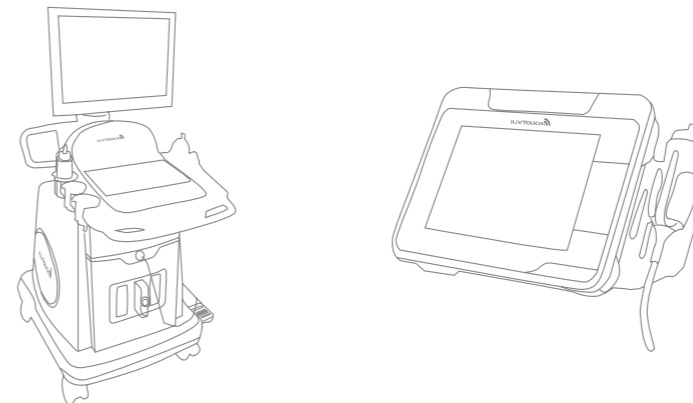




Innovative Solution for Liver Diagnosis

Shear Wave Quantificational
Ultrasound Diagnostic System



Follow Us:    

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.

iLivTouch, our self-developed non-invasive liver fibrosis diagnostic system, is capable of making quantitative detection and assessment of liver fibrosis and steatosis. Today, iLivTouch 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.

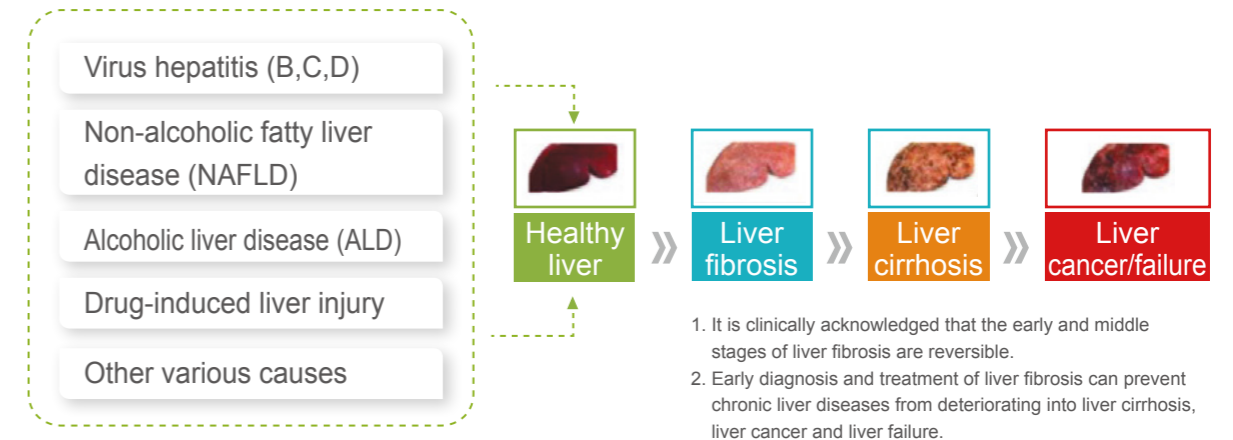
Liver Health Killer: Liver Fibrosis

What is liver fibrosis?

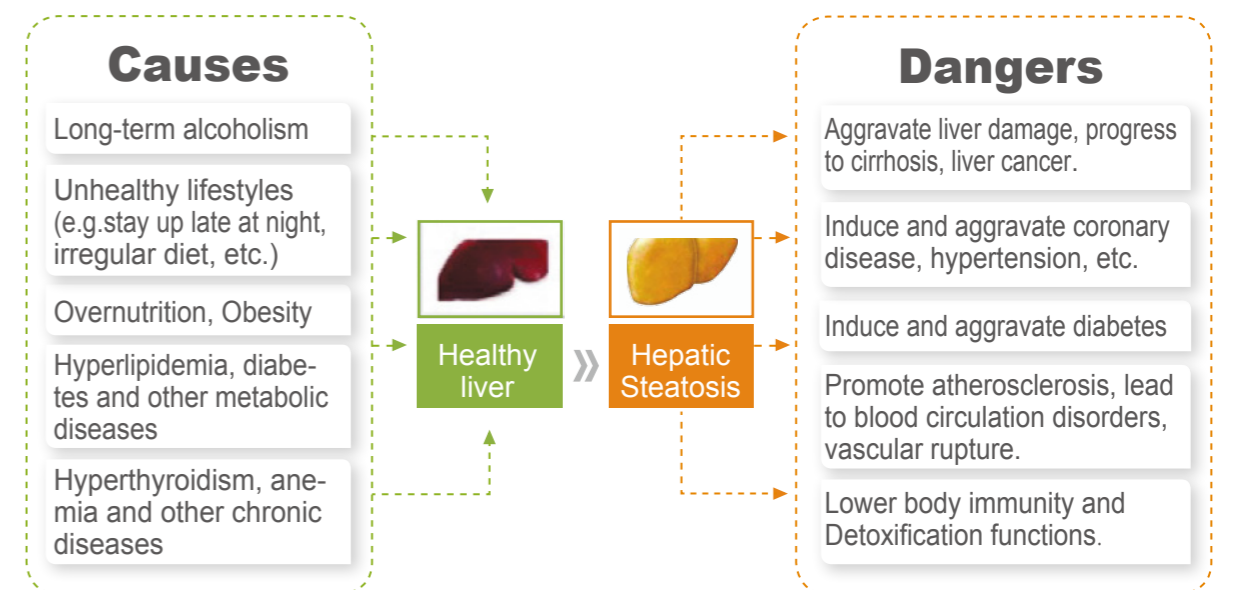
Liver fibrosis is the excessive accumulation of extracellular matrix proteins including collagen that occurs in most types of chronic liver diseases.

“ 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.

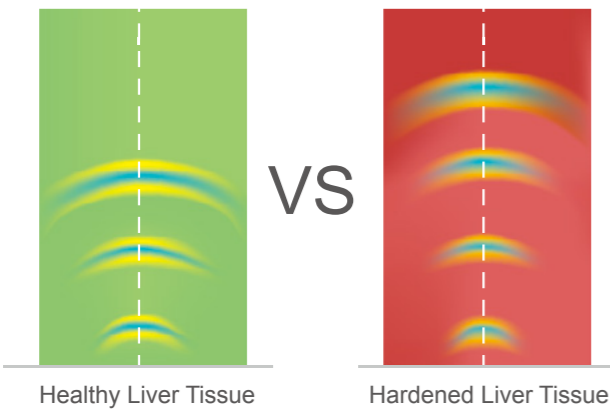


Liver Health Killer: Hepatic Steatosis

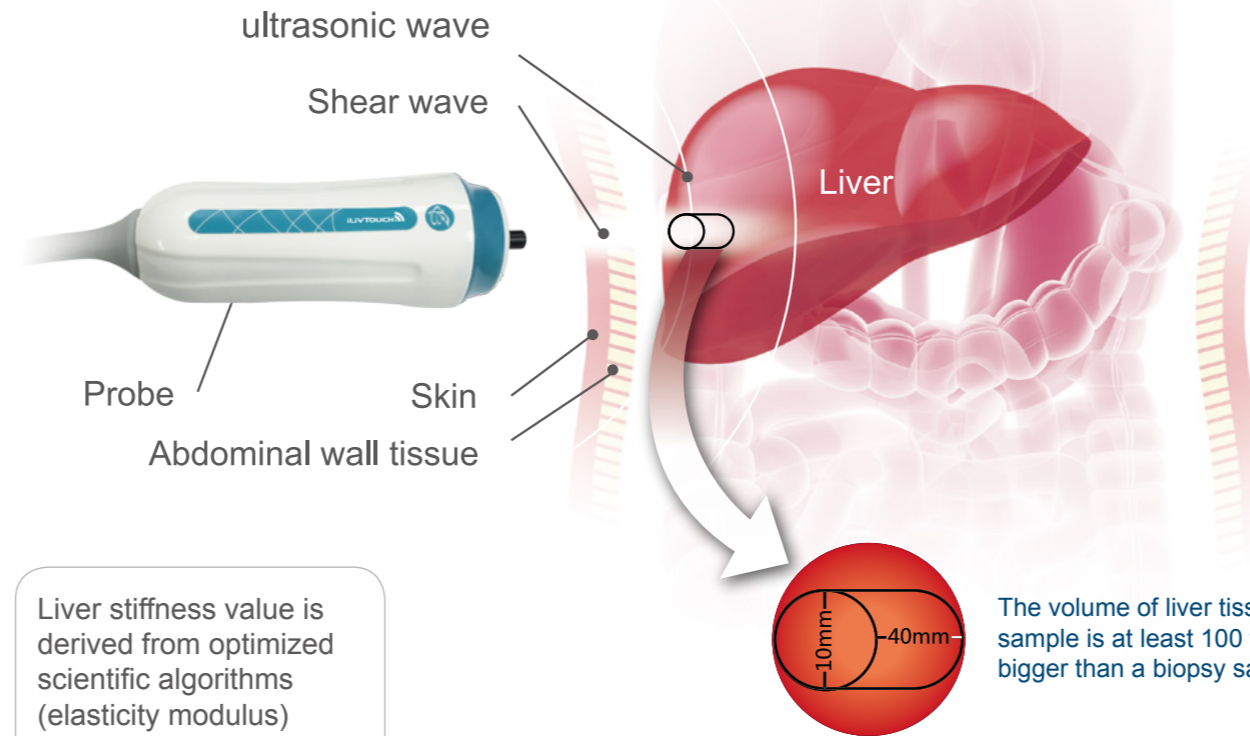


Determination of Liver Fibrosis

Liver Stiffness Measurement (LSM) using Transient Elastography



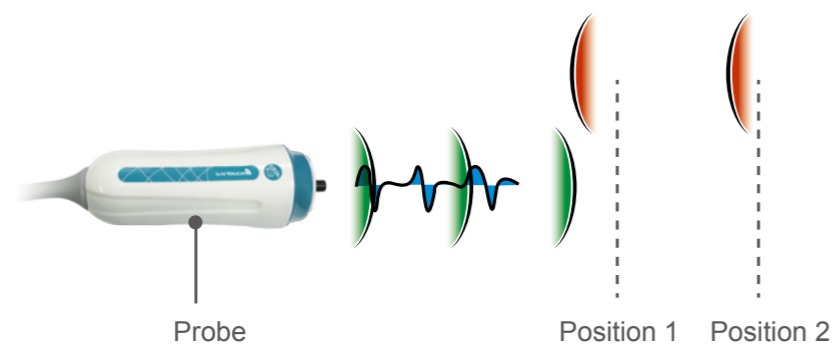
Shear Wave travels faster in the cirrhotic liver tissue in unit time.



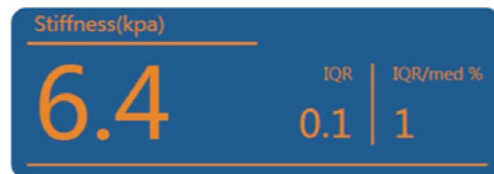
iLivTouch uses controlled low-frequency shear wave to vibrate the liver

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



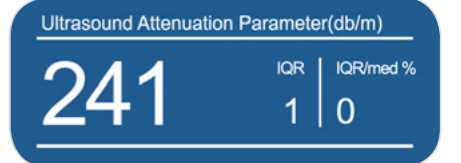
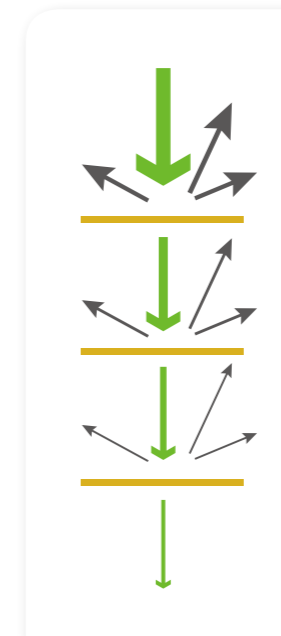
Determination of Hepatic Steatosis

Ultrasound Attenuation Parameter (UAP)

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



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

- Transient elastography (TE), as a relatively mature non-invasive examination, has the advantages of simple operation and good repeatability, and can accurately identify mild liver fibrosis and 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)

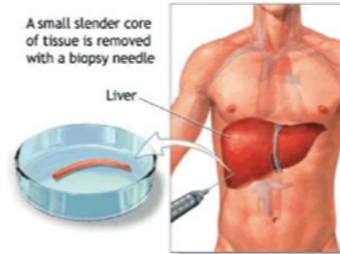
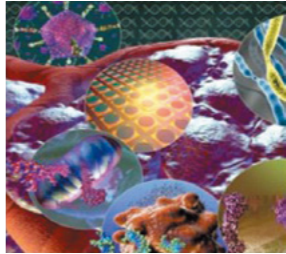
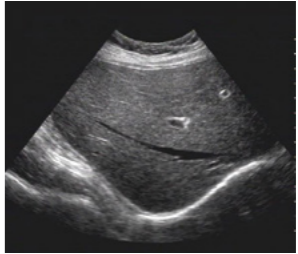
- Transient elastography (TE) can be used for reflecting the degree of liver fibrosis by liver stiffness measurement (LSM). Due to the advantages of being non-invasive, simple, rapid, easy-to-perform, reproducible, safe and well tolerated, transient elastography has been recommended as an important method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

Liver Biopsy	Serological Test	Imaging Methods
 <p>A small slender core of tissue is removed with a biopsy needle.</p>		
<ul style="list-style-type: none"> • Invasive • Complications • Sampling error • Irreproducible 	<ul style="list-style-type: none"> • Minimally invasive • Low accuracy • Susceptible to inflammation • Low clinical acceptance 	<ul style="list-style-type: none"> • Ultrasound <ul style="list-style-type: none"> -Only provide histomorpho-logical 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 <ul style="list-style-type: none"> -Costly -Radioactive • MR Elastography <ul style="list-style-type: none"> -Not applicable in case of iron overloaded -Time-consuming -Costly

Clinical Advantages

• Non-Invasive	No need for blood collection, repeatable, thus good for follow-up of patients and evaluation of treatment effect
• Rapid	The examination only takes a few minutes, and the measurement results can be obtained immediately
• 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 and quantitative detection of liver fibrosis and steatosis, easily track and compare multiple measured results for the same patient

FT100

Shear Wave Quantificational
Ultrasound 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 128G hard disk (70G storage space) 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)

FT9000 FT1000

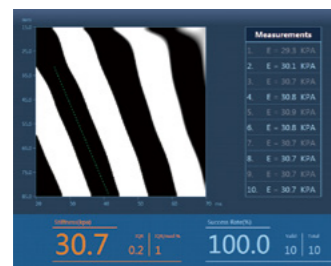
Shear Wave Quantificational
Ultrasound Diagnostic System

Image-Guided

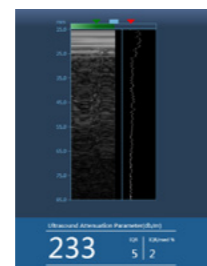


Applied Technology	Transient Elastography (TE), 2D imaging technology
Examination Method	Probe touch detection
Data Processing	Optimized scientific algorithms
Convex probe	Scanning depth >200mm, real-time transmitting and receiving ultrasonic wave
Fibrosis Scanning Probe	Dynamic wideband frequency, real-time transmitting and receiving ultrasonic waves, controlled low-frequency shear wave
Functions	Liver Stiffness Measurement (LSM) Ultrasound Attenuation Parameter (UAP)
Hardware	Assessment of liver tissue morphology by 2D ultrasound 19" high-resolution broadband LCD monitor 1T hard disk 4×USB 2.0 ports RJ45 port Control panel Foot switch
Power	AC power, 230V±10%, 50Hz/60Hz±1Hz
Dimensions	100cm L × 62cm W × 140cm H
Net Weight	75kg

Reliable Clinical Examination Results



LSM, kPa



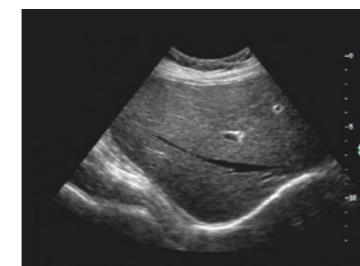
UAP, dB/m

Light-weight

Easy to carry and transport

3 hours of battery life

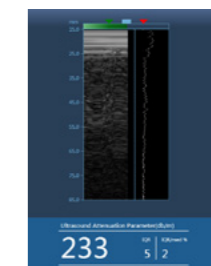
Comprehensive Clinical Examination Results



Morphology of Liver Tissue



LSM, kPa

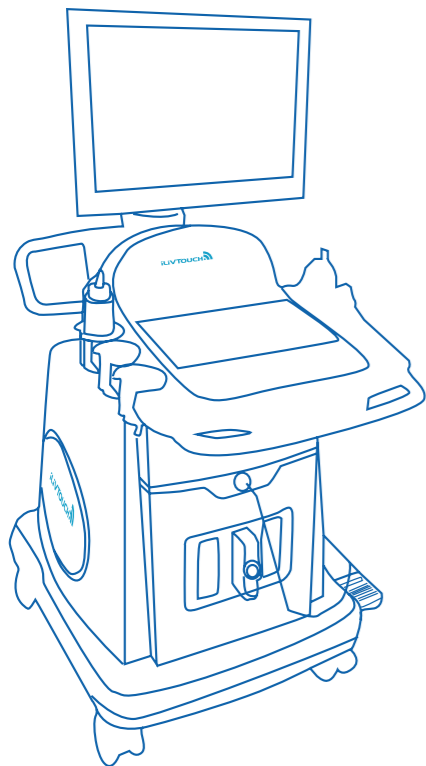


UAP, dB/m



Wideband Fibrosis Scanning Probe

- Innovative 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 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

- iLivTouch devices are designed with prominent ergonomics and comfortability
- Unique foot switch design reduces the risk of losing the located firing position



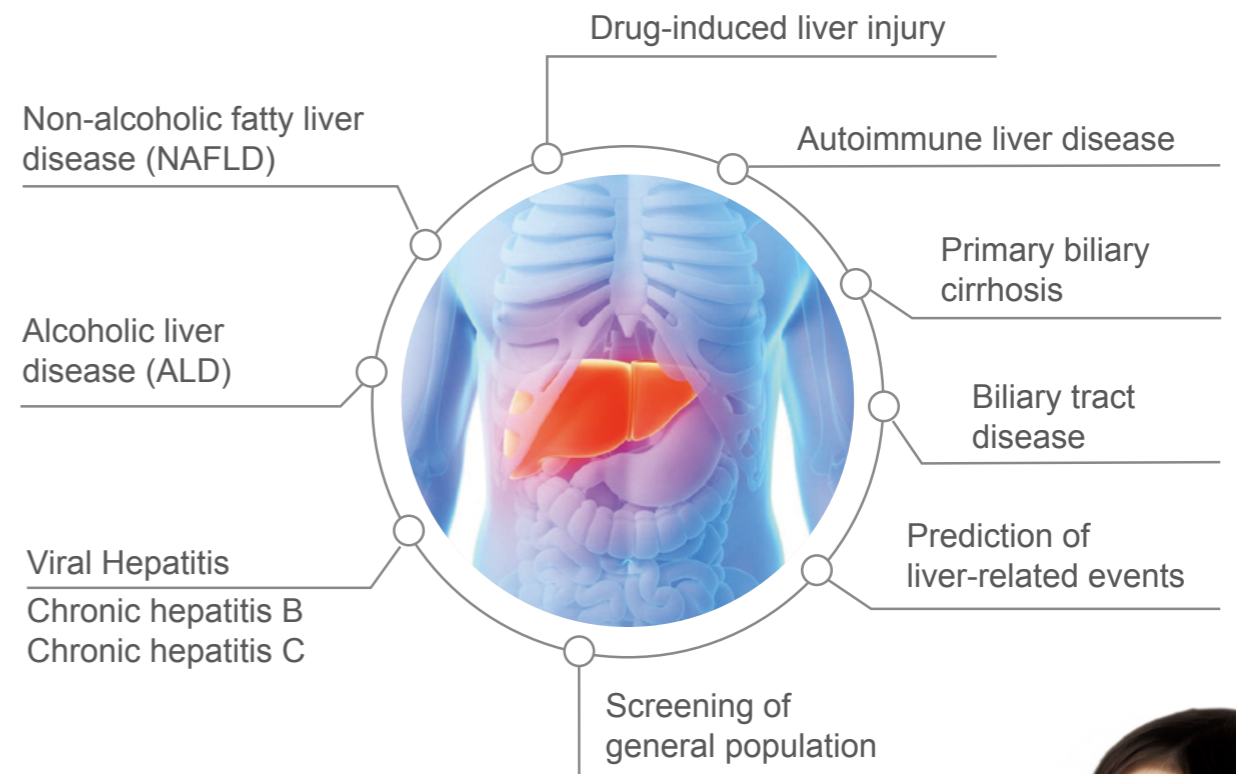
Non-invasive Solution for Liver Diagnosis

Early Screening

Early Diagnosis

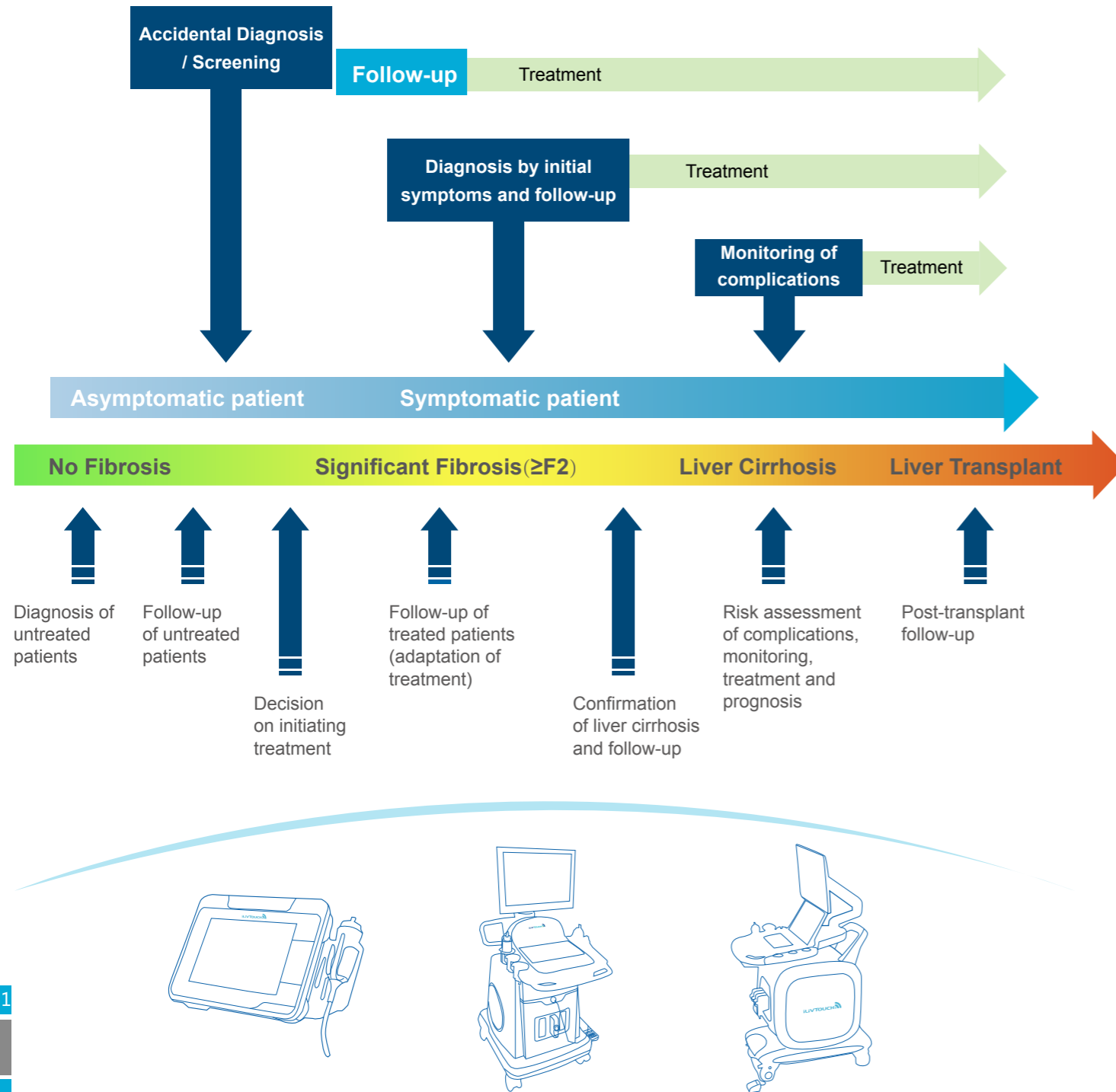
Early Treatment

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

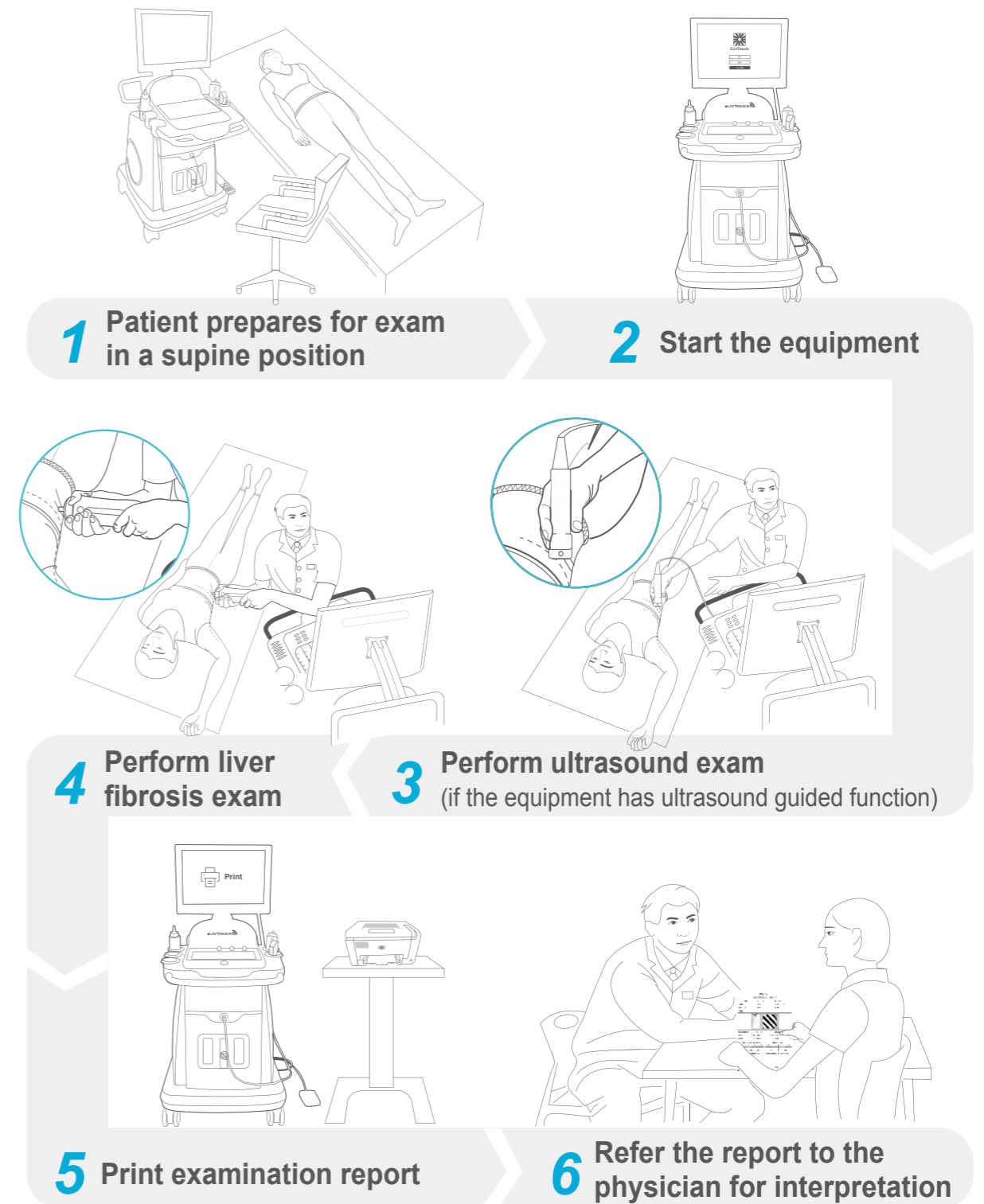


Application Range

Across Chronic Liver Diseases Spectrum Screening, Follow-Up, Prognosis



Examination Procedure



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 iLivTouch after the completion of the above training.



After-Sales Service



■ Local Service

Local distributors will be responsible for after-sales service of iLivTouch 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 iLivTouch devices.

■ Probe Calibration

To maintain proper performance, the fibrosis scanning probes need to be calibrated once a year or every 30,000 shots. 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@hiskymedical.com or local distributors for help.

About HISKY

R&D Center (Beijing)



Tsinghua Science Park

Manufacturing Base (Wuxi)



Taihu International Science & Technology Park

Milestones



- 2019 Launched new brand **livTOUCH** series products (MigTE*)
- 2018 Received U.S. FDA 510(k) clearance
- 2014 Obtained CE certificate
- 2010 HISKY founded in July and launched **FIBROTOUCH** series products

Global Installations



>2,000 Hospitals & Medical Institutions

>30 Countries & Regions

* Multichannel image-guided Transient Elastography

Our Commitment To Quality



CE



ISO 13485



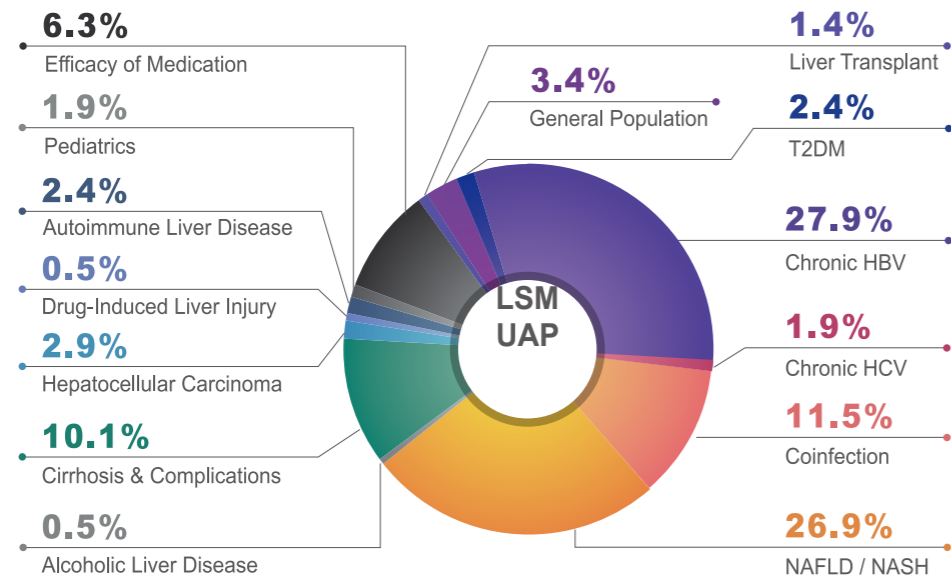
U.S. FDA 510(k) PMN SE*



* Premarket Notification Substantially Equivalent

Clinical Research

Peer-Reviewed Publications per Etiology (200+ Publications Since 2014)



Transient Elastography is Widely Recommended in the Clinical Practice Guidelines of Leading Organizations Worldwide.

EASL	European Association for the Study of the Liver	ALEH	Asociación Latinoamericana para el Estudio del Hígado
APASL	Asia Pacific Association for the Study of Liver	WHO	World Health Organization
AASLD	American Association for the Study of Liver Diseases	CSH	Chinese Society of Hepatology

And more scientific bodies.

APASL 2016

- TE is an established technique and is recommended as the initial assessment for significant liver fibrosis and cirrhosis.
- TE helps to predict complications of cirrhosis and its prognosis.
- TE is a highly reproducible and user-friendly technique for assessing liver fibrosis in patients with CLD.

Reference: Asian-Pacific Association for the Study of the Liver (APASL) consensus guidelines on invasive and non-invasive assessment of hepatic fibrosis: a 2016 update.

EASL- ALEH 2015

- TE is a fast, simple, safe and easy to learn procedure that is widely available.
- TE can be considered the non-invasive standard for the measurement of LS.
- TE is the most accurate non-invasive method for detecting cirrhosis in patients with viral hepatitis.

Reference: EASL-ALEH Clinical Practice Guidelines: Non-invasive tests for evaluation of liver disease severity and prognosis.

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 ultrasonic 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