	300/300
	Matrix	200 x 64	64 x 64
	TE (msec)	min or 20	min or 58
	TR (msec)	50	1000
	Flip Angle (degree)	30	default (90)
	NSA, EPI shots	1	1, 1shot
	Bandwidth (Hz/Pixel)	218 Hz/pixel	88 Hz/pixel
	Freq Encoding Dir	FH	FH
	Acceleration	None	None
	Acceleration factor	1	1
No. of breath holds	0	0	

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	Shimming	Auto	Auto
	REST slabs	No	No
	scan time	1:44 (note 2)	19 sec
Driver Parameters (Generic) (note 5)	Driver Power (%)	10	10
	Driver frequency (Hz)	60	60
	Driver cycles/ trigger (Duration)	3 (auto-calculated)	Auto-calculated

Motion Encoding Gradients (Generic) (note 5)	MEG frequency (Hz) (or Period Mismatch)	60 Hz	60 Hz
	MEG Amplitude (G/cm)	18.4	18.4
	Axis of MEG	AP	AP
	Number of phase	4	4
Specific Parameters (To be specified)			

NOTE: (1) Always use head coil ; if other coils that do not support parallel imaging is used. (2) For FFE MRE, scan time can vary depending on the FOV (in phase dir) setup - decreasing phase FOV can slightly decrease scan time; however, do not do this for the phantom. (3) Depending on your gradient hardware performance, the absolute gradient strength could be different. (4) FOV is recommended to be a fixed value (300 mm), even for this 16-cm diameter cylinder phantom. (5) The specific tab and parameters can be different for different software versions and MRE sequences; the generic MRE parameters for driver and motion encoding gradients are the guidelines to those specific tab and parameters (MRE-related); overall, this recommendation is conservative so that it can be successfully performed at all software versions and scanners.

Philips 3T - Phantom 2DMRE Parameter Recommendations - June 2020

Scanners and Sequences	Scanner	Achieva, Elition, Ingenia	
	Software versions	MR R5.1.7 SP2	
	Pulse sequence	GRE MRE	2D SE-EPI MRE
	Mode	2D	2D
	Shimming Volume	Auto	Auto
	REST slabs	No	No
	scan time	1:44 s (note 2)	19 sec
Driver Parameters (Generic) (note 5)	Driver Power (%)	10	10
	Driver frequency (Hz)	60	60
Motion Encoding Gradients (Generic) (note 5)	MEG frequency (Hz) (or Period Mismatch)	60 Hz	60 Hz
	MEG Amplitude (G/cm)	18.4	18.4
	Axis of MEG	AP	4AP
	Number of phase	4	4

NOTE: (1) Always use head coil. (2) For FFE MRE, scan time can vary depending on the FOV (in phase dir) setup - decreasing phase FOV can slightly decrease scan time; however, do not do this for the phantom. (3) Depending on your gradient hardware performance, the absolute gradient strength could be different. (4) FOV is recommended to be a fixed value (300 mm), even for this 16-cm diameter cylinder phantom. (5) The specific tab and parameters can be different for different software versions and MRE sequences; the generic MRE parameters for driver and motion encoding gradients are the guidelines to those specific tab and parameters (MRE-related); overall, this recommendation is conservative so that it can be successfully performed at all software versions and scanners.

Appendix E: Sample Phantom QA Protocol

440 This activity describes MRE system Quality Assurance (QA) method using MRE QA phantoms, including the phantom setup, phantom imaging parameters and region of interest (ROI) for measuring phantom stiffness, as well as a QA schedule and pass criteria.

QA PHANTOM

445 The MRE system QA phantom is made of Polyvinyl Chloride (PVC) in a 12.5cm x Ø15.5cm cylinder container with 0.15 cm wall thickness. It should be handled carefully when being transferred from one location to another to avoid dropping.



Figure 1. MRE QA Phantom

PHANTOM SETUP:

450 The MRE system QA phantoms setup uses the patient liver MRE driver, the patient elastic belt, a phantom specific friction cloth, and the patient torso RF coil. There are 10 steps for a typical QA phantom setup; the goal of the setup is to make sure the phantom is sitting on the table vertically and stably:

- 455 1) Position the bottom part of the patient torso coil on the patient table
- 2) Put the patient elastic belt on the bottom coil
- 3) Put the MRE standard phantom on the elastic belt vertically
- 460 4) Put the friction cloth on the top of the phantom
- 5) Put the patient liver driver on the friction cloth
- 6) Wrap the phantom, friction cloth and driver with the elastic belt tightly
- 7) Put some cushions around the MRE Phantom to support the top part of the torso coil, which should not contact the phantom
- 465 8) Put the top part of the torso coil on the cushions
- 9) Connect the liver driver to the tube of MRE active driver
- 10) Advance to scan

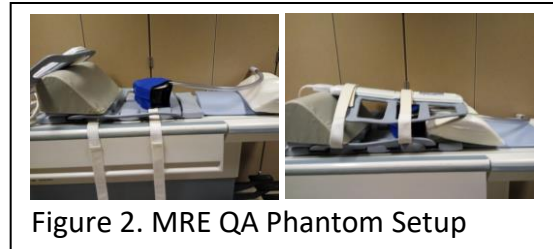


Figure 2. MRE QA Phantom Setup

PHANTOM IMAGING PARAMETERS

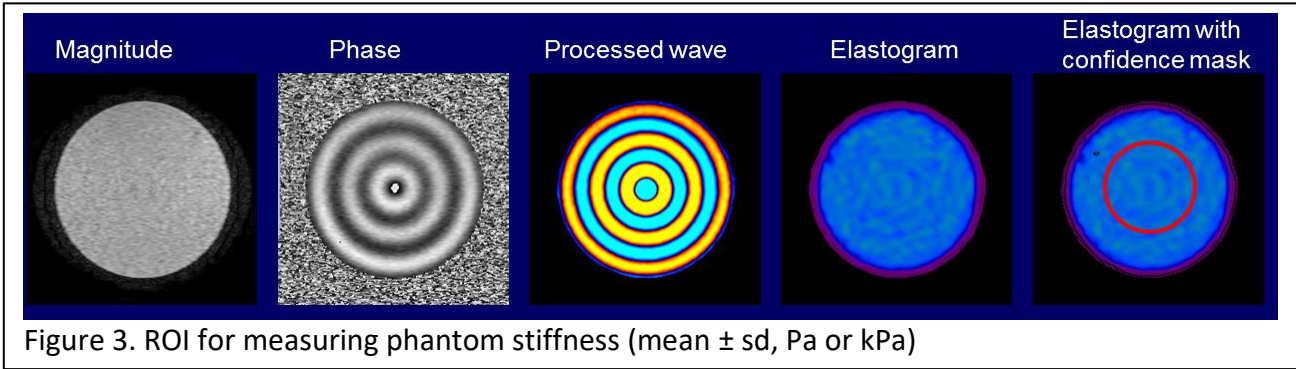
470 Patient MRE sequences are used for the MRE system QA, but with different imaging parameters. Phantom imaging parameters have been optimized according to its T1 and T2 relaxation time, chemical spectrum and geometry, which are very different from the patients. Detailed parameters for GRE MRE and EPI MRE sequences at both 1.5-T and 3-T platforms of the three vendors (GE, Siemens and Philips) are attached ([Phantom 2DMRE Parameters - Hepatic Driver - Sept 2016 Draft 1c.pdf](#)).

REGION OF INTEREST (ROI) FOR MEASURING PHANTOM STIFFNESS

475 Position a circular ROI in the middle of the phantom with half of the phantom diameter on the elastogram (with or without confidence mask). A high quality phantom exam should have the majority

of phantom uncovered with the confidence mask. Phantom edges should be avoided from the ROI due to the edge effect. Mean and standard deviation of the pixel values in the ROI are reported as the phantom stiffness (in the unit of Pa or kPa).

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QA SCHEDULE AND PASS CRITERIA

The MRE system QA phantom exams should be scheduled on site every six months. The current mean stiffness measurement ($E_{current}$) of the phantom should be compared to the average of the current and the previous measurement ($E_{previous}$); measurement difference = $2 \times \text{abs}(E_{current} - E_{previous}) / (E_{current} + E_{previous})$. Pass criteria for the current exam: measurement difference $\leq 10\%$.

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Table 1: MRE QA Schedule and Criteria

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	$2 \times \text{abs}(E1 - E0) / (E1 + E0)$	$\leq 10\%$
Next 6 months	E2	SD2	$2 \times \text{abs}(E2 - E1) / (E2 + E1)$	$\leq 10\%$
⋮	⋮	⋮	⋮	⋮

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Appendix F



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QIBA Checklist:

Magnetic Resonance Elastography of the Liver

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INSTRUCTIONS

This Checklist is organized by "Actor" for convenience. If a QIBA Conformance Statement is already available for an actor (e.g. your analysis software), you may choose to provide a copy of that statement rather than confirming each of the requirements in that Actors checklist yourself.

505

Within an Actor Checklist the requirements are grouped by the corresponding Activity in the QIBA Profile document. If you are unsure about the meaning or intent of a requirement, additional details may be available in the Discussion section of the corresponding Activity in the Profile.

Site Conformity indicates whether you have performed the requirement and confirmed conformance.

510

Site Opinion allows you to indicate how the requirement relates to your current, preferred practice. If a requirement is not feasible or not worth it to achieve the Profile Claim, please explain to help us understand why.

Since several of the requirements mandate the use of specific assessment procedures, those are also included at the end to minimize the need of referring to the Profile document.

Feedback on all aspects of the Profile and associated processes is welcomed.

515

<u>PHYSICIST CHECKLIST</u>	<u>PAGE 69</u>
<u>RADIOLOGIST CHECKLIST</u>	<u>PAGE 70</u>
<u>TECHNOLOGIST CHECKLIST</u>	<u>PAGE 71-72</u>

PHYSICIST CHECKLIST

520 Note: The role of the Physicist actor may be an in-house medical physicist, a physics consultant or other staff (such as a vendor service or specialists) qualified to perform the validations described.

<i>Parameter</i>	<i>Conforms?</i>	<i>Specification</i>
<i>Periodic QA (section 3.3)</i>		
Required QA	<input type="checkbox"/> Yes <input type="checkbox"/> No	Measurements of liver stiffness (magnitude of the complex shear modulus) obtained with MRE depends on the spatial fidelity of the acquired phase images. Therefore, the validity of the field of view and image linearity shall be assessed and confirmed on an ongoing basis, using manufacturer-recommended procedures.
	<input type="checkbox"/> Yes <input type="checkbox"/> No	While other instrumental causes of drift in stiffness measurements have not been documented in the literature, technical failures such as faulty synchronization of the driver system or incorrect driver frequency settings can cause incorrect measurements. The physicist shall confirm correct driver frequency settings as outlined in Appendix D.
Optional QA	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall confirm correct user set-up and proper functioning of the MRE system can be confirm using a phantom with previously-measured stiffness properties. These usually consist of a uniform, tissue-simulating material with known stability over time and storage conditions. An MRE phantom can be used to confirm proper functioning of the MRE system after initial installation and as a periodic test of correct functioning. There is as of yet, no consensus on recommendations for the frequency of phantom testing. Optional QA testing with a phantom should employ a protocol recommended by the phantom manufacturer. Appendix 2 describes a sample protocol for a currently available phantom.
<i>Imaging Equipment (section 4.1.1)</i>		
<i>Imaging Equipment</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	As outlined in Section 3.2, installation and initial functional validation shall be performed according to manufacturer-defined procedures and specifications. This includes specific guidelines on the MRI scanner and MRE driver system. The scanner must be under quality assurance and quality control processes as outlined by local institution and vendor requirements. The scanner software version should be identified and tracked across time.

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RADIOLOGIST CHECKLIST

Note: The Radiologist is responsible for image analysis, image QA, and interpretation. The Radiologist is also responsible for ensuring that the protocol has been validated, although the Physicist actor is responsible for performing the validation.

535

Parameter	Conforms?	Specification
<i>Image QA (section 3.8)</i>		
<i>Image QA</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	At the time of image review, the suitability of the data shall be checked again by confirming the presence of signal loss in subcutaneous fat under the driver in the magnitude images, and the presence of visible waves in the liver in the phase and wave images (Figure 3).
<i>Image Analysis (section 3.10)</i>		
<i>Mean shear stiffness of the liver</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	Mean shear stiffness of the liver shall be calculated using manually specified regions of interest (ROIs). The ROIs are drawn manually in the largest possible area of liver parenchyma in which coherent shear waves are visible, while excluding major blood vessels seen on the MRE magnitude images.
	<input type="checkbox"/> Yes <input type="checkbox"/> No	To avoid areas of incoherent waves, the radiologist shall avoid regions immediately under the passive driver and stay ~1 cm inside the liver boundary and contain a minimum of 500 pixels for an acquisition with a 420 mm FOV and reconstruction matrix of 256x256 total, corresponding to approximately 12.8 cm ³ [17,3].
	<input type="checkbox"/> Yes <input type="checkbox"/> No	ROIs shall be placed in individual slices and in the right lobe whenever possible. MRE magnitude and phase/wave images should be used to guide the placement of the ROIs. (Figure 9)
	<input type="checkbox"/> Yes <input type="checkbox"/> No	Image shall be rejected if the acquisition failed due to hepatic iron overload. (Figure 7)
	<input type="checkbox"/> Yes <input type="checkbox"/> No	Image shall be rejected if colonic interposition between the passive driver and liver is present. (Figure 5)
<i>Image Interpretation (section 3.11)</i>		
<i>Liver Stiffness</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	Overall mean stiffness of liver shall be reported by calculating the mean stiffness value of each ROI and then reporting the mean value across all slices.

TECHNOLOGIST CHECKLIST

<i>Parameter</i>	<i>Conforms?</i>	<i>Specification</i>
<i>Subject Handling (section 3.5)</i>		
Fasting state	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall confirm that the subject is fasting for at least 4 hours before the scheduled time of imaging [12,13].
MR Scanner and MRE device	<input type="checkbox"/> Yes <input type="checkbox"/> No	For follow-up exams, the technologist shall confirm that the subject will be scanned on the same MRI scanner and passive driver hardware as the baseline liver MRE in order to satisfy the specific requirements for the claim.
Subject positioning	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall scan the subject in supine position.
	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall place the passive driver over the right lower chest wall at the level of xiphisternum in midclavicular line. (Can be placed in the right mid-axillary line if colon is present between the anterior body wall and the liver) (16, 17).
	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall ensure the passive driver is held in firm contact with the body wall using an elastic band.
	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall ensure connection of the plastic tube between the passive & active driver, which is located outside the scan room.
<i>Image Data Acquisition (section 3.6)</i>		
Image acquisition	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall acquire image data during suspended expiration in a natural end-expiratory position.
Slice selection	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall acquire sections for MRE positioned at the level of the widest transverse extent of the liver, avoiding the lungs, liver dome and inferior tip of the right lobe, prescribed in a coronal image in relaxed end-expiration. (Figure 2)
Image Acquisition	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall use an EPI-MRE sequence at 3T if available due to the higher technical success rate. Note, GRE MRE sequences are susceptible to T_2^* effects resulting in poor SNR or failures in tissue with short T_2^* relaxation times, particularly at 3T.[16]
Image acquisition	<input type="checkbox"/> Yes <input type="checkbox"/> No	For follow-up exams, technologist shall confirm that subjects are scanned with the same parameters and software as the baseline liver MRE.
<i>Technical Success (section 3.6.2)</i>		
Image Acquisition	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall review the raw magnitude and phase images obtained from the MRE acquisition on the scanner console at the time of the exam.
Technical success	<input type="checkbox"/> Yes <input type="checkbox"/> No	The technologist shall confirm that the magnitude images should show

<i>Parameter</i>	<i>Conforms?</i>	<i>Specification</i>
		signal loss in the subcutaneous fat just below the passive driver placement, confirming that mechanical waves are being applied. The phase images (also known as wave images) should demonstrate shear waves in the liver. (Figure 3)
<i>Technical success</i>	<input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	If no waves are imaged in the liver, then the technologist shall check driver system.
<i>Technical Success (section 3.7.2)</i>		
<i>Image Reconstruction</i>	<input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	The technologist shall confirm that the scanner computer automatically processes the information to generate the following images on the scanner console: quantitative stiffness maps, confidence maps, and unwrapped phase images. (Figure 8)
<i>Imaging Procedure (section 4.1.2)</i>		
<i>Imaging Procedure</i>	<input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	Currently, there is not a standard imaging phantom for standardized image acquisition and processing procedures. The technologist shall follow Appendix E for phantom imaging protocols.