An intelligent solution to aid clinical diagnosis, FibroScan® uses state of the art fibrosis and steatosis quantification with the most advanced non-invasive technology.

This unique, accurate and efficient device brings you extra clinical confidence to support your patient management.
Sharing **INNOVATIVE** technology

**USE THE FIRST-IN-CLASS ELASTOGRAPHY**

Based on patented Vibration-Controlled Transient Elastography (VCTE™), FibroScan® 502 Touch provides multiple controls for reliable, accurate and reproducible assessment of liver tissue stiffness: **CONTROLLED VIBRATION, CONTROLLED ENERGY, CONTROLLED ALGORITHM.**

### CONTROLLED VIBRATION

- A custom-designed ergonomic transducer generates a controlled vibration which induces a mechanical shear wave with consistent frequency and energy
- Static force is monitored in real time to prevent wave distortions
- Shear wave center frequency is 50Hz

![ControllEd Vibration Diagram](image)

### CONTROLLED ENERGY

- Propagation of the mechanical shear wave through the skin and liver tissues is measured using low energy 3.5 MHz ultrasound
- Large explored volume 3 cm³ (at least 100 times more than a biopsy)
- Measurement depths from 15 to 75 mm depending on probe

![ControllEd Energy Diagram](image)

### CONTROLLED ALGORITHM

<table>
<thead>
<tr>
<th>CAP (dB/m)</th>
<th>Median</th>
<th>IQR</th>
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<tbody>
<tr>
<td>177</td>
<td>23 %</td>
<td>41</td>
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<table>
<thead>
<tr>
<th>E (kPa)</th>
<th>Median</th>
<th>IQR</th>
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<tbody>
<tr>
<td>8.1</td>
<td>22%</td>
<td>1.8</td>
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</table>

- VCTE™ guidance process ensures the operator obtains measurements of the liver
- A sophisticated algorithm computes liver stiffness and ultrasound attenuation
- A quality controlled calculation is performed automatically, the algorithm selects the valid measurements

![ControllEd Algorithm Diagram](image)
Stiffness (E)

- Stiffness is computed from the ELASTOGRAM
- The Elastogram is a GRAPHIC REPRESENTATION of the shear wave propagation as a function of time and depth
- The Young’s Modulus (E) is expressed in KILOPASCAL (kPa)

Controlled Attenuation Parameter (CAP™)

- CAP™ is computed from the ULTRASOUND acquired for stiffness measurement
- CAP™ IS ONLY CALCULATED if the acquisition of stiffness is VALID
- CAP™ is expressed in DECIBEL PER METER (dB/m)

FIBROSIS

- At least 100 TIMES LARGER than with a liver biopsy
- Both Stiffness and CAP™ are simultaneously measured IN THE SAME LIVER VOLUME
- Stiffness & CAP™ results are the MEDIAN of 10 valid measurements

STEATOSIS

Explored volume with m+ Probe

- 3 CM³
- At least 100 TIMES LARGER than with a liver biopsy
- Both Stiffness and CAP™ are simultaneously measured IN THE SAME LIVER VOLUME
- Stiffness & CAP™ results are the MEDIAN of 10 valid measurements
CAP™ is a measure of the ultrasound attenuation which corresponds to the decrease in amplitude of ultrasound waves as they propagate through the liver.

CAP™ is powered by a sophisticated guidance process based on VCTE™ that ensures that:

- CAP™ and liver stiffness are simultaneously measured in the same liver volume
- CAP™ is calculated only if liver stiffness measurement is valid

<table>
<thead>
<tr>
<th>Gain (ultrasound amplitude)</th>
<th>ARE CONTROLLED AND PREDEFINED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrasound frequency</td>
<td></td>
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<tr>
<td>Region of measurement</td>
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</table>

- CAP™ is measured with the M probe at 3.5 MHz at depth between 25 and 65 mm
- CAP™ is expressed in decibel per meter (dB/m)

**CAP™ measurement**

Like for liver stiffness measurement with the FibroScan® 502 Touch, CAP™ measurement:

- **IS NON INVASIVE**
- **IS IMMEDIATE**: does not lengthen the FibroScan® examination
- benefits from an established examination procedure: the final CAP™ result is the median of at least 10 valid CAP™ measurements
- can be performed by an operator without any ultrasound imaging skills

**CAP™ is a tool for non invasive assessment and quantification of steatosis** enhancing the spectrum of non invasive methods for the examination and follow-up of patients with liver disease.
CAP™ is a novel non invasive physical quantitative parameter AVAILABLE with the FibroScan 502.
Sharing CLINICAL DATA

LITERATURE OVERVIEW

FibroScan® procedures are easy to put into routine practice for all chronic liver diseases.

→ To date, more than 369 peer reviewed original articles have demonstrated the usefulness of liver stiffness measurement with the FibroScan®

→ As a stand-alone tool or as an adjunct to liver biopsy, FibroScan® allows accurate decisions as part of your patient management strategy

→ From mass screening to follow-up of post transplanted patients and prognostic value, liver stiffness measured by FibroScan® has a wide range of use

Liver stiffness

Liver stiffness assessed by FibroScan® has been studied in all major causes of chronic liver diseases.

CHRONIC HEPATITIS B (HBV)
The diagnosis accuracy of FibroScan® to assess fibrosis has been shown to be similar in patients with chronic hepatitis B compared to patients with chronic hepatitis C [2]. However, necro-inflammatory activity has also been shown to significantly affect liver stiffness in this etiology [3].

HIV-HCV CO-INFECTION
The presence of HIV co-infection with HCV, does not impair the diagnosis accuracy of FibroScan® [4].

ALCOHOLIC LIVER DISEASE (ALD)
Liver stiffness measured by FibroScan® can be used to assess liver fibrosis in patients with alcoholic liver disease with diagnosis accuracies similar to those obtained in chronic viral hepatitis [5]. Moreover, the FibroScan® procedure is very well accepted by patients with alcohol dependence or abuse and therefore appears as a first choice tool to detect advance fibrosis or cirrhosis in population at risk with a better accuracy than simple biological evidence [6].

NON ALCOHOLIC FATTY LIVER DISEASE (NALFD)
A recent meta-analysis [7] based on 6 different studies has shown that liver stiffness measured with FibroScan® is good to detect liver fibrosis with a mean AUROC of 0.84 (95% CI: 0.79-0.90) and excellent to detect cirrhosis with a mean AUROC of 0.94 (0.86-0.99).

* AUROC: area under Receiver Operator Characteristics curve
** 95% CI: 95% confidence interval
Moreover, the availability of the new XL probe dedicated to overweight patients with a skin-to-liver capsula distance greater than 2.5 cm will allow assessment of a large portion of the patients that could not previously benefit from the FibroScan® procedure [8].

**BILIARY DISEASE**

Liver stiffness has also been shown to be of clinical use to detect fibrosis and cirrhosis in patients with primary biliary cirrhosis and primary sclerosing cholangitis [9].

**Controlled Attenuation Parameter (CAP™)**

In addition to measuring liver stiffness, FibroScan® 502 Touch now allows you to also assess the Controlled Attenuation Parameter (CAP™) which has been developed for the detection of liver steatosis. Several publications and communications support this new feature of the FibroScan® 502 Touch.

→ A proof of concept publication on the CAP™ technology [23]

In a cohort of 115 patients with various chronic liver diseases, the AUROC of CAP™ to assess steatosis were:

• 0.91 for steatosis superior or equal to 11%
• 0.94 for steatosis superior or equal to 34%
• 0.89 for steatosis superior or equal to 67%

→ Several communications in international hepatology meetings (AASLD, EASL, APASL) [24-27]

FibroScan® 502 Touch with its dedicated probes is a diagnostic aid measuring liver stiffness and Controlled Attenuation Parameter.

*These values must be interpreted by a medical doctor specialized in liver disease taking into account the complete medical record of the patient, presence of identified confounding factors and the quality of the measurement procedure (number of valid measurements, dispersion,...).*
FibroScan® is of use throughout the course of chronic liver disease.
Your patients will be asking you: “Can I have a FibroScan® exam?”
Sharing **POWERFUL** practice

AN INNOVATIVE DESIGN WHICH IMPROVES PRODUCTIVITY

To date **1000 FibroScan®** devices have been installed worldwide. FibroScan® is used to aid diagnosis in 1.5 million men, women and children every year.

Software 2.0

**TACTILE INTERFACE WITH A NEW DESIGN**
- Optimized ergonomy & data workflow
- User-Friendly interface
- Easy to use

**PATIENT DATA MANAGEMENT**
- Organized by patients
- Multi-criteria search (last name, first name, date...)

**NETWORK CONNECTION**
- Easy data export
- Push data to shared network directories

**Smart Tools**

**AUTOMATED PROBE SELECTION**
- An indicator to recommend the probe best suited to the patient’s morphology

**FIBROSCAN® REPORTS**
- Generate and edit multilingual reports
- Personalize reports with hospital logo, address...
- Print examination history
FibroScan® 502 Touch expert tools

Non invasive liver stiffness measurement
Innovative steatosis quantification

Hardware

17” TOUCH SCREEN
→ Optimal comfort & image quality in all situation
→ High contrast & brightness
→ Wide viewing angle

ADVANCED CONNECTIVITY OPTIONS
→ Save & export data to removable drive (USB key...) or network

2 PROBE CONNECTORS
→ Connect two probes simultaneously

FRONT AND REAR HANDLES
→ Easy to move and manipulate

ADVANCED ELECTRONIC FOR FAST AND EFFECTIVE EXAMINATION
→ High speed elastrometry engine
Probes

THREE DIFFERENT ERGONOMIC PROBES ENABLE YOU TO ADDRESS A FULL RANGE OF CLINICAL AND MORPHOLOGICAL NEEDS

Each patient is different. Echosens has designed its probes to ensure efficient diagnosis in all circumstances.

**PROBE: FOR CHILDREN**
- Transducer specifically designed for being placed into narrow intercostal space
- A higher ultrasound frequency, 5 MHz, enabling measurements adapted for chest perimeter from 45 to 75 cm
- Measurement depths are adapted between 15 to 50 mm depending on children’s morphology

**PROBE: STANDARD PROBE**
- The M probe is designed for the general population. It is used for adults with a thoracic perimeter of more than 75 cm
- Ultrasound frequency is 3.5 MHz
- Measurements of liver stiffness take place between 25 and 65 mm under the skin

**PROBE: FOR OVERWEIGHT PATIENTS**
- A more sensitive ultrasound sensor at the frequency of 2.5 MHz has been designed to enhance deeper signal penetration through tissues over a 35 to 75 mm depth
- XL probe must be used on patient with a Skin Capsule Distance (SCD) greater than 2.5 cm. Automated probe selection will recommend the probe best suited to the patient’s morphology

**RECOMMENDATIONS FOR USE**
- Training: Echosens or its representative must certify the operator to ensure the proper use of the device and all its features
- Examination procedures provide better reproducibility and accuracy with 10 valid stiffness measurements at the same measurement point

**PRECAUTIONS FOR USE**
- FibroScan® should not be used on pregnant women, patient with active implantable medical device and person with ascites
- Presence of ascites may prevent from obtaining valid measurements
Sharing SERVICE solutions
DISTRIBUTION, TRAINING AND AFTER-SALES SERVICE

Distribution

OUR DISTRIBUTOR NETWORK IN YOUR COUNTRY IS YOUR DIRECT CONTACT
Echosens has an exclusive distribution network that provides sales, training and after-sales support.
We will also provide direct support in countries which we serve directly.

For more information, contact our sales team: distribution@echosens.com or your local distributor

Training

HOW TO ACHIEVE BEST PRACTICE
After on site training, you will be certified to use FibroScan®. The training is mandatory in order to obtain accurate and reliable measurements. Nurses can use the equipment but only physicians can interpret the results in light of the patient’s history.

Dedicated training includes:
→ A custom-designed theory session aimed at understanding indications and criteria for use of the device and individual probes
→ A practical session to teach in good examination practice

For more information, contact our training team: training@echosens.com
After-sales service

LOCAL SUPPORT IS AVAILABLE
Distributors are in charge of ensuring the after-sales service of all Echosens products. Our specially trained and certified engineers will take care of your device. We ensure fast and efficient answers that will keep your device up and running*.

ACCESSORIES AND SUPPLIES
To enhance your productivity, the Echosens Service Centre or your local distributor will support you with calibration, repairs, parts and maintenance services.

→ *FibroScan® probes need to be calibrated every six months to maintain proper performance.*

SERVICE CONTRACT
Service contracts with local support.
It can range from probe maintenance alone to an all-inclusive contract bringing added piece of mind. You’re free to choose.

For more information, contact our team after-sales service:
service@echosens.com

*After acceptance of an estimate or under a service contract
Echosens is actively expanding its global presence. We are supported by a team of medical experts who have helped to transform our core technology*, VCTE™, into the first commercially available product with Transient Elastography: FibroScan®.

**OUR MISSION**
Offer to our customers ergonomic and technological solutions in hepatology to improve patient quality of life based on:
- A robust portfolio of patents
- A totally non-invasive solution

**OUR PARTNERS**
Echosens establishes many medical and scientific partnerships around the world (Germany, China, USA, United Kingdom...).

In France, we develop strong links with the universities as:
- Université Rabelais de Tours
- Centre d’investigation Clinique – Innovation Technologie, CHRU de Tours, Hôpital Bretonneau
- Institut Pierre et Marie Curie, Paris
- Telecom ParisTech
- INSERM

**OUR COMMITMENT**
Our commitment to quality is shown by:
- ISO 13485 certification since 2005
- CE mark since 2003

* Echosens owns 9 patents in the domain of transient elastography.
BIBLIOGRAPHY


