Innovative Solution for Liver Diagnosis

Non-invasive Assessment of Liver Fibrosis and Steatosis
We Care about Your Liver Health

Liver: An Important but Silent Organ

- A Core Organ in Human Body
  The functions of liver are synthesis and metabolism of protein, cholesterol, blood coagulation factors, as well as detoxification of alcohol and drugs.

- A Silent Organ
  Without pain-sensing nerves, early lesions of liver can be easily ignored. Many lesions don't cause symptoms until they become very large. So they are commonly diagnosed accidentally during a medical exam for other health issue.

Chronic liver diseases represent major clinical and public health issues worldwide. For various reasons, when chronic liver diseases are not controlled in time, then liver fibrosis and cirrhosis develop gradually. It is clinically acknowledged that the liver fibrosis at early and middle stages is reversible. Therefore, if the liver fibrosis in patients with chronic liver diseases can be accurately evaluated at early stages and be treated in time, we can stop the progress of diseases and reduce the occurrence of liver cirrhosis, liver failure and liver cancer.

FibroTouch®, our self-developed non-invasive liver fibrosis diagnostic system, is capable of making quantitative detection and assessment of liver fibrosis and steatosis. Today, FibroTouch® has been widely used in screening, diagnosis, monitoring and follow-up before, during and after treatment for patients with liver problems. It has greatly contributed to early detection, early prevention and early treatment of chronic liver diseases.
Liver Health Killer: Liver Fibrosis

What is liver fibrosis?
Liver fibrosis is the excessive accumulation of extracellular matrix proteins including collagen that occurs in most types of chronic liver diseases.

"Anyone who can stop or delay liver fibrosis would be able to cure most chronic liver diseases."
— Prof. Hans Popper, world's leading authority on liver diseases

Liver fibrosis is the common pathological process in various chronic liver diseases leading to liver cirrhosis.

Viruses hepatitis (B,C,D)
Non-alcoholic fatty liver disease (NAFLD)
Alcoholic liver disease (ALD)
Drug-induced liver injury
Other various causes

1. It is clinically acknowledged that the early and middle stages of liver fibrosis are reversible.
2. Early diagnosis and treatment of liver fibrosis can prevent chronic liver diseases from deteriorating into liver cirrhosis, liver cancer and liver failure.

Liver Health Killer: Hepatic Steatosis

Causes
Long-term alcoholism
Unhealthy lifestyles (e.g. stay up late at night, irregular diet, etc.)
Overnutrition, Obesity
Hyperlipidemia, diabetes and other metabolic diseases
Hyperthyroidism, anemia and other chronic diseases

Dangers
Aggravate liver damage, progress to cirrhosis, liver cancer.
Induce and aggravate coronary disease, hypertension, etc.
Induce and aggravate diabetes
Promote atherosclerosis, lead to blood circulation disorders, vascular rupture.
Lower body immunity and Detoxification functions.
Determination of Liver Fibrosis

Liver Stiffness Measurement (LSM) using Transient Elastography

Shear wave travels faster in the cirrhotic liver tissue in unit time.

FibroTouch® uses controlled low-frequency shear wave to vibrate the liver

The propagation speed of shear wave traveling through the liver tissue is tracked by high frequency ultrasonic beams

Liver stiffness value is derived from optimized scientific algorithms (elasticity modulus)

| Green waveform | ultrasound transmitted wave |
| Red waveform   | ultrasound echo            |
| Blue waveform  | shear wave                  |

Stiffness (kPa) 6.4

IQR 0.1  IQR/med % 1
Determination of Hepatic Steatosis

Ultrasound Attenuation Parameter (UAP)

The volume of liver tissue sample is at least 100 times bigger than a biopsy sample.

A large number of 2-4um fat droplets accumulate in hepatocytes of fatty liver, which will lead to considerable scattering of incident ultrasound, making ultrasound attenuation higher than that of the normal liver.

Ultrasound attenuation increases when hepatic steatosis gets severe.

UAP is an important indicator of hepatic steatosis.

All FibroTouch® devices can provide simultaneous determination of liver fibrosis and steatosis.
Clinical Guidelines

THE GUIDELINE OF PREVENTION AND TREATMENT FOR CHRONIC HEPATITIS B (2015 EDITION)

—Chinese Society of Hepatology and Chinese Society of Infectious Diseases, Chinese Medical Association

• The advantages of transient elastography (TE), as a mature non-invasive examination, are that it is easy-to-perform, reproducible and can accurately identify mild liver fibrosis, progressive liver fibrosis or early liver cirrhosis.

EXPERT CONSENSUS ON CLINICAL APPLICATION OF TRANSIENT ELASTOGRAPHY (TE) (2015)

—Expert Committee on Clinical Application of Transient Elastography (TE)

• Transient elastography (TE) can be used for reflecting the degree of liver fibrosis by liver stiffness measurement (LSM). Due to the advantages of being non-invasive, simple, rapid, easy-to-perform, reproducible, safe and well tolerated, transient elastography has been recommended as an important method for the clinical evaluation of hepatitis B and C virus associated liver fibrosis by the American Association for the Study of Liver Diseases (AASLD), the European Association for the Study of the Liver (EASL) and China Guideline of Prevention and Treatment for Chronic Hepatitis B.

GUIDELINES FOR THE SCREENING, CARE AND TREATMENT OF PERSONS WITH HEPATITIS C INFECTION (APRIL 2014)

—World Health Organization (WHO)

• Deciding when to initiate therapy for HCV infection is challenging and requires reliable assessment of the degree of liver fibrosis......However, if transient elastography is available and the cost of the test is not a barrier to its use, it is also recommended.
## Traditional Detection Methods

<table>
<thead>
<tr>
<th>Liver Biopsy</th>
<th>Serological Test</th>
<th>Imaging Methods</th>
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</thead>
<tbody>
<tr>
<td><img src="image" alt="Liver Biopsy Image" /></td>
<td><img src="image" alt="Serological Test Image" /></td>
<td><img src="image" alt="Imaging Methods Image" /></td>
</tr>
<tr>
<td>A small slender core of tissue is removed with a biopsy needle</td>
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</table>

- **Liver Biopsy**
  - Invasive
  - Complications
  - Sampling error
  - Irreproducible

- **Serological Test**
  - Minimally invasive
  - Low accuracy
  - Susceptible to inflammation
  - Low clinical acceptance

- **Imaging Methods**
  - Ultrasound
    - Only provide histomorphological information
    - Can merely find the late stage of liver fibrosis as there's no obvious morphological changes of liver fibrosis in the early and middle stages
    - Hard to be detected by ultrasound if liver steatosis is less than 30%
  - CT
    - Costly
    - Radioactive
  - MRI
    - Cannot be performed in a liver with an iron overload
    - Longer examination time
    - Costly

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FibroTouch® can be used in screening, diagnosing, tracking and monitoring of the following diseases:

- Non-alcoholic fatty liver disease (NAFLD)
- Alcoholic liver disease (ALD)
- Chronic hepatitis B
- Chronic hepatitis C
- Drug-induced liver injury
- Autoimmune liver disease
- Primary biliary cirrhosis
- Biliary tract disease
FT100
Portable non-invasive liver fibrosis diagnostic system

Applied Technology: Transient Elastography (TE)
Examination Method: Probe touch detection
Data Processing: Optimized scientific algorithms
Fibrosis Scanning Probe: Dynamic wideband frequency, real-time transmitting and receiving ultrasonic waves, controlled low-frequency shear wave
Functions: Liver Stiffness Measurement (LSM), Ultrasound Attenuation Parameter (UAP)
Hardware: 12.3" high-resolution touchscreen LCD monitor, 4GB internal memory, 500G storage space, 4xUSB 2.0 ports, 2xMiniDP ports, Foot switch
Power: AC power, 100V~240V, 47~63Hz
Dimensions: 40cm L x 8cm W x 30cm H
Net Weight: 7kgs (with accessories)

Reliable Clinical Examination Results

Degree of Liver Fibrosis (LSM,kPa)
Degree of Steatosis (UAP,dB/m)

Light-weight
Easy to carry and transport
3 hours of battery life
FT1000
Image-guided non-invasive liver fibrosis diagnostic system

**Applied Technology**

Transient Elastography (TE), 2D imaging technology

**Examination Method**

Probe touch detection

**Data Processing**

Optimized scientific algorithms

**Convex probe**

Scanning depth >200mm, real-time transmitting and receiving ultrasonic wave

**Fibrosis Scanning Probe Functions**

Dynamic wideband frequency, real-time transmitting and receiving ultrasonic wave

Liver Stiffness Measurement (LSM)

Ultrasound Attenuation Parameter (UAP)

Assessment of liver tissue morphology by 2D ultrasound

**Hardware**

19" high-resolution broadband LCD monitor

500G storage space

4xUSB 2.0 ports

RJ4 port

Control panel

Foot switch

**Power**

AC power, 230V±10%, 50Hz/60Hz±1Hz

**Dimensions**

100cm L × 62cm W × 140cm H

**Net Weight**

75kg

**Comprehensive Clinical Examination Results**

![Morphology of Liver Tissue (B mode image)](image1)

![Degree of Liver Fibrosis (LSM,kPa)](image2)

![Degree of Steatosis (UAP,dB/m)](image3)

*Fibrosis scanning probe needs to be calibrated once a year or every 30,000 measurements (around 3,000 patients) to maintain proper performance.*
Dynamic Wideband Fibrosis Scanning Probe

- Innovative dynamic wideband technology effectively reduces signal attenuation caused by subcutaneous fat layer, realizes dynamic self-adaption of the probe's frequency for children, general population and obese patients, meeting the demand for a more extensive morphological and clinical need without changing the probe.

- Built-in dynamic pressure balance sensor inside the probe intelligently indicates probe pressure, thus ensuring accuracy of detection and improving precision of tests.

Intelligent Diagnosis Software

- Efficient workflow and user-friendly interface
- Comprehensive management and analysis of patient data
- Medical digital imaging and DICOM 3.0 supported

Ergonomic Design

- FibroTouch® devices are designed with prominent ergonomics and comfortability
- Unique foot switch design reduces the risk of losing the located firing position
Non-invasive Solution for Liver Diagnosis

Early Screening  Early Detection  Regular Follow-up

Clinical Advantages of FibroTouch®

- **Non-Invasive**: No need for blood collection, repeatable, thus good for follow-up of patients with liver fibrosis and steatosis and evaluation of treatment effect.

- **Rapid**: The examination only takes a few minutes, and the measurement results can be obtained quickly.

- **Accurate**: The liver tissue sample volume is 100 times larger than a liver biopsy sample, which can fully reflect the liver condition. The test results have high consistency with liver biopsy results.

- **Quantitative**: Simultaneous detection of liver fibrosis and steatosis quantitatively, easily track and compare multiple measured results for the same patient.
Examination Procedure

1. Patient prepares for exam in a supine position
2. Start the equipment
3. Perform ultrasound exam (if the equipment has ultrasound guided function)
4. Perform liver fibrosis exam
5. Print examination report
6. Refer the report to the physician for interpretation
Training

The professional training will be provided by our application specialists to help users ensure accurate and reliable scanning. The dedicated training includes:

■ Theoretical Training
Gain an understanding and knowledge of basic principle, system configurations, features, requirements for successful measurements, and the criteria of use of the device and probe.

■ Practical Training
Hands-on training is provided to ensure that the appointed users will have good examination skills and practice.

The appointed users will be certified to use FibroTouch® after the completion of the above training.

After-sales Service

■ Local Service
Local distributors will be responsible for after-sales service of FibroTouch® devices. The manufacturer offers extensive and dedicated service training to the distributors to make sure their service engineers master the skills of supporting field engineering and maintenance service of FibroTouch® devices.

■ Probe Calibration
To maintain proper performance, the fibrosis scanning probes need to be calibrated once a year or every 30,000 shots (around 3,000 patients). The manufacturer provides probe calibration after distributors send the probes back to the factory.

■ Manufacturer Support
The manufacturer will support the distributors with repairs, spare parts and maintenance services. Highly qualified well-trained service engineers as well as the R&D team will provide prompt technical support to the distributors worldwide.

For service issues, please feel free to contact us at service@fibrotouch.com or local distributors for help.

Certificates

![CE Certificate](image)

CE

![ISO 13485 Certificate](image)

ISO 13485
### Granted Patents

<table>
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<th>Application No.</th>
<th>Patent Description</th>
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<td>ZL200910235731.3</td>
<td>Method and device for ultrasonic and nondestructive detection of viscoelastic medium</td>
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<td>Composite probe for elasticity measurement</td>
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<td>System for combining and displaying quantitative elasticity information and structural information of tissue</td>
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<td>Device for selecting detection area, and elasticity detection system</td>
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<td>Ultrasonic diagnostic apparatus</td>
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<td>Fiber scanning probe</td>
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<td>Data analyzing and processing method of elastic detector, and elastic detector</td>
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<td>15</td>
<td>ZL201520386539.5</td>
<td>Quantitative system of liver fat based on ultrasonic wave</td>
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<td>16</td>
<td>ZL201520058481.1</td>
<td>Medical equipment based on shear wave formation of image</td>
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<td>ZL201520180123.8</td>
<td>Portable ultrasonic detection equipment used for elasticity measuring</td>
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<td>Ultrasonic detection device and system used for elasticity measuring</td>
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<td>Portable non-invasive hepatic fibrosis diagnosis instrument</td>
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<td>Elastic imaging system</td>
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<td>Front-end receiver of ultrasonic imaging system</td>
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<td>ZL201520864199.2</td>
<td>Medical coupler heater</td>
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<td>Heat processing device of elastic detection equipment</td>
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<td>25</td>
<td>ZL201620185362.7</td>
<td>Automatic triggered elasticity detection device</td>
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<td>26</td>
<td>US13497648</td>
<td>Method and device for detecting elasticity of viscous elastic medium</td>
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<td>Chin J Hepatol, February 2017, Vol.25, No.2</td>
<td>Chen Gaofeng, Liu Chenghai, et al</td>
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<td>J Clin Gastroenterol</td>
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<td>of complications in patients with liver cirrhosis</td>
<td>Hepat Mon.2016</td>
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<td>Hong Deng, Zhi-Liang Gao, et al</td>
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<td>Correlation between spleen stiffness measured by FibroTouch and the parameters of liver cirrhosis with portal hypertension</td>
<td>J Clin Gastroenterol</td>
<td>Gang Qin, Lu-Jun Wang, et al</td>
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<td>Diagnostic efficacy of FibroTouch by measuring fat attenuation index in detecting liver steatosis in patients with non-alcoholic fatty liver diseases</td>
<td>J Prac Hepatol, Jan. 2016, Vol.19 No.1</td>
<td>Yuan Pingge</td>
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<td>APASL2016</td>
<td>Huabing ZHANG, Anlin MA</td>
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<td>Correlation Analysis between Serum Fibrosis Index and Liver Stiffness Measured by FibroTouch</td>
<td>Journal of China Medical University Vol.46 No.1 Jan. 2017</td>
<td>Zhou Linyan, Li Yan</td>
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