

White paper

Ultrasound-derived fat fraction (UDFF)

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Disclaimer:

The UDFF feature is cleared only as an aid to physicians in the management of hepatic steatosis. The studies cited in this document are provided for informational purposes to illustrate the use of UDFF in clinical research settings. These references do not imply broader clinical indications or effectiveness beyond what is cleared by regulatory authorities. Physicians should interpret UDFF results in conjunction with standard clinical assessment and judgment.

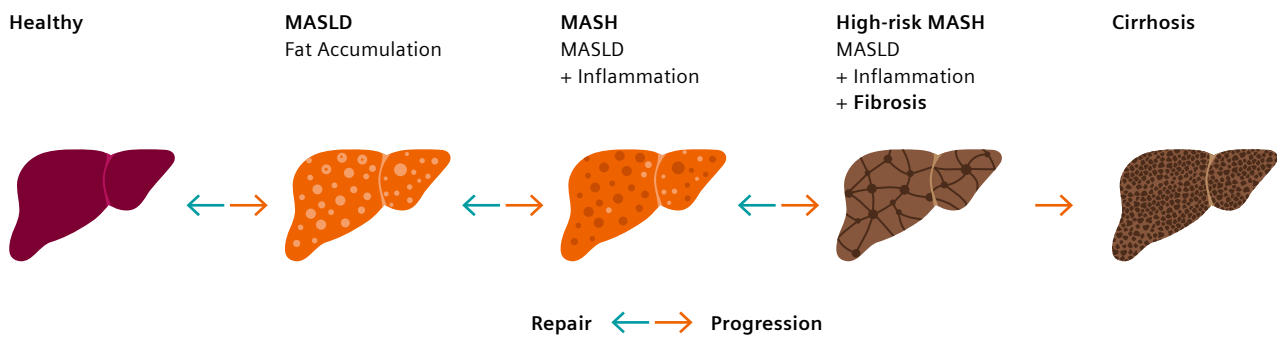


Figure 1: Schematic illustrating the progression of liver disease

MASLD: Silent epidemic

Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD), formerly known as Non-Alcoholic Fatty Liver Disease (NAFLD), is the most common chronic liver disease worldwide, affecting roughly 30% of adults and an increasing number of children [1]. MASLD is largely silent, only about 5% of affected individuals are aware of their condition. Although often asymptomatic in its early stages, the disease can have serious long-term consequences.

MASLD represents a spectrum of liver disease, ranging from simple steatosis – the accumulation of fat within hepatocytes – to Metabolic Dysfunction-Associated Steatohepatitis (MASH), a more severe form characterized by hepatocellular injury and inflammation. MASH carries an elevated risk of progression to fibrosis, cirrhosis, or hepatocellular carcinoma (HCC).

The accumulation of fat in the liver is a defining feature of MASLD. Early detection and accurate quantification of liver fat are essential for identifying at-risk individuals, guiding intervention and monitoring response to treatment [2]. Reducing hepatic fat content has been shown to improve MASH [3], highlighting the clinical importance of precise and reproducible measurement techniques.

Current diagnostic tools, including liver biopsy and MRI-derived proton density fat fraction (PDFF), provide accurate assessment of liver fat but have several limitations. Ultrasound offers a non-invasive, accessible, and scalable approach for early detection and ongoing monitoring, making it an essential tool in addressing this silent epidemic.

Liver biopsy

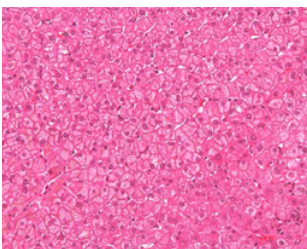
Liver biopsy remains the gold standard for diagnosing MASH, as it provides direct histological evaluation of hepatocellular fat accumulation, inflammation, and fibrosis [4]. Biopsy allows grading of steatosis based on the proportion of hepatocytes containing fat. **Table 1** summarizes the histologic grades ranging from Grade 0 (normal, <5% of hepatocytes affected) to Grade 3 (severe, >66% of hepatocytes affected). **Figure 2** shows representative histology images of liver tissue across steatosis grades 0 to 3, illustrating the increasing accumulation of fat droplets in hepatocytes with disease severity.

Despite its clinical value, liver biopsy has important limitations [4]. It is invasive, carries procedural risks, and is subject to sampling variability, as only a small portion of the liver is examined. These factors make biopsy less suitable for routine screening or repeated monitoring, underscoring the need for non-invasive alternatives.

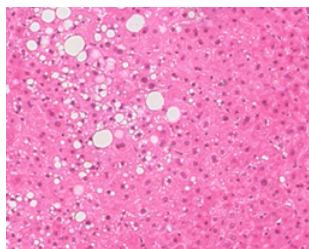
Percentage of Hepatocytes Containing Fat (%)	Histologic Steatosis Grade
<5%	Grade 0 (normal)
5%-33%	Grade 1 (mild)
33%-66%	Grade 2 (moderate)
>66%	Grade 3 (severe)

Table 1: Histologic grades of hepatic steatosis (adapted from Kleiner et al. [5])

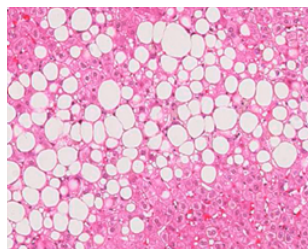
Grade 0



Grade 1



Grade 2



Grade 3

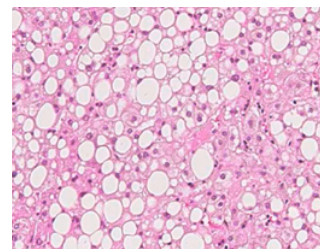


Figure 2: Representative hematoxylin-eosin-stained liver tissue images from patients with steatosis grades 0-3, showing increasing lipid accumulation within hepatocytes. (Image adapted from Jiménez-Agüero et al. [6])

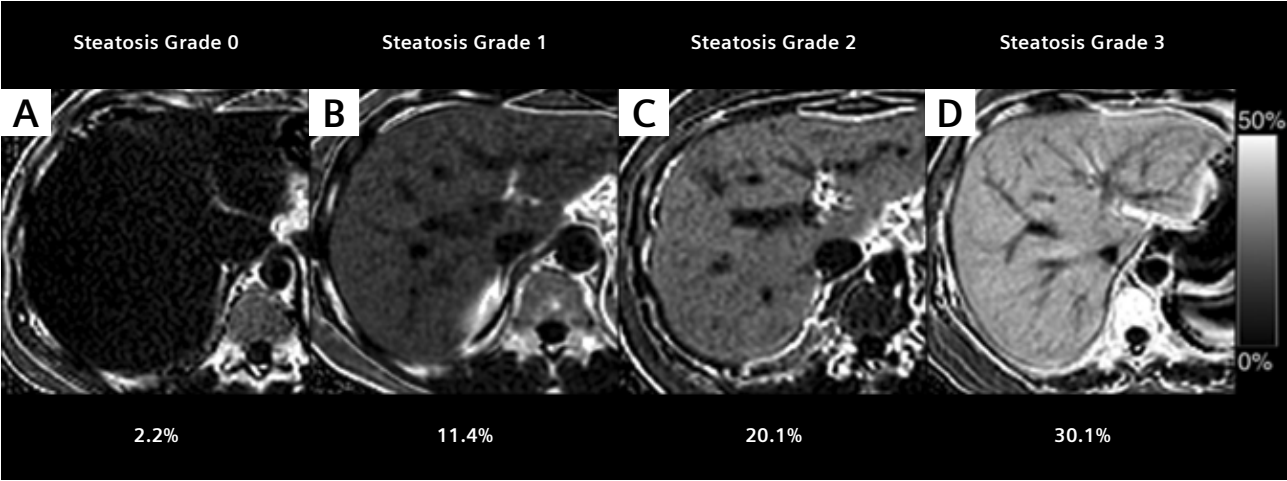


Figure 3: Representative MR PDFF images from patients with different degrees of liver steatosis (grades 0 to 3).
(Image adapted from Tang et al. [9])

MRI-derived proton density fat fraction (PDFF)

Magnetic resonance imaging proton density fat fraction (PDFF) is a quantitative, non-invasive biomarker that provides a chemical measure of tissue fat (triglyceride) concentration. PDFF is calculated as the ratio of mobile protons in fat molecules to the total mobile protons in fat and water. It has been validated against liver biopsy and MR spectroscopy and demonstrates excellent reproducibility across different field strengths and scanner vendors, as shown in several meta-analyses [7]. **Table 2** shows the PDFF thresholds commonly used in clinical practice [8]. These thresholds are based on comparisons between PDFF measurements and biopsy histologic grades [9]. **Figure 3** presents representative MR PDFF images from patients with different degrees of steatosis, illustrating the progressive increase in fat accumulation with disease severity [9].

PDFF (%)	Histologic Steatosis Grade
<6%	Grade 0 (normal)
6%-17%	Grade 1 (mild)
17%-22%	Grade 2 (moderate)
>22%	Grade 3 (severe)

Table 2: PDFF thresholds for histologic grades of hepatic steatosis (adapted from Guglielmo et al. [8])

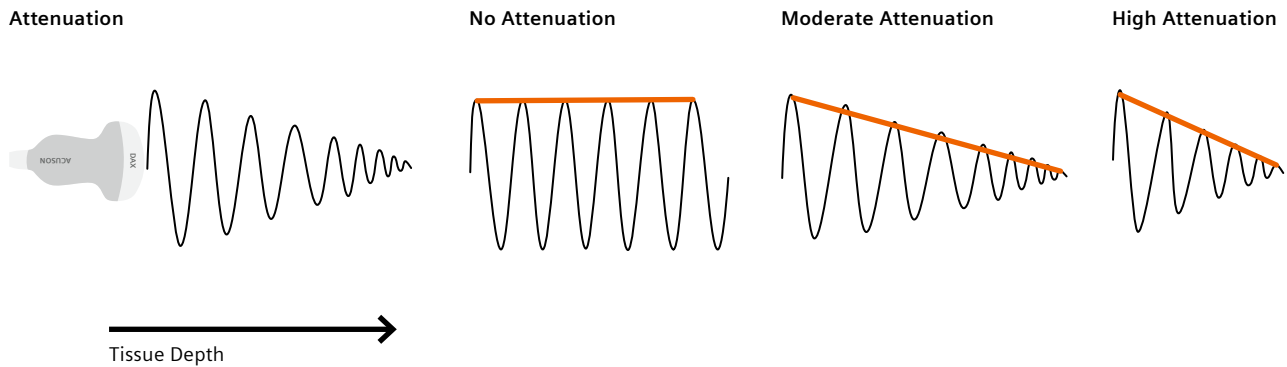


Figure 4: Schematic illustration of ultrasound attenuation in liver tissue. As sound waves travel through tissue, their amplitude decreases with increasing attenuation. The slope of the amplitude decay (orange line) reflects the attenuation coefficient, which increases with higher fat content. No attenuation represents minimal liver fat, moderate attenuation corresponds to intermediate fat content, and high attenuation reflects severe hepatic steatosis.

Ultrasound-derived fat fraction (UDFF)

While MRI PDFF is considered the most accurate non-invasive method for assessing hepatic fat, ultrasound offers a more accessible and scalable approach. The World Federation for Ultrasound in Medicine and Biology (WFUMB) [10] recommends PDFF as the reference standard in studies evaluating new ultrasound algorithms for estimating liver fat content.

Siemens Healthineers **ultrasound-derived fat fraction (UDFF)** provides a non-invasive ultrasound-based estimate of PDFF. It combines measurements of **ultrasound attenuation** and **ultrasound backscatter** through a validated algorithm [11]. The system employs a **reference phantom method** [12] to correct for system-dependent factors, such as transducer gain and beam-focusing characteristics. Reference phantom data are obtained by scanning a phantom with known

acoustic properties using production-equivalent transducers. These data are stored within the system and serve as the calibration baseline for UDFF acquisition.

Ultrasound attenuation is the reduction or loss of energy (intensity) from sound waves, and greatly affects the ultrasound image. Sound is lost (attenuated) more readily with increasing depth, making structures located deep within the body more difficult to visualize. Fatty tissue absorbs and scatters sound more than non-fatty tissue, resulting in greater energy loss. Attenuation is influenced by depth, frequency, and tissue type, and is measured by estimating how the frequency content of the sound wave decreases at increasing tissue depths compared with a reference.

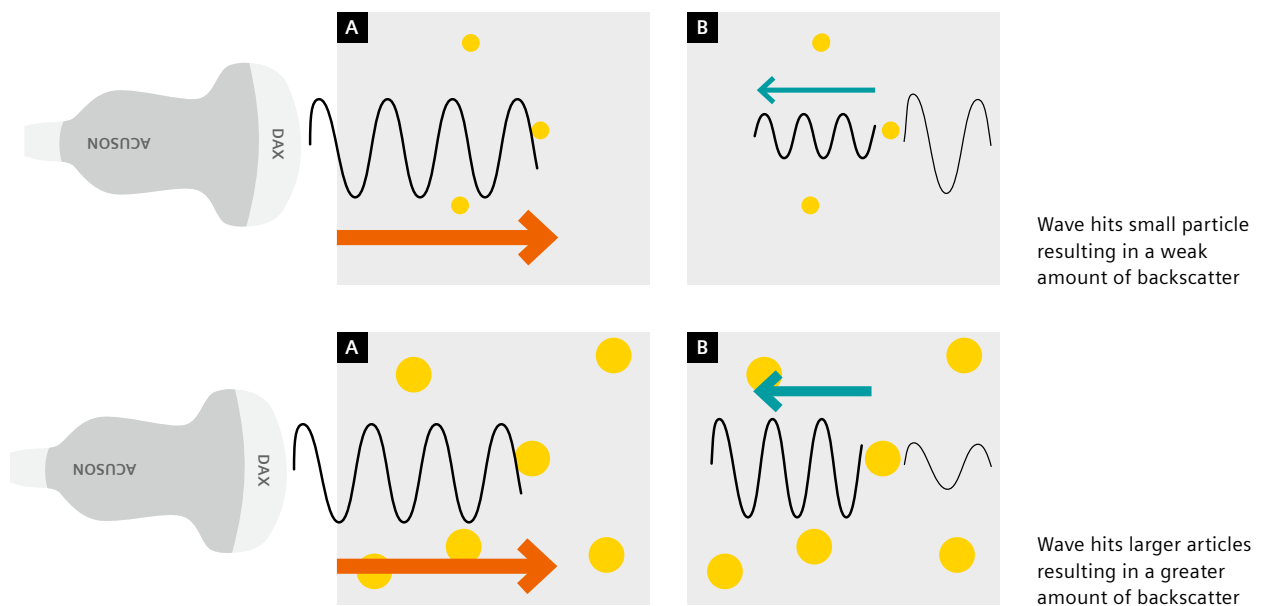


Figure 5: Schematic illustration of ultrasound backscatter in liver tissue. Top panels: waves encountering smaller fat droplets produce weak backscatter. Bottom panels: waves encountering larger fat droplets produce stronger backscatter. The amount of reflected sound increases with the size and abundance of fat-containing cells, explaining how ultrasound backscatter correlates with liver fat content.

Ultrasound backscatter measures the energy of sound waves reflected from tissue, providing a quantitative parameter similar to the echogenicity seen on B-mode imaging. The reflection of sound is determined by the physical characteristics and size of cells within the liver. As fat accumulates, liver cells enlarge, and larger cells reflect more sound. Therefore, the greater the proportion of large fat-containing cells, the higher the amount of ultrasound energy returned to the transducer. This increase in backscatter correlates with the degree of hepatic fat accumulation.

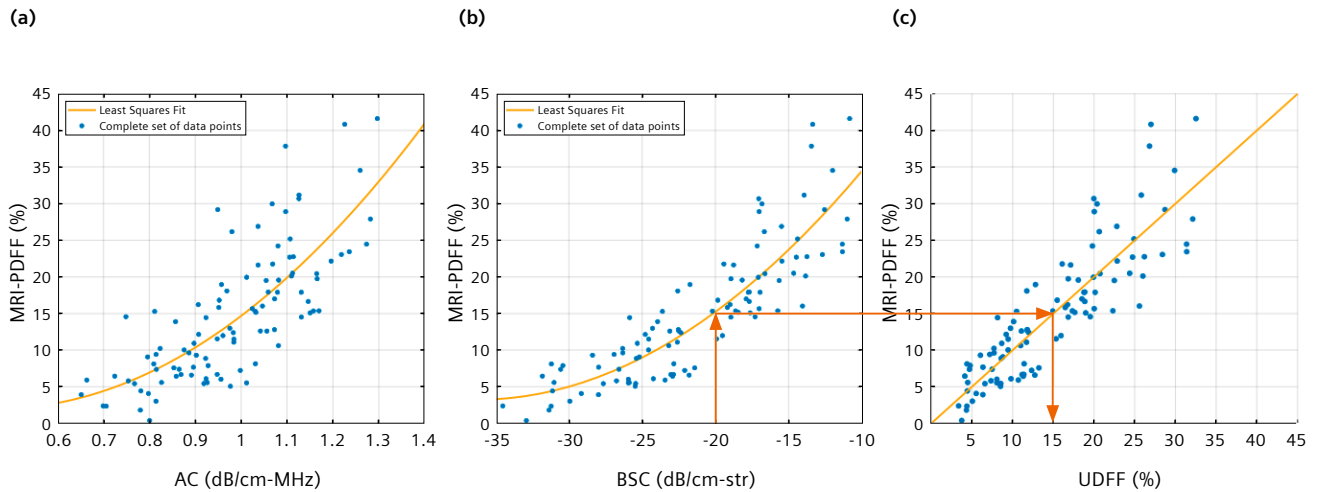


Figure 6: Relationship between ultrasound acoustic parameters and MRI-PDFF. (a) MRI-PDFF versus attenuation coefficient (AC). (b) MRI-PDFF versus backscatter coefficient (BSC), both showing nonlinear relationships with MRI-PDFF. (c) MRI-PDFF versus predicted ultrasound-derived fat fraction (UDFF). The orange arrows depict the mapping of a BSC value to its corresponding UDFF value. (Image adapted from Labyed et al. [11])

Figure 6 shows the relationship between ultrasound acoustic parameters and liver fat content. Both the attenuation coefficient (AC) and backscatter coefficient (BSC) exhibit nonlinear relationships with MRI-PDFF. To linearize this relationship, a least-squares regression is used to determine the optimal mapping between the BSC and MRI-PDFF. The resulting regression coefficients are then incorporated into the UDFF formula to predict PDFF from the BSC values, as shown in **Figure 6(c)**.

UDFF is currently available on three Siemens Healthineers ultrasound systems: ACUSON Juniper, ACUSON Redwood, and ACUSON Sequoia. Representative images from each system demonstrate consistent visualization and quantification of liver fat content in participants with normal, mild, and severe steatosis.

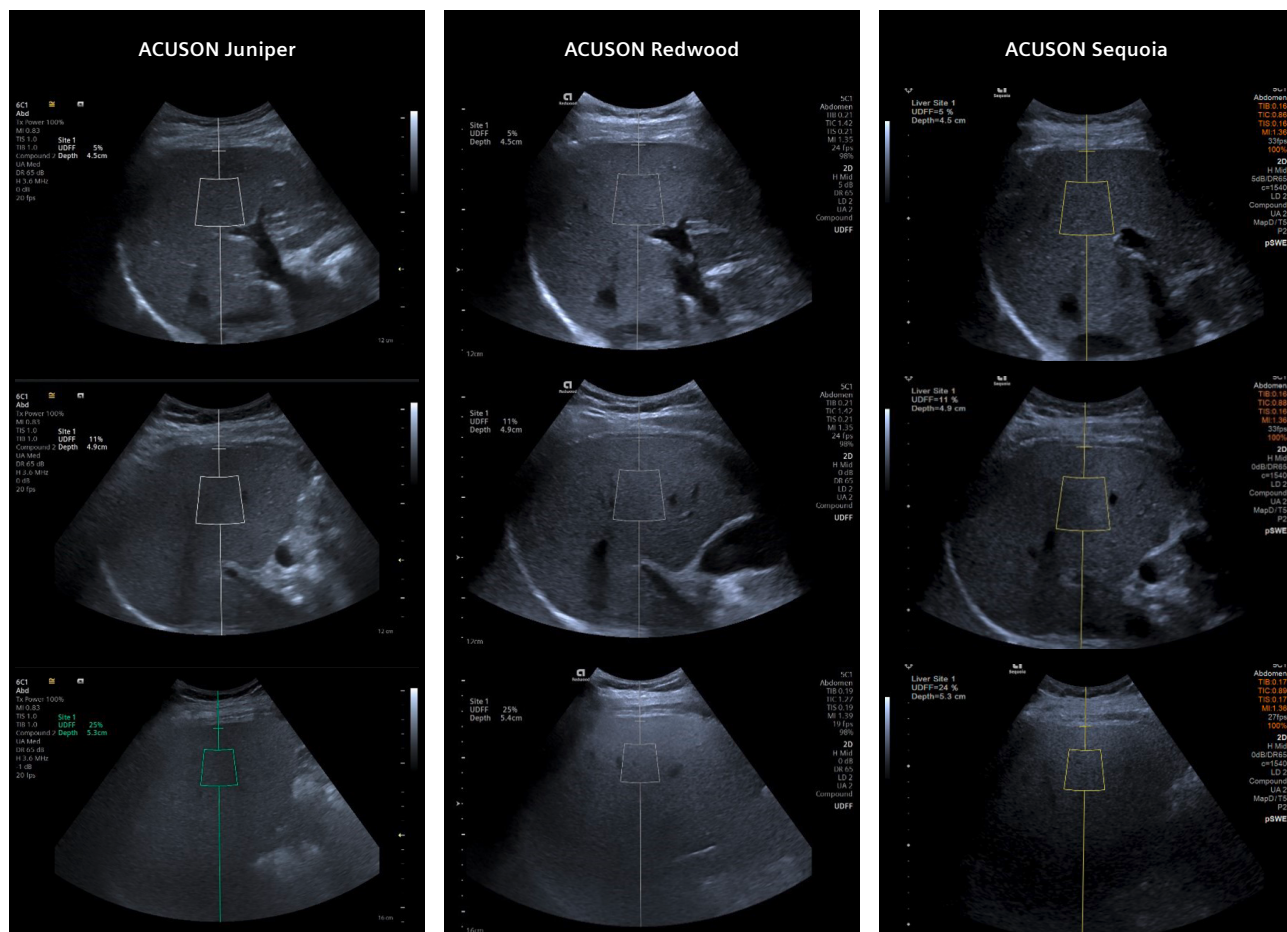


Figure 7: Representative ultrasound images with UDFF measurements from three Siemens Healthineers systems – ACUSON Juniper, ACUSON Redwood, and ACUSON Sequoia – in three participants with normal, mild, and severe steatosis, respectively.

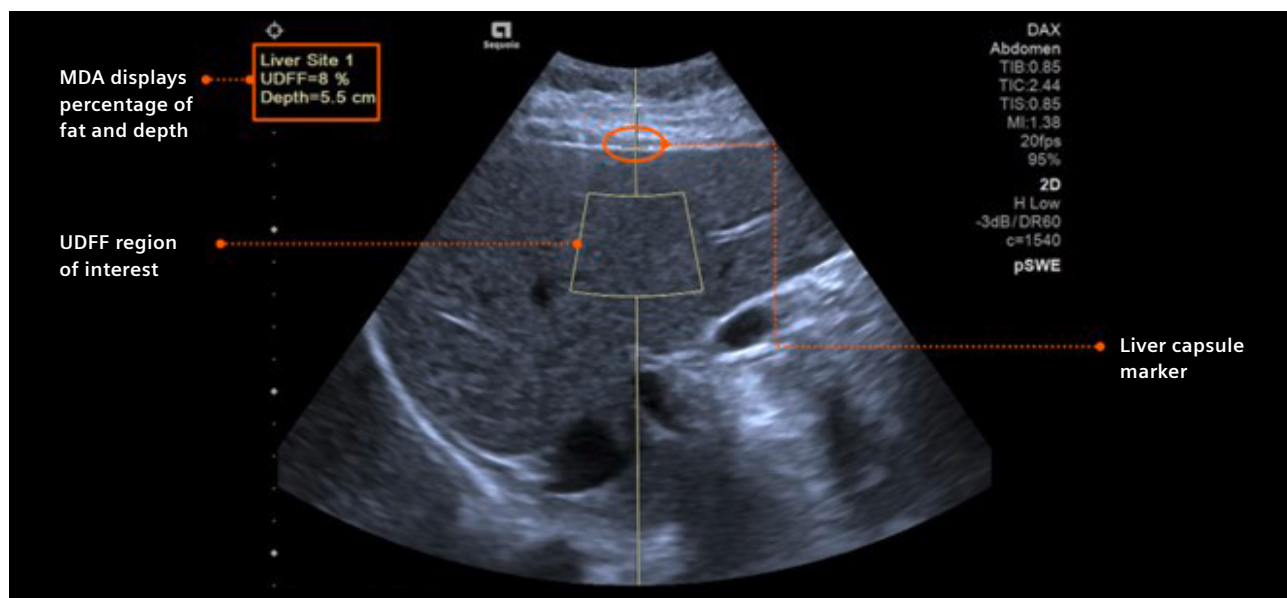
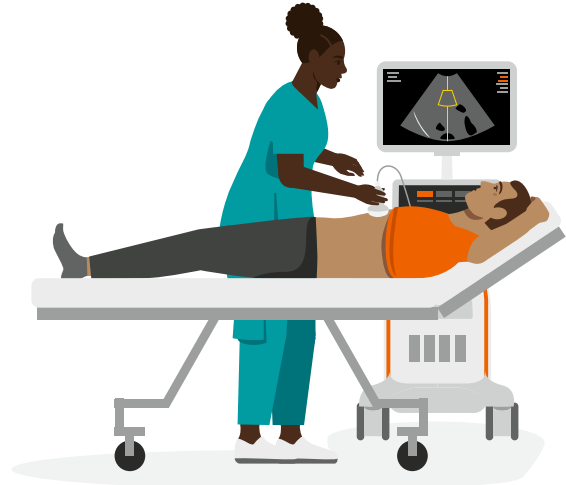


Figure 8: An ultrasound image of the liver showing the measurement of ultrasound-derived fat fraction (UDFF), which indicates a percentage of 8% within the specified region of interest (ROI). The liver capsule marker simplifies the positioning of the ROI according to the suggested scanning guide.

Scanning protocol

Scan the right hepatic lobe using a lateral intercostal approach with the patient in a supine position and the right arm maximally abducted to widen intercostal spaces and minimize rib interference. Patients should fast for at least four hours when liver stiffness is measured in conjunction with UDFF. Obtain a high-quality B-mode image by minimizing rib shadows, ensuring adequate transducer contact with ample gel and maintaining light, consistent pressure. Place the measurement box perpendicular to the transducer within homogeneous liver parenchyma, avoiding large vessels, ducts, shadows, anatomic interfaces, focal lesions, and ribs. Position the upper edge 1.5-2 cm below the liver capsule, refining alignment by gentle tilting or rocking of the transducer. Acquire data during shallow expiration breath-holds to minimize motion artifacts, avoiding deep inspiration, full expiration, or Valsalva maneuvers. Obtain five valid UDFF measurements at the same site and report the median value.



Protocol	Notes
Fasting is mandatory	Fast for at least four hours if measuring liver stiffness with UDFF.
Right intercostal space	Supine position with arm at maximum abduction to maximize intercostal spacing and avoid ribs.
Best quality of B-mode image	Minimize rib shadows and ensure good transducer contact with ample ultrasound gel and maintain light pressure throughout the scan.
Measurement box perpendicular to transducer	Place box in liver parenchyma and avoid areas with large vessels, large ducts, shadows, anatomic interfaces, focal pathology, or ribs.
Upper edge of measurement box 1.5 to 2 cm below liver capsule	Position measurement box below the liver capsule and align the indicator with the capsule. Tilting or rocking the transducer may be needed for alignment.
Breath hold	Take measurement at neutral breathing during a breath hold to minimize blurring during acquisition.
Median value of 5 valid UDFF measurements	Acquire five valid measurements at the same site and report the median value. Invalid measurements are indicated by X.X.

Table 3: Suggested scanning protocol for UDFF based on the WFUMB [10]/SRU [13] guide.

Clinical evidence

UDFF is a software tool indicated as an aid in managing patients with hepatic steatosis. It is indicated for adults and children on the ACUSON Sequoia ultrasound system and for adults only on the ACUSON Redwood and ACUSON Juniper ultrasound systems. UDFF is the first ultrasound biomarker to quantify liver fat content as a percentage, similar to MRI-PDFF. Total examination time is typically under one minute based on three to five acquisitions. The percentage fat value is straightforward for clinicians and patients to interpret.

A recent meta-analysis published in *European Radiology* [14] reviewed nine studies including more than 1,100 patients. The analysis found that UDFF demonstrates good sensitivity (90.4%) and specificity (83.8%) for detecting steatosis as measured by MRI-PDFF, supporting its value as a noninvasive screening tool.

Clinical studies have shown that UDFF has good agreement with MRI-PDFF [15, 16] and strong diagnostic performance in detecting and grading hepatic steatosis [11, 15-23]. UDFF also exhibits excellent repeatability and reproducibility [15, 24, 25]. Note that UDFF showed a slight positive bias compared with MRI-PDFF, and both intra-operator and inter-operator variability increased with higher degrees of steatosis [15].

Key findings from these studies are summarized in the following tables: **Table 4** – UDFF versus histologic steatosis grades; **Table 5** – UDFF versus MRI-PDFF grades; and **Table 6** – UDFF reliability, including repeatability and reproducibility.

Author [year]	Country [number of participants]	Study type	Patient selection	BMI range	Steatosis grade	AUC	UDFF cutoff (%)	Sensitivity (%)	Specificity (%)
Xue ²³ [2025]	China [790]	Prospective	Adults suspected of MASLD	IQR 22.6-38.4	0 vs ≥1	0.95	6.0	93	96
					≤1 vs ≥2	0.90	12.0	93	90
					≤2 vs 3	0.92	16.0	92	92
Labyed ¹¹ [2020]	USA [90]	Prospective	Adults with known or suspected MASLD	min-max 17.6-43.3	0 vs ≥1	0.94	8.1	84	100
					≤1 vs ≥2	0.88	15.9	77	89
					≤2 vs 3	0.83	16.1	100	78
Nakamura ¹⁷ [2024]	Japan [73]	Prospective	Adults with liver disease	IQR 22.2-29.5	0 vs ≥1	0.96	6.0	95	82
					≤1 vs ≥2	0.93	15.0	71	92
					≤2 vs 3	0.97	20.0	100	94
Kale ²² [2025]	Turkey [121]	Prospective	Adults suspected of liver disease	IQR 24.2-31.1	0 vs ≥1	0.97	8.4	93	93
					≤1 vs ≥2	0.93	10.4	100	80
					≤2 vs 3	0.96	18.3	100	77
Sun ²¹ [2024]	China [85]	Retrospective	Obese adults with liver biopsy	min-max 32.2-60.9	≤1 vs ≥2	0.82	20.5	86	68
					≤2 vs 3	0.75	23.5	81	65

Table 4: Summary of clinical studies comparing UDFF with **histologic** steatosis grades.

Author [year]	Country [number of participants]	Study type	Patient selection	BMI range	MRI-PDFF grade	AUC	UDFF cutoff (%)	Sensitivity (%)	Specificity (%)
Zalcman ²⁰ [2024]	USA [46]	Prospective	Children with clinically indicated abdominal MRI	min-max 15-39	≤6% vs >6%	0.95	6.0	90	94
Labyed ¹¹ [2020]	USA [101]	Prospective	Adults with known or suspected MASLD	min-max 17.6-43.3	≤5% vs >5%	0.97	6.3	94	100
Dillman ²⁶ [2022]	USA [56]	Prospective	Overweight and obese age ≥16 years	IQR 29.1-39.3	≤5.5% vs >5.5%	0.90	5.0	94	64
Kubale ¹⁵ [2024]	Germany [187]	Prospective	Adults scheduled to undergo MRI	min-max 17.8-55.8	≤6% vs >6%	0.90	6.8	92	67
					≤17% vs >17%	0.95	15.8	91	87
					≤22% vs >22%	0.95	19.8	93	88
Wang ¹⁹ [2024]	China [217]	Prospective	Adults suspected of having MASLD	IQR 20.0-29.3	≤6% vs >6%	0.99	6.0	97	91
					≤17% vs >17%	0.96	15.0	100	82
					≤22% vs >22%	0.97	23.0	88	95
Qi ¹⁶ [2024]	China [176]	Prospective	Adults scheduled to undergo MRI and US	IQR 29.0-47.8	≤6% vs >6%	0.85	5.5	79	82
					≤17% vs >17%	0.95	15.5	88	91
					≤22% vs >22%	0.95	17.5	89	90
Huang ¹⁸ [2025]	China [300]	Prospective	Adults scheduled to undergo MRI and US	IQR 24.6-30.1	<5% vs ≥5%	0.90	7.6	87	81
					<15% vs ≥15%	0.90	15.9	83	84
					<22% vs ≥25%	0.91	22.3	80	91

Table 5: Summary of clinical studies comparing UDFF with MRI-PDFF grades.

Author [year]	Country [number of participants]	Study type	Patient selection	BMI range	ICC: Intra-operator repeatability	ICC: Inter-operator reproducibility
Kubale ¹⁵ [2024]	Germany [30]	Prospective	Adults scheduled to undergo MRI	min-max 18.3-45.7	≥0.98	≥0.90
Gao ²⁵ [2020]	USA [21]	Prospective	Adults	IQR~ 23.4-38.6	≥0.97	≥0.93
Song ²⁴ [2024]	China [105]	Prospective	Adults	IQR~ 19.8-30.2	≥0.96	≥0.93

ICC = Intra-class correlation coefficient

Table 6: Summary of clinical studies evaluating the reliability of UDFF, including repeatability and reproducibility.



Figure 9: UDFF is currently available on three Siemens Healthineers ultrasound systems: ACUSON Sequoia, ACUSON Redwood, and ACUSON Juniper.

Conclusion

Liver disease is increasingly recognized as a major public health concern worldwide. Nearly 30% of the global population is affected by MASLD, yet only a small fraction is aware of their condition. While symptoms often remain unnoticed, the underlying damage continues to progress. Early detection is therefore critical – when identified in time, liver disease can be treated and, in many cases, reversed.

Ultrasound is redefining how liver disease can be detected and monitored. Unlike MRI or biopsy, it is more accessible and scalable. With advances like UDFF technology, a comprehensive liver assessment can now be completed in less than one minute based on **three to five acquisitions**. This enables seamless integration

into routine abdominal scans. Clinicians can now detect liver abnormalities proactively during standard check-ups, without adding burden to workflow or patient experience.

The **ACUSON liver imaging suite**, enhanced by UDFF, delivers MRI-comparable diagnostic insights with far greater reach and affordability. Together, these innovations are positioning ultrasound as a frontline, non-invasive solution for liver assessment – bridging the gap between advanced imaging and everyday clinical care and supporting large-scale public health initiatives aimed at tackling the global burden of liver disease.

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