

*Anexa nr. 1*  
*La Procedurile administrative pentru notificarea*  
*dispozitivelor medicale care dețin marcajul CE*

Către Agenția Medicamentului  
și Dispozitivelor Medicale

**NOTIFICARE**

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

Solicitantul TRIUMF MOTIV SRL, cu sediul or. Chișinău str. Grenoble 193  
(adresa)  
\_\_\_\_\_, tel./fax: 022768462, e-mail triumf.motiv@mail.ru,  
solicit 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:

Ultrasonograf General model XBit 80, ;  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Se anexează următoarele acte:  
DECLAȚIE DE CONFORMITATE CE  
CERTIFICATUL DE CONFORMITATE CE  
Scrisoare de autorizare de la producător

Data 23.05.2023

Semnătura \_\_\_\_\_

**Tabelul de recepționare a notificării**

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

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. **352<sup>1</sup>**, 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

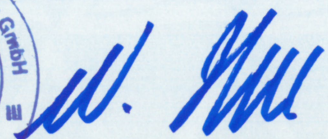
Scope: Design and Development, Manufacture and Distribution of Ultrasound Diagnostic Systems;  
And the capability of Design and Development, Manufacture and Distribution of Veterinary Ultrasound Diagnostic Systems



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

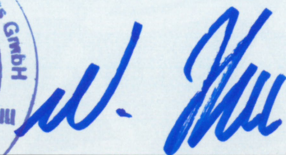
Registration No.: SX 2102189-1

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

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



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](mailto: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

Best regards,

  
Dipl.-Ing. W. Hsu  
Certification body

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](mailto:service@de.tuv.com)  
[www.tuv.com/safety](http://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

**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**

**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**

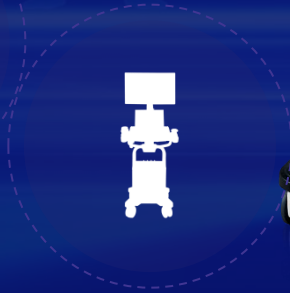
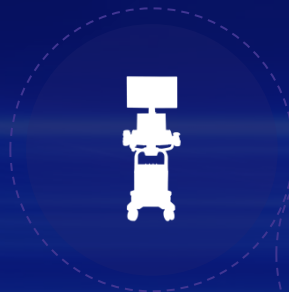


# CHISON

 Powered Performance

 Diversified Clinical Application

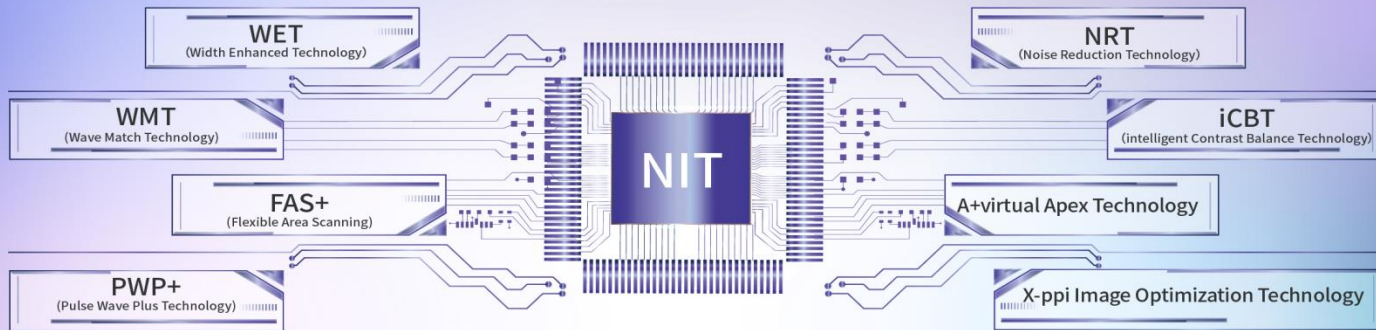
 Versatile Gallery



# CHISON

## Powered Platform by NIT

### New Image Technology



**1+**  
Probe Precision



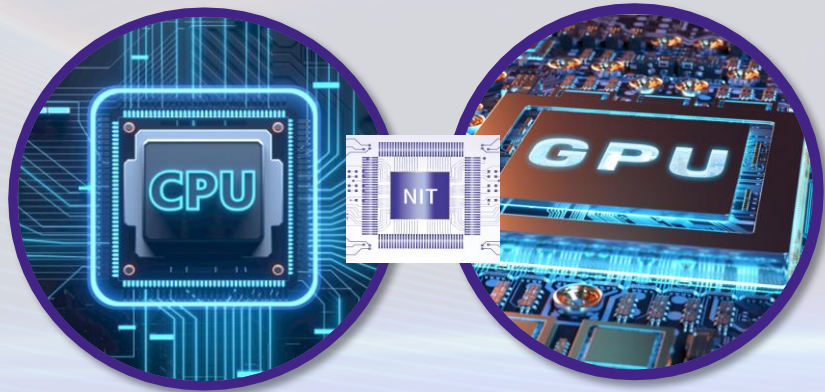
**3+**  
Signal Processing



**4+**  
Image Algorithm



## High Performance by Parallel Processing



CPU

GPU

Faster

Better

Powerful

# CHISON

## Diversified Clinical Application



Radiology



Cardiovascular



OB/GYN



# CHISON

## Muti - Elastography

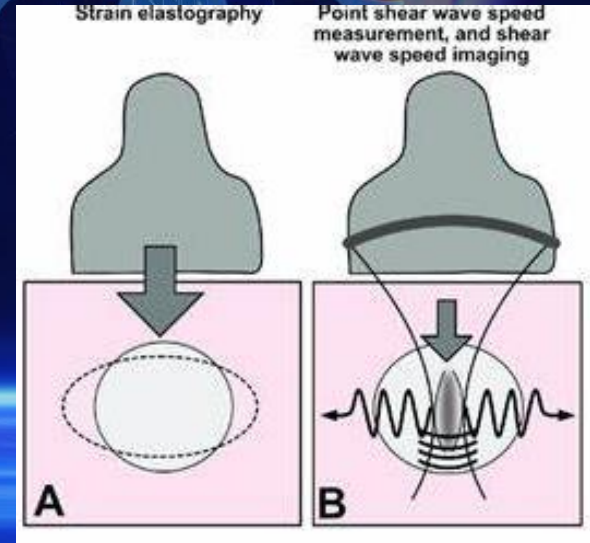
### ◆ Strain Elastography

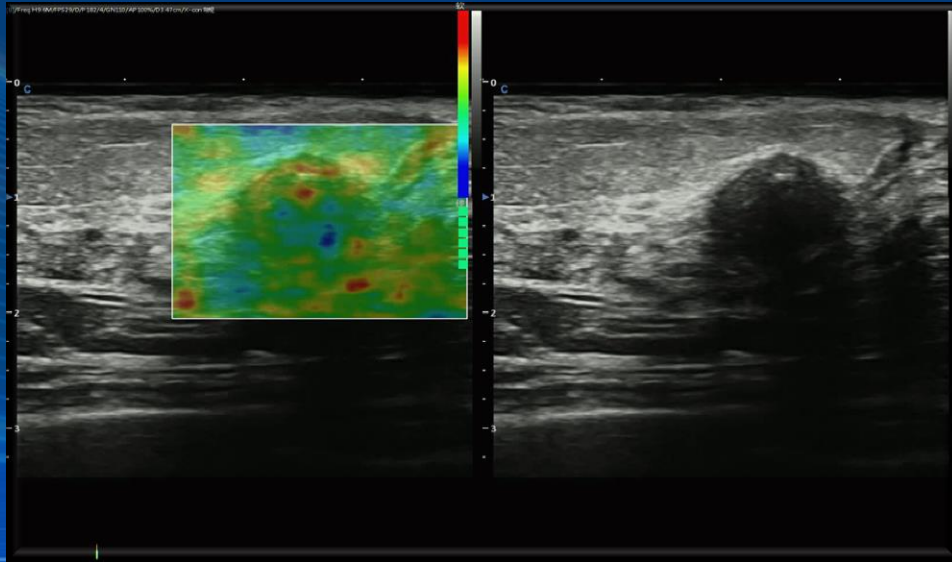
Produced by breath and vessel impulse.

### ◆ pSWE and 2D SWE

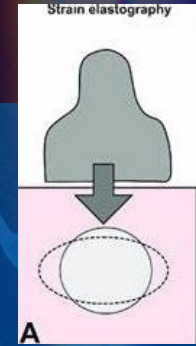
Generated by ultrasound transverse propagation

- High Reliability
- High Repeatability





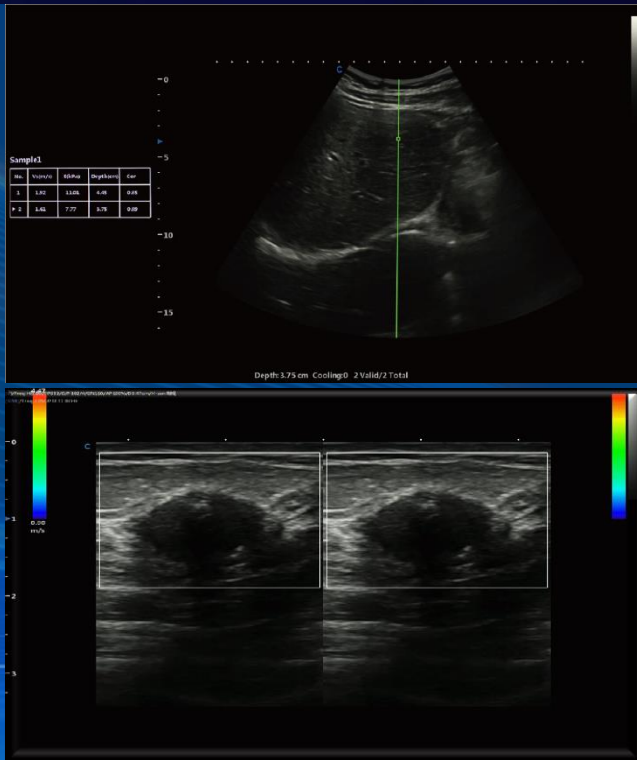
## Strain Elastography



- ◆ 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



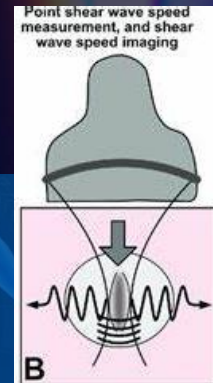


## Shear Wave Elastography

- ◆ 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



# CHISON

## 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

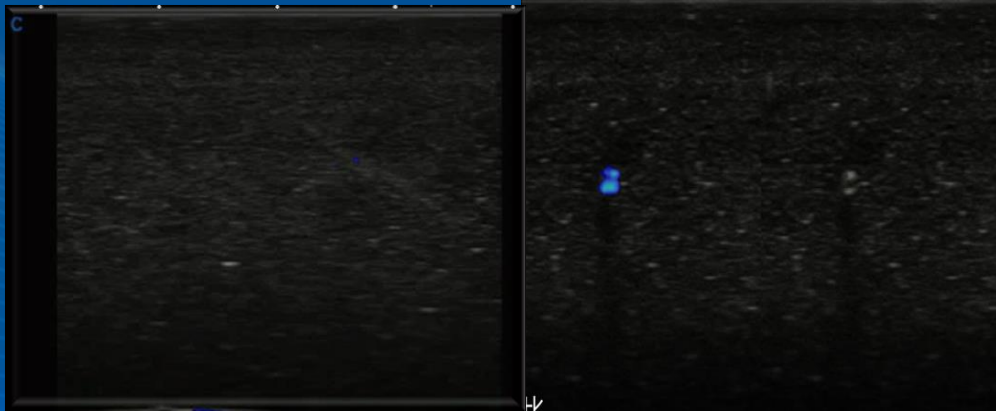
Low resolution

## 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



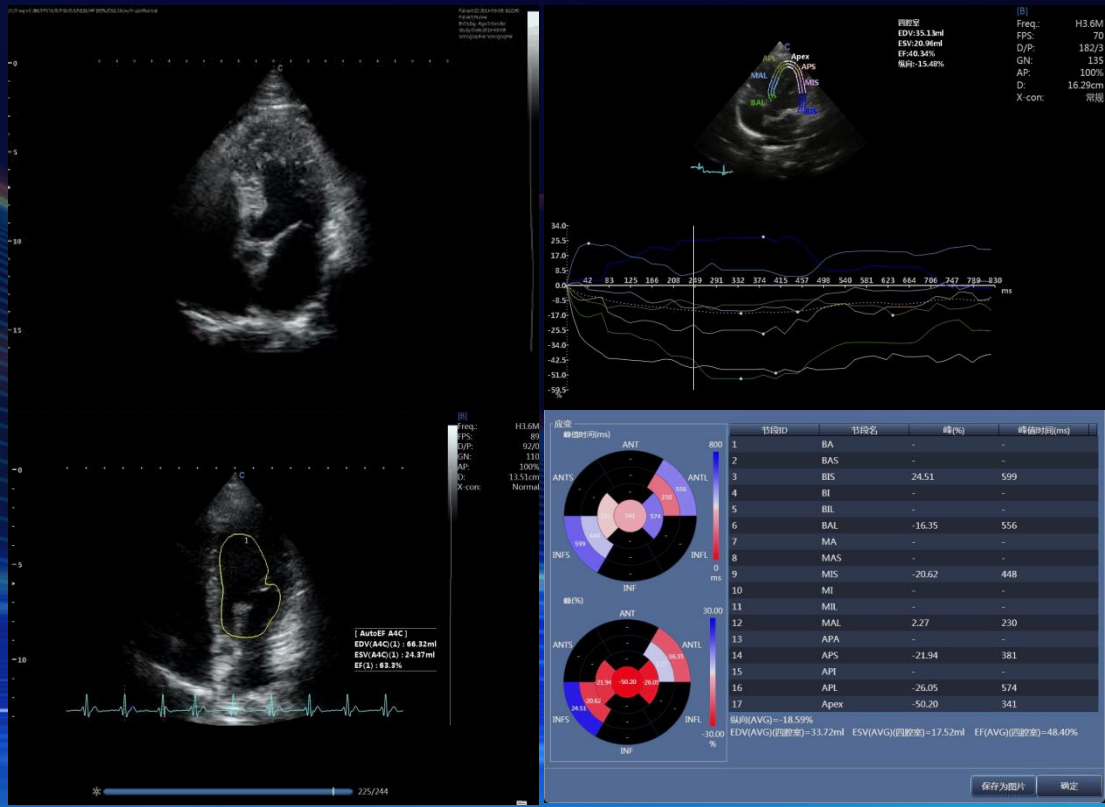
Cardiovascular



OB/GYN



# CHISON

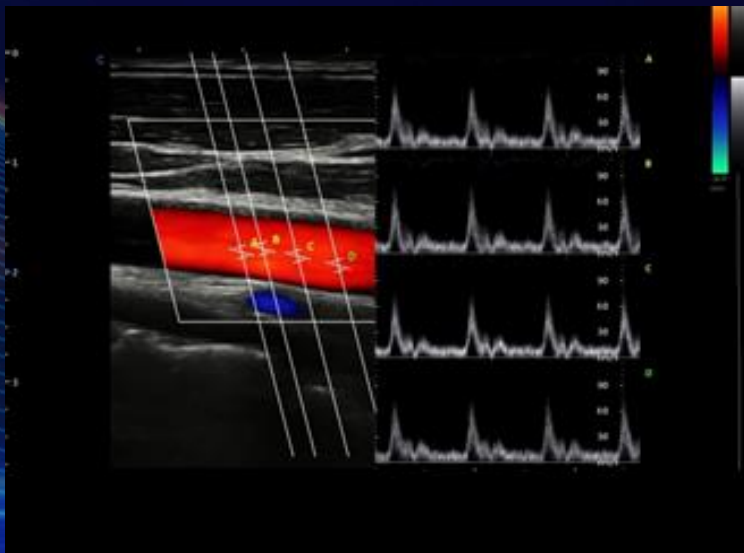


## Auto EF

## Strain and Strain Ratio

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

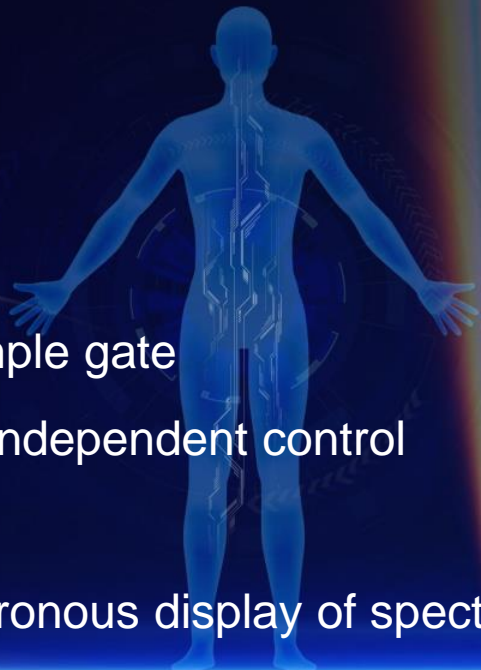
# CHISON



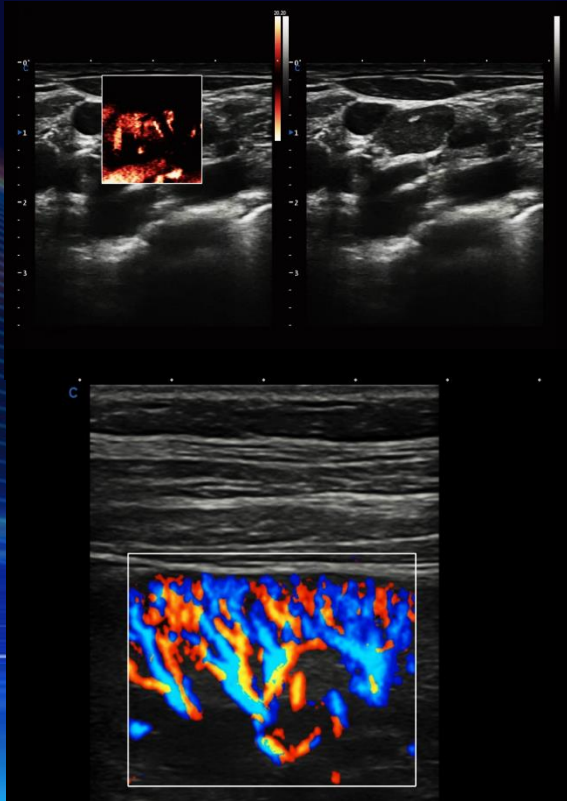
## SonoPW

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

Support synchronous display of spectrum and speed value.



# CHISON

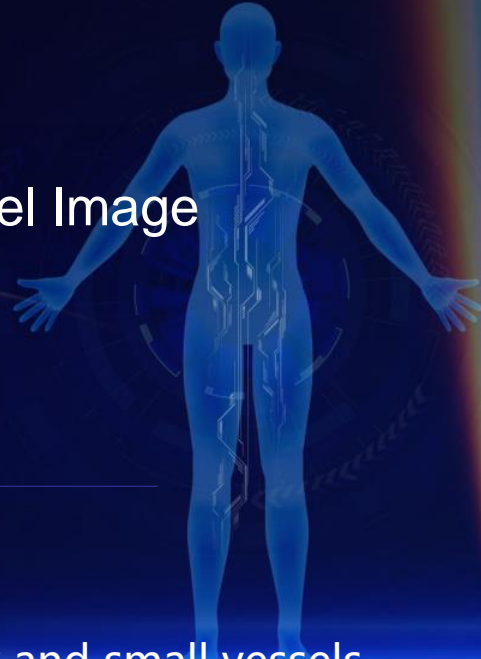


MVI - Micro Vessel Image

New brand

New algorithm

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





# CHISON

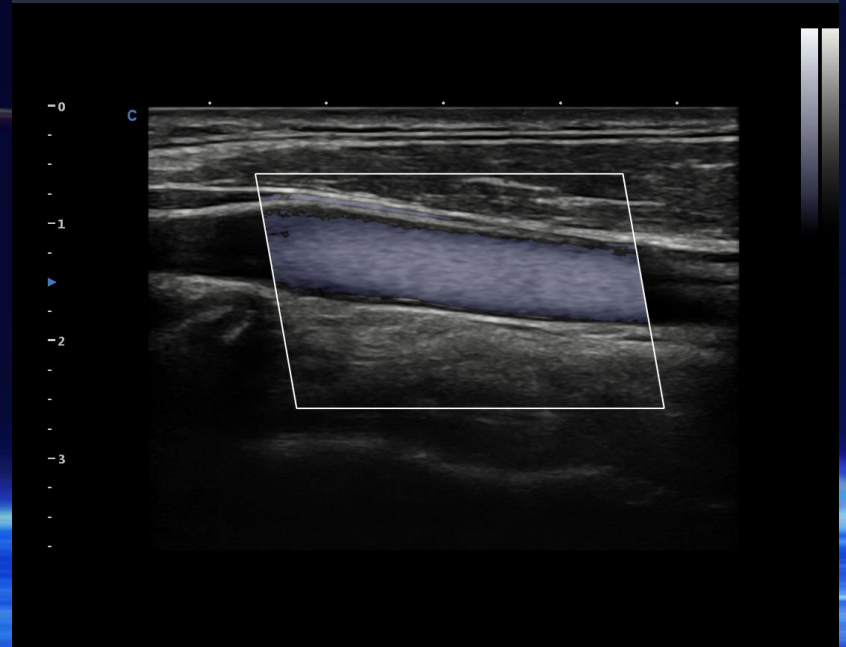
Sound Flow

Innovation Technology

Latest Algorithm

---

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



# CHISON

## Diversified Clinical Application



Radiology



Cardiovascular

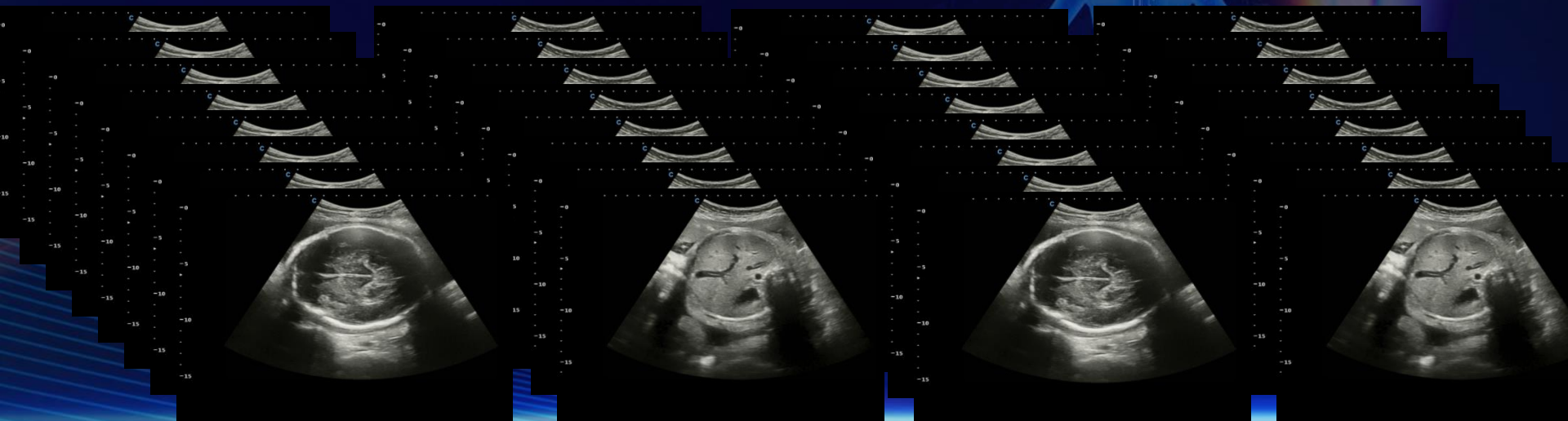


OB/GYN



# CHISON

## Sono-OB



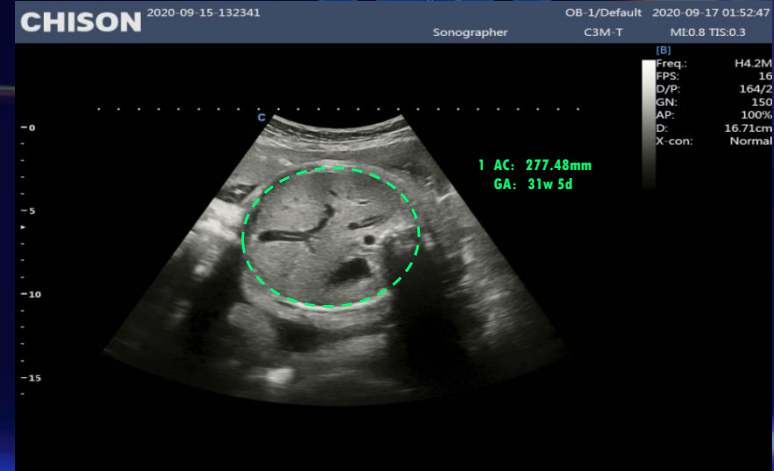
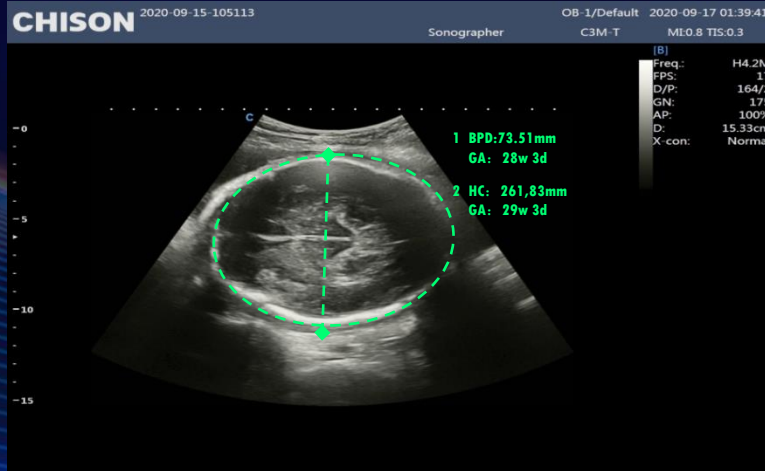
Massive data

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

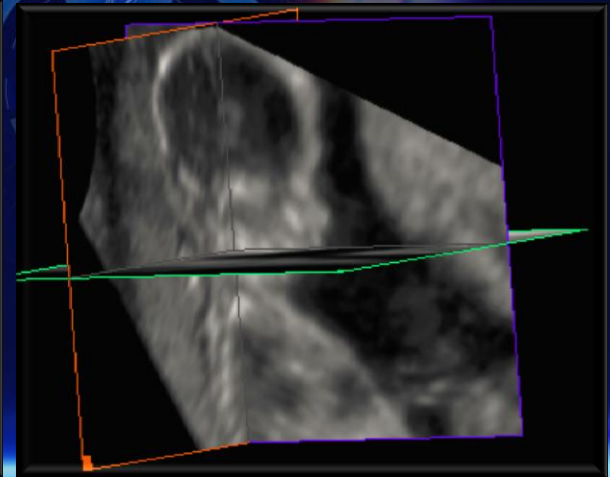


Provide context and surface

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

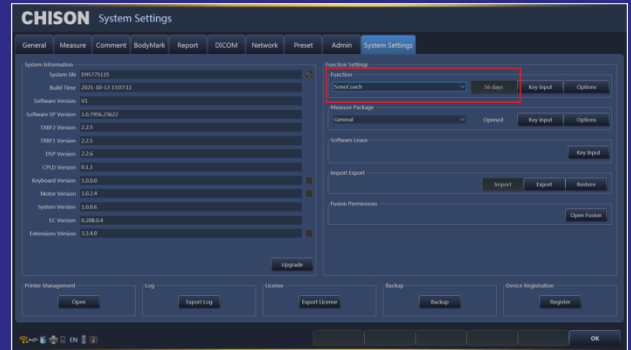


# CHISON

## SonoTrial

Everything is Ready for You.

HERE  
FOR YOU



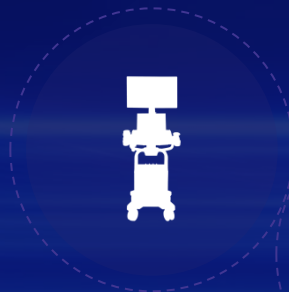
One Key to Trial

- > System Settings
- > Function Settings

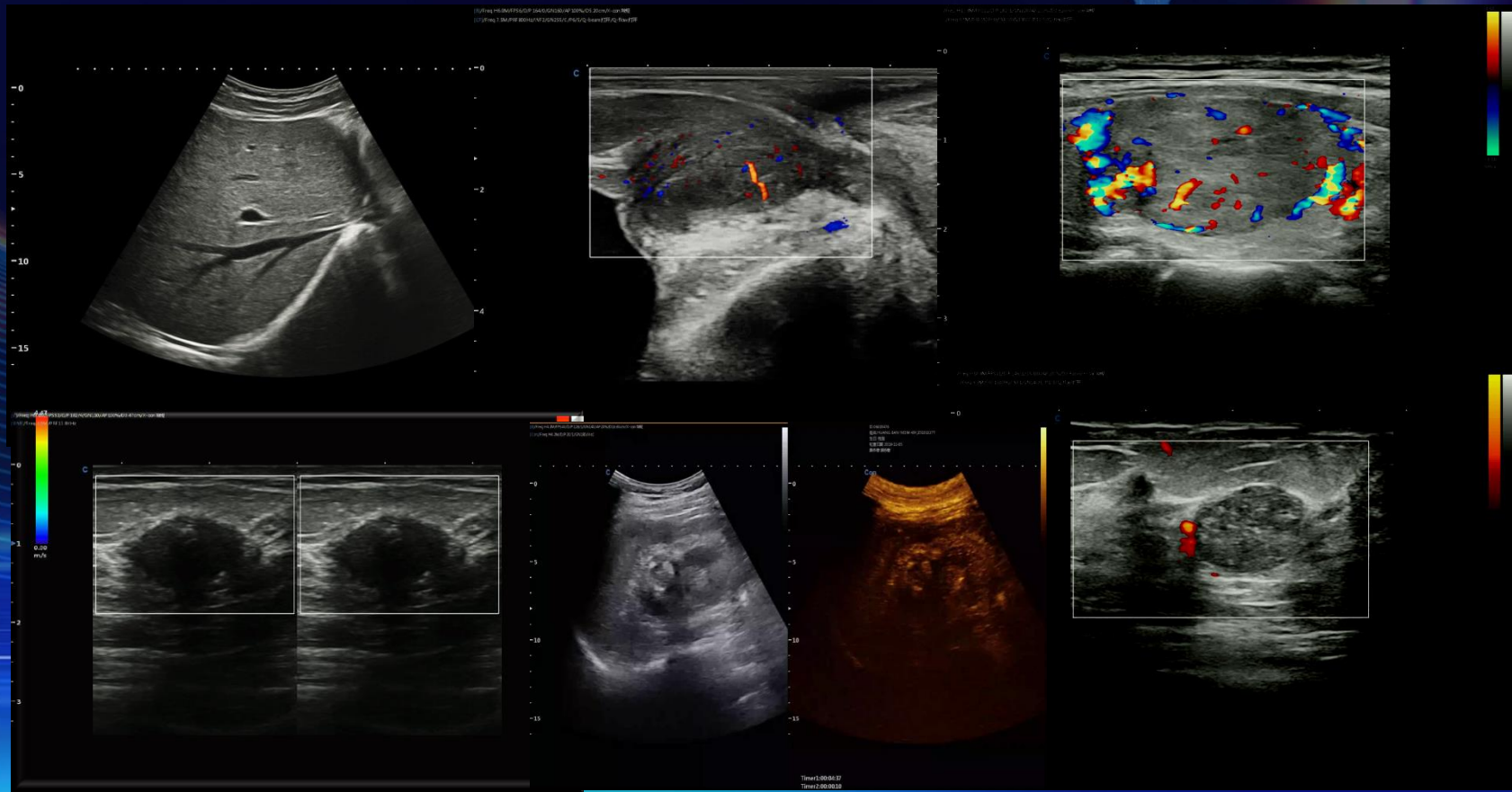


# CHISON

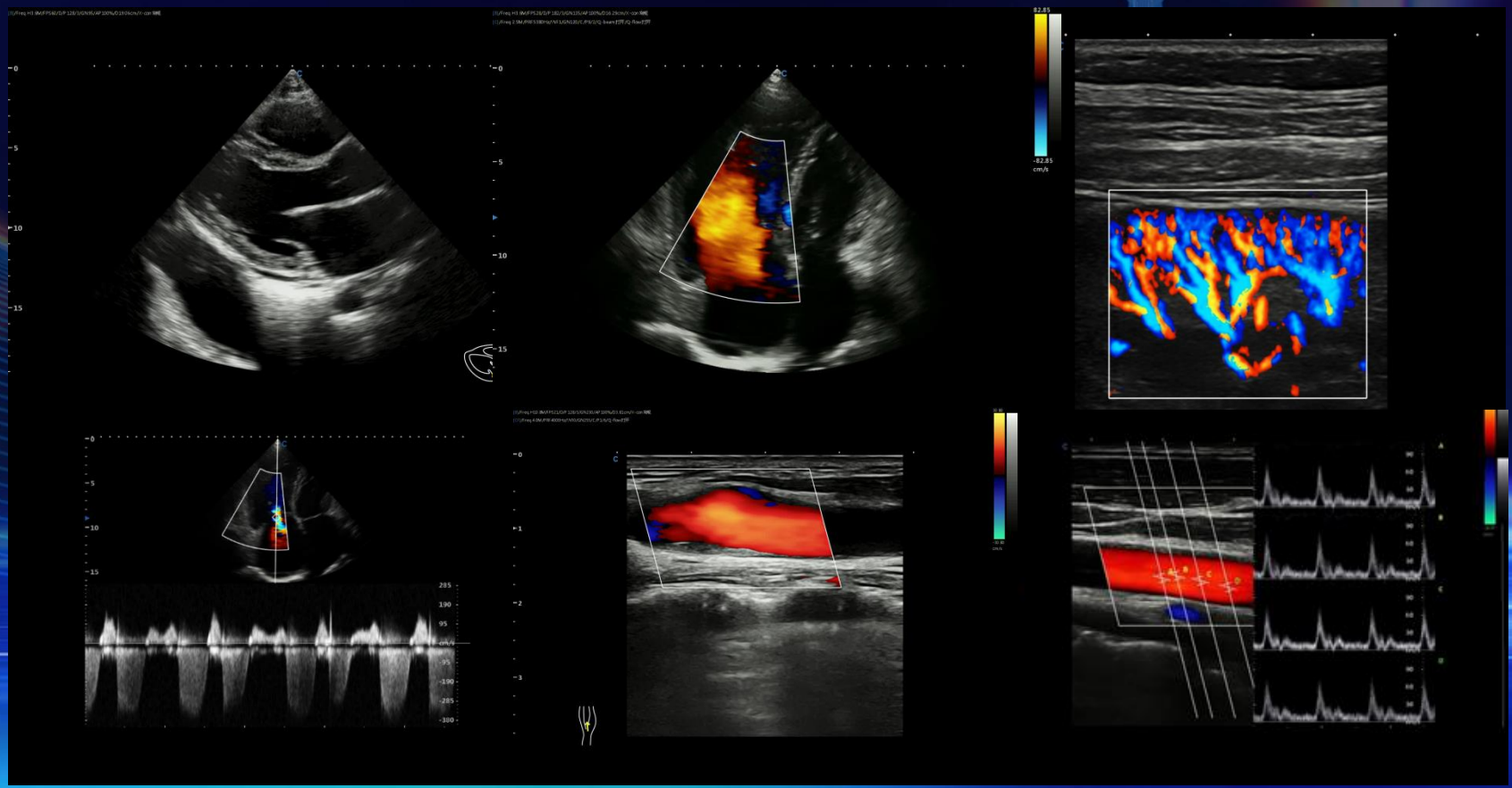
- Powered Performance
- Diversified Clinical Application
- Versatile Gallery



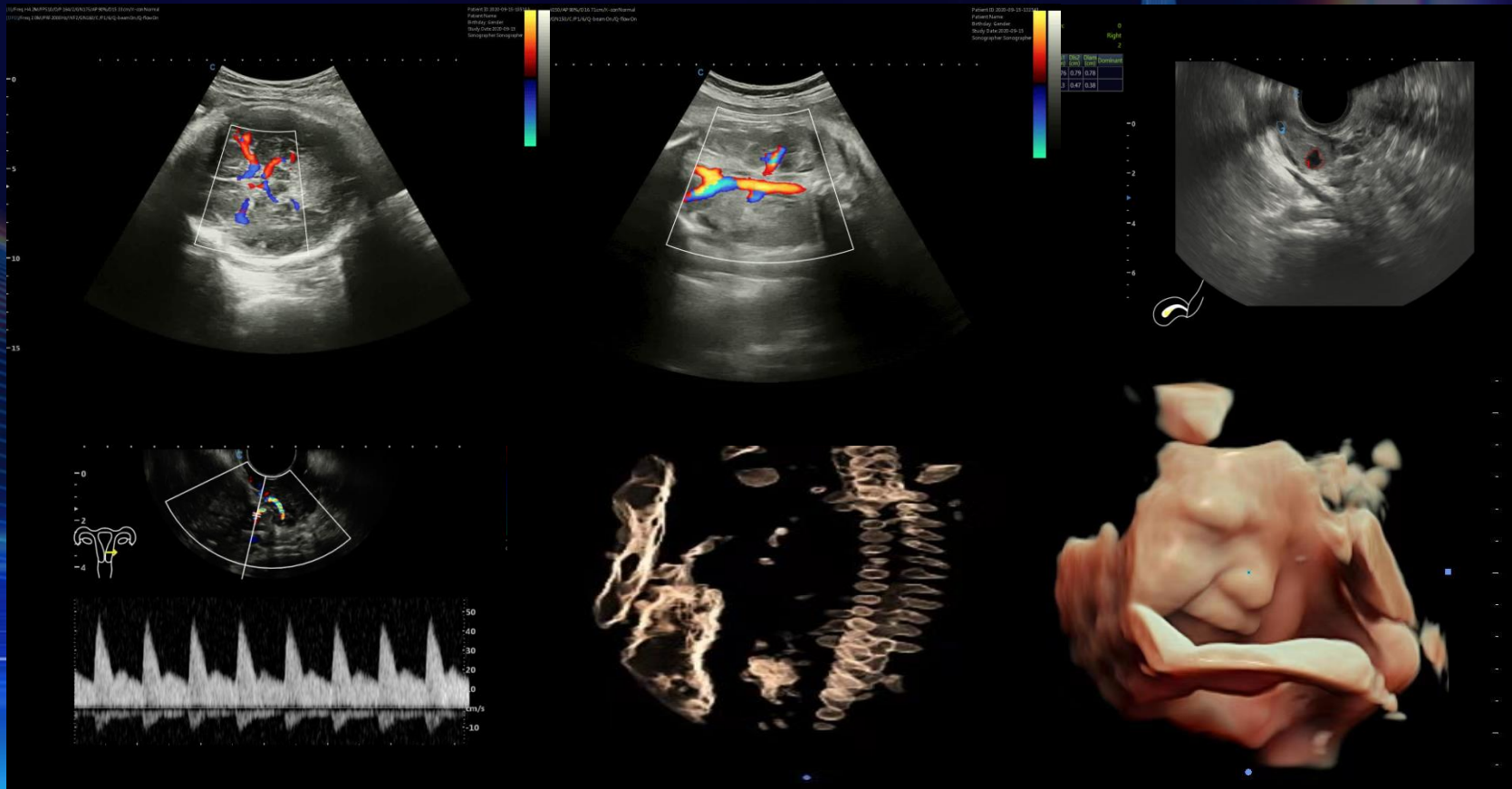
# CHISON



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



	XBit 80	XBit 90
<b>Elastography</b>	Yes, option	Yes, option
<b>Share Wave Elas</b>	Yes, option pSWE and 2D SWE	Yes, option pSWE and 2D SWE
<b>SonoContrast</b>	Yes, option <a href="#">Linear/Convex/TV</a>	Yes, option <a href="#">Linear/Convex/TV/Sector</a>
<b>SonoFusion</b>	<a href="#">No</a>	<a href="#">Yes, option</a>
<b>MVI</b>	Yes	Yes
<b>SoundFlow</b>	Yes	Yes
<b>NanoFlow</b>	<a href="#">No</a>	<a href="#">Yes, option</a>
<b>SonoPW</b>	Yes	Yes
<b>TDI+SonoPW</b>	<a href="#">No</a>	<a href="#">Yes, option</a>
<b>SonoBreast</b>	<a href="#">No</a>	<a href="#">Yes, option</a>

**CHISON**

**Thank You**





## 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.

Anexa nr. 1  
La Procedurile administrative pentru notificarea  
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului  
și Dispozitivelor Medicale

**NOTIFICARE**  
pentru înregistrarea dispozitivelor medicale în Registrul de stat  
al dispozitivelor medicale  
nr. TR-6 din 28.03.2023

Solicitantul TRIUMF MOTIV SRL, cu sediul or. Chișinău str. Grenoble 193  
(adresa)

tel./fax: 022768462, e-mail triumf.motiv@mail.ru,  
solicitează 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:

Ultrasound Diagnostic Systems	Xbit 20
Ultrasound Diagnostic Systems	XBit30
Ultrasound Diagnostic Systems	Xbit 40
Ultrasound Diagnostic Systems	Xbit 50
Ultrasound Diagnostic Systems	Xbit 60
Ultrasound Diagnostic Systems	Xbit 70
Ultrasound Diagnostic Systems	Xbit 80
Ultrasound Diagnostic Systems	Xbit 90

Se anexează următoarele acte:

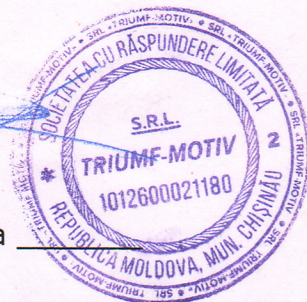
DECLARAȚIE DE CONFORMITATE CE

CERTIFICATUL DE CONFORMITATE CE

Scrisoare de autorizare de la producător

Data 28.03.2023

Semnătura



Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	Accept
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	Nr. 6641 din 24.05.2023
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	Glavatechi Doinița
Semnătura persoanei responsabile	CDJ

**Tablelul de recepționare a notificării**

(se completează de către Agenție în momentul depunerii notificării de către  
solicitant)

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. **352<sup>1</sup>**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Ultrasound Diagnostic Systems	Xbit 20
Ultrasound Diagnostic Systems	XBit30
Ultrasound Diagnostic Systems	Xbit 40
Ultrasound Diagnostic Systems	Xbit 50
Ultrasound Diagnostic Systems	Xbit 60
Ultrasound Diagnostic Systems	Xbit 70
Ultrasound Diagnostic Systems	Xbit 80
Ultrasound Diagnostic Systems	Xbit 90

**Sunt autentice și corespund realității.**

*Numele, prenumele și funcția* Jighili Tatiana, Administrator

*Semnătura* \_\_\_\_\_

*Data* 28.03.2023