

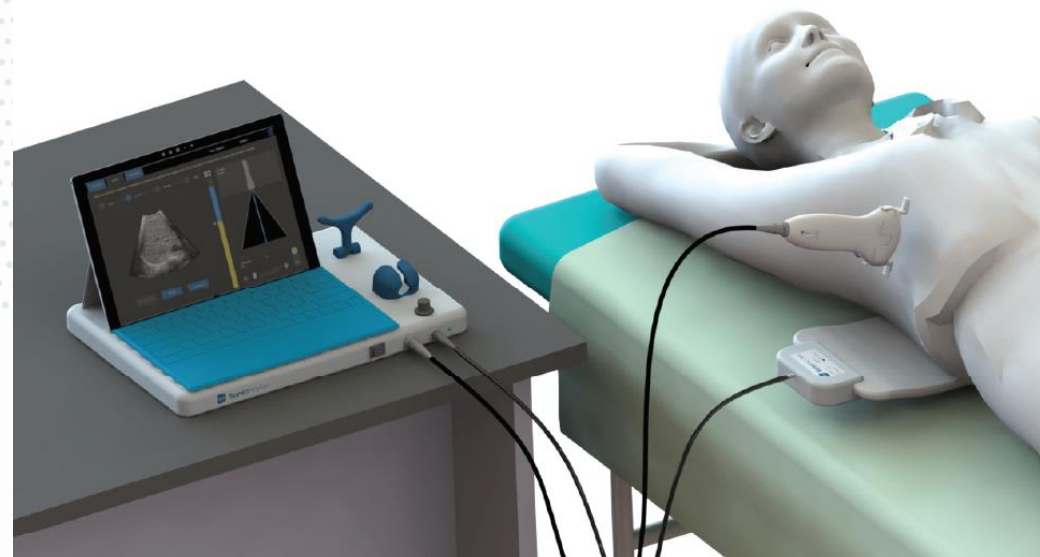
Product Profile

Velacur™ is a portable handheld ultrasound solution, using technology similar to MRI elastography for assessing and managing chronic liver disease.

The device is intended to non-invasively determine liver tissue stiffness and attenuation. These are to be used in conjunction with other clinical indicators in order to assist in clinical management of patients with liver disease.

This device is portable and consists of three parts:

- **Portable computing device**
- **Handheld ultrasound probe**
- **Activation pad & control unit**



Process

The procedure takes 5-10 minutes and requires 1-day of training. The physician can choose to delegate the procedure to a trained operator.

01

Activation

An activation pad is placed under the patient's back creating steady state waves similar to MRI elastography.

02

Ultrasound Scan

Machine learning ensures an optimal probe position followed by a guided 3D sweep with a handheld ultrasound.

03

Readout

Accurate and reliable steatosis and fibrosis measurements are generated for immediate clinical assessment.

[Click here for our procedure video](#)



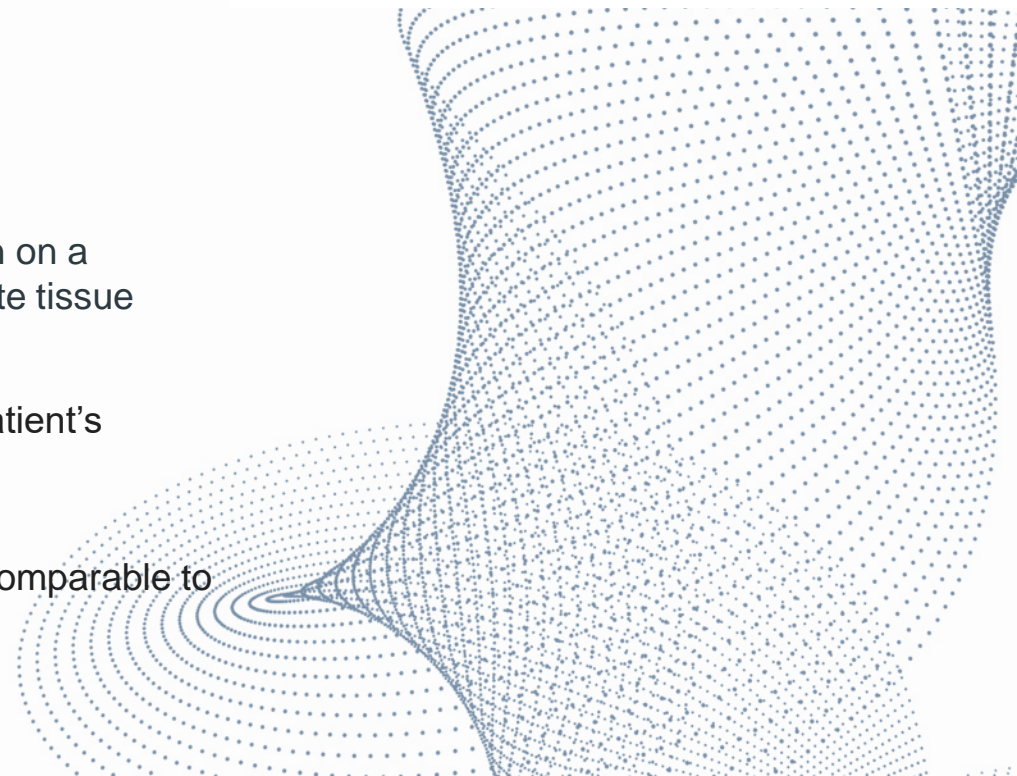
Features

- Visual confirmation of liver (via machine learning enhanced ultrasound B-mode)
- 3D tissue sampling - volume of 100 cm³ (>5% of an adult liver)
- Deep tissue sampling - measurement depth of 15 cm
- Applicable for all body types
- Advanced users have the ability to focus in on a particular region of interest to accommodate tissue heterogeneity
- Integrated patient data analytics to view patient's results over time
- Accuracy for both Steatosis and Fibrosis comparable to MRI and greater than FibroScan

Velacur™
Volume
=100 cm³

FibroScan®
Volume
=3 cm³

30x larger tissue sampling contributes to higher accuracy and reliability.



Outputs

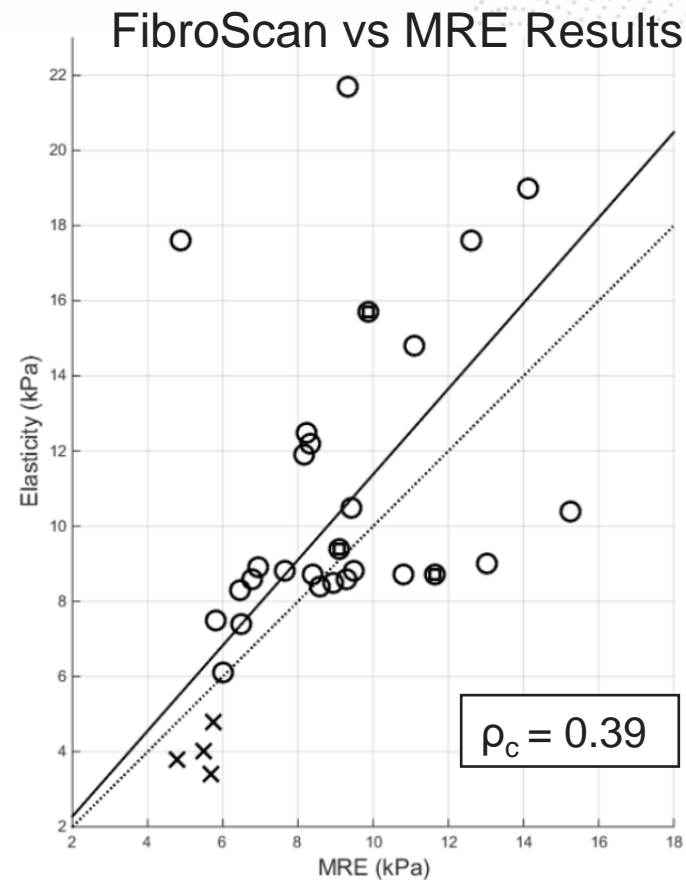
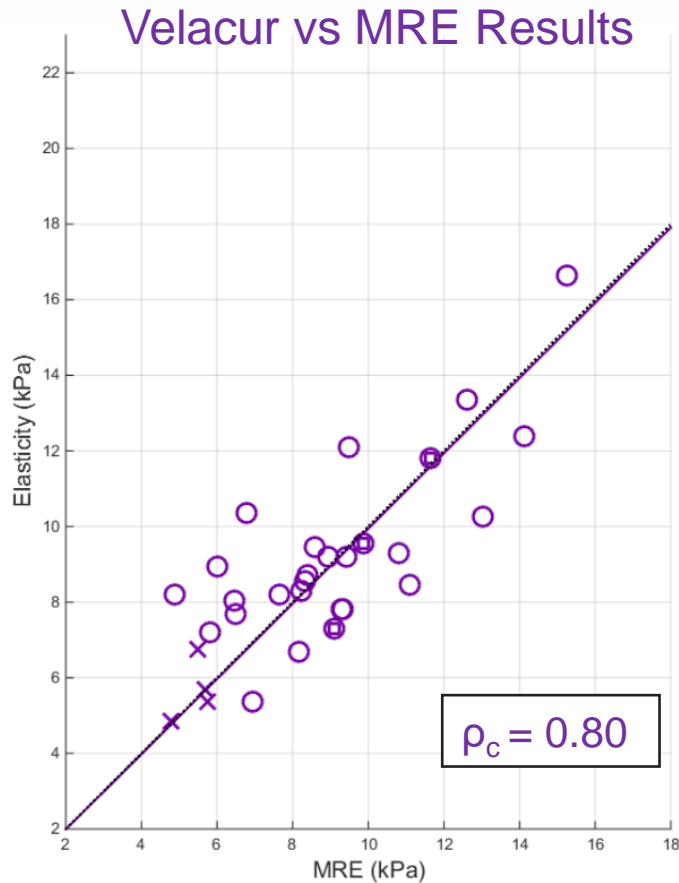
Elasticity (kilopascals)
– a biomarker for fibrosis

Attenuation (decibels per meter)
– a biomarker for fat content or steatosis

Clinical Assessment
– quantification of steatosis and staging of fibrosis for a more definitive diagnosis

Velacur™ Results: Elasticity ($n = 35$)

Examining the concordance (1 to 1) between Velacur and FibroScan stiffness measurements with MRE results.

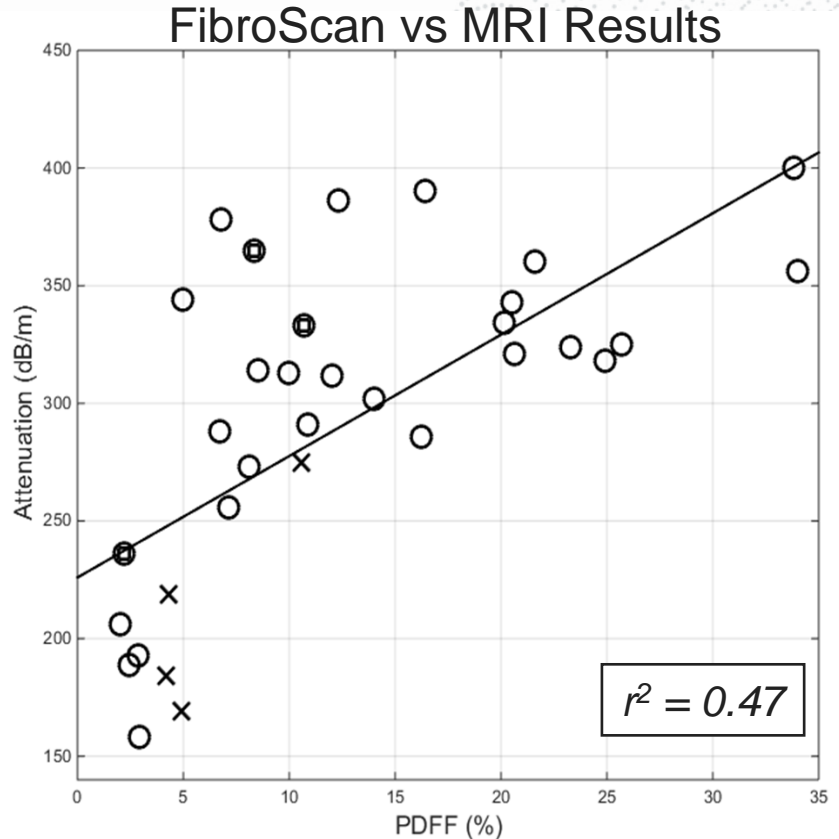
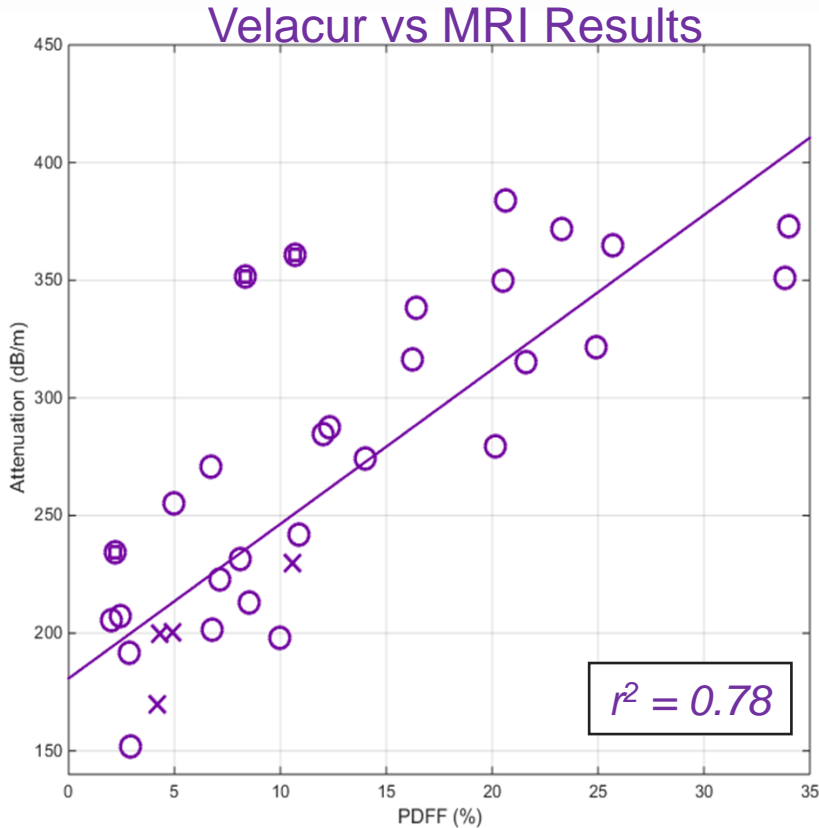


Graphs of the concordance coefficient (P_c) between Velacur™ and MRE in purple and FibroScan® and MRE in black.

Dotted line shows the 1 to 1 line, while the solid lines are linear fits which cross the origin.

Velacur™ Results: Attenuation ($n = 35$)

Examining the correlation between Velacur and FibroScan attenuation measurements and MRI-PDFF results.



Graphs of the correlation coefficient (r^2) between Velacur™ ACE and MRI PDFF in purple and FibroScan® CAP and MRI PDFF in black.

These graphs include some healthy volunteers from a previous pilot study, and 3 patients were removed as invalid scans due to user or technical error.

Velacur™ Reimbursement Present and Future

Elastography of the Liver

- Velacur integrates technology common to transient & ultrasound elastography
- Velacur eligible for both 91200 and 76981
- Use of 76981 not restrictive to particular settings & minimal supervision requirements
- **Future:** opportunity to add attenuation to existing elastography reimbursement

| | Transient | Ultrasound |
|------|-----------|------------|
| CPTC | 91200 | 76981 |

| CMS (RVU/Rate) | 1.05 | 3.04 |
|-------------------|---------|----------|
| | \$37.89 | \$109.71 |

Allows non-radiologists to claim higher reimbursement

Estimated to be 50% of above CPTC rate (+\$19-55)