

White paper

Updated abdomen shear wave elastography for liver assessment

ACUSON Sequoia 3.9

siemens-healthineers.com/ultrasound

Introduction

Chronic liver disease is a worldwide problem associated with a broad range of contributing factors. While these factors may differ between individuals, the pathway and progression of liver disease does not. The major consequence of this disease state is the increasing deposition of fibrous tissue within the liver that can lead to the development of liver cirrhosis. Once the liver becomes cirrhotic, this disease state can ultimately lead to complications such as portal hypertension, hepatic insufficiency, and hepatocellular carcinoma.

Acoustic Radiation Force Impulse (ARFI) imaging is an ultrasound-based quantitative elastography technology that has been increasingly used in the assessment and management of chronic liver disease. This shear wave elastography tool is based on the principle that as advanced liver disease increases, there is an associated increase in liver stiffness. This increase in liver stiffness is also indicative of a loss (decrease) in tissue elasticity. With this principle in mind, the evaluation of chronic liver disease is an important factor to determine the patient’s initial degree of disease, continued surveillance, prioritization for treatment, and even to evaluate the clinical outcome [1].

Contents

Liver elastography guidelines	3
How ARFI works	4
Best practice techniques	6
ACUSON Sequoia 3.9 liver elastography multicenter study	7
Conclusion	11

Interpretation of liver stiffness measurement obtained using ARFI-SWE technique (rule of four)

ARFI-SWE LSM	Interpretation
≤ 5 kPa (1.3 m/s)	High probability of being normal
< 9 kPa (1.7 m/s)	In the absence of other known clinical signs, rules out cACLD. If there are known clinical signs, further testing may be needed for confirmation.
9-13 kPa (1.7-2.1 m/s)	Suggestive of cACLD but further testing is required for confirmation.
> 13 kPa (2.1 m/s)	Rules in cACLD
> 17 kPa (2.4 m/s)	Suggestive of CSPH
> 21 kPa (2.6 m/s)	High probability of CSPH

Reproduced (modified), with permission, from Barr et al. [1].

ARFI, acoustic radiation force impulse; cACLD, compensated advanced chronic liver disease; CSPH, clinically significant portal hypertension; LSM, liver stiffness measurement.

Table 1: Table reproduced from WFUMB, 2024 [2].

Liver elastography guidelines

The identification of compensated advanced chronic liver disease allows for screening and surveillance of varices and hepatocellular carcinoma. In 2020, the Society of Radiologists in Ultrasound (SRU) introduced the “rule of four” for interpreting stiffness values measured by acoustic radiation force impulse (ARFI) elastography imaging. The guide is based on the probability of chronic liver disease for given stiffness values. In 2024, the World Federation for Ultrasound

in Medicine and Biology (WFUMB) panel “agrees that the ‘rule of four’ for ARFI-SWE techniques may be considered for evaluating the risk of advanced disease” [2]. The “rule of four” stratifies stiffness values into categories for assessing the severity of liver disease (Table 1).

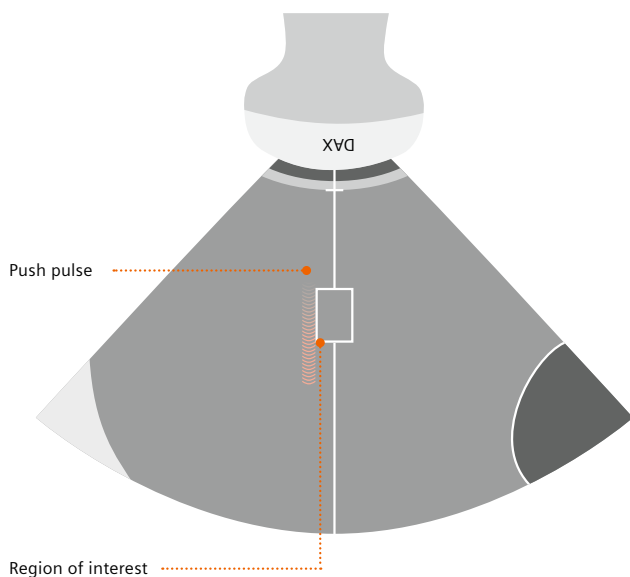


Fig. 1a: Tissue is compressed using an acoustic push pulse focused on a user-defined region of interest (ROI). This approach maximizes the local displacement of the tissue resulting in a more controllable application of stress than with manual (surface) compression. This ROI-focused approach improves the uniformity of the elastogram.

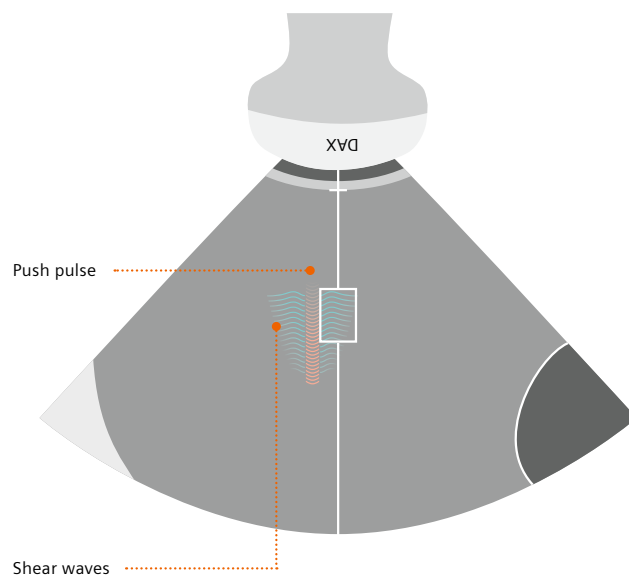


Fig. 1b: The tissue displacement caused by the push pulse results in the generation of shear waves. Shear waves are weak waves that travel laterally and perpendicularly to the push pulse. The speed of these waves (1-10 m/s) is influenced by the tissue through which they are propagating.

How ARFI works

To assess liver stiffness, ARFI uses brief ultrasound “push pulses” to excite a narrow region within the liver parenchyma (Figure 1a). This excitation results in minute displacements of tissue, resulting in shear waves that move laterally away from the line of the push pulse (Figure 1b). These shear waves can be tracked by lower energy ultrasound beams which then measure the speed of the propagating shear wave. The shear wave velocity is measured within a small region of interest and is expressed in meters per second (m/s) and/or kilopascals (kPa) (Figure 1c).

The ACUSON Sequoia platform includes three ARFI-based methods for liver stiffness assessment

Point Shear Wave Elastography (pSWE) – Provides an average shear wave velocity from multiple ARFI “push pulses” within the same region of interest (ROI). pSWE is designed for monitoring diffuse liver disease, including cirrhosis.

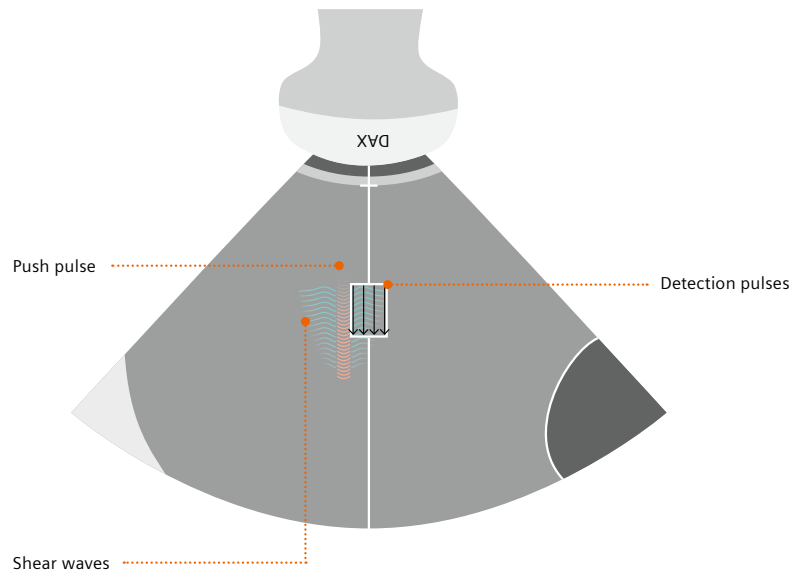


Fig. 1c: The low velocity aspect of the shear waves allows for easy tracking as they propagate through the tissue. Multiple detection pulses (arrows) are applied within the ROI. The detection pulses measure the arrival time of the shear wavefront at multiple locations. This information is used to calculate the shear wave propagation speed.

Auto pSWE – Workflow enhancement based on pSWE technology. Acquires up to 15 individual pSWE measurements with one button-press providing up to 15 valid assessments in under 1 minute. Every sub-ROI generates a pSWE result from independent ARFI “push pulses”.

2D Shear Wave Elastography (2D SWE) – Creates a color-coded display of tissue velocity, stiffness, quality and ARFI displacement. Multiple spatially lateral ARFI “push pulses” generate shear waves that are blended to generate the color-coded display. Designed for visual assessment of lesions or other regions of interest with the goal of identifying possible variations in stiffness.

Best practice techniques

The key to performing a successful liver shear wave elastography exam lies within following best practice techniques. Deviation from these recommendations can negatively impact (elevate) shear wave measurements or produce invalid (X.XX m/s or XX.X kPa) results. The following section discusses proper patient preparation, positioning, and scanning technique, based on the SRU and WFUMB recommended protocol for the acquisition of reliable liver stiffness measurements [1], [2].

Patient preparation and positioning

Prior to the ultrasound exam, the patient must fast for at least 4 hours. Exams performed on a non-fasted liver can produce falsely increased shear wave values. The patient should be comfortably positioned in a supine or slight left lateral decubitus position with their right arm raised above their head. Raising the arm allows for better intercostal window access when scanning the liver.

Scanning technique

Once the patient is correctly positioned, the next step is to ensure proper transducer and ROI placement. For optimal and reproducible results, it is recommended to:

- Obtain measurements within the right lobe of the liver via an intercostal approach with the transducer perpendicular to the skin line.
- Use ample ultrasound gel to ensure good contact with the skin and maintain light pressure throughout the scan. Firm pressure may artificially elevate the observed shear wave speed measurement.
- To place the region of interest (ROI), select a good acoustic window with no rib shadowing, vessels, large ducts, or focal pathology.
- Place the ROI perpendicular and at least 1.5-2 cm deep to the liver capsule using the “+” depth marker. Ensure that the marker is parallel to the capsule – tilting or rocking the transducer may be necessary to achieve this alignment.
- When acquiring a measurement, instruct the patient to suspend respiration in a way that provides a good window as described above. Avoid prolonged inspiration, expiration, and Valsalva which can artificially elevate the pSWE results.
- To prevent invalid measurements resulting from motion, avoid relative movement between the transducer and ROI. Cardiac motion is also to be avoided.
- Obtain one acquisition per suspended respiration; attempting to take more than one reading tends to result in respiratory motion or a part Valsalva.

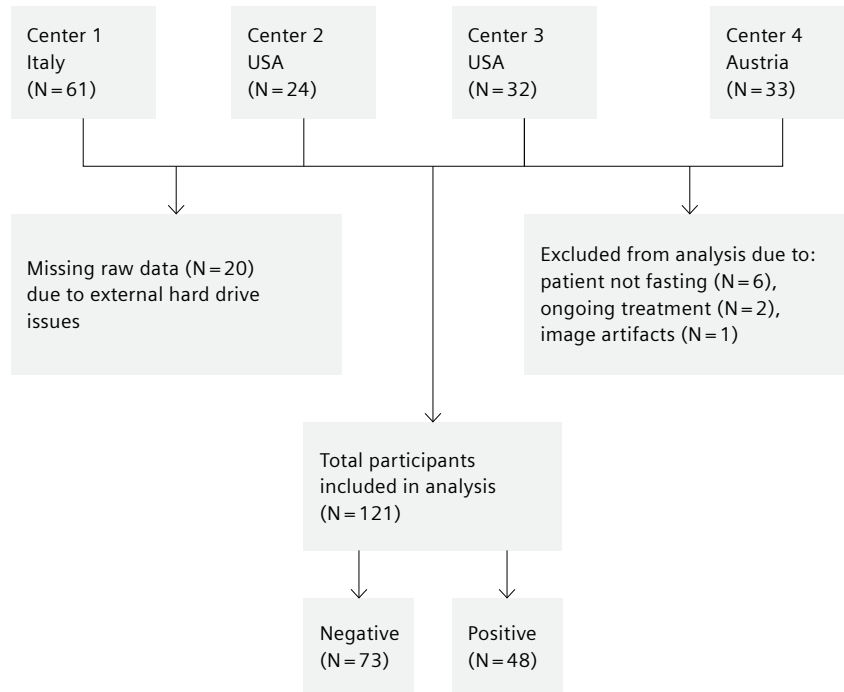


Fig. 2: Inclusion flowchart for multi-center liver SWE study.

ACUSON Sequoia 3.9 liver elastography multicenter study

This study aimed to evaluate the performance of shear wave elastography on the ACUSON Sequoia ultrasound system for assessing advanced liver disease in adult patients, with reference to independent diagnosis performed by the radiologist. This study compared predicate release software to the updated abdomen shear wave elastography algorithm in the Sequoia 3.9 release.

A multicenter study was conducted using the ACUSON Sequoia Ultrasound System. The study included adult patients from four centers who had indications for diagnostic abdominal ultrasound examinations.

Center 1 in Italy (September 2022 to December 2022), Center 2 in the USA (October 2023 to November 2024), Center 3 in the USA (August 2020 to October 2020), and Center 4 in Austria (August 2021 to September 2023). Patients were grouped into negative and positive cases based on established clinical criteria for liver assessment, including imaging, laboratory results, and, where applicable, biopsy. Shear wave elastography (SWE) measurements were acquired following WFUMB scanning guidelines for liver elastography [1]. For statistical analysis, liver stiffness measurements were stratified in the following thresholds: ≤ 5 kPa, < 9 kPa, 9–13 kPa, and > 13 kPa.

Parameter	Overall (N = 121)	Negative (N = 73)	Positive (N = 48)	P Value
Age (y)	50.2 ± 17.0 [18.0-88.0]	52.0 ± 15.7 [18.0-81.0]	47.6 ± 18.5 [18.0-88.0]	0.124
BMI (kg/m ²)	30.9 ± 9.4 [16.9-62.3]	29.6 ± 7.5 [18.8-51.4]	32.8 ± 11.6 [16.9-62.3]	0.321
BMI (kg/m²)				0.785
BMI ≤ 25	30.6% (37/121)	62.2% (23/37)	37.8% (14/37)	
BMI > 25	69.4% (84/121)	59.5% (50/84)	40.5% (34/84)	
Sex				0.025
Male	43.8% (53/121)	49.1% (26/53)	50.9% (27/53)	
Female	56.2% (68/121)	69.1% (47/68)	30.9% (21/68)	
Updated software				
SWE (kPa)	7.4 ± 4.8 [2.5-32.9]	5.6 ± 2.6 [2.5-17.6]	10.2 ± 5.9 [4.0-32.9]	< .001
IQR/Median	14.4 ± 9.9 [1.0-52.0]	13.7 ± 8.9 [2.6-51.9]	15.5 ± 11.2 [1.0-52.0]	0.662
Predicate software				
SWE (kPa)	4.9 ± 3.0 [1.3-17.3]	3.8 ± 1.7 [1.3-11.1]	6.7 ± 3.6 [2.5-17.3]	< .001
IQR/Median	10.1 ± 8.4 [1.0-76.0]	9.5 ± 5.2 [1.0-25.9]	11.2 ± 11.7 [1.3-76.0]	0.964

Table 2: Participant characteristics and imaging results.

The proportions of patients identified as positive or negative were calculated for each liver stiffness stratum. To compare patient characteristics between both groups, Mann-Whitney U tests were used for continuous variables, and Chi-square tests were used for categorical variables. A p-value of <0.05 was considered statistically significant.

Figure 2 shows the inclusion flowchart. Table 2 shows the patient characteristics. The cohort comprised 121 patients (68 female, 53 male) with a mean age of 50.2 ± 17 years (range, 18-88 years). Of these, 40% (48/121) were identified as positive. In positive patients, the mean SWE stiffness value was 10.2 ± 5.9 kPa, compared to 5.6 ± 2.6 kPa in negative patients (p < 0.001).

Raw data was processed for both updated and predicate ARFI-SWE software, to perform a one-to-one comparison for the multicenter study. Figure 3 shows the set of boxplots of SWE stiffness values for the two groups, comparing updated and predicate software.

For the updated software, the probability of liver disease increased with higher stiffness: 18.6% (8/53) for ≤ 5 kPa, 27.8% (25/90) for < 9 kPa, 61.1% (11/18) for 9-13 kPa, and 92.3% (12/13) for > 13 kPa. For the predicate software, the trend increased in a similar fashion, however with lower cases in higher stiffness thresholds: 25.3% (21/83) for ≤ 5 kPa, 35.7% (40/112) for < 9 kPa, 80.0% (4/5) for 9-13 kPa, and 100.0% (4/4) for > 13 kPa.

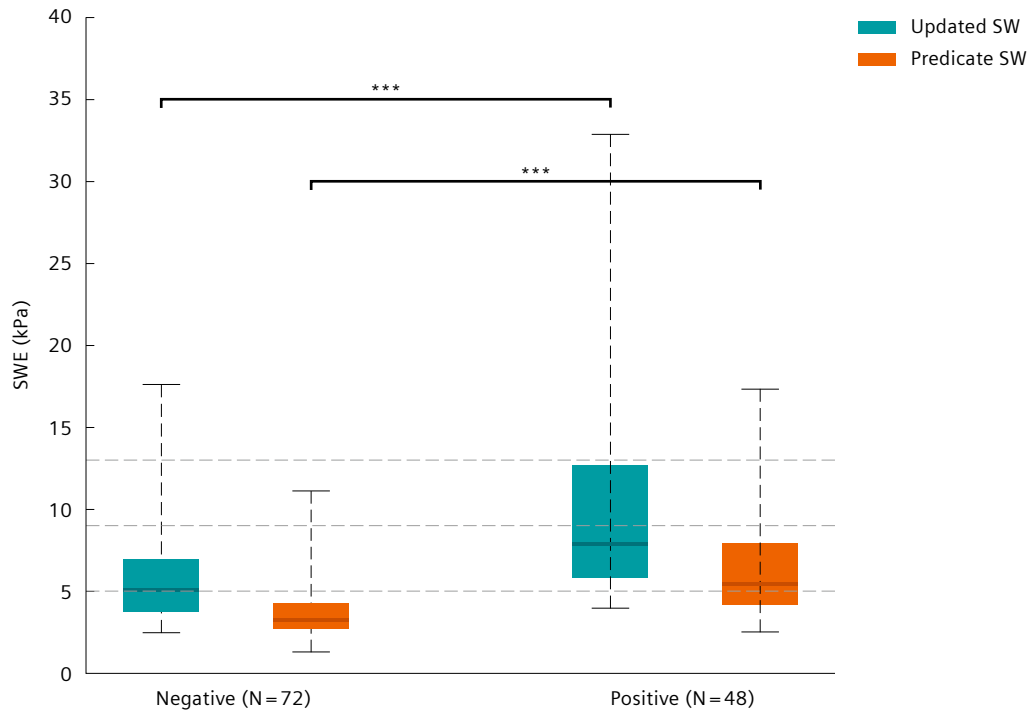
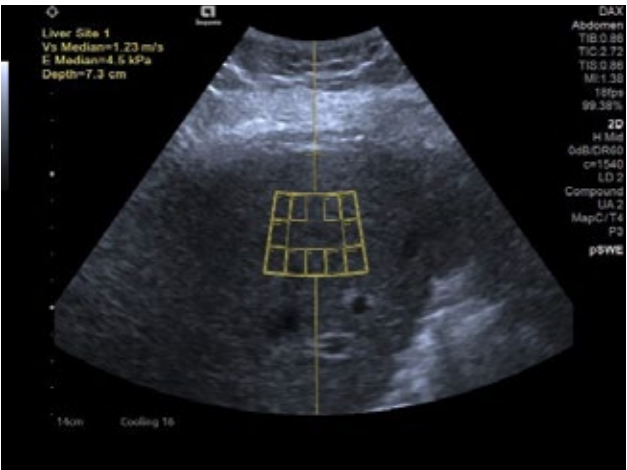


Fig. 3: Box-and-whisker plots of SWE versus liver disease diagnosis in adults, comparing updated software to predicate software. The panel compares confirmed negative and positive results in adults. Data are presented as median (solid line), interquartile range (box), and full range (whiskers). In both plots, the two cohorts had statistically significant differences based on the Mann–Whitney test (** $P < .001$). Dashed lines represent SRU/WFUMB cutoff guidelines [1], [2].

In comparison to the predicate software, for results ≤ 5 kPa, the number of false negatives decreased from 25.3% to 18.6% with the updated software; for results < 9 kPa, the number of false negatives decreased from 35.7% to 27.8% with the updated software, representing an improved sensitivity. In terms of true positives, the predicate software identified 4 cases of confirmed positive patients with stiffness 9–13 kPa, and 4 cases of confirmed positive patients with stiffness > 13 kPa, whereas the updated software identified 11 cases of confirmed positive patients with stiffness 9–13 kPa and 12 cases of confirmed positive patients with stiffness > 13 kPa, representing an improved performance for stratification of stiffness values using the thresholds for analysis.

The study results indicate that the new SWE algorithm on the ACUSON Sequoia 3.9, expands the dynamic range of estimated stiffness values, compared to previous releases. The SWE values in ACUSON Sequoia 3.9 are more aligned with published expected ranges, including the SRU/WFUMB “rule of four” [1], [2]. For longitudinal studies and longitudinal patient monitoring, the differences in SWE compared to previous releases (Table 2) must be considered per clinical guidelines used on the corresponding site. Higher SWE stiffness values can help support clinical decisions regarding the probability of liver disease. SWE on the ACUSON Sequoia 3.9 is for general liver assessments in patients with indication for abdominal ultrasound examinations.

Predicate release



ACUSON Sequoia 3.9

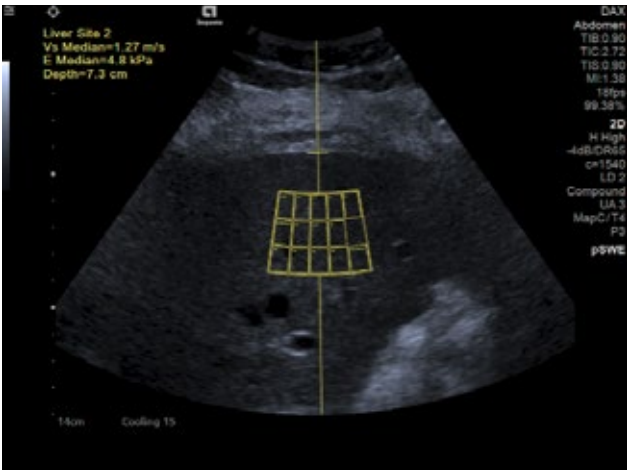


Fig. 4: Example 48-year-old healthy liver patient with BMI=44, scanned with predicate (left) vs. ACUSON Sequoia 3.9 liver elastography software using the DAX transducer with Auto pSWE.

ACUSON Sequoia 3.9

Parameter	Overall (N = 121)	Negative (N = 73)	Positive (N = 48)
SWE (kPa)	7.4 ± 4.8 [2.5-32.9]	5.6 ± 2.6 [2.5-17.6]	10.2 ± 5.9 [4.0-32.9]
IQR/Median	14.4 ± 9.9 [1.0-52.0]	13.7 ± 8.9 [2.6-51.9]	15.5 ± 11.2 [1.0-52.0]
Stiffness range			
≤ 5 kPa	35.5% (43/121)	81.4% (35/43)	18.6% (8/43)
< 9 kPa	74.4% (90/121)	72.2% (65/90)	27.8% (25/90)
9-13 kPa	14.9% (18/121)	38.9% (7/18)	61.1% (11/18)
> 13 kPa	10.7% (13/121)	7.7% (1/13)	92.3% (12/13)

Table 3: ACUSON Sequoia 3.9 liver elastography results.

As indicated by the WFUMB guidelines, it is important to recognize that the thresholds between liver disease grades are not absolute and that factors other than fibrosis may impact pSWE measurements. Two examples of confounding factors are acute inflammatory activity or venous congestion. In each case, these disease processes can elevate the pSWE values and artificially elevate the stiffness staging. With these limitations in mind, results should be interpreted within an individual patient’s given clinical context [2].

Predicate release



ACUSON Sequoia 3.9



Fig. 5: Example 49-year-old healthy liver patient with BMI=26, scanned with predicate (left) vs. ACUSON Sequoia 3.9 liver elastography software using the 9C2 transducer with pSWE.

Conclusion

Chronic liver disease is a growing worldwide issue with a wide range of contributing factors. A key element in managing this prevalent global burden is early and accurate diagnosis. Noninvasive, ARFI based ultrasound quantification tools such as pSWE, Auto pSWE and 2D SWE, can be used to detect and assess the degree of liver disease. Best practice techniques are critical for acquisition of reliable shear wave measurements, as indicated by the SRU and WFUMB guidelines [1], [2]. Assessment of liver disease can aid a clinician in determining a patient's prioritization for treatment, in their continued surveillance, and, in some cases, to determine if there is a potential for reversibility of the disease.

A multicenter study encompassed N=121 patients to assess liver elastography. The velocity and elasticity values in this release are higher in the liver: In negative patients, SWE increased from 3.8 ± 1.7 kPa to 5.6 ± 2.6 kPa. In positive patients, SWE increased from 6.7 ± 3.6 kPa to 10.2 ± 5.9 kPa. For longitudinal studies and longitudinal patient monitoring, the differences in SWE compared to previous releases must be considered and addressed per clinical guidelines used on the corresponding site.

Shear wave elastography on the ACUSON Sequoia 3.9 is aimed for general liver assessments in patients with indication for abdominal ultrasound examinations.

At Siemens Healthineers, we pioneer breakthroughs in healthcare. For everyone. Everywhere. Sustainably. As a leading medical technology company, we want to advance a world in which breakthroughs in healthcare create new possibilities sustainably. We've been pushing the boundaries in medical technology for more than 125 years. Today, we are active in imaging, diagnostics, cancer care, and minimally invasive therapies – augmented by digital technologies and artificial intelligence.

With our unique combination of strengths in Patient Twinning¹, Precision Therapy, and Healthcare AI, we take on the greatest challenges in healthcare. We help improve access to healthcare for underserved communities worldwide and overcome the most threatening diseases: Neurodegenerative and cardiovascular diseases, stroke, and cancer. We partner with healthcare providers to address their most pressing challenges so that they can deliver high-quality, patient-centered care, efficiently.

Motivated by our purpose and guided by our values, we foster an inclusive and innovative workplace for our diverse and engaged teams globally. We are a team of around 74,000 Healthineers in over 70 countries passionately pushing the boundaries of what is possible in healthcare so that patients can live with hope, not fear of disease.

¹ Early detection, accurate diagnosis, individualized therapy selection, simulation and planning, continuous monitoring, and aftercare.

References

- [1] Barr RG, Wilson SR, Rubens D, Garcia-Tsao G, Ferraioli G. Update to the society of radiologists in ultrasound liver elastography consensus statement. Radiology; 2020.
- [2] Ferraioli G, Barr RG, Berzigotti A, et al. WFUMB Guideline/Guidance on Liver Multiparametric Ultrasound: Part 1. Update to 2018 Guidelines on Liver Ultrasound Elastography. Ultrasound Med Biol; 2024.
- [3] Shinagare A, Boland GW, Marcelo Di Carli MD, Mayo-Smith W, Silverman SG, Sodickson A, Khorasani R. RAD-ASSIST. <https://rad.bwh.harvard.edu/diagnostic-certainty-scale/>

Siemens Healthineers Headquarters

Siemens Healthineers AG
Siemensstr. 3
91301 Forchheim, Germany
Phone: +49 9191 18-0
[siemens-healthineers.com](https://www.siemens-healthineers.com)

Manufacturer

Siemens Medical Solutions USA, Inc.
Ultrasound
22010 S.E. 51st Street
Issaquah, WA 98029, USA
Phone: 1-888-826-9702
[siemens-healthineers.com/ultrasound](https://www.siemens-healthineers.com/ultrasound)