



FibroScan[®] 402

POWERED BY VCTE[™]

THE ESSENTIAL tool for liver stiffness measurement

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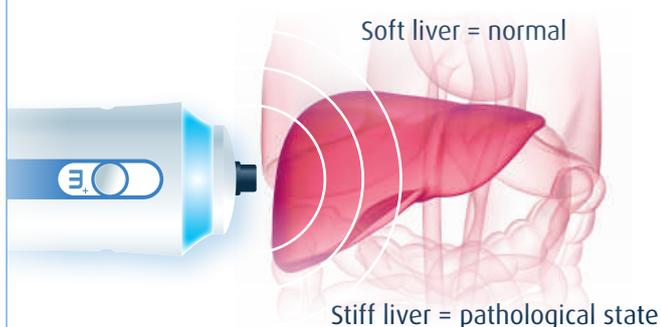
THE ESSENTIAL tool for liver stiffness measurement

A ROBUST TECHNOLOGY Vibration-Controlled Transient Elastography (**VCTE™**)

- Assess liver stiffness
- Provide reproducible and operator independent examination⁽¹⁾
- Explore a large volume (100 times larger than the biopsy)



LIVER STIFFNESS DETERMINES THE PATHOLOGICAL STATE



FibroScan® measures liver stiffness that is directly related to liver conditions such as fibrosis, inflammation⁽²⁾.

EASY TO USE & TO INTEGRATE into your routine practice

- Quantitative & immediate result in kPa
- Plug & play device
- Start your training online

An extra clinical **CONFIDENCE**

- Same technology as FibroScan® 502
- Established clinical data



INTEGRATED
printer



ERGONOMIC
probe



User-friendly
TOUCH-SCREEN
INTERFACE



LIGHT & EASY
to handle device

TECHNICAL parameters

FibroScan® 402

- Size: 275 x 434 x 252 mm (H x D x W)
- Weight: 8 kg
- Power: 100 - 230 Volts (+10%/-15%)
- Connection: Ethernet, USB, Video (DVI)
- Dedicated software
- Touch screen display: 10.4"

M⁺ PROBE

- Size: 158 x 52 mm (L x Ø)
- Weight: 0.5 kg
- Transducer diameter: 7 mm
- Frequency: 3.5 MHz
- Cable: 1.5 m
- Connection: Push Pull



M⁺ probe needs to be calibrated EVERY 6 MONTHS to maintain proper performance

OPTION

- Compatible with Desk Solution, a FibroScan® review software

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: 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



BIBLIOGRAPHY

1. Fraquelli, M., et al., Reproducibility of transient elastography in the evaluation of liver fibrosis in patients with chronic liver disease. Gut 2007;56:968-73.
2. Mueller, S. and L. Sandrin, Liver stiffness: a novel parameter for the diagnosis of liver disease. Hepatic Medicine: Evidence and Research, 2010: p. 49-67is C.

FS40220092012EN- Revision date 20/09/2012 - FibroScan® is a class IIa medical device according to Directive EC/93/42 and is manufactured by Echosens. Assessment of its conformity with the essential requirements of the Directive EC/93/42 is established by the LNE-G-MED (France). FibroScan® is indicated for the non invasive measurement of liver stiffness (E) in adult human beings.

It is expressly recommended to closely read the instruction of the users' guide and labeling of the device. FibroScan® examination must be performed only by operator certified by the manufacturer or its accredited local representative. FibroScan® must not be used in the following situation: other organs but liver, patients with active implantable medical devices (such as pacemaker, defibrillators, pump, etc.), wound at the measurement point, pregnant women. Presence of ascites can prevent from obtaining valid measurements. The values obtained with FibroScan® must be interpreted by a physician experienced in dealing with liver disease, taking into account the complete medical record of the patients.

In France, liver stiffness measurement by FibroScan® is included on the list of acts and services covered by the national Social Security medical insurance under the code HLM002 and the following conditions. Indications: assessment of chronic untreated hepatitis C adult patients with HIV coinfection except obvious diagnosis of cirrhosis. Invoicing note: Within the limit of one examination per year except in case of risk factors of rapid evolution toward cirrhosis, if this new examination is expected to have an impact on the therapeutic management of the patient. In case of chronic hepatitis C: as second line test (in case of non agreement between the first line test and the clinical context or in case of non interpretable first line test) as an alternative to liver biopsy. In case of HIV-HCV coinfection: as first line test to evaluate the presence of cirrhosis. Environment: consultation specialized in the management of patients with HCV, in collaboration with a center specialized in the management of the HIV infection for the second indication.



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