

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. TR-5 din 23.05.2023

_____, tel./fax: 022768462, e-mail triumf.motiv@mail.ru,
solicite înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor
categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție
pe piață a:

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	

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:

Ultrasonograf General model XBit 80, ;
____ ;
____ ;
____ ;
____ ;
____ ;
____ .

Sunt autentice și corespund realității.

Numele, prenumele și funcția

Semnătura _____

Data 23.05.2023

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

Republic Of Moldova, MD 2043-str. Grenoble 193, et.13, of.1

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*

无锡祥生医疗科技股份有限公司
CHISON MEDICAL TECHNOLOGIES CO., LTD.

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2102189-1

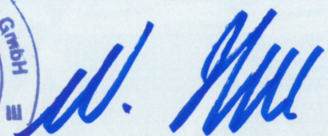
Organization: CHISON Medical Technologies Co., Ltd.
No.3 Changjiang South Road,
Xinwu District, Wuxi,
214028 Jiangsu
P.R. China

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

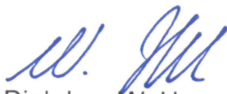
Dipl.-Kfm.
Dr. Jörg Schlösser

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

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



CHISON



XBit 80

Advanced Healthcare at Your Fingertips

Product Department

2022-1-27

CHISON

23.8 HD LED

**Large Size
High Definition**

**13.3 Touch
Screen**

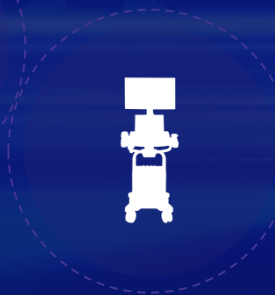
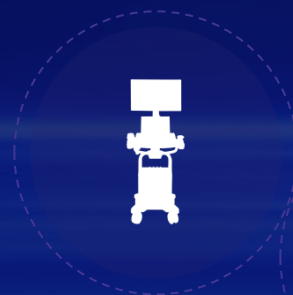
**High Sensitivity
Streamlined Workflow**

Hearo Kit

**All in ONE
Hassle Free**



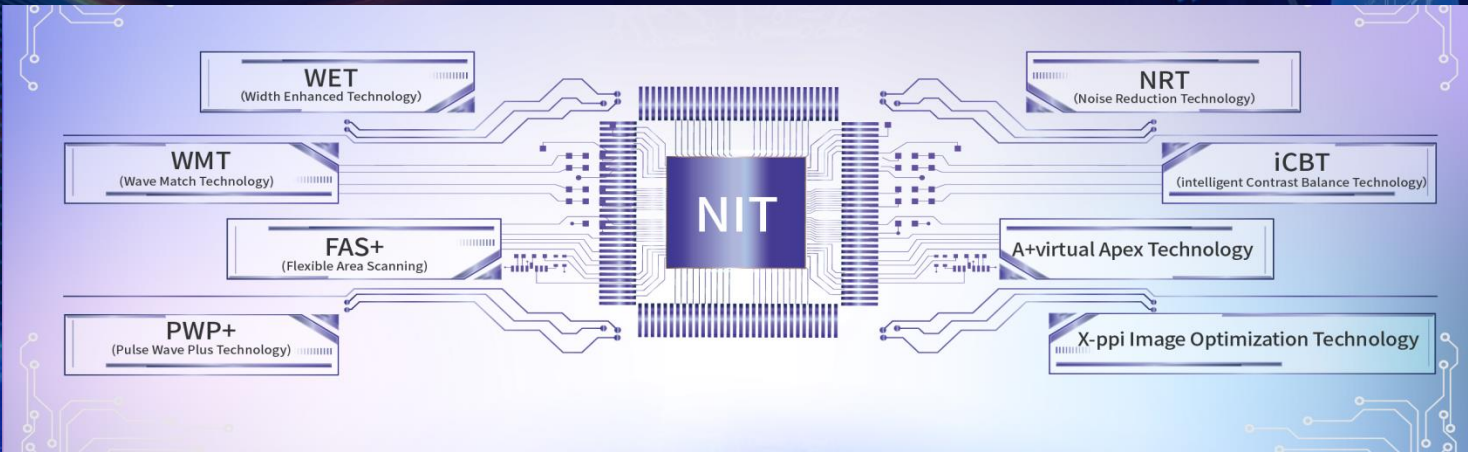
- Powered Performance
- Diversified Clinical Application
- Versatile Gallery



CHISON

Powered Platform by NIT

New Image Technology



1+
Probe Precision



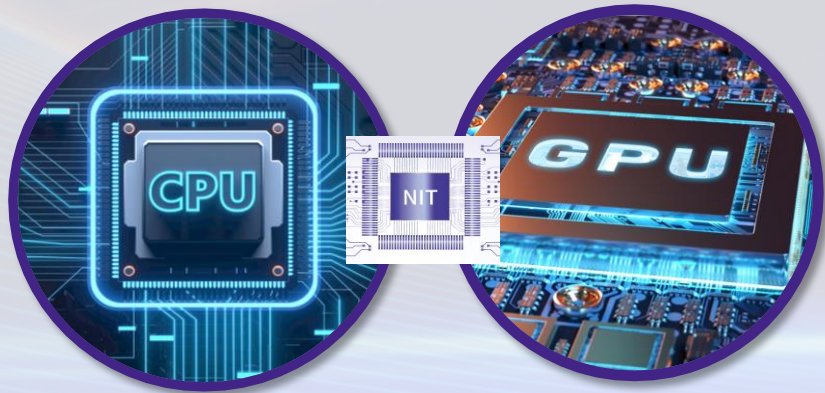
3+
Signal Processing



4+
Image Algorithm



High Performance by Parallel Processing



CPU

GPU

Faster

Better

Powerful

CHISON

Diversified Clinical Application



Radiology



Cardiovascular



OB/GYN



Muti - Elastography

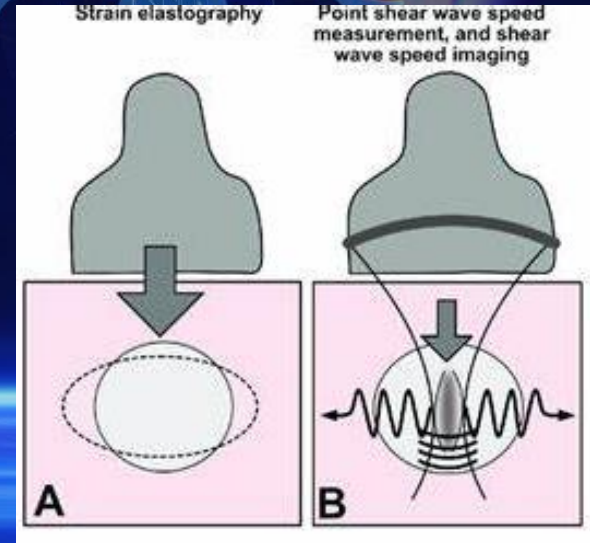
◆ Strain Elastography

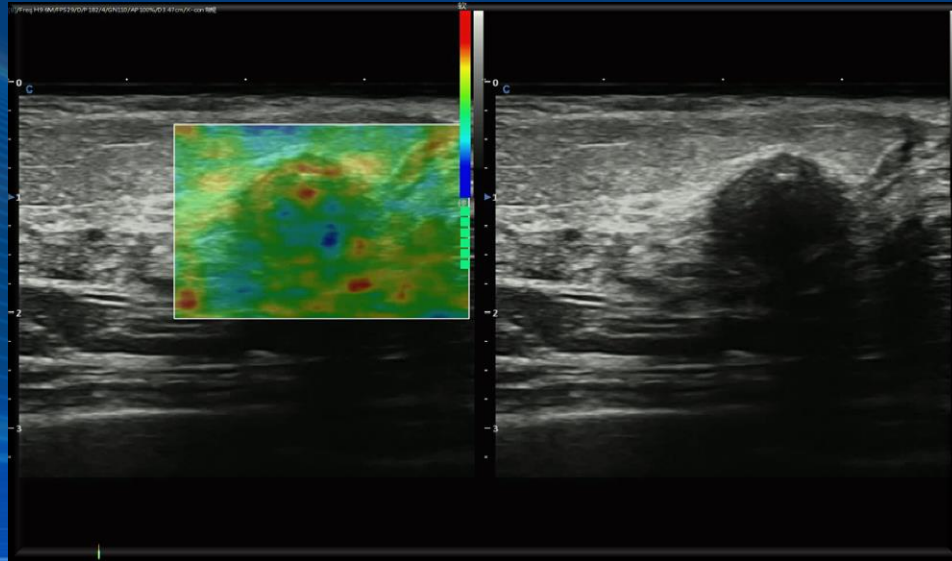
Produced by breath and vessel impulse.

◆ pSWE and 2D SWE

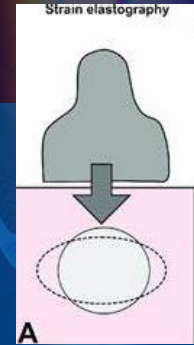
Generated by ultrasound transverse propagation

- High Reliability
- High Repeatability



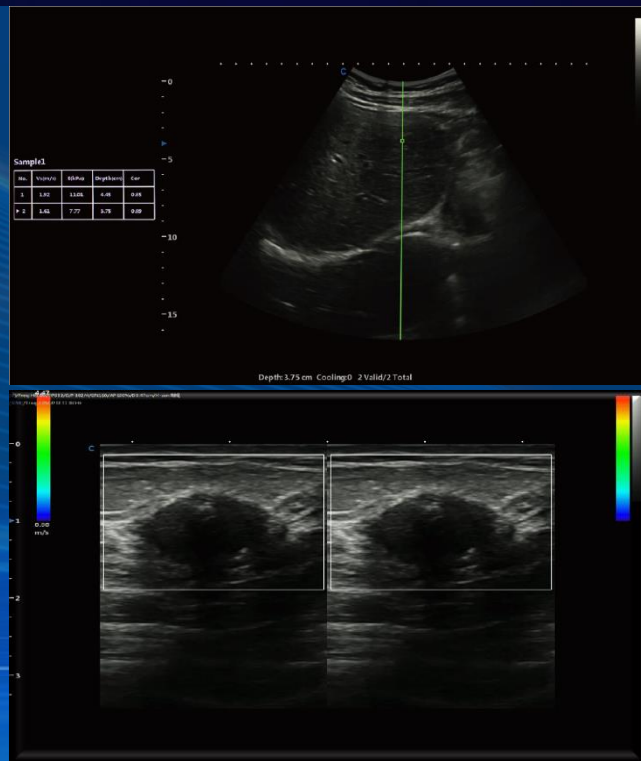


Strain Elastography



- ◆ Produced by breath and vessel impulse
- ◆ Different color to show the tissue
- ◆ Qualitative Strain ratio measurement
- ◆ Comparison different area

Support with Linear, Convex, TV probe

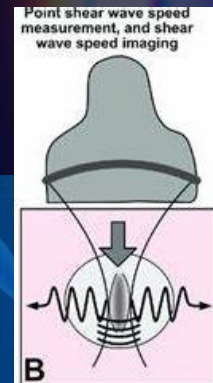


Shear Wave Elastography

- ◆ p-SWE High precision single point Measurement
- ◆ 2D-SWE Real-time two-dimensional measurement
- ◆ Quantitative Analysis parameters
velocity values
Young's modulus and so on.

High penetration

support with Linear, Convex, TV probe



Multi- Elastography



Strain Elas

Repeatability

Impulses by breath And vessel blood

Qualitative

Low Penetration, better for Superficial

High Frame Rate

Low Acoustic Radiation

High resolution, clear edge

Supple All, the Best Solution



SWE

High Repeatability

Ultrasound

Quantitative

Superficial and deep tissue

Low Frame Rate

High Acoustic Radiation

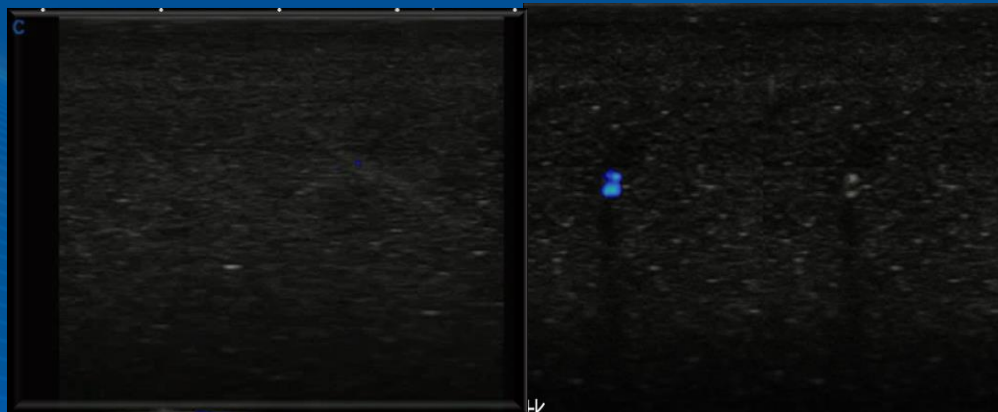
Low resolution

SonoContrast

- ◆ TIC -Time Intensity Curves
- ◆ Auto Tracking for ROI
- ◆ High Sensitivity Better Performance

Available for Convex, Linear, Endocavity





In-Plane Biopsy

Out-plane Biopsy

SonoNeedle

- ◆ Safe, Reliable and efficient tool
- ◆ No limit of angle, capabilities for shallow and deep access.
- ◆ Shorten procedure time and improved accuracy.

CHISON

Diversified Clinical Application



Radiology



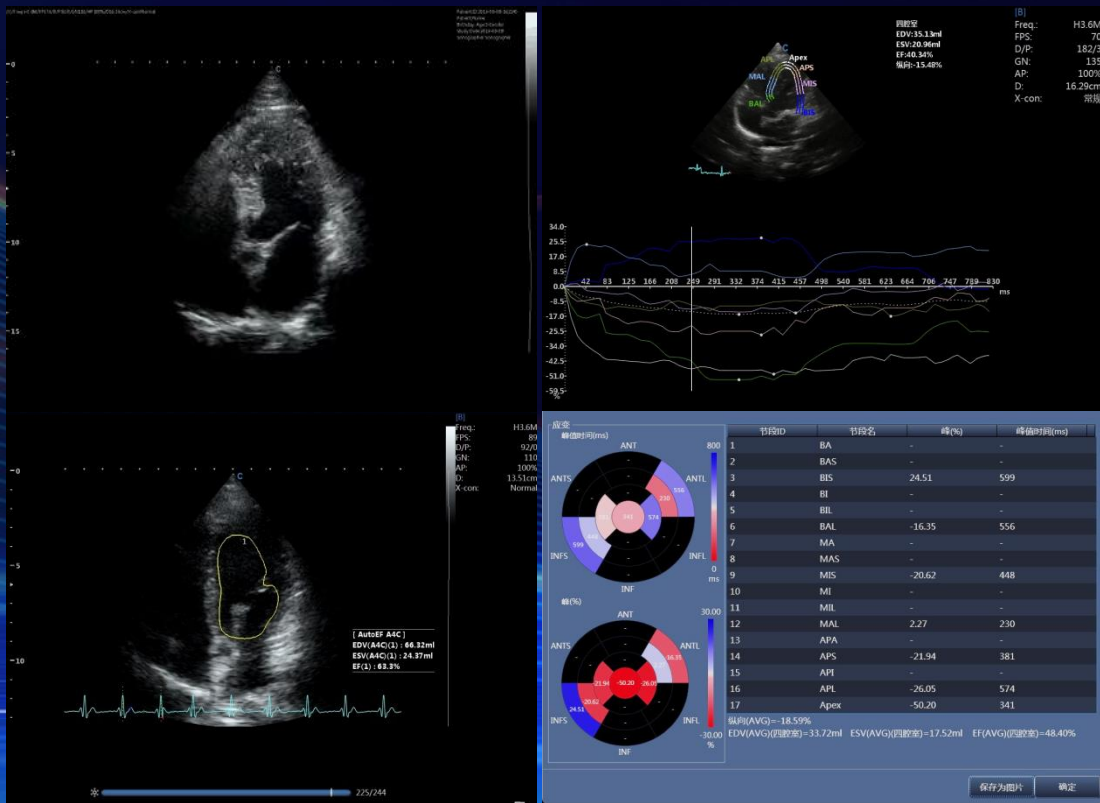
Cardiovascular



OB/GYN



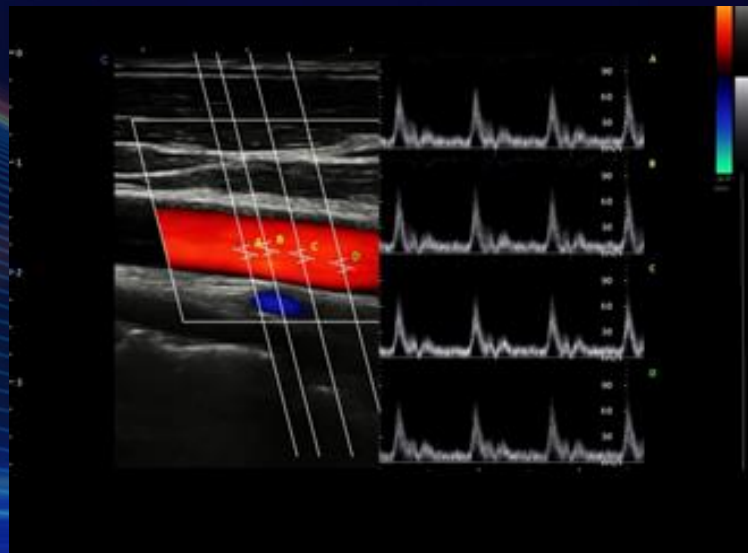
CHISON



Auto EF

Strain and Strain Ratio

- ◆ Multi planes (A4C/A2C/PS/AX)
- ◆ Auto - envelope in real time
- ◆ Reditable for Multi Point



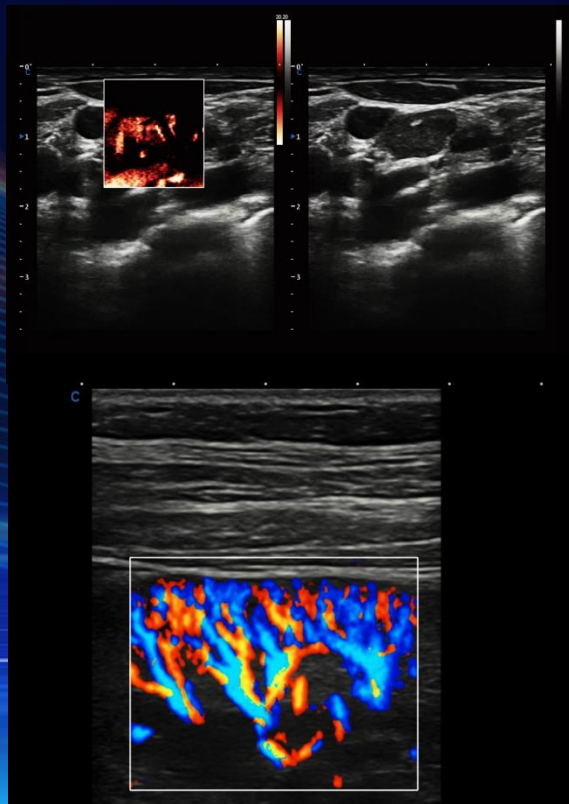
SonoPW

- ◆ Up to 4 sample gate
- ◆ Parameter independent control

Support synchronous display of spectrum and speed value.



CHISON

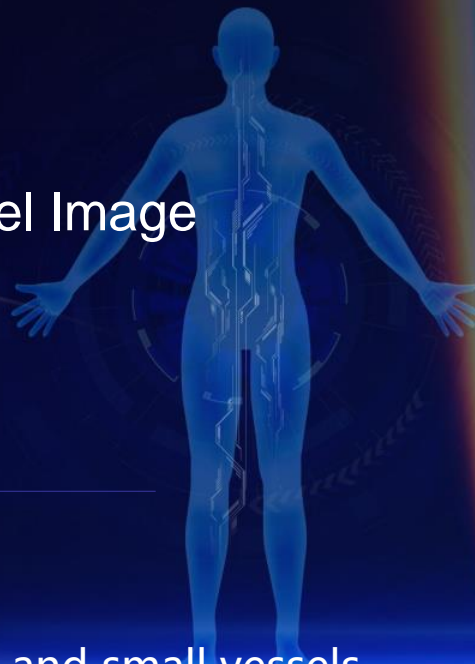


MVI - Micro Vessel Image

New brand

New algorithm

- ◆ High sensitivity
- ◆ Easy to show low and small vessels
- ◆ Provide more and accurate blood flow information.

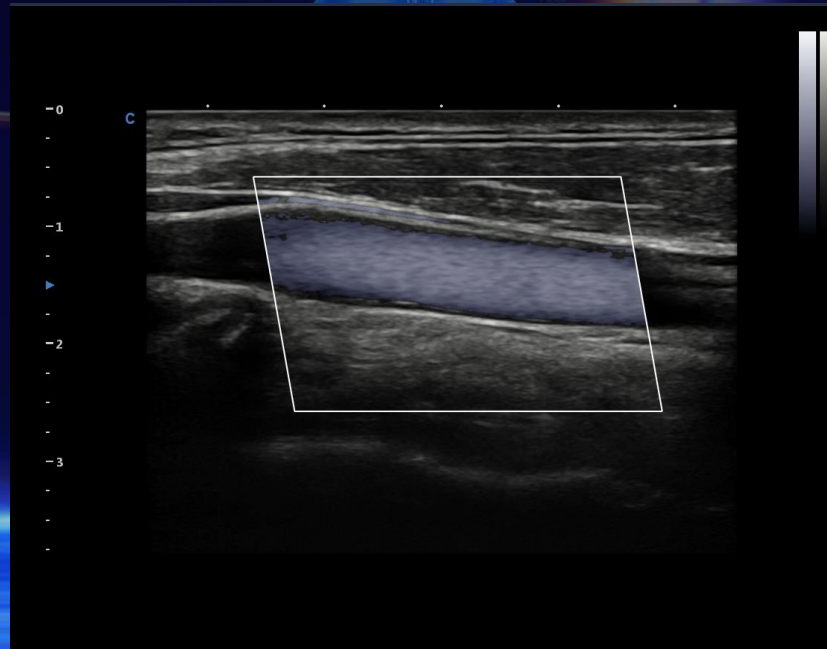


Sound Flow

Innovation Technology

Latest Algorithm

- ◆ High sensitivity
- ◆ Easy to show low and small vessels



CHISON

Diversified Clinical Application



Radiology



Cardiovascular

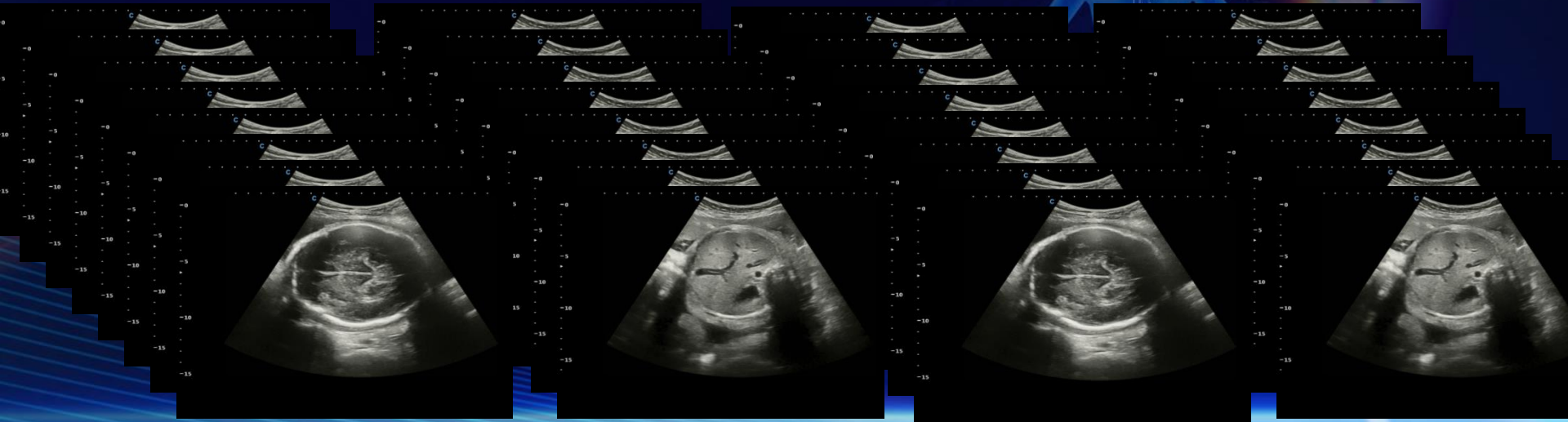


OB/GYN



CHISON

Sono-OB



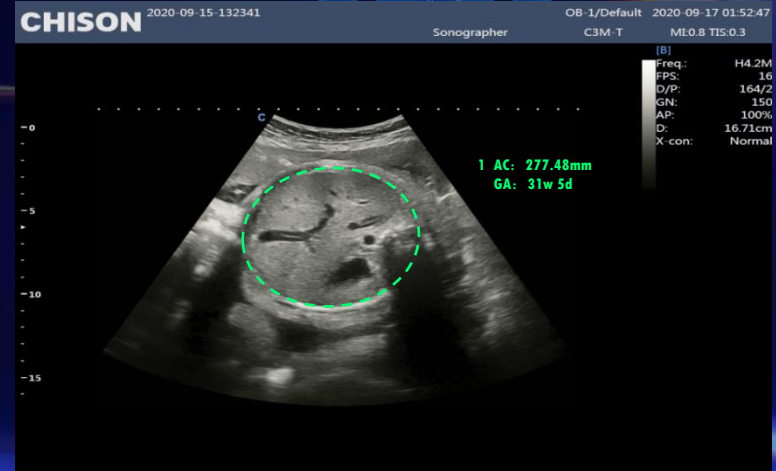
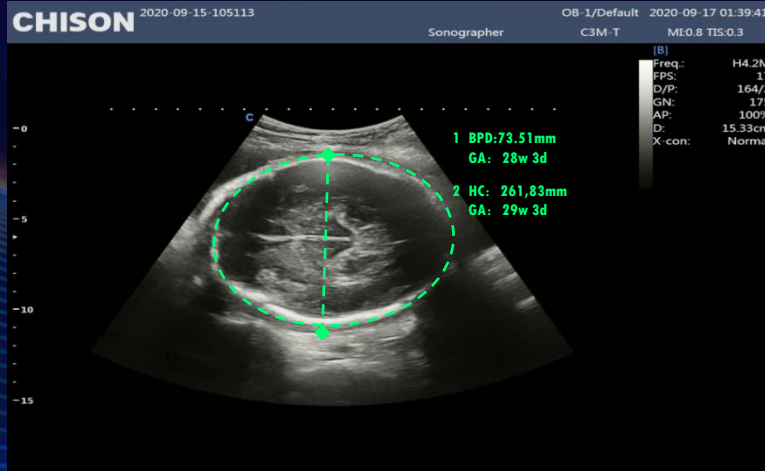
Massive data

Learnig to
extract feature

Recognizes image

CHISON

Sono-OB



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

CHISON

4D- Auto Face

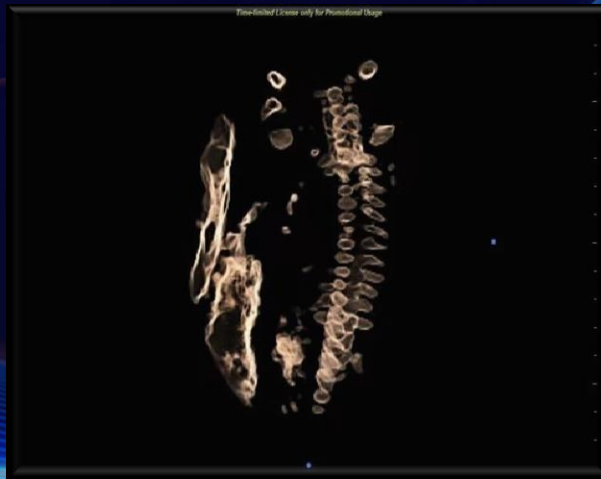


Automatically Recognize

Automatically Remove

Fast to get fetal face

4D- SonoCrystal

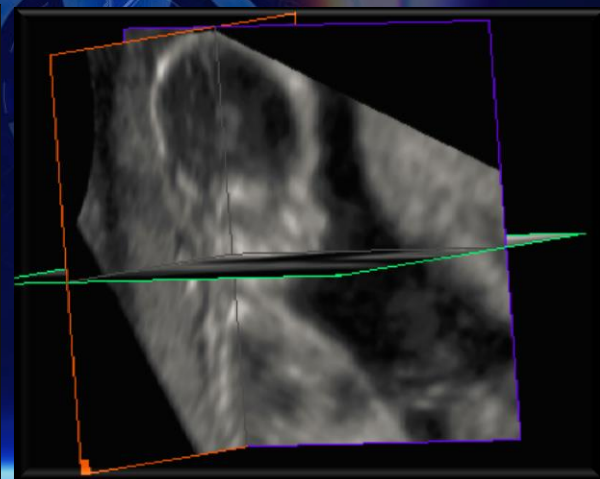


Provide context and surface

Display the internal organs

Easily to differentiates

4D- HD Nitch



Show the context and surface

Display the internal organs

Easily to differentiates

CHISON

Ultra Remote



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

CHISON

UltraRemote

Remote Demo



Remote Diagnos



Remote Service



Remote Training



Remote Contral

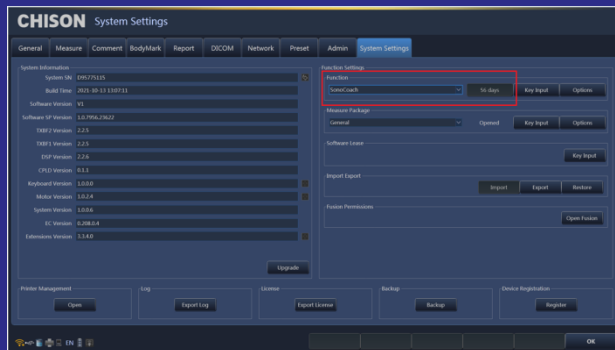


CHISON

SonoTrial

Everything is Ready for You.

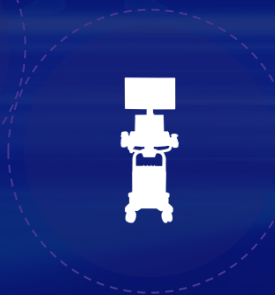
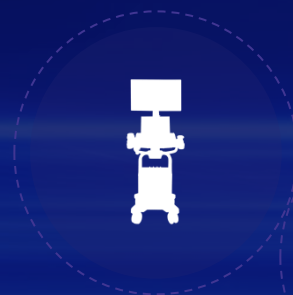
HERE
FOR YOU



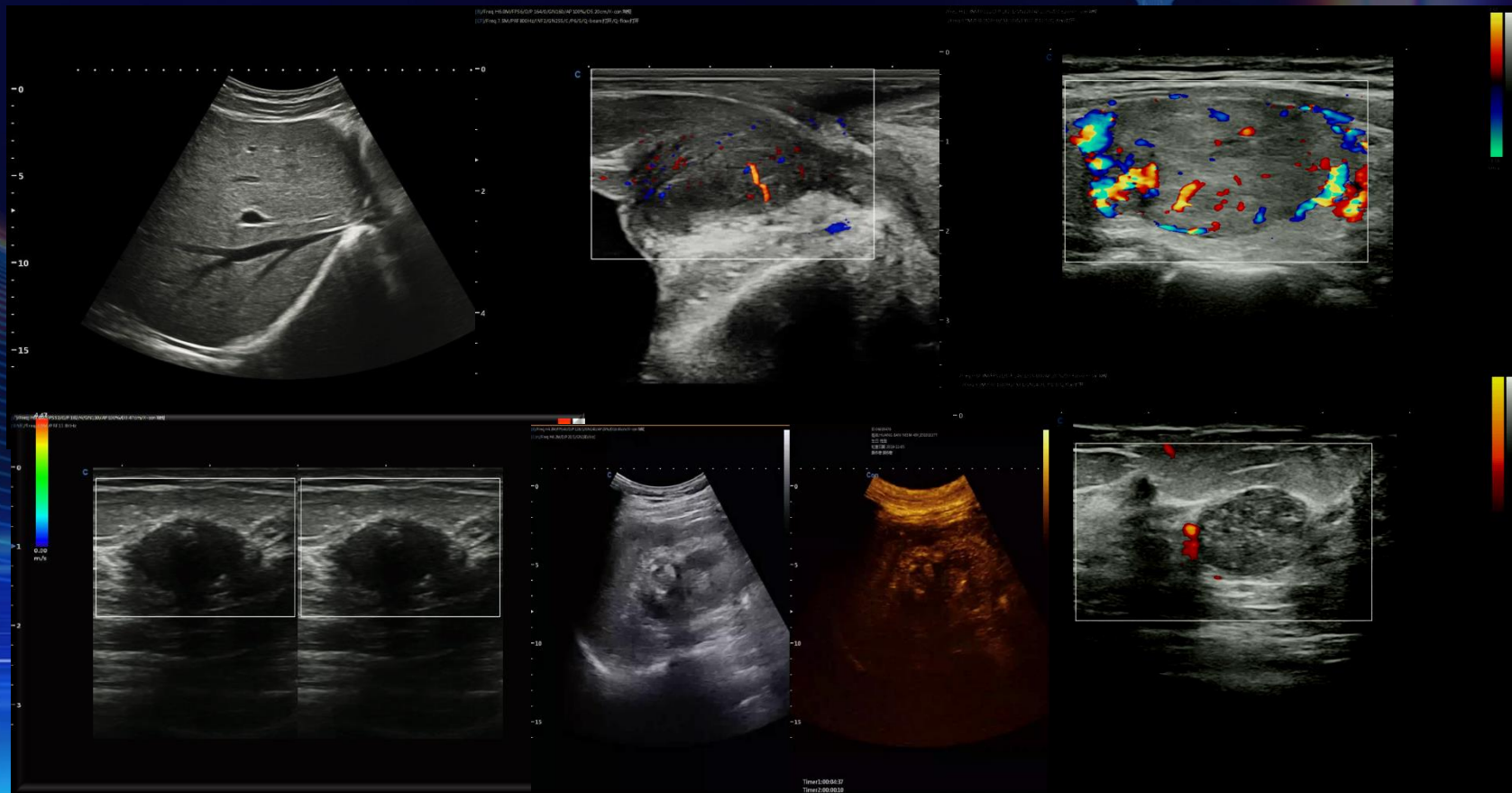
One Key to Trial

- > System Settings
- > Function Settings

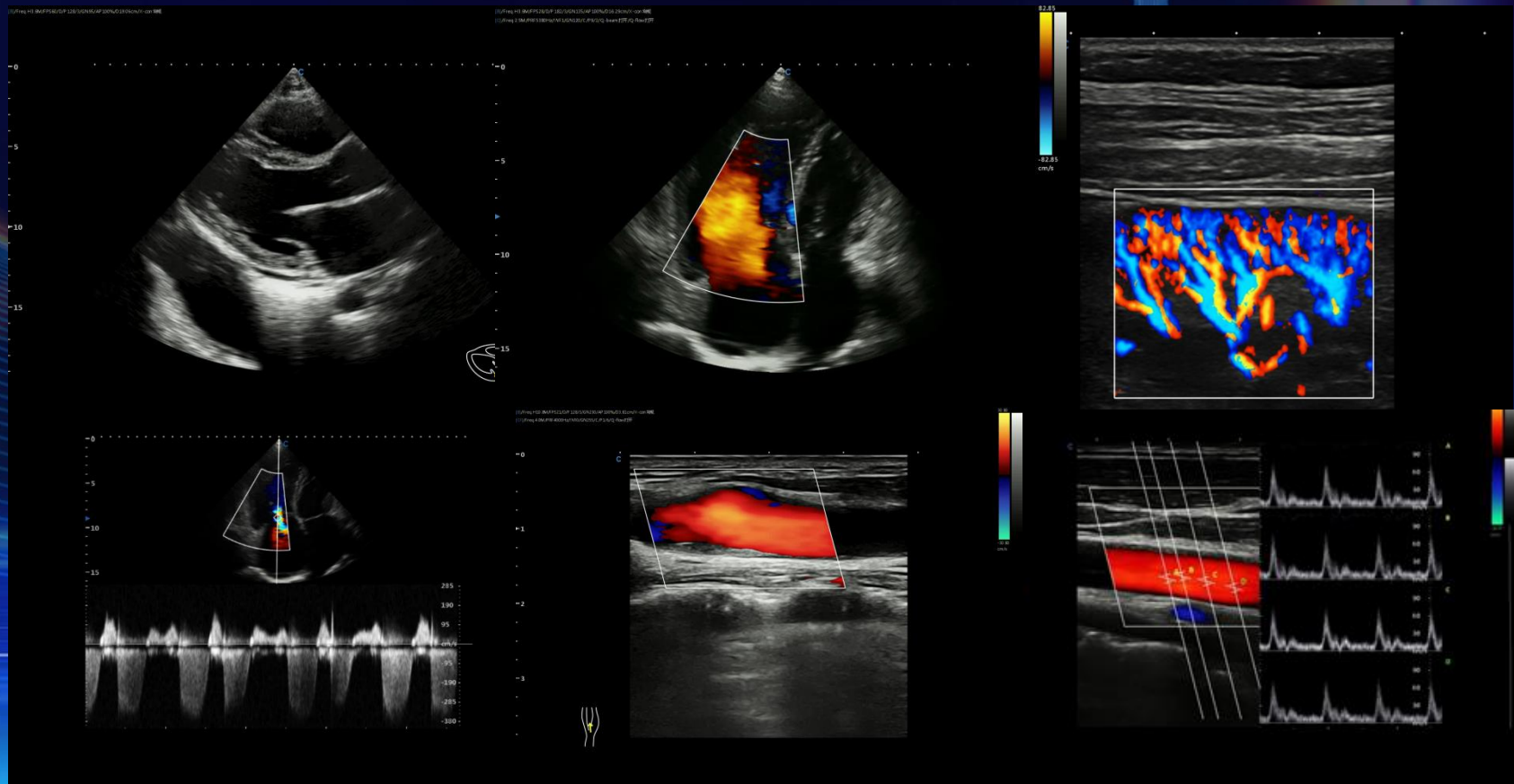
- Powered Performance
- Diversified Clinical Application
- Versatile Gallery



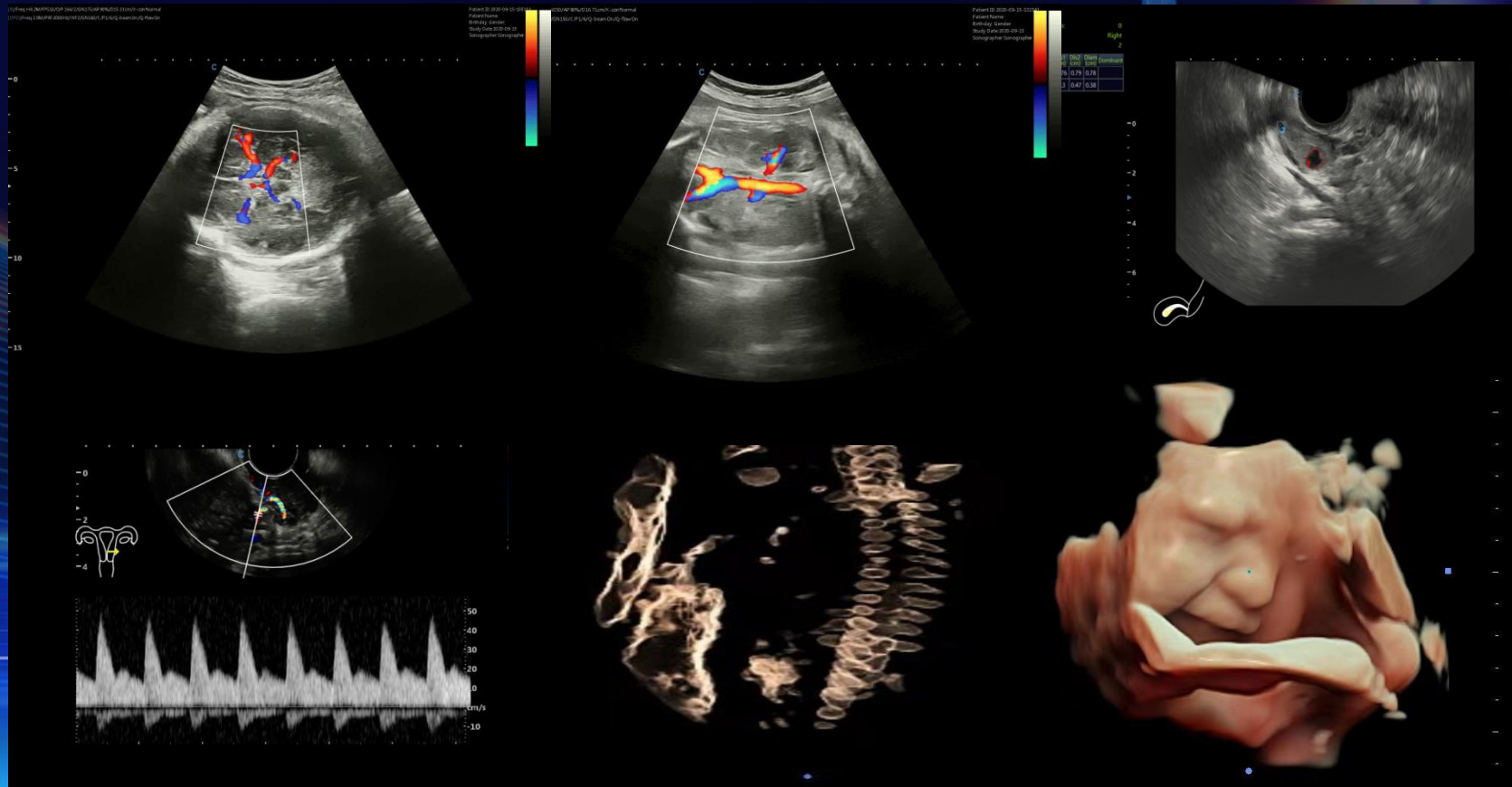
CHISON



CHISON



CHISON



CHISON



Unique Fetures

23.8 inch Monnitor
13.3 inch Touch Screen
NIT Platform
Hearo Kit
UltraRemote
SonoTrail

Radiology

Multi-Elastography
Contrast
SonoNeedle

Cardiovascular

SonoPW
Auto EF
Strain

OB&GYN

SonoOB
Advanced 4D
TV Angle up to 210



	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



	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

Thank You

