Innovative Solution for Liver Diagnosis
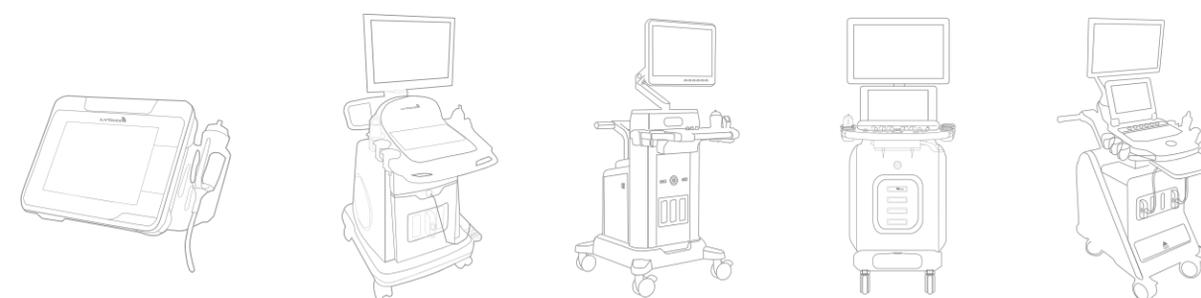
Shear Wave Quantificational Ultrasound Diagnostic System

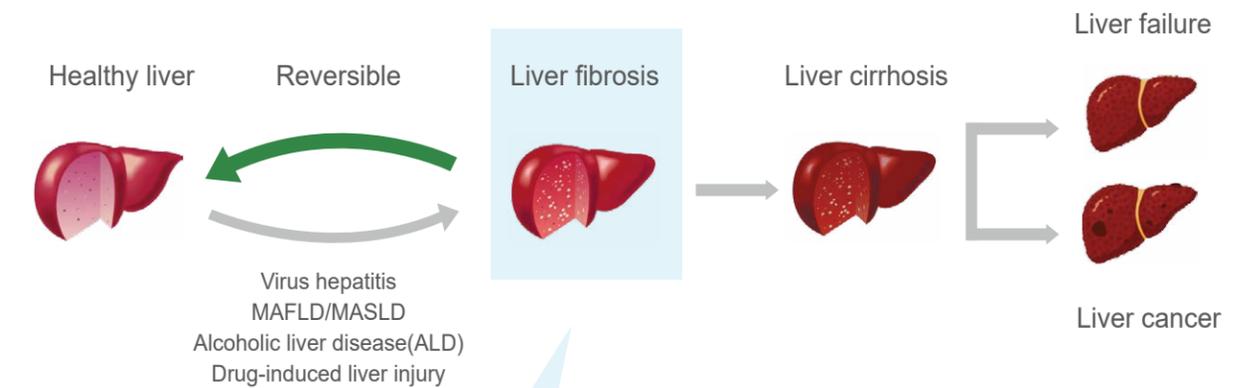Follow Us: LinkedIn Facebook Twitter YouTube

U.S. FDA 510(k) Clearance CE 0123

HISKY

en.hiskymedical.com

Liver Health Killer: Liver Fibrosis

> " 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.

We Care about Your Liver Health

Empowering Early Detection with iLivTouch®

·Precise quantitative detection and assessment of liver fibrosis and steatosis.

iLiVTOUCH

Early detection is key to slowing the progression of liver disease

Healthy liver　Reversible　Liver fibrosis　Liver cirrhosis　Liver failure

Liver cancer

Virus hepatitis
MAFLD/MASLD
Alcoholic liver disease(ALD)
Drug-induced liver injury

ⓘ
- It is clinically acknowledged that the early and middle stages of liver fibrosis are reversible.
- Early diagnosis and treatment of liver fibrosis can prevent chronic liver diseases from deteriorating into liver cirrhosis,liver cancer and liver failure.
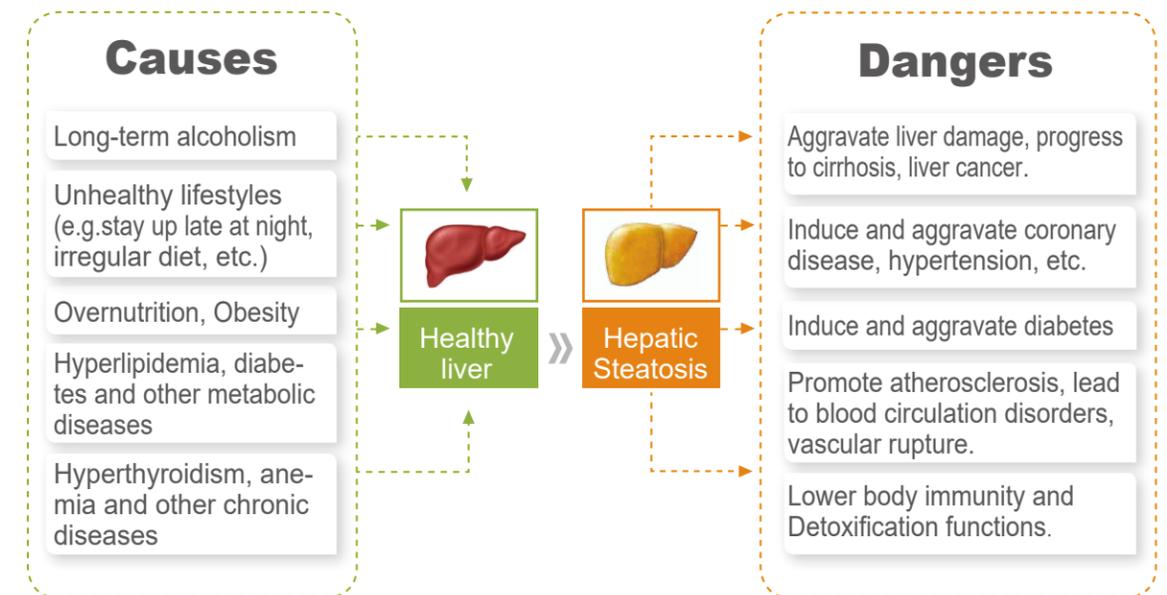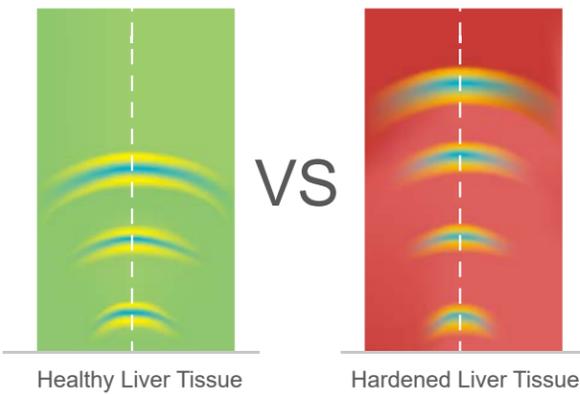
Liver Health Killer: Hepatic Steatosis

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 |

Healthy liver　》　Hepatic Steatosis

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

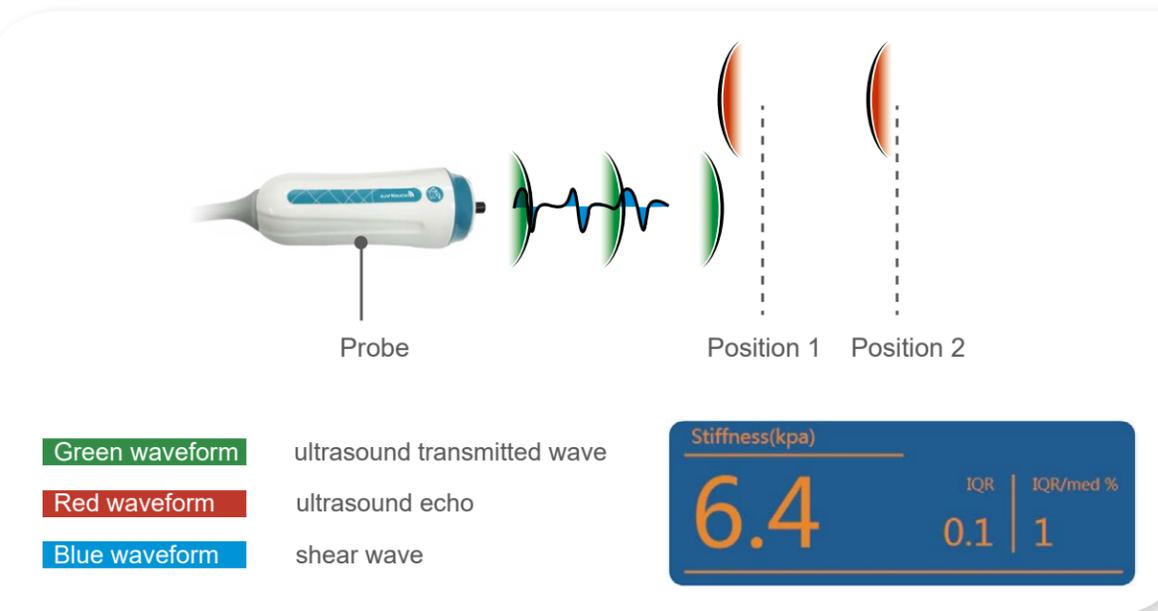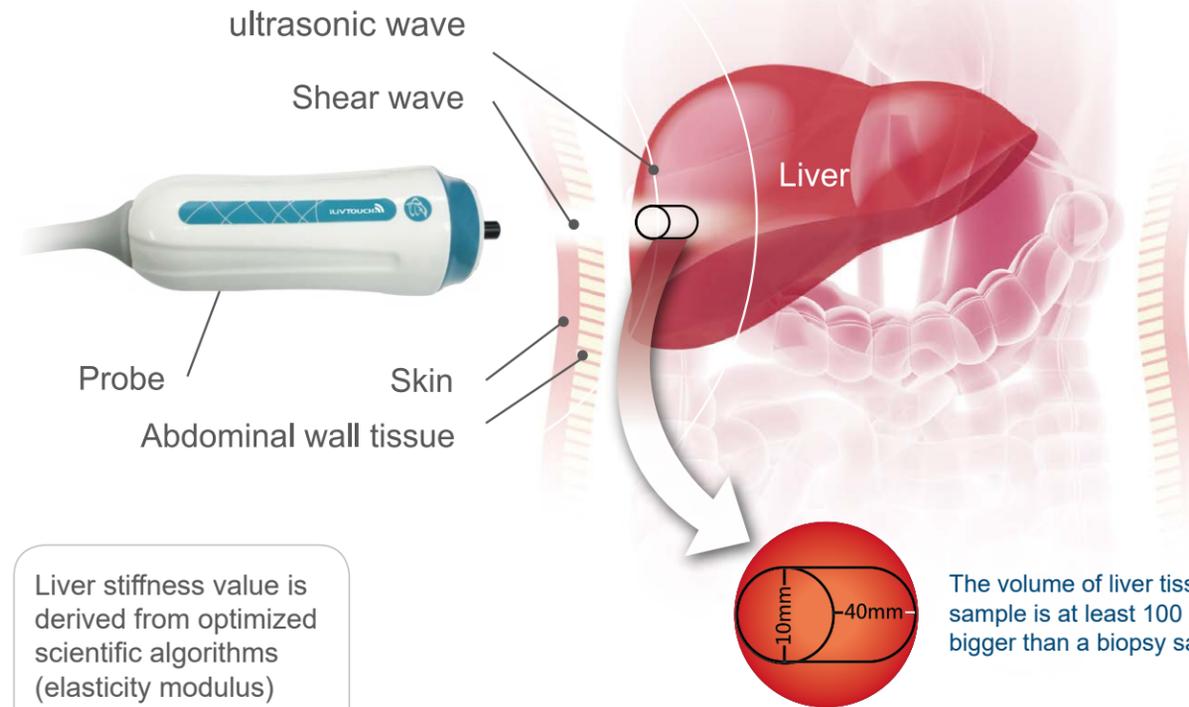Healthy Liver Tissue **VS** Hardened Liver Tissue

💡 **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

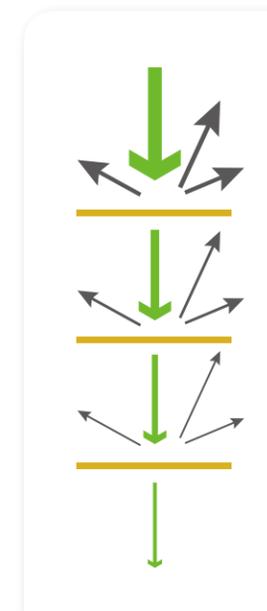» Liver stiffness value is derived from optimized scientific algorithms (elasticity modulus)

Probe   Position 1   Position 2

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

Stiffness(kpa)

6.4   IQR | IQR/med %
            0.1 | 1

LSM and UAP may be used as an aid to diagnosis of liver fibrosis and steatosis.

Determination of Hepatic Steatosis

Ultrasound Attenuation Parameter (UAP)

ultrasonic wave
Shear wave
Liver
Probe   Skin
Abdominal wall tissue

10mm — 40mm

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

Ultrasound Attenuation Parameter(db/m)

241   IQR | IQR/med %
            1 | 0

iLivTouch® systems can provide simultaneous determination of LSM and UAP.

FT100
Mini560/800

Shear Wave Quantificational
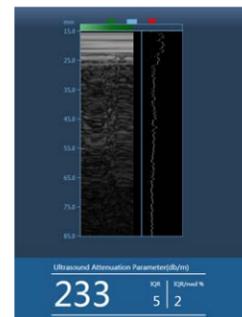Ultrasound Diagnostic System

Compact

- 7kg of weight, easy to carry around
- 3 hours of battery life for remote use
- Fully featured with the ability to test LSM and UAP
- Compatible with add-on ultrasound probe

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)

Available
With Trolley

LSM, kPa

UAP, dB/m

*The specifications may vary based on regional considerations and requirements.

FT9000
Pro1000

Shear Wave Quantificational
Ultrasound Diagnostic System

Image-Guided

Pro9000

- Image-guided Ultrasound for accurate positioning
- 19" high-resolution LCD to better visualize the testing process
- Integrated design brings stable performance

Applied Technology	Transient Elastography (TE), 2D imaging technology
Examination Method	Probe touch detection
Data Processing	Optimized scientific algorithms
Fibrosis Scanning 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) Assessment of liver tissue morphology by 2D ultrasound

FT9000

LSM, kPa
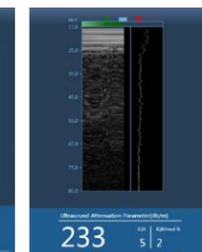
UAP, dB/m

Morphology of Liver Tissue

*The specifications may vary based on regional considerations and requirements.

Fibrosis scanning probe needs to be calibrated once a year or every 30,000 measurements to maintain proper performance.

Plus9000

Shear Wave Quantificational
Ultrasound Diagnostic System

Multi-Use Color Doppler

Plus9000

- Color Doppler system capable of color ultrasound application in abdomen
- Simultaneous determination of LSM and UAP
- Build-in touchscreen for easy operation

Applied Technology	Transient Elastography (TE), 2D imaging technology
Examination Method	Probe touch detection
Data Processing	Optimized scientific algorithms
Convex probe	Scanning depth >190mm, 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) Assessment of liver tissue morphology by 2D ultrasound
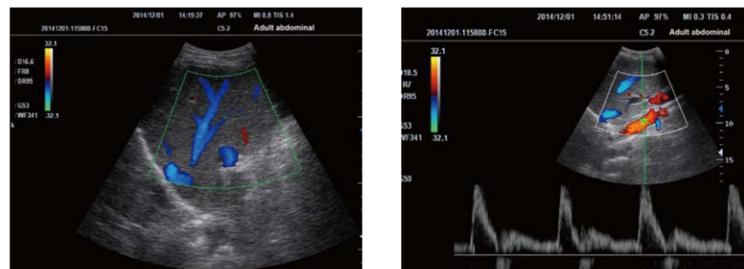
Morphology of Liver Tissue (Color Doppler Image)

* The specifications may vary based on regional considerations and requirements.

FH9000

Multi-Channel Non-Invasive
Liver Detection System

Image-Guided

FH9000

- One Multi-Mode Fusion does ultrasound imaging and measurement of liver stiffness and UAP
- Multichannel and large-scale tissue information reconstruction, detection sample volume is 30cm^3
- Dual Display Of Multiple Results On One Screen
- High-End Color Doppler Ultrasound Assists In Diagnosis
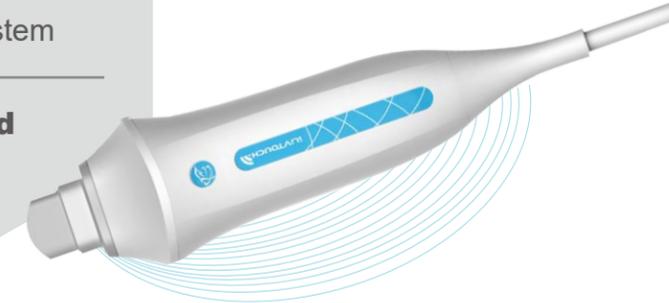
Applied Technology	MigTE(Multichannel image guided Transient Elastography), Color Doppler Ultrasound Guidance
Examination Method	Probe touch detection
Data Processing	Optimized scientific algorithms
Universal Fibrosis Scanning Probe	Multi-mode Fusion Probe, wideband frequency
Convex Probe (Optional)	Support ultrasound examination of abdomen, e.g. liver, pancreas, spleen, kidney, etc.
Functions	Liver Stiffness Measurement(LSM) Ultrasound Attenuation Parameter (UAP) Color Doppler Ultrasound Guidance

* The specifications may vary based on regional considerations and requirements.

⚠ Fibrosis scanning probe needs to be calibrated once a year or every 30,000 measurements to maintain proper performance.

iLivTouch® Advantage

Signature Wideband Probe

- Wideband Frequency: 1.5-5MHz
- One probe scans all
  (adults, overweight/obese, children)
- Efficient and convenient
- Cost-effective

Multiple Quality Control

Ensures Reliable Measurements

- A mode /M mode /E mode
- Pressure Indicator
- IQR/Med
- Success Rate

Scientific Algorithm

- Reduce the impact of the subcutaneous fat on the detection, improving measurement accuracy

Smart Connection

- DICOM 3.0 Supported

Foot Switch Design

- Reduce the risk of losing the located test position

Scientific Locating Method*

- Ultrasound guidance
- Reduce errors caused by blind tests and operator's experience
- Avoid cysts, nodules, large blood vessels and other non-liver tissues, improving accuracy

*Available on specific models

| Non-invasive | Rapid | Quantitative | Accurate |

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

General Population — Healthy Liver — Health Checkup/ Liver Screening/ Primary Care

Asymptomatic Patients — Liver Fibrosis — Aid to Diagnosis, Treatment Evaluation, Follow-Up for Prognosis

Symptomatic Patients — Liver Cirrhosis — Aid to Diagnosis, Treatment Evaluation, Risk Stratification

HCC — Pre-Operative Evaluation, Post-Transplant Follow-Up

01 Hepatology
02 Endocrinology
03 Health Check-up
04 Gastro-enterology
05 Infectious Disease
06 Hepatobiliary Surgery / Liver Transplantation

Clinical Guidelines

Guidelines for The Prevention, Diagnosis, Care and Treatment for People with Chronic Hepatitis B Infection (March 2024)

——World Health Organization (WHO)

- Evidence of significant fibrosis (≥F2) should be based on an APRI score of >0.5 or **transient elastography** value of >7.0 kPa, and cirrhosis (F4) should be based on clinical criteria.

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

——European Association for the Study of the Liver, Asociación Latinoamericana para el Estudio del Hígado

- Advantages of TE include a short procedure time (<5 min), immediate results, and the ability to perform the test at the bedside or in an outpatient clinic (Table 3). Finally, it is not a difficult procedure to learn which can be performed by a nurse or a technician after minimal training (about 100 examinations).

Guidelines for Diagnosis and Treatment of Liver Cirrhosis

——Chinese Society of Hepatology, Chinese Medical Association

- Liver stiffness measurement (LSM) or transient elastography (TE) is the simplest method for non-invasive diagnosis of liver fibrosis and early cirrhosis. Fibroscan(FS) and **Fibrotouch(FT)** are commonly used clinical liver LSM measurement tools. For liver fibrosis and cirrhosis with different causes, their LSM critical value (cut-off value) is also different.

LSM diagnosis of liver fibrosis has high consistency with liver biopsy

Multicenter prospective study to validate a new transient elastography device for staging liver fibrosis in patients with chronic hepatitis B

Aims	To validate the operational and diagnostic performances of a new device for transient elastography (TE), FibroTouch, for liver fibrosis in patients with chronic hepatitis B (CHB).
Methods	517 patients with histologically proven CHB were enrolled
	Patients with CHB and valid liver pathological results were recruited to validate the operational and diagnostic performance of a TE device by FibroTouch for staging liver fibrosis.
Results& Diagrams	**TABLE 3** Cut-off value and corresponding diagnostic indices of transient elastography

Stage	Cut-off (kPa)	AUROC (95% CI)	Se (%)	Sp (%)	PPV (%)	NPV (%)
≥ F1	5.5	0.846 (0.808-0.880)	82.0	81.8	99.4	11.1
≥ F2	7.85	0.850 (0.811-0.883)	75.7	77.5	82.3	69.8
≥ F3	10.0	0.908 (0.876-0.934)	84.3	82.8	67.1	92.7
F4	12.7	0.874 (0.836-0.903)	92.3	76.2	20.7	99.3

FIGURE 3
Area under the receiver operating characteristic curve for ——— aspartate aminotransferase-to-platelet ratio index (APRI), ——— fibrosis index based on 4 factors (FIB-4) index, ——— gammaglutamyl transpeptidase-to-platelet ratio(GPR), and ——— liver stiffness measurement (LSM) in detecting different stages of fibrosis: (A) ≥ F1, (B) ≥ F2, (C) ≥ F3, (D) F4.LSM was more accurate than GPR, FIB-4,and APRI in diagnosing fibrosis at stages F2-F4 (P = 0.007 to P < 0.0001)

Conclusions	FibroTouch has a high success rate and good reliability in staging liver fibrosis in patients with CHB.

UAP diagnosis of liver steatosis has high consistency with liver biopsy

Diagnostic Performance of FibroTouch Ultrasound Attenuation Parameter and Liver Stiffness Measurement in Assessing Hepatic Steatosis and Fibrosis in Patients With Nonalcoholic Fatty Liver Disease

Aims	To evaluate the diagnostic performance of ultrasound attenuation parameter (UAP) and liver stiffness measurement (LSM) by FibroTouch for diagnosis of hepatic steatosis and fibrosis in patients with nonalcoholic fatty liver disease (NAFLD).
Methods	237 patients undergoing FibroTouch and liver biopsy within 2 weeks
	The pathological findings of liver biopsy were scored by Nonalcoholic Steatohepatitis Clinical Research Network, and the diagnostic accuracy of UAP for steatosis and LSM for fibrosis was evaluated by area under the receiver operating characteristic curve (AUROC). The impacts of histological parameters on UAP and LSM were analyzed, and diagnostic performance of FibroTouch UAP and LSM was compared with other noninvasive biomarkers.
Results& Diagrams	

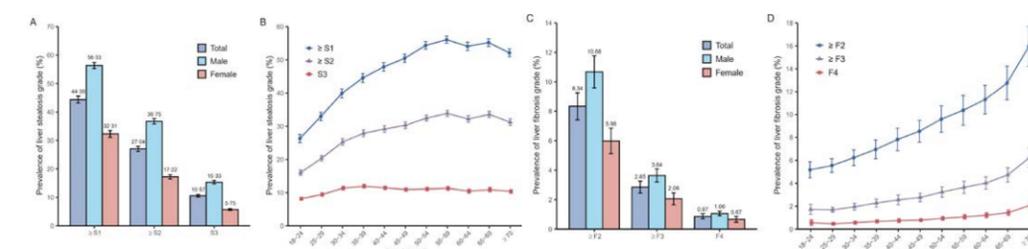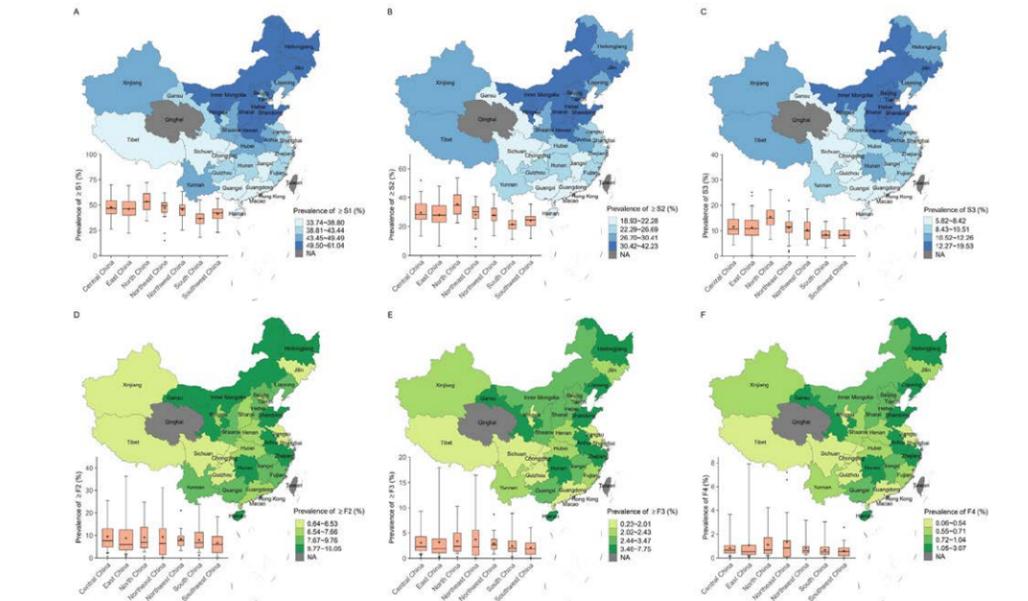|	
Conclusions	FibroTouch has a low failure rate with moderate to high diagnostic performance for discriminating the steatosis degree and fibrosis stage and is suitable for clinical evaluation and monitoring of patients with NAFLD.

Expansion of liver health diagnosis based on iLivTouch®

A novel quantitative ultrasound technique for identifying non-alcoholic steatohepatitis

Aims	To develop and validate a diagnostic tool, based on QUS analysis, for identifying NASH.
Methods	259 Chinese individuals with biopsy-proven non-alcoholic fatty liver disease (NAFLD)
	The histological spectrum of NAFLD was classified according to the NASH clinical research network scoring system. Radiofrequency (RF) data, raw data of iLivTouch, was acquired for further QUS analysis. The least absolute shrinkage and selection operator (LASSO) method was used to select the most useful predictive features.
Results& Diagrams	
	FIGURE 3 Diagnostic performance of the QUS score for the diagnosis of NASH. A, AUROC of the training set, B, AUROC of the validation set, C, calibration curve of the training set and D, calibration curve of the validation set. AUROC, area under the receiver operating characteristic curve; NASH, non-alcoholic steatohepatitis; QUS, quantitative ultrasound
Conclusions	The QUS score, which was developed from QUS, provides a novel, non-invasive and practical way for identifying NASH.
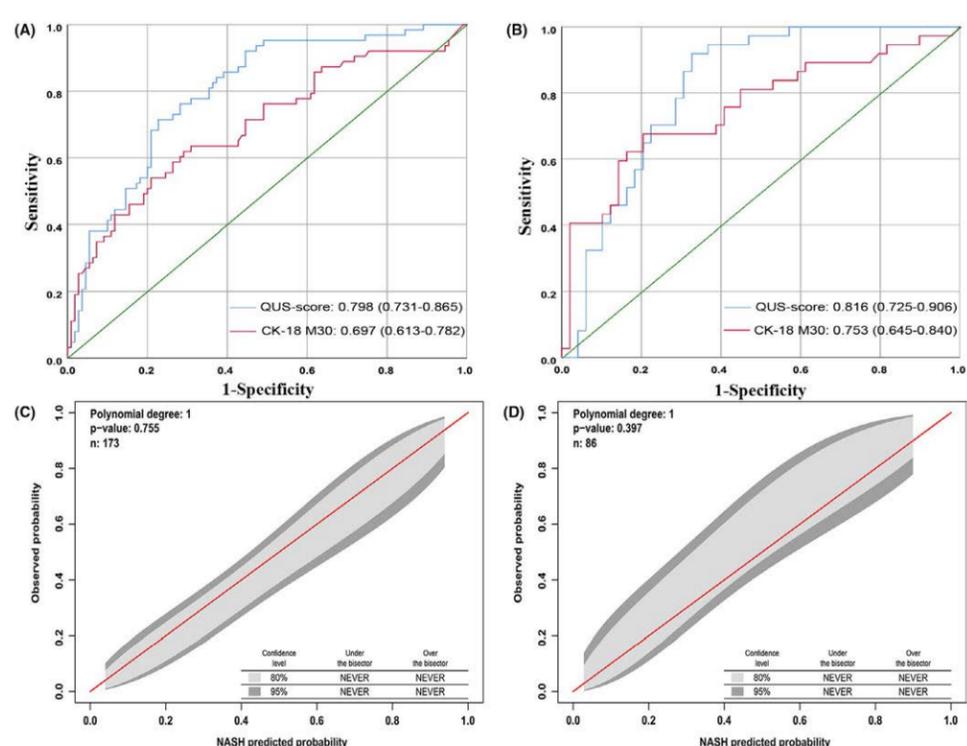
Using iLivTouch for large population screening reveals the current status of liver health

Prevalence of Liver Steatosis and Fibrosis in the General Population and Various High-Risk Populations: A Nationwide Study With 5.7 Million Adults in China

|	
Aims	To estimate the prevalence of liver steatosis and fibrosis in the general population and populations with potential risk factors in China, so as to inform policies for the screening and management of fatty liver disease and liver fibrosis in general and high-risk populations.
Methods	5,757,335 participants from 30 provinces who underwent a check-up between 2017 and 2022 were included.
	Patients with CHB and valid liver pathological results were recruited to validate the operational and diagnostic performance of a TE device by FibroTouch for staging liver fibrosis.
Results& Diagrams	
	Figure 1. Prevalence of liver steatosis and fibrosis according to sexes and age groups.
	Figure 2. Geographic disparity in the prevalence of liver steatosis and fibrosis in China.
Conclusions	A substantial burden of liver steatosis and fibrosis was found in China. Our study provides evidence for shaping future pathways for screening and risk stratification of liver steatosis and fibrosis in the general population. The findings of this study highlight that fatty liver and liver fibrosis should be included in disease management programs as targets for screening and regular monitoring in high-risk populations, especially in those with diabetes.

Examination Procedure
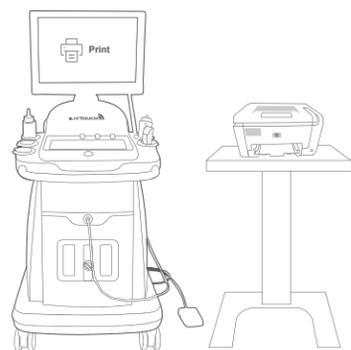

1 **Patient prepares for exam in a supine position**

2 **Start the equipment**

4 **Perform liver fibrosis & steatosis exam**
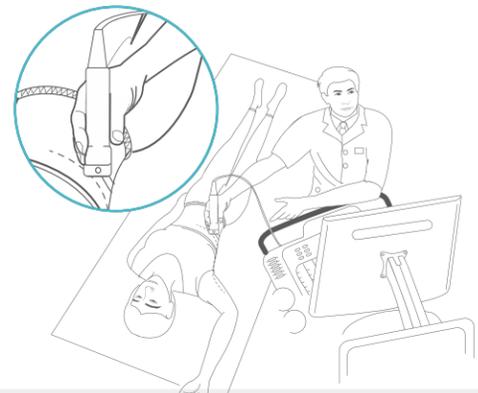
3 **Perform ultrasound exam** (if ultrasound-guidance is available)

5 **Print examination report**

6 **Refer the report to the physician for interpretation**

About HISKY

R&D Center (Beijing)

Shangdi Science and Technology Mansion

Manufacturing Base (Wuxi)

Taihu International Science & Technology Park

Milestones

2019 Launched new brand series products (MigTE*) iLiVTOUCH

2018 Received U.S. FDA 510(k) clearance

2014 Obtained CE certificate

2010 HISKY founded in July and launched FIBROTOUCH series products

Academics and Patents

320+ Peer-Reviewed Publications Since 2014

500+ patents have been obtained and applied globally

Global Installations

3000+ Hospitals & Medical Institutions

60+ Countries & Regions

* Multichannel image-guided Transient Elastography