QUIC Chronic Liver Disease Implementation Roadmap Whitepaper

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Abstract

Quantitative imaging biomarkers (QIBs) are increasingly utilized for clinical decision making in patients with chronic liver disease (CLD), including for initial diagnosis, risk stratification, staging, monitoring, and treatment response assessment. However, several barriers have hindered the widespread clinical adoption and implementation of these QIBs, with key barriers including limited access to the appropriate hardware and software, need for personnel training, complex reimbursement, variability across vendors, and lack of standardization in image acquisition, analysis, quality control (QC), interpretation, and reporting. This Quantitative Imaging Committee (QUIC) whitepaper seeks to promote clinical adoption and use of QIBs for CLD across geographic regions and institutions with varying resources by providing a practical framework aimed at addressing these barriers. More specifically, this whitepaper focuses on commercially available techniques for non-invasive quantitative assessment of hepatic steatosis, iron content, and fibrosis by magnetic resonance imaging and/or ultrasound that are commonly used in clinical care. This document describes indications for use; provides guidance on technical requirements, personnel requirements, insurance pre-authorization and reimbursement, imaging order in electronic health records (EHRs), scheduling considerations, patient preparation; describes standardized image acquisition methods, analysis, QC, interpretation and reporting, longitudinal consistency; and issues guidance on QC and image transfer to EHR. Potential gaps and barriers, along with potential solutions, and future directions are briefly discussed. Standardized biomarker cutoffs, common causes of unreliable or non-diagnostic imaging exams, and reporting templates are provided in four annexures.

This whitepaper was developed by a multidisciplinary group of experts in the field, with input from patient advocates, industry representatives, and other key stakeholders, to ensure that the recommendations reflect diverse perspectives and address practical considerations for implementation across clinical settings. To support ongoing implementation and continuous improvement, an accompanying website will host a living, dynamic resource that complements this whitepaper along with annexures, acquisition protocols (vendor-specific exam cards), and post-processing software, enabling the dissemination of updated guidance, practical tools, and implementation resources as evidence, technologies, and clinical practices evolve.

Abbreviations

2D = two-dimensional
2D-SWE = two-dimensional shear-wave elastography
2D-TE = two-dimensional transient elastography
3D = three-dimensional
AC = attenuation coefficient
AI = artificial intelligence
ALD = alcohol use-associated liver disease
ALT = alanine aminotransferase
AP = anteroposterior
ARFI = acoustic radiation-force impulse
ASQ = acoustic structure quantification
AST = aspartate aminotransferase
BQP = Biomarker Qualification Program
BSC = backscatter coefficient
CAP = controlled attenuation parameter
CLD = chronic liver disease
CPT = Current Procedural Terminology
CSE = chemical-shift-encoded
CSE-MRI = chemical-shift-encoded MRI
CT = computed tomography
cT1 = iron-corrected T1
DICOM = Digital Imaging and Communications in Medicine
EHR = electronic health record
ELF = enhanced liver fibrosis
EPI = echo-planar imaging
F = fibrosis stage
FDA = U.S. Food and Drug Administration
FIB-4 = fibrosis-4 index
FOV = field of view
GBCA = gadolinium-based contrast agent
GRE = gradient-recalled echo
IFU = indication for use
IP/OP = in-phase/opposed-phase
IQR = interquartile range
IQR/median = interquartile range-to-median ratio
kPa = kilopascal
LIC = liver iron concentration
LS = liver stiffness [often referred to as liver stiffness measurement (LSM) in existing literature]
MASH = metabolic dysfunction-associated steatohepatitis
MASLD = metabolic dysfunction-associated steatotic liver disease
MetALD = metabolic dysfunction- and alcohol use-associated liver disease
METAVIR = Meta-analysis of Histological Data in Viral Hepatitis
MHz = megahertz
MR = magnetic resonance
MRCP = magnetic resonance cholangiopancreatography
MRE = magnetic resonance elastography
MRI = magnetic resonance imaging
MRS = magnetic resonance spectroscopy
NAFLD = nonalcoholic fatty liver disease
NASH CRN = Nonalcoholic Steatohepatitis Clinical Research Network
NPO = nil per os [nothing by mouth]
PACS = picture archiving and communication system

PDFF = proton density fat fraction
PEQUS = pulse-echo quantitative ultrasound
pSWE = point shear-wave elastography
QA = quality assurance
QC = quality control
QIB = quantitative imaging biomarker
QUIC = Quantitative Imaging Committee
R2 = transverse relaxation rate
R2* = apparent transverse relaxation rate
RC = repeatability coefficient
RDC = reproducibility coefficient
RIS = radiology information system
ROI = region of interest
S = steatosis grade
SE = spin echo
SE-EPI = spin-echo echo-planar imaging
SLD = steatotic liver disease
SNR = signal-to-noise ratio
SoS = speed of sound
SRU = Society of Radiologists in Ultrasound
SWE = shear-wave elastography
SWS = shear-wave speed
T2* = apparent transverse relaxation time
TE = echo time
TR = repetition time
TSI = tissue scatter distribution imaging
UDFF = ultrasound-derived fat fraction
US-FF = ultrasound-based fat fraction
VCTE = vibration-controlled transient elastography
VLFF = volumetric liver fat fraction

1. Introduction

This whitepaper presents an implementation roadmap for ultrasound- and magnetic resonance imaging-(MRI-) based quantitative imaging biomarkers (QIBs) of hepatic steatosis, iron content, and fibrosis for use in patients with known or suspected chronic liver disease (CLD). It is intended as a consensus-style reference guide and a structured framework for institutions of different sizes and resources to correctly acquire, analyze, perform quality control (QC), interpret, and report these QIBs for clinical care. The focus of this document is on QIBs that are commercially available and commonly used in clinical practice. The main document covers key concepts and general principles. The annexures provide more details, including technical operational parameters (e.g., vendor-specific acquisition parameters), checklists, common causes of unreliable or non-diagnostic exams, reporting templates, and modality- or vendor-specific biomarker cutoffs.

2. Stakeholders

Successful implementation of QIBs for CLD requires a multidisciplinary approach involving relevant stakeholders, including consideration of the following issues and factors:

- patients, their families, and their advocates who are the intended beneficiaries of improved CLD diagnosis, staging, and monitoring (and whose experience with insurance authorization, costs, scheduling, preparation, procedures, and results communication may affect their participation, benefit, and potential physical, financial, and psychological harms);
- referring providers with a range of liver care expertise (e.g., primary care practitioners, endocrinologists, bariatric surgeons, weight-management specialists, and hepatologists) who see patients at varying levels of risk for CLD, and rely on the accuracy and precision of the QIBs discussed here to diagnose, stage, monitor, make treatment decisions in, and assess treatment response in their patients;
- imaging personnel (schedulers, front desk staff, translators, imaging technologists, radiologists, trainees, medical physicists) who are key to adequate acquisition, QIB value determination, quality assessment and control, reporting of QIBs, and providing recommendations for further workup or referral, when appropriate;
- information technology personnel, who support, maintain, and ensure harmonization between picture archiving and communication systems (PACS), radiology information systems (RIS), and electronic health records (EHR), and who need to review, approve, and support cloud-based services for select patients;
- imaging device and software vendor partners, who provide hardware, software, cloud-based services in some cases, PACS integration, phantoms when applicable, implementation support, training, technical documentation, and service support for QIB acquisition, reconstruction, QA, QC, and interpretation;
- PACS, RIS, reporting, and EHR vendors, who provide infrastructure, interoperability, display, structured reporting, data capture, and technical support needed for QIB interpretation, reporting, longitudinal review, and downstream data use;
- payors and regulators who influence access and sustainability through coverage decisions and policy frameworks;
- researchers (academia and industry, including pharmaceutical company sponsors and device vendors) who contribute to evidence generation, validation, and implementation science that inform indications, cutoffs, and outcomes;
- regulators who approve imaging devices, including hardware and software for clinical use; and
- radiology, gastroenterology, hepatology, endocrinology, and other medical societies and organizations that develop and disseminate practice guidelines and guidance documents that include recommendations or suggestions on the use and interpretation of QIBs for CLD.

3. Specific diseases and conditions

This whitepaper addresses QIBs for assessing hepatic steatosis, iron content, and fibrosis for use in patients with known or suspected CLD due to any etiology, including (but not limited to) the entities listed below:

- steatotic liver disease (SLD), which has many subtypes, the most common being:
    - metabolic dysfunction-associated steatotic liver disease (MASLD) and its more advanced subtype metabolic dysfunction-associated steatohepatitis (MASH),
    - alcohol use-associated liver disease (ALD),
    - metabolic dysfunction- and alcohol use-associated liver disease (MetALD),
- chronic viral hepatitis (e.g., hepatitis B and C),
- autoimmune hepatitis,
- primary biliary cholangitis,
- primary sclerosing cholangitis,
- hereditary hemochromatosis and other conditions associated with iron overload, and
- congestive hepatopathy.

Hepatic steatosis is the accumulation of excess triglyceride droplets in hepatocytes and is a defining manifestation of SLD. Histologic steatosis grading is based on the percentage of hepatocytes containing visible lipid droplets and is usually reported as a 4-point ordinal score (S0, no steatosis; S1, mild steatosis; S2, moderate steatosis; S3, severe steatosis) (1,2). For simplicity and to inform clinical management, steatosis is often stratified into presence of steatosis or not (S ≥ 1, any steatosis).

Hepatic iron content refers to the amount of hepatic iron deposition and can be graded histologically (sometimes with separate grades for hepatocellular and reticuloendothelial iron) or quantified biochemically as liver iron concentration (LIC, mg Fe/g dry liver weight or μmol Fe/g dry liver weight) (3,4).

Hepatic fibrosis represents extracellular matrix deposition and architectural remodeling from chronic liver injury and is a marker of cumulative liver damage. Histology stages fibrosis as a 5- or 7-point ordinal score, depending on the system. In this whitepaper, we apply a 5-point score (F0, no fibrosis; F1, mild fibrosis; F2, moderate fibrosis; F3, severe or bridging fibrosis; F4, cirrhosis), as defined by the Meta-analysis of Histological Data in Viral Hepatitis (METAVIR) or the Nonalcoholic Steatohepatitis Clinical Research Network (NASH CRN) systems (1,5–7). For simplicity and to inform clinical management, fibrosis is often stratified into clinically relevant categories (F ≥ 1, any fibrosis; F ≥ 2, significant fibrosis; F ≥ 3, advanced fibrosis; F = 4, cirrhosis; and F = 2 or F = 3, non-cirrhotic significant fibrosis, a fibrosis range that indicates potential eligibility for MASH-directed pharmacologic therapy) (8,9). In addition to their use in patients with known or suspected CLD, QIBs of hepatic steatosis and fibrosis may be used in determining candidacy for living liver donation and hepatic resection for treatment of liver lesions. The same concepts and general principles apply as in assessing CLD, although interpretation cutoffs may require adjustment, as explained later. Other important histologic abnormalities may occur in CLDs (e.g., inflammation, hepatocellular injury, apoptosis, necrosis, and biliary stasis) but are beyond the scope of this whitepaper.

4. QIBs

This whitepaper addresses QIBs acquired in ultrasound or MRI exams. While computed tomography (CT)-based QIBs have been developed and some are available for clinical use, CT is rarely ordered for the sole purpose of assessing QIBs in the context of CLD, so inclusion of CT-based QIBs is currently beyond the scope of this whitepaper but may be expanded in the future with emerging applications of dual-energy CT and photon-counting CT.

There are ultrasound- and MRI-based methods and associated QIBs of both hepatic steatosis and fibrosis, and MRI-based methods and associated QIBs of hepatic iron accumulation. Ultrasound is insensitive to the presence of iron, as iron accumulates in tissue in the form of ferritin and hemosiderin deposits, which are typically much smaller than clinical ultrasound wavelengths and therefore do not scatter, attenuate, or otherwise affect the beam, and so there are no ultrasound-based QIBs of hepatic iron content.

Table 1 summarizes the main U.S. Food and Drug Administration (FDA)-cleared, non-invasive, ultrasound- and MRI-based methods and QIBs to quantify hepatic steatosis, fibrosis, and iron content. These QIBs are most reliable when acquired using standardized acquisition and post-processing frameworks, and when interpreted in conjunction with clinical context using non-imaging data such as liver chemistries, non-invasive fibrosis scores, and clinical risk factors (10).

Table 1. Main FDA-cleared liver imaging methods and their associated QIBs for assessing hepatic steatosis, fibrosis, and iron content

Modality	Target Disease Process	Method	QIB	Units	Comments
Ultrasound	Steatosis	PEQUS	US-FF	%	Vendor implementation and sequence/product names vary. Intended to correlate with PDFF.
			AC	dB/cm or dB/cm/MHz	Vendor implementation and sequence/product names vary.
	Fibrosis	pSWE 2D-SWE 3D-SWE	SWS LS	m/s (for SWS) kPa (for LS)	Can be reported as shear-wave speed (m/s) or Young's modulus (kPa). Often called 'elasticity' in published papers.
MRI	Steatosis	CSE-MRI	PDFF	%	PDFF is standardized when it is confounder-corrected; vendor sequence names and implementations vary.
	Fibrosis	MRE	LS	kPa	Reported as the magnitude of the complex shear modulus (kPa). Often called 'shear stiffness' in published papers.
	Iron content	CSE-MRI	R2* LIC	s^{-1}, mg of iron/g by dry weight	Can be quantified simultaneously with PDFF using multi-echo CSE-MRI; severe iron overload may require optimized echo spacing.

Abbreviations
2D = Two-dimensional
3D = Three-dimensional
AC = Attenuation coefficient
CSE = Chemical-shift-encoded
dB = decibels
FDA = (United States) Food and Drug Administration
kPa = kilopascals
LIC = Liver iron concentration
LS = Liver stiffness
MHz = megahertz
MRE = Magnetic resonance elastography
MRI = Magnetic resonance imaging
PDFF = Proton density fat fraction
PEQUS = Pulse-echo quantitative ultrasound
pSWE = Point shear-wave elastography
R2 = Apparent transverse relaxation rate*
QC = Quality control
QIB = Quantitative imaging biomarker
s^{-1} = per second, or inverse seconds
SWS = Shear-wave speed
US-FF = Ultrasound-based fat fraction

Ultrasound-based QIBs

Ultrasound-based QIBs of hepatic steatosis and fibrosis are available as vendor-supported modules and can be integrated into standard ultrasound exams.

Hepatic steatosis

Several ultrasound platforms offer pulse-echo quantitative ultrasound (PEQUS) methods to quantify acoustic properties such as attenuation coefficient (AC), backscatter coefficient (BSC), speed of sound (SoS), or proprietary combinations of these parameters. These parameters are affected by and therefore serve as QIBs of hepatic steatosis. As they are not direct measures of steatosis, empirical calibration is needed to interpret the biomarker values or convert them into steatosis grades. AC, the most used QIB, is a marker of energy loss of the ultrasound beam as it traverses tissue. It is depth and frequency dependent and so has units of dB/cm or dB/cm/MHz. Ultrasound vendors have now started to offer ultrasound-based fat fraction (US-FF) as a continuous QIB of hepatic steatosis. While details vary across vendors, US-FF is generally calculated using proprietary formulas combining different acoustic parameters such as AC and BSC and is intended to correlate with proton density fat fraction (PDFF; below) (11,12). Technical concepts are discussed in Sections 14 and 15; details are provided in **Annexure A**.

Hepatic fibrosis

Point shear-wave elastography (pSWE) and two-dimensional shear-wave elastography (2D-SWE) provide quantitative ultrasound-based QIBs of hepatic fibrosis (13,14). Briefly, these methods apply focused ultrasound energy in the form of an acoustic radiation-force impulse (ARFI) in the liver to create transient shear waves, and

then use ultrasound to track and quantify wave speed. 3D-SWE relies on an external vibration source to create steady-state waves. Under simplifying assumptions, shear-wave speed (SWS, units, m/s) is converted to Young's modulus (units, kPa), reflecting stiffness of a material subject to compression or tension. pSWE quantifies stiffness within a single, fixed region of interest (ROI) (~0.5 - 1 cm^3), whereas 2D-SWE assesses stiffness across a 2D field of interest (up to 20 cm^3) (15), and 3D-SWE assesses stiffness across a 3D field of interest (up to 100 cm^3) (16). The frequency of the shear wave induced by the ARFI or by external vibration sources depends on variable tissue response, which can affect the wave's speed and therefore the calculated stiffness. SWS and liver stiffness (LS; sometimes termed 'liver stiffness measurement (LSM)' in the literature) are associated with but not identical to histologic fibrosis, and empirical calibration is needed to convert the values of LS to fibrosis stage. Moreover, these QIBs can be influenced by factors other than fibrosis, including but not limited to liver inflammation, congestion, cholestasis, and fasting/postprandial state. Technical concepts are discussed in Sections 14 and 15; details are provided in **Annexure B**.

Hepatic iron content

There are no ultrasound-based QIBs of hepatic iron content.

MRI-based QIBs

MRI-based QIBs of hepatic steatosis, fibrosis, and iron content may be derived from vendor-supported methods, and can be performed as stand-alone focused exams or integrated into standard MRI exams (17).

Hepatic steatosis

Chemical-shift-encoded MRI (CSE-MRI) generates quantitative PDFF maps by separating water and fat signals while correcting for or minimizing confounders such as T1 bias, T2*/R2* decay, noise bias, eddy currents, and the multi-peak fat spectrum (18,19). When acquired and reconstructed with validated confounder-corrected methods, PDFF is a standardized and field-strength-independent QIB of hepatic steatosis (20). PDFF has been correlated with phantoms with known fat content, histologic steatosis grade (S0, S1, S2, S3) or category ($S \geq 1$, $S \geq 2$, $S = 3$), and magnetic resonance spectroscopy (MRS), and is widely regarded as the most accurate and precise imaging biomarker for liver fat quantification (20,21). MRI-PDFF quantifies hepatic fat; it does not independently establish a diagnosis of MASH; however, changes in PDFF may support treatment-response assessment in defined MASH settings when interpreted with the clinical context and applicable evidence (22). Changes in liver PDFF values over time should be interpreted in the appropriate clinical context and with knowledge of the repeatability and reproducibility of the QIB technique (23,24). Technical concepts are discussed in Sections 14 and 15; details are provided in **Annexure C**.

Hepatic fibrosis

Magnetic resonance elastography (MRE) offers a quantitative parametric map of LS by visualizing and analyzing the propagation of externally induced continuous shear waves (25). The maps display the magnitude of the complex shear modulus (units, kPa), reflecting tissue stiffness when subject to shearing. For simplicity, the magnitude of the complex shear modulus is often called the 'shear modulus' or 'shear stiffness'. Although the shear modulus (as derived from MRE exams) and Young's modulus (as derived from SWE exams) are both measures of stiffness, they are not the same; at the same frequency and under simplifying assumptions, the shear modulus is one third of the Young's modulus (26). MRE usually samples a larger portion of liver parenchyma than most ultrasound-based methods. MRE uses a controlled shear-wave frequency, typically 60 Hz for clinical liver 2D-MRE, reducing one source of variability (27–30). MRE has shown strong diagnostic performance for fibrosis staging in MASLD (13,14,31,32) and other CLD etiologies (33). MRE requires specialized hardware to generate the waves in addition to the appropriate acquisition and reconstruction software (25,29,30). As for SWE, LS values derived from MRE exams are related to but not identical to histologic fibrosis stage; they require empirical calibration to be converted to fibrosis stage and can be confounded by the aforementioned factors. Quantitative Medical Imaging Coalition guidelines define acquisition protocols, reconstruction requirements, image quality assurance (QA) procedures, and analysis methods necessary to achieve reproducible quantitative assessments of hepatic stiffness (27). Interpretation of longitudinal LS differences, including measurement variability and clinical significance, is discussed in **Annexure D**. Technical concepts are discussed in Sections 14 and 15; details are provided in **Annexure D.**

Iron content

MRI can estimate hepatic iron content because iron accelerates T2*-related signal decay, resulting in increased R2* on multi-echo gradient-echo sequences. R2* map values generated by CSE-MRI or other validated multi-echo methods can be converted to LIC values using field-strength-specific calibration equations (10). R2* MRI is increasingly being used clinically because it is fast, broadly available, and can be acquired simultaneously with PDFF, but severe iron overload requires adjusted echo spacing and technical validation (34). Technical concepts are discussed in Sections 14 and 15; details, including equations to convert R2* to LIC, are provided in **Annexure C.**

Other commercially available or emerging QIBs

Other quantitative methods may be clinically available, FDA-cleared for selected uses, or used in research, clinical trials, or disease-specific contexts. Because regulatory status, reimbursement, availability, and evidence strength vary by device, implementation, and jurisdiction, these methods are summarized here and may be addressed in future whitepaper versions or annexures as appropriate. Four of these are:

- MRI T1 mapping approaches, including iron-corrected T1 (cT1), an emerging biomarker of fibro-inflammatory activity (35,36) and Dixon-based water-only T1 mapping, which reduces fat-related confounding of T1 assessment (37);
- MRCP+, a proprietary quantitative post-processing approach for the biliary tree that is relevant for select cholestatic liver diseases (38);
- FerriScan® (R2), an FDA-cleared MRI spin-echo-based method for measuring R2 and LIC based on vendor-defined acquisition and centralized/proprietary analysis (39–41); the vendor currently offers FerriScan at 1.5 T and 3 T, subject to scanner and protocol qualification; and
- HepaFatScan®, an FDA-cleared, vendor-specific MRI method for measuring volumetric liver fat fraction (VLFF), validated against stereological measurements in liver biopsy sections (42), PDFF, and steatosis grade (43). Acquisition and analysis must follow the applicable vendor instructions.

Future QIB directions

Other potential QIBs that may be included in future versions of this whitepaper include:

- acoustic structure quantification (ASQ);
- tissue scatter distribution imaging (TSI);
- 3D-MRE with advanced analysis of the complex-valued shear modulus, including elastic and viscous properties;
- emerging low-field, portable MRI-PDFF implementations;
- AI/radiomics for assessing hepatic steatosis, fibrosis, and iron content;
- QIBs to assess inflammation or cellular injury; and
- CT biomarkers.

5. Other non-invasive tests

Non-imaging non-invasive tests are commonly used before, at, or after imaging QIBs in CLD care pathways. Blood-based scores such as the fibrosis-4 index (FIB-4) are inexpensive, widely available first-line tools for fibrosis risk stratification and are typically estimated as follows (age in years, ALT and AST in IU/L, and platelet count in 10^9/L):

$$\text{FIB4 index} = \frac{(\text{age} \times \text{AST})}{\text{platelet count} \times \sqrt{\text{ALT}}}$$

FIB-4 is age-dependent, unreliable in acute illness, and insufficiently specific for definitive staging (44–46). Secondary tests such as the enhanced liver fibrosis test (ELF) and vibration-controlled transient elastography (VCTE)-derived LS can further stratify fibrosis risk, while VCTE-derived controlled attenuation parameter (CAP)

provides a non-imaging ultrasound-based estimate of hepatic steatosis (13,47). Radiologists should be familiar with these tests because imaging QIBs are often ordered to adjudicate indeterminate, discordant, technically limited, or treatment-relevant non-invasive test results, and because interpretation of liver QIBs is strengthened by correlation with laboratory values, clinical risk factors, and prior or concurrent non-invasive test results.

6. FDA clearance status and regulatory considerations

The QIBs and associated post-processing software packages for quantitative analysis addressed in this whitepaper are available as FDA-cleared products from major imaging and software vendors and may be used for clinical care or as tools in clinical trials to support drug development and regulatory approval. The focus in this whitepaper is on their use for clinical care. More detailed information is summarized in the four annexures.

While the focus is on clinical care, radiologists should be aware that regulatory considerations become more stringent when a QIB is proposed as a component of a companion diagnostic or a regulatory endpoint in clinical drug trials. In those contexts, collaboration between imaging experts, trial sponsors, and regulators is necessary to ensure that QIB performance characteristics and analytical validation are adequately documented. None of the QIBs and software packages discussed in this whitepaper have completed qualification by the FDA through its Biomarker Qualification Program (BQP) for use in drug development, but that level of qualification is not required for clinical use, and some of the biomarkers discussed in this whitepaper have FDA BQP applications in progress.

7. Indications for use (IFUs)

In keeping with the broad Quantitative Imaging Committee (QUIC) effort to harmonize terminology across disease areas, this whitepaper assumes a common set of IFU categories in patients with CLD, including but not limited to the categories listed in **Table 2**. QIB modality selection requires balancing technical, clinical, and logistical considerations. Of note, general-population screening with the liver imaging QIBs discussed here is currently not recommended. Imaging QIBs may contribute to risk stratification and further assessment in selected at-risk patients within disease-specific care pathways. Their role in screening and case finding is evolving and should be distinguished from established diagnostic, staging, and monitoring indications. QIB interpretation should be linked to the intended IFU.

Ultrasound-based QIBs

Each vendor uses its own proprietary nomenclature for QIBs of hepatic steatosis, which can cause confusion, and its own algorithm for acquiring and processing PEQUS and SWE data, which can cause inter-vendor discordance for acquiring and interpreting QIBs of hepatic steatosis and fibrosis (13,48,49). Because PEQUS and SWE methods differ by vendor in acquisition, processing, nomenclature, quality metrics, and recommended cutoffs, values should not be assumed to be interchangeable across platforms. See **Annexures A** and **B** for vendor-specific cutoffs for hepatic steatosis and fibrosis. Societal guidelines provide useful interpretive frameworks for specific methods and clinical contexts, but serial follow-up is most reliable when performed on the same platform using the same protocol (13,49).

MRI-based QIBs

PDFF > 5% is commonly used as a cutoff for elevated (i.e., any) hepatic steatosis. A pragmatic radiology grading scheme uses < 6% as normal, 6% to < 17% as mild (grade 1), 17% to < 22% as moderate (grade 2), and ≥ 22% as severe steatosis (grade 3) (10,20). Published MRI-PDFF grading thresholds vary with reference standard and study population (50). Note should be made that MRI-PDFF percentages are not equivalent to the percentage of hepatocytes containing fat on histology. Other cutoffs (e.g., MRI-PDFF ≥ 8% as a clinical trial inclusion criterion) may be used in research or treatment contexts and should not be substituted for clinical severity grading without specifying the IFU.

LIC estimated from validated R2* should be reported in mg Fe/g dry liver weight or μmol Fe/g dry liver weight, with the method, calibration reference and field strength specified. When expressed in mg Fe/g dry liver

weight, a commonly used classification is normal < 1.8, borderline iron overload 1.8 to < 3.2, mild iron overload 3.2 to < 7.0, moderate iron overload 7.0 to < 15.0, and severe iron overload ≥ 15.0 mg Fe/g dry liver weight (10,51). Use cutoffs expressed in the same units as the reported LIC (10,51). As R2* cutoffs depend on field strength and calibration equation, we recommend that they be specified in the report, and reports should use cutoffs expressed in the same units as the reported LIC.

Table 2. QIB indications for use
(Screening is not listed as an established indication in this roadmap. Imaging QIBs may support risk stratification in selected at-risk patients; their role in screening and case finding continues to evolve.)

IFU category	Notes
Diagnosis	A QIB is used to diagnose or help diagnose a condition (e.g., SLD).
Grading and staging	A QIB is used to grade or stage a condition (e.g., severity of steatosis or iron accumulation, stage of fibrosis).
Risk stratification	A QIB is used to classify patients based on their risk of disease progression (e.g., to cirrhosis from a pre-cirrhotic stage) or future adverse events (e.g., development of portal hypertension, decompensation or liver cancer).
Prediction	A QIB is used to determine if the patient is likely or unlikely to respond favorably to a treatment under consideration, or to help decide which of multiple treatments is most likely to work.
Prognosis	A QIB is used to assess prognosis (e.g., probability of a future adverse event).
Disease monitoring	A QIB is repeated periodically to help track disease evolution in patients followed without intervention or managed with lifestyle recommendations (i.e., food intake, sleep, exercise). If the patient has had treatment, then it is considered treatment response assessment.
Treatment response assessment	A QIB is repeated before and a suitable time after treatment initiation to help determine if the patient has had a favorable treatment response.

Abbreviations
IFU = Indication for use
QIB = Quantitative imaging biomarker
SLD = Steatotic liver disease

Although MRI-based liver iron quantification can be performed at 1.5 T, 2.89 T, and 3.0 T, T2* values are shorter at the higher field strengths because susceptibility effects increase with field strength. Consequently, R2* values are approximately doubled at these higher field strengths compared with 1.5 T for the same LIC. As a result, field-strength-specific calibration equations are required (see **Annexure C**) (10). The shorter T2* values observed at 2.89 T and 3.0 T result in relatively more rapid signal decay in heavily iron-loaded livers, increasing the risk of signal loss, fitting instability, and reduced accuracy at very high iron concentrations. Consequently, 1.5 T has historically been regarded as the reference field strength for liver iron quantification and remains the most extensively validated platform, particularly in patients with moderate-to-severe iron overload.

MRE-derived LS values can support assessment of fibrosis stage or assignment of fibrosis-based risk categories when interpreted using an appropriate validated framework and clinical context. Clinically relevant categories include significant fibrosis, advanced fibrosis, cirrhosis, and non-cirrhotic significant fibrosis (8,9). LS cutoffs may vary by modality, vendor, acquisition method, disease etiology, and IFU; therefore, disease- and method-specific cutoffs should be provided and applied with clinical context. See **Annexure D** for details.

8. Technical requirements (hardware and software)

There are important technical requirements for acquiring QIBs correctly. These requirements are specific to each QIB, modality, and vendor. Lack of correct, current hardware or software; deviation from recommended acquisition instructions and parameters; and departure from standardized analysis methods can cause QIB variability and error. The four annexures describe detailed technical requirements for each QIB and vendor. Key concepts are briefly described below.

Implementation of CLD QIBs begins with a careful inventory of existing imaging hardware and software capabilities, as well as appropriate informatics, PACS, and reporting system infrastructure to store, display, and report parametric maps and derived QIB quantification values. Vendor-provided service and technical support are necessities. Local support from medical physicists or other experts is desirable when available.

For ultrasound, institutions should maintain a local inventory of scanners that support PEQUS for hepatic steatosis assessment, and pSWE, 2D-SWE or 3D-SWE for hepatic fibrosis assessment, including software version, licensing status, available quality metrics, and supported report/export workflows.

For MRI/MRE, institutions should maintain a local inventory of scanners that support CSE-MRI and MRE, including field strength, coil configuration, installed software version, available reconstruction outputs, driver hardware for MRE, and supported DICOM/PACS/reporting workflows.

Sites should develop both stand-alone quantitative liver protocols and integrated protocols that can be embedded within routine abdominal ultrasound or MRI exams. EHR orderables, protocol names as entered locally on the scanners, technologist instructions, post-processing workflows, and reporting templates should be aligned so that the requested QIB exams are reliably acquired and analyzed, and that the relevant data and images are transferred to PACS, reviewed by radiologists, stored, and reported. This alignment is especially important in multi-site practices, where mismatches between order names and scanner protocols can lead to missed QIB acquisitions or inconsistent longitudinal follow-up. Serial exams should preferably use the same modality, vendor, scanner/platform, acquisition protocol, and analysis method, whenever feasible.

9. Personnel requirements

Successful QIB acquisition relies on availability of trained personnel for image acquisition, post-processing, and interpretation. Sonographers performing quantitative ultrasound methods should receive focused exam acquisition training, either from vendors or through professional societies and expert-led workshops, emphasizing proper patient positioning, breath-hold or respiration guidance, probe placement, acquisition windows, and ROI placement (52). They should be familiar with device-specific quality metrics and know when testing is unreliable or needs to be repeated. Similarly, MRI technologists should be trained in acquisition of CSE and MRE exams, including appropriate fasting instructions, driver placement (for MRE), sequence selection, and real-time assessment of images (for PDFF and R2* maps for CSE; wave and magnitude images for MRE) to confirm technical adequacy before the patient leaves the scanner (17,28,51). Coaching must match the selected method. Staff should recognize protocol deviations and consult the analysis service before releasing or repeating a technically questionable study.

For interpretation and reporting, radiologists should be board-certified or equivalent and have demonstrable familiarity with quantitative liver imaging (10,17,53). Radiologists should understand advantages and disadvantages, technical limitations, artifacts, and expected output(s) for each method and its QIB(s); appreciate the evidence base for key cutoffs and the expected repeatability or reproducibility for each QIB in the clinical scenario, including the effects of vendor, protocol, operator, and patient preparation; be comfortable interpreting and integrating QIB results with other imaging modalities and clinical data; and appreciate how to recognize and manage failed acquisitions that may necessitate call-backs or referral to another modality. If automated analysis software is used, radiologists should be able to assess the quality and reliability of the automated results, and to override the results as appropriate. Institutions may choose to develop internal training modules or micro-credentialing for QIB interpretation to ensure consistent standards and support cross-coverage. All personnel should be familiar with local stand-alone and integrated QIB exam protocols, and interpreting radiologists should be able to advise referrers on appropriate protocol selection for individualized patient management.

10. Insurance pre-authorization and reimbursement

Pre-authorization and reimbursement requirements vary by modality, payor, IFU, and local contracting environment. Ultrasound exams that incorporate PEQUS or SWE may often be ordered within existing abdominal or right upper quadrant ultrasound workflows when clinically indicated, whereas MRI exams that include CSE-MRI, MRE, or liver iron quantification may more frequently require prior authorization. Efficient authorization depends on clear documentation of medical necessity, such as known or suspected CLD, abnormal liver chemistries or non-invasive tests, metabolic risk factors, suspected advanced fibrosis, iron overload risk, preoperative risk assessment, treatment eligibility assessment, or longitudinal monitoring.

Institutions should create standardized IFU language for order sets and prior-authorization workflows, adapted to local payor requirements. Where EHR capabilities permit, relevant clinical data such as diagnoses, laboratory abnormalities, and prior imaging findings may be incorporated into structured order fields or authorization templates. Detailed Current Procedural Terminology (CPT) and billing guidance should be verified locally.

11. Imaging order in EHR

Institutions should decide whether liver QIB exams will be ordered as stand-alone quantitative exams, embedded options within existing abdominal imaging orders, or both. Order names should use consistent, modality-neutral terminology for the QIB exam and requested output value, such as CSE-MRI hepatic PDFF, MRE LS, or CSE-MRI liver iron content quantification, while allowing local vendor sequence names to remain in scanner protocols. Structured order fields can map the requested QIBs to IFU categories such as diagnosis, staging, risk stratification, monitoring, treatment eligibility, or treatment response assessment.

Suggested standardized order examples (**Table 3**) should use consistent naming and downstream data capture; institutions may adapt these to local practice and EHR build.

Table 3. Imaging order checklists

Quantitative Liver Ultrasound (with drop-down menu in EHR order set) • ☐ PEQUS for hepatic steatosis quantification • ☐ SWE for hepatic fibrosis quantification
Ultrasound Abdomen + Quantitative Liver Ultrasound (with drop-down menu in EHR order set) • ☐ PEQUS for hepatic steatosis quantification • ☐ SWE for hepatic fibrosis quantification
Quantitative Liver MRI (with drop-down menu in EHR order set) • ☐ CSE-MRI PDFF for hepatic steatosis quantification • ☐ MRE for hepatic fibrosis quantification • ☐ CSE-MRI for liver iron content quantification
Abdomen MRI without contrast + Quantitative Liver MRI (with drop-down menu in EHR order set) • ☐ CSE-MRI PDFF for hepatic steatosis quantification • ☐ MRE for hepatic fibrosis quantification • ☐ CSE-MRI for liver iron content quantification
Abdomen MRI without and with contrast + Quantitative Liver MRI (with drop-down menu in EHR order set) • ☐ CSE-MRI PDFF for hepatic steatosis quantification • ☐ MRE for hepatic fibrosis quantification • ☐ CSE-MRI for liver iron content quantification
Abbreviations *CSE = Chemical-shift-encoded* *EHR = Electronic health record* *LIC = Liver iron concentration* *MRE = Magnetic resonance elastography* *MRI = Magnetic resonance imaging* *PDFF = Proton density fat fraction* *PEQUS = Pulse-echo quantitative ultrasound* *SWE = Shear-wave elastography*

12. Scheduling considerations / Patient preparation

QIB exams should be performed in outpatient settings, whenever possible. Exams in hospitalized or emergency-department patients should be postponed until their acute illness has stabilized or resolved, if possible. Scheduling outpatient QIB exams requires attention to modality-specific constraints, patient preparation, and coordination with clinic visits. For both ultrasound- and MRI-based QIBs, patients are typically asked to fast for ≥ 4 hours to minimize variability from postprandial hemodynamic changes and to reduce peristalsis-related motion artifact. Breath-hold capability and ability to follow instructions are important and may limit feasibility in certain patients (e.g., young children, older adults, frail patients, or patients with impaired hearing, cognition, or comprehension); schedulers should be aware of this and, when appropriate, flag cases where alternative (shortened) protocols or additional support may be needed. Finally, schedulers should assign patients to the same imaging location as was used in prior exams, if possible; if that is not possible or if the patient prefers a different location, a site with the same imaging technology (vendor, system, field strength for MRI) should be selected. Coordination with gastroenterology/hepatology, endocrinology, bariatric surgery, and primary care can improve patient adherence and reduce management delays.

Patients should receive clear instructions regarding fasting, medication management, and arrival time, with special attention to those with diabetes or other conditions in which fasting is more complex. For serial exams, patient instruction should be consistent across visits to reduce variance unrelated to patient factors. Patient preparation instructions should be available in concise, standardized documents (see annexures). For MRE, patients should be informed that they will feel vibrations from the passive driver, which in some patients may be uncomfortable.

Table 4. Summary of patient preparation methods for ultrasound- and MRI-based methods.

Modality	Method	Notes
Ultrasound	PEQUS	• NPO except sips of water for medications: 4 hours to reduce bowel gas and motion artifact • Breath hold: Patients should be able to hold breath for short end-expiration holds (2-5 s) • Coach breath-holding and other instructions before scanning
	SWE (pSWE, 2D-SWE, 3D-SWE)	
MRI	CSE-MRI	• NPO except sips of water for medications: 4 hours to reduce bowel gas and motion artifact • Metal screening: Per institutional MRI safety policy • Breath-hold: Patients should be able to hold breath for short end-expiration holds (12-22 s) • Clothing: Change into MRI-safe gown to avoid artifact from metallic fibers/buttons • Coach breath-holding and other instructions before scanning
	MRE	• Same as CSE-MRI plus explain that vibrations will be felt

Abbreviations
2D = Two-dimensional
CSE = Chemical-shift-encoded
MRE = Magnetic resonance elastography
MRI = Magnetic resonance imaging
NPO = nil per os (nothing by mouth)
PDFF = Proton density fat fraction
PEQUS = Pulse-echo quantitative ultrasound
pSWE = Point shear-wave elastography
SWE = Shear-wave elastography

13. QIB acquisition technique

QIB acquisition should follow standardized, modality-specific protocols that are consistent with vendor instructions, published technical recommendations, and local expert guidance.

For ultrasound-based QIBs, the sonographer or other operator should select an appropriate intercostal window and acquire the vendor-recommended number of valid observations from the right hepatic lobe under consistent breath-hold or quiet-respiration conditions. ROIs should avoid large vessels, bile ducts, focal lesions, the liver edge, rib shadowing, and reverberation artifacts. The device should provide the summary value and quality metrics required for that method. Acquisition requirements are detailed in **Annexures A** and **B**; analysis and QC are addressed in Section 14.

For MRI-based QIBs, technologists should ensure appropriate coil selection, breath-hold coaching, sequence selection, field-of-view and coverage, and, for MRE, correct active and passive driver setup. MRI methods should use validated acquisition parameters. For PDFF and R2* (multi-echo CSE-MRI), key parameters include repetition time, flip angle, echo number, echo spacing (which might be determined indirectly by choices for imaging matrix, field of view (FOV), and receive bandwidth), slice thickness, and liver coverage. For MRE, key parameters include repetition time, echo time, FOV, and slice prescription through the widest part of the liver. When R2* is used to estimate LIC, acquisition should be performed before contrast administration. For other QIB acquisitions, sites should follow the validated protocol and standardize contrast timing for serial follow-up, noting that gadolinium-based contrast agents may alter R2* (54). In patients with severe iron overload, R2* acquisition may require shorter first echo time, shorter echo spacing, or other signal-to-noise and bandwidth adjustments; such changes should be made only with vendor or local MRI physics support (34,40,55). Scanner-generated maps should not be assumed for every MRI QIB. Detailed service-specific checkpoints are provided in **Annexure C**.

14. QIB QC, QA, and analysis

In this whitepaper, QC refers to case-level assessment of acquisition adequacy, source images, parametric maps, ROI placement, artifacts, device-specific quality metrics, and reportability. Broader QA, including scanner maintenance, phantom testing, software validation, and personnel credentialing, follows institutional and professional standards and is largely beyond scope for this whitepaper; QA-relevant technical details are provided in the annexures only where directly relevant.

Before a QIB value is reported, operators and interpreting radiologists should confirm technical adequacy and review variability among valid acquisitions. PACS and post-processing tools should support image and map review, ROI documentation, and transfer of verified values to the report.

Ultrasound-based QIBs

For ultrasound-based QIBs, radiologists should review the acquired images, sonographer-placed ROIs, number of valid acquisitions, summary value, and device-specific reliability metrics. Confirm that the applicable vendor criteria are met. If acquisition is inadequate, obtain additional data when feasible or document a limited or non-diagnostic examination. See **Annexures A** and **B**.

MRI-based QIBs

Manual analysis is extensively detailed in **Annexures C** and **D**. Automated analysis methods for hepatic PDFF, R2*, and MRE LS are now available for clinical use. These methods can support liver segmentation, ROI selection, quality filtering, and summary values, according to the software's intended use and supported acquisition methods. For either approach, the interpreting radiologist should verify segmentation or ROI placement, exclusions, map integrity, units, and summary values. Technically inadequate or implausible results should prompt review, reanalysis or repeat acquisition when feasible, or a limited or non-diagnostic designation. See **Annexures C** and **D**.

15. QIB image and data transfer to EHR

QIB images and values should be stored in PACS and the EHR in a manner that preserves both image context and quantitative meaning. Source images, parametric maps, ROIs, and key derived QIB values should be archived with the exam when technically feasible. Reported QIB values should be captured as discrete structured report fields when local reporting systems support this functionality; where they do not, values should still be displayed clearly and consistently in the narrative report. From the clinician's perspective, key QIB values should be easy to find, interpret, and compare with prior exams. Where available, DICOM structured reports, structured reporting fields, or analytics tools can support longitudinal displays, registries, quality improvement, clinical decision support, and research. Because these capabilities are not universally available, this whitepaper frames structured transfer as an implementation goal rather than a prerequisite for QIB deployment.

16. Interpretation and reporting

Interpretation should distinguish the acquired QIB value from the clinical category inferred from that value. Reports should include the QIB name, value, units, QIB value determination/calculation approach, technical adequacy, and relevant quality metrics when available (17,51,53). When validated cutoffs exist, the impression may translate QIB values into clinically meaningful categories, such as elevated hepatic steatosis, LS category or fibrosis category, or liver iron content severity. Reports should acknowledge limitations when cutoffs are disease-, vendor-, field-strength-, or context-specific. Management-oriented recommendations, such as hepatology referral, additional testing with a different modality or a non-invasive test, treatment eligibility assessment, or surveillance planning, should be included only when supported by local clinical pathways and agreed-upon reporting standards.

For longitudinal imaging QIB exams, reports should compare current and prior values using the same QIB and, whenever possible, the same scanner, vendor implementation, acquisition protocol, and analysis method. Observed changes should be interpreted cautiously when acquisition platform, field strength, vendor software, patient preparation, or technical adequacy differs between exams. When repeatability and reproducibility data exist for a QIB's specific context of use, determination of whether a change is likely to exceed expected QIB measurement variability or not can be made; however, the clinical consequence of an observed QIB value change may still depend on disease context, treatment, and outcome data. Further research is needed to better define and understand the consequences of QIB value changes on health outcomes. Treatment assessment increasingly relies on QIBs. As pharmacotherapy options for MASLD/MASH expand, therapeutic eligibility often depends on demonstration of substantial steatosis and/or fibrosis, sometimes within defined staging cutoffs (56,57). QIBs can provide a quantitative basis for these assessments and supply a robust baseline for subsequent monitoring. They also can play an important role in the selection and stratification of patients in clinical trials, where standardized imaging endpoints are required. Reporting templates should use standardized fields for the above elements. Suggested QIB-specific reporting templates and cutoffs are provided in the annexures.

17. Gaps/barriers and potential solutions

Gaps/barriers

Despite the promise of QIBs for CLD, several gaps and barriers remain. Not all sites have uniform access to QIB-capable ultrasound and MRI hardware, and software licensing may be incomplete or fragmented. Staff training is heterogeneous, with some sonographers and MRI/MRE technologists highly experienced and others unfamiliar with protocols or quality metrics. ROI placement can be inconsistent between and within readers, contributing to QIB reporting variability and error. Radiologists differ in their comfort in interpreting quantitative liver imaging and integrating QIB results with other clinical information into reports. Moreover, referring clinicians may be unaware of the availability or utility of QIBs, leading to underutilization or inconsistent ordering patterns. Additionally, evidence gaps persist around certain cutoffs, especially for assessing longitudinal change, and regarding QIB behavior in specific subpopulations such as children, very elderly patients, or those with overlapping hepatic etiologies. Reimbursement remains inconsistent and, in some settings, fragile, making it challenging to justify investment in new equipment or intensive training.

A further barrier is that QIB values are not always interchangeable across vendors, software versions, acquisition implementations, or field strengths. This is particularly important for ultrasound-based QIBs, because acquisition, processing, display, and quality metrics differ across platforms (52). MRI-based QIBs generally show stronger cross-platform reproducibility than ultrasound-based QIBs, but vendor, software, sequence, field-strength, acquisition-parameter, and reconstruction dependencies still exist, especially for R2* and, in some settings, MRE (40,58–62). These dependencies can possibly complicate establishing universal cutoffs and longitudinal comparisons. Moreover, terminology, imaging output and appearance, and parametric map scaling can vary by vendor, potentially causing confusion and user error.

Potential solutions

Phased implementation with pilot sites can help develop and refine protocols, training packages, and templates before broader rollout. Formal training programs, potentially developed in collaboration with professional societies and vendors, can help standardize practice (23,58,61,63). Harmonized reporting templates and indication matrices, aligned across QUIC disease groups, can promote consistency and aid in data aggregation. Multi-stakeholder collaborations may address evidence gaps by pooling data to refine cutoffs, evaluate longitudinal change criteria, and explore the impact of QIB-guided care pathways on outcomes and resource use. Ongoing dialogue with payors, supported by data on clinical impact and cost-effectiveness, will be crucial for long-term sustainability. Ultrasound vendors are investing considerable effort to harmonize QIB methodology and reported values, reduce vendor-dependent variability, and develop vendor-agnostic cutoffs. Despite these efforts, vendor dependencies for ultrasound- and MRI-based QIBs and field-strength dependencies for MRI-based QIBs may be impossible to eliminate entirely. As a cautionary measure, patients who undergo serial exams should be scanned on the same system each time when possible.

18. Future directions

Ongoing technical and operational improvements may further strengthen CLD QIB implementation. Examples include improved quality and confidence maps, more robust free-breathing acquisitions for patients unable to perform adequate breath-holds, harmonized vendor outputs, automated routing and labeling of QIB images, structured data capture, and clinician-facing longitudinal displays that integrate imaging QIBs with laboratory values, medications, interventions, and clinical events.

Beyond technical tools, institutions may benefit from modeling frameworks that estimate financial and clinical impact of QIB implementation, considering reduced biopsy rates, changes in therapeutic utilization, and potential improvements in outcomes. Such tools could support local business case models and contribute to broader policy discussions.

Future research should define and validate practical strategies for integrating blood-based tests, VCTE-based quantitative biomarkers, ultrasound-based QIBs, and MRI- and MRE-based QIBs into coherent CLD care pathways. This includes sequential algorithms, such as low-cost, first-line, blood-based risk stratification followed

by ultrasound or MRI/MRE QIBs for patients with indeterminate, discordant, technically limited, high-risk, or treatment-relevant results. It also includes composite biomarkers that combine imaging, laboratory, demographic, and clinical variables to improve diagnostic accuracy, prognostic value, treatment selection, and monitoring. These approaches require multicenter validation in geographically and biologically diverse populations across disease etiologies, vendors, field strengths, and real-world workflows, with attention to cost, access, patient burden, health equity, and outcome impact.

Finally, while QIBs are used in clinical care and clinical trials to monitor disease severity over time and assess treatment response after intervention, the appropriate application of QIBs for these IFUs is not well understood. Research is needed to inform the interpretation of longitudinal change in measured QIB values, to assess whether such changes represent true change or merely reflect measurement variability, and to determine whether changes, even if true, are clinically meaningful.

19. Annexures

List of Annexures:

- Annexure A - Ultrasound Hepatic Steatosis Assessment / PEQUS
- Annexure B - Ultrasound Elastography
- Annexure C - MRI-PDFF and R2* Quantification
- Annexure D - Two-dimensional MR Elastography

The annexures cover the following aspects of each QIB:

- Image acquisition: equipment and hardware, patient preparation and setup, acquisition protocol, and motion mitigation techniques
- Image reconstruction: technique, motion or artifact mitigation, and acquisition failure modes
- Image analysis: ROI placement and basic QC
- Interpretation
- Reporting template
- QIB availability
- Recommended QIB cutoffs

20. References

See end of document

21. Version history

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Annexure A: Ultrasound Hepatic Steatosis Assessment / PEQUS

Scope and purpose

This annexure provides a high-level summary of technical and reporting guidance for ultrasound-based hepatic steatosis quantification using PEQUS methods. PEQUS methods estimate acoustic properties that are associated with hepatic steatosis; they do not directly quantify hepatic steatosis. Vendor-specific implementations may report AC, US-FF, SoS, BSC, and backscatter-derived parameters or multiparametric combinations of these QIBs. More detailed summaries of these methods are available in the following review papers:

- Pulse-Echo Quantitative US Biomarkers for Liver Steatosis: Toward Technical Standardization (64)
- Assessment of Hepatic Steatosis in Nonalcoholic Fatty Liver Disease by Using Quantitative US (65)
- Quantitative Ultrasound and Ultrasound-Based Elastography for Chronic Liver Disease: Practical Guidance, From the AJR Special Series on Quantitative Imaging (49)

How the method works

PEQUS quantifies hepatic steatosis based on quantified acoustic properties derived from ultrasound pulse-echo data. AC reflects the rate of ultrasound energy loss, which increases with depth and with the ultrasound probe operating frequency. Backscatter-related QIBs and SoS both provide additional information about tissue composition. Some vendors combine multiple acoustic parameters to generate a US-FF value intended to correlate with PDFF. Because acquisition, processing, nomenclature, quality metrics, and cutoffs vary by vendor, PEQUS results should be acquired and interpreted according to device-specific instructions and published validation data.

Strengths of PEQUS:

PEQUS provides non-invasive quantitative assessment of acoustic properties associated with hepatic steatosis without ionizing radiation. On appropriately equipped ultrasound systems, it can be incorporated into a routine liver examination and performed alongside B-mode imaging and SWE. Real-time visualization allows the operator to select liver parenchyma and avoid vessels, lesions, and artifacts (64).

Limitations of PEQUS:

PEQUS values depend on the acoustic parameter, vendor implementation, transducer, acquisition depth, and analysis method; hence results and cutoffs should not be assumed to be interchangeable across systems. Reliability may be reduced by obesity, a limited acoustic window, rib or lung shadowing, bowel gas, motion, and suboptimal ROI placement. PEQUS assesses acoustic properties associated with fat rather than histologic steatosis directly, and other tissue properties may influence the result. Validation studies differ in reference standard and population, and universally applicable grading and longitudinal-response thresholds have not been established. Technical quality and the applicability of the chosen interpretive framework should therefore be assessed for each examination.

Equipment and software

Sites should maintain a local inventory of ultrasound systems that support PEQUS QIBs for hepatic steatosis quantification, including location within site, vendor, platform, transducer, software version, available QIBs, quality metrics, and reporting/export capability. Sites should verify vendor software versions when published cutoffs or quality metrics are applied. Commercially available PEQUS systems are listed in **Table A1**, including vendor-specific QC measures and recommended numbers of measurements per exam.

System specifics:

- Each system should be configured with a protocol that specifies transducer selection, patient position, ROI depth, acquisition window, number of acquisitions, quality criteria, and reporting units.

Patient preparation and setup

Patients should fast according to local protocols, commonly ≥ 4 hours when feasible, to reduce bowel gas and physiologic variability. The patient is typically positioned supine or in slight left lateral decubitus position with the right arm elevated to widen the intercostal spaces. QIB values should be acquired from the right hepatic lobe through an intercostal approach, avoiding large vessels, bile ducts, focal lesions, liver edge, rib shadowing, reverberation artifact, and regions of poor B-mode visualization.

PEQUS exam acquisition protocol

The operator should optimize ROI placement within liver parenchyma on the acquired B-mode images according to vendor recommendations. ROIs should be placed on images acquired during consistent relaxed expiratory breath-hold or quiet-respiration conditions, as recommended by the device vendor. The final reported QIB value should be based on the vendor-recommended number of valid acquisitions, typically a median or mean value across repeated acquisitions.

Protocol specifics:

- For AC, a commonly used approach is to place the upper edge of the ROI approximately 2 cm below the liver capsule, and to use an ROI length of approximately 3 cm (when supported by the device).

Common causes of limited or non-diagnostic PEQUS exams

Motion, poor breath-holding, suboptimal acoustic window, rib or lung shadowing, bowel gas, deep ROI location, and poor B-mode image quality can degrade PEQUS reliability. When quality criteria are not met, the operator should repeat acquisitions after breath-hold coaching, adjust the intercostal window, or document that the exam is limited or non-diagnostic. Serial follow-up is most reliable when performed using the same vendor platform, transducer, acquisition protocol, and quality criteria.

PEQUS image analysis and QC

Analysis QC should confirm that the measurement box or ROIs were placed in appropriate hepatic parenchyma and that device-specific quality criteria were satisfied. Reports should include the number of valid acquisitions, the reported value and units, and the applicable quality metric, such as IQR/median or vendor confidence/reliability indices. If a vendor specifies an IQR/median cutoff, the report should state whether the acquired QIB value met that cutoff. For example, an IQR/median > 30% for AC may suggest reduced reliability for some vendor implementations, whereas IQR/median $\leq$ 30% may support reportability. The exact cutoff should follow vendor-specific guidance and supporting literature. It is advisable to use device-provided IQR/median values since applying one of the many highly variable IQR/median calculation techniques can introduce reporting bias (66).

Interpretation

Single exam: Interpret the measured value in the context of the provided cutoffs, which evaluate for (a) presence or absence of any hepatic steatosis (**Table A2**) and (b) the grade of hepatic steatosis (mild [**Table A3**], moderate [**Table A4**], or severe [**Table A5**]). Cutoffs may be vendor specific or agnostic. Users should apply vendor-specific cutoffs if available and vendor-agnostic cutoffs otherwise.

Follow-up exam: In addition to reporting the value(s) for the current exam, report value(s) from prior exam(s) when applicable and whether the change, if any, is within or beyond measurement variability.

Serial follow-up measurements are most reliably interpreted when performed under consistent technical conditions, including the same vendor, system, acquisition protocol, software, operator, analysis method, and quality assurance criteria. Under these standardized conditions, the different-day reproducibility coefficient (RDC), where available, provides the most appropriate reference for assessing longitudinal changes. In general, differences less than the RDC may be due to measurement variability and should not be interpreted as true change. Differences greater than the RDC may or may not represent true change; radiologists should use their judgment. If the RDC is unavailable, the same-day repeatability coefficient (RC) may be used with caution, recognizing that it does not account for day-to-day variability and represents an optimistic, best-case scenario. When technical or methodological conditions differ between examinations, greater caution is warranted, and an RDC that accounts for the relevant sources of variability should be used, if available.

A separate issue is whether a change, even if true, is clinically meaningful, as the threshold defining clinically meaningful change is unknown. Estimating the RDCs that account for the most common sources of variability in clinical practice and identifying the thresholds for defining clinically meaningful change are current knowledge gaps and important future directions.

Reporting template

Below is a suggested template for reporting PEQUS values.

- Technique:
  - PEQUS was performed using [vendor/platform/transducer and method] through a right intercostal

approach.
    - Acquisitions were obtained in accordance with vendor instructions, avoiding vessels, bile ducts, liver edge, focal lesions, and artifacts.
- Findings:
    - [Mean/Median][QIB name]: […] [units], from […] valid acquisitions
    - Quality metric: [metric name] [meets/does not meet] device-specific criteria.
    - Technical adequacy: [adequate/limited/non-diagnostic] [specific limitation, if present].
- Comparison:
    - [No prior comparable examination / Compared with examination dated ___].
    - Prior [QIB value and units]
    - [Optional: absolute difference: […] [units].]
    - [Optional: relative difference: […]%.]
    - [Relevant differences in method or preparation.]
- Impression:
    - [QIB] value is [not suggestive of/consistent with/indeterminate for] hepatic steatosis [reference table].
    - [Optional: [QIB] value supports steatosis grade (S1, S2, S3) [reference table].]
    - [[QIB] value is discordant with conventional imaging findings. [Comment]]
    - [[QIB] could not be reliably quantified because [reason]. No steatosis grade is assigned.]
    - [Compared to prior: [[QIB] has increased/decreased/stayed about the same (change if any is within expected measurement variability)][Change in QIB cannot be evaluated. [Comment]]
    - [Recommendations: ___]

The radiologist should report if QIB values are discordant with conventional imaging findings, if and why QIB values could not be quantified, and suggest additional workup considerations to resolve these issues. Cases requiring technical review should be routed to the designated modality or software lead. Recurrent issues should inform protocol updates, training, and vendor feedback. Corrected results must be identifiable as amendments in downstream systems.

Table A1. Commercially available PEQUS systems and vendor-specific QC measures and recommended numbers of measurements (N1)

1 Method (generic)	2 QIB name (generic)	3 QIB name (proprietary)	4 Vendor	5 System name	6 Required software	7 QC measures, recommended numbers of measurements	8 Vendor website	9 FDA 510(k) clearance "K-number"	10 References
PEQUS	AC	Pending	Canon	Pending	Pending	Pending	Pending	Pending	Pending
		TBA	E-Scopics	TBA	TBA	TBA	TBA	TBA	TBA
		UGAP	GE Healthcare	LOGIQ E10 LOGIQ E10s LOGIQ Fortis LOGIQ Totus	UGAP	Quality map, IQR/Median, 10 measurements recommended	W1	K200158	R1
		TBA	Fujifilm	TBA	TBA	TBA	TBA	TBA	TBA
		USAT	Mindray (N2)	Resona A20 Resona R9 Resona I9	USAT	M-STB Index; RLB Map, RLB Index, CI	Pending	Pending	R2
		LiSA		Hepatus Resona 6	LiSA	M-STB Index; QC Assistant	Pending	Pending	R3
		Atten	Philips	EPIQ Affiniti Alturion	LFQ	Confidence Map	W2	K212704	R4
		TAI	Samsung	R20 V8	QUS	R^2 value, 5 measurements recommended	W3	K252018 (R20) K243702 (V8)	R5
		UDFF	Siemens	Pending	Pending	Pending	Pending	Pending	Pending
		ACE	Sonic Incytes	Velacur Velacur ONE	All	IQR/Median, Quality measure, at least 5 volumes collected	W4	K251728	R6
		TBA	Supersonic	TBA	TBA	TBA	TBA	TBA	TBA
		TBA	Toshiba	TBA	TBA	TBA	TBA	TBA	TBA
		Pending	United Imaging	Pending	Pending	Pending	Pending	TBA	Pending
	SoS	TSSI	Mindray	Resona A20	TSSI	M-STB Index, CI	TBA	TBA	R2
		TBA	Supersonic	TBA	TBA	TBA	TBA	TBA	TBA
	Nakagami	TSI	Samsung	R20 V8	QUS	Not applicable	W3	K252018 (R20) K243702 (V8)	R5
Multiparametric ultrasound	US-FF	Real-Time Multi-Parametric Ultrasound Imaging and Analysis Tool, M-Ref.Live	Mindray	Resona A20 Resona R9 Resona I9	M-Ref.Live	M-STB index; RLB MAP, RLB index, CI	TBA	TBA	R2
		USFF	Samsung	R20 V8	QUS	R^2 value, 5 measurements recommended	W3	K252018 (R20) K243702 (V8)	R7
		VDFF	Sonic Incytes	Velacur Velacur ONE	All	IQR/Median, Quality Measure, at least 5 volumes collected	W4	K233977	R8
		UGFF	GE Healthcare	LOGIQ E10 LOGIQ E10s LOGIQ Fortis LOGIQ Totus	UGFF	Quality map, IQR/Median, 5 measurements recommended	W1	K251985	R9

Notes

N1 - Our intent is that data presented here match that available on vendor websites. If any discrepancies are noted, please let us know.

N2 - Reference phantom used for device calibration

References

R1 - Imajo et al (2022) (PMID: 34768008)

R2 - https://www.mindray.com/en/products/ultrasound/general-imaging/resona-a20

R3 - https://www.mindray.com/en/products/ultrasound/liver-care/hepatus-series

R4 - https://www.usa.philips.com/healthcare/white-paper/liver-fat-quantification-white-paper

R5 - Jeon et al (2023) (PMID: 36594835)

R6 - Loomba et al (2024) (PMID: 38517204)

R7 - Jeon et al (2023) (PMID: 37709827)

R8 - Honarvar et al (2024) (PMID: 40416420)

R9 - Kuroda et al (2023) (PMID: 37787670)

Websites

W1 - https://logiqportal.net/clinical-specialty/liver/care-pathway

W2 - https://www.usa.philips.com/healthcare/procedure/liver-ultrasound

W3 - Pending

W4 - Sonicincytes.com

Abbreviations

AC = Attenuation coefficient

ACE = Attenuation coefficient estimate

CI = Confidence Interval

PEQUS = Pulse-echo quantitative ultrasound

LFQ = Liver fat quantification

LiSA = Liver ultrasound attenuation

M-STB = Motion stability

QC = Quality control

QUS = Quantitative ultrasound

RLB = Reliability

SoS = Speed of sound

TAI = Tissue attenuation imaging

TSI = Tissue scatter distribution imaging

TSSI = Tissue sound index

UDFF = Ultrasound-derived fat fraction

UGAP = Ultrasound-guided attenuation parameter

UGFF = Ultrasound-guided fat fraction

USAT = Ultrasound attenuation analysis

US-FF = Ultrasound-based fat fraction

VDFF = Velacur-determined fat fraction

Table A2. Diagnosis of any (S ≥ 1) steatosis (i.e., S1-S2-S3 vs. S0) (N1)

1 Method (generic)	**2 QIB** (generic)	**3 QIB** (proprietary)	**4 Vendor**	**5 Reference standard** (histology, MRI, MRS)	**6 AUROC**	**7 Vendor QIB cutoff** (with units)	**8 Sensitivity**	**9 Specificity**	**10 Classification criteria for selecting cutoff** (e.g., Youden, etc.)	**11 Population in which cutoff was derived and assessed**	**12 References**
PEQUS	AC	Pending	Canon	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
		TBA	E-Scopics	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
		UGAP	GE Healthcare	MRI	0.901	0.65 dB/cm/MHz	86.7%	82.0%	Youden	1010 patients with chronic liver disease	R1
		TBA	Fujifilm	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
		USAT	Mindray (N2)	histology	0.94	0.56 dB/cm/MHz	84.6%	97.1%	Pending	Healthy volunteers (N3)	R2
				MRI	Pending	0.57 dB/cm/MHz	Pending	Pending	Pending	Healthy volunteers (N3)	R2
		LiSA		histology	Pending	275 dB/m	Pending	Pending	Pending	Meta-analysis of 19 publications (N4)	R3
		Atten	Philips	MRI	0.922	0.63 dB/cm/MHz	94.4%	80.0%	Youden	Healthy/MASLD	R4
		TAI	Samsung	MRI	0.917	0.72 dB/cm/MHz	82.5%	91.5%	Youden	173	R5
		UDFF	Siemens	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
		ACE	Sonic Incytes	MRI	0.84	234 dB/m (5.2% PDFF)	90%	88%	Youden	133 study participants, MASLD/MASH	R6
		TBA	Supersonic	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
		TBA	Toshiba	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
		Pending	United Imaging	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	SoS	TSSI	Mindray	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
		TBA	Supersonic	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	Nakagami	TSI	Samsung	MRI	0.905	95.6	83.3	80.9	Youden	173	R5
Multiparametric ultrasound	US-FF	Real-Time Multi-Parametric Ultrasound Imaging and Analysis Tool, M-Ref.Live	Mindray	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
		USFF	Samsung	MRI	0.943	8.7%	81%	95.7%	Youden	173	R7
		VDFF	Sonic Incytes	MRI	0.99	5.2%	100%	41%	Youden	38 study participants, MASLD/MASH	R8
		UGFF	GE Healthcare	MRI	0.86	5.3%	89%	90%	Youden	582 patients with chronic liver disease	R9

Notes

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N2 - Reference phantom used for device calibration

N3 - A prospective, single-center cohort of adult living donor liver transplantation candidates (Inonu University, Türkiye, April-August 2024). All donors were healthy volunteers without liver or systemic disease and without alcohol consumption. Liver biopsy, performed within 1 week of imaging in definitive donors, served as the reference standard.

N4 - Data from 19/21 eligible papers were provided, comprising 3830/3968 (97%) of patients. Considering data overlap and exclusion criteria, 2735 patients were included in the final analysis (37% hepatitis B, 36% hepatitis C, 20% NAFLD/NASH, 7% other). Steatosis distribution was 51%/27%/16%/6% for S0/S1/S2/S3.

N5 - Central value corresponding to histologic steatosis grade

References

R1 - Imajo et al (2022) (PMID: 34768008)
R2 - Dag et al (2025) (PMID: 40231394)
R3 - Sterling et al (2025) (PMID: 38489518)
R4 - Ferraioli et al (2025) (PMID: 40237427)
R5 - Jeon et al (2023) (PMID: 36594835)
R6 - Loomba et al (2024) (PMID: 38517204)
R7 - Jeon et al (2023) (PMID: 37709827)
R8 - Honarvar et al (2024) (PMID: 40416420)
R9 - Kuroda et al (2023) (PMID: 37787670)

Abbreviations

AC = Attenuation coefficient
ACE = Attenuation coefficient estimate
LiSA = Liver ultrasound attenuation
MRI = Magnetic resonance imaging
MRS = Magnetic resonance spectroscopy
PDFF = Proton density fat fraction
PEQUS = Pulse-echo quantitative ultrasound
QIB = Quantitative imaging biomarker
TAI = Tissue attenuation imaging
TSI = Tissue scatter distribution imaging
UDFF = Ultrasound-derived fat fraction
UGAP = Ultrasound-guided attenuation parameter
UGFF = Ultrasound-guided fat fraction
USAT = Ultrasound attenuation analysis
US-FF = Ultrasound-based fat fraction
VDFF = Velacur-determined fat fraction

Table A3. Diagnosis of mild (S = 1) steatosis (N1)

1 Method (generic)	2 QIB (generic)	3 QIB (proprietary)	4 Vendor	5 Reference standard (histology, MRI, MRS)	6 Vendor QIB lower cutoff (with units)	7 Vendor QIB upper cutoff (with units)	8 Sensitivity	9 Specificity	10 Classification criteria for selecting cutoffs (e.g., Youden, etc.)	11 Population in which cutoffs were derived and assessed	12 References
PEQUS	AC	Pending	Canon	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
		TBA	E-Scopics	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
		UGAP	GE Healthcare	MRI	0.65 dB/cm/MHz	0.71 dB/cm/MHz	Pending	Pending	Youden	1010 patients with chronic liver disease	R1
		TBA	Fujifilm	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
		USAT	Mindray (N2)	histology	Pending	Pending	Pending	Pending	Pending	Healthy volunteers (N3)	R2
				MRI	Pending	Pending	Pending	Pending	Pending	Healthy volunteers (N3)	R2
		LiSA		histology	248 dB/m (N5)		Pending	Pending	Pending	Meta-analysis of 19 publications (N4)	R3
		Atten	Philips	MRI	0.63 dB/cm/MHz	0.71 dB/cm/MHz	Pending	Pending	Youden	Healthy/MASLD	R4
		TAI	Samsung	MRI	0.72 dB/cm/MHz	0.83 dB/cm/MHz	Pending	Pending	Youden	173	R5
		UDFF	Siemens	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
		ACE	Sonic Incytes	MRI	234 dB/m (5% PDFF)	283 dB/m (11% PDFF)	Pending	Pending	Youden	133 study participants, MASLD/MASH	R6
		TBA	Supersonic	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
		TBA	Toshiba	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
		Pending	United Imaging	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	SoS	TSSI	Mindray	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
		TBA	Supersonic	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	Nakagami	TSI	Samsung	MRI	95.6	98.4	Pending	Pending	Youden	173	R5
Multiparametric ultrasound	US-FF	Real-Time Multi-Parametric Ultrasound Imaging and Analysis Tool, M-Ref.Live	Mindray	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
		USFF	Samsung	MRI	8.7%	14.9%	Pending	Pending	Youden	173	R7
		VDFF	Sonic Incytes	MRI	5.2%	11%	Pending	Pending	Youden	38 study participants, MASLD/MASH	R8
		UGFF	GE Healthcare	MRI	5.3%	8.8%	Pending	Pending	Youden	582 patients with chronic liver disease	R9

Notes

N1 - Our intent is that data presented here match that available on vendor websites. If any discrepancies are noted, please let us know.

N2 - Reference phantom used for device calibration

N3 - A prospective, single-center cohort of adult living donor liver transplantation candidates (Inonu University, Türkiye, April-August 2024). All donors were healthy volunteers without liver or systemic disease and without alcohol consumption. Liver biopsy, performed within 1 week of imaging in definitive donors, served as the reference standard.

N4 - Data from 19/21 eligible papers were provided, comprising 3830/3968 (97%) of patients. Considering data overlap and exclusion criteria, 2735 patients were included in the final analysis (37% hepatitis B, 36% hepatitis C, 20% NAFLD/NASH, 7% other). Steatosis distribution was 51%/27%/16%/6% for S0/S1/S2/S3.

N5 - Central value corresponding to histologic steatosis grade

References

R1 - Imajo et al (2022) (PMID: 34768008)

R2 - Dag et al (2025) (PMID: 40231394)

R3 - Sterling et al (2025) (PMID: 38489518)

R4 - Ferraioli et al (2025) (PMID: 40237427)

R5 - Jeon et al (2023) (PMID: 36594835)

R6 - Loomba et al (2024) (PMID: 38517204)

R7 - Jeon et al (2023) (PMID: 37709827)

R8 - Honarvar et al (2024) (PMID: 40416420)

R9 - Kuroda et al (2023) (PMID: 37787670)

Abbreviations

AC = Attenuation coefficient

ACE = Attenuation coefficient estimate

LiSA = Liver ultrasound attenuation

MRI = Magnetic resonance imaging

MRS = Magnetic resonance spectroscopy

PDFF = Proton density fat fraction

PEQUS = Pulse-echo quantitative ultrasound

QIB = Quantitative imaging biomarker

TAI = Tissue attenuation imaging

TSI = Tissue scatter distribution imaging

UDFF = Ultrasound-derived fat fraction

UGAP = Ultrasound-guided attenuation parameter

UGFF = Ultrasound-guided fat fraction

USAT = Ultrasound attenuation analysis

US-FF = Ultrasound-based fat fraction

VDFF = Velacur-determined fat fraction

Table A4. Diagnosis of moderate (S = 2) steatosis (N1)

1 Method (generic)	2 QIB (generic)	3 QIB (proprietary)	4 Vendor	5 Reference standard (histology, MRI, MRS)	6 Vendor QIB lower cutoff (with units)	7 Vendor QIB upper cutoff (with units)	8 Sensitivity	9 Specificity	10 Classification criteria for selecting cutoffs (e.g., Youden, etc.)	11 Population in which cutoffs were derived and assessed	12 References
PEQUS	AC	Pending	Canon	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
		TBA	E-Scopics	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
		UGAP	GE Healthcare	MRI	0.71 dB/cm/MHz	0.77 dB/cm/MHz	Pending	Pending	Youden	1010 patients with chronic liver disease	R1
		TBA	Fujifilm	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
		USAT	Mindray (N2)	histology	0.68 dB/cm/MHz (N5)		Pending	Pending	Pending	Healthy volunteers (N3)	R2
				MRI	Pending	Pending	Pending	Pending	Pending	Healthy volunteers (N3)	R2
		LiSA		histology	268 dB/m (N5)		Pending	Pending	Pending	Meta-analysis of 19 publications (N4)	R3
		Atten	Philips	MRI	0.71 dB/cm/MHz	0.75 dB/cm/MHz	Pending	Pending	Youden	Healthy/MASLD	R4
		TAI	Samsung	MRI	0.83 dB/cm/MHz	0.86 dB/cm/MHz	Pending	Pending	Youden	173	R5
		UDFF	Siemens	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
		ACE	Sonic Incytes	MRI	283 dB/m (11% PDFF)	321 dB/m (17% PDFF)	Pending	Pending	Youden	133 study participants, MASLD/MASH	R6
		TBA	Supersonic	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
		TBA	Toshiba	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
		Pending	United Imaging	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	SoS	TSSI	Mindray	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
		TBA	Supersonic	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	Nakagami	TSI	Samsung	MRI	98.4	98.9	Pending	Pending	Youden	173	R5
Multiparametric ultrasound	US-FF	Real-Time Multi-Parametric Ultrasound Imaging and Analysis Tool, M-Ref.Live	Mindray	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
		USFF	Samsung	MRI	14.9%	16.0%	Pending	Pending	Youden	173	R7
		VDFF	Sonic Incytes	MRI	11%	17%	Pending	Pending	Youden	38 study participants, MASLD/MASH	R8
		UGFF	GE Healthcare	MRI	8.8%	11.4%	Pending	Pending	Youden	582 patients with chronic liver disease	R9

Notes

N1 - Our intent is that data presented here match that available on vendor websites. If any discrepancies are noted, please let us know.

N2 - Reference phantom used for device calibration

N3 - A prospective, single-center cohort of adult living donor liver transplantation candidates (Inonu University, Türkiye, April-August 2024). All donors were healthy volunteers without liver or systemic disease and without alcohol consumption. Liver biopsy, performed within 1 week of imaging in definitive donors, served as the reference standard.

N4 - Data from 19/21 eligible papers were provided, comprising 3830/3968 (97%) of patients. Considering data overlap and exclusion criteria, 2735 patients were included in the final analysis (37% hepatitis B, 36% hepatitis C, 20% NAFLD/NASH, 7% other). Steatosis distribution was 51%/27%/16%/6% for S0/S1/S2/S3.

N5 - Central value corresponding to histologic steatosis grade

References

R1 - Imajo et al (2022) (PMID: 34768008)

R2 - Dag et al (2025) (PMID: 40231394)

R3 - Sterling et al (2025) (PMID: 38489518)

R4 - Ferraioli et al (2025) (PMID: 40237427)

R5 - Jeon et al (2023) (PMID: 36594835)

R6 - Loomba et al (2024) (PMID: 38517204)

R7 - Jeon et al (2023) (PMID: 37709827)

R8 - Honarvar et al (2024) (PMID: 40416420)

R9 - Kuroda et al (2023) (PMID: 37787670)

Abbreviations

AC = Attenuation coefficient

ACE = Attenuation coefficient estimate

LiSA = Liver ultrasound attenuation

MRI = Magnetic resonance imaging

MRS = Magnetic resonance spectroscopy

PDFF = Proton density fat fraction

PEQUS = Pulse-echo quantitative ultrasound

QIB = Quantitative imaging biomarker

TAI = Tissue attenuation imaging

TSI = Tissue scatter distribution imaging

UDFF = Ultrasound-derived fat fraction

UGAP = Ultrasound-guided attenuation parameter

UGFF = Ultrasound-guided fat fraction

USAT = Ultrasound attenuation analysis

US-FF = Ultrasound-based fat fraction

VDFF = Velacur-determined fat fraction

Table A5. Diagnosis of severe (S = 3) steatosis (N1)

1 Method (generic)	**2 QIB** (generic)	**3 QIB** (proprietary)	**4 Vendor**	**5 Reference standard** (histology, MRI, MRS)	**6 AUROC**	**7 Vendor QIB cutoff** (with units)	**8 Sensitivity**	**9 Specificity**	**10 Classification criterion for selecting cutoff** (e.g., Youden, etc.)	**11 Population in which cutoff was derived and assessed**	**12 References**
PEQUS	AC	Pending	Canon	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
		TBA	E-Scopics	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
		UGAP	GE Healthcare	MRI	0.894	0.77 dB/cm/MHz	81%	82.6%	Youden	1010 patients with chronic liver disease	R1
		TBA	Fujifilm	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
		USAT	Mindray (N2)	histology	Pending	Pending	Pending	Pending	Pending	Healthy volunteers (N3)	R2
				MRI	Pending	0.76 dB/cm/MHz	Pending	Pending	Pending	Healthy volunteers (N3)	R2
		LiSA		histology	Pending	294 dB/m	Pending	Pending	Pending	Meta-analysis of 19 publications (N4)	R3
		Atten	Philips	MRI	0.808	0.75 dB/cm/MHz	75.0%	78.8%	Youden	Healthy/MASLD	R4
		TAI	Samsung	MRI	0.898	0.86 dB/cm/MHz	100%	79.8%	Youden	173	R5
		UDFF	Siemens	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
		ACE	Sonic Incytes	MRI	0.98	321 dB/m (17% PDFF)	77%	95%	Youden	133 study participants, MASLD/MASH	R6
		TBA	Supersonic	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
		TBA	Toshiba	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
		Pending	United Imaging	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	SoS	TSSI	Mindray	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
		TBA	Supersonic	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	Nakagami	TSI	Samsung	MRI	0.813	98.9	100%	54.0%	Youden	173	R5
Multiparametric ultrasound	US-FF	Real-Time Multi-Parametric Ultrasound Imaging and Analysis Tool, M-Ref.Live	Mindray	MRI	0.905	16.0%	100%	Pending	Pending	Pending	Pending
		USFF	Samsung	MRI	0.905	16.0%	100%	79.8%	Youden	173	R7
		VDFF	Sonic Incytes	MRI	0.98	17%	100%	97%	Youden	38 study participants, MASLD/MASH	R8
		UGFF	GE Healthcare	MRI	0.94	11.4%	87%	88%	Youden	582 patients with chronic liver disease	R9

Notes

N1 - Our intent is that data presented here match that available on vendor websites. If any discrepancies are noted, please let us know. Cutoff values correspond to PDFF values in Table C2 unless otherwise noted

N2 - Reference phantom used for device calibration

N3 - A prospective, single-center cohort of adult living donor liver transplantation candidates (Inonu University, Türkiye, April-August 2024). All donors were healthy volunteers without liver or systemic disease and without alcohol consumption. Liver biopsy, performed within 1 week of imaging in definitive donors, served as the reference standard.

N4 - Data from 19/21 eligible papers were provided, comprising 3830/3968 (97%) of patients. Considering data overlap and exclusion criteria, 2735 patients were included in the final analysis (37% hepatitis B, 36% hepatitis C, 20% NAFLD/NASH, 7% other). Steatosis distribution was 51%/27%/16%/6% for S0/S1/S2/S3.

N5 - Central value corresponding to histologic steatosis grade

References

R1 - Imajo et al (2022) (PMID: 34768008)
R2 - Dag et al (2025) (PMID: 40231394)
R3 - Sterling et al (2025) (PMID: 38489518)
R4 - Ferraioli et al (2025) (PMID: 40237427)
R5 - Jeon et al (2023) (PMID: 36594835)
R6 - Loomba et al (2024) (PMID: 38517204)
R7 - Jeon et al (2023) (PMID: 37709827)
R8 - Honarvar et al (2024) (PMID: 40416420)
R9 - Kuroda et al (2023) (PMID: 37787670)

Abbreviations

AC = Attenuation coefficient
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TAI = Tissue attenuation imaging
TSI = Tissue scatter distribution imaging
UDFF = Ultrasound-derived fat fraction
UGAP = Ultrasound-guided attenuation parameter
UGFF = Ultrasound-guided fat fraction
USAT = Ultrasound attenuation analysis
US-FF = Ultrasound-based fat fraction
VDFF = Velacur-determined fat fraction

Annexure B: Ultrasound Elastography

Scope and purpose

This annexure provides a high-level summary of technical and reporting guidance for ultrasound-based LS quantification using pSWE, 2D-SWE, and 3D-SWE methods. These methods provide quantification of LS, which is associated with but is not identical to fibrosis staging. More detailed summaries of these methods are available in the following review papers:

- Quantitative Ultrasound and Ultrasound-Based Elastography for Chronic Liver Disease: Practical Guidance, From the *AJR* Special Series on Quantitative Imaging (49)
- Update to the Society of Radiologists in Ultrasound Liver Elastography Consensus Statement (67)
- AASLD Practice Guideline on imaging-based non-invasive liver disease assessment of hepatic fibrosis and steatosis (68)

How the method works

SWE uses an ARFI to generate orthogonal transient shear waves in the liver and then uses real-time ultrasound methods to track and quantify shear-wave propagation speed through tissue (67). Shear-wave speed may be reported in meters per second (m/s) or converted to Young's modulus (kPa) using simplifying assumptions. Acquisition of SWE exams follows strict consensus guidelines to maximize signal quality and mitigate potential confounders.

There are three types of liver SWE.

- pSWE acquires images at a single point (or a small region) within the liver.
- 2D-SWE displays a 2D color map of Young's modulus or of shear-wave speed in a larger region of the liver. For 2D-SWE, an operator places an ROI of at least 1 cm diameter within what they consider to be the most representative region of the liver to obtain quantitative estimates of LS.
- 3D-SWE uses an external vibration source under the patient to create steady-state waves in the liver. A sweep motion of the probe is used to collect signal from the liver. LS is calculated from an ROI of about 10 cm^3 volume placed on a liver image and a shear-wave quality map image.

Strengths of SWE:

Advantages of SWE include the possibility to visualize liver parenchyma using B-mode ultrasound and place a measurement box (pSWE) or an ROI (2D-SWE, 3D-SWE) away from the liver capsule, major vessels, and focal lesions. The location of the ROI may be saved and used in follow-up studies to achieve reliable monitoring. The shear waves are generated within the liver and hence SWE exams should be technically feasible even in the presence of ascites (69,70).

Limitations of SWE:

There are biological confounders which may cause elevation of SWE LS values. LS increases with fibrosis but can also be elevated in the presence of inflammation, cholestasis, congestion, postprandial state, technical factors, and poor QIB acquisition conditions (71). Additional sources of confounders include recent food intake, measurement during a Valsalva maneuver or strained breath-holding.

Equipment and software

Sites should maintain a local inventory of ultrasound systems that support pSWE, 2D-SWE, or 3D-SWE, including vendor, model, transducer, software version, available quality metrics, QIB units, and reporting/export workflow. The local protocol should specify whether LS is reported in kPa, m/s, or both. Commercially available ultrasound elastography systems are listed in **Table B1**, including vendor-specific QC measures and recommended numbers of measurements per exam.

System specifics:

- Quality metrics vary by vendor and may include IQR/median, propagation maps, confidence maps, reliability indices, or acquisition success indicators.

Patient preparation and setup

Patients should fast according to local protocols, commonly ≥ 4 hours when it is feasible, to reduce bowel gas and physiologic variability. The patient is typically positioned supine or in slight left lateral decubitus position with the right arm elevated to widen the intercostal spaces. QIB values should be acquired from the right hepatic lobe through an intercostal approach, avoiding large vessels, bile ducts, focal lesions, liver edge, rib shadowing, reverberation artifact, and regions of poor B-mode visualization.

SWE exam acquisition protocol

For ultrasound elastographic imaging, a sufficient number of valid acquisitions should be acquired according to vendor guidance and imaging society guidelines, commonly 10 acquisitions, whenever feasible. Some vendors now provide applications that permit multiple acquisitions to be obtained during a single breath hold to minimize acquisition time, though this approach has not yet been validated.

The sonographer should ensure, whenever possible, that:

- there is adequate B-mode image visualization of hepatic parenchyma without substantial rib shadowing, lung, bowel gas, or reverberation artifact,
- the transducer is positioned perpendicular to the liver capsule,
- there is complete probe-skin coupling, and
- the ROI is placed in homogeneous liver parenchyma, avoiding skin surface, large vessels, bile ducts, focal lesions, liver edge, and artifacts.

Protocol specifics:

- For pSWE, ROIs are commonly placed 15-20 mm below the liver capsule to reduce reverberation artifact, and less than 6.5 cm from the skin surface. In obese patients with thick abdominal walls, ROI placement at an optimal target depth may be impractical. In this setting, the subcapsular liver should be avoided due to the risk of reverberation artifact falsely elevating shear-wave speed, though the exam may ultimately be non-diagnostic due to push-pulse attenuation at the deeper depth.
- For 2D-SWE and 3D-SWE, the elastogram box should be positioned according to vendor instructions, taking into account any quality or propagation maps. Many vendors support a side-by-side QIB parametric quality map, created according to vendor-specific quality metrics, to guide elastogram box placement. These tools allow operators to potentially place the elastogram box closer to the liver capsule since they can visually detect and avoid areas of reverberation artifact.

Common causes of limited or non-diagnostic SWE exams

Acquisitions should be obtained during neutral breathing or brief breath hold as recommended by device vendors. Limited or non-diagnostic QIB values may result from poor acoustic window, excessive depth, obesity, ascites, rib shadowing, respiratory motion, poor B-mode visualization, vascular contamination, and inadequate shear-wave propagation. Non-fasting state, acute hepatitis or marked transaminase elevation, biliary obstruction, and hepatic congestion can elevate stiffness independent of fibrosis and should be considered during interpretation.

SWE image analysis and QC

Analysis QC should confirm appropriate ROI placement, adequate B-mode visualization, and satisfaction of device-specific reliability criteria. Reports should include the median LS, units, number of valid QIB values, an IQR/median value when available, and any technical limitations. For LS estimates derived from SWE exams (units of kPa), an IQR/median value $\leq$ 30% is commonly used as a reliability indicator and when measured in m/s, an IQR/median of $\leq$ 15% is commonly used as a reliability indicator. It is advisable to use device-provided IQR/median values since applying one of the many highly variable IQR/median calculation techniques can introduce reporting bias (66). When quality criteria are not met, the result should be reported as limited or non-diagnostic.

Interpretation

Single exam: Interpret the measured SWE LS value as being supportive of or consistent with an LS category or a fibrosis risk category, but not in isolation as a direct indication of histologic fibrosis stage. LS may also be elevated by inflammation, cholestasis, hepatic congestion, postprandial state, and other non-fibrotic processes. General clinical reporting cutoffs and disease-specific cutoffs should be labeled separately. Society of Radiologists in Ultrasound (SRU)-style cutoffs may be used for compensated advanced CLD risk stratification, whereas vendor-, disease-, or histology-specific cutoffs may be used when supported by published validation data. Users should apply vendor-specific cutoffs when available. Cutoffs for MASLD, viral hepatitis, cholestatic disease, congestive hepatopathy, and post-transplant settings may differ; therefore, reports should specify the framework used when a category is assigned.

Clinical SWE performance is summarized for any (F ≥ 1) fibrosis (**Table B2**), significant (F ≥ 2) fibrosis (**Table B3**), advanced (F ≥ 3) fibrosis (**Table B4**), cirrhosis (F = 4) (**Table B5**), and 'at-risk' or noncirrhotic significant (F2 or F3) fibrosis (**Table B6**). Cutoffs may be vendor specific or agnostic. Users should apply vendor-specific cutoffs if available and vendor-agnostic cutoffs otherwise..

Follow-up exam: In addition to reporting the values for the current exam, report the value from prior exam(s) when applicable and whether the change, if any, is within or beyond measurement variability.

Serial follow-up measurements are most reliably interpreted when performed under consistent technical conditions, including the same vendor, system, acquisition protocol, software, operator, analysis method, and quality assurance criteria. Under these standardized conditions, the different-day RDC, where available, provides the most appropriate reference for assessing longitudinal changes. In general, differences less than the RDC may be due to measurement variability and should not be interpreted as true change. Differences greater than the RDC may or may not represent true change; radiologists should use their judgment. If the RDC is unavailable, the same-day RC may be used with caution, recognizing that it does not account for day-to-day variability and represents an optimistic, best-case scenario. When technical or methodological conditions differ between examinations, greater caution is warranted, and an RDC that accounts for the relevant sources of variability should be used, if available.

A separate issue is whether a change, even if true, is clinically meaningful, as the threshold defining clinically meaningful change is unknown. Estimating the RDCs that account for the most common sources of variability in clinical practice and identifying the thresholds for defining clinically meaningful change are current knowledge gaps and important future directions.

Reporting template

Below is a suggested template for reporting SWE values.

- Technique:
  - [pSWE/2D-SWE] was performed using [vendor/platform/transducer and method] through a right intercostal approach.
  - Acquisitions were obtained in accordance with vendor instructions, avoiding vessels, bile ducts, liver edge, focal lesions, and artifacts.
- Findings:
  - Median [liver stiffness: […] kPa / shear-wave speed: […] m/s], from […] valid acquisitions
  - IQR/median: […]% [other device-specific reliability metric, if applicable]
  - Technical adequacy: [adequate/limited/non-diagnostic] [specific limitation or relevant stiffness confounder, if present]
- Comparison:
  - [No prior comparable examination / Compared with examination dated ___.]
  - Prior [liver stiffness/shear-wave speed]: […] [units]
  - [Optional: absolute difference: […] [units].]
  - [Optional: relative difference: […]%.]
  - [Relevant acquisition or preparation differences.]
- Impression:
  - [Liver stiffness/Shear-wave speed] is [within the reference range/consistent with fibrosis category (F ≥ 1, F ≥ 2, F ≥ 3, F=4) category/indeterminate]. [reference table]
  - [[Liver stiffness/Shear-wave speed] value is discordant with conventional imaging findings. [Comment]]
  - [Liver stiffness/Shear-wave speed] could not be reliably quantified because [reason]. [No fibrosis category is assigned.]
  - [Compared to prior: [[liver stiffness/shear-wave speed] has increased/decreased/stayed about the same (change if any is within expected measurement variability)] [Change in [liver stiffness/shear-wave speed] cannot be evaluated.] [Comment]]
  - [Recommendations: ___]

The interpreting radiologist should report if LS/SWS values are discordant with conventional imaging findings, if and why LS/SWS could not be quantified, and suggest additional workup considerations to resolve these issues. Cases requiring technical review should be routed to the designated modality or software lead; clinically discordant results should be reviewed with the referring team when appropriate. Recurrent issues should inform protocol updates, training, and vendor feedback. Corrected results must be identifiable as amendments in downstream systems.

Table B1. Commercially available ultrasound elastography systems, and vendor-specific QC measures and recommended numbers of measurements (N1)

1 Method (generic)	2 Method (proprietary)	3 QIB (generic)	4 Vendor	5 System name	6 Required software	7 QC Measures, recommended numbers of measurements	8 Vendor website	9 FDA 510(k) clearance "K-number"	10 References
pSWE	Pending	Liver stiffness (Young's modulus)	Siemens	Pending	Pending	Pending	Pending	Pending	Pending
2D-SWE	Pending		Canon	Pending	Pending	Pending	Pending	Pending	Pending
	TBA		E-Scopics	TBA	TBA	TBA	TBA	TBA	TBA
	TBA		Fujifilm	TBA	TBA	TBA	TBA	TBA	TBA
	Comb-Push		GE Healthcare	LOGIQ E9 LOGIQ E10 LOGIQ E10s LOGIQ Fortis LOGIQ Totus	Shear Wave Elastography	Quality Map, IQR/Median, 10 measurements recommended	W1	K142160	R1
	STE STQ		Mindray	Resona/Nuewa A20 Resona/Nuewa R9 Resona/Nuewa I9 Consona N9	STE STQ	M-STB index, RLB MAP, RLB Index	Pending	Pending	R2
	ElastQ		Philips	EPIQ Affiniti Alturion	ElastQ	Confidence Map, IQR/Median	W2	K163120 (EPIQ, Affiniti) K260667 (Alturion)	Pending
	S-shearwave imaging		Samsung	R20 V8	S-shearwave imaging	RMI	W5	K252018 (R20) K243702 (V8)	R6
	Pending		Siemens	Pending	Pending	Pending	Pending	Pending	Pending
	TBA		Supersonic	TBA	TBA	TBA	TBA	TBA	TBA
	TBA		Toshiba	TBA	TBA	TBA	TBA	TBA	TBA
	Pending		United Imaging	uSONIQUE series: Genesis, Pulse, Venus; Nova, Vita, Grace	Dolphin	Reliability map (displayed with the elastogram to guide ROI placement); Stability Score; median and IQR/median of repeated acquisitions	W3	Pending	Pending
2D-TE	TBA		E-Scopics	TBA	TBA	TBA	TBA	TBA	TBA
3D-SWE	S-WAVE		Sonic Incytes	Velacur Velacur ONE	All	IQR/Median, Quality Measure, at least 5 volumes collected	W4	K251728	R3,R4,R5

Notes
N1 - Our intent is that data presented here match that available on vendor websites. If any discrepancies are noted, please let us know.
References
R1 - https://gehealthcare-ultrasound.com/en/logiq-family/logiq-e10-series/download-shear-wave/
R2 - Wang et al (2022) (PMID: 33910257)
R3 - Loomba et al (2024) (PMID: 38517204)
R4 - Shekh et al (2025) (PMID: 40075862)
R5 - Surapaneni et al (2026) (PMID: 42205166)
R6 - https://www.samsunghealthcare.com
Websites
W1 - https://logiqportal.net/clinical-specialty/liver/care-pathway
W2 - https://www.usa.philips.com/healthcare/procedure/liver-ultrasound
W3 - https://usa.united-imaging.com/products/ultrasound
W4 - Sonicincytes.com
W5 - https://global.samsungsuite.com/courses/prospective-evaluation-of-liver-fibrosis-using-s-shearwave-imaging/
Abbreviations
2D = Two-dimensional
M-STB = Motion stability
RLB = Reliability
pSWE = Point shear-wave elastography
QIB = Quantitative imaging biomarker
RMI = Reliability measurement index
STE = Sound touch elastography
STQ = Sound touch quantification
S-WAVE = Shear wave absolute vibro-elastography
SWE = Shear-wave elastography
2D-TE = two-dimensional transient elastography

Table B2. Diagnosis of 'any' (F ≥ 1) fibrosis (i.e., F1-F2-F3-F4 vs. F0 (N1)

1 Method (generic)	2 Method (proprietary)	3 QIB (generic)	4 Vendor	5 Reference standard (histology, MRE)	6 AUROC	7 Vendor QIB cutoff (units of kPa)	8 Sensitivity	9 Specificity	10 Classification criterion for selecting cutoff (e.g., Youden, etc.)	11 Population in which cutoff was derived and assessed	12 References
pSWE	Pending	Liver stiffness (Young's modulus)	Siemens	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
2D-SWE	Pending		Canon	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	TBA		Fujifilm	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	Comb-Push		GE Healthcare	histology	0.8656	5.48	86.4%	79.0%	Youden	85 patients with chronic liver disease	R1
	STE, STQ		Mindray	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	ElastQ		Philips	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	S-shearwave imaging		Samsung	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	Pending		Siemens	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	TBA		Supersonic	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	TBA		Toshiba	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	Pending		United Imaging	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
2D-TE	TBA		E-Scopics	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
3D-SWE	S-WAVE		Sonic Incytes	MRE	0.83	5.3 (N2)	86%	54%	Youden	133 study participants, MASLD/MASH	R2

Notes
N1 - Our intent is that data presented here match that available on vendor websites. If any discrepancies are noted, please let us know.
N2 - Corresponds to an MRE liver stiffness of 2.61 kPa
References
R1 - Wang et al (2022) (PMID: 33910257)
R2 - Loomba et al (2024) (PMID: 38517204)
R3 - Shekh et al (2025) (PMID: 40075862)
R4 - Surapaneni et al (2026) (PMID: 42205166)
Abbreviations
2D = Two-dimensional
3D = Three-dimensional
AUROC = Area under ROC curve
MRE = Magnetic resonance elastography
pSWE = Point shear-wave elastography
QIB = Quantitative imaging biomarker
STE = Sound touch elastography
STQ = Sound touch quantification
S-WAVE = Shear wave absolute vibro-elastography
SWE = Shear-wave elastography
2D-TE = two-dimensional transient elastography

Table B3. Diagnosis of 'significant' (F ≥ 2) fibrosis (i.e., F2-F3-F4 vs. F0-F1) (N1)

1 Method (generic)	2 Method (proprietary)	3 QIB (generic)	4 Vendor	5 Reference standard (histology, MRE)	6 AUROC	7 Vendor QIB cutoff (units of kPa)	8 Sensitivity	9 Specificity	10 Classification criterion for selecting cutoff (e.g., Youden, etc.)	11 Population in which cutoff was derived and assessed	12 References
pSWE	Pending	Liver stiffness (Young's modulus)	Siemens	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
2D-SWE	Pending		Canon	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	TBA		Fujifilm	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	Comb-Push		GE Healthcare	histology	0.9401	8.29	80.5%	97.7%	Youden	85 patients with chronic liver disease	R1
	STE,STQ		Mindray	histology	0.76	8.35	60.5%	84.0%	Pending	Pending	R1
	ElastQ		Philips	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	S-shearwave imaging		Samsung	MRE	0.978	6.82	93.2%	91.0%	Youden	Pending	R3

	Pending		Siemens	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	TBA		Supersonic	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	TBA		Toshiba	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	Pending		United Imaging	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
2D-TE	TBA		E-Scopics	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
3D-SWE	S-WAVE		Sonic Incytes	MRE	0.88	5.7 kPa (N2)	87%	73%	Youden	133 study participants, MASLD/MASH		R2

Notes
N1 - Our intent is that data presented here match that available on vendor websites. If any discrepancies are noted, please let us know.
N2 - Corresponds to an MRE liver stiffness of 2.97 kPa
References
R1 - Wang et al (2022) (PMID: 33910257)
R2 - Loomba et al (2024) (PMID: 38517204)
R3 - https://global.samsungsuite.com/courses/prospective-evaluation-of-liver-fibrosis-using-s-shearwave-imaging/
Abbreviations
2D = Two-dimensional
3D = Three-dimensional
AUROC = Area under ROC curve
MRE = Magnetic resonance elastography
pSWE = Point shear-wave elastography
QIB = Quantitative imaging biomarker
STE = Sound touch elastography
STQ = Sound touch quantification
S-WAVE = Shear wave absolute vibro-elastography
SWE = Shear-wave elastography
2D-TE = two-dimensional transient elastography

Table B4. Diagnosis of 'severe' (F ≥ 3) fibrosis ([i.e., F3-F4 vs. F0-F1-F2) (N1)

1 Method (generic)	**2 Method** (proprietary)	**3 QIB** (generic)	**4 Vendor**	**5 Reference standard** (histology, MRE)	**6 AUROC**	**7 Vendor QIB cutoff** (units of kPa)	**8 Sensitivity**	**9 Specificity**	**10 Classification criterion for selecting cutoff** (e.g., Youden, etc.)	**11 Population in which cutoff was derived and assessed**	**12 References**
pSWE	Pending	Liver stiffness (Young's modulus)	Siemens	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
2D-SWE	Pending		Canon	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	TBA		Fujifilm	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	Comb-Push		GE Healthcare	histology	0.9784	9.40	90.9%	96.2%	Youden	85 patients with chronic liver disease	R1
	STE, STQ		Mindray	histology	0.74	9.58	100%	91.1%	Pending	Pending	R1
	ElastQ		Philips	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	S-shearwave imaging		Samsung	MRE	0.982	8.63	93.1%	95.2%	Youden	Pending	R3
	Pending		Siemens	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	TBA		Supersonic	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	TBA		Toshiba	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	Pending		United Imaging	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
2D-TE	TBA		E-Scopics	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
3D-SWE	S-WAVE		Sonic Incytes	MRE	0.955	6.9 kPa (N2)	75%	94%	Youden	133 study participants, MASLD/MASH	R2

Notes
N1 - Our intent is that data presented here match that available on vendor websites. If any discrepancies are noted, please let us know.
N2 - Corresponds to an MRE liver stiffness of 3.62 kPa
References
R1 - Wang et al (2022) (PMID: 33910257)
R2 - Loomba et al (2024) (PMID: 38517204)
R3 - https://global.samsungsuite.com/courses/prospective-evaluation-of-liver-fibrosis-using-s-shearwave-imaging
Abbreviations
2D = Two-dimensional
3D = Three-dimensional
AUROC = Area under ROC curve
MRE = Magnetic resonance elastography
pSWE = Point shear-wave elastography
QIB = Quantitative imaging biomarker
STE = Sound touch elastography
STQ = Sound touch quantification
S-WAVE = Shear wave absolute vibro-elastography
SWE = Shear-wave elastography
2D-TE = two-dimensional transient elastography

Table B5. Diagnosis of cirrhosis (F = 4) (i.e., F4 vs. F0-F1-F2-F3) (N1)

1 Method (generic)	**2 Method** (proprietary)	**3 QIB** (generic)	**4 Vendor**	**5 Reference standard** (histology, MRE)	**6 AUROC**	**7 Vendor QIB cutoff** (units of kPa)	**8 Sensitivity**	**9 Specificity**	**10 Classification criterion for selecting cutoff** (e.g., Youden, etc.)	**11 Population in which cutoff was derived and assessed**	**12 References**
pSWE	Pending	Liver stiffness (Young's modulus)	Siemens	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
2D-SWE	Pending		Canon	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	TBA		Fujifilm	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	Comb-Push		GE Healthcare	histology	0.9408	11.9	81.8%	92.1%	Youden	85 patients with chronic liver disease	R1
	STE, STQ		Mindray	histology	0.87	10.34	81.3%	79.1%	Pending	Pending	R1
	ElastQ		Philips	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	S-shearwave imaging		Samsung	MRE	0.974	9.66	100.0%	92.1%	Youden	173	R3
	Pending		Siemens	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	TBA		Supersonic	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	TBA		Toshiba	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	Pending		United Imaging	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
2D-TE	TBA		E-Scopics	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
3D-SWE	S-WAVE		Sonic Incytes	MRE	0.972	8.4 kPa (N2)	73%	98%	Youden	133 study participants, MASLD/MASH	R2

Notes
N1 - Our intent is that data presented here match that available on vendor websites. If any discrepancies are noted, please let us know.
N2 - Corresponds to an MRE liver stiffness of 4.69 kPa
References
R1 - Wang et al (2022) (PMID: 33910257)
R2 - Loomba et al (2024) (PMID: 38517204)
R3 - https://global.samsungsuite.com/courses/prospective-evaluation-of-liver-fibrosis-using-s-shearwave-imaging
Abbreviations
2D = Two-dimensional
AUROC = Area under ROC curve
MRE = Magnetic resonance elastography
pSWE = Point shear-wave elastography
QIB = Quantitative imaging biomarker
STE = Sound touch elastography
STQ = Sound touch quantification
S-WAVE = Shear wave absolute vibro-elastography
SWE = Shear-wave elastography
2D-TE = two-dimensional transient elastography

Table B6. Diagnosis of 'at risk' or noncirrhotic significant fibrosis (i.e., F = 2 or F = 3 fibrosis, but not F0, not F1, and not F=4) (N1)

1 Method (generic)	**2 Method** (proprietary)	**3 QIB** (generic)	**4 Vendor**	**5 Reference standard** (histology, MRE)	**6 Vendor QIB lower cutoff** (units of kPa)	**7 Vendor QIB upper cutoff** (units of kPa)	**8 Sensitivity**	**9 Specificity**	**10 Classification criteria for selecting cutoffs** (e.g., Youden, etc.)	**11 Population in which cutoffs were derived and assessed**	**12 References**
pSWE	Pending	Liver stiffness (Young's modulus)	Siemens	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
2D-SWE	Pending		Canon	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	TBA		Fujifilm	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	Comb-Push		GE Healthcare	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	STE, STQ		Mindray	histology	8.5	15.4	Pending	Pending	Pending	Pending	Pending
	ElastQ		Philips	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	S-shearwave imaging		Samsung	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending

	Pending		Siemens	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
	TBA		Supersonic	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	TBA		Toshiba	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
	Pending		United Imaging	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending
2D-TE	TBA		E-Scopics	TBA	TBA	TBA	TBA	TBA	TBA	TBA	TBA
3D-SWE	S-WAVE		Sonic Incytes	Pending	Pending	Pending	Pending	Pending	Pending	Pending	Pending

Notes

N1 - Our intent is that data presented here match that available on vendor websites. If any discrepancies are noted, please let us know.

Abbreviations

2D = Two-dimensional
3D = Three-dimensional
MRE = Magnetic resonance elastography
pSWE = Point shear-wave elastography
QIB = Quantitative imaging biomarker
STE = Sound touch elastography
STQ = Sound touch quantification
S-WAVE = Shear wave absolute vibro-elastography
SWE = Shear-wave elastography
2D-TE = two-dimensional transient elastography

Annexure C: MRI-PDFF and Iron Quantification

Scope and purpose

This annexure provides high-level technical and reporting guidance for CSE-MRI used to quantify PDFF, a biomarker of hepatic steatosis, and to estimate LIC from R2*. CSE-MRI can provide PDFF and R2* from the same multi-echo acquisition when the acquisition and reconstruction are appropriate for the expected fat and iron ranges. More detailed summaries of these methods are available in the following review papers:

- Hepatic Steatosis, Liver Fibrosis, Fat, and Iron Evaluation with MRI and Fibrosis and Fat Evaluation with US: A Practical Guide for Radiologists (10)
- Magnetic resonance imaging quantification of liver iron (72)
- Magnetic resonance imaging of the pediatric liver: imaging of steatosis, iron deposition, and fibrosis (17)

How the method works

CSE-MRI separates water and fat signals by acquiring multi-echo gradient-echo images and modeling differences in signal phase and amplitude over time. Validated confounder-corrected implementations account for the multi-peak fat spectrum, T1 bias, R2* decay, noise bias, and phase errors to generate quantitative PDFF parametric maps. Because R2* is estimated during the same signal-decay modeling, it can be used for liver iron assessment when field-strength-specific calibration equations are applied.

Strengths of CSE-MRI:

CSE-MRI can image the entire liver within a single breath hold. It provides simultaneous assessment of hepatic steatosis and iron. Post-processing is automated, and parametric maps of PDFF and R2* values are sent to PACS. The technique is robust and comparable across vendors. PDFF is independent of magnetic field strength.

Limitations of CSE-MRI:

R2* is dependent on magnetic field strength (1.5 T, 2.89 T, or 3.0 T) and hence its interpretation and calibration curves for computing LIC require knowledge of the magnetic field strength. In the presence of severe iron overload, R2* values may be less reliable due to T2* shortening leading to signal loss to a level below the noise floor. Local signal loss may also be caused by artifacts due to metallic objects (e.g., surgical clips or coils) and bowel gas adjacent to the liver.

Equipment and software

CSE-MRI PDFF/R2* is currently performed clinically on 1.5 T, 2.89 T, or 3.0 T scanners with appropriate body coils, gradient performance, and vendor or third-party confounder-corrected reconstruction. Sites should maintain an inventory of MRI systems that support CSE-MRI QIBs, including location(s) within site, vendor, field strength, bore size, platform, software version, sequence name(s), reconstruction(s), coil requirements, expected parametric map outputs, and availability of automated analysis software. Conventional single-echo or dual-echo in-phase/opposed-phase imaging should not be used as a substitute for quantitative PDFF or R2* imaging. Commercially available CSE-MRI systems are listed in **Table C1**.

System specifics:

- 1.5 T, 2.89 T, or 3.0 T scanner required; CSE-MRI is currently not validated at other field strengths, although CSE-MRI capability may be emerging (e.g., 0.55 T, 5 T).
- Appropriate and functioning surface coils necessary to allow adequate signal-to-noise ratio (SNR) and parallel imaging; adequate imaging is unlikely if surface coils are unavailable, too small, positioned incorrectly, disconnected, or malfunctioning.
- Using adequate hardware is recommended to achieve acquisition and analysis of reportable CSE-MRI QIB values.
- QA testing is recommended for new scanners, new operating systems, and major software upgrades, with periodic QA testing after that as recommended by vendors.
- Axial sequences are recommended, either 2D or 3D, ***either*** a validated CSE-MRI multi-echo sequence from a commercial vendor that addresses technical PDFF and R2* confounders (usually 6-echo, avoiding or correcting for T1 weighting, R2*, and spectral correction confounders) ***or a multi-echo gradient-echo*** acquisition paired with a third-party reconstruction method that addresses technical confounders.
- Conventional single-echo and T1-weighted dual-echo (in- and opposed-phase) imaging are not acceptable.

Patient preparation and setup

Patients should fast according to local protocols, commonly ≥ 4 hours when it is feasible, to reduce bowel gas and physiologic variability. The patient is typically positioned supine. Patients should follow institutional MRI safety procedures and should be prepared for breath-hold imaging up to 25 s. Metallic objects, external devices, or implants near the liver can cause susceptibility artifact and may render parametric maps not analyzable. For serial exams, acquisition should be performed on the same scanner, field strength, vendor implementation, and protocol whenever feasible.

Safety considerations:

- Ensure that the MRI scanner and especially the imaging FOV have metal objects removed, even if they are MRI-safe or MRI-conditional.
- Patients should follow institutional MRI safety procedures and should be prepared for breath-hold imaging up to about 25 s.
- Metallic objects, external devices, or implants near the liver can cause susceptibility artifacts and may cause parametric maps to be limited or non-diagnostic.

CSE-MRI exam acquisition protocol

For CSE-MRI exams, a vendor-validated multi-echo 2D or 3D sequence should be used. Echo timing should permit robust water-fat separation and R2* estimation. Echo spacing and first-echo time-to-echo (TE) should be appropriate for the expected degree of iron overload. A low flip angle and a short repetition time (TR) should be used to minimize T1 bias. FOV, matrix, slice thickness, and acceleration should provide adequate liver coverage, sufficient SNR, and anatomic conspicuity for ROI placement or segmentation. In severe iron overload, shorter first TE, shorter echo spacing, or other vendor-supported protocol adjustments may be required; shortening the first echo and echo spacing may require increasing the receiver bandwidth and/or using fractional echo sampling.

Protocol specifics:

- TEs should be optimized for separating fat and water signals while permitting simultaneous acquisition of and correction for R2* signal decay. Commercial vendors typically use so-called complex-data or hybrid-data signal-fitting algorithms, in which optimal TEs may depart from nominal out-of-phase and in-phase values. Third-party reconstruction methods may use magnitude-data signal-fitting algorithms, in which the optimal TEs should be at or close to alternating nominal out-of-phase and in-phase values. It is important to avoid having all TEs be at or near the same phase in the IP/OP cycle. Ideally, TE choices should be validated at QA and/or by case-by-case QC by comparing acquired to ground-truth PDFF and R2* values in phantoms, if available.
- FOV, bandwidth, and frequency matrix should be standardized to allow optimal TE spacing. Changes to FOV, bandwidth, or frequency matrix may alter the TEs inadvertently, and cause them to be suboptimal for PDFF estimation.
- Flip angle and TR should be low enough to minimize T1 weighting, as T1 weighting will introduce PDFF and R2* inaccuracy.
- Rectangular phase FOV, number of phase encodes, and number of slices should be adjusted so that all of the liver is covered, aliasing is avoided, and SNR is acceptable. FOV, frequency matrix, and receive bandwidth should not be changed, unless acceptable TE values are confirmed.
- Suggest ≤ 10 mm slice thickness to avoid blurring and partial volume effects with surrounding tissues, and to avoid through-plane dephasing from gradients in the B_0 field.
- Fat saturation and signal intensity homogenization filters should be disabled.
- Usually phase-encoding is set to AP direction so that motion artifact is minimized in the right lobe of the liver. Imaging failure or degradation may result from uncompensated eddy currents which may introduce spurious phase shifts in one or more echoes.

Motion mitigation techniques:

- Factors that could interfere with breath-holding include poor instructions to patient, poor understanding/compliance by patient, and patient inability to hold breath.
- Newer motion-insensitive methods are in development but may not yet be commercially available.
- Factors that could interfere with respiratory gating and triggering methods include poor instructions to patient, poor understanding/compliance by patient, and poor tracker detection of motion.

Common causes of limited or non-diagnostic CSE-MRI exams

Potential failure modes include fat-water swaps, phase errors, eddy-current artifact, intermittent phase shifts, parallel-imaging artifact, susceptibility from metal or calcification, motion, and very high R2* causing rapid signal loss. Gadolinium-based contrast agents alter R2* and should not be used for LIC calculation.

Image reconstruction technique specifics:

- Reconstruction should be confounder-corrected and should account for R2* decay, T1 weighting, spectral complexity of fat, noise bias, and means to mitigate or correct for the effects of eddy currents and other phase errors as supported by the MRI vendor or third-party software.

Possible image reconstruction problems that could render exams non-diagnostic:

- Fat-water swaps
- Eddy currents, concomitant gradients and other sources of phase error that are not corrected or mitigated. Stochastic / unexpected / intermittent phase shifts on one or more echoes, e.g., swapping of in-phase and quadrature (I/Q) channels; these are difficult to identify, and overarching QC can be performed by using internal controls, such as subcutaneous fat.
- High susceptibility objects (e.g., metal in or near the liver)
- High acceleration factor causing parallel imaging artifact.
- High R2* due to iatrogenic or physiologic factors, from:
  - Liver iron (worse at higher field strengths) increases R2* and, at high levels, may render PDFF non-diagnostic
  - Gadolinium-based contrast agents (GBCAs) do not affect PDFF, but may slightly increase R2*
  - Iron-based contrast agents, worse at higher field strengths, impact R2*, may render PDFF non-diagnostic at very high levels

CSE-MRI image analysis and QC

ROIs should be placed manually on PDFF parametric map images within liver parenchyma, avoiding major vessels, bile ducts, lesions, artifacts, liver edges, adjacent organs, and surrounding tissues. Placement of at least three ROIs is recommended, with sampling of both lobes when technically feasible. Segmental or whole-liver automated analysis software exists; however, the radiologist should verify that the segmentation includes only liver parenchyma and excludes artifacts, vessels, lesions, and non-hepatic tissue. If CSE-MRI parametric map images are technically inadequate, results should be reported as limited or not reportable.

PDFF and R2* analysis QC:

- Verify patient identity and exam date
- Verify that liver PDFF and R2* values are consistent with imaging appearance
- Verify that correct scaling was used for PDFF and R2* ROI values; some QIB parametric maps display values 10 times larger than their actual values (e.g., PDFF map values of 200 indicating 20% PDFF, R2* map values of 200 indicating 20 s^{-1}, etc.).
- Verify that averaged ROI values have been correctly calculated.
- Verify that PDFF and R2* values were not interchanged inadvertently.
- Verify that spleen and kidney have low PDFF, and that subcutaneous fat has high PDFF.
- Verify that R2* and T2* have not been confused.
- Verify that ROIs were placed on PDFF parametric maps and not on other ancillary images that may resemble and be confused with PDFF parametric maps (e.g., fat images that may resemble PDFF parametric map images).

LIC analysis QC:

- Verify that R2* units are correct.
- Verify that correct field-strength-dependent formula was used to calculate LIC from R2*.
- Verify that LIC is derived from pre-contrast imaging.

Interpretation

PDFF:

Single exam: Interpret the measured value in the context of the provided cutoffs, which evaluate for (a) presence or absence of hepatic steatosis and (b) the grade of hepatic steatosis (mild, moderate, or severe). For routine

clinical reporting, MRI-PDFF may be interpreted using a pragmatic radiology grading scheme: < 5% normal / no elevated steatosis; 5% to < 15% mild steatosis; % to < 25% moderate steatosis; and ≥ 25% severe steatosis (**Table C2**).

Follow-up exam: In addition to reporting the value for the current exam, report value(s) from prior exam(s) when applicable, and whether the change, if any, is within or beyond measurement variability.

Serial follow-up measurements are most reliably interpreted when performed under consistent technical conditions, including the same vendor, system, acquisition protocol, software, operator, analysis method, and quality assurance criteria. Under these standardized conditions, the different-day RDC, where available, provides the most appropriate reference for assessing longitudinal changes. In general, differences less than the RDC may be due to measurement variability and should not be interpreted as true change. Differences greater than the RDC may or may not represent true change; radiologists should use their judgment. If the RDC is unavailable, the same-day RC may be used with caution, recognizing that it does not account for day-to-day variability and represents an optimistic, best-case scenario. When technical or methodological conditions differ between examinations, greater caution is warranted, and an RDC that accounts for the relevant sources of variability should be used, if available. **(Note to reviewers during open comment period: we plan to provide evidence-based RCs and RDCs for PDFF estimation by CSE-MRI in the final version of this document).**

A separate issue is whether a change, even if true, is clinically meaningful, as the threshold defining clinically meaningful change is unknown. Unlike QIBs of steatosis measured by PEQUS, where thresholds for clinically meaningful change have not been established, a ≥ 30% relative reduction in PDFF (defined as 100 x [(baseline PDFF - follow-up PDFF) / baseline PDFF]) suggests histologic response to intervention in adults with MASH (8,50).

Example: Baseline PDFF = 20%. Follow-up PDFF = 14%. Absolute PDFF reduction = 6 percentage points. Relative reduction = 30%. Interpretation: the relative reduction of 30% suggests histologic response to intervention.

R2* (and LIC derived from it):
R2* can be converted to LIC using a validated field-strength-specific calibration equation using the Hernando multi-center calibration (10):

- LIC at 1.5 T may be estimated as 0.02603 x R2* (s^{-1}) - 0.16
- LIC at 2.89 T may be estimated as 0.01400 x R2* (s^{-1}) - 0.03
- LIC at 3.0 T may be estimated as 0.01349 x R2* (s^{-1}) - 0.03

Approximate clinical ranges of LIC and R2* values for LIC classification are provided in **Table C3**.

Single exam: Interpret the measured value in the context of the provided cutoffs, which evaluate for (a) presence or absence of hepatic iron overload and (b) the severity of hepatic iron overload.

Follow-up exam: In addition to reporting the value(s) for the current exam, report value(s) from prior exam(s) when applicable, and whether the changes, if any, are within or beyond measurement variability.

Serial follow-up measurements are most reliably interpreted when performed under consistent technical conditions, including the same vendor, system, acquisition protocol, software, operator, analysis method, and quality assurance criteria. Under these standardized conditions, the different-day RDC, where available, provides the most appropriate reference for assessing longitudinal changes. In general, differences less than the RDC may be due to measurement variability and should not be interpreted as true change. Differences greater than the RDC may or may not represent true change; radiologists should use their judgment. If the RDC is unavailable, the same-day RC may be used with caution, recognizing that it does not account for day-to-day variability and represents an optimistic, best-case scenario. When technical or methodological conditions differ between examinations, greater caution is warranted, and an RDC that accounts for the relevant sources of variability should be used, if available.

A separate issue is whether a change, even if true, is clinically meaningful, as the threshold defining clinically meaningful change is unknown. Estimating the RDCs that account for the most common sources of variability in clinical practice and identifying the thresholds for defining clinically meaningful change are current knowledge gaps and important future directions.

Reporting template

Below is a suggested template for reporting CSE-MRI values.

- Technique:
  Confounder-corrected multi-echo CSE-MRI was performed at […] T using [vendor/method/software] [before contrast administration] with [ROI-based/whole-liver] analysis.
- Findings:
  - Mean hepatic PDFF: [[…]%] [Could not be reliably quantified because [reason]]
  - Mean hepatic R2*: [[…] s^{-1}. Estimated LIC: […] [mg Fe/g or µmol Fe/g] dry liver weight [reference table or formula]. [Could not be reliably quantified because [reason]]
- Comparison:
  - [No prior comparable examination / Compared with examination dated ___]
  - Prior PDFF: […]%
    - [Optional: absolute difference: [value and %].]
    - [Optional: relative difference: […]%.]
    - [Relevant differences in patient preparation, method, or analysis]
  - Prior [R2*/LIC]: [[…] s^{-1}/[…] mg Fe/g dry liver weight/ […] µmol Fe/g dry liver weight]
    - [Optional: absolute difference: […] [units].]
    - [Optional: relative difference: […]%.]
    - [Relevant differences in patient preparation, method, or analysis.]
- Impression:
  - MRI-PDFF of […]% is consistent with [no/mild/moderate/severe] steatosis [reference table].
  - [PDFF value is discordant with conventional imaging findings. [Comment]]
  - [PDFF could not be reliably quantified because [reason]. No steatosis grade is assigned.]
  - [Compared to prior: [PDFF has increased/decreased/stayed about the same (change if any is within expected measurement variability)][The relative reduction in PDFF exceeds 30% and may represent histologic response after intervention] [Change in PDFF cannot be evaluated. [Comment]]
  - [Recommendations: ___]
  - [R2* value of […] s^{-1} at […]T] [LIC of […] [units]] is consistent with [no, borderline, mild, moderate, or severe iron overload] [reference table]]
  - [[R2*/LIC] value is discordant with conventional imaging findings. [Comment]]
  - [[R2*/LIC] could not be reliably quantified because [reason]. No iron overload category is assigned.]
  - [Compared to prior: [[R2*/LIC] has increased/decreased/stayed about the same (change if any is within expected measurement variability)][Change in [R2*/LIC] cannot be evaluated. [Comment]]
  - [Recommendations: ___]

The interpreting radiologist should report if PDFF, R2*, or LIC values are discordant with conventional imaging findings, if and why PDFF, R2*, or LIC could not be quantified, and suggest additional workup considerations to resolve these issues. Cases requiring technical review should be routed to the designated modality or software lead; clinically discordant results should be reviewed with the referring team when appropriate. Recurrent issues should inform protocol updates, training, and vendor feedback. Corrected results must be identifiable as amendments in downstream systems.

Table C1. Commercially available CSE-MRI systems (N1)

1 Method (generic)	2 Method (proprietary)	3 QIB (generic)	4 Vendor	5 System name(s)	6 Required software	7 Vendor website	8 FDA 510(k) clearance "K-number"	9 References
CSE-MRI	FFQ	PDFF	Canon	Vantage Fortian 1.5T Vantage Orian 1.5T Vantage Galan 3T	FFQ for V7 or higher	W1, W2	K203053 K203553 K211633	R1, R2
	IDEAL-IQ		GE Healthcare	All 1.5T and 3T systems	IDEAL-IQ	W1	K103411	R3, R4, R5
	3D mDIXON Quant		Philips	Systems supporting mDIXON Quant	Pending	Pending	Pending	R6
	VIBE q-Dixon		Siemens	All 1.5T and 3T systems	Multi-echo Dixon VIBE (LiverLab package)	Pending	Pending	R7, R8
	3D FACT		United Imaging	uMR series 1.5T, 3T, and 5T systems	Pending	Pending	Pending	R9

Notes

N1 - Our intent is that data presented here match that available on vendor websites. If any discrepancies are noted, please let us know.

References

R1 - Starekova et al (2025) (PMID: 40251801)
R2 - Starekova et al (2026) (PMID: 42159302)
R3 - GE HealthCare. Quick and reproducible liver iron concentration measurements with MR [Internet], GE HealthCare, Waukesha, WI, USA. [2020. SIGNA Pulse] https://signapulse.gehealthcare.com/spring-2020/liver-iron-concentration-measurement-mr
R4 - Pooler et al (1995) (PMID: 30917020)
R5 - Corrias et al (2018) (PMID: 30103108)
R6 - Philips Healthcare. mDIXON Quant MR clinical application [Internet]. Best, The Netherlands: Philips Healthcare; [cited 2026 Oct 29]. Available from: Philips mDIXON Quant
R7 - Zhong et al (2014) (PMID: 24323332)
R8 - Jhaveri et al (2019) (PMID: 30291649)
R9 - Cheng et al (2017) (PMID: 27295968)

Websites

W1 - https://global.medical.canon/products/magnetic-resonance-imaging/vantage-galan-3t-supreme/supreme-image-quality/
W2 - https://global.medical.canon/content/dam/canon/global-master/commons/products/magnetic-resonance-imaging/good-to-know/MOIMR0119EA_G2K_FFQ_final_a.pdf.coredownload.inline.pdf
W3 - https://www.gehealthcare.com/en-us/products/magnetic-resonance-imaging/applications/ideal?srsltid=AYCX9vLg4SPp2uW4vXroUmD8FPK1AwneXSevlWG9hxPn9ihb6-PA2Sop

Abbreviations

3D = Three-dimensional
CSE = Chemical-shift encoded
FACT = Fat analysis calculation technique: chemical shift-encoded multi-echo gradient echo
IDEAL-IQ = Iterative decomposition of water and fat with echo asymmetry and least-squares estimation quantification
MRI = Magnetic resonance imaging
PDFF = Proton-density fat fraction
QIB = Quantitative imaging biomarker
VIBE = Volumetric-interpolated breath-hold examination

Table C2. Pragmatic clinical PDFF interpretation ranges

1 Routine PDFF interpretation	2 MRI-PDFF
Normal / no elevated hepatic steatosis	< 5%
Any (S ≥ 0) steatosis	≥ 5%
Mild (S =1)steatosis	≥ 5% to < 15%
Moderate (S = 2) steatosis	≥ 15% to < 25%
Severe (S = 3) steatosis	≥ 25%

Abbreviations

MRI = Magnetic resonance imaging
PDFF = Proton density fat fraction

Table C3. Clinical LIC classification

1 LIC category	2 LIC dry liver (mg Fe/g)	3 R2* cutoff at 1.5T (s^{-1})	4 R2* cutoff at 3T (s^{-1})
Normal	< 1.8	< 75	< 136
Borderline iron overload	1.8-3.2	75-129	136-239
Mild iron overload	3.2-7.0	129-275	239-521
Moderate iron overload	7.0-15.0	275-582	521-1114
Severe iron overload	≥ 15.0	≥ 582	≥ 1114

Abbreviation

LIC = Liver iron concentration

Annexure D: Two-dimensional MR Elastography

Scope and purpose

This annexure provides high-level technical and reporting guidance for two-dimensional MR elastography (2D-MRE) used to quantify LS in patients with known or suspected CLD. 2D-MRE LS quantification is associated with fibrosis stage, and can be used to support fibrosis staging, risk stratification, and longitudinal monitoring when interpreted in clinical context. More detailed summaries of these methods are available in the following review papers:

- Magnetic resonance elastography of the liver: everything you need to know to get started (28)
- MR Elastography: Practical Questions, From the *AJR* Special Series on Imaging of Fibrosis (73)
- Reporting template: Moura Cunha G, et al. Interpretation, Reporting, and Clinical Applications of Liver MR Elastography. Radiology (53)

How the method works

2D-MRE estimates LS by applying mechanical vibrations (typically at 60 Hz) to the liver and imaging the resulting shear waves with motion-sensitive MRI sequences. Reconstruction algorithms convert wave information into LS parametric maps, usually reported as the magnitude of the complex shear modulus in units of kPa. As for SWE, LS is related to but not identical to hepatic fibrosis; other processes, including inflammation, portal hypertension, and hepatic venous congestion may also affect LS (74). Reliable interpretation requires adequate driver coupling, wave penetration, liver coverage, and review of confidence or quality maps to ensure that reported values are based on analyzable liver parenchymal images.

Strengths of 2D-MRE:

2D-MRE samples a relatively large cross-section of the liver and depicts regional variation in stiffness, reducing dependence on a small focal sample. It supports quantitative assessment across a range of body habitus when technically adequate (13,14). Fibrosis of the liver may be spatially heterogeneous, particularly in the early stages of disease. This can result in sampling errors if only a portion of the liver is interrogated with techniques such as vibration-controlled transient elastography (VCTE), ultrasound SWE or even percutaneous needle biopsy (commonly regarded as the reference standard for the diagnosis of hepatic fibrosis). With 2D-MRE, the distribution of stiffness can be demonstrated, while providing an opportunity for biopsy guidance.

Limitations of 2D-MRE:

Currently, the main limitation of 2D-MRE is that it may fail in patients with moderate to severe iron overload secondary to hemochromatosis or hemosiderosis (75). In iron overload of the liver parenchyma, the liver MRI signal becomes too low and becomes undetectable with the standard 2D-MRE sequence, which is gradient-echo (GRE) based. However, spin echo (SE) and echo planar (SE-EPI) based MRI sequences can better assess LS in patients with mild to moderate iron deposition (76–78). Other limitations of 2D-MRE are that the number of analyzable pixels may be small, especially in livers with normal or only mildly elevated stiffness values, and that the acquisition, QC, and analysis are more complex than for other quantitative methods.

Equipment and software

2D-MRE requires an active or passive driver, connecting tubing, a 2D-MRE acquisition sequence and reconstruction software. It is available on major 1.5 T and 3 T MRI scanners, but local implementations vary by vendor and software version. LS is a mechanical property that does not depend on magnetic field strength. Studies support good cross-platform reproducibility when patient preparation, acquisition parameters, driver frequency, breath-hold status, sequence, and inversion algorithm are comparable (62). Commercially available 2D-MRE systems are listed in **Table D1**.

System specifics:

- Nevertheless, longitudinal follow-up is most reliable when performed using the same platform and protocol.

Patient preparation and setup

Patients should rest before 2D-MRE exams when feasible and should be fasting according to local protocol, commonly for ≥ 4 hours to reduce bowel gas and physiologic variability. The patient is typically positioned supine. Patients should be informed that they will feel vibrations, which can be uncomfortable for some individuals. The passive driver should be placed over the right anterior lower chest or upper abdomen overlying the right hepatic

lobe, commonly near the level of the xiphoid and centered near the right midclavicular line. The driver should be secured firmly with an elastic belt to ensure adequate coupling during end-expiration. The active driver must be turned on, remains outside the scan room, and transmits mechanical waves to the passive driver through connecting tubing. The tubing must be intact and without kinking. For serial exams, acquisition should be performed on the same scanner, field strength, vendor implementation, and protocol whenever feasible.

Safety considerations:

- Patients should follow institutional MRI safety procedures and should be prepared for breath-hold imaging up to about 25 s.
- Metallic objects, external devices, or implants near the liver can cause susceptibility artifacts and may render parametric maps not analyzable.

2D-MRE exam acquisition protocol

2D-MRE exams are typically acquired during end-expiration breath-holds. Patients should be prepared for breath-hold imaging up to about 25 s. Pre-exam localizers should also be obtained in end-expiration to ensure reproducible slice positioning and to confirm driver position. Axial images should be prescribed through the widest transverse extent of the liver while avoiding the dome, lung base, inferior tip, and large vessels when possible. A standard liver 2D-MRE exam commonly obtains four slices. GRE and SE-EPI implementations exist; SE-EPI methods may improve technical success in patients with low hepatic signal, including some patients with iron overload, and at higher field strengths. The driver amplitude can be set at different levels based on patient weight, body habitus, and vendor recommendations. Larger patients may need higher amplitude settings.

2D-MRE reconstruction generates grayscale magnitude and phase images (the raw data), wave images, and elastogram (LS) parametric map images. These outputs are standardized across vendors. Magnitude images provide anatomic information, and phase images can be used to assess presence of shear waves qualitatively. Magnitude and phase images can be assessed by the technologist in real-time before the patient is taken off the scanner table to help confirm exam technical success. Shear waves should be present on phase images, and magnitude images can be used to confirm presence of abdominal wall paddle signal void for proper slice selection, and to assess respiratory motion and other artifacts. Grayscale elastograms provide the quantitative stiffness values that are used for analysis.

Users may also request that the scanner produce confidence maps, and color-coded phase, wave, and elastogram images. Confidence maps can help locate regions of reliable information suitable for ROI placement. Color elastograms are useful for identifying hot spots which should be avoided when placing ROIs and can be used for qualitative overview of the liver for a rapid visual assessment of whether acquired LS values will be normal or elevated. In some cases, a color elastogram can be generated by the scanner with an expanded stiffness scale from 0 to 20 kPa. These images may help appreciate heterogeneity and identify hot spots to be avoided in MRE analysis (see below) in livers with mean LS values ≥ 6 kPa.

Safety considerations:

- Metallic objects, external devices, or implants near the liver can cause susceptibility artifact, may render parametric maps not analyzable, and may represent a safety hazard to the patient.
- For serial exams, acquisition should be performed on the same scanner, field strength, vendor implementation, and protocol whenever feasible.

Common causes of limited or non-diagnostic 2D-MRE exams

Motion mitigation depends on patient coaching, consistent end-expiration breath-holds, and proper driver coupling. Limited or non-diagnostic exams may result from loose driver placement, driver positioned away from the liver, inadequate wave penetration, respiratory motion, poor slice prescription, severe hepatic iron overload with low magnitude signal, susceptibility artifact, inadequate confidence-map coverage, or use of non-quantitative display images. If 2D-MRE fails, the reason and any corrective action should be documented.

2D-MRE image analysis and QC

Manual ROIs should be drawn within analyzable liver parenchyma with reference to magnitude, wave, stiffness, and confidence images. ROIs should exclude the liver capsule, large vessels, fissures, lesions, and hot spots (focal areas in the image with disproportionately high stiffness values compared to adjacent areas). ROIs should be modified as needed 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. ROIs should also exclude areas

of low confidence, as indicated on confidence maps by a checkerboard pattern.

The left lobe of the liver is more susceptible to cardiac motion artifacts. For this reason, ROIs should be confined mainly or completely to the right lobe of the liver. A weighted mean LS value derived from all four acquired slices should be reported. For automated analysis, the radiologist should verify that the ROIs include only liver parenchyma, and exclude artifacts, vessels, lesions, non-hepatic tissue, and hot spots.

Technologist QC Checklist:
Before the patient leaves, confirm that the required series are present and that wave propagation and analyzable liver coverage are adequate under the local protocol. In particular, verify that the magnitude images show signal loss in the subcutaneous fat just below the passive driver, that phase images show shear waves in the liver, and that the patient reported feeling vibrations. If acquisition appears unsuccessful, perform the agreed corrective step or seek radiologist review when feasible, and document the reason for failure.

Technologists should be aware that the following patient and technical factors can affect 2D-MRE quality and LS values:

- Fasting vs. fed state
- Snugness of passive driver fastened to the abdominal wall in end-expiration
- Kinking or disconnection of the tubing from the active to the passive driver
- Active driver on or off
- Consistency between calibration scan, localizer scan, and 2D-MRE acquisitions in end-expiration
- Acquisition of MRE at the widest portion of liver (excluding dome and inferior tip of right lobe)
- Driver frequency at 60 Hz or other
- Driver amplitude set at the right level for the patient's weight and body habitus

Radiologist QC:
At the time of image review, the suitability of the data must 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. The quantitative elastograms of successful 2D-MRE exams should demonstrate areas of valid stiffness data within the liver in the confidence maps.

Interpretation
Although elevated 2D-MRE-based LS probably represents, mostly or predominantly, elevated hepatic fibrosis, current clinically available 2D-MRE techniques cannot distinguish contributions to LS resulting from hepatic fibrosis from those due to other conditions such as inflammation or congestion. Increased LS may be seen in patients with acute liver inflammation, even without fibrosis. When 2D-MRE is performed in patients with CLD in the postprandial state, increased portal blood flow results in a dynamic rise in LS, leading to overestimation of hepatic fibrosis stage (79). However, this can be overcome by instructing patients to fast for ≥ 4 hours prior to their 2D-MRE exam, and any follow-up exams. Acute biliary obstruction and passive congestion of the liver can also give rise to increased LS (80,81). Liver 2D-MRE should be interpreted with caution when such conditions exist.

Single exam: Interpret the measured 2D-MRE QIB value as being supportive of or consistent with an LS category or a fibrosis risk category, but not in isolation as a direct indication of histologic fibrosis stage. As stated above, LS may also be elevated by inflammation, cholestasis, hepatic congestion, postprandial state, and other non-fibrotic processes, which should be kept in consideration for interpretation. For routine clinical reporting, 2D-MRE-based LS may be interpreted using a pragmatic radiology scoring scheme: < 3kPa no fibrosis (F = 0) / fibrosis unlikely; ≥ 3.0 kPa suggests any (F ≥ 1) fibrosis; ≥ 3.5 kPa suggests significant (F ≥ 2) fibrosis; ≥ 4.0 kPa suggests advanced (F ≥ 3) fibrosis; and ≥ 5.0 kPa suggests cirrhosis (F = 4) (**Table D2**).

Follow-up exam: Follow-up exam: In addition to reporting the value for the current exam, report value(s) from prior exam(s) when applicable, and whether the change, if any, is within or beyond measurement variability.

Serial follow-up measurements are most reliably interpreted when performed under consistent technical conditions, including the same vendor, system, acquisition protocol, software, operator, analysis method, and quality assurance criteria. Under these standardized conditions, the different-day RDC, where available, provides the most appropriate reference for assessing longitudinal changes. In general, differences less than the RDC may be due to measurement variability and should not be interpreted as true change. Differences greater than

the RDC may or may not represent true change; radiologists should use their judgment. If the RDC is unavailable, the same-day RC may be used with caution, recognizing that it does not account for day-to-day variability and represents an optimistic, best-case scenario. When technical or methodological conditions differ between examinations, greater caution is warranted, and an RDC that accounts for the relevant sources of variability should be used, if available. **(Note to reviewers during open comment period: we plan to provide evidence-based RCs and RDCs for LS estimation by 2D-MRE in the final version of this document).**

A separate issue is whether a change, even if true, is clinically meaningful, as the threshold defining clinically meaningful change is unknown.

Reporting template

Below is a suggested template for reporting MRE values.

- Technique:
  - 2D-MRE was performed at […] T using a [GRE/SE-EPI] sequence and […] Hz mechanical vibration.
  - ROIs were selected [manually/automatically with radiologist verification].
- Findings:
  - Mean liver stiffness: [[…] kPa across [number] valid slices] [Could not be reliably quantified because [reason]]
  - Quantitative results are [concordant/discordant] with other imaging findings [___].
- Comparison:
  - [No prior comparable examination / Compared with examination dated ___]
  - Prior liver stiffness […] kPa
  - [Optional: absolute difference […] kPa]
  - [Optional: relative difference: […]%.]
  - [Relevant difference in patient preparation, method, or analysis.]
- Impression:
  - Liver stiffness of […] kPa is [consistent with fibrosis category/indeterminate] [reference table].
  - [Liver stiffness value is discordant with conventional imaging findings. [Comment]]
  - [Liver stiffness could not be reliably quantified because [reason]. No fibrosis stage category category is assigned.]
  - [Recommendations: ___]

The interpreting radiologist should report if LS values are discordant with conventional imaging findings, if and why LS could not be quantified, and suggest additional workup considerations to resolve these issues. Cases requiring technical review should be routed to the designated modality or software lead; clinically discordant results should be reviewed with the referring team when appropriate. Recurrent issues should inform protocol updates, training, and vendor feedback. Corrected results must be identifiable as amendments in downstream systems.

Table D1. Commercially available 2D-MRE systems (N1)

1 Method (generic)	2 Method (proprietary)	3 QIB (generic)	4 Vendor	5 System name	6 Required software	7 Vendor website	8 FDA 510(k) clearance "K-number"	9 References
2D-MRE (SE-EPI)	*Same as generic*	Liver stiffness (shear modulus)	Canon	Vantage Fortian 1.5T Vantage Orian 1.5T Vantage Galan 3T	MRE for V8 or higher	W1, W2	K220018	Pending
	MR Touch		GE Healthcare	All 1.5T and 3T SIGNA MR Systems	MR Touch, Hepatogram+	W3	K083421	R1, R2
	Same as generic		Philips	Systems supporting MR Elastography	Pending	Pending	Pending	R3
	Syngo		Siemens	Most 0.55T, 1.5T, 3T systems	Pending	W4	Pending	Pending
	Same as generic		United Imaging	uMR series 1.5T, 3T, and 5T systems	Pending	Pending	Pending	R4, R5

Notes
N1 - Our intent is that data presented here match that available on vendor websites. If any discrepancies are noted, please let us know.
References
R1 - https://signapulse.gehealthcare.com/autumn-2019/non-invasive-liver-health-assessment
R2 - https://signapulse.gehealthcare.com/spring-2023/An%20automated%20and%20consistent%20reporting%20solution%20for%20liver%20disease%20facilitates%20procedure%20growth
R3 - Philips Healthcare. MR Elastography: non-invasive assessment of liver tissue stiffness [product brochure]. Best, The Netherlands: Koninklijke Philips N.V.; 2016 (https://www.usa.philips.com/healthcare/product/HCNMRB870/mr-elastography-mr-clinical-application)
R4 - Li et al (2020) (PMID: 32624152)
R5 - Venkatesh et al (2014) (PMID: 25086938)
Websites
W1 - https://global.medical.canon/products/magnetic-resonance-imaging/vantage-galan-3t-supreme/supreme-image-quality/
W2 - https://global.medical.canon/content/dam/canon/global-master/commons/products/magnetic-resonance-imaging/good-to-know/MOIMR0129EA_G2K_MRE_final_a.pdf.coredownload.inline.pdf
W3 - https://www.gehealthcare.com/en-in/products/magnetic-resonance-imaging/mr-applications/mr-touch-body?srsltid=AYCX9vL_TYcwAhTUc31sKVZIhUblwugvTuZoujEUDrby2g0Mit4Bqpyc
W4 - https://www.resoundant.com/
Abbreviations
2D = Two-dimensional
MRE = Magnetic resonance elastography
QIB = Quantitative imaging biomarker
SE-EPI = Spin-echo echo-planar

Table D2. Pragmatic 2D-MRE cutoffs

1 Context	2 2D-MRE liver stiffness	3 Interpretation
General reporting cutoff	< 3.0 kPa	Fibrosis unlikely
General reporting cutoff	≥ 3.0 kPa	Suggests any (F≥1) fibrosis
General reporting cutoff	≥ 3.5 kPa	Suggests significant (F≥2) fibrosis
General reporting cutoff	≥ 4.0 kPa	Suggests advanced (F≥3) fibrosis
General reporting cutoff	≥ 5.0 kPa	Suggests cirrhosis (F=4)
MASLD cutoffs for at-risk or noncirrhotic significant (F2 or F3) fibrosis	pending	Suggests F2 or F3 fibrosis and possible eligibility for pahramcotherapy

Abbreviations
MASLD = Metabolic dysfunction-associated steatotic liver disease
MRE = Magnetic resonance elastography

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