

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: _____ TRIUMF MOTIV SRL _____, cu
sediul _____ or. Chișinău str. Grenoble 193 _____,

declar pe proprie răspundere, cunoscând prevederile art. **352¹**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Ultrasound Diagnostic Systems	Xbit 90
-------------------------------	---------

Sunt autentice și corespund realității.

Numele, prenumele și funcția Jighili Tatiana, Administrator
Semnătura _____

Data 24.05.2023

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60147775 0001

Report No.: 15054160 024

Manufacturer: CHISON Medical Technologies
Co., Ltd.
No.228, Changjiang East Road
Block 51 and 53
Phase 5, Shuofang Industrial Park
Xinwu District
Wuxi

Products: 214142 Jiangsu
P.R. China
Ultrasound Diagnostic Systems

(see attachment for additional site included)

Replaces Approval, Registration No.: HD 60123652 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-04-03

Date: 2020-04-03

Notified Body

Jason Pan



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60147775 0001
Report No.: 15054160 024

Manufacturer: CHISON Medical Technologies
Co., Ltd.
No.228, Changjiang East Road
Block 51 and 53
Phase 5, Shuofang Industrial Park
Xinwu District
Wuxi
214142 Jiangsu
P.R. China

Site included:

No.9, Xinhuihuan Road, Xinwu District,
Wuxi, 214028 Jiangsu, China

Date: 2020-04-03

Notified Body

Jason Pan



EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

Chison Medical Technologies Co., Ltd.

Shanghai International Holding
Corp.GmbH(Europe)

No.3 Changjiang South Road,
Xinwu District, Wuxi, 214028
Jiangsu, P.R. China

Eiffestrasse 80,20537Hamburg,Germany
DIMDI NO.:DE/0000040627

No.9, Xinhuihuan Road, Xinwu District,
Wuxi, Jiangsu, China 214028

We, the manufacturer, herewith declare that the products

Ultrasound Diagnostic Systems

Model: SonoTouch10, SonoTouch20, SonoTouch30, SonoTouch50, SonoTouch60, SonoTouch 80,
ECO 1, ECO 2, ECO 3, ECO 4, ECO 5, ECO 6, ECO 1 EXPERT, ECO 2 EXPERT, ECO 3 EXPERT,
ECO 4 EXPERT, ECO 5 EXPERT, ECO 6 EXPERT, QBit 1, QBit 2, QBit 3, QBit 4, QBit 5, QBit 6,
QBit 7, QBit 8, QBit 9, QBit 10, QBit 11, QBit 12, EBit 10, EBit 20, EBit 30, EBit 40, EBit50, EBit60,
EBit70, EBit80, EBit 90, SonoBook1, SonoBook2, SonoBook3, SonoBook4, SonoBook5,
SonoBook6, SonoBook 7, SonoBook 8, SonoBook 9, CBit 1, CBit 2, CBit 3, CBit 4, CBit 5, CBit 6,
CBit 7, CBit 8, CBit 9, CBit 10, XBit 20, XBit 30, XBit 40, XBit 50, XBit 60, XBit 70, XBit 80, XBit 90,
SonoEye P1, SonoEye P2, SonoEye P3, SonoEye P5, SonoEye P6, SonoAir 10, SonoAir 20,
SonoAir 30, SonoAir 40, SonoAir 50, SonoAir 60, SonoAir 70

UMDNS-Code: **15976**

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex II of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany

Certificate No.: HD 60147775 0001

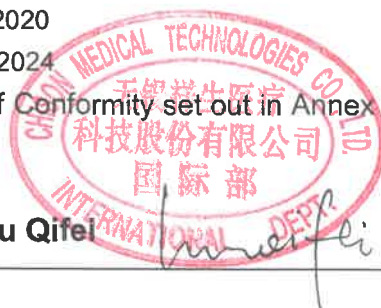
Issue date: 03.04.2020

Expiry date: 26.05.2024

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

10.05.2023

Liu Qifei



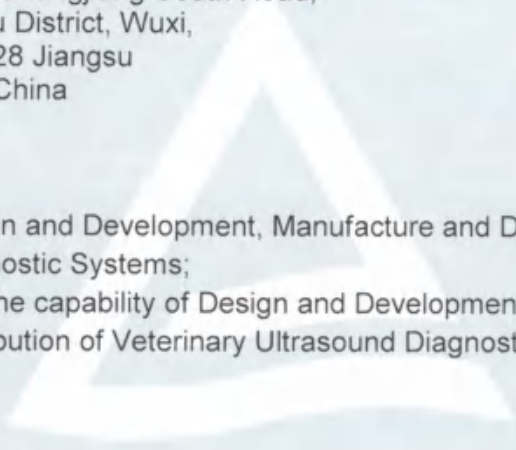
Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2102189-1

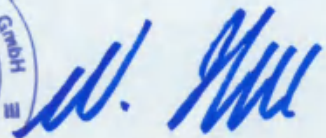
Organization: CHISON Medical Technologies Co., Ltd.
No.3 Changjiang South Road,
Xinwu District, Wuxi,
214028 Jiangsu
P.R. China

Scope: Design and Development, Manufacture and Distribution of Ultrasound
Diagnostic Systems;
And the capability of Design and Development, Manufacture and
Distribution of Veterinary Ultrasound Diagnostic Systems


TÜVRheinland[®]

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 244379887-200
Effective date: 2022-02-14
Expiry date: 2023-11-14
Issue date: 2022-02-14



Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2102189-1

Organization: CHISON Medical Technologies Co., Ltd.
No.3 Changjiang South Road,
Xinwu District, Wuxi,
214028 Jiangsu
P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o CHISON Medical Technologies Co., Ltd. No.3 Changjiang South Road, Xinwu District, Wuxi, 214028 Jiangsu P.R. China	Manufacture of Ultrasound Diagnostic Systems; And the capability of Design and Development, Manufacture and Distribution of Veterinary Ultrasound Diagnostic Systems
/02	c/o CHISON Medical Technologies Co., Ltd. No.9, Xinhuihuan Road, Xinwu District, Wuxi, 214028 Jiangsu P.R. China	Design and Development, Distribution of Ultrasound Diagnostic Systems; And the capability of Design and Development, Manufacture and Distribution of Veterinary Ultrasound Diagnostic Systems

Report No.: 244379887-200
Effective date: 2022-02-14
Expiry date: 2023-11-14
Issue date: 2022-02-14

TÜV Rheinland LGA Products GmbH • 51105 Köln

CHISON Medical Technologies Co., Ltd.
No.3 Changjiang South Road,
Xinwu District, Wuxi,
214028 Jiangsu
P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com
Date February 22, 2022

Application for : QMS
Certificate No. : HD 60147775 0001
Requirement : Richtlinie 93/42/EWG
Confirmation letter ID : 2020-04-03_ HD 60147775 0001
Report no. : 244379887-200

Dear Madame or Sir,

Update of information to Certificate no. HD 60147775 0001, issued on 14.02.2022

The change notification received on 25.08.2021 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.

We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).

With this document we would like to confirm the following updated information to the afore mentioned certificate

Revised Manufacturer address

Old Manufacturer address: No.228, Changjiang East Road, Block 51 and 53, Phase 5, Shuofang Industrial Park, Xinwu District, Wuxi, 214142 Jiangsu, P.R. China

New Manufacturer address: No.3 Changjiang South Road, Xinwu District, Wuxi, 214028 Jiangsu, P.R. China

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

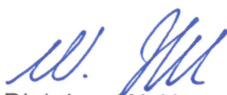
Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dipl.-Ing. Ralf Scheller

Best regards,



Dipl.-Ing. W. Hsu
Certification body

MS-0045446 rev.0

≡

XBit

The Passion to Lead, The Power to Care

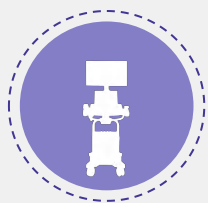
P r o d u c t I n t r o d u c t i o n





CHISON
Value Beyond Imaging

Smart Inside with Elegant Appearance



Dedicated Design



Innovative Technology



Premium Intelligence





CHISON
Value Beyond Imaging

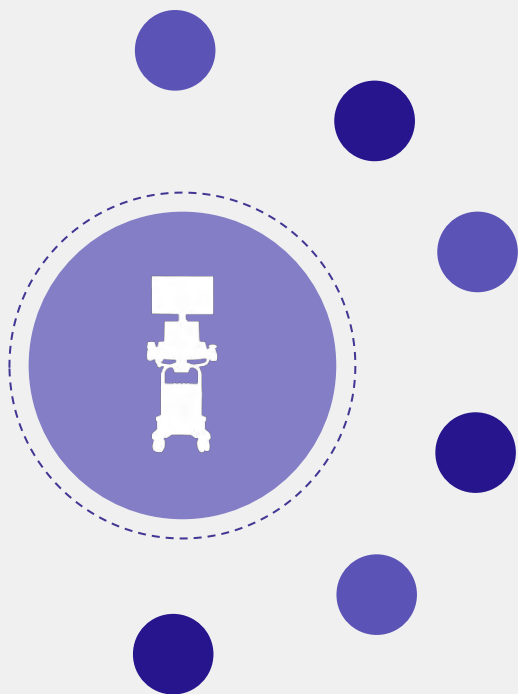


Dedicated Design





CHISON
Value Beyond Imaging



Ergonomic Design

- Elegant outlook
- User friendly





CHISON

Value Beyond Imaging

23.8"

HD LED



Gel warmer with adjustable temperature



13.3"

High sensitive touch screen

all in **ONE** hassle free



4+1

probe connectors



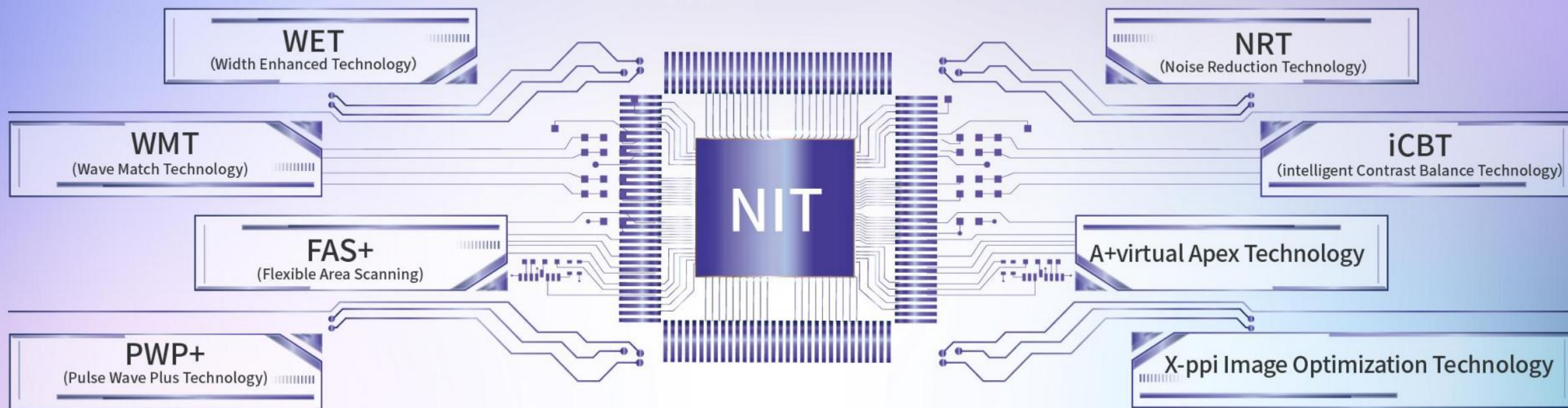


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Innovative Technology







CHISON
Value Beyond Imaging

Innovative “NIT” (New Imaging Technology) Platform

CPU

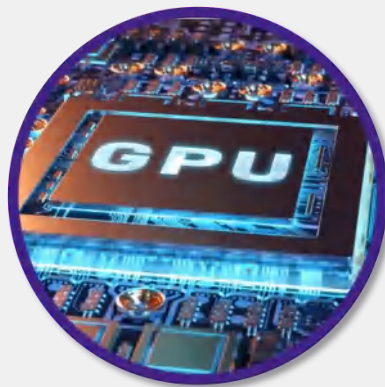


Faster

Better

Powerful

GPU



High Performance Parallel Processing





CHISON
Value Beyond Imaging

WET (Width Enhanced Technology)

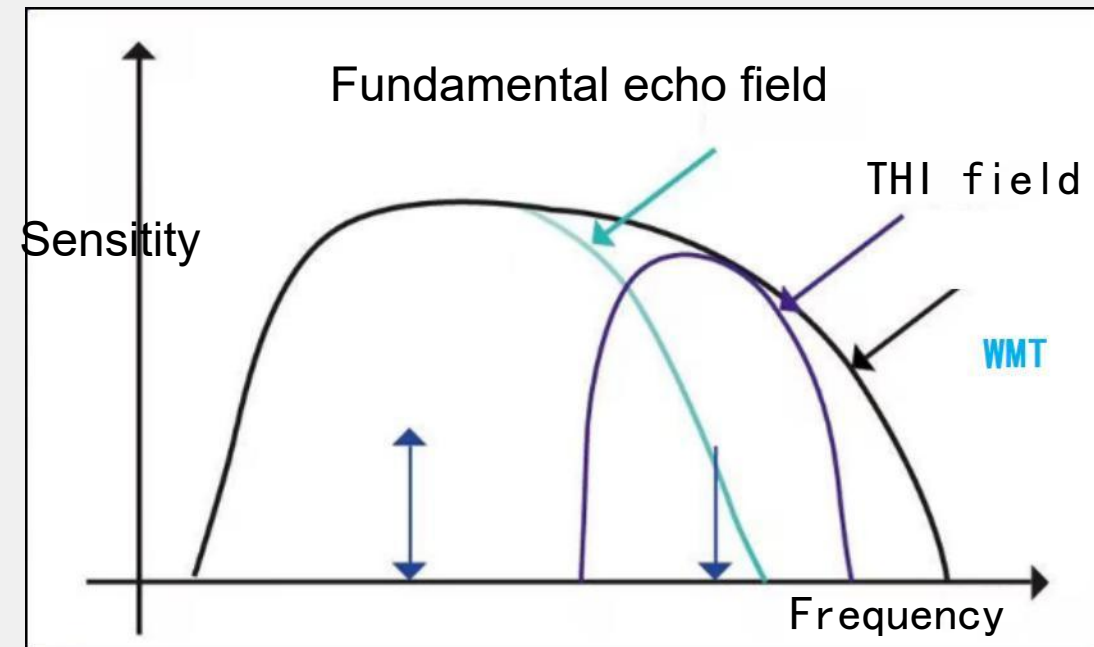
- Ultra-wideband, multi-frequency transducers provide superior sensitivity and resolution for both near and far field.
- Reduced heating of the probe, Lengthen probe life.
- Results in images with better penetration and detail resolution.





WMT (Wave Match technology)

- Multi- pulse transmission harmonic imaging.
- Perfect matching of fundamental wave and harmonic wave.
- It used for different tissues,can automatically adjusted to match far-field penetration,and improve the tissue spatial resolution to obtain excellent image quality.





CHISON
Value Beyond Imaging

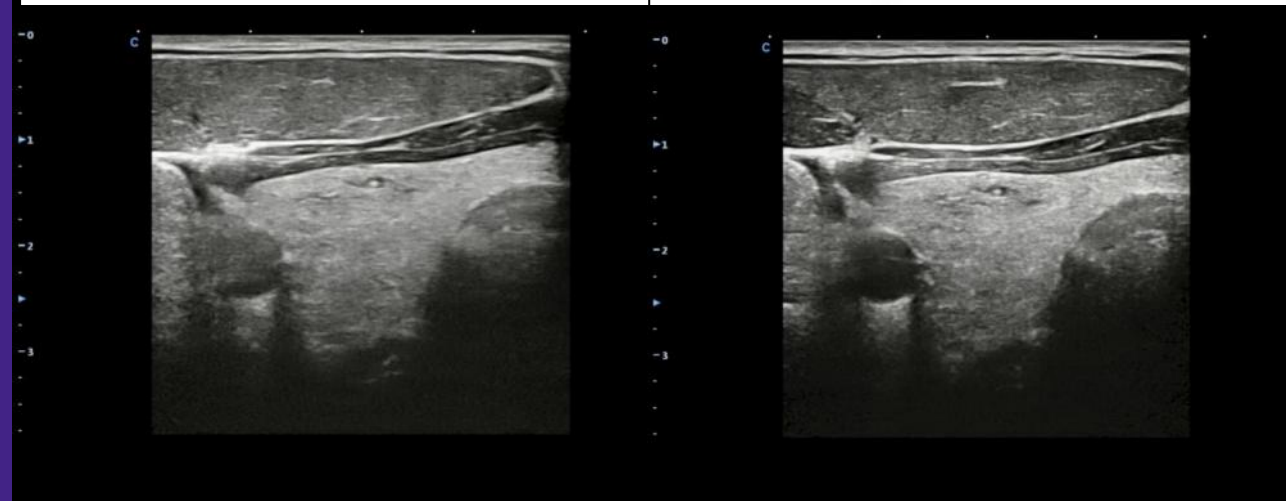
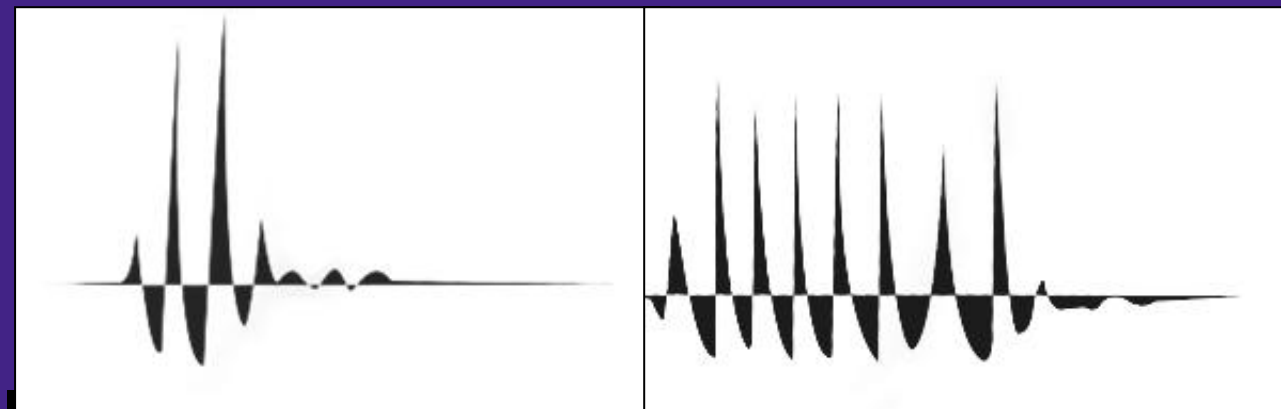
FAS+(Flexible area scanning)

- Improve the spatial resolution.
- More clear and faster for image acquisition.
- Ensure uniform and consistent images.
- Accurate image display of interested tissues.



PWP+ (Pulse Wave Plus Technology)

- Improve image resolution.
- Improve anti- interference.
- Reduce tissue speckle.
- Optimize the display of internal.

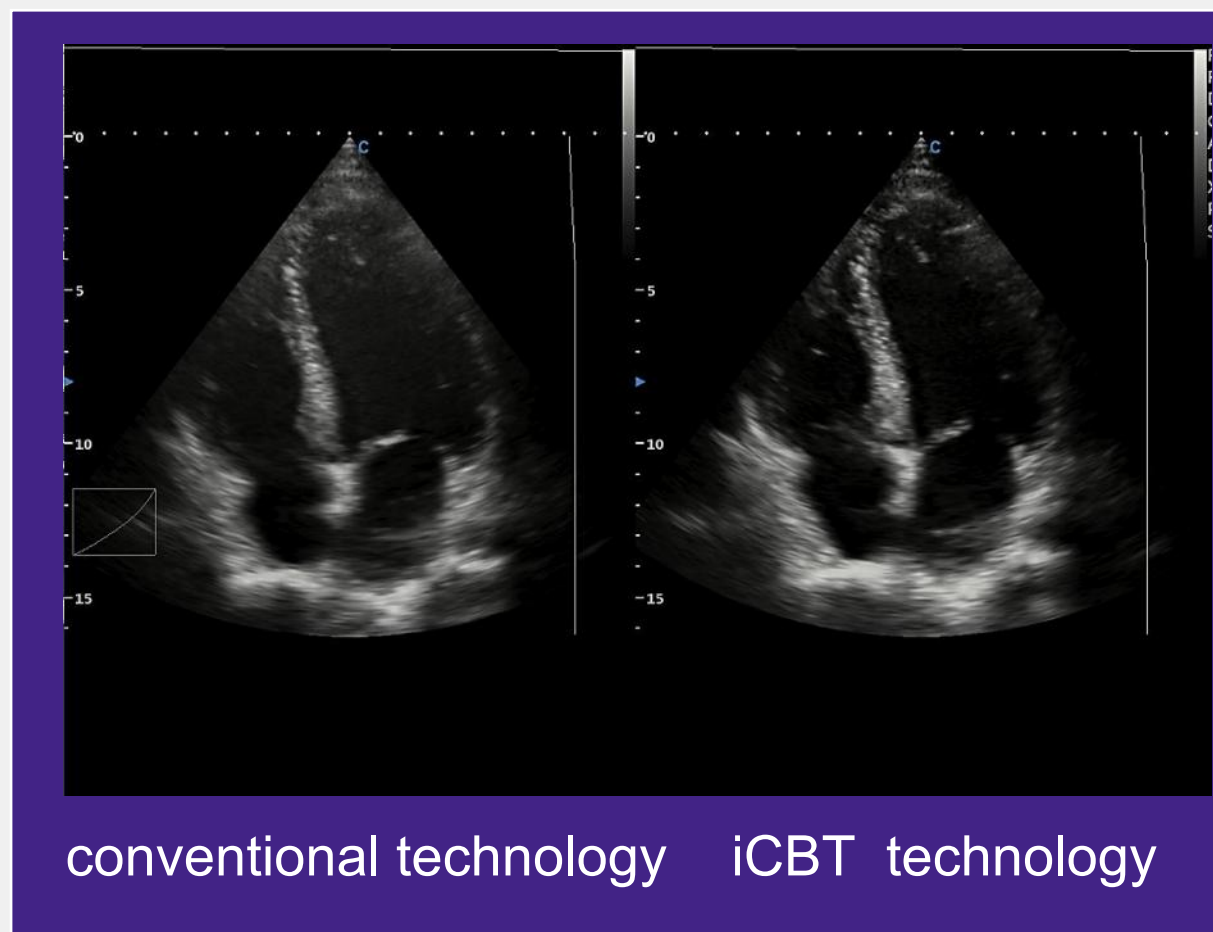


conventional technology

PWP+ technology

iCBT(intelligent Contrast Balance Technology)

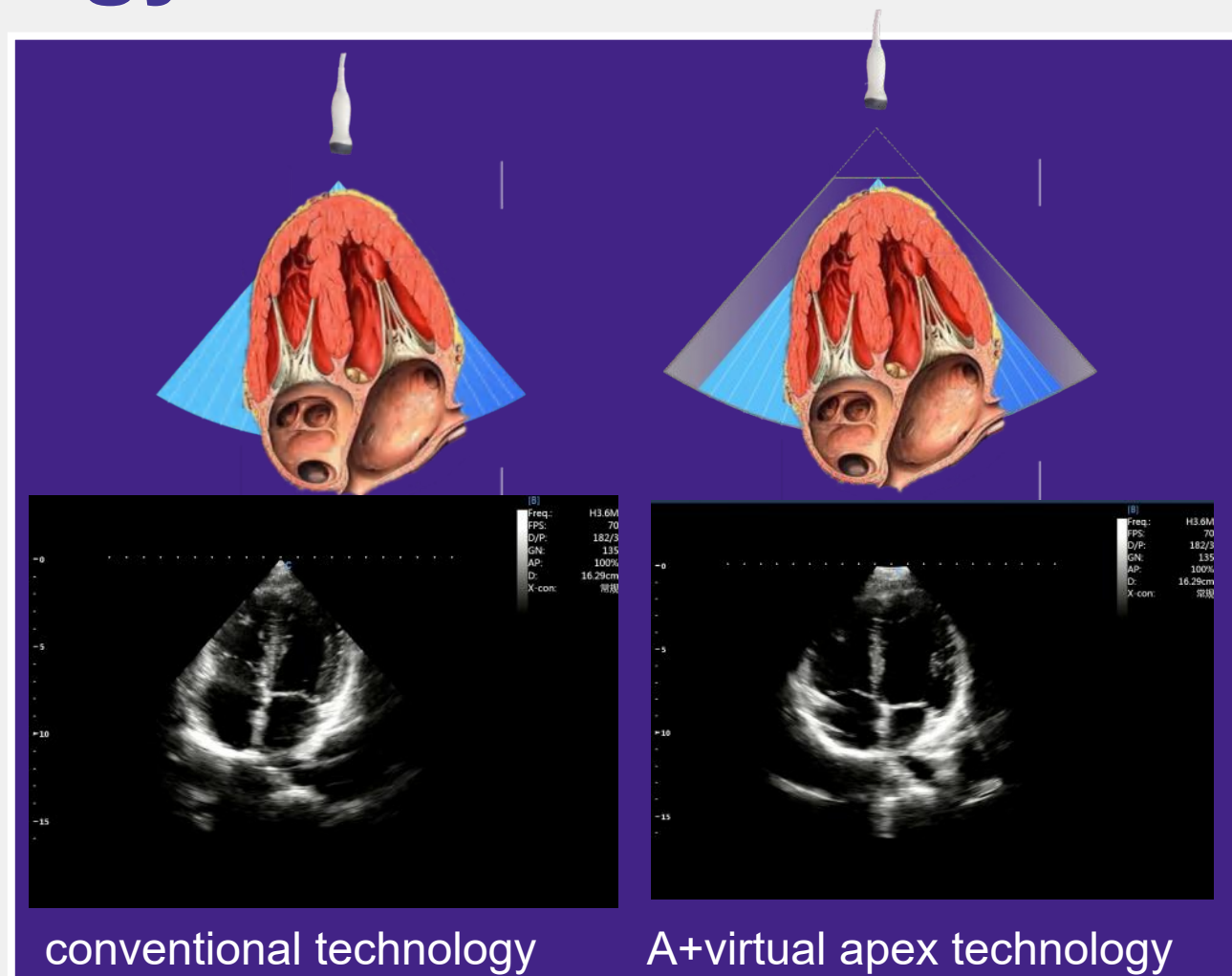
- Enhance the contrast of 2D images.
- Enhance the Contrast resolution of the different tissue, show more details.
- Ensure the time resolution(frame rate) without losing the spatial resolution.



A+virtual apex technology

The establishment of virtual vertices through intelligent algorithm can effectively increase the image viewing angle range and diagnosis information in the process of ultrasonic diagnosis, and obtain more uniform and high-quality imaging at the same time.

- Increase apical imaging range of the cardiac
- Apical structure is clearly displayed

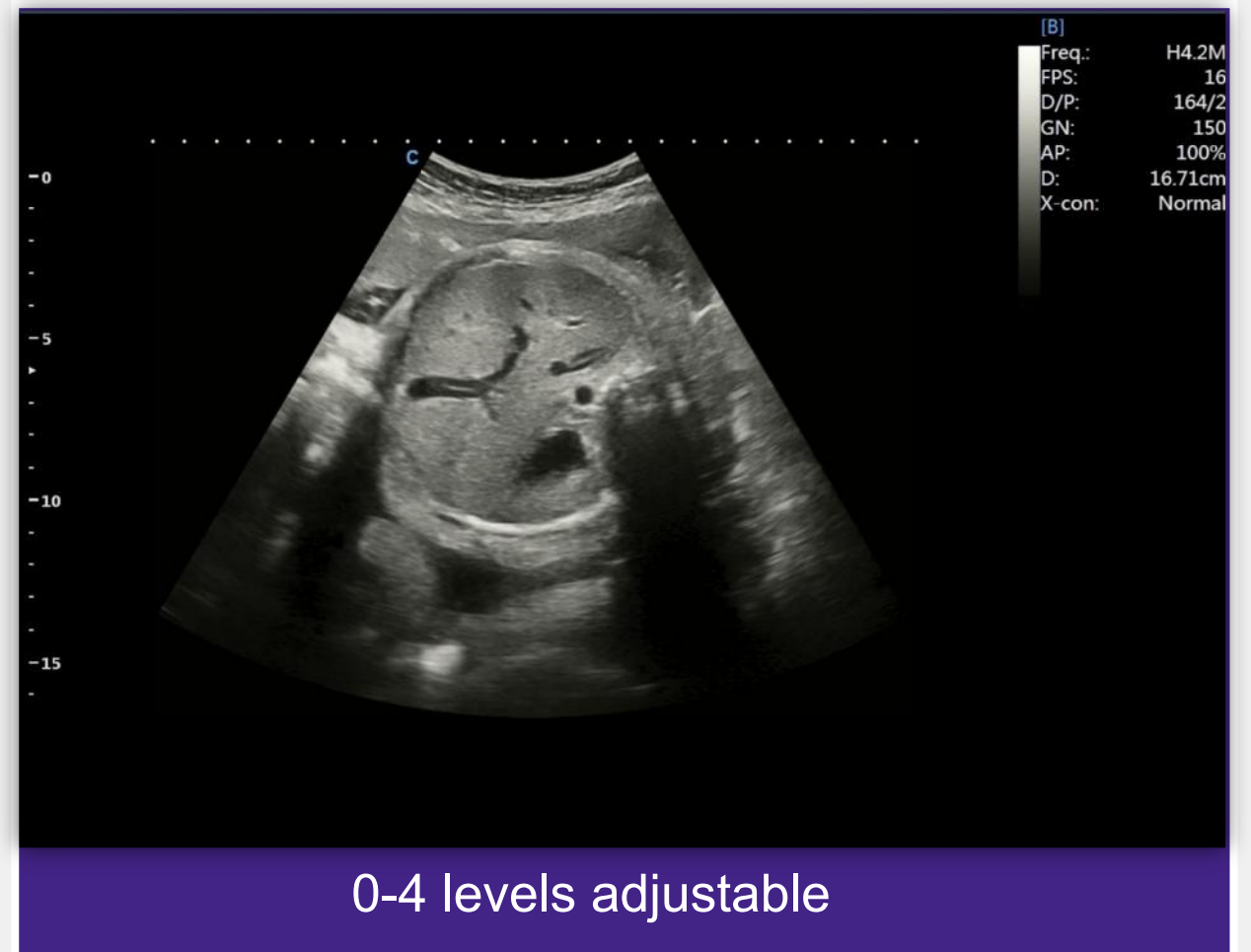




CHISON
Value Beyond Imaging

X-ppi image optimization technology

- Improved Resolution with exponential increase in line density of the image.
- Better depth penetration with defined image differentiation.
- Clear visualization and Elite Diagnosis experience.





CHISON
Value Beyond Imaging

Cardiovascular

**Shared -
service
Ultrasound**

OB/GYN

General Imaging





CHISON
Value Beyond Imaging

Cardiovascular

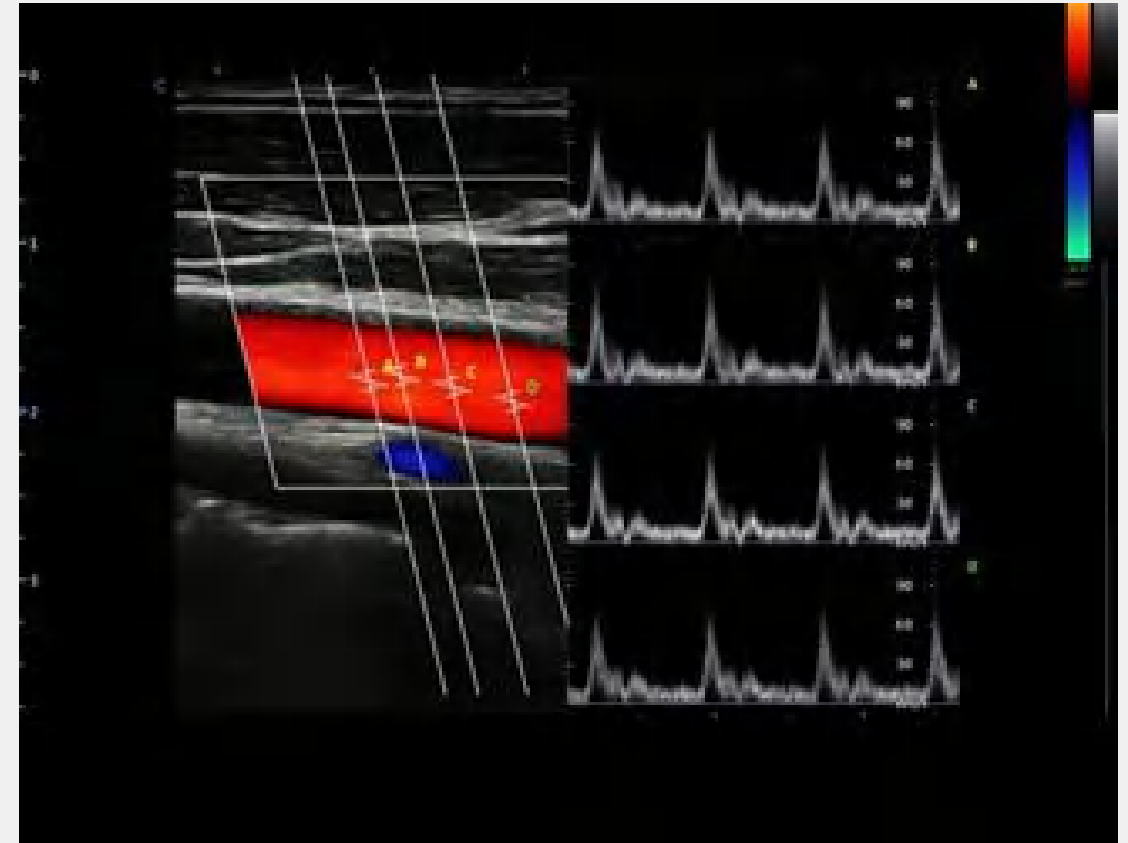
- ✓ **SonoPW**
- ✓ **TDI-SonoPW**
- ✓ **Intelligent Doppler**
- ✓ **SonoIMT**
- ✓ **AutoEF**
- ✓ **strain/strain rate**
- ✓ **MVI**
- ✓ **SoundFlow**
- ✓ **Enhanced Free Steering M Mode**
- ✓ **SonoContrast**





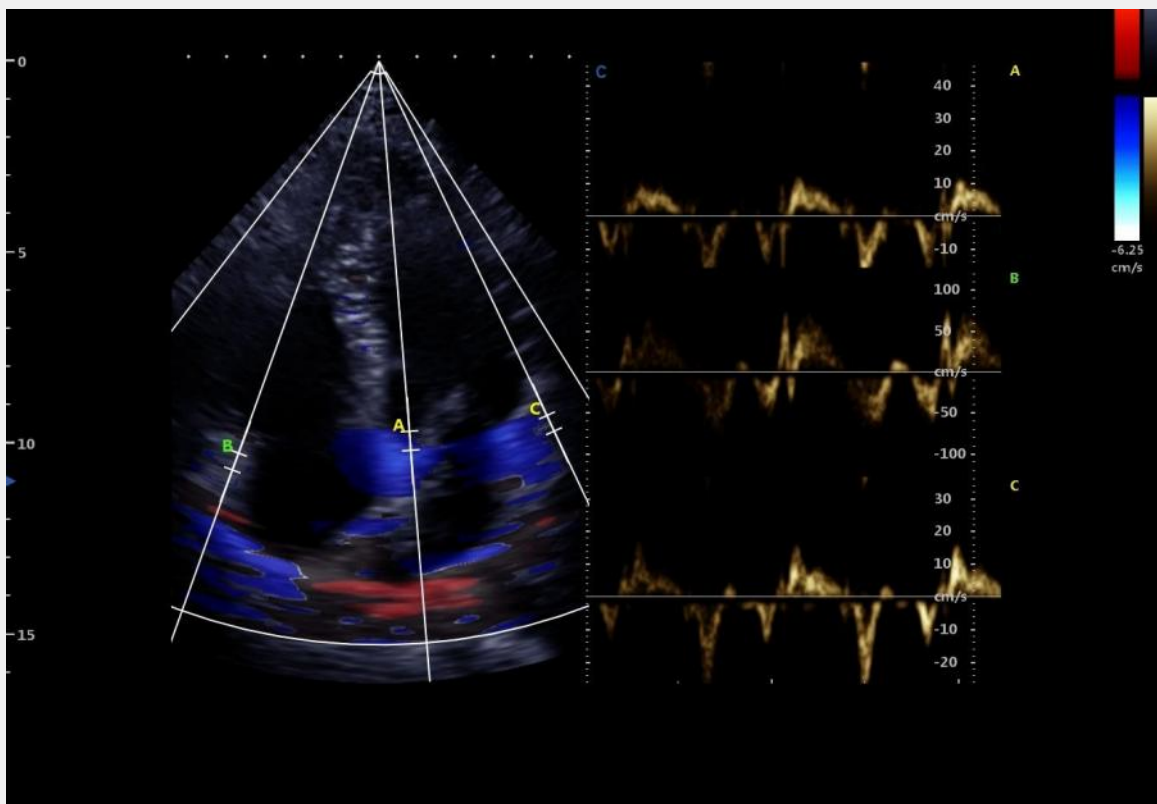
❖ SonoPW ❖

- Up to 4 sample gate for PW.
- PW calculation for different point.
- Synchronous display of image and calculation result.
- Carotid Artery diseases, Cardiac Diseases, Fetal Congenital Heart Issues Predict.



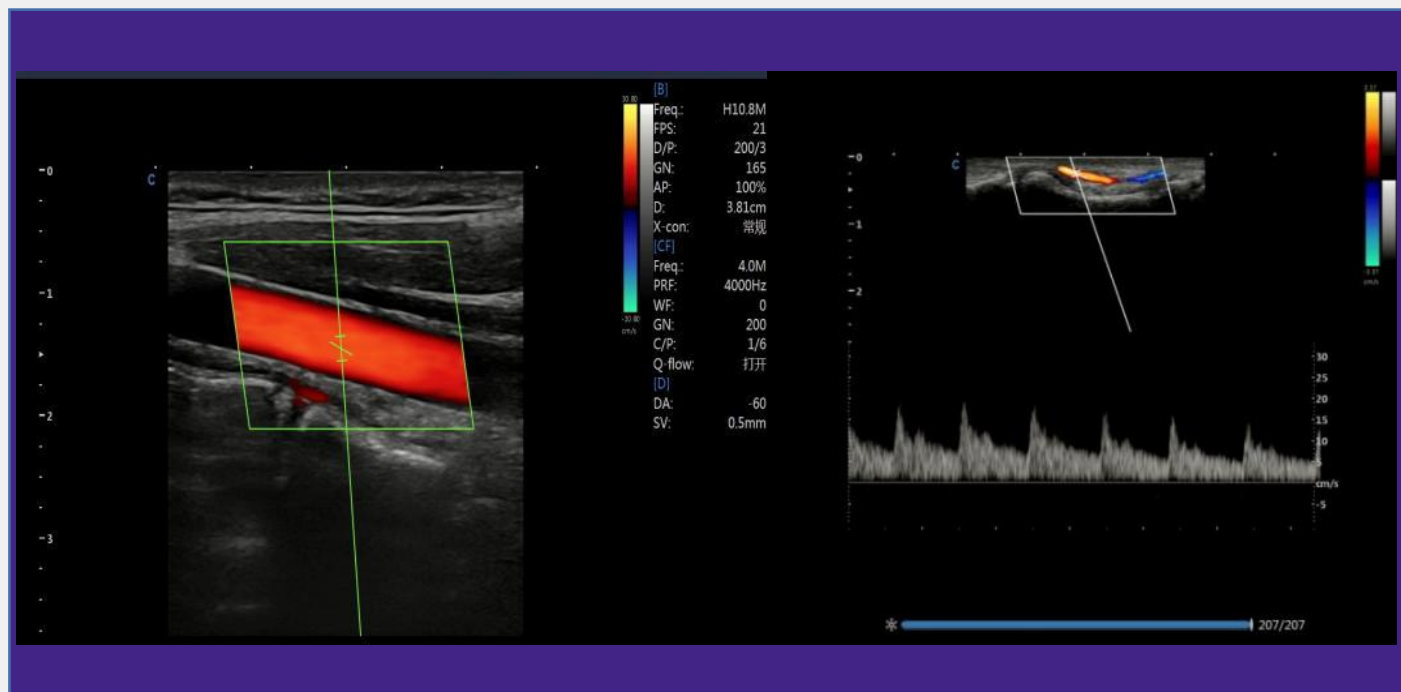
✂ TDI-SonoPW ✂

- It is a new technology to obtain information about the movement speed, direction and time of myocardial tissue, so as to analyze the cardiac function more intuitively
- Observing the movement speed of different parts of the cardiac, judging whether there are pathological changes, and evaluating the early diastolic function
- The PW sample gate can up to 4 , so it can evaluate the myocardial velocity and status in the same plane at one cardiac cycle.



❖ Intelligent Doppler ❖

- Automatically adjust the ROI direction and PFR in color mode, and doppler gate in PW mode
- Much easier for the sonographer



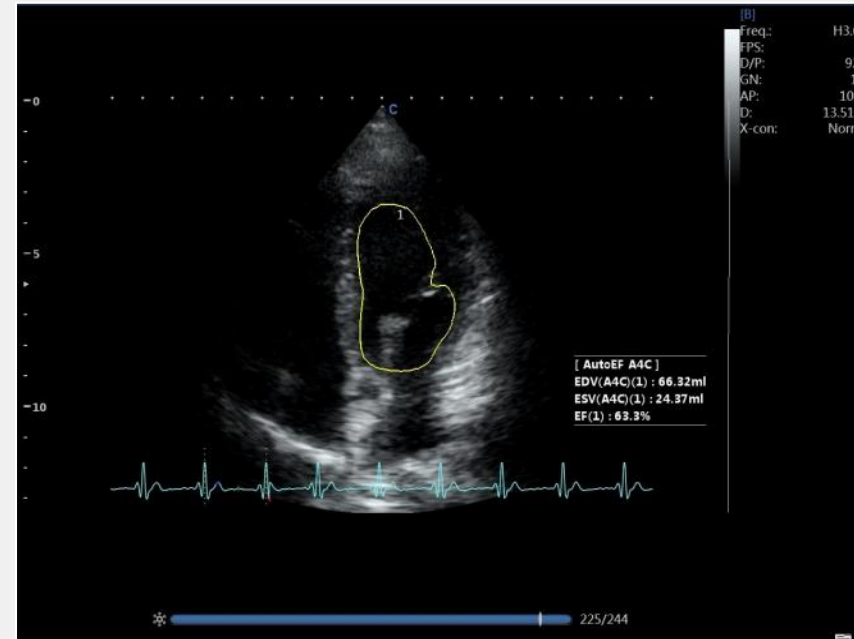
※ SonoIMT ※

- Auto trace/ Manual Trace.
- Monitor the IMT regularly,
Analysis the data which is helpful
for chronic disease management.





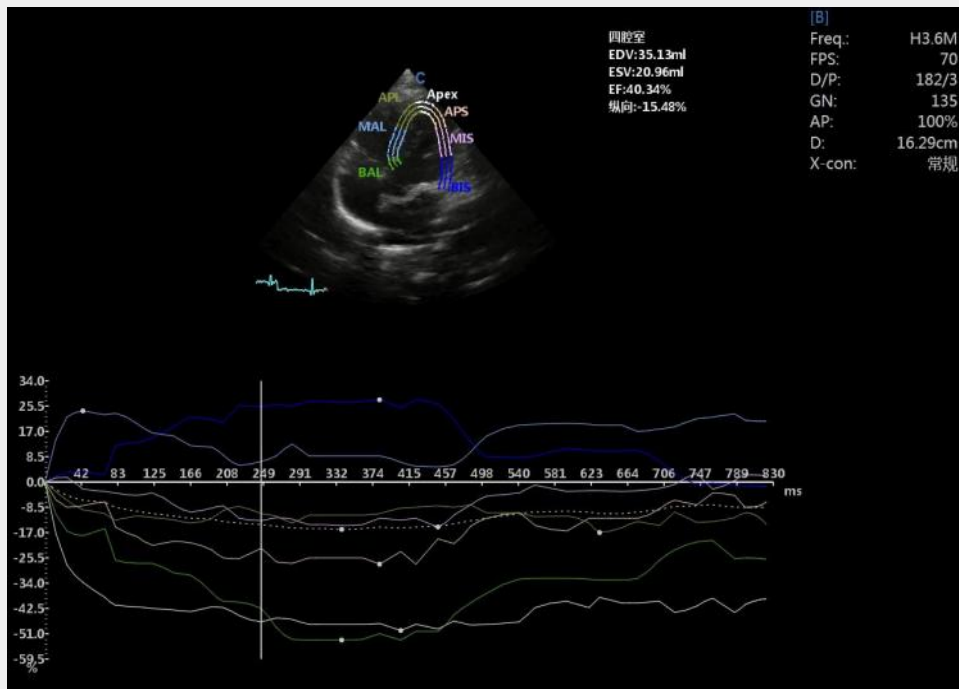
✕ AutoEF ✕



- Support multi planes (A4C/A2C/PS/AX).
- One- Key Auto- envelope in real time.
- Multi points adjustable, accurate measurement data .



※ (Strain and Strain Ratio) ※



- Real- time myocardial speckle tracking .
- 17- segment, multi- directional display (horizontal/vertical/circular).



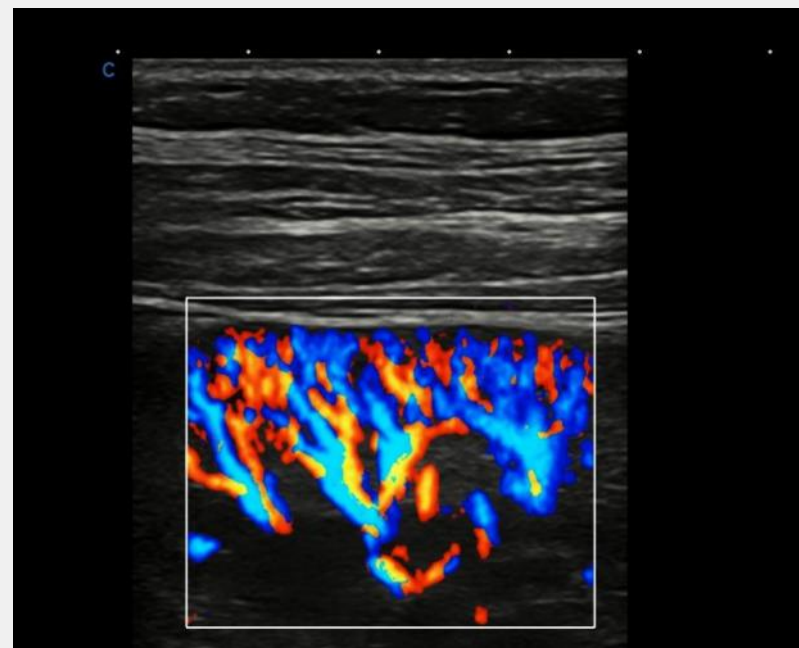
- Multi- segment comparison, precise positioning.
- Provide a variety of efficient quantitative analysis tools (Strain and Strain Ratio).



CHISON
Value Beyond Imaging

※ (MVI) ※

- It applied a brand- new algorithm to check the blood flow.
- Greatly improve the visualization sensitivity of low velocity and small blood vessels.
- Provide more and accurate blood flow information for clinic.

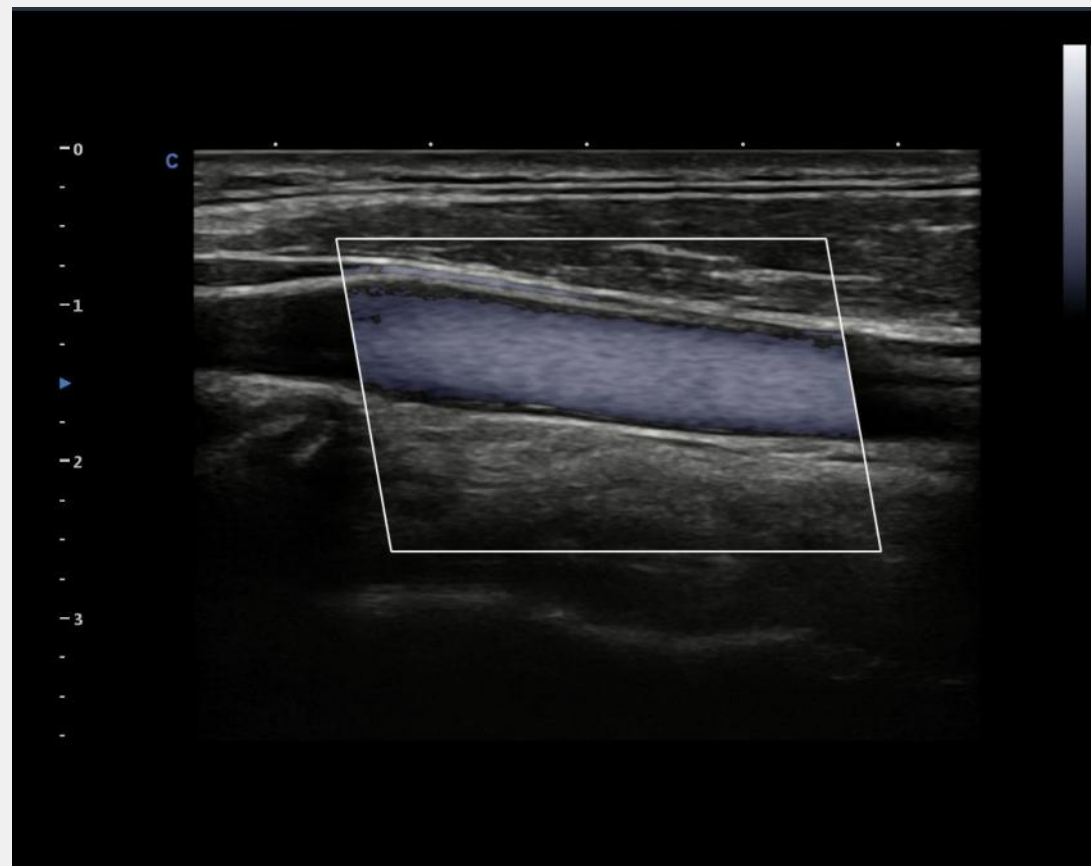




CHISON
Value Beyond Imaging

✕ SoundFlow ✕

- Due to the latest color technology, to display the color scale .
- Improve the color sensitivity .





✖ SonoContrast ✔

- Been developed in order to visualize the micro-circulation in tissue, that is, the blood flow in very small blood vessels.
- Potentially be used for improved diagnosis and therapy in several clinical situations.
- Available for convex, linear, endocavity and phased array.
- More sensitivity, better performance .





CHISON
Value Beyond Imaging

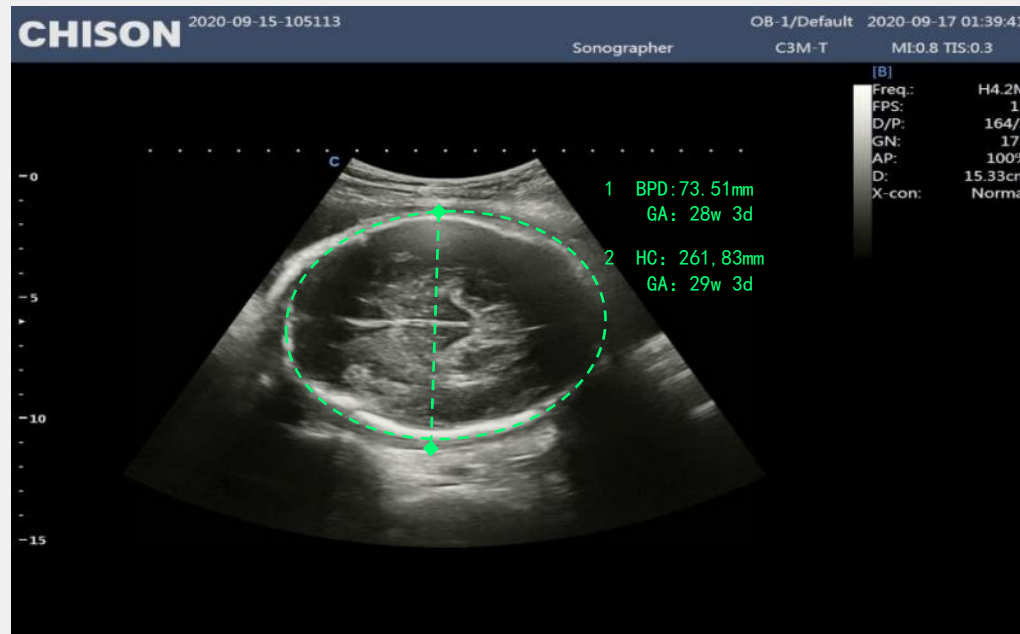
OB/GYN

- ✓ **Sono-OB**
- ✓ **Auto Face**
- ✓ **Gflow**
- ✓ **Enhanced 4 D Mode
(Auto Face, SonoCrystal)**
- ✓ **SonoFollicle**
- ✓ **Ultra-wide transvaginal probe $\geq 250^\circ$**





✖ Sono-OB ✔



- Automatically measure: BPD, HC, AC, FL, NT.
- Efficiency and accuracy.



✂ Enhanced 4 D Mode ✂

-Auto Face

- Automatically recognize fetal face.
- Automatically remove the tissues covering the face .
- Fast to get fetal face.





CHISON
Value Beyond Imaging

✂ Enhanced 4 D Mode ✂

-SonoCrystal

- Provide context and surface information.
- Display the internal organs to get more diagnostic information.
- Easily differentiates between soft tissue and structure.

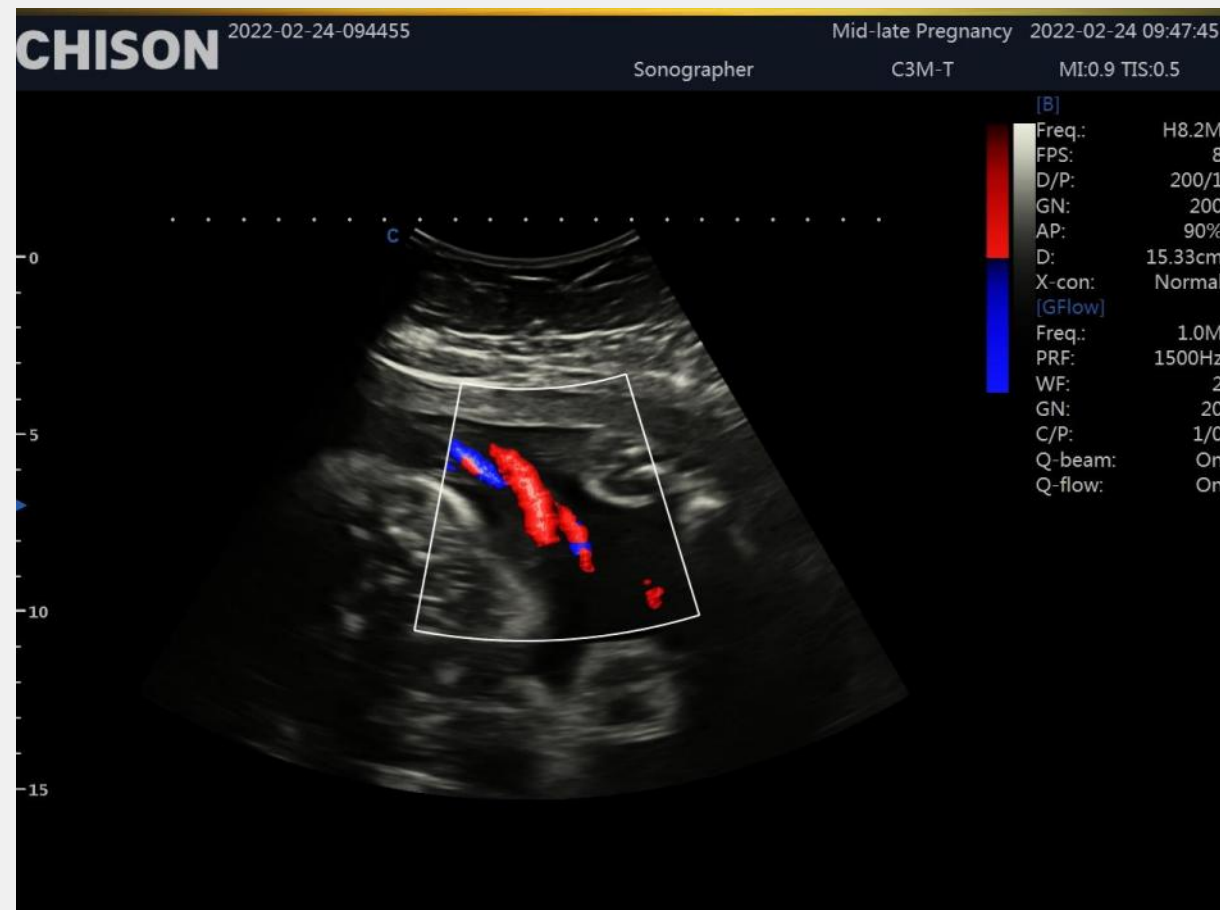




CHISON
Value Beyond Imaging

✖ GFlow ✖

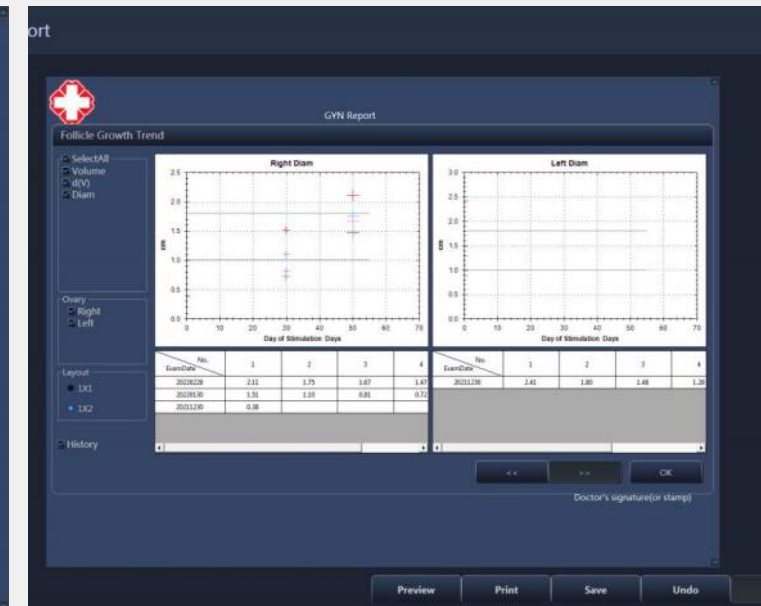
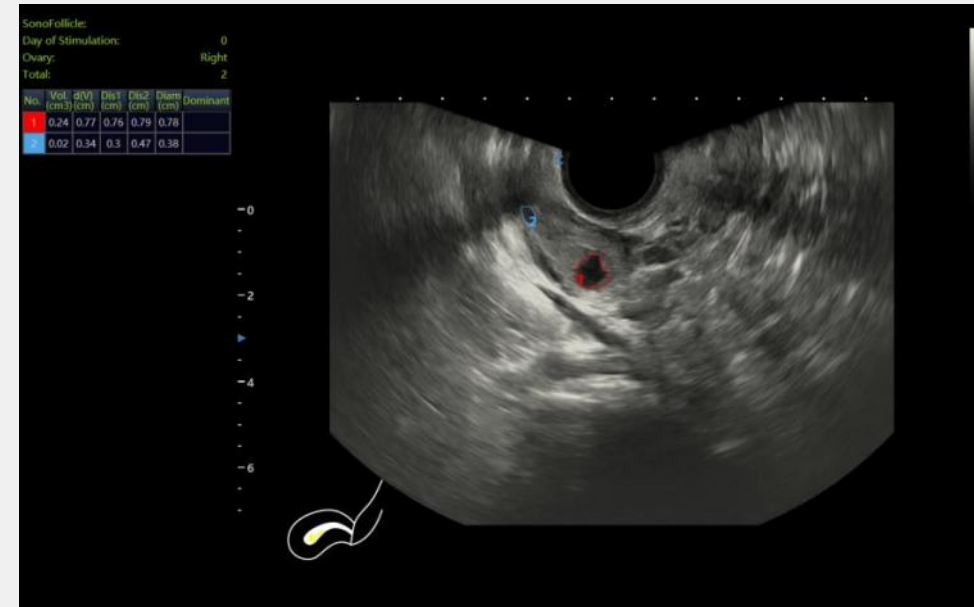
- With 2D probe
- Get the Get three-dimensional blood flow
- Better display of microvessels





❖ SonoFollicle ❖

- Follicle automatic measurement.
- Automatic recognition of follicular structure.
- Trace and get measurement results.





※ Ultra-wide transvaginal probe $\geq 250^\circ$ ※



- Ultra-Angle
- Ultra-View
- Ultra-Area
- Large angle probe, Scan with high efficiency



CHISON
Value Beyond Imaging

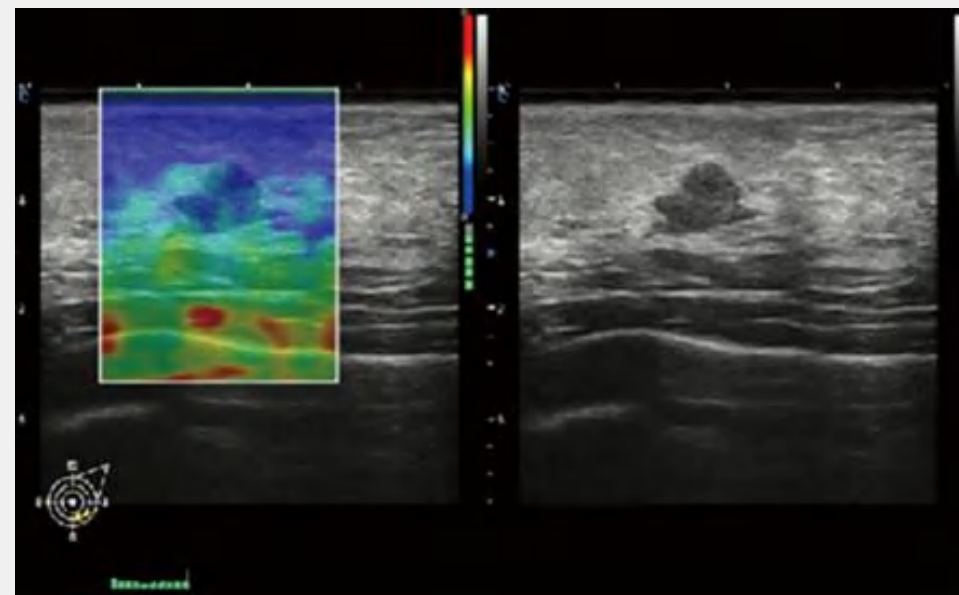
General Imaging

- ✓ **Elastography**
- ✓ **SonoNeedle**
- ✓ **Color Panoramic**
- ✓ **Shear Wave Elastography**
- ✓ **SWD**
- ✓ **SonoCoach**



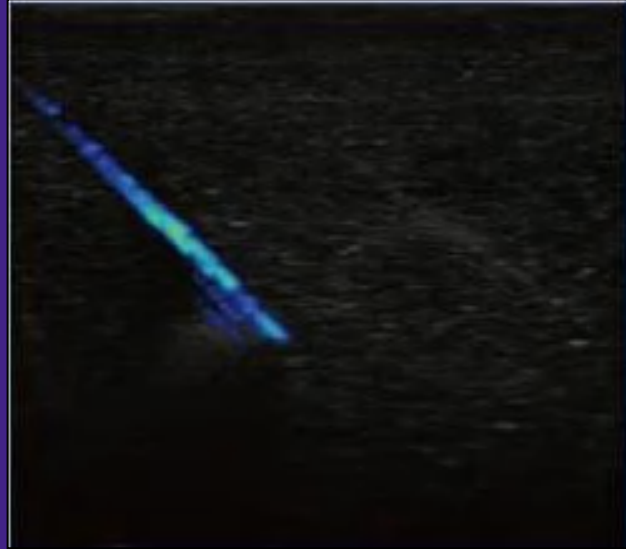
✖ Elastography ✖

- Display the elasticity of different tissues in different color.
- Provide more clinical information, especially for breast tumor, thyroid, liver and prostate, including linear, convex, transvaginal.
- Strain ratio measurement quantitatively gives the ratio between the average strain of the selected region and of the nearby normal tissue region.

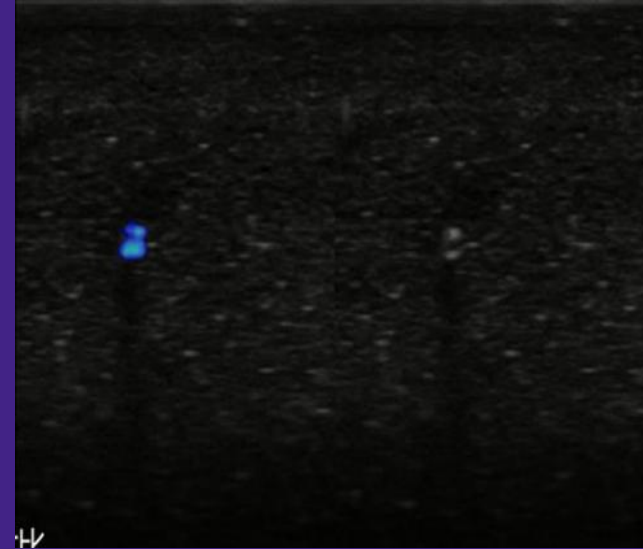




✧ SonoNeedle ✧



In-Plane Biopsy

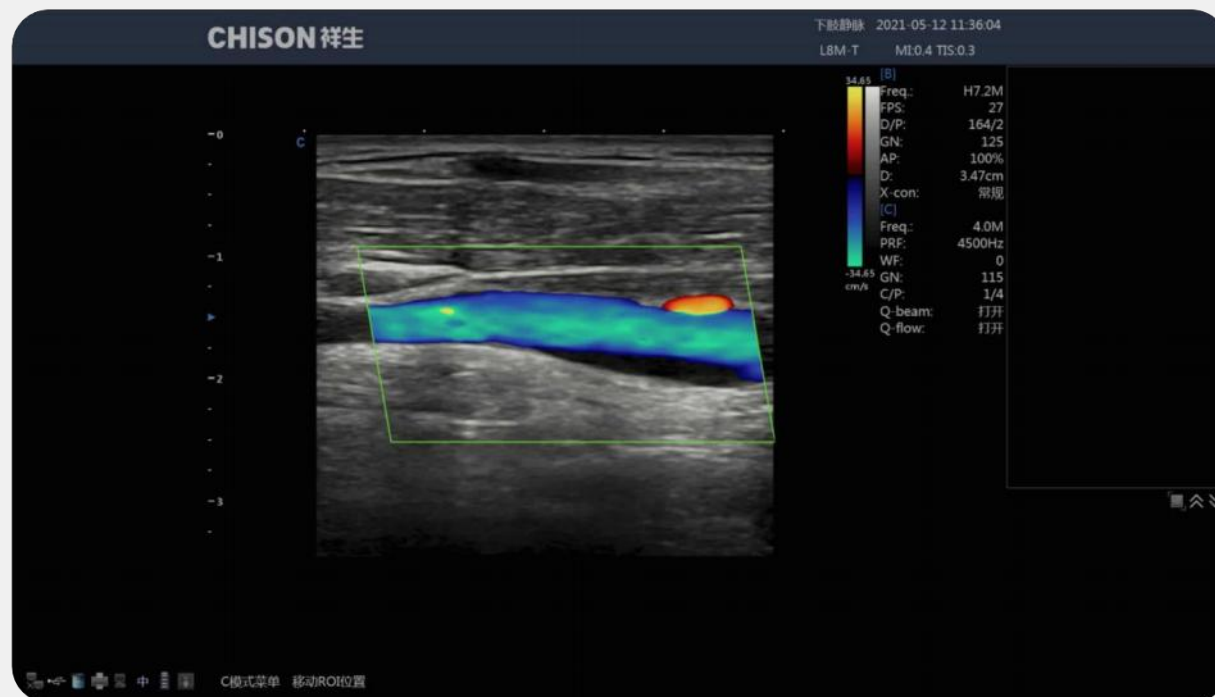


Out-plane biopsy

- Safe, Reliable and efficient tool to increase clinical confidence in ultrasound guided procedure.
- Offers multiple angle capabilities for shallow and deep access.
- Highly recommended in regional anesthesia imaging applications to shorten procedure time and improved accuracy.

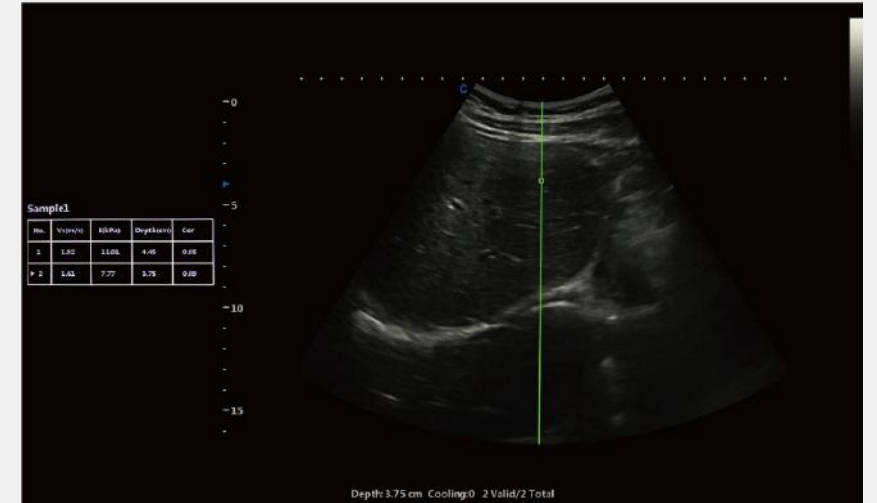
❖ Color Panoramic ❖

- Real time scan to enlarge the color image.
- Shows the blood flow of whole vessel.

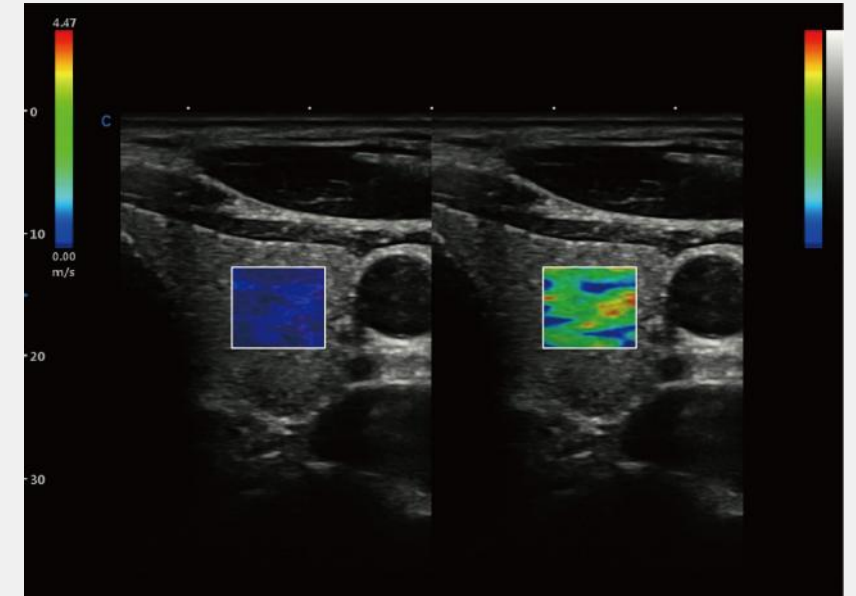


✘ Shear Wave Elastography ✘

- P-SWE point shear wave imaging, high precision single point measurement, higher penetration.
- 2D-SWE surface shear wave imaging, real-time two-dimensional measurement to obtain more diagnostic information.
- The system can provide variety of quantitative analysis parameters, such as velocity values, Young's modulus and so on.



P-SWE point shear wave imaging



2D-SWE surface shear wave imaging

✕ SWD ✕

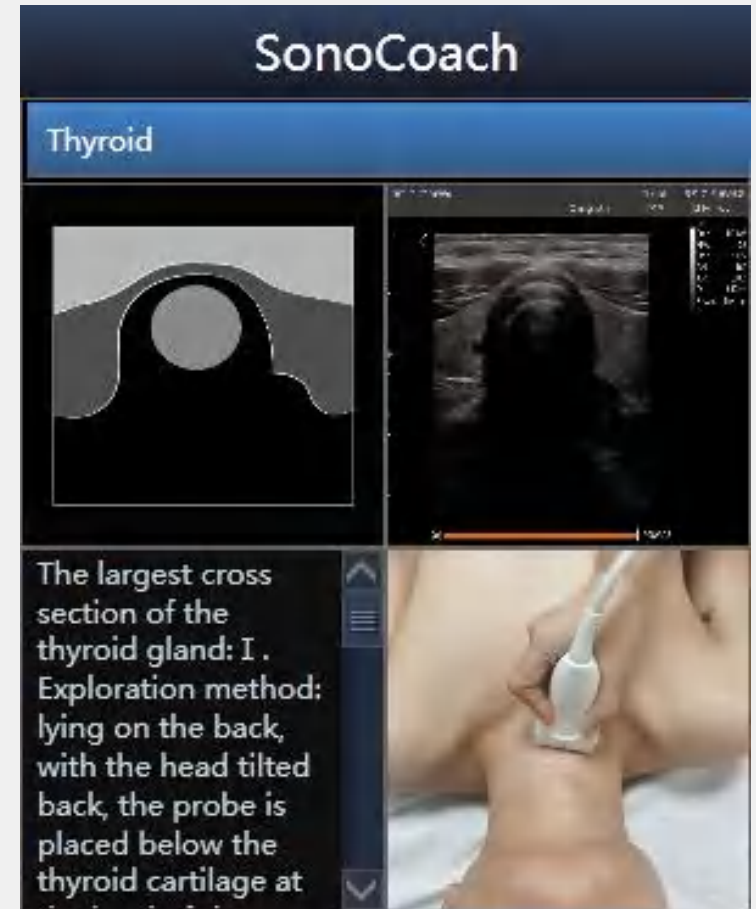
- SWD Shear wave dispersion imaging,
- the combination of SWE and SWD adds stiffness and viscosity information for a more complete liver assessment. .





✂ SonoCoach ✂

- Built in teaching software
- Provide ultrasonic diagram, anatomical diagram, scanning schematic diagram and text explanation

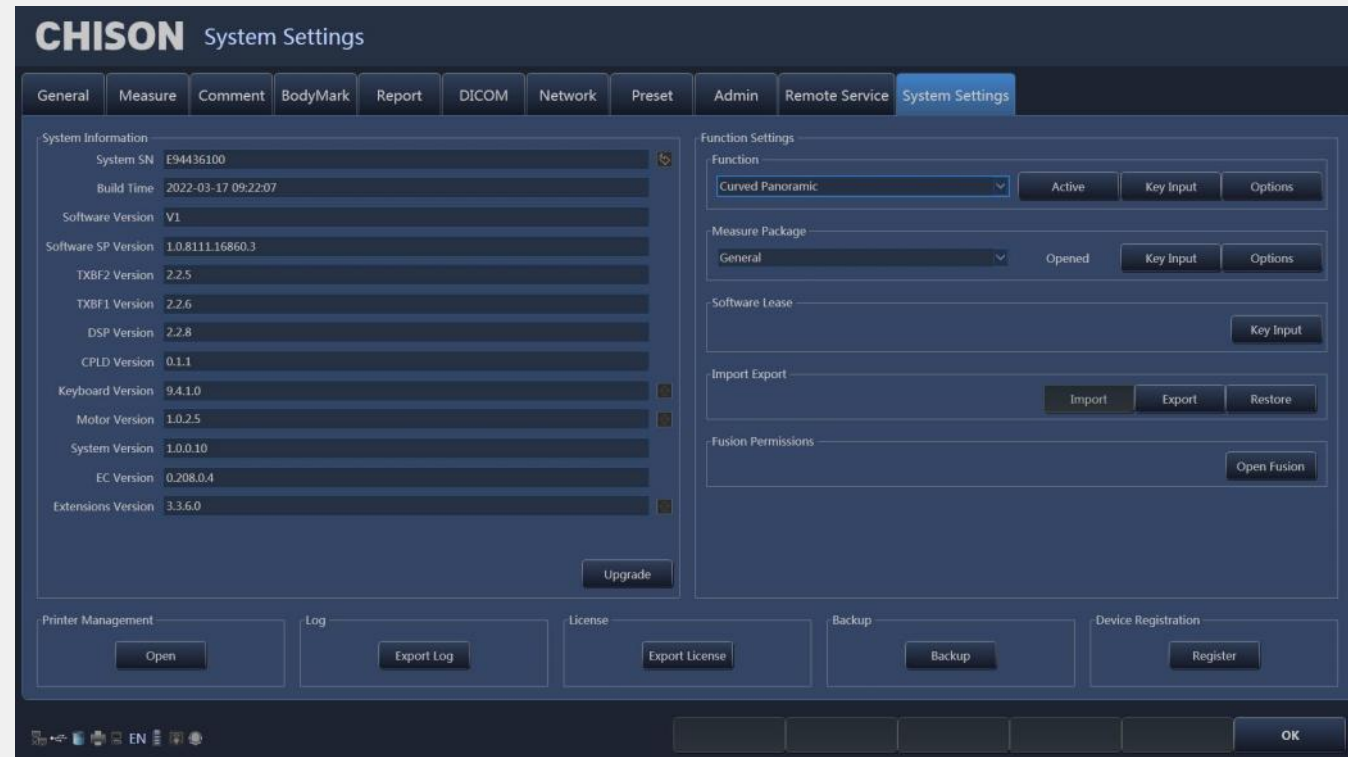




CHISON
Value Beyond Imaging

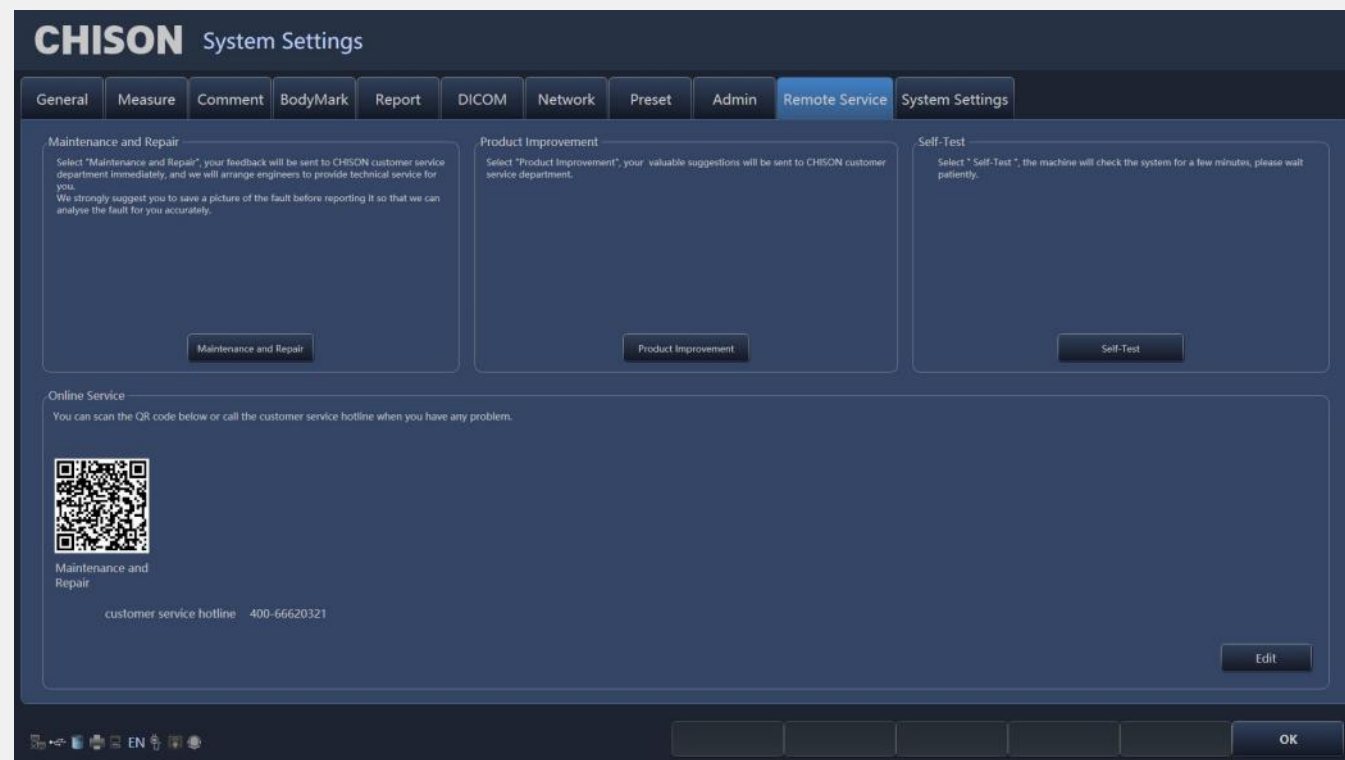
✂ SonoTrial ✂

- Used for all functions (except 4D functions)
- Each function can be tried for free for 30 days



✕ Remote Service ✕

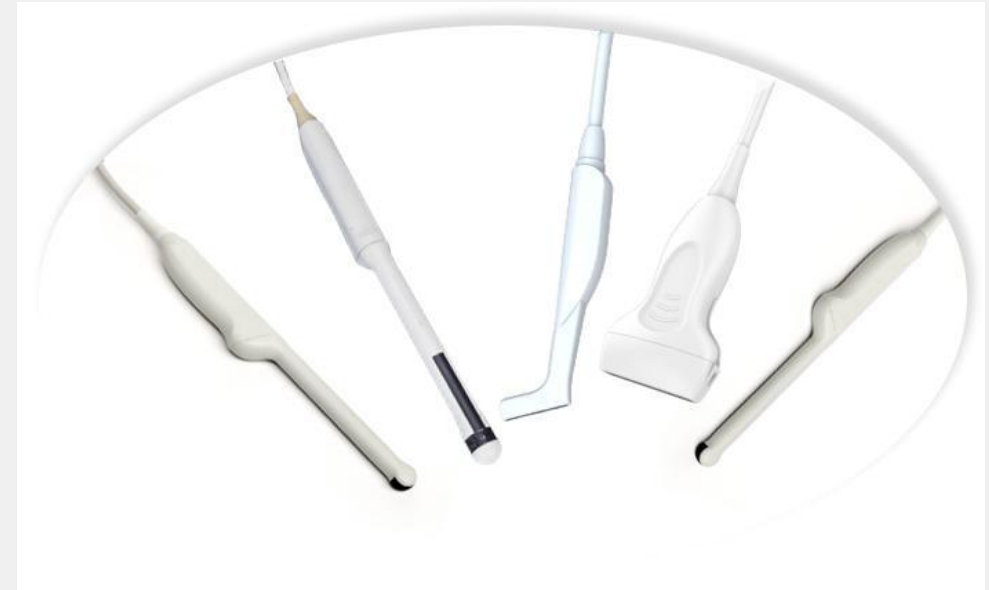
- Built in remote service system
- One click repair or scan QR code for repair
- Pictures and error messages can be transmitted





Variety Transducers

- Signal- crystal transducer: phased array, linear, etc.
- High density transducer : 192.
- Trans-vaginal volume transducer .
- Bi-plane transducer: linear & micro-convex.
- TEE transducer: adult and pediatric.
- Button probe.
- Wide angle trans-vaginal probe: 250°.





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Premium Intelligence



✕ Sono - Breast ✕

- accuracy: up to 95%
- fast: less than 3s
- four classification

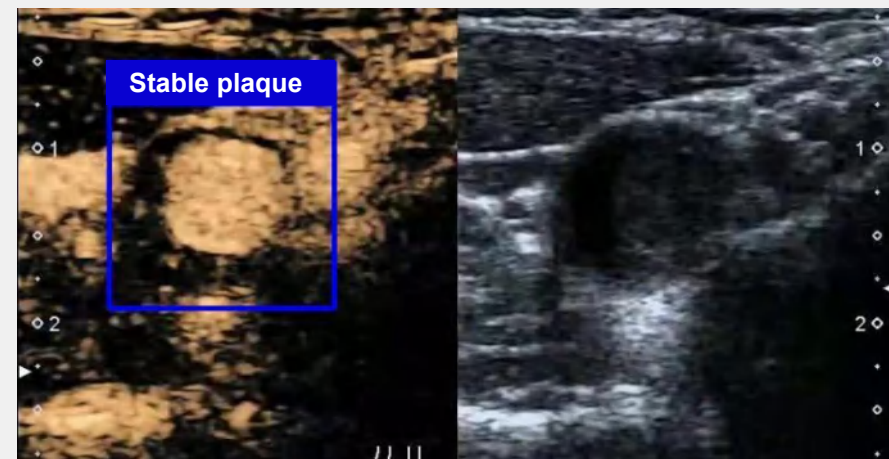
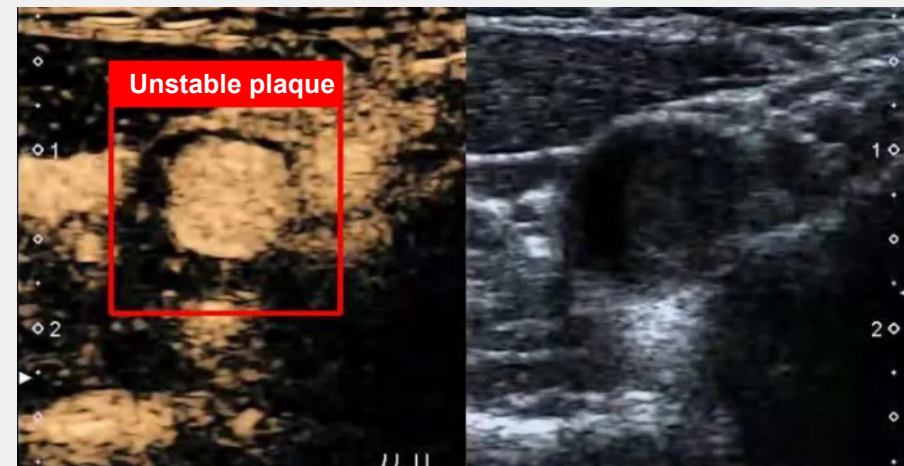
benign tumor | malignant tumor | mastitis | adenosis



✂ Sono - Plaque ✂

- Accuracy: up to 80-85%
- The **fast** :less than 30s (per video with contrast imaging)
- **World's first** to detect carotid plaque: (estimate stroke risk)

Stable plaque | Unstable plaque





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✖ Sono Remote ✔

CHISON SonoRemote



End User



Remote Center

Remote Diagnose



Remote Demo



Remote Training



Remote Service





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Value Beyond Imaging

✧ The XBit Series ✧

	XBit 80	XBit 90
PlateForm	NIT New Image Techonology	NIT New Image Techonology
Monitor	23.8 inch HD LED	23.8 inch HD LED
Touch Screen	13.3 inch Sensitivity Touch Sscreen	13.3 inch Sensitivity Touch Sscreen
Hard Disk	512G SSD	512G SSD
Control Panel	Adjustable- Left and Right Adjustabl-Up and Down	Adjustable- Left and Right Adjustabl-Up and Down
USB	8, USB 3.0	8, USB 3.0
Built-in Battery	Yes , option	Yes , option
Gel Warm	Yes	Yes
WiFi	Yes, option	Yes, Standard
Hero Kit	Yes	Yes



✧ The XBit Series ✧

	XBit 80	XBit 90
Elastography	Yes, option	Yes, option
Share Wave Elas	Yes, option pSWE and 2D SWE	Yes, option pSWE and 2D SWE
SonoContrast	Yes, option Linear/Convex/TV	Yes, option Linear/Convex/TV/Sector
SonoFusion	No	Yes, option
MVI	Yes	Yes
SoundFlow	Yes	Yes
NanoFlow	No	Yes, option
SonoPW	Yes	Yes
TDI+SonoPW	No	Yes, option
SonoBreast	No	Yes, option



CHISON
Value Beyond Imaging

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XBit

The Passion to Lead, The Power to Care

Thanks

WWW.CHISON.COM



We keep the rights to change.

XBit 90

Color Doppler System Datasheet

V1.0



General Information

Dimensions and Weight

- Dimensions of main unit (approx.):
764mm*630mm*1440mm
- Net weight of main unit (approx): 75kg (no probe included)

Electrical Power

- Power supply voltage: Auto adaptable for AC100-240V
- Power supply frequency: 50-60 Hz
- Power consumption: 600 VA
- Stand-by mode
- Battery for option

User Interface

Operation Panel

- Control panel
 - Height adjustable: 15 cm
 - Rotatable with 100° left and right
 - released from the machine body
- Alphanumeric keyboard
- 8 TGC Slides
- Interactive backlit keys
- Integrated speaker
 - Volume adjustable

Touch panel

- 13.3 inch Touch screen
 - customizable layout
 - can show the image real time
 - sensitive to use

Display Screen

- High resolution color LED
- Dimension: standard 23.8 inch
- Resolution: 1920×1080
- Image Area: 800×600
Full Screen: 1120×840
1440×1080
- Brightness and contrast adjustment

System Overview

Applications

- Abdominal (Gynecology & Urology)
- Fetal/OB
- Small Parts
 - Breast
 - Thyroid
 - Scrotum
- Pediatrics
- MSK_Conventional & Superficial
- Cardiac (adult & pediatric)
- Transvaginal

Scanning Method

- Electronic convex
- Electronic linear
- Electronic phased array
- Volume convex

Transducer Types

- Convex probe:
C3-T, C3M-T
- Linear probe:
L7-T, L7R-T, L12-T, L8M-T, L12M-T, L10i-T, L8M6-T, L8M5-T, L18-T, L7SVA-T (Button probe)
- Trans-vaginal probe:
E7-T, E7MW-T
- Phased array probe:
P2-T, P2M-T, P5-T, P3T-T
- Volume probe:
VC4-T, VE6-T
- Micro convex probe:
MC6-T, MC3-T
- TEE probe (Transoesophageal):
T5-T
- Pencil probe:
CW2-T
- Bi-plane probe:
R7B8-T

Image Modes

- B Mode
- B/M mode
- M mode
- 2B Mode
- 4B Mode
- CFM Mode
- 2D Steer
- PD Mode
- DPD Mode
- PW Mode
- B/BC Mode
- Triplex
- Quadplex
- CW Mode
- Free Steering M Mode
- TDI
- Color M Mode
- Curved Panoramic Imaging
- Trapezoidal imaging
- Compound
- SRA
- Elastography
- Stress Echo
- ECG
- Super Needle
- 4D
- Virtual HD
- FHI mode
- AIO

Display Mode

- Quad/Dual display
- Duplex mode
- Triplex mode
- Quadplex mode

Display Annotation

- Hospital name

- Date/Time
- Patient Name and Patient ID
- Gray/Color bar
- Cine guide
- Scanning direction
- Measurement results window
- Transducer type
- Frequency
- Application name
- Menu indication
- Trackball functions indication
- Imaging parameters displayed on the screen

Standard Configuration

- 23.8 inch LED monitor
- 13.3 inch touch screen
- 4 active transducer ports
- 500G integrated hard disk
- DVD-R/W
- USB ports: 8
- TGC
- LGC
- B, 2B, 4B, B/M, B/BC, CFM, PW, Power Doppler/Directional PD, Instant Triplex, Duplex, Quadplex, Trapezoidal, Chroma B&M&PW, Full Screen
- Automatic PW trace and measurement in real time
- Super Image module: FHI, Multiple Compound Imaging, SRA (Speckle Reduction Algorithm), AIO
- Q-image (intelligent image optimization), X-contrast, Q-beam, Q-flow
- Measurement & calculation software packages: General, OB&GYN, Cardiac
- Zoom
 - Zoom navigator
 - Improve the fps
 - High resolution Zoom
 - Real-time Zoom

- Frozen Zoom
- PIP Zoom
- Pan Zoom

Software Options

- 4D module
- Virtual HD/Depth View
- HD Niche/ Smart Volume Slice/SonoCrystal
- 2D steer
- Stress Echo
- Auto EF
- Strain and Strain rate
- Intelligent Doppler
- SonoAI OB
- SonoContrast
- SonoPW
- SonoColor
- SonoNeedle
- UltraRemote
- SoundFlow
- Virtual Apex
- Static 3D
- Nano Flow
- MVI Mode
- Elastography
- SWE
- Super Needle
- Curved panoramic
- Color Panoramic
- Curved expanding
- HPRF
- TSS
- HIPPA
- Extended Cardiac Package: ECG Software, Free M, Color M, CW, TDI, IMT
- DICOM 3.0
- WIFI Function
- Bluetooth

- Biopsy kit: for convex/linear/TV/ Micro-Convex probe respectively
- PSWE
- SonoBreast
- SonoFollicle
- RemoteSevice
- SonoFusion
- SonoCoach
- SonoCompare
- HD 3D
- RTIMT
- SonoDiaph
- Curved M

Hardware Options

- Footswitch
- ECG Lead

Peripherals

- SONY UP-X898MD B&W Video Printer
- SONY UP-D25MD

Imaging Parameters

B Mode

- Gain
- Compound
- SRA
- Focus Number
- Focus Position
- Full Screen
- X-contrast
- Q-image
- Persistence
- Density
- 2D Map
- Noise Reject
- Scan Width
- Image Rotate
- Gamma

- Chroma
- Smooth
- Edge enhance
- A.power
- Frequency
- Dynamic
- Depth: depend on the probes
- Zoom
- TGC
- Center Line
- Trapezoidal Mode
- Biopsy
- Biopsy Level
- Super Needle
- Needle angle
- 2D steer

M Mode

- Gain
- Layout
- Display Format
- Chroma
- Free Steering M Mode
- Color Map
- 2D map
- Dynamic
- Speed

Color Mode

- Gain
- Color Map
- Color Invert
- Q-flow
- Q-beam
- Persistence
- Color Mode
- Wall Filter
- Density
- Wall Thre

- Blood Efection
- B/BC
- Frequency: depend on the probes
- Baseline
- Scale: depend on the probes
- Steer
- PRF

CPA/DPD Mode

- Gain
- Wall Filter
- Q-beam
- Q-flow
- Wall Thre
- Persistence
- Frequency: depend on the probes
- PRF: depend on the probes
- Steer
- Color Map

PW Mode

- Gain
- 2D Map
- Wall Filter
- Spectrum Enhance
- Dynamic Range
- Invert
- Display format
- Triplex
- Quadplex
- Auto Cal Parameter
- DTrace Smooth
- Threshold
- DVmean
- DVmax
- Trace area
- Audio
- Color Map
- QuickAngle

- Auto Cal
- Freq: depend on the probes
- Baseline
- PRF: depend on the probes
- Steer
- Speed

CW Mode

- Gain
- 2D Map
- Spectrum Enhance
- Dynamic
- Audio
- Wall Filter
- Color Map
- QuickAngle
- Baseline
- PRF: depend on the probes
- Speed: depend on the probes

SonoContrast

- SonoContrast provides exceptional Contrast agent detecting capability, not only extracts second harmonic, but also non-linear fundamental signals
- Available for convex, linear, phased array and endocavitary probe
- Available for abdomen, GYN, URO, Thyroid, Breast,
- Analysis package
- mechanical index
- Timer1: on/off
- Timer2: on/off
- Retro capture and Pro capture storage
- Comparative analysis on complex curves
- Dual live: side by side displays tissue image and contrast image
- Mix: mix contrast image with tissue image
- Visual: Contrast/Mix/Tissue
- Center line

- Mark
- Cine Save
- Flash
- Q-image
- Edge Enhance
- Mix map
- Dynamic range
- 2D map
- Chroma
- Supports U/D Flip and L/R Flip
- Rotation

Triplex Mode

- B+C+D
- Available on all probes

Quadplex Mode

- B+C+D+auto trace
- DTrace Calc Parameters: Vs, Vd, TAMAX, VTI, Time, RI, PI, S/D, HR

Technology and Function

Fusion Harmonic Imaging

- Available on all probes
- FHI key ON/OFF
- Second active multi-frequency

Trapezoidal

- Available for linear probe
- combined with compound algorithm space

SonoAI-OB

- Automatic measurement: BPD, HC, AC, FL, NT ,OFD
- Efficiency and accuracy

HIPPA

- Password to get into the system
- User define

Curved panoramic

- Real time
- Support measurement
- Erasable design
- Color map
- Available for convex and linear

Elastography

Available on linear, convex, endocavitary

- Dual images simultaneous
- Modifiable ROI

- Support strain ratio measurement
- Real-time display of pressure column
- Quantitative comparison

Dynamic focusing

- Wider the focus area
provide image more detail and higher resolution

Post Processing for raw data

- Support measurement
- Adjust the gain, TGC, 2D map, chroma, dynamic range, invert etc.

Stress Echo

- Available on phased array probes
- 36 factory protocols
- User-defined protocols
- Analysis system: wall motion scoring
- Professional report

Cineloop

- Cine loops: up to 2000 frames
- Perspective: Save cine in real time
- Retrospective: Save cine loops in frozen mode
- Support 2D, M, PW, CFM, CPA, DPD, CW, Color M, Free Steering M
- Simultaneous and independent review in duplex mode
- Cineloop auto/manual
- Variable cine playback speed
- User-define start and end frame of cine storage
- User-define start and end frame of cine review
- storage in hard disk and display in real-time modes
- Slide show: slide show function

Storage

- 500GB integrated SSD
- DVD-R/W driver
- USB ports
- Still images storage format: IMAG
- Still images export format: BMP, JPG, DCM, PNG, TIFF
- Cine loops storage format: CINE

- Cine loops export format: AVI
- Fast storage setting
- System suitable to avoid the loss of data / images

EasyView

- Image review Layout: 1×1, 2×2
- Image management

Exam Review

- Search Exam
- Exam review: patient view, study view
- Exam management
 - Delete selected exam
 - Export selected exam
 - Backup selected exam
 - Recover from the backup exam
 - Selected all
 - Expand all
 - Collapse all
 - Edit selected Exam
 - Review selected Exam
 - Continue selected Exam

Connectivity

- Ethernet work connection
- USB for USB Device
- DICOM support(option)
 - Verify
 - Print
 - Store
 - Worklist
 - Structure report
 - MPPS
 - Query/retrieve

Measurement and Calculations

General Measurement Package

- Software packages for various specific clinical use
- Comprehensive analysis methods
- Clinical analysis reports

General measurement package

- B mode General measurement

Distance

Length__Area (Ellipse)

Length__Area (Trace)

Volume (1 Distance)

Volume (2 Distance)

Volume (3 Distance)

Volume (1 Ellipse)

Volume (2 Ellipse)

Volume (1 Distance 1 Ellipse)

Ratio

Angle

Strain Ratio

HR Manual

SonoColor

SWE

- M mode normal measurement

MDistance

MTime

Velocity

HR

HR Manual

- PW mode Normal measurement

Velocity

Distance

Peak

Auto Trace

Manual Trace

StD%

StA%

Area

ICA/CCA

HR

Volume Flow

HR Manual

Clinical Analysis Packages

- B mode GYN measurement

Distance

UT

Cervix Vol.

ENDO

OV Volume

FO_D

FO Auto

Uterine Artery

HR Manual

Strain Ratio

- M mode GYN measurement

MDistance

MTime

Velocity

HR

HR Manual

- PW mode GYN measurement

Umb A

MCA

Uterine Artery

Fetal AO

HR Manual

- B mode OB measurement

Distance

GS

CRL

BPD

Auto BPD

AC(Ellipse)

Auto AC

HC

Auto HC

FL

Auto FL

Humerus

OFD

Auto OFD

NT

Free NT

Fetal Biometry

Fetal Long Bones

Fetal Cranium

OB Others

Z Score

AFI

Ductus Venosus

CX_L

Aorta	PTA
Descending Aorta	PERON
MCA	DRPED
Umb A	HR Manual
Uterine Artery	Strain Ratio
Pulmonary Artery	● M mode Vessel measurement
Fetal Select	MDistance
HR Manual	MTime
Strain Ratio	Velocity
● M mode OB measurement	HR
MDistance	HR Manual
MTime	● PW mode Vessel measurement
Velocity	CCA
HR	ICA
HR Manual	ECA
FHR	Vertebral A
● PW mode OB measurement	INT IIL
Umb A	EXT IL
Aorta	ILIAC
Descending Aorta	CFA
Left Uterine Artery	ProFun
Right Uterine Artery	LTCIR
Pulmonary Artery	SFA
MCA	Pop A
FHR	ATA
HR Manual	PTA
Duct Venosus	PERON
● B mode Vascular measurement	DRPED
IMT (Auto)	HR
IMT Mean	Volume Flow
SonoColor	HR Manual
CCA	● B mode URO measurement
ICA	Distance
ECA	Void Vol.
Vertebral A	Prostate Vol.
EXT IL	Kidney Volume
INT IIL	T-Zone Vol.
ILIAC	Bladder Vol.
CFA	StA%
ProFun	StD%
LTCIR	Vessel Area
SFA	Vessel Dis
Pop A	HR Manual
ATA	Strain Ratio

-
- M mode URO measurement
 - MDistance
 - MTime
 - Velocity
 - HR
 - HR Manual
 - PW mode URO measurement
 - Velocity
 - Acceleration
 - Distance
 - Peak
 - Auto Trace
 - Manual Trace
 - StD%
 - StA%
 - Area
 - ICA/CCA
 - HR
 - Volume Flow
 - HR Manual
 - B mode Small Parts measurement
 - Distance
 - Length__Area (Ellipse)
 - Length__Area (Trace)
 - Volume (1 Distance)
 - Volume (2 Distance)
 - Volume (3 Distance)
 - Volume (1 Ellipse)
 - Volume (2 Ellipse)
 - Volume (1 Distance 1 Ellipse)
 - Ratio
 - Angle
 - Strain Ratio
 - Breast
 - Auto Breast
 - Thyroid
 - Auto Thyroid
 - HR Manual
 - SWE
 - M mode Small Parts measurement
 - MDistance
 - MTime
 - Velocity
 - HR
 - HR Manual
 - PW mode Small Parts measurement
 - Velocity
 - Distance
 - Peak
 - Auto Trace
 - Manual Trace
 - StD%
 - StA%
 - Area
 - ICA/CCA
 - HR
 - Volume Flow
 - HR Manual
 - B mode Pediatrics measurement
 - HIP
 - Vol(3Dis)
 - HR Manual
 - Strain Ratio
 - M mode Pediatrics measurement
 - MDistance
 - MTime
 - Velocity
 - HR
 - HR Manual
 - PW mode Pediatrics measurement
 - Velocity
 - Distance
 - Peak
 - Auto Trace
 - Manual Trace
 - StD%
 - StA%
 - Area
 - ICA/CCA
 - HR
 - Volume Flow
 - HR Manual
 - B mode Carotid measurement
 - Subclavian A
 - CCA
 - Bulb
 - ICA
 - ECA

Vertebral A	HR Manual
General Measurement	● M mode Cardiac measurement
Strain Ratio	MDistance
HR Manual	MTime
● M mode Carotid measurement	Slope
MDistance	HR
MTime	Left Ventricle
Velocity	Mitral Valve
HR	Aortic Valve
HR Manual	Tricuspid Valve
● PW mode Carotid measurement	Pulmonary Valve
Subclavian A	RV/LV
CCA	LV Mass
Bulb	TAPSE
ICA	Vp
ECA	HR Manual
Vertebral A	● PW mode Cardiac measurement
General Measurement	Velocity
ICA/CCA	Acceleration
HR	Time
Volume Flow	Slope
HR Manual	HR
● B mode Cardiac measurement	ED/PS
Auto EF	Mitral Valve
Teichholz	Aortic
Simpson SP	Tricuspid Valve
Simpson Biplane	Pulmonary Valve
Modify Simpson	Pulmonary Vein
Cube	PISA
Bullet Volume	Qp/Qs
Gibson	Tei Index
Mitral Valve	TDI
Aortic Valve	HR Manual
Pulmonary Valve	● B mode Abdomen measurement
Tricuspid Valve	CBD
LVOT	GB Wall
RVOT	Liver Length
PISA	Artery
LV Mass	Spleen
Qp/Qs	Renal Vol.
RV/LV	GB Volume
IVC	Iliac
RA/LA	HR Manual
AO/LA	Strain Ratio

- M mode Abdomen measurement
 - MDistance
 - MTime
 - Velocity
 - HR
 - HR Manual
- PW mode Abdomen measurement
 - Velocity
 - Acceleration
 - Distance
 - Peak
 - Auto Trace
 - Manual Trace
 - StD%
 - StA%
 - Area
 - ICA/CCA
 - HR
 - RAR
 - Volume Flow
 - HR Manual
- B mode TCD measurement
 - ICA
 - CS
 - MCA
 - ACA
 - PCA
 - ACOA
 - PCOA
 - OA
 - Vertebral A
 - BA
 - PICA
 - HR Manual
- PW mode TCD measurement
 - ICA
 - CS
 - MCA
 - ACA
 - PCA
 - ACOA
 - PCOA
 - OA
 - Vertebral A

BA
PICA
HR Manual

SYSTEM SETUP

By using system setup, users could

- Customize hospital information
- Customize language
- Customize fast storage time
- Customize color map
- Customize functions to Footswitch,P1 key, Print key
- Customize functions to alphanumeric 0~9
- Customize PC and Video Print
- Option
- Customize Measure
- Customize Comment library
- Customize Report

User Define Functions

- By user-define function, users could customize user-define preset, including
 - Applications name, Presets name
 - Applications exam type
 - Imaging parameters

Multi-language Display Interface

- English
- Chinese
- Other languages

Note: other languages for detailed, please contact CHISON.

Inputs and outputs

- AC Power In: 1
- AC power Out: 1
- Power Button: 1
- USB Port: 8
- Ethernet: 1
- Remote Control: 1
- S-Video Out: 1
- Audio: L,R
- DVI: 1
- VGA Out: 1
- Video Out: 1
- Footswitch Port: 2

-
- Ground pole: 1

Operating conditions

- Ambient temperature: 10°C to 40°C
- Relative humidity: 30% to 75% (no condensation)
- Atmospheric pressure: 700 hPa to 1060 hPa

Storage and Transport conditions

- Ambient temperature: -5°C to 40°C
- Relative humidity: ≤80% (no condensation)
- Atmospheric pressure: 700 hPa to 1060 hPa

Not all features or specifications described in this document may be available.

CHISON Medical Technologies Co., Ltd. reserves the right to make changes in specifications and features shown herein, or discontinues the product at any time without notice or obligation. For the most current information, Contact CHISON Representative.

Manufacturer's Authorization

Date: MAY 22, 2023

AUTHORIZATION LETTER

To whom it can refer

We, CHISON Medical Technologies Co., Ltd., who are official manufacturers of Medical Diagnostic Ultrasound Machines.

Address: No. 9, Xinhuihuan Road, Xinwu District, Wuxi City, Jiangsu Province, China 214028.

Hereby authorizes your company :

Triumf Motiv SRL

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tel: (+373 22) 76 84 62, 76 88 41

Triumf-Motiv SRL is our authorized representative and distributor on the territory of the Republic of Moldova.

We allow this company to register our products with the competent authorities on the territory of the Republic of Moldova, as well as to promote, sell, distribute our products in the Republic of Moldova, and we will provide all necessary assistance to expand the market of medical supplies and devices of our brand in your country.

This letter of authorization remains valid for five years, starting from March 10.2023 and expiring on MAY 22, 2025.

Name: Eric Yang

Title: International Sales Manager

Signature: *Eric Yang*

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CHISON MEDICAL TECHNOLOGIES CO., LTD.