QIBA Profile:
Magnetic Resonance Elastography of the Liver

Stage: 3: Clinically Feasible
November 7, 2023

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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.

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**.

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**.

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.

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

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].

Conformance to this Profile <u>by all relevant staff and equipment</u> 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

This claim is based on the normal liver stiffness within-subject coefficient of variation (wCV) which we have estimated as 7% [8]. The Repeatability Coefficient is then 2.77 $\times$ 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) ± 1.96 x sqrt($[Y1x0.07]^2$ + $[Y2 x0.07]^2$) kPa.

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.

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.

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.

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
Physicist	Installation and Periodic QA	3.3.
Technologist	Subject Handling	3.5.
	Image Data Acquisition	3.6.
	Image Data Reconstruction	3.7.
Radiologist	Image QA	3.8.
	Image Analysis	3.10.
	Image Interpretation	3.11.

This Profile does not require an imaging site or vendor to directly demonstrate that they have achieved the performance stated in the Claim. Section 4.2: Assessment Procedure: Liver Stiffness Repeatability is provided, however, for any sites or vendors that wish to perform such an assessment. To confirm the Claim performance, a minimum of N=40 normal subjects should be imaged and the resulting RC should be 19% or less. It would be appropriate for a vendor introducing a new version of MRE to perform such an assessment.

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.

3.3. Installation and Periodic QA

Measurements of liver stiffness (magnitude of the complex shear modulus) obtained with MRE depends on the spatial fidelity of the acquired phase images.

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.

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.

The software version of the scanner, however, should be identified and tracked across time.

There are currently no consensus recommendations for the frequency of phantom testing. Optional QA can be performed using the protocol recommended by the phantom manufacturer. Appendix B describes a sample protocol. The phantom consists of a uniform, tissue-simulating material with known stability over time and storage conditions.

Parameter	Actor	Requirement
Installation	Physicist	Shall perform installation and initial functional validation of the MRI Scanner and MRE driver system according to manufacturer-defined procedures and specifications.
Required QA	Physicist	Shall assess and confirm the validity of the field of view and image linearity on an ongoing basis, using manufacturer-recommended procedures.
	Physicist	Shall confirm correct driver frequency settings as outlined in Appendix D.

3.5. Subject Handling

3.5.1 Subject preparation and positioning

Parameter	Actor	Requirement
Fasting state	Technologist	Shall confirm that the subject has fasted for at least 4 hours before the time of imaging [12,13].
MR scanner and MRE device selection	Technologist	Shall confirm for follow up exams that the subject is scanned on the same MRI scanner and passive driver hardware as the baseline exam.

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 (Figure 1). 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.

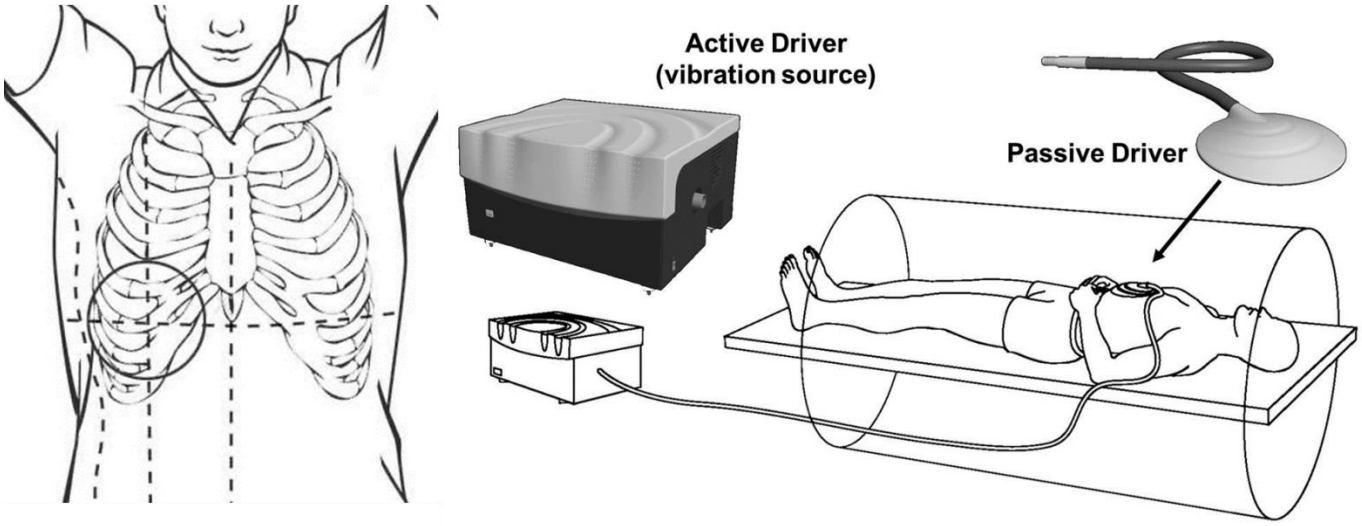

Figure 1: Place the passive driver over the right lower anterior chest wall at the level of the xiphisternum, centered on the mid-clavicular line, ensuring the belt is firmly tightened around the body (see 3.5.1).

3.6. Image Data Acquisition

EPI-MRE sequence at 3T are specified due to the higher technical success rate. GRE MRE sequences are susceptible to T2* effects resulting in poor SNR or failures in tissue with short T2* relaxation times, particularly at 3T. [16]

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 axial 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 (Figure 2)
Image Acquisition	Technologist	Shall use an EPI-MRE sequence at 3T, if available (GRE-MRE if not available).
Image acquisition	Technologist	Shall confirm that subjects are scanned with the same parameters and software during follow up exams as the baseline liver MRE.
Image Acquisition	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.
Technical success	Technologist	Shall confirm the phase images (also known as wave images) demonstrate shear waves in the liver. (Figures 3-7)
Technical success	Technologist	Shall review the post-processed elastograms (with or without confidence map, as available) to confirm technical success of the exam.
Technical success	Technologist	Shall re-acquire the exam if possible if the above technical success criteria are not met.

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

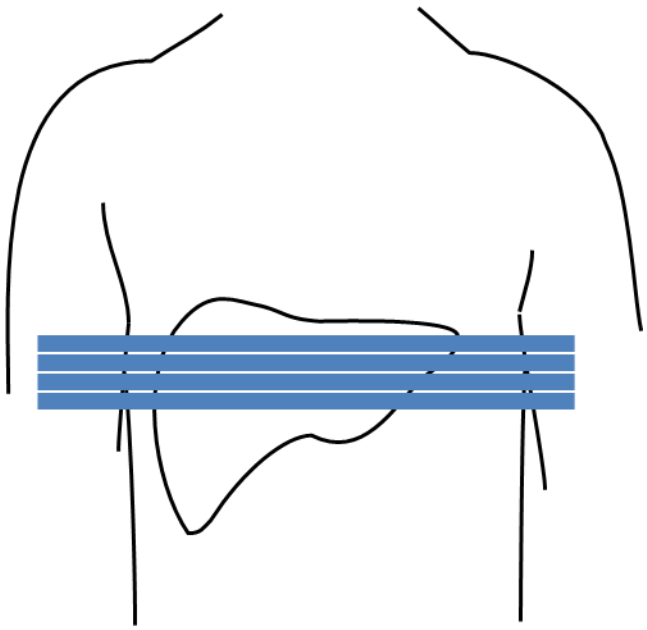

Figure 2: Position sections for MRE at the level of the widest transverse extent of the liver, avoiding the lung, liver dome and inferior tip of the right lobe.

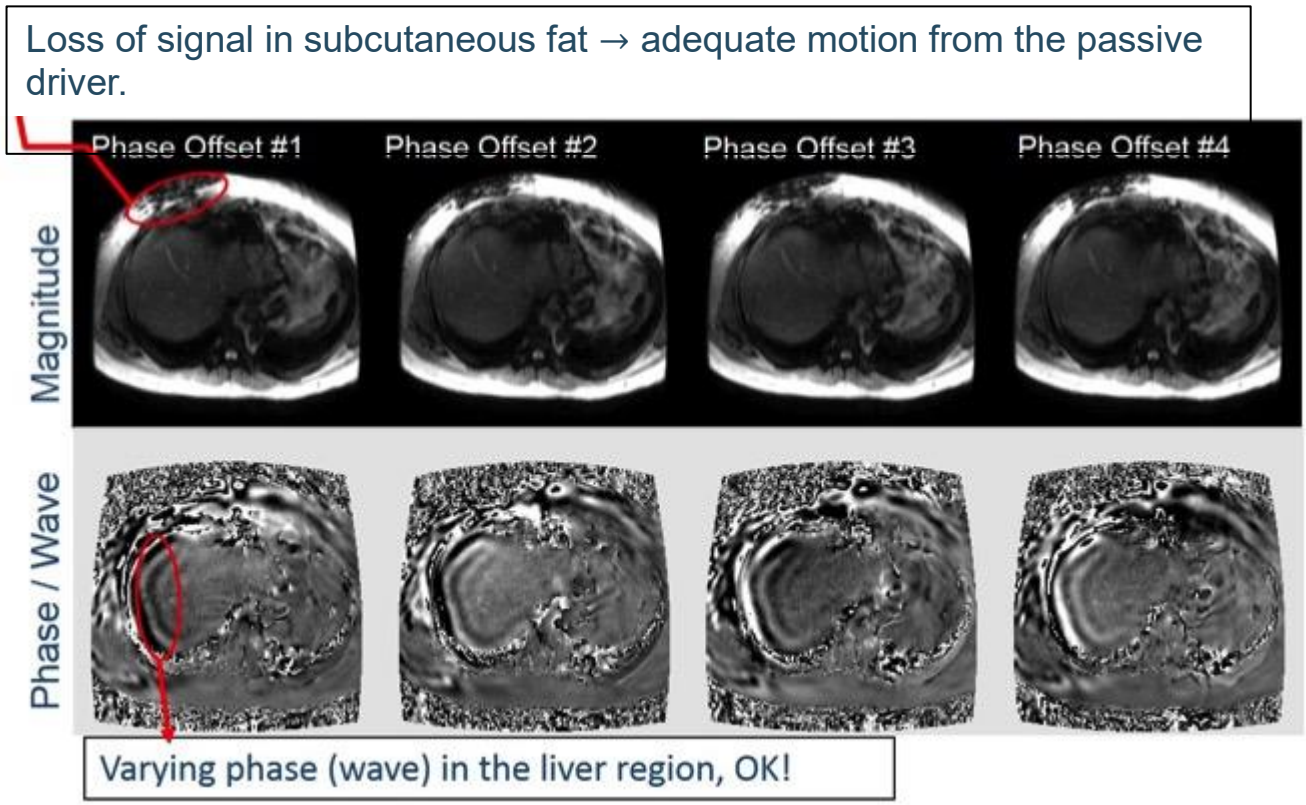

Figure 3: Valid MRE. Top row shows the magnitude images of four time offsets and bottom row shows the phase (wave) images. The four time offsets belong to a single slice location.

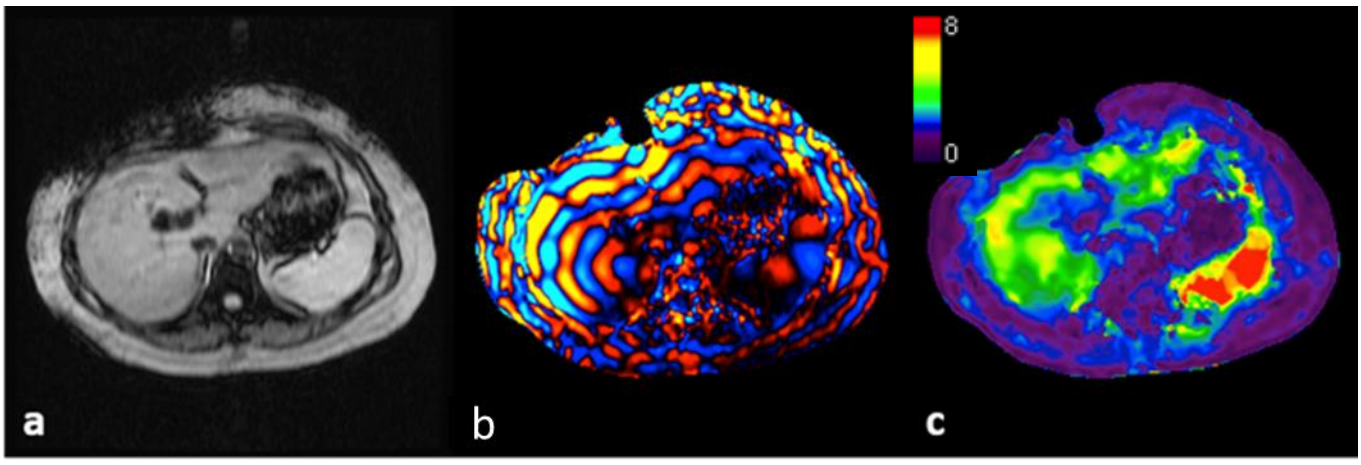

Figure 4: Magnitude (a) and color-coded wave (b) images of a successful MRE showing excellent illumination of waves through the liver. Stiffness map (c) shows elevated liver stiffness consistent with

significant fibrosis.

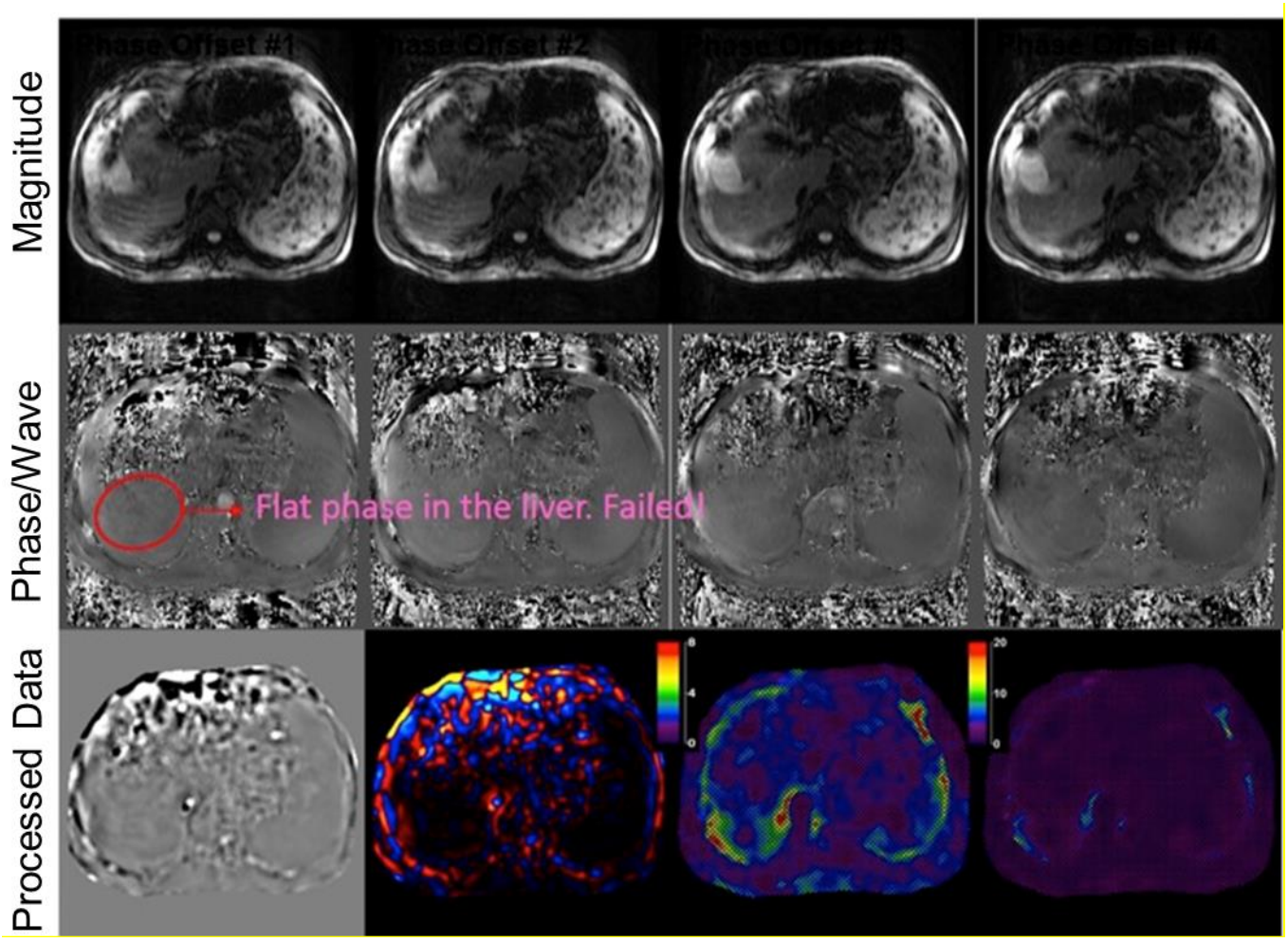

Figure 5: Failed MRE exam – Representative images of failed MRE exam due to colonic interposition between the passive driver and the liver.

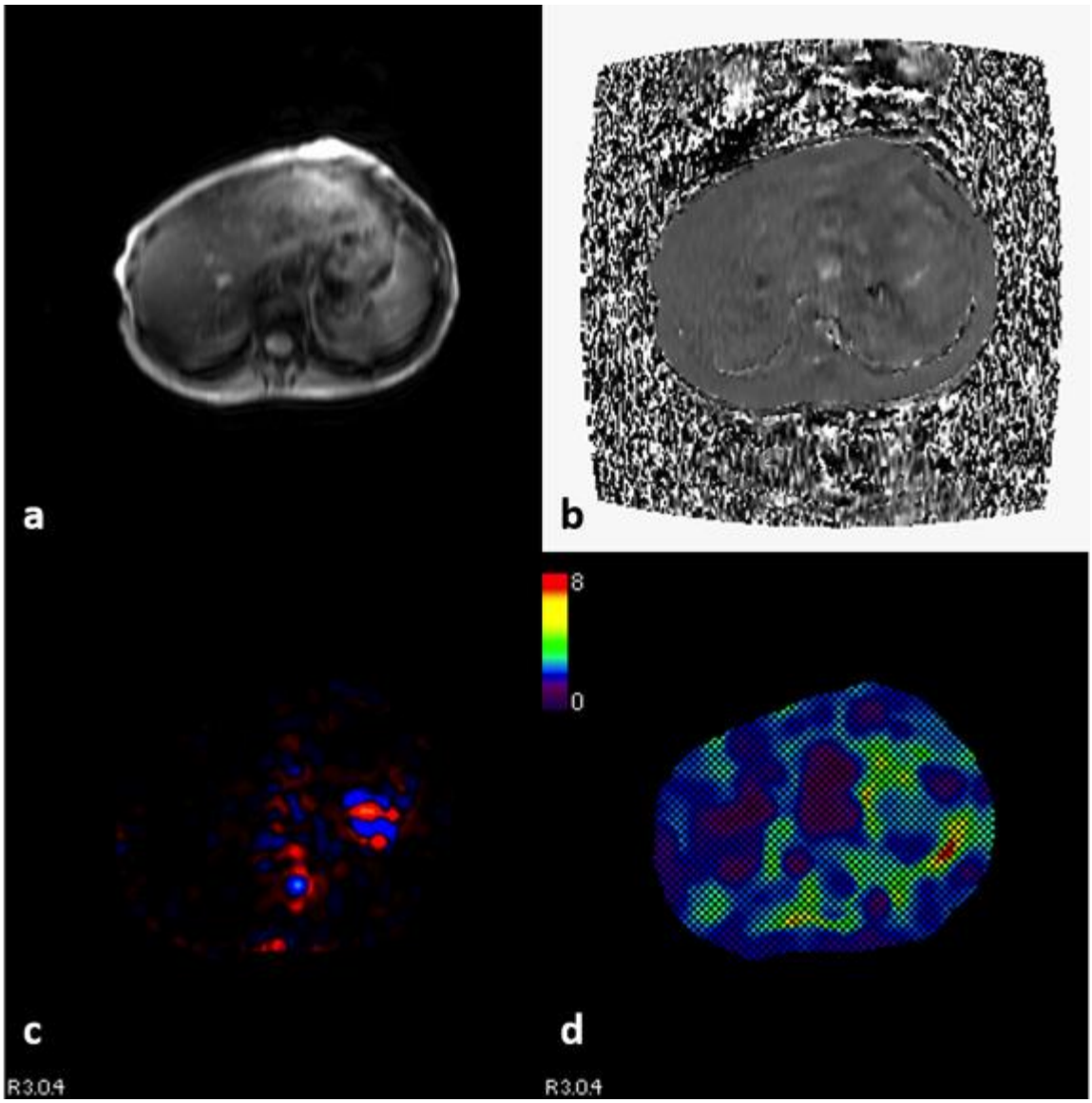

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Figure 6: Failed MRE exam – Representative images of failed MRE exam due to a disconnection of the plastic tube between the passive and active drivers. Magnitude (a), phase (b), and color-coded wave (c) images show no waves traversing the liver. Stiffness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

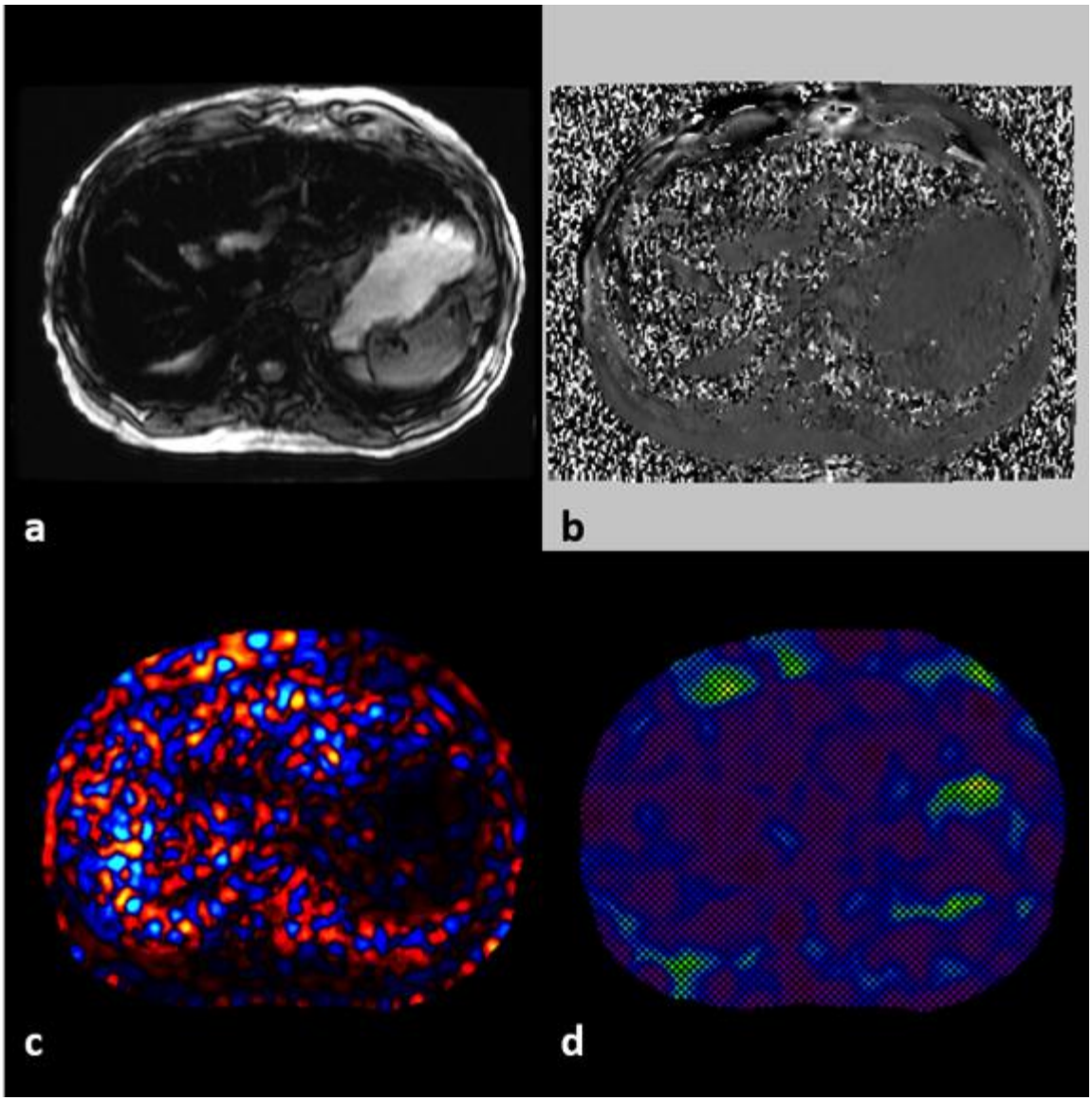

Figure 7: Failed MRE exam – Representative images of failed MRE exam due to hepatic iron overload. Magnitude (a) shows a lack of liver signal while the phase (b) and color-coded wave (c) images show no waves traversing the liver. Stiffness map (d) has no valid data (represented with the hashed-out area).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

3.7. Image Data Reconstruction

3.7.1 DISCUSSION

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 SPECIFICATION

Parameter	Actor	Requirement
Image Reconstruction	Technologist	Shall confirm that the following images have been generated: quantitative stiffness maps (grayscale or color with look up table), confidence maps, and unwrapped wave images. (Figure 8)

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.
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.

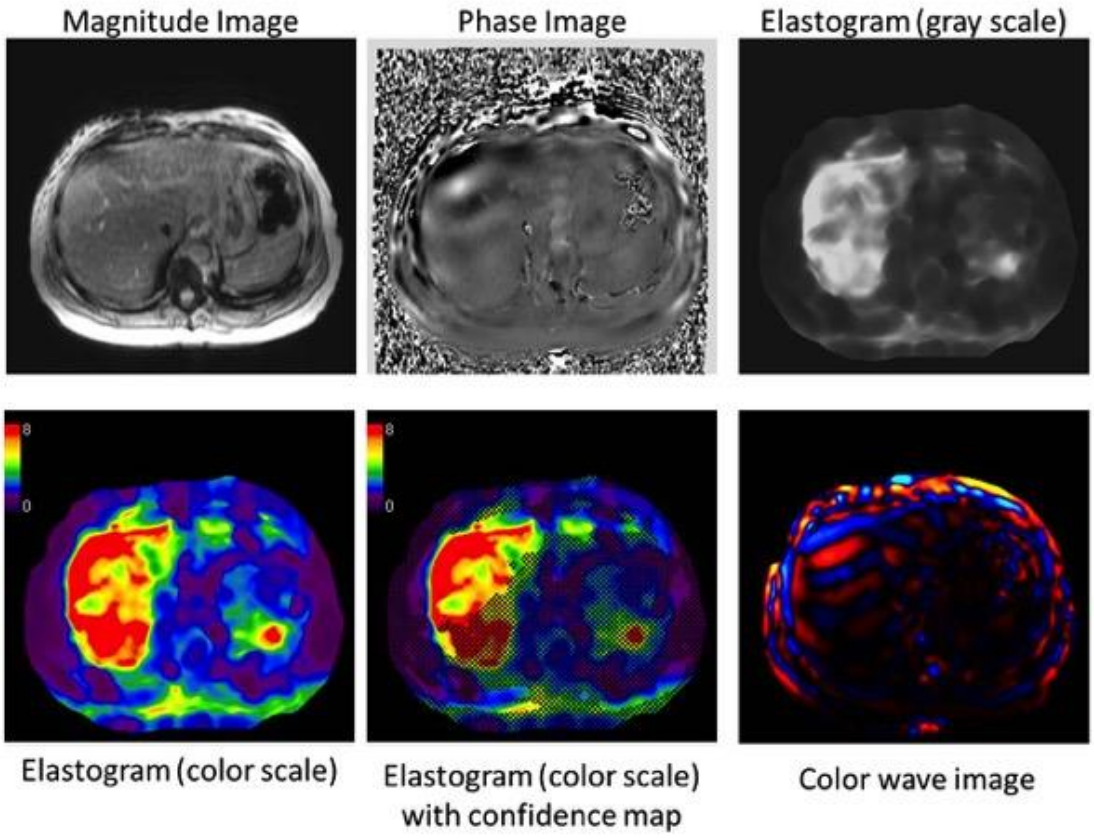

Figure 8: Representation of images generated in an MRE study. Additional post-processed images may be available depending on the software version installed on the scanner.

3.8. Image QA

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).

Parameter	Actor	Requirement
Image QA	Radiologist	Shall check the suitability of the data 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).

3.10. Image Analysis

Parameter	Actor	Requirement
Mean shear stiffness of the liver	Radiologist	Shall reference the magnitude image to draw ROIs in the largest possible area of liver parenchyma, staying ~1 cm inside the liver boundary, avoiding the area directly underneath the passive driver, and excluding major blood vessels seen on the MRE magnitude images. (Figure 9)
	Radiologist	Shall use the phase or wave images to avoid areas of 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) (Figure 9)
	Radiologist	Shall place ROIs in individual slices and in the right lobe whenever possible. (Figure 9)
	Radiologist	Shall exclude areas of low confidence, as seen by the checkerboard pattern in the masked elastogram images (Figure 9).
	Radiologist	Shall calculate mean shear stiffness of the liver using manually specified regions of interest (ROIs) containing 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 [17,3,18].
	Radiologist	Shall reject the elastography if the acquisition failed due to hepatic iron overload, colonic interposition, or other cause of inadequate waves and the scan repeated. (Figure 5, 7)

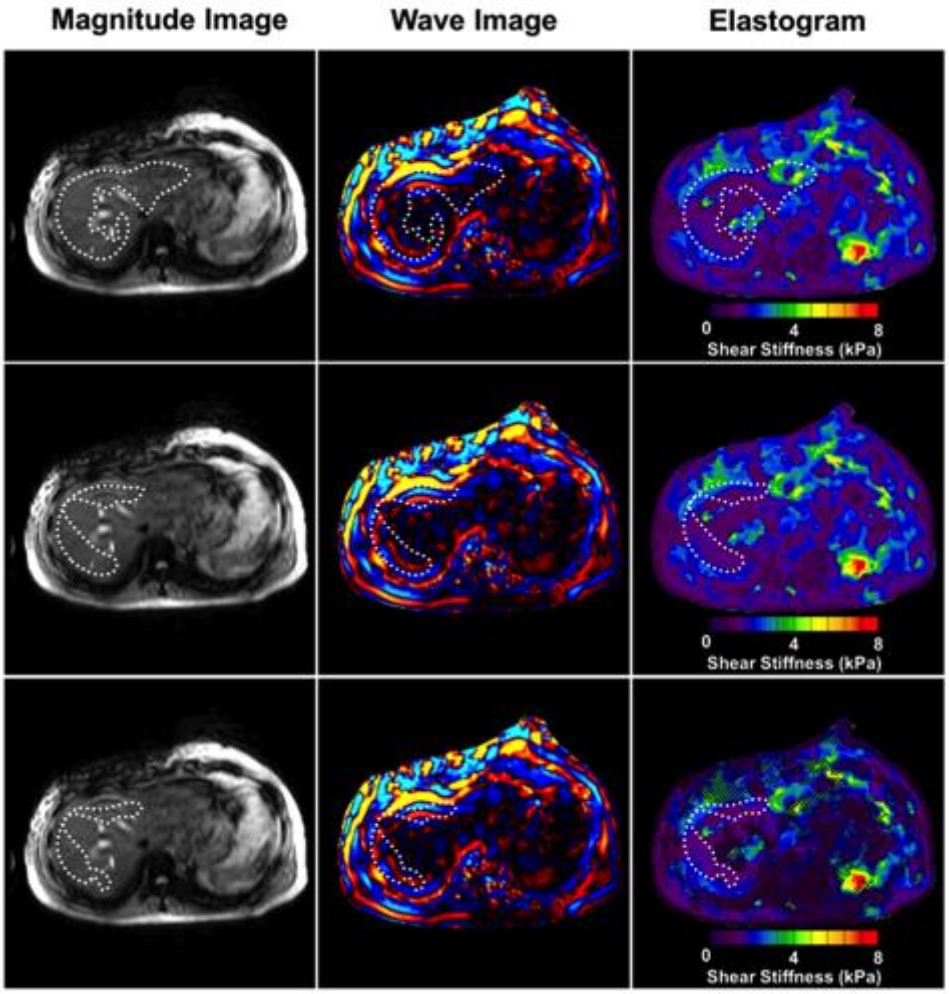

Figure 9: Regions of interest (ROIs) should be drawn with reference to the magnitude, wave, and elastogram images. The ROI should be within the contour of the liver, excluding areas near the margins and major vessels (top row). The ROI should be modified to exclude areas with low wave amplitude as well 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	Shall report overall mean stiffness 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.

4. Assessment Procedures

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

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.

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: Liver Stiffness Repeatability

This procedure can be used by a vendor or an imaging site to assess the repeatability of liver stiffness measurements using MRE. Repeatability is assessed in terms of a percent Repeatability Coefficient (RC) which is based on the within-subject coefficient of variation (wCV) during a test-retest study.

The test-retest repeatability study may be performed in a group of healthy volunteer subjects.

The Assessor shall:

- Image each subject twice on the same day (and additionally, image some subjects a third time within one week).
- Use the same scanner, driver hardware, parameters, and software
- Follow the guidelines outlined in Section 3.5 for subject preparation and positioning.
- Ask subjects to stand following the liver MRE acquisition and reposition them for the second MRE exam.
- Perform a third MRE exam within 7 days.
- Reconstruct and analyze the data as described in Section 3.7 and 3.10 respectively.

Let Y_{i1} denote the liver stiffness measurement for the i-th subject from the first scan, 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. 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 for the N subjects:

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

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

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

References

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
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
5. Shire NJ, Yin M, Chen J, Railkar 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
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
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
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
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
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
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
18. Middleton MS, Henderson WC, Potu CK, Delgado TI, Chung C, Djedjos CS, Myers RP, Chen J, Sirlin C (2019) Evaluation of liver MRE analyzability criteria using a simulation method based on successively decreasing the size of the selected region-of-interest: a proof-of-concept study. Paper presented at the Radiological Society of North America, Chicago, IL, December 5, 2019

Appendices

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.

The following were members of the QIBA MR Elastography Biomarker Committee during the writing of this Profile (in alphabetical order):

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Appendix B: Background Information

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.

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 for Appendix B

[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.

[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; 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.

[8] Jajamovich Gll. 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.

[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.

Appendix C: Conventions and Definitions

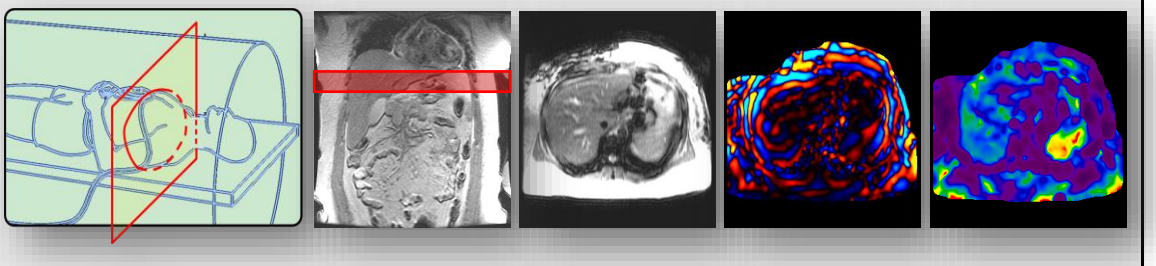
Definitions/Abbreviations

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

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.

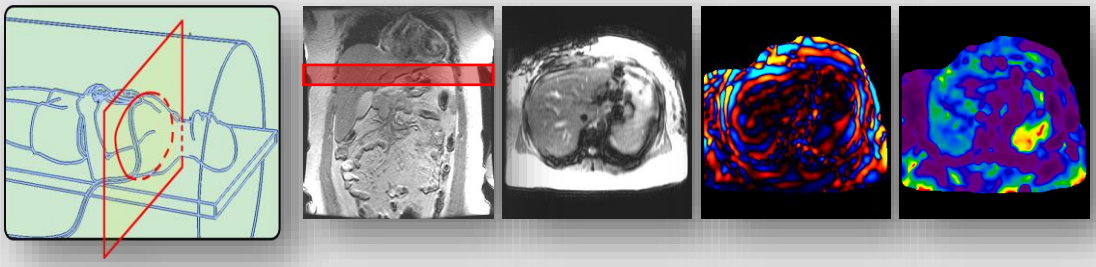
GE 1.5T – Hepatic MRE Protocols – November 2023				
Scanners and Sequences	Scanner	Artist, Creator, Explorer, HDx, Optima MR450w, Voyager		
	Software versions	HD16 and ≥DV22.1	HD16 and ≥DV22.1	≥DV22.1
	Pulse sequence	**fgremre (Mayo-GE)**	**epimre (Mayo-GE)**	**MR-Touch (GRE)**
	Mode	2D, zoom gradient	2D, zoom gradient	2D
	Options	Fast, ASSET, MultiPhase	FC, ASSET, MultiPhase	Fast, ASSET, MultiPhase
Patient Cooperation	(1) Patients shall fast at least 4hours 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.			
Slice Positioning	 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.			
Patient Information Input	Position	feet-first, supine	feet-first, supine	feet-first, supine
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	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)

GE 1.5T – Hepatic MRE Protocols – November 2023				
	Matrix	256 × 64	96 × 96	256 × 64
	TE (ms)	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 (ms)	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
	scan time	55 s (note 2)	11 sec	55 sec (note 2)
Driver Parameters	Driver Power (%)	50	50	50

GE 1.5T – Hepatic MRE Protocols – November 2023				
(Generic) (note 5)	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 (s)		0	
	CV12 -Fraction of Max Gradient Amplitude		1	
	CV13 -Desired MEG Frequency (Hz)		80	
	CV14 -Driver Amp. % (-1 = not V3)		50	
	CV15 -Recon (Def-1912;3D ver =1914;Brain=1915;2D MMDI = 1916)		1916	

GE 1.5T – Hepatic MRE Protocols – November 2023				
	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 (Specific fgremre-DV22.1, DV24) (note 5)	Temporal Phases	4		
	MEG Frequency (Hz)	75		
	Driver Amplitude (%) (note 6)	50		

GE 1.5T – Hepatic MRE Protocols – November 2023				
	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 – November 2023				
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	(1) Patients shall fast at least 4 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.			
Slice Positioning	 Place 4 axial slices at the largest portion of the liver in corol view, and avoid the heart, the liver dome and the liver bottom tip.			
Patient Information Input	Position	feet-first, supine	feet-first, supine	feet-first, supine
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
	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 × 64	96 x 96	96 x 96

GE 3T – Hepatic MRE Protocols – November 2023				
	TE (ms)	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 (ms)	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
Driver Parameters (Generic) (note 5)	Driver Power (%)		50	50
	Driver frequency (Hz)	60	60	60

GE 3T – Hepatic MRE Protocols – November 2023				
	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 μm/(π radian) (note 3)	~30 μm/(π radian) (note 3)	~30 μm/(π radian) (note 3)
	Axis of MEG	4 (Z)	4 (Z)	4 (Z)
User CV or Advanced Table (Specific: epimre - HD16 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		0.5	
	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	
	CV15 -Recon (Def-1912;3D ver =1914;Brain=1915;2D MMDI = 1916)		1916	

GE 3T – Hepatic MRE Protocols – November 2023				
	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 (Specific fgremre-≥DV22.1) (note 5)	Temporal Phases	4		
	MEG Frequency (Hz)	80		
	Driver Amplitude (%) (note 6)	50		

GE 3T – Hepatic MRE Protocols – November 2023				
	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 is32lose32endded 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

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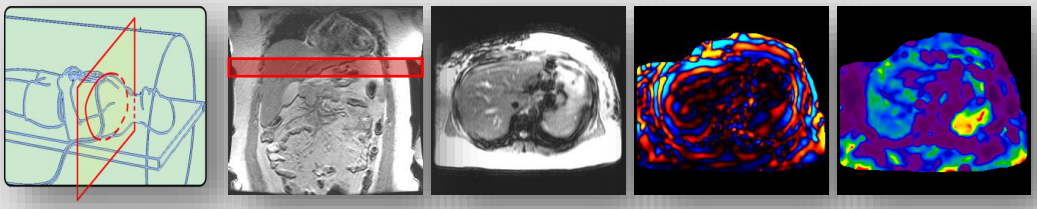
Siemens 1.5T and 3T – Hepatic MRE Protocols – November 2023			
Scanners and Sequences	Scanner	All 1.5T – MAGNETOM AvantoFIT, Aera, Sola All 3T	
	Software versions	N4 VE11C SP01 and above	N4 VE11E / NX XA20A and above
	Pulse sequence	**greMRE**	**ep2D_se_mre**
	Mode	2D	2D
Patient Cooperation	(1) Patients shall fast at least 4 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. (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.		
Slice Positioning	 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 or feet-first, supine	head-first or feet-first, supine
Coil (note 1)	Coil	Body & Spine matrix	Body & Spine matrix
Imaging Parameters	Imaging Plane	Axial	Axial
	No. of slices	4	4
	Slice thickness (mm)/dist. Factor	10 mm / 0% (0)	8 mm / 25% (2mm)
	FOV (mm) / Phase FOV (100%)	420/80% (note 4)	420/100% (note 4)
	Matrix (Base × Phase)	128 × 70% (64)	100 × 100% (128)
	TE (ms)	typ. 21ms (note 7)	typ. 47ms (note 7)

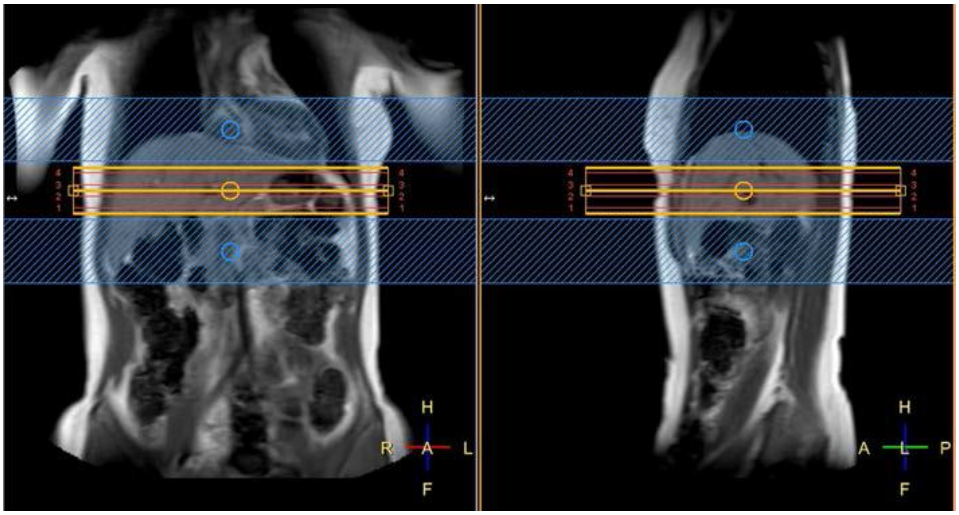
Siemens 1.5T and 3T – Hepatic MRE Protocols – November 2023			
	TR (ms)	50/25 (note 8)	1200
	Flip Angle (degree)	20/12 (note 8)	90 (default)
	NEX, EPI shots	1	1, 1shot (default)
	Bandwidth (Hz/Pixel)	399 Hz/pixel	2174 Hz/pixel
	Phase enc.dir.	Anterior-Posterior	Anterior-Posterior
	Acceleration	GRAPPA (note 1)	GRAPPA (note 1)
	Acceleration factor	2	2
	Ref lines PE / type	20 / integrated	32 / GRE / separate
	No. of breath holds	4 (each 19s/11s rapid) (notes 2,8)	1 (11 s)
	Shimming Volume	auto	auto
	Spectrum Peaks	Water Peak	Water Peak
	Saturation Band	Parallel H/F (note 9)	Parallel H/F (note 9)
	Fat Suppression		SPAIR
	Fat Sat. mode		Strong
	scan time	4 × 19 s/ 4 x 11 s rapid	11…13 s
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)

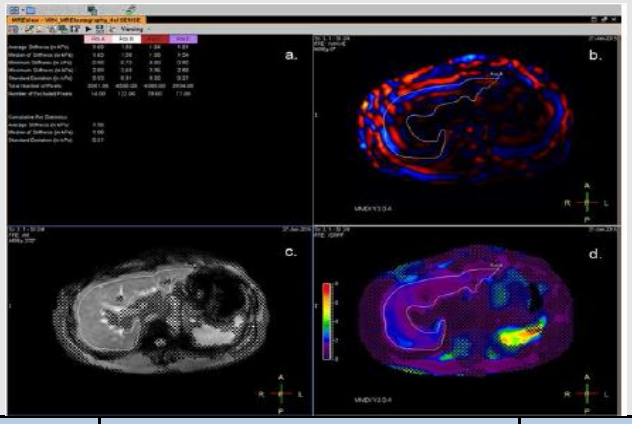
Siemens 1.5T and 3T – Hepatic MRE Protocols – November 2023

Motion Encoding Gradients (Generic) (note 5)	MEG fractional encoding	100% (note 7)	100% (note 7)
	MEG frequency (Hz)	60 Hz (hard coded)	60 Hz (hard coded)
	MEG Amplitude	depends on gradient mode (note 3)	depends on gradient mode (note 3)
	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	YES (note 9)	not available
	Resolution – Filter Image – Prescan Normalize	Check	Check

NOTE: (1) Use system body coil instead of Body matrix if patients cannot fit into the bore with the Body matrix; scan time is longer if parallel imaging is turned off (automatically). (2) For greMRE, scan time can vary depending on the phase FOV, matrix and #of iPAT ref lines - decreasing phase FOV can slightly decrease scan time and breath-hold time. (3) MEG amplitude depends on the gradient mode. Fast gradient mode is best in most situations but step down to normal if the subject is sensitive to gradient stimulation. 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 typically 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 (via separate Laptop); all sequences deliver one trigger every 50ms, so changes to active driver settings are not required. (7) fractional encoding is controlled by the TE parameter: TE values lower than the “gap” in the UI (shown in the image below) will use 65% fractional encoding (92Hz MEG frequency); this is recommended only for cases with signal loss, e.g., through liver iron overload.

(8) greMRE with TR 25 will go into “Rapid” mode, which allows shorter breath-holds. (9) Saturation pulses and flow compensation may not be possible depending on base sequence timing, e.g., in Rapid mode for greMRE.

Philips 1.5T and 3T – Hepatic MRE Protocols – November 2023			
Scanners and Sequences	Scanner	Achieva, Ambition, Ingenia, Elition	
	Software versions	MR R5.1.7 SP2 (or later)	
	Pulse sequence	**FFE MRE**	**SE-EPI MRE**
	Mode	2D	2D
Patient Cooperation	(1) Patients shall fast at least 4 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.		
Slice Positioning			

Philips 1.5T and 3T – Hepatic MRE Protocols – November 2023			
	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
Coil	Coil	Torso	Torso
Imaging Parameters	Imaging Plane	Transverse	Transverse
	No. of slices	4	4
	Slice thickness (mm)/gap	10 mm / 1 mm	10 mm / 1 mm “default”
	FOV (mm) / Phase FOV (mm)	450(required)x403(or less) (Note 2)	400(required)x400(or less) (Note 2)
	Matrix	300 × 86	100 x 100
	TE (ms)	20 (“shortest”)	58 “shortest”
	TR (ms)	50	1000
	Flip Angle (degree)	20 (for 1.5T), 30 (for 3.0T)	90
	NSA, EPI shots	1	1, 1shot
	Bandwidth (Hz/Pixel)	~288 Hz/pixel	~2000 Hz/pixel
	Freq Encoding Dir	right – left	right – left

Philips 1.5T and 3T – Hepatic MRE Protocols – November 2023			
	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 (~17 s breath holds) (note 1)	~13 s
Driver Parameters	Driver Power	Moderate (50%)	Low (25%) (note 4)
	Driver frequency (Hz)	60	60
Motion Encoding Gradients	MEG frequency (Hz) (or Period Mismatch)	60 Hz (note3)	60 Hz (note3) (note 4)
	Axis of MEG	FH	FH
Specific Parameters (To be specified)	Patient experience scan	“yes”	“yes”
	Flow compensation	No	No
	Fat suppression	No	“SPAIR” Suppression level: strong
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 the same as the driver frequency; in future versions, there will be a 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 version will have flexible MEG number, as well as fractional MEGs so the TE can be reduced, which is important for liver applications and 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%. (5) The patient experience scan will give an additional breath-hold, so the subject can experience the vibrations for a full breath hold before the data is acquired. Can turn this off if not the first MRE exam performed or to save time.			

Appendix E: Phantom Parameter Recommendations

GE 1.5T – Phantom 2DMRE Parameter Recommendations – November 2023				
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 Positing	Place one coronal slice at the center of the height of the phantom, with a fixed squared FOV (200 mm). 			
Information Input	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 × 64	64 × 64	256 × 64
	TE (msec)	in-phase TE (about 18.2) (note 7)	min full TE (note 1)	min full TE (type a value 39lose 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	

GE 1.5T – Phantom 2DMRE Parameter Recommendations – November 2023				
	Acceleration	ASSET (Note 1)	ASSET (Note 1)	ASSET (Note 1)
	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
	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)	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	

GE 1.5T – Phantom 2DMRE Parameter Recommendations – November 2023				
	CV17 -MEG Direction (F/P/S=1/2/4, Tetra=8)		4	
	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.

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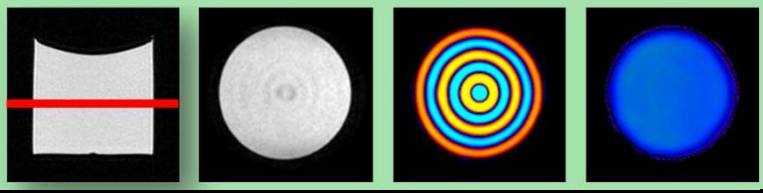
GE 3T – Phantom 2DMRE Parameter Recommendations – November 2023					
Scanners and Sequences	Scanner	HDx	HDx	MR750w	3T (MR750W)
	Software versions	DV16 and DV22.1 and 24	DV16 and DV22.1 and 24	DV22.1 and 24	DV22.1 and 24
	Pulse sequence	**fgremre (Resoundant-GE)**	**epimre (Resoundant-GE)**	**MR-Touch (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	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 Parameters	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 × 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 – November 2023					
	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, ½/3 = 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 = ½/4, 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 – November 2023					
	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)
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).					

Siemens 1.5T and 3T – Phantom 2DMRE Parameter Recommendations – November 2023			
Scanners and Sequences	Scanner	MAGNETOM (AvantoFit, Aera, Sola, Skyra, Prisma, Vida)	
	Software versions	N4 VE11C SP01 and above	N4 VE11E / NX XA20A and above
	Pulse sequence	**greMRE**	**ep2d semre**
	Mode	2D	2D
Phantom Setup	Place the 16-cm diameter cylinder phantom vertically in the spine matrix, place the liver driver (facing down) on the top of the phantom and secure them with the liver MRE elastic belt tightly. Strap the Body matrix coil over the phantom.		
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	Body & Spine Matrix	Body & Spine Matrix
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/100% (note 4)	200mm/100% (note 4)

	Matrix (Base × Phase)	128 x 100%	100 x 100%
	TE (ms)	21	47
	TR (ms)	50 / 25 rapid	1200
	Flip Angle (degree)	25 / 12 rapid	default (90)
	NEX, EPI shots	1	1, 1shot
	Bandwidth (Hz/Pixel)	399 Hz/pixel	2174 Hz/pixel
	Phase enc.dir.	Right-Left	Right-Left
	Acceleration	GRAPPA (note 1)	GRAPPA (note 1)
	Acceleration factor	2	2
	32 / GRE / separate	Ref lines PE / type	20 / integrated
	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	4 x 21s / 4 x 11s rapid	11 s

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	Controlled by gradient mode	Controlled by gradient mode
	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	Not available
	Resolution – Filter Image – Prescan Normalize	Check	Check
NOTE: (1) Place phantom on the spine matrix and strap body matrix over the top of the phantom. (2) For greMRE, scan time can vary depending on the phase FOV, matrix and #of iPAT ref lines - decreasing phase FOV can slightly decrease scan time; however, do not do this for the phantom. (3) MEG amplitude depends on the gradient mode. Fast gradient mode is best in most situations. 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 (via separate Laptop); Both greMRE and ep2d_se_mre sequences deliver one trigger every 50ms, so changes to active driver settings are not required between sequence types.			

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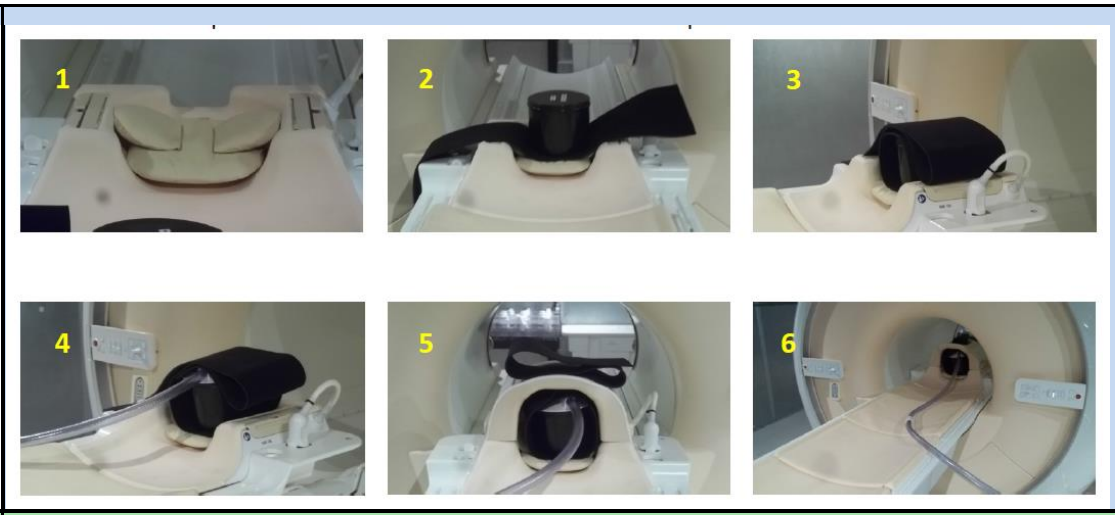
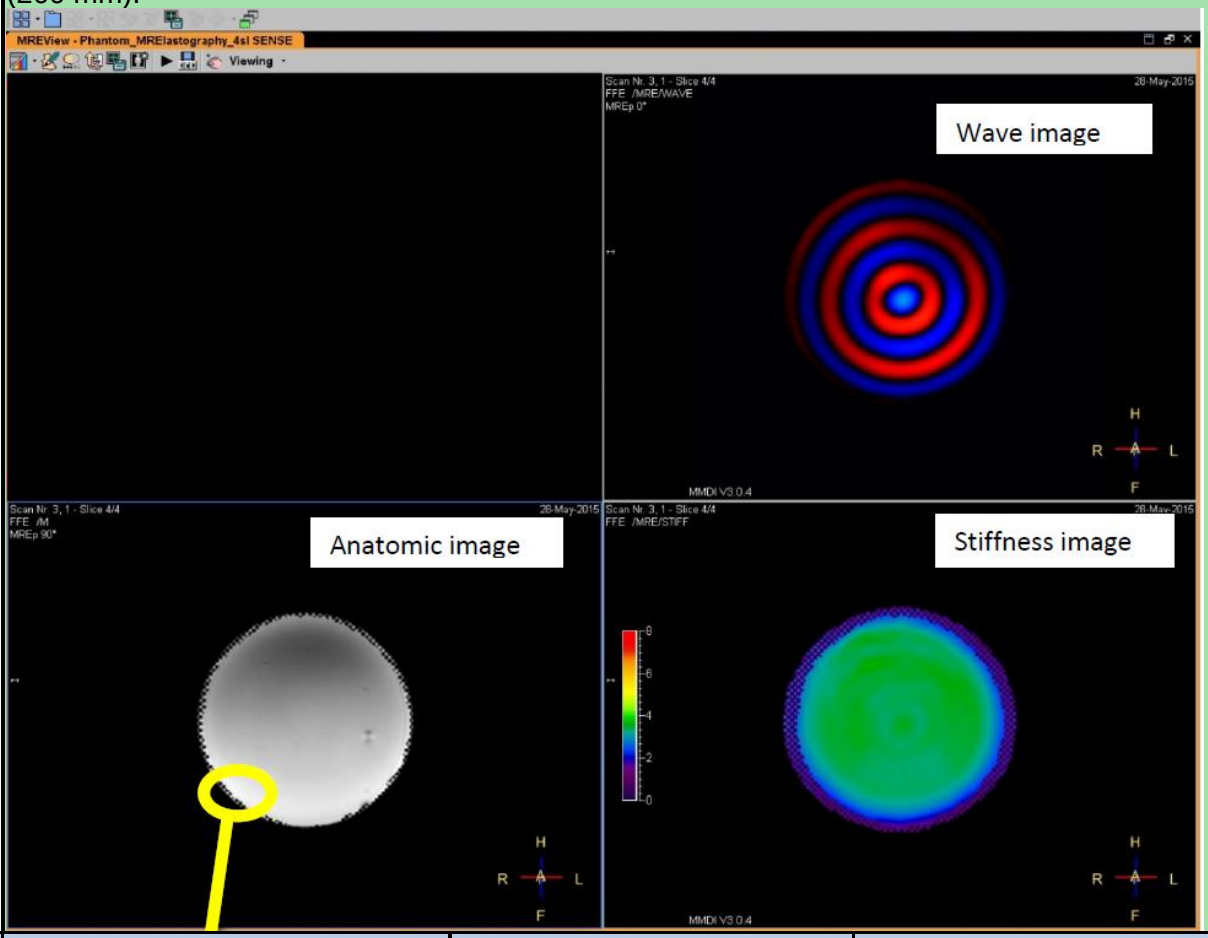
Philips 1.5T and 3T – Phantom 2DMRE Parameter Recommendations – November 2023			
Scanners and Sequences	Scanner	Achieva, Ambition, Ingenia	
	Software versions	MR R5.1.7 SP2 (or later)	
	Pulse sequence	**FFE MRE**	**2D SE-EPI MRE**
	Mode	2D	2D
Phantom Setup	Place the 16-cm diameter cylinder phantom vertically 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.		

			
Slice Positing	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
Coil (note 1)	Coil	Torso	Torso

Imaging Parameters	Imaging Plane	Coronal	Coronal
	No. of slices	4	4
	Slice thickness (mm)/gap	10 mm / 1 mm	10 mm / 1 mm
	FOV (mm) / Phase FOV (100%)	450 (required) x 403 (or less)	400 x 400 (or less)
	Matrix	300 x 86	100 x 100
	TE (ms)	20 “shortest”	58 “shortest”
	TR (ms)	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	None	None
	Acceleration factor	2	2
	No. of breath holds	4	1
	Shimming	Auto	Auto
	REST slabs	No	No
	scan time (s)	71	9
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)	Patient experience scan	“no”	“no”
NOTE: (1) Always use coil that supports 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, 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.			

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4.3 Assessment Procedure: Stiffness Measurement Stability

This procedure can be used by a vendor or an imaging site to assess MRE stiffness measurement stability. Stiffness measurement stability is assessed in terms of the Stiffness Measurement Difference between successive MRE QA phantom scans.

4.3.1 MRE QA PHANTOM

The MRE QA phantom is made of Polyvinyl Chloride (PVC) gel in a 12.5cm × 15.5cm cylinder container with a 0.15 cm wall thickness. It should be handled carefully when being transferred from one location to another to avoid dropping.

4.3.2 PHANTOM SETUP:

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

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

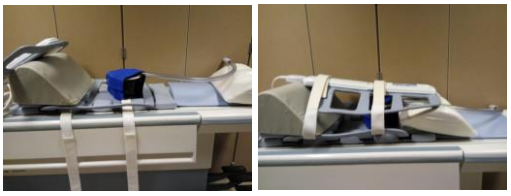

Figure 2. MRE QA Phantom Setup

4.3.3 PHANTOM IMAGING PARAMETERS

Patient MRE sequences are used for this procedure, 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 can be found in Appendix E).

4.3.4 REGION OF INTEREST (ROI) FOR MEASURING PHANTOM STIFFNESS

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.

Compute the mean and standard deviation of the pixel values in the ROI (in units of Pa or kPa).

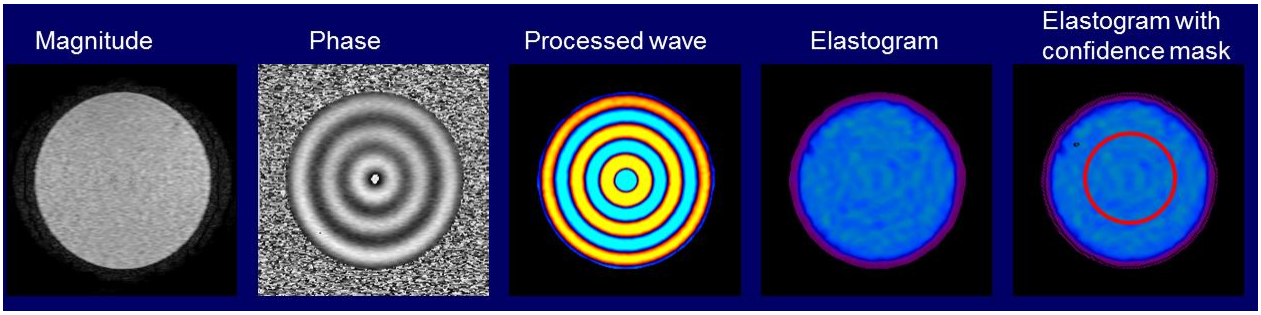

Figure 3. ROI for measuring phantom stiffness (mean ± sd, Pa or kPa)

4.3.5 QA RECORD

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

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

Table 1: MRE QA Record

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

Appendix F

QIBA Checklist:

Magnetic Resonance Elastography of the Liver

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.

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.

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.

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PHYSICIST CHECKLIST

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.

Parameter	*Specification*
Periodic QA (section 3.3)	
Installation	Shall perform installation and initial functional validation of the MRI Scanner and MRE driver system according to manufacturer-defined procedures and specifications.
Required QA	Shall assess and confirm the validity of the field of view and image linearity on an ongoing basis, using manufacturer-recommended procedures.
	Shall confirm correct driver frequency settings as outlined in Appendix D.
Installation	Shall perform installation and initial functional validation of the MRI Scanner and MRE driver system according to manufacturer-defined procedures and specifications.

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.*

Parameter	*Conforms?*	Specification
	Image QA (section 3.8)	
Image QA	□ *Yes* □ *No*	Shall check the suitability of the data 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).
	Image Analysis (section 3.10)	
Mean shear stiffness of the liver	□ *Yes* □ *No*	Shall reference the magnitude image to draw ROIs in the largest possible area of liver parenchyma, staying ~1 cm inside the liver boundary, avoiding the area directly underneath the passive driver, and excluding major blood vessels seen on the MRE magnitude images. (Figure 9)
	□ *Yes* □ *No*	Shall use the phase or wave images to avoid areas of 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) (Figure 9)
	□ *Yes* □ *No*	Shall place ROIs in individual slices and in the right lobe whenever possible. (Figure 9)
	□ *Yes* □ *No*	Shall exclude areas of low confidence, as seen by the checkerboard pattern in the masked elastogram images (Figure 9).
	□ *Yes* □ *No*	Shall calculate mean shear stiffness of the liver using manually specified regions of interest (ROIs) containing 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 [17,3,18].
		Shall reject the elastography if the acquisition failed due to hepatic iron overload, colonic interposition, or other cause of inadequate waves and the scan repeated. (Figure 5, 7)
	Image Interpretation (section 3.11)	
Liver Stiffness	□ *Yes* □ *No*	Shall report overall mean stiffness by calculating the mean stiffness value of each ROI and then reporting the mean value across all slices.

TECHNOLOGIST CHECKLIST

Parameter	**Conforms?**	*Specification*
	Subject Handling (section 3.5)	
Fasting state	□ *Yes* □ *No*	Shall confirm that the subject has fasted for at least 4 hours before the time of imaging [12,13].
MR Scanner and MRE device	□ *Yes* □ *No*	Shall confirm for follow up exams that the subject is scanned on the same MRI scanner and passive driver hardware as the baseline exam.
Subject positioning	□ *Yes* □ *No*	Shall scan the subject in supine position.
	□ *Yes* □ *No*	Shall place the passive driver over the right lower chest wall at the level of xiphisternum in midclavicular line (Figure 1). Can be placed in the right mid-axillary line if colon is present between the anterior body wall and the liver) [14,15].
	□ *Yes* □ *No*	Shall ensure the passive driver is held in firm contact with the body wall using an elastic band.
	□ *Yes* □ *No*	Shall ensure connection of the plastic tube between the passive & active driver, which is located outside the scan room.
	Image Data Acquisition (section 3.6)	
Image acquisition	□ *Yes* □ *No*	Shall acquire image data during suspended expiration in a natural end-expiratory position.
Slice selection	□ *Yes* □ *No*	Shall acquire coronal 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. (Figure 2)
Image Acquisition	□ *Yes* □ *No*	Shall use an EPI-MRE sequence at 3T, if available (GRE-MRE if not available).
Image acquisition	□ *Yes* □ *No*	Shall confirm that subjects are scanned with the same parameters and software during follow up exams as the baseline liver MRE.
Image Acquisition	□ *Yes* □ *No*	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.
Technical success	□ *Yes* □ *No*	Shall confirm the phase images (also known as wave images) demonstrate shear waves in the liver. (Figures 3-7)
		Shall review the post-processed elastograms (with or without confidence map, as available) to confirm technical success of the exam.
		Shall re-acquire the exam if possible if the above technical success criteria are not met.

Parameter	**Conforms?**	*Specification*
		Image Data Reconstruction (section 3.7)
Image Reconstruction	□ *Yes* □ *No*	Shall confirm that the following images have been generated: quantitative stiffness maps (grayscale or color with look up table), confidence maps, and unwrapped phase images. (Figure 8)
Parameter	*Conforms?*	Specification
		Subject Handling (section 3.5)
Fasting state	□ *Yes* □ *No*	Shall confirm that the subject has fasted for at least 4 hours before the time of imaging [12,13].
MR Scanner and MRE device	□ *Yes* □ *No*	Shall confirm for follow up exams that the subject is scanned on the same MRI scanner and passive driver hardware as the baseline exam.
Subject positioning	□ *Yes* □ *No*	Shall scan the subject in supine position.
	□ *Yes* □ *No*	Shall place the passive driver over the right lower chest wall at the level of xiphisternum in midclavicular line (Figure 1). Can be placed in the right mid-axillary line if colon is present between the anterior body wall and the liver) [14,15].
	□ *Yes* □ *No*	Shall ensure the passive driver is held in firm contact with the body wall using an elastic band.
	□ *Yes* □ *No*	Shall ensure connection of the plastic tube between the passive & active driver, which is located outside the scan room.
		Image Data Acquisition (section 3.6)
Image acquisition	□ *Yes* □ *No*	Shall acquire image data during suspended expiration in a natural end-expiratory position.
Slice selection	□ *Yes* □ *No*	Shall acquire coronal 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. (Figure 2)
Image Acquisition	□ *Yes* □ *No*	Shall use an EPI-MRE sequence at 3T, if available (GRE-MRE if not available).
Image acquisition	□ *Yes* □ *No*	Shall confirm that subjects are scanned with the same parameters and software during follow up exams as the baseline liver MRE.
Image Acquisition	□ *Yes* □ *No*	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.
Technical	□ *Yes*	Shall confirm the phase images (also known as wave images) demonstrate

Parameter	**Conforms?**	*Specification*
success	□ *No*	shear waves in the liver. (Figures 3-7)
		Shall review the post-processed elastograms (with or without confidence map, as available) to confirm technical success of the exam.
		Shall re-acquire the exam if possible if the above technical success criteria are not met.
Image Data Reconstruction (section 3.7)		
Image Reconstruction	□ *Yes* □ *No*	Shall confirm that the following images have been generated: quantitative stiffness maps, confidence maps, and unwrapped phase images. (Figure 8)

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