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FIBROTOUCH®

Innovative Solution for Liver Diagnosis

Non-invasive Assessment of Liver Fibrosis and Steatosis



CE 0123

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HISKY

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.

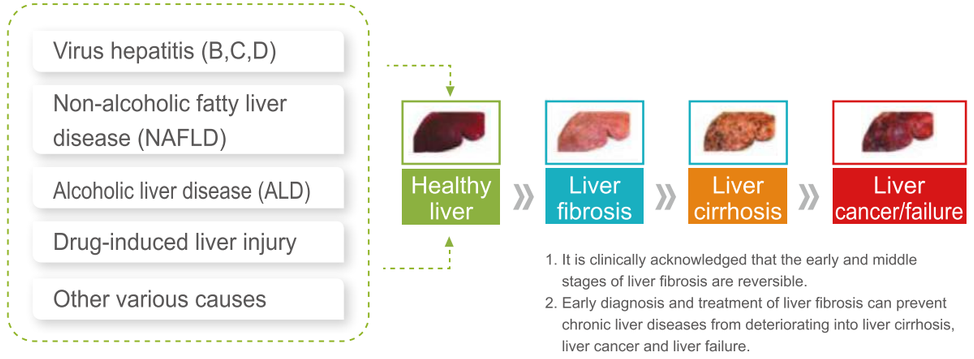
Liver Health Killer: Liver Fibrosis

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.

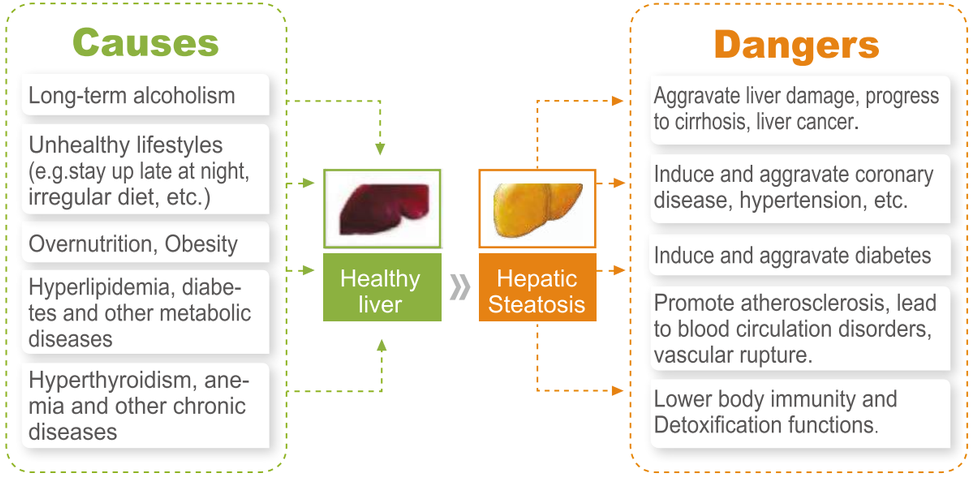
> Anyone who can stop or delay liver fibrosis would be able to cure most chronic liver diseases.
>
> ——Prof.Hans Popper, world's leading authority on liver diseases

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



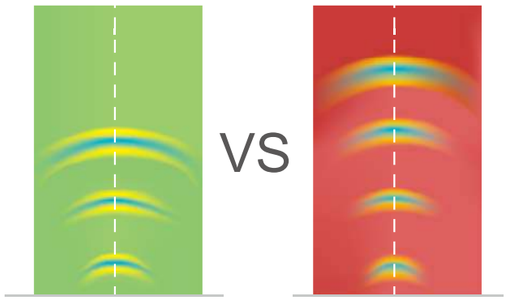
1. It is clinically acknowledged that the early and middle stages of liver fibrosis are reversible.
2. Early diagnosis and treatment of liver fibrosis can prevent chronic liver diseases from deteriorating into liver cirrhosis, liver cancer and liver failure.

Liver Health Killer: Hepatic Steatosis



Determination of Liver Fibrosis

Liver Stiffness Measurement (LSM) using Transient Elastography



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

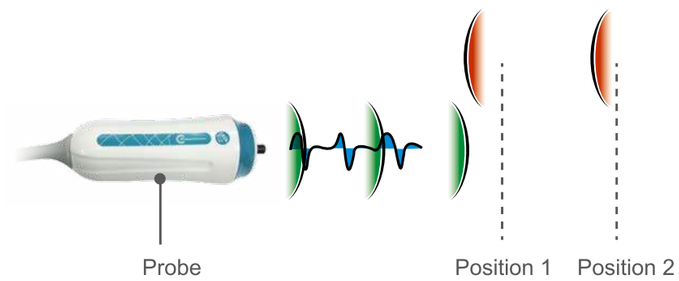
FibroTouch® uses controlled low-frequency shear wave to vibrate the liver

»

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)

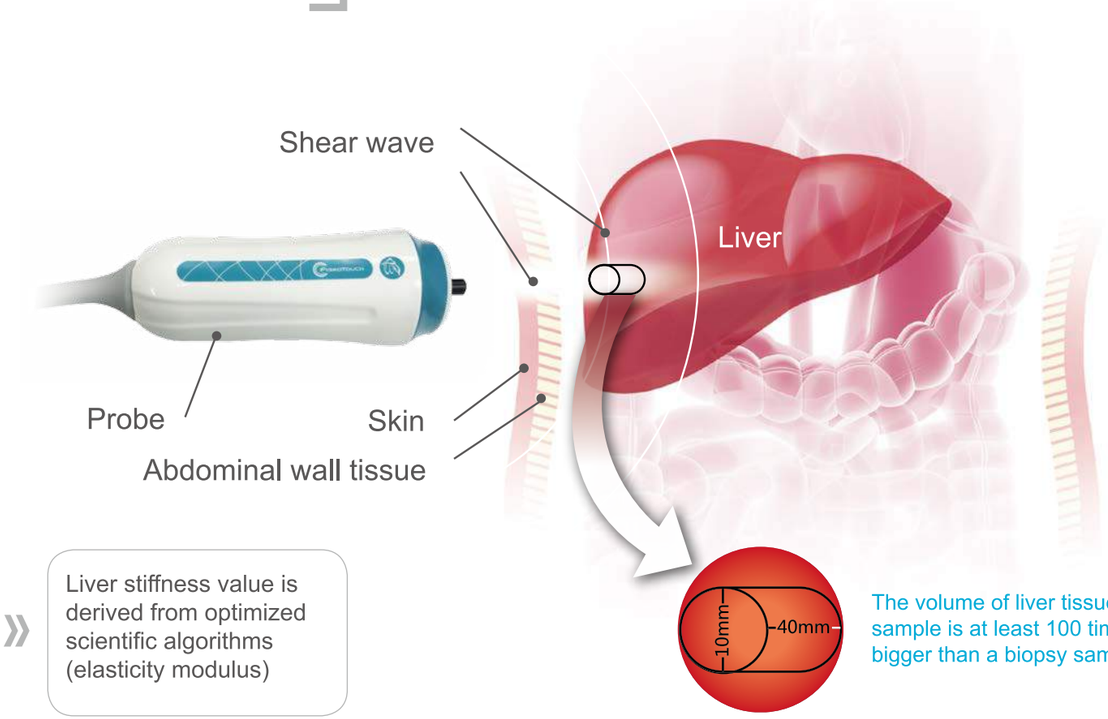


Green waveform	ultrasound transmitted wave
Red waveform	ultrasound echo
Blue waveform	shear wave

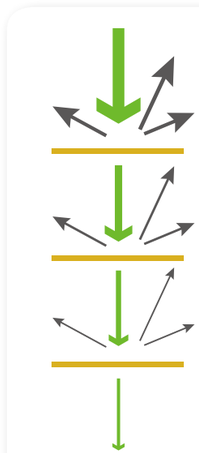


Determination of Hepatic Steatosis

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)

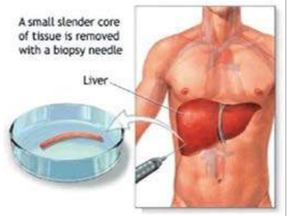
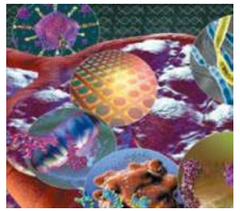
- Transient elastography (TE) can be used for reflecting the degree of liver fibrosis by liver stiffness measurement (LSM). Due to the advantages of being non-invasive, simple, rapid, easy-to-perform, reproducible, safe and well tolerated, transient elastograpy has been recommended as an important method 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

Liver Biopsy	Serological Test	Imaging Methods
		
• Invasive • Complications • Sampling error • Irreproducible	• Minimally invasive • Low accuracy • Susceptible to inflammation • Low clinical acceptance	• 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

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

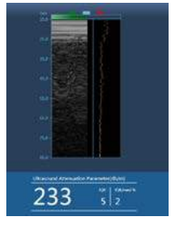


Applied Technology	Transient Elastography (TE)
Examination Method	Probe touch detection
Data Processing	Optimized scientific algorithms
Fibrosis Scanning Probe	Dynamic wideband frequency, real-time transmitting and receiving ultrasonic waves, controlled low-frequency shear wave
Functions	Liver Stiffness Measurement (LSM) Ultrasound Attenuation Parameter (UAP)
Hardware	12.3" high-resolution touchscreen LCD monitor 4GB internal memory 70G storage space (128G hard disk) 2×USB 2.0 ports 1×MiniDP port Foot switch
Power	AC power, 100V~240V, 47~63Hz
Dimensions	40cm L × 8cm W × 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	Dynamic wideband frequency, real-time transmitting and receiving
Functions	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 4×USB 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

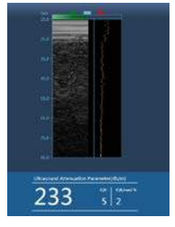
Comprehensive Clinical Examination Results



Morphology of Liver Tissue
(B mode image)



Degree of Liver Fibrosis
(LSM,kPa)



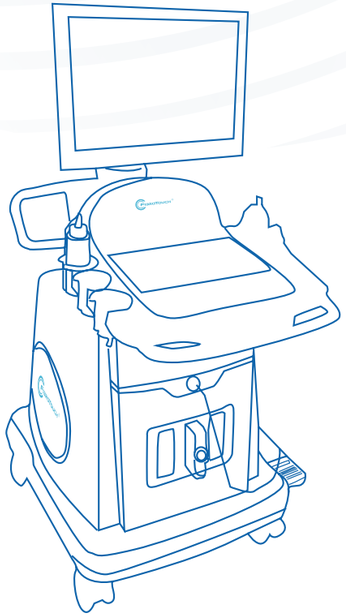
Degree of Steatosis
(UAP,dB/m)

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

FibroTouch®

Non-invasive Solution for Liver Diagnosis

Early Screening | **Early Detection** | **Regular Follow-up**

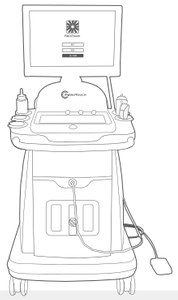
Clinical Advantages of FibroTouch®

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



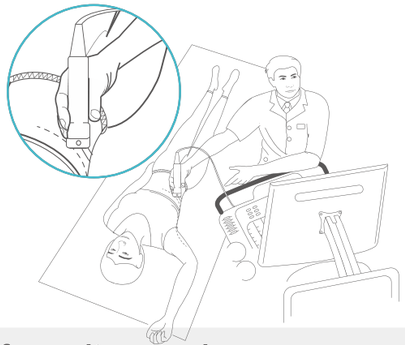
1 Patient prepares for exam in a supine position



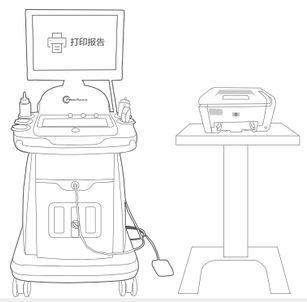
2 Start the equipment



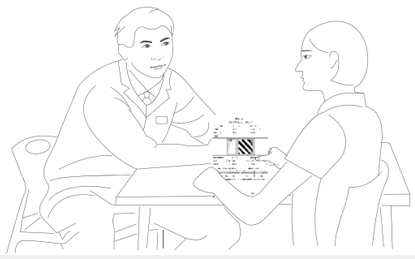
4 Perform liver fibrosis exam



3 Perform ultrasound exam
(if the equipment has ultrasound guided function)



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



ISO 13485

Granted Patents

NO.	APPLICATION NO.	PATENT DESCRIPTION	STATUS
1	ZL200910235731.3	Method and device for ultrasonic and nondestructive detection of elasticity of viscoelastic medium	Granted
2	ZL201210022224.3	Composite probe for elasticity measurement	Granted
3	ZL201320300525.8	System for combining and displaying quantitative elasticity information and structural information of tissue	Granted
4	ZL201320891747.1	Instant elasticity detecting device	Granted
5	ZL201420611897.7	Device for selecting detection area, and elasticity detection system	Granted
6	ZL201420533373.0	Image-guided type elastic detection system	Granted
7	ZL201420610343.5	Elasticity detection device and system	Granted
8	ZL201420526844.5	Elastic detection probe	Granted
9	ZL201420527337.3	Elastic detection probe	Granted
10	ZL201430327029.1	Ultrasonic diagnostic apparatus	Granted
11	ZL201430326893.X	Fiber scanning probe	Granted
12	ZL201530052708.7	Ultrasonic diagnostic apparatus	Granted
13	ZL201530052522.1	Ultrasonic diagnostic apparatus	Granted
14	ZL201510076909.X	Data analyzing and processing method of elastic detector, and elastic detector	Granted
15	ZL201520386539.5	Quantitative system of liver fat based on ultrasonic wave	Granted
16	ZL201520058481.1	Medical equipment based on shear wave formation of image	Granted
17	ZL201520180123.8	Portable ultrasoic detection equipment used for elasticity measuring	Granted
18	ZL201520182775.5	Ultrasonic detection device and system used for elasticity measuring	Granted
19	ZL201520239932.1	Elastic detection device	Granted
20	ZL201530104787.1	Portable non-invasive hepatic fibrosis diagnosis instrument	Granted
21	ZL201520963057.1	Elastic imaging system	Granted
22	ZL201521081496.6	Front-end receiver of ultrasonic imaging system	Granted
23	ZL201520864199.2	Medical coupler heater	Granted
24	ZL201520863010.8	Heat processing device of elastic detection equipment	Granted
25	ZL201620185362.7	Automatic triggered elasticity detection device	Granted
26	US13497648	Method and device for detecting elasticity of viscous elastic medium	Granted

Clinical Reserach Literatures

TITLE	PUBLICATION	AUTHORS
Correlation of liver stiffness measured by FibroTouch and FibroScan with Ishak fibrosis score in patients with chronic hepatitis B	Chin J Hepatol, February 2017, Vol.25, No.2	Chen Gaofeng, Liu Chenghai, et al
Predictive value of FibroTouch combined with FIB- 4 index in prediction of complications in patients with liver cirrhosis	J Prac Hepatol, Mar. 2017, Vol.20, No.2	Liu Yan, Zhao Weifeng, et al
Efficiency of FibroScan and FibroTouch in liver stiffness measurement and fat quantification: a comparative analysis	Chin J Hepatol, September 2016, Vol.24, No.9	Zeng Jing, Fan Jiangao, et al
Correlation of FibroTouch and FibroScan with the stage of primary biliary cirrhosis	Chin J Hepatol, December 2016, Vol.24, No.12	Zhang Yuguo, Nan Yuemin, et al
Correlation between spleen stiffness measured by FibroTouch and the parameters of liver cirrhosis with portal hypertension	Chin J Clinicians(Electronic Edition), February 15, 2016, Vol.10, No.4	Hu Na, Ou Xiaojuan
Liver and spleen stiffness combine with portal vein width to evaluate the risk of esophageal and gastric varices bleeding	Chin J Hepatol, December 2016, Vol.24, No.1	Guo Yunlei, Lu Xiaolan, et al
Noninvasive Diagnosis of Hepatic Steatosis Using Fat Attenuation Parameter Measured by FibroTouch and a New Algorithm in CHB patients	Hepat Mon.2016 September; 16(9):e40263	Hong Deng, Zhi-Liang Gao, et al
Population-representative Incidence of Acute-On-Chronic Liver Failure A Prospective Cross-Sectional Study	J Clin Gastroenterol	Gang Qin, Lu-Jun Wang, et al
Factors influencing controlled attenuation parameter measured by FibroTouch in healthy individuals	WCJD, April 2016; 24(12): 1874-1879	Yu-Jun Song, Zi-Bin Tian, et al
Diagnostic efficacy of FibroTouch by measuring fat attenuation index in detecting liver steatosis in patients with non-alcoholic fatty liver diseases	J Prac Hepatol, Jan. 2016. Vol.19 No.1	Yang Shuo, Xu Youqing, et al
Clinical significance of FibroTouch, ultrasound, and computed tomography in diagnosis of fatty liver disease: a comparative analysis	J Clin Hepatol, Vol.32 No.3, Mar.2016	Li Jingbo, Wang Bingyuan, et al
The value of FibroTouch fat attenuation parameter in patients with chronic hepatitis B complicated with nonalcoholic fatty liver disease	Chin J Infect Dis, June 2015, Vol.33, No.6	Mao Zhongshan, Shang Jia, et al
Current perspectives on the application of transient elastography in diagnosis of liver diseases	J Prac Hepatol, Jan. 2016.Vol.19 No.1	Yuan Pingge
Comparison of FibroTouch and acoustic radiation force impulse in diagnosis of liver fibrosis in patients with chronic hepatitis B	JOURNAL OF ZHEJIGNG UNIVERSITY (MEDICAL SCIENCES), July 2016	Liu Fang, Huang Bin, et al
Liver Stiffness Measured by Transient Elastography is Superior to APRI and FIB-4 in CHB Patients	APASL2016	Huabing ZHANG, Anlin MA
Correlation Analysis between Serum Fibrosis Index and Liver Stiffness Measured by FibroTouch	Journal of China Medical University Vol.46 No.1 Jan. 2017	Zhou Linyan, Li Yan
Comparison of FibroTouch and FibroScan for the assessment of fibrosis in chronic hepatitis B patient	Clin J Hepatol,February 2015, Vol.23, No.2	Ou Xiaojuan, Jia Jidong, et al
Clinical study on FibroTouch and multi-parameter model for diagnosis of hepatic fibrosis in patients with chronic liver disease	Clin J Hepatol, January 2015, Vol.23, No.1	Wang Rongqi, Nan Yuemin, et al
Correlation study of spleen stiffness measured by FibroTouch with esophageal and gastric varices in patients with liver cirrhosis	J Clin Hepatol, Vol.31, No.3, Mar.2015	Wei Yutong, Pan Liulan, et al
Identifying patients with chronic hepatitis B at high risk of type 2 diabetes mellitus: a cross-sectional study with pair-matched controls	BMC Gastroenterology (2015) 15:32	Yi Shen, Gang Qin, et al