

System Overview

General description

FreeSono Flex is a battery-operated general-purpose diagnostic ultrasound imaging system for use by qualified and trained healthcare professionals enabling visualization and measurement of anatomical structures and fluid. It can also be useful for procedural guidance.

FreeSono Flex consists of a comprehensive range of probes which integrates curved, linear, sector array transducers, and an app which can be installed on Android or iOS mobile devices.

Its pocket-sized portability and simplified user interface enable integration into examination and training sessions indoors and in other environments.

Principles of operation

Medical ultrasound images are created by computer and digital memory from the transmission and reception of mechanical high-frequency waves applied through a probe. The mechanical ultrasound waves spread through the body, producing an echo where density changes occur. The echoes return to the probe where they are converted back into electrical signals.

These echo signals are amplified and processed by several analog and digital circuits having filters with many frequency and time response options, transforming the high-frequency electrical signals into a series of digital image signals which are stored in memory. Once in memory, the image can be displayed in real-time on the display device. A probe is an accurate, solid-state device, providing multiple image formats. The digital design and use of solid-state components provides highly stable and consistent imaging performance with minimal required maintenance.

Intended use

The FreeSono Flex 9 Handheld Diagnostic Ultrasound System is intended for the real-time visualization and qualitative assessment of internal body structures and fluids for diagnostic and procedural guidance purposes.

Indications for use

The device shall be capable of supporting, but not limited to, the following clinical applications:

Focused Assessment with Sonography for Trauma (FAST)

eFAST (Extended FAST)

Rapid Cardiac Assessment (e.g., pericardial effusion, gross contractility)

Vascular Access (PIV, Central Line, Arterial Line guidance)

Pulmonary Assessment (Pneumonia, Pulmonary Edema, Pneumothorax)

Abdominal & Renal Assessment (AAA, hydronephrosis, gallbladder)

Obstetric Quick Checks (fetal presentation, heartbeat confirmation)

Musculoskeletal (joint effusions, soft tissue masses)

Superficial (Dermatology, Aesthetics, Plastic Surgery, Podiatry, Rheumatology)

Gynecology (routine, IVF)

Urology (Prostate, Bladder)

Small parts (Thyroid, testicle)

Breast

Description of all configurations/variants of the product

The FreeSono Flex Handheld Diagnostic Ultrasound System includes multiple models. All of them share the same hardware and software platform. The only difference is the choice of transducer heads where FreeSono Flex 9 equipped with the entire range of transducers. The details are described in the following table:

FreeSono Flex Handheld Diagnostic Ultrasound Quick User Guide REV1.0

Model	Is the transducer replaceable	Probe heads
FreeSono Flex 9	Yes	C3 L7 L15 L20 E6 P3
FreeSono Flex 8	Yes	C3 L7 L15 L20 P3
FreeSono Flex7	No	E6
FreeSono Flex6	No	L20
FreeSono Flex5	No	L15
FreeSono Flex4	No	L7
FreeSono Flex3	No	C3

Quick user guide

1. Unpacking

When you receive our pocket ultrasound, first is to unpack the carton box and check the system and accessories.

1 开箱

收到掌超第一步骤是开箱并检查下图的附件



2 Connect the transducer head to ultrasound main unit

Second is to take the transducer head you want to use and connect to the ultrasound main unit. At first you have to remove the transducer socket protective clamp and save into the small clamp holder inside the carrying case inlay. Pay attention the endocavity(transvaginal) transducer head has to use a clamp to connect with the ultrasound main unit, you may take the clamp off when changing to a different transducer head

2 连接可拆卸的声头到超声主机（磁吸插头）注意保存声头插头保护卡箍至保护性手提箱内衬内的卡槽，防止丢失。



3 Charging the system

Third is to charge the pocket ultrasound before using it. During the charging, you will see the LED light keep flickering. When it's fully charged, all LED lights are full bright and no flickering. If you are charging the system through a wireless charger pad, make sure you place the system charging spot on the center of the wireless charger pad

3. 充电

第三步是给掌超充电，充电过程中，你会看到电池电量指示灯不停的闪烁，当充满后，指示灯会恒亮，如果是使用无线充电板充电，需要确保探头充电位置处于无线充电板充电位置的中央



Alternatively the FreeSono Flex ultrasound system also supports the flexibility to swap the battery and the battery also can be charged separately. 该掌超系统支持换电选项，电池也可单独充电



4 Download FreeSono App and install on your smart device

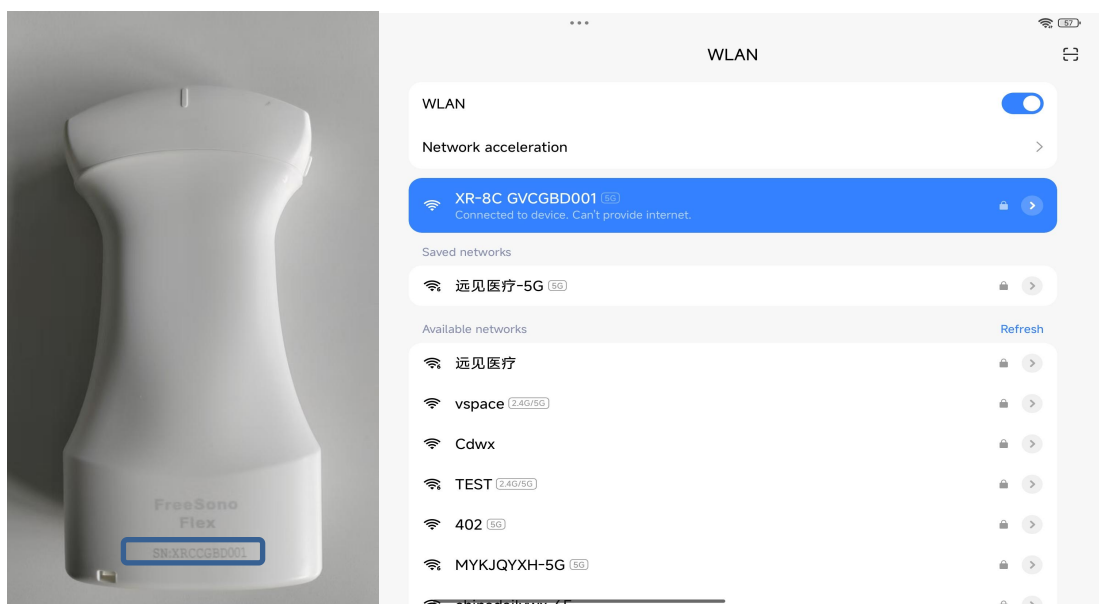
(本次外部测试平板已预装好FreeSono应用软件， 管理员初始登录密码vue123)
(本次外部测试平板登录密码170110)

5 Power on, make WIFI connection, config screen direction and system setting

Power on the system with a short press on the round central button (BLUE battery LED indication light on) A short press of the round central button during the scanning will freeze/unfreeze the system. Long press (5 seconds) will shut down the system



Once the system is on, you can find the system on the WIFI list in your smart device. Last 7 digits of the SN printed on the back of the system in BIG Letter matches the last 7 digits of the WIFI NAME, full SN in SMALL Letter is the PASSWORD of the WIFI



Click system setting (gear shape icon at top right corner) and config screen direction (Default is horizontal direction) enable vertical will be vertical display

5 电源开关，无线连接，设置屏幕方向跟其他系统设置

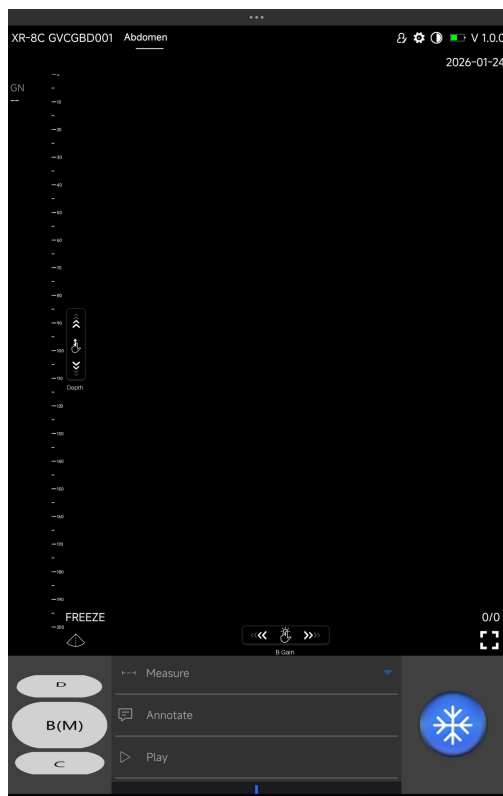
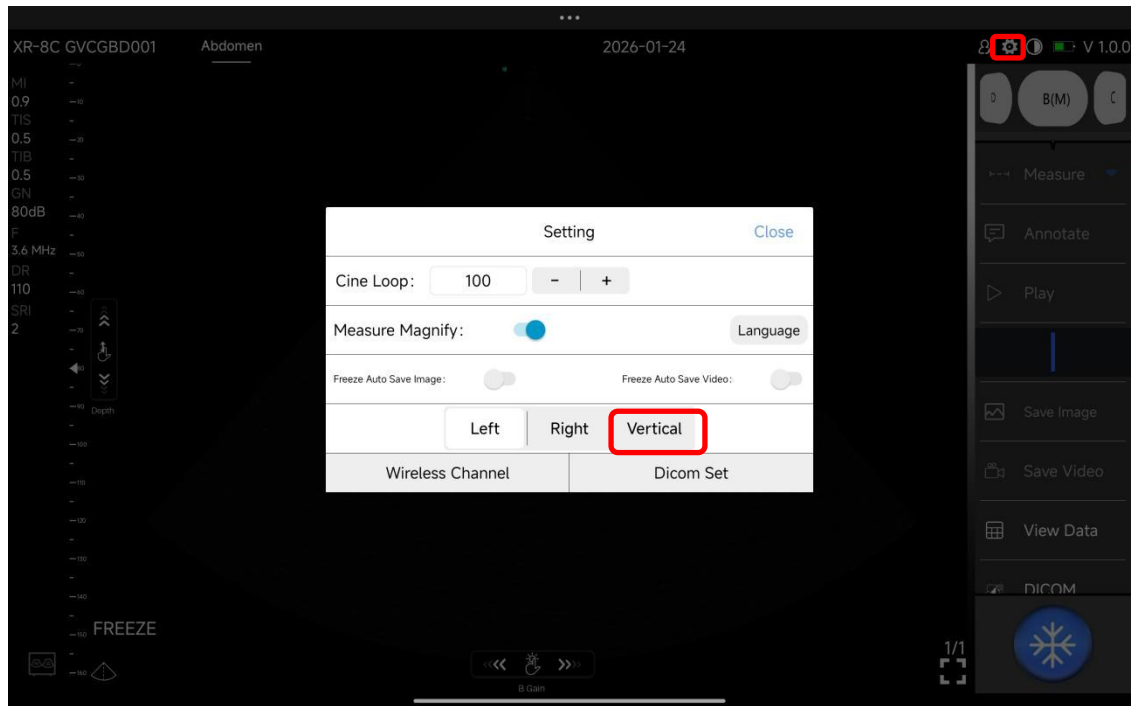
短按按钮开机，蓝灯亮。工作时短按一下电源开关，就可以冻结或者解冻机器；继续长按开发5秒就会关闭主机

FreeSono Flex Handheld Diagnostic Ultrasound Quick User Guide REV1.0

探头开启后就可以在智能设备的无线设置列表里找到探头无线热点（名字尾椎7位同探头背面流水号串码后7位）

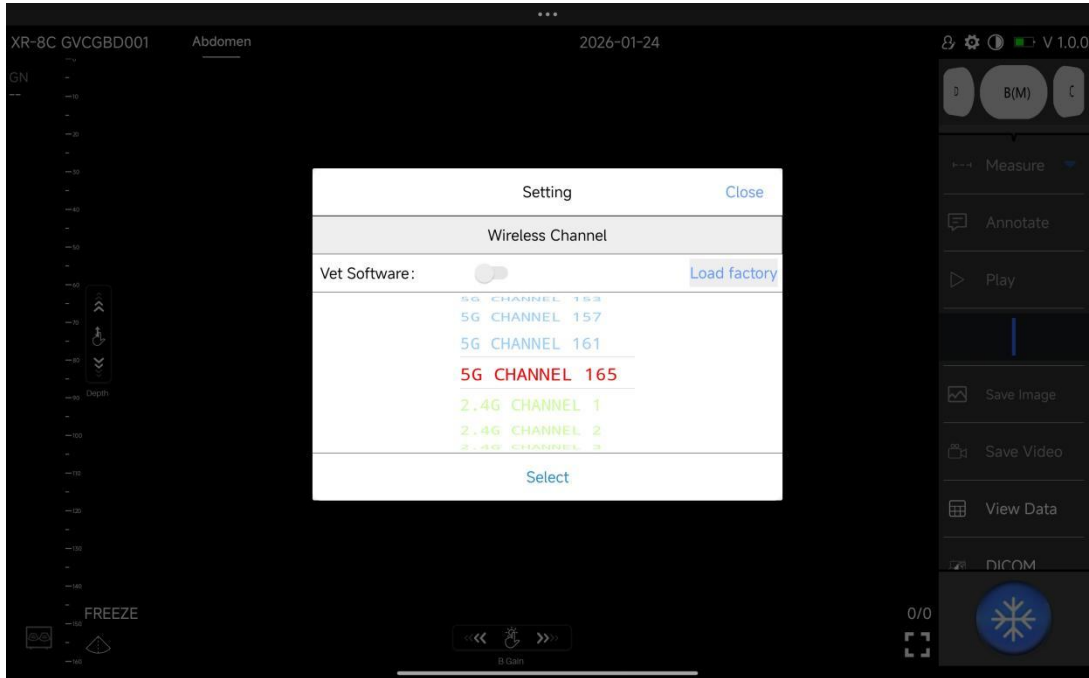
点击“连接”无线密码为探头背面的产品序列号，用小写字母输入

点击屏幕右上角的小齿轮图案，就可以进入系统设置，系统默认是横屏方向，在设置里开启竖屏显示就可以完成切换



FreeSono Flex Handheld Diagnostic Ultrasound Quick User Guide REV1.0

If you click wireless channel, you will find two hidden settings “Vet software” and “Load factory”
Enable Vet software, the software will automatically switch from Human software to Vet software
If you click default setting, system will be recovered to factory default

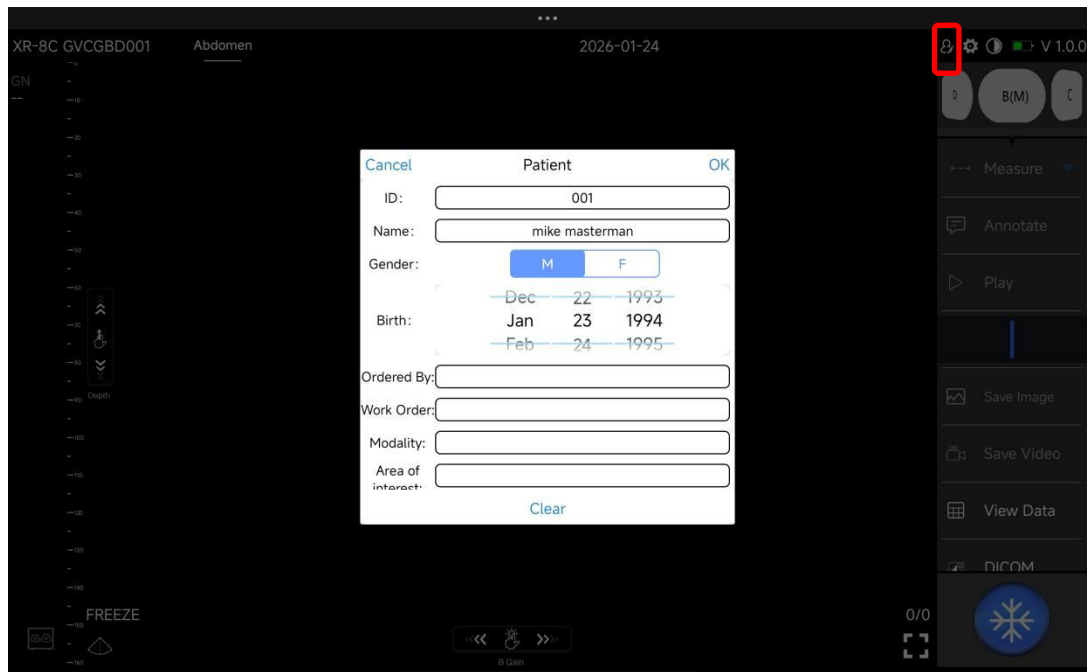


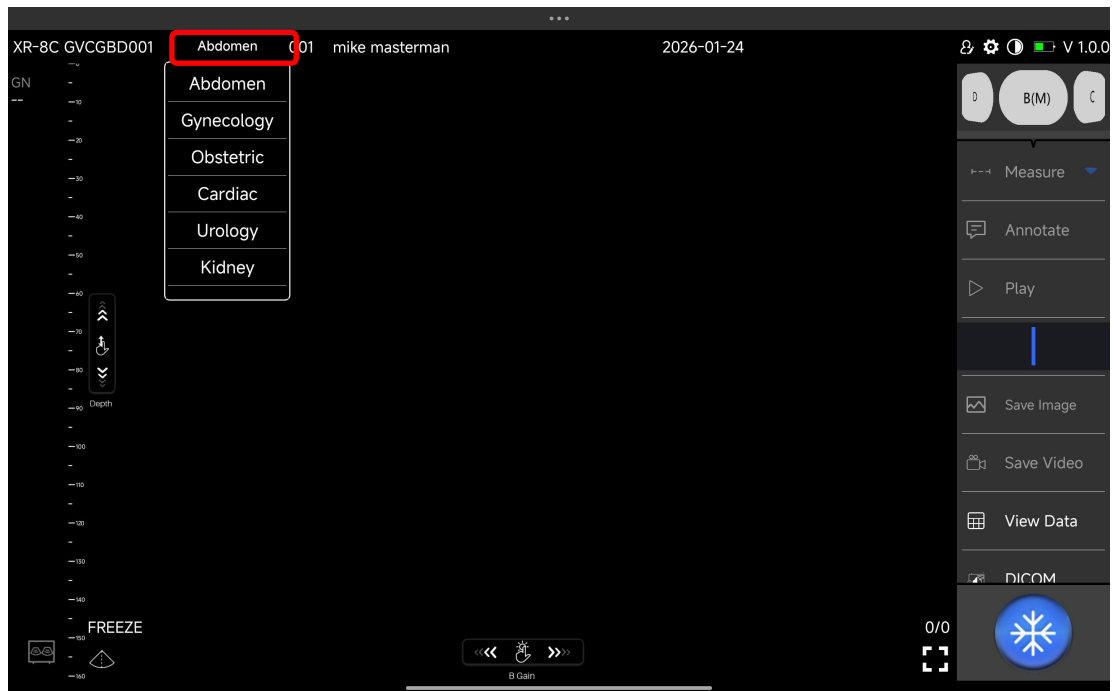
6 Patient info and select clinical application

In frozen mode, click the patient icon on the upper right corner and you can input patient info as you like.
After this, you can choose the right clinical application and you can ready to scan

6 病人信息输入跟临床应用选择

在图像冻结的状态下，点击屏幕右上角的人像图标，可以设置和修改病例信息，然后点击图像区域的左上角会弹出临床应用菜单，根据扫描部位需求可选择不同的临床应用





7 Imaging modes, Dual Screen and Parameters adjustment

Select different imaging modes by a simple slide or press on the screen upper right corner (Horizontal screen display) Under vertical screen display, you have to use the roller on left bottom corner B/M/C/PD/D all are available.

Dual screen icon is at the left down corner of the display as below, click the icon you will be able to enter Dual screen and do side by side comparison during live scanning or under frozen mode

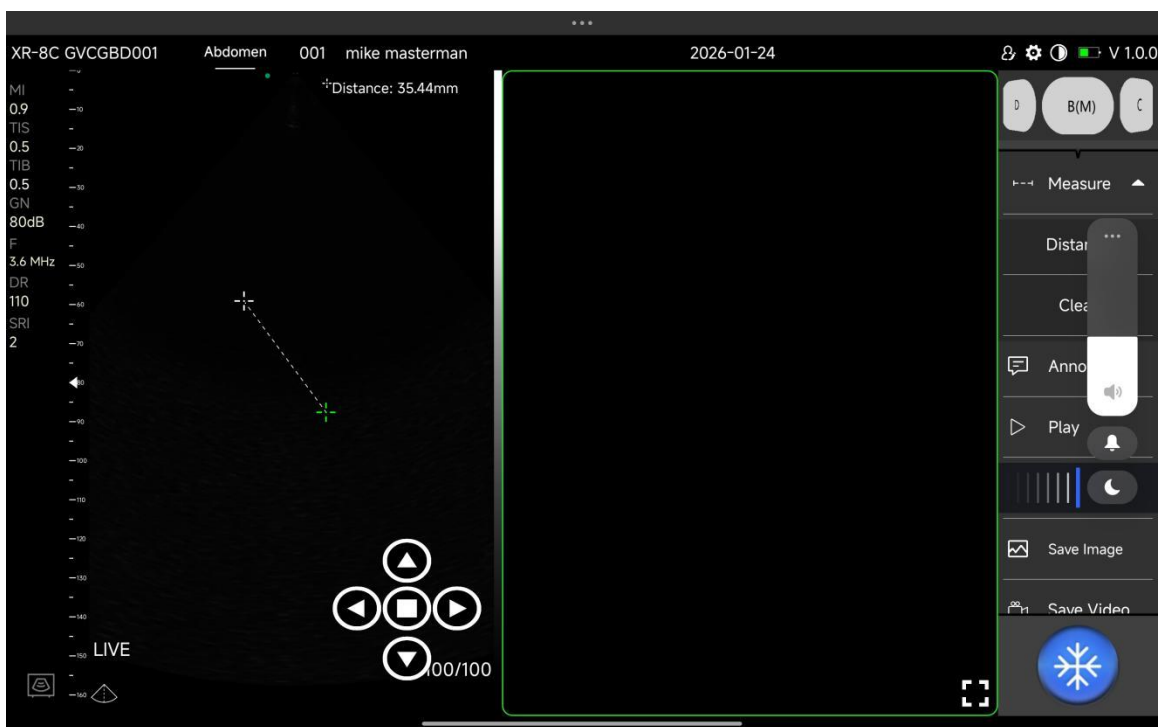
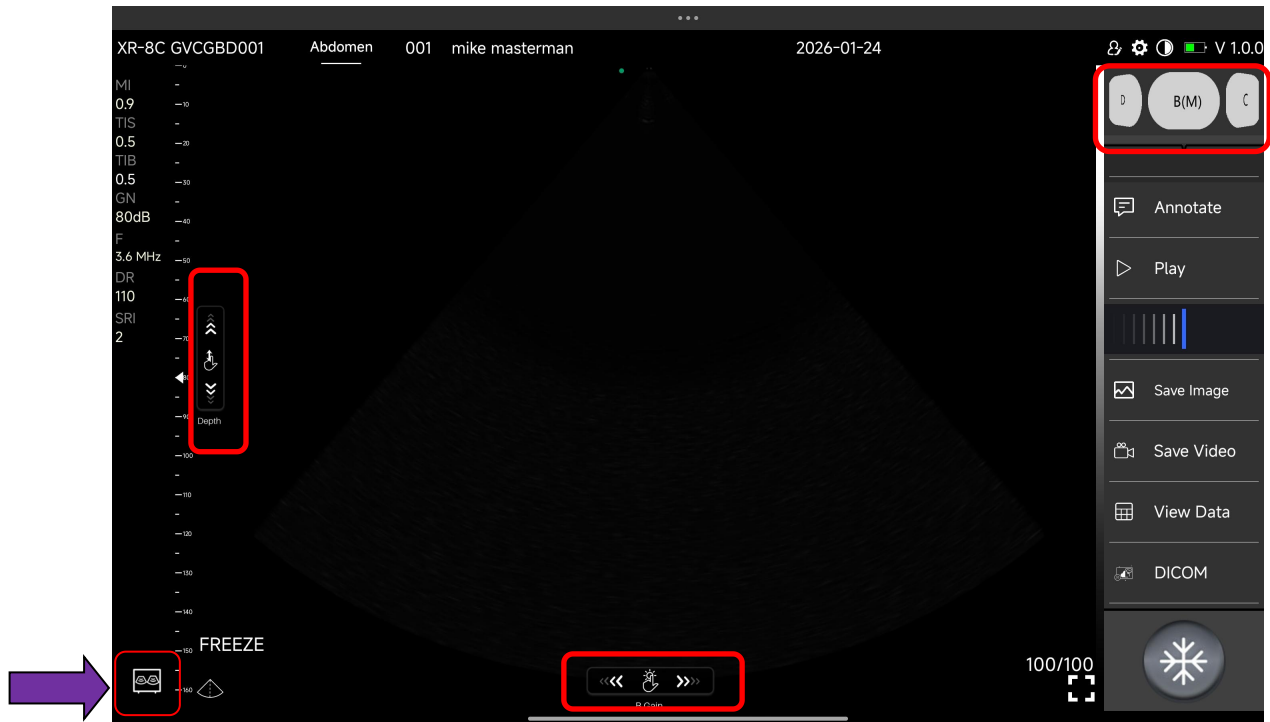
Slide up/down "Depth" on the left side of the image area you can adjust the scanning depth and slide left/right "B Gain" on the bottom of the image area you can adjust the total gain of 2D image

Other parameters are listed on the right side menu, you can adjust them with a simple touch

7 图像模式，双屏显示以及参数调节

在主界面右上角的“B(M),C,PD,D”之间左右滑动就可以切换图像模式。双屏模式的按钮在主界面的左下角，点击按钮就可以进入双屏模式，在实时扫描跟冻结状态下，进行图像诊断对比，或者在扫描不同的切面做测量

在图像左侧“Depth”处上下滑动调整深度，图像底部“B Gain”处左右滑动调整B模式（黑白图像）增益，其他参数调节都在图像右侧参数区轻触即可调节

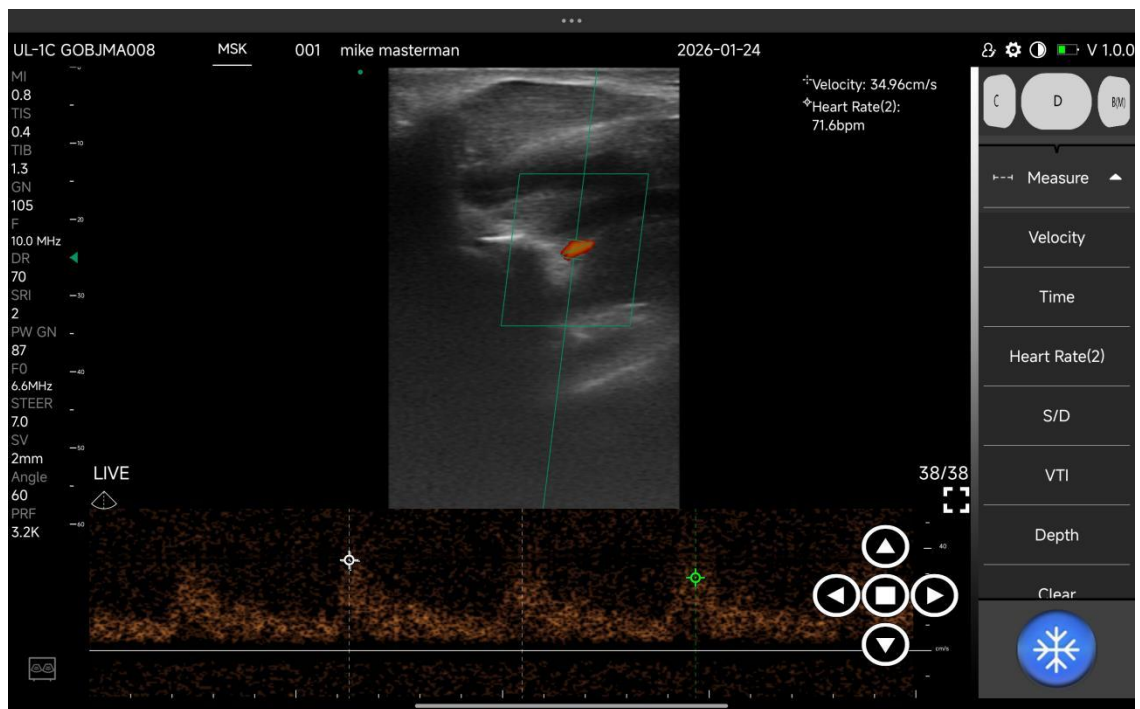


8 Measurement

Measurement package is quite simple in our pocket ultrasound. When the screen is frozen, system side menu will automatically display measure on the top, click it you will find general measurements eg distance, area and depth. In addition, you will be able to find specific OB measurements eg BPD, HC, AC, FL and etc for screening use

FreeSono Flex Handheld Diagnostic Ultrasound Quick User Guide REV1.0

测量前需要冻结图像，点击“测量”显示测量界面，用户可根据需要选择测量的项目，常规测量包含距离，速度，心率，S/D等，产科临床应用下有特殊的产科测量包



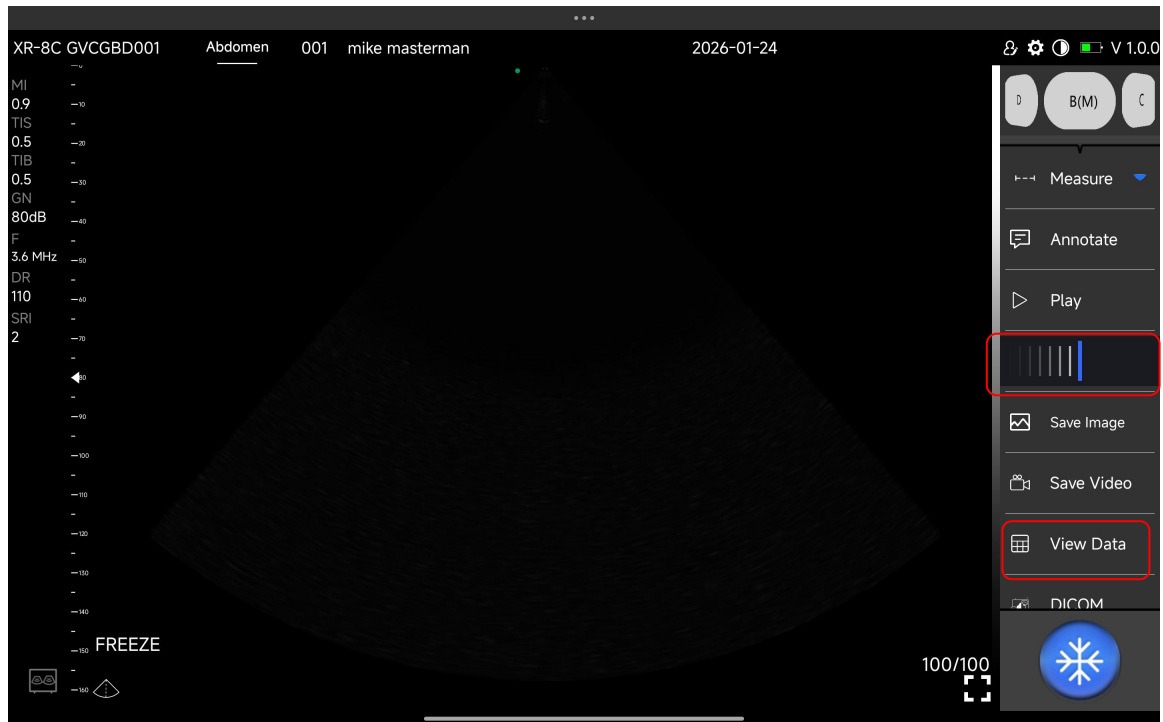
9 Cine Play(Frame Review), Save Image/Cine, Archiving, Dicom and report

In frozen mode, you can choose the Cine Play to play back the cine loop automatically or alternatively you can use the roller bar under Cine Play to review the clips one frame by one frame.

9 视频回播（逐帧回放），保存图像和视频，如何查看图像和视频

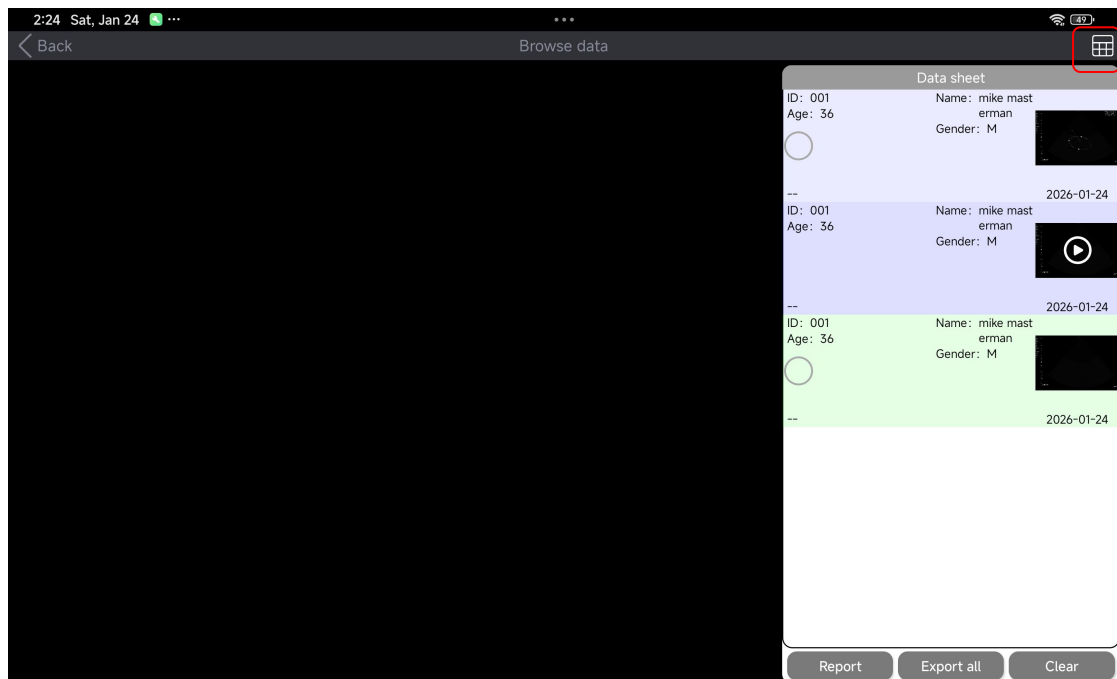
在冻结状态下，你可以选择播放视频或者你可以选择下方的滚轮逐帧回放

FreeSono Flex Handheld Diagnostic Ultrasound Quick User Guide REV1.0

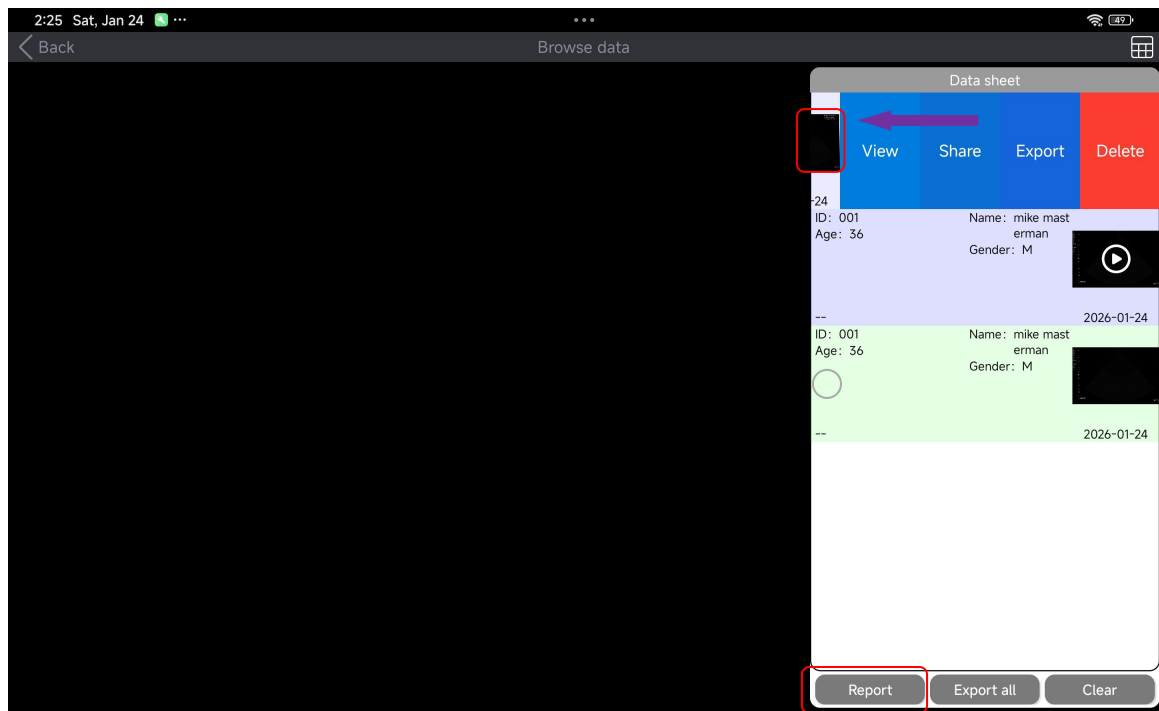


You can save images and cine loops (videos). Saved images and cine loops you will be able to get a quick access by click "View Data" on the menu under frozen mode. Once you are in the image browser, Click the review board icon on the top up corner, you will be able to see the saving records of images and clips. Gently slide left on the small image displayed on the right, you can choose to watch/share/export or delete. The share function will enable you to share it easily with any specialist for consultation or second opinion through any social media App installed on your smart device. Dicom is under View Data on the menu

冻结状态下，点击“保存图片”或者“保存视频”系统会将图片或者动态图像保存到数据库中，点击“数据库”你就可以进入数据库然后点击右上角图像浏览小百叶窗，就可以展开病人数据列表，在图片或者视频上向左滑动，可以“导出 查看 分享或删除”，如果选择导出，则会用默认文件名保存到智能设备的本地文件夹

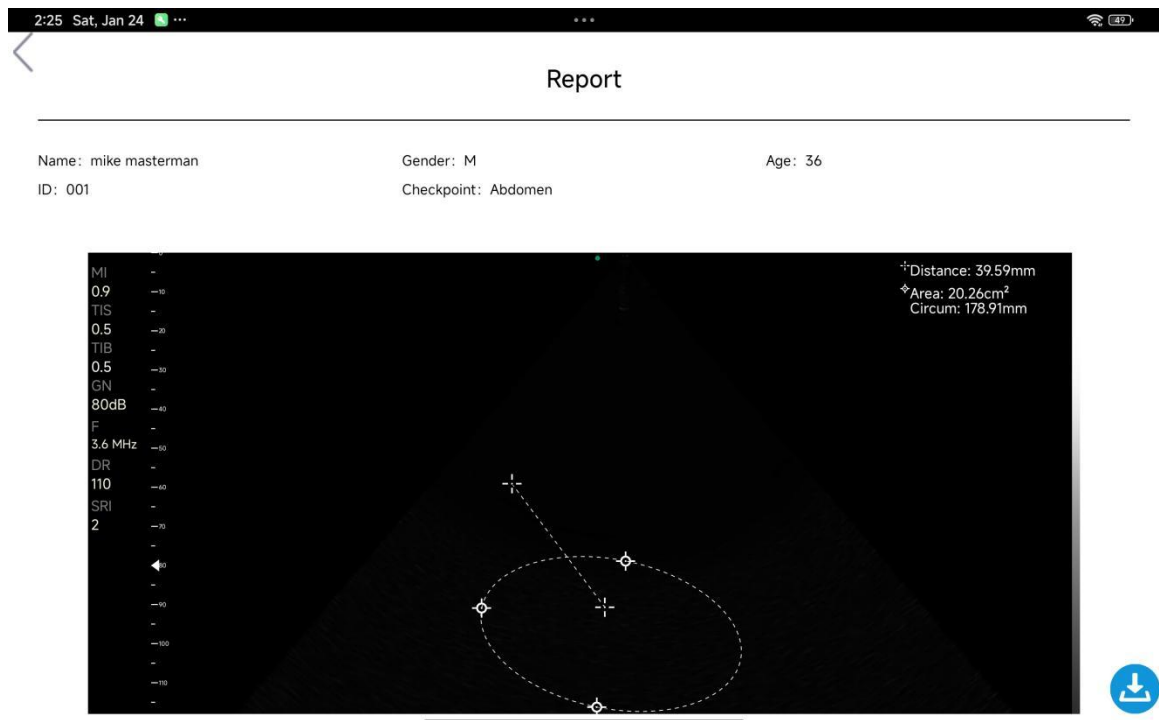


FreeSono Flex Handheld Diagnostic Ultrasound Quick User Guide REV1.0



Click "Report" at the right down corner as above you will be able to generate patient report seamlessly and download to your smart device right away

如上图在病人数据库的右下角点击报告就会无缝衔接生成病人报告然后下载到本地设备上



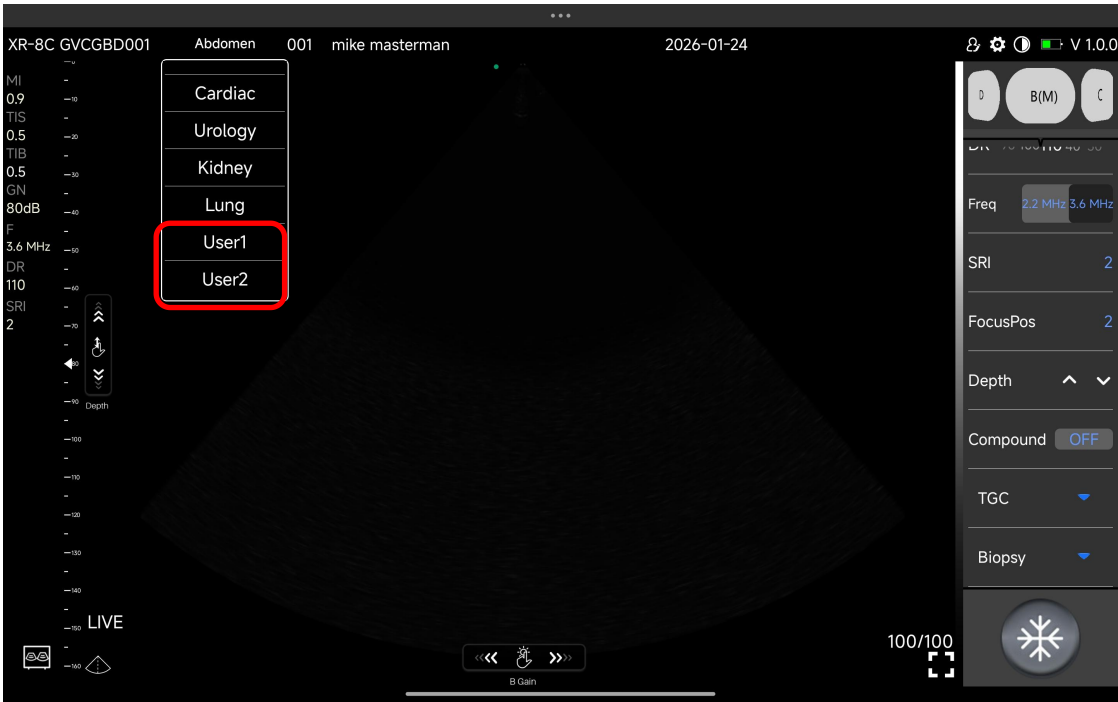


10 User define presets

Whenever you change any parameters, the system will automatically remember it for next time use. In addition, you can also create your own presets or new clinical application by using user 1 and user 2

10 客户自定义参数

任何时候你改变任何参数，系统机会自动记忆并于你下次使用。另外你可以根据你个人喜好在用户1 用户2下 定制临床应用以及对应的特殊参数



FCC Regulations

- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.
positions, they all meet the government requirements.

This EUT is compliance with SAR for general population/uncontrolled exposure limits in ANSI/IEEE C95.1-1999 and had been tested in accordance with the measurement methods and procedures specified in OET Bulletin 65 Supplement C.

Body 1g SAR 0.95W/Kg(limit 1.6W/Kg), Extremity 10g SAR 1.19(limit 4W/Kg)

This device is restricted to indoor use only when operating in 5150 to 5250MHz frequency range.