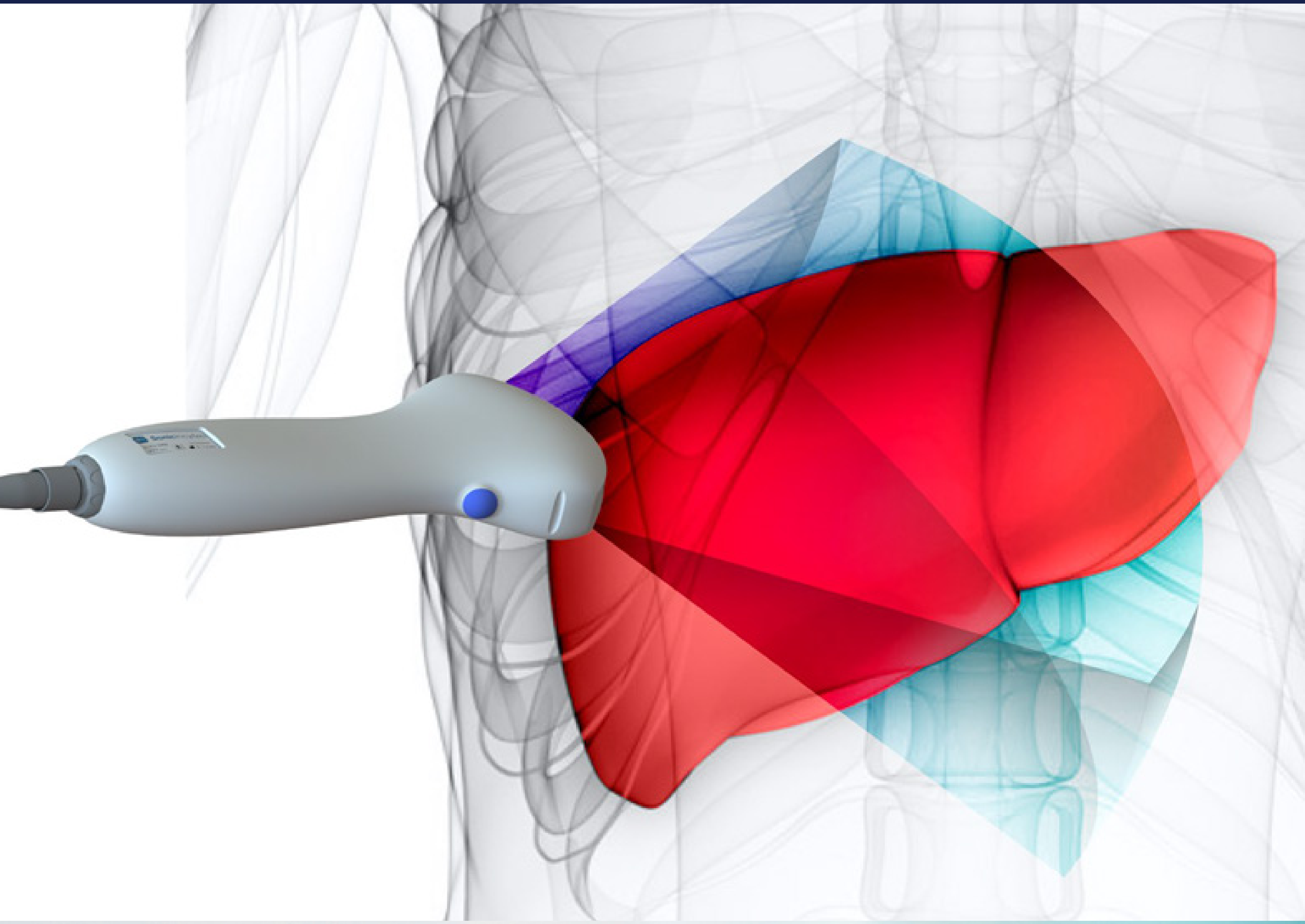


Velacur™ Shear Wave Absolute Vibro-Elastography

White Paper

Quantitative Elastography

Quantitative elastography is increasingly being used as a non-invasive method for assessment of liver stiffness, a component of liver fibrosis measurements. All quantitative elastography methods are based on the idea that shear waves travel at different speeds through tissues of different stiffness, i.e. tissue with more fibrosis causes waves to travel faster than softer (healthier) tissue.

Multiple different methods have been tested in clinical practice, but all have similar key components: a method to create shear waves, and a method to track these waves. A full comparison of methods can be found at the end of this paper.

	Imaging Modality	Shear Wave Source	Imaging
Transient Elastography	Ultrasound	Transient Mechanical (Probe mounted)	1D
Shear Wave Elastography	Ultrasound	Acoustic Force	2D
Shear Wave Elastography	Magnetic Resonance Imaging	Continuous Mechanical (Pneumatic)	2D
Shear Wave Elastography	Ultrasound	Continuous Mechanical	3D

S-WAVE Theory

Shear Wave Absolute Vibro-Elastography (S-WAVE) is based on the same principles as other liver elastography methods. However, Velacur™ uses an external vibration source to create **steady state shear waves** within the liver. The wavelength/speed of these waves are then measured over a **volume** using ultrasound imaging. The Young's modulus, expressed in kilopascals, is calculated from these shear waves.

To counteract the effects of possible artifacts from a single steady state wave, a multi-frequency signal with four excitation frequencies, 45 Hz, 50 Hz, 55 Hz and 60 Hz, is used to generate shear waves. Special ultrasound sequences, similar to Doppler imaging, allow the waves to be imaged at very high frames rates, allowing for accurate wavelength estimation[1]. The different frequencies are combined using a least squares fit to calculate the stiffness at each point within the volume. The mean value over the measured volume is presented to the user.

In order to measure a volume of the liver, the probe is moved in a sweeping motion, during which multiple image frames are automatically acquired. To reconstruct the volume, the ultrasound probe contains an inertial measurement unit (IMU), which records the relative position of each image frame.

Notable advantages to this new technique include:

1. Steady state shear waves allow for much deeper measurements (only limited by the depth of the ultrasound probe).
2. 3D scanning allows for a much larger tissue volume to be assessed.

Velacur™ System

The Velacur™ system is a self-contained portable elastography imaging system. The system contains an ultrasound probe, a control unit, an activation unit, a mobile computing device and the Velacur™ software.

Control Unit

The Control Unit is connected to all parts of the system. It acts as a collection/transfer point for all data and generates the signal for the activation unit synchronized with the ultrasound imaging.

Activation Unit

The Activation Unit consists of a composite board and a voice coil actuator, which produces the mechanical vibrations. The patient lies on the board during the exam and the mechanical vibrations are then transferred to the patient.

The vibration amplitude can be adjusted to account for a patient's size. A heavier patient will require more vibration to induce the necessary shear waves.

Ultrasound Probe

The ultrasound probe is a typical abdominal ultrasound transducer which can be used to a depth of 15cm. This type of probe allows for direct visualization of the tissue to be measured, giving the user confidence in the measurement location.

Since the vibrations are not produced from the probe, elastography measurements can be made down to the imaging depth of the probe, much deeper than other ultrasound-based elastography methods. Further, this system requires only a single probe for a range of body types and does not require frequent re-calibration.

Ultrasound Attenuation

With the rising incidence of fatty liver disease, which is quickly becoming the leading cause of chronic liver disease globally, it is vital to measure the amount of fat within liver tissue alongside tissue stiffness.

Ultrasound attenuation, or measuring the beam scattering, is one type of quantitative ultrasound measurement. Ultrasound attenuation has been shown to be a parameter in the non-invasive measurement of liver fat, and can be seen subjectively on ultrasound scans once patients reach high levels of fat accumulation[2].

By measuring the power returning to the ultrasound probe, Velacur™ is able to measure this quantitatively during the exam, in decibels/ meter. The attenuation measurement is also measured over the collected volume.

Ultrasound attenuation measurements require significant averaging to improve accuracy[3]. The Velacur™ ACE (attenuation coefficient estimation) measurement takes advantage of a non-standard sampling technique required for S-WAVE measurements to acquire several repeated ACE measurements over a volume. This allows for both spatial and temporal averaging of the attenuation measurement.

Velacur™ Software

The Velacur™ software comes preinstalled on the provided mobile computing device. The software displays an ultrasound image to allow the user to visually confirm they are scanning liver tissue. The software then guides the user through a step-by-step process to ensure the scan is conducted properly (i.e. good quality image, good shear waves and effective sweep). The Velacur™ user interface is shown in Figure 1.

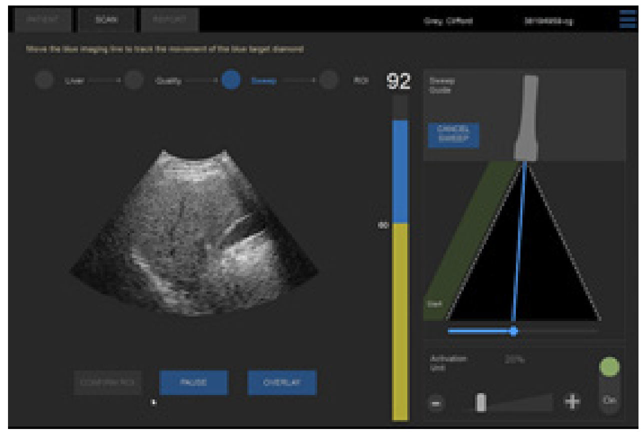
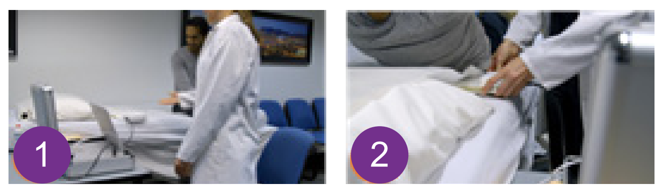
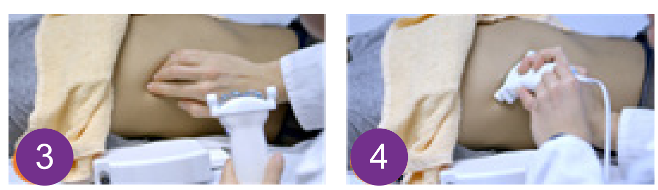


Figure 1

Using the Device



The patient is instructed to lie on top of the activation unit on the examination bed (steps 1 and 2). The operator palpates for a rib space in



line with the sternum (step 3), and maneuvers the ultrasound transducer (step 4) with guidance from the B-mode image shown on screen. The operator then switches on the activation unit and adjusts the amplitude of the mechanical waves while monitoring the shear wave image quality, displayed as a percentage range from 0 to 100% (Figure 1).

Once the quality is above an acceptable threshold, the operator informs the patient to hold his/her breath and then initiates a sweep (step 6).

After the scan is complete, the operator selects a region of interest within the scanned volume in which elasticity and attenuation are computed. The values obtained are displayed and recorded. This procedure is repeated five times. Median elasticity and attenuation values, as well as interquartile ranges are displayed and recorded.

Velacur™ Comparison To Existing Methods

	Velacur™	**Fibroscan®**	**MRE / MR-PDFF**	**SWE**	**Biopsy**
Liver Tissue Sample Size	100,000 mm^3	3,142 mm^3 (1)	300,000-500,000 mm^3 (2)	400-800 mm^2 (3)	14.4 mm^3
Maximum Depth of Measurement	15 cm	3.5-7 cm	Limited by size of bore	~6 cm	N/A
Measurement Dimensions	3D	1D	2D	1D or 2D	N/A
Single Probe	Yes	No	N/A	Yes	N/A

(1) Sample size: 1cm diameter and 40mm depth (M Probe).
(2) Estimated from the total liver cross section, MRE slice thickness and the estimated number of valid pixels per slice.
(3) Assumes 9 regions of 1cm diameter.

Conclusion

Shear Wave Absolute Vibro-Elastography and the Velacur™ device offer a significant advancement in the capabilities of ultrasonic elastography. Cost-effective, portable and accurate tools for determining liver stiffness are now available with the introduction of the Velacur™ system. As the world's only 3D ultrasonic elastography machine, Velacur™ provides measurements to best assist in the management of patients with chronic liver diseases.

References

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