

# Samsung quantifications tools for liver steatosis and liver fibrosis

V series

## Introduction

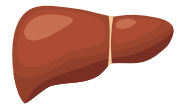
For non-invasive and cost-effective diagnosis of chronic liver disease, Samsung Ultrasound provides new ultrasound quantification tools for the assessment of liver steatosis and liver fibrosis. Samsung's QUS techniques, Tissue Attenuation Imaging (TAI™) and Tissue Scatter distribution Imaging (TSI™), measure the attenuation and backscatter of ultrasound signals to assess the degree of hepatic steatosis and finally provide the estimated fat fraction value as a percentage. Samsung's 2D SWE technique (2D-SWE), S-Shearwave Imaging™ is a non-invasive technique capable of displaying tissue elasticity in real-time as a color-coded map. By measuring the speed of the shear waves in the tissues, it is possible to quantify liver stiffness in kPa or m/s.

## Scan Recommendations [1]

1. Fast at least 4 hours before the examination.
2. Scan on intercostal area in the supine or slightly left decubitus position with the right arm in maximal extension.
3. Image right lobe, keeping the liver capsule parallel to the transducer surface.
4. Position the ROI at least 15~20 mm away from the liver capsule and locate it in the center of the image.
5. Ask patient to breath normally and hold the breath, avoiding deep inspiration prior to the breath hold.
6. At least 5 measurements should be obtained in different image frames to increase reproducibility.

## QUS (TAI™ and TSI™) [2]

The diagnostic performance of QUS parameters(TAI™ & TSI™) for evaluating hepatic steatosis based on MRI PDFF are summarized in the below.

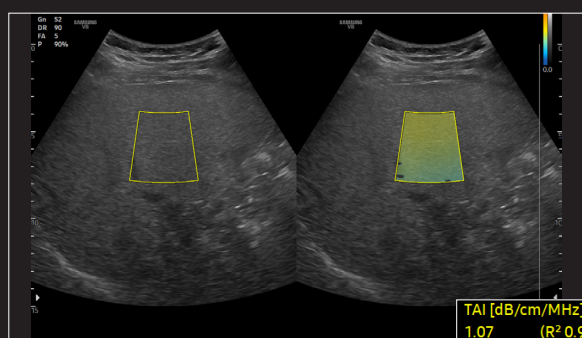


Study results (n=173)	TAI™ (dB/cm/MHz)				TSI™			
	AUC	Cutoff	Sensitivity (%)	Specificity (%)	AUC	Cutoff	Sensitivity (%)	Specificity (%)
MRI-PDFF ≥5% (≥S1)	0.917	0.72	82.5	91.5	0.905	95.6	83.3	80.9
MRI-PDFF ≥15% (≥S2)	0.914	0.83	78.7	91.3	0.843	98.4	93.6	64.3
MRI-PDFF ≥25% (≥S3)	0.898	0.86	100	79.8	0.813	98.9	100	54.0

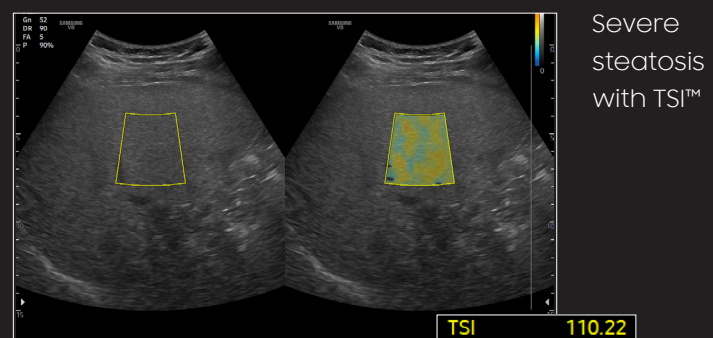
\* These cut-off values were obtained by averaging the five measurements from QUS.

## Guidelines for Obtaining Reliable Measurements

Quantification Tool	Reliability Indicator	Description
QUS (TAI™)	R <sup>2</sup> value	- The reliability of TAI™ measurements is represented as an R <sup>2</sup> value. - The R <sup>2</sup> value <b>over 0.6</b> is regarded valid.

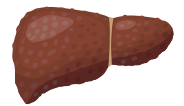


Severe steatosis with TAI™



Severe steatosis with TSI™

## S-Shearwave Imaging™ [3]



The diagnostic performance of S-Shearwave Imaging™ for evaluating hepatic fibrosis based on liver biopsy are as below.

Fibrosis Stage	Cutoff (kPa)	AUC	P-value	Sensitivity (%)	Specificity (%)
Moderate fibrosis (≥F2)	6.82	0.978 (0.937 - 0.996)	<0.001	93.2	91.0
Severe fibrosis (≥F3)	8.63	0.982 (0.942 - 0.997)	<0.001	93.1	95.2
Cirrhosis (F4)	9.66	0.974 (0.931 - 0.994)	<0.001	100.0	92.1

\* The median value of multiple measurements is used as a representative value in SWE study.

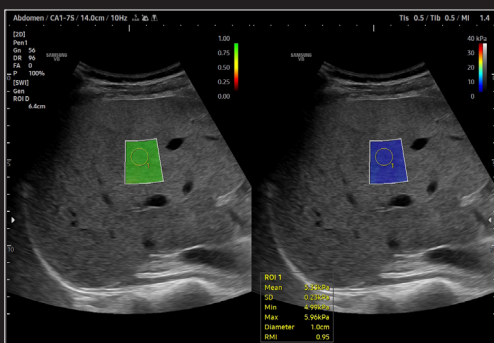
## Guidelines for Obtaining Reliable Measurements

Quantification Tool	Reliability Indicator	Description
S-Shearwave Imaging™	RMI map (Reliable Measurement Index)	<ul style="list-style-type: none"> <li>Stiffness map and RMI map should be displayed simultaneously <b>on Dual Live mode</b>.</li> <li>RMI map indicates the reliable value as green and less reliable value as yellow to red.</li> <li>To get a reliable measurement, place <b>the ROI (1cm)</b> on the <b>green area</b> of RMI map. (RMI values above 0.4)</li> </ul>
	IQR/Med	<ul style="list-style-type: none"> <li><b>IQR/Med ratio less than 30%</b> is considered to be reliable. (IQR/M ≤ 15% for m/s)</li> <li>* <b>Median value:</b> a representative stiffness value from 5 measurements.</li> </ul>

## SRU (Society of Radiologists in Ultrasound) guideline

According to the SRU guidelines for shear wave elastography, a “rule of four” approach is recommended for interpreting liver stiffness measurements, providing a vendor-neutral method to categorize fibrosis severity based on stiffness values across different ultrasound systems.

Liver Stiffness Value	Recommendations
≤ 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, may need further test for confirmation
9-13 kPa (1.7-2.1m/s)	Suggestive of cACLD but need further test for confirmation
> 13 kPa (2.1m/s)	Rules in cACLD
> 17 kPa (2.4m/s)	Suggestive of CSPH



Normal liver (5.3 kPa)



Cirrhosis (16.2 kPa)

### Disclaimer:

- The features, options may not be commercially available in some countries.
- TAI™, TSI™, and S-Shearwave Imaging™ are optional features that require additional purchase.
- Sales and shipments are effective only after the approval by the regulatory affairs. Please contact your local sales representative for further details.
- Diagnostic performance of TAI™ and TSI™ is performance result using V8 V1.0 ultrasound system with CA1-7S probe.
- Diagnostic performance of S-Shearwave Imaging™ is performance result using V8 V1.0 ultrasound system with CA1-7S probe.

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### References:

1. G. Ferraioli et al., WFUMB Guideline/Guidance on Liver Multiparametric Ultrasound: Part 1. Update to 2018 Guidelines on Liver Ultrasound Elastography, Ultrasound in Medicine & Biology (2024), <https://doi.org/10.1016/j.ultrasmedbio.2024.03.013>
2. Sun Kyung Jeon, Jeong Min Lee, et al., Two-dimensional Convolutional Neural Network Using Quantitative US for Noninvasive Assessment of Hepatic Steatosis in NAFLD. Radiology 2023 Jan 3;221510. doi:10.1148/radiol.221510
3. Prospective Evaluation of Liver Fibrosis using S-Shearwave Imaging™ : Comparison with Magnetic Resonance Elastography. Jeong Eun Lee, M.D., Ph.D., Kyung Sook Shin, M.D., Ph.D. Department of Radiology, Chungnam National University Hospital
4. Update to the Society of Radiologists in Ultrasound Liver Elastography Consensus Statement. 2020 Aug;296(2):263-274.doi: 10.1148/radiol.2020192437.Epub 2020 Jun 9.

