Ultrasound Scanner

User manual

Content

Preface

Dear customer, thank you for purchasing Edge Life Technologies, LLC. (hereinafter referred to as Edge Life) wireless handheld color doppler Ultrasound imaging system. In order to ensure the safe and correct operation of the product, please read and understand the contents of this manual carefully before use.

This manual is formulated and explained by our company.

The company reserves the right to change the contents of the manual without notice.

Important Statement!

1. It is prohibited to copy or copy part or all of the contents of this manual without written permission.
2. It is forbidden to modify the software or hardware of this product.
3. This product can provide doctors with images and data needed for clinical diagnosis. The doctor is responsible for the diagnosis process. The company is not responsible for the diagnosis process.
4. Even during the quality assurance period, the quality assurance does not include the following:
(1) Damage or loss caused by incorrect installation or environmental conditions that do not meet the requirements.
(2) Damage or loss caused by charging power supply voltage exceeding the specified range of the product.
(3) Damage or loss of instruments or parts not purchased from the company or its authorized distributors or agents.
(4) Damage or loss caused by not using this product in the area where it was originally purchased.
(5) Damage or loss caused by maintenance by personnel not authorized by the company.
(6) Damage or loss caused by force majeure such as fire, earthquake, flood or lightning.
(7) Damage or loss caused by wrong or rough use.
(8) Other failures not caused by the product itself.
5. The company is not responsible for any risks caused by users' disassembly or use of illegal software.
6. When this product is used or after its expiration date, some wastes or vulnerable parts may be generated. Disposing of these wastes at will will cause serious pollution or cross-infection to the environment. It should be dealt with in accordance with local laws and regulations and other relevant regulations. Manage and process. It cannot be handled in the same way as normal waste products.

Product information

Product Name: Ultrasound Scanner

Models: D5CL, D6CL, D5CE, D6CE

Security Type: Internal Power, Type BF

After-sale Service Center: MediEquip Biomedical

After-sale Service Address: 8405 NW 29th Street, Doral, Florida 33122, USA

Production Address: 8405 NW 29th Street, Doral, Florida 33122, USA

After-sale Service Telephone:01-786-538-5588

Date of Production and Operating Life: see product body

Intellectual property

This manual and its corresponding product information are confidential information of Edge Life, and the user has the obligation to keep it confidential. Without the written permission of Edge Life, no organization or individual may disseminate it in any form.

Edge Life has the final right to interpret this manual.

Version: A/0 (the version number of this manual may upgrade at any time because of software or the change of technical specifications and upgrade, and without prior notice, please refer to our latest product function, configuration and kind prevail).

Safety precautions

Security Classification

Type of electric shock protection: internal power supply equipment.

Degree of electric shock protection: BF type application part and cannot be directly applied to the heart.

Icons

Symbols	Description
⚠dangerous	Indicates that there will be an imminent dangerous situation that, if not avoided, will cause death or serious injury to personnel.
⚠warning	Indicates that potentially dangerous situations will occur, which, if not avoided, may cause death or serious injury.
⚠careful	Indicates that potentially dangerous situations will occur, and if not avoided, it may cause minor or moderate injuries to personnel.
Note	Indicates a possible dangerous situation, which, if not avoided, may cause property damage.

Safety warning message

For this product, in order to ensure the safety of patients and operators, please strictly observe the following safety regulations when using it.

⚠dangerous	Do not use the probe in an environment where combustible gas (such as anesthetic gas, hydrogen, etc.) or combustible liquid (such as ethanol, etc.) exists, otherwise it may cause an explosion.
⚠warning	1. It is forbidden to disassemble this equipment without authorization, as this may cause electric shock.The device contains no user serviceable parts. No modification of this equipment is allowed. 2. Please use a charging device that meets the requirements of the standard IEC60601-1, otherwise charging the ultrasonic device may bring the risk of electric shock. 3. Use the probe carefully. If the contact surface between the probe and the human body is scratched, please stop using the probe immediately and contact the service representative. If you use a scratched probe, there is a danger of electric shock. 4. It is forbidden to contact the patient with the live parts of the equipment or other equipment (such as various signal input and output ports, etc.). If the equipment or other equipment fails, the patient will be in danger of electric shock. 5. The user must check that the equipment functions safely and see that it is in proper working condition before being used. Whether the shell and probe are damaged, do not subject the probe to impact, and it is forbidden to knock the probe. The damaged shell and Ultrasound probe may cause electric shock to the patient. 6. Before performing ultrasonic inspection, please check the surrounding environment to ensure safe use in the environment. Do not operate this product in an environment with flammable or explosive liquids, vapors or gases (such as oxygen or hydrogen). 7. Be sure to put a sterile probe protective cover on the probe when performing Ultrasound intracavity inspection. 8.The transducer has an IPX7 waterproof rating, and only the surface of the transducer can be immersed in liquid. it is forbidden to immerse other parts of the product (The main unit has an IPX1 waterproof rating) in liquids such as water or disinfectant solutions, as immersion may cause electric shock or malfunction. 9. Do not use this equipment with electronic equipment such as high-frequency electric knife, high-frequency treatment equipment or defibrillator at the same time. Otherwise, it may cause electric shock to the patient. 10. The probe must not scan the eyes. 11. Within a reasonable range, the lowest possible output power should be used. The time for physical examination should not be too long, and only limited to the time necessary to make a diagnosis. Extending the use time will damage the health of the human body. 12. When there is a need for clinical indications, the user of the instrument must have a sufficient understanding of the acoustic output or be able to obtain the relevant thermal index value. Ultrasound probes that can detect self-heating in the air cannot be used for transvaginal exploration. special attention should be paid to reducing the Acoustic output power and irradiation time of the embryo or fetus. 13.The device requires no calibration. 14. When the monitor is in use, there should not be any great power appliances such as high voltage cables, X-ray machine, ultrasound equipment and electrizer nearby. 15. Magnetic and electrical fields are capable of interfering with the proper performance of the ultrasound scanner. For this reason make sure that all external devices operated in

	the vicinity of the ultrasound scanner comply with the relevant EMC requirements. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation. 16.Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (See IEC 60601-1 or clause 16 of the 3Ed. of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.
⚠careful	1. Precautions about clinical examination technology: This product can only be operated by qualified medical personnel. This manual does not introduce clinical examination techniques. The correct inspection technique must be selected based on professional training knowledge and clinical experience. 2. This product cannot check the fetus for a long time. 3. Do not use incompatible couplants, disinfectants, probe protective covers, etc. 4. When using this product, you must wear sterile gloves to prevent infection. 5. Be sure to use sterile Ultrasound gel during operation. Please use a coupling agent that complies with local regulations. In addition, the Ultrasound gel must be properly managed and used to ensure that it does not become a source of infection. 6. In normal Ultrasound examination, there is no danger of burns at room temperature. however, if the Ultrasound probe is placed in the same place for a long time, it may burn the patient. 7. The protective cover of the probe is made of natural rubber. People who are allergic to natural rubber should use it with caution. 8. The probe has not been disinfected before leaving the factory. It must be processed according to the requirements of this manual before use. 9. The daily maintenance of the product must be performed after turning off the power. 10. The signal input part and signal output part need to be connected to the specified equipment that meets the requirements of this equipment standard. 11. Before using this Ultrasound equipment for clinical examination, please read carefully the section on the principles of Acoustic output. 12. The outer surface of the portions of TRANSDUCER ASSEMBLY which is intended to be inserted into a PATIENT should be checked to ensure that there are no unintended rough surfaces, sharp edges or protrusions which may cause harm.

Note	1.In order to prevent abnormal probe function, please read the following safety precautions: After each ultrasonic inspection, the ultrasonic couplant on the surface of the probe must be completely wiped. Otherwise, the ultrasonic couplant will freeze on the acoustic head lens of the probe and affect the quality of the ultrasonic image. Before and after each Ultrasound inspection, the probe must be cleaned and disinfected. 2. Surrounding environment requirements: Please use this product in the specified environment: ●Ambient temperature: 5℃～ 40℃ ●Relative humidity: 35%～85% (non-condensing) ●Atmospheric pressure: 700hPa ～ 1060hPa. To prevent damage to the product, please do not expose the product to the following environments: ●Places exposed to direct sunlight ●Places where the temperature changes drastically ●A dusty place ●Places prone to vibration ●Near the heat source 3. Repeated disinfection will cause the safety and performance of the probe to decrease, so the performance of the probe should be checked regularly. 4. In order to ensure data security, it is recommended that this product be used by a dedicated person. The user sets a login password for the general computer platform and

	does not operate the automatic lock screen function. if the collected image needs to be stored for a long time, it is recommended to store it in the PACS software in time. Safekeeping.

Symbols Glossary

Symbol	Description
	Switch
IPX7	Flooding Safety（short time）
IPX1	Water drop protection
	To identify a type BF applied part complying with IEC 60601-1.
	Follow instructions for use
	Requires separate collection for electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE).
	Non-ionizing electromagnetic radiation
	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Indicates the date when the medical device was manufactured.

Chapter 1 Overview

1.1 Introduction

1.1.1 Manual introduction

1) This manual introduces the wireless handheld color Doppler Ultrasound imaging system in detail.

2) This manual contains necessary and sufficient information to ensure safe operation of the equipment, please read it carefully before use.

3) This manual is composed of independent chapters, and some chapters partly overlap. Each chapter is written in consideration to provide users with convenience, consistency and ease of reading.

4) If there is any problem in operation, please contact Sonokan Customer Service Department or designated service provider.

1.1.2 Device introduction

The Edge Life Ultrasound Scanner is a portable, general purpose, software controlled, diagnostic Ultrasound system used to acquire and display high-resolution, real-time Ultrasound data through a commercial off-the-shelf (COTS) Apple iOS or Android™ device. The Edge Life Ultrasound Scanner series of wireless scanners are Wi-Fi-based scanners that communicate with a traditional tablet/smartphone via direct Wi-Fi to allow users to export Ultrasound images and display in different modes of operation. The Edge Life Scanner houses a battery and internal power supplies, multichannel beamformer, prescan converter and Wi-Fi components.

The system is a transportable Ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals. The scanners can be used in the emergency medical services (EMS) environment, including road ambulances during patient transport. All models of the Edge Life Scanner are not to be used in a fixed- or rotary-winged air ambulance.

1.2 Indications for use

The Edge Life Ultrasound Scanner is a software-based Ultrasound imaging system and accessories, intended for diagnostic imaging. It is indicated for diagnostic Ultrasound imaging in the following applications: abdominal, small organ, urology, gynecology, obstetrics, peripheral vessel.

The system is a transportable Ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals.

1.3 Contraindications

This product should not be used on the eyes.

1.4 Operating environment requirements

Ambient temperature:+5℃～+40℃.(charging battery in temperature：+10℃～+45℃)

Relative humidity:35％～85％(Non-condensing).

Atmospheric pressure:700hPa～1060hPa.

1.5 Packing List

Scanner.

Accessory: manual.

Chapter 2 Structure composition and principle

2.1 Structure composition

This product consists of a main unit and special control software. The main unit is composed of probe, circuit and battery, etc.

Figure1 Product structure composition

- Probe: Touch the surface of the human body, realize the conversion of electric energy and Acoustic energy through piezoelectric effect and inverse piezoelectric effect, and collect human tissue structure and hemodynamic information.
- Ultrasonic circuit: complete ultrasonic scanning control, beam synthesis, signal processing and data transmission.
- Battery: power the system.
- Dedicated control software: installed on general-purpose mobile computing terminals such as tablets, which can adjust imaging parameters, display images, measure, and store.

2.2 Principle

Using ultrasonic Doppler technology (the frequency shift caused by the scattering or reflection of Acoustic waves from a moving object) and the principle of ultrasonic echo (the image or signal formed by the reflection and scattering echo of ultrasonic waves in different tissues) to collect blood flow movement , Tissue movement information and human organ tissue imaging.

The Ultrasound system is highly integrated and connected to the display terminal via wireless. It can be widely used in human clinical Ultrasound examination.

Chapter 3 Specifications

3.1 Software Function

a) Imaging mode: B,B/M,C,PW.

b) The scanner and dedicated control software can use wifi connection.

c) With the function of puncture guide wire.

d) With movie playback function.

e) Adjustable parameters include: freeze/unfreeze, B gain, depth, dynamic range, frequency, image enhancement, focus position, TGC, Color doppler gain, Color doppler PRF, wall filter, red and blue flip, Color doppler frame size, Color doppler frame position, Color Doppler frame angle, PW gain, sampling volume, deflection angle, correction angle, PW PRF, baseline, sampling gate position.

f) It has the functions of editing/creating new patient information, annotations, saving images, saving videos, viewing data, center line identification, brightness adjustment, application preset mode, and setting functions.

g) With measurement functions: length, angle, circumference, area, trajectory, depth, heart rate, duration, distance, speed, blood flow systolic/diastolic ratio (S/D), obstetric measurement package.

h) Storage DICOM file function: used to store patient image information.

3.2 Cybersecurity

a) User access control:

User identification method: password.

User type: administrator, operator.

User authority: the administrator can set the password of the administrator and the operator, set the wifi channel, browse the pictures and videos stored by the administrator and the operator. the operator can only modify the operator password, and cannot set the wifi channel, only browse the operator Stored pictures and videos. other persons who do not have permission cannot perform the above operations.

b) The transmission protocol of the wifi connection between the host and the dedicated control software is the wireless standard protocol 802.11n.

c) Storage format: The file type of pictures is JPG and DCM, and the file type of video is MP4.

3.3 Host function

With wireless charging function.

3.4 Firmware version information

Firmware version: V1.

3.5 Software release version information

a) The release version of the embedded software for handheld Ultrasound is: V1.

b) The release version of the special control software for handheld Ultrasound is:

iOS version: V1. Android version: V1.

3.6 Power supply conditions

Internal power supply: DC3.85V.

Wireless charger input : 5W(DC5V, 1A) by wireless charging.

Can not work when charging.

Chapter 4 Product instructions

4.1 Host operating instructions

4.1.1 On/Off

Short press [⏻] key to turn on. long press [⏻] key for 3 seconds to swich probe,long press [⏻] key for 5 seconds to turn off.

4.1.2 Freeze/Unfreeze key

After powering on, you need to short press the physical button [⏻] of the host to unfreeze, or click the freeze/thaw button in the screen image to enter the real-time working mode.

4.1.3 Battery/Charging Operation

A total of 4 grids of power display. charging method is wireless charging. When wireless charging, the side of the charging coil of the machine needs to be aligned with the wireless charging equipment that meets the requirements of the IEC60601-1 standard.

Through a wireless charger that meets the standard requirements to charge the device wirelessly. The charging power supply for this device must meet the following requirements: Wireless charger output: 5W(DC5V, 1A).

Internal power supply specifications: DC3.85V, 2800mAh, meet the following requirements when used:

When the battery is used for the first time, there may be little residual power in the battery, and the battery needs to be charged first.

The new fully charged internal battery can last about 2.5 hours in B mode. The battery will self-discharge (approximately 1% a day), and the battery should be fully charged and discharged once a month. If your device is not used for a long time, the battery will be insufficient or even run out due to long-term self-discharge. This is an inherent characteristic of lithium batteries and is a normal phenomenon. At this time, use an external power supply to charge it for a long time.

4.2 Connection between the scanner and the dedicated control software

4.2.1 Description of network security

1) Operating environment

Control software operating environment requirements

Software	Hardware platform configuration	Software Environment	Network conditions
Handheld Ultrasound special control software iOS version	Processor frequency：≥1.8GHz, Memory: ≥2G, Display screen: ≥9.7 inches, Screen resolution: ≥2048x1536, Brightness: Ambient light detection function, display brightness correction function	Operating system: iOS12.3 or above	Network protocol needs to be compatible with 802.11n protocol
Handheld Ultrasound special control software Android version	Processor frequency：≥2.2GHz, Memory: ≥4G, Display screen: ≥8 inches, Screen resolution: ≥1920x1200, Brightness: Ambient light detection function, display brightness correction function	Operating system: Android 8.1.0 or above	Network protocol needs to be compatible with 802.11n protocol

Please choose a mobile terminal device which meets the requirements of the IEC60601-1-2 standard.

2）Security software

This control software does not include safety software. The software supports general security software (such as 360 Security Guard), and the security software should be an effective version that can ensure the safety of

the computer system.

3) Data and equipment interface

The transmission protocol of the wifi connection between the host and the dedicated control software is the wireless standard protocol 802.11n.

Storage format: The file type of pictures is JPG and DCM, and the file type of video is MP4.

4) User access control mechanism

When logging in, the user selects the administrator or operator according to the identity, and enters password to enter the main interface. The administrator can set the password of the administrator and the operator, set the wifi channel, browse the pictures and videos stored by the administrator and the operator. the operator can only modify the operator password, cannot set the wifi channel, and can only browse the pictures stored by the operator And video. other personnel who do not have authority cannot perform the above operations.

5) Relevant requirements for software environment and security software updates

The control software will be updated in due course to be compatible with the latest version of general safety software.

4.2.2 Install special control software for handheld Ultrasound

Contact the manufacturer to download the control software.

4.2.3 Connection between host and mobile device

When the host is on, use the mobile device to find the host's wifi hotspot and enter the password to connect.

4.2.4 Run the software

After connecting the host, open the special control software for handheld Ultrasound and enter the software interface.

Note	1. Because Bluetooth and wifi share antennas, you need to turn off the Bluetooth function of the mobile terminal, otherwise it will affect the wifi transmission and cause image transmission to freeze. 2. Turn off the mobile phone "location" function. 3. When you change the connection of the mobile terminal device, you need to restart the Ultrasound host before connecting.

4.3 Introduction of Software

The control software has a self-check function of the operating environment, which can automatically adapt to the screen display of different sizes and resolutions.

Encryption technology is used to ensure that the image data is unavailable, and relevant data information cannot be obtained without logging in.

In the Android system, enter the file system of the universal mobile computing terminal, find the file directory of the handheld Ultrasound special control software, and view the stored data files. They are in an encrypted state and cannot be opened. Only in the control software interface can view, export and delete. Specific path: Open the universal mobile computing terminal "File Management/Tablet/Android/data/com.Edge Life.microVue/files/pictures/", you can see the saved image data, which cannot be opened after encryption.

iOS system, access to the file system of the universal mobile computing terminal, without the file directory of the special control software for handheld Ultrasound, and unable to access the stored data files. Only in the control software interface can view, export and delete. Specific path: Open the general mobile computing terminal "File Management/My iPad/", without the file directory of the special control software for handheld Ultrasound, and cannot access the stored data files.

4.3.1 B mode

1)Real-time

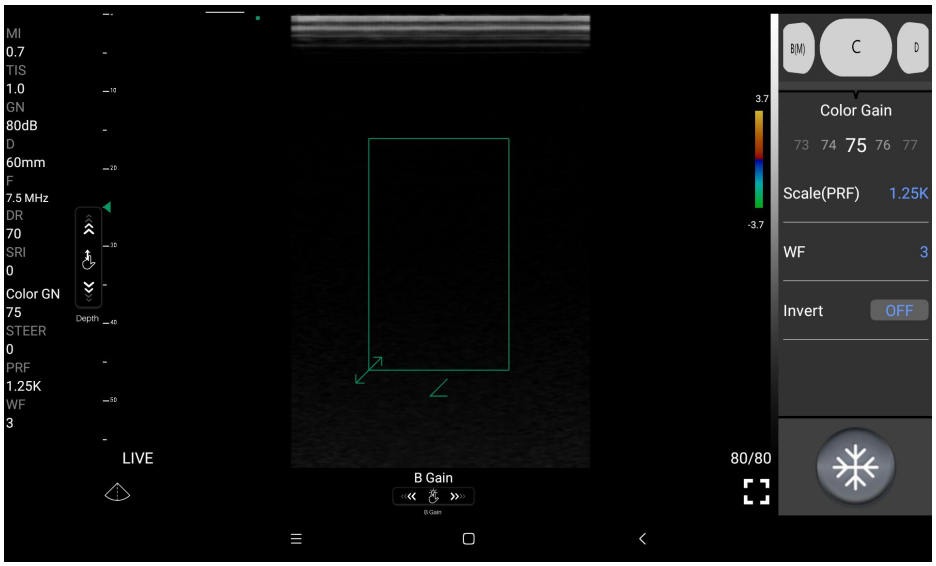
Preset	Select preset according to application
B Gain	The current gain amount, if you want to change the gain amount, slide left and right at the B Gain indicator at the bottom of the screen to adjust. Adjustment range: G30～G105.
Depth	Slide up and down at the Depth indicator on the left side of the screen to adjust the depth range of 20mm-95mm for linear array and 90mm-305mm for convex array.
DR	The dynamic range is adjustable between 40-110dB.
Freq	Frequency, Linear array is 7.5MHz/10MHz, convex array is 3.5MHz/5MHz.
SRI	Specke reduction imaging,has a total of 5 levels 0-4. Suppress speckle noise.
Focus position	Linear array fixes 2 focal points, convex array 1 focal point, a total of 4 groups of positions. adjust the focal position according to the region of interest.
TGC	Controllable segment gain.
Puncture guide line function	There are two puncture auxiliary functions: In-Plane (in-plane guide line), Out-Plane (out-of-plane guide line), Clear (clear)

2）Freeze

Freeze/unfreeze	Click to switch between image freeze and real-time display status
measurement	Including length, angle, circumference, area, trajectory, depth, heart rate, duration, distance, speed, blood flow systolic/diastolic ratio (S/D), obstetric measurement package, etc.
annotation	In the frozen state, click the comment button, and then click anywhere in the image. A comment box will appear, and then write the content that needs to be commented. You can slide the image left and right to add comments in each frame of the image screen.
Replay	Video can be played back
Save image	Save the image of the current frozen screen
Save video	Save the video picture with the preset number of frames before freezing
Setting	1. Frames (the number of movie frames) can be set, 100~1000 frames can be set. 2. The page layout can be set. 3. Wireless Channel (wifi channel), when the connection screen appears stuck, it may be because the wifi channel is too crowded, you can choose other wifi channels to connect, then restart the host, the motherboard and the tablet reconnect. 4. User access control: Users who need a password to log in to use the software, have administrator and operator user types, the administrator has the highest authority, can set the operator's password and set the channel, the operator cannot set the channel.
Patient	Can create or edit patient information, including number, name, gender, date of birth, etc.

4.3.2 Color Doppler mode

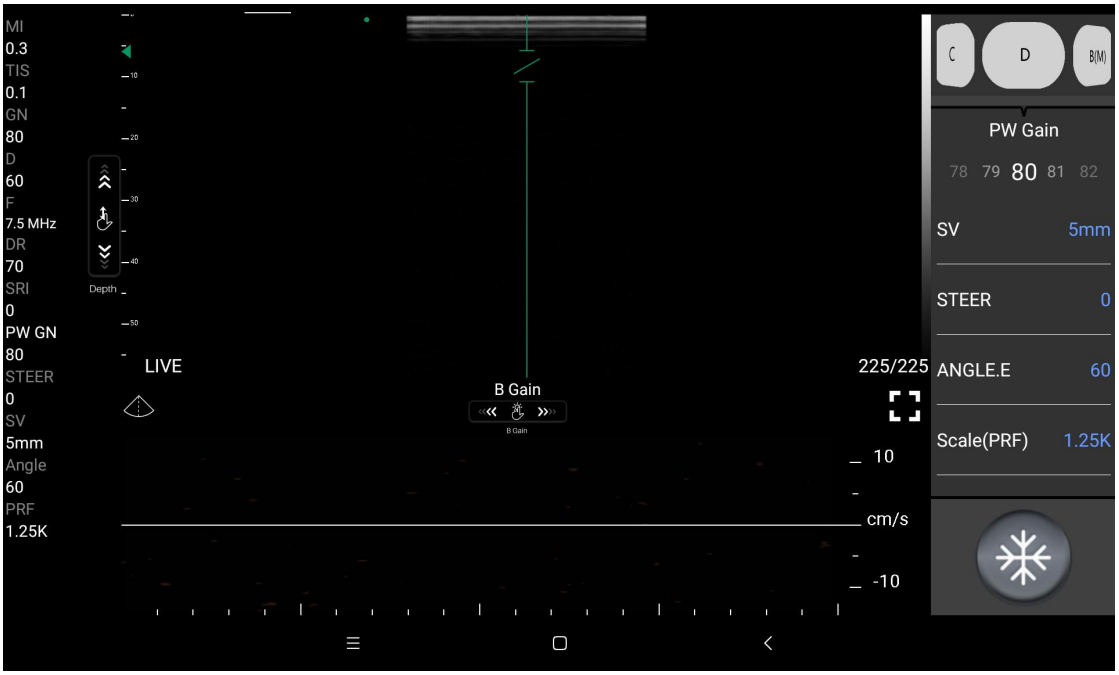
1）real-time



Enter and exit C mode	At the top of the parameter adjustment bar on the right, slide left and right to switch modes
Color Gain	The Color Gain on the right control window adjusts the color gain, the range is 0-100
Scale（PRF）	The right control window adjusts the pulse repetition frequency. There are 4 sets of frequencies: linear array is 1.25K, 2.0K, 3.2K, 4.0K. convex array is 1.0K, 1.25K, 1.6K, 2.0K.
WF	Wall filter:The right control window adjusts the size of the wall filter, which can be adjusted in 16 levels from 0-15.
Invert	Color coding flip
Color box size	Press and slide one finger at the arrow at the lower left corner of the colored frame to adjust the size of the sampling frame
Color box position	Single-finger touch slide at any position of the screen image area to adjust the position of the sampling frame.
Steer	At the bottom of the color frame, slide one finger left and right to adjust the angle of the color frame. There are 3 groups of angles: -12, 0, +12.

4.3.3 PW Doppler mode

1）real-time



Enter and exit PW mode	At the top of the parameter adjustment bar on the right, slide left and right to switch modes
PW Gain	The PW Gain on the right control window adjusts the PW gain, the range is 0-100
SV	Sampling Volume,Click the sampling volume on the right control window to adjust the sampling volume to 1mm\2mm\5mm
Steer	The right control window adjusts the angle of the PW sampling line, there are 5 groups of angles: -12, -7, 0, +7, +12
Angle	In the control window on the right, click the correction angle to adjust the sampling door angle, +60 degrees, 0, -60 degrees.
PRF	The right control window adjusts the pulse repetition frequency. There are 4 groups of frequencies: linear array is 1.25K, 2.0K, 3.2K, 4.0K. convex array is 1.25K, 1.6K, 2.0K, 2.5K.
Baseline	The right control window adjusts the 0 bit of the spectrum.
Sampling gate position	Slide one finger on the screen to adjust the position of the sampling gate

2）Freeze

It can measure speed, heart rate, blood flow systolic/diastolic ratio (S/D).

Speed: the speed of blood flow. In the frozen state, click the "Measure" button in the right control window, and the drop-down menu will show "Speed", click "Speed", and then in the lower spectrum display area, select the position where blood flow velocity needs to be measured, click, and click on the upper right corner of the image area. The speed measurement value of the selected position will appear.

Heart rate: The number of heartbeats per minute. This device uses a two-cycle heart rate method. In the frozen state, click the "Measure" button in the right control window, and the drop-down menu will show "Heart Rate (2)", click "Heart Rate (2)", and then select a peak in the lower spectrum display area and click, and then a peak interval on the right Select the next peak, and the heart rate measurement value will appear in the upper right corner of the image area.

Blood flow systolic/diastolic ratio (S/D): The ratio of blood flow velocity during systole to end-diastole. In the frozen state, click the "Measure" button in the control window on the right, and the drop-down menu will show "S/D", click "S/D", and then click on a systolic peak in the lower spectrum display area, and then select the same cardiac cycle Click on the end diastolic trough in the image area, and the S/D measurement value will appear in the upper right corner of the image area.

Chapter 5 Transportation and Storage

5.1 Transportation requirements

Environmental requirements:

Environment temperature: -20℃~+55℃.

Relative humidity: 10%~93% (non-condensing).

Atmospheric pressure: 700hPa~1060hPa.

Note description:

The packaging of this product meets the requirements of aviation, railway, highway and ship transportation, but rain and snow splashes, severe collisions and long-term exposure to strong sunlight should be avoided during transportation.

5.2 Storage requirements

Environmental requirements:

Environment temperature: -20℃~+55℃.

Relative humidity: 10%~93% (non-condensing).

Atmospheric pressure: 700hPa~1060hPa.

Note description:

The product should be placed indoors and the room should be well ventilated.

Avoid prolonged exposure to strong sunlight or contact with corrosive gases.

Stored at a location ≥10cm away from the ground and the wall.

Stacking layers ≤ 10 layers.

Storage battery power requirement: 60%～80%.

When the storage period exceeds 6 months, the instrument should be taken out of the warehouse, and the instrument should be turned on and checked to confirm that it is working normally and the battery power meets the storage requirements before re-stocking.

Chapter 6 Upgrade and Maintenance

6.1 Upgrate

The software upgrade of this product can be done by the user installing the application upgrade installation package provided by the company, or by downloading and installing the latest version of the software from the application market.

6.2 Maintenance

1) Product use

a) In order to increase the service life of the product and obtain the best performance possible, please be careful when operating the product. Please follow the following precautions:

- Before use, check whether the whole shell and the surface of the transducer, the position of the buttons, the indicator light, and the interface are intact and undamaged.
- Appropriate amount of medical ultrasonic couplant is applied to the surface of the transducer during diagnosis. If couplant is not used, the image obtained will be unclear.
- Avoid products falling on the floor or colliding with other hard surfaces. Misoperation will affect their performance.
- Do not heat the product.

⚠warning	**Do not use products with damaged appearance, otherwise it may cause serious consequences and endanger the lives and health of operators and patients.**

⚠careful	**1. Long-term repeated staining of couplant on the probe may damage the probe. 2. Frequently check the probe shell for cracks to avoid immersion in liquid to damage internal components.**

b) In order to minimize the spread of disease, it is necessary to take some protective measures. Clinically, the probe sheath helps prevent infection. It is strongly recommended to use a sterile probe sheath that meets the requirements for intracavity inspection.

⚠careful	**1. In order to avoid infection, the protective cover of the probe can only be used once during the inspection. Do not use a damaged protective cover. 2. The probe sheath is made of natural latex and talc, which may cause allergies to some people. 3. Do not use expired probe sheaths. Before using the probe sheath, check whether the probe sheath has expired.**

Operation steps (for reference only):

- Apply a proper amount of ultrasonic couplant to the inside of the protective cover or on the surface of the probe. If couplant is not used, the image obtained will be unclear.
- When putting the probe into the protective cover of the probe, make sure that it is sterile. Tighten the protective cover to remove wrinkles and bubbles. Be careful not to pull the head too far.
- Tie tightly with a rope to ensure the safety of the protective cover.
- Check the protective cover to make sure it is not damaged.

2) Cleaning and disinfection

The probe is a part directly in contact with the patient. In order to avoid bacterial infection, after completing a test and turning off the host, please clean and disinfect the probe as required.

⚠warning	**1. Before cleaning, please check carefully, and only after confirming that there is no damage (such as cracks, defects, etc.).** **2. If the coupling agent is not completely clear after the test, it will solidify and affect the quality of the probe.** **3. The transducer has an IPX7 waterproof rating, and only the surface of the transducer can be immersed in liquid. it is forbidden to immerse other parts of the product (The main unit has an IPX1 waterproof rating) in liquids such as water or disinfectant solutions, as immersion may cause electric shock or malfunction.** **4. It is strictly forbidden to sterilize the probe with gas or heating.**

Note	1. The probe must be cleaned after each use. 2. Surgical brushes cannot be used to clean the probe, even if a soft brush is used, the probe may be damaged. Only a soft cloth can be used. 3. When cleaning or disinfecting, wear anti-bacterial gloves to prevent infection. 4. After disinfection, follow the instructions of the disinfectant manufacturer to thoroughly remove disinfection residues, chemical residues or harmful to the human body. 5. Precautions for disinfectant: Please refer to the instructions for disinfectant concentration and disinfection method in the instructions for use provided by the disinfectant manufacturer for the method of dilution, concentration, disinfection, and use process.

Clean

a) Wear anti-bacterial gloves to prevent infection.

b) Wipe the probe with a clean soft cloth dipped in clean water or soapy water to remove the attached stains until the probe is completely clean.

c) After cleaning the probe, be sure to remove all remaining cleaning agents, and dry the probe with a clean soft cloth, do not dry the probe.

Disinfection

a) Wear anti-bacterial gloves to prevent infection.

b) Use a clean soft cloth dipped in glutaraldehyde hospital disinfectant, wipe the probe to disinfect.

c) After disinfection, be sure to remove all traces of disinfectant. Please wipe the probe with a clean soft cloth dipped in clean water. It is recommended to wipe three times to remove all residual disinfectant. And dry the probe with a clean soft cloth, do not dry the probe.

3) Safe use and maintenance of rechargeable batteries

Note	1. The built-in rechargeable battery can only be replaced by professionals with tools. 2. In order to ensure the safe use of the battery, please pay attention to the battery to maintain a certain amount of power at all times to avoid overcharging and overdischarging. 3. Maintain a complete charge and discharge of the battery once a month. 4. In order to ensure the safe use of batteries, use in high temperature environments should be avoided.

4) The equipment is inherently aging during use, and it needs regular performance and function maintenance.

5) Regularly clean up the mobile terminal memory to ensure sufficient storage space to prevent insufficient space to cause some software functions, such as image/movie storage functions, to fail.

6.3 TROUBLE SHOOTING

Fault handling:

Item	Failure Problem	Solution
1	No response after press the Power ON/OFF button	Charging, check the power supply
2	Intelligent display can't connect probe WIFI	Check the WIFI signal channel is ready; Test whether the WIFI password input is correct; Check if other Intelligent display is already connected to the probe.
3	Displayed on the screen with interference like snow	Check if other equipment started which cause electromagnetic interference, shut down the device or get far from the device.
4	The image not bright	Adjust brightness
5	Charging not work	Detect circuit and electrical outlet, check if the USB interface is damaged; Check whether the probe has not been used for a long time and is not charged, if so, the probe needs to be charged for a long time to activate the battery.

Charpter 7 Safety

7.1 Electromagnetic compatibility

Instructions for use

The ME EQUIPMENT or ME SYSTEM is suitable for Professional healthcare facility environment and so on.

Warning：Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning： Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

Warning：Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ultrasound scanner (D5CL,D6CL,D5CE,D6CE), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Warning：The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

If any：a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

If any：the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

RF parameter

item	parameter
working frequency band	5.725GHz-5.850GHz
transmit power	<20dBm
protocol	IEEE 802.11n
wireless charge	100KHz - 205KHz(Receive Frequency)

Technical description

1.all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.

2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	N/A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2 Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines：±2 kV input/output lines：±1 kV 100 kHz repetition frequency	N/A
Surge IEC 61000-4-5	line(s) to line(s)：±0.5, ±1 kV line(s) to earth：±0.5, ±1, ±2 kV	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 250 cycle	N/A
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF * IEC61000-4-6	150KHz to 80MHz： 3Vrms 6Vrms (in ISM bands) 80% Am at 1kHz	N/A
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE UT is the a.c. mians voltage prior to application of the test level. Remark: "*" : Only test for Patient Coupling line.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity								
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	**Test Frequency** (MHz)	**Band** (MHz)	**Service**	**Modulation**	**Maximum Power**(W)	**Distance** (m)	**IEC 60601-1-2 Test level** (V/m)	**Compliance level** (V/m)
	385	380-390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27	27
	450	430–470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9	9
	745							
	780							
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
	870							
	930							
	1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
	1845							
	1970							
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9	9
	5240							
	5785							

7.2 FCC Safety

Label statement:

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 my cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment

FCC Statement：

Note: 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.

7.3 Probe surface temperature rise

⚠careful	**Normal ultrasound examination will not have the risk of burning, even when the probe surface temperature exceeds the patient's body temperature due to the difference in ambient temperature and examination mode. During the ultrasound examination, do not place the probe on the same part of the patient's body for a long time. In the case of meeting the diagnostic requirements, try to shorten the inspection time.**

7.4 Waste or disposal pollution control management

At the end of its service life, this product should pay attention to the image quality. If you find that the image quality has declined, please contact the manufacturer or local distributor.

Disposal

Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. Contact your local government for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being.

Battery Disposal

Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

Chapter 8 Warranty

This product implements a global warranty. If the product you purchase from any organization authorized by Edge Life worldwide fails, you can contact Edge Life, and Edge Life's professional customer service staff will solve your problems.

The warranty period of the purchased product is subject to the sales contract.

If the product fails during the warranty period, please send the whole machine back to our company after the Edge Life after-sales service personnel confirm that it needs to be returned to the factory. After the repair is completed, Edge Life will send the product back to you.

After the warranty period expires, Edge Life can continue to provide chargeable maintenance services.

The company declares that before use, you must read the instruction manual, and operate and use in strict accordance with the requirements and operating methods of the instruction manual. The company does not assume responsibility for safety, reliability and performance guarantees for any abnormal phenomena or personal and machine hazards caused by operation, use, maintenance, and storage not in accordance with the requirements of this manual.

⚠warning	**Do not modify this product, including equipment components, software, internal wiring, etc. User modification of the product may cause safety issues or degradation of system performance.**

Note	The following conditions are not covered by the warranty: 1. This warranty only applies to failures that occur when the equipment is operated under the conditions specified in the manual. Please ensure that the equipment is only used in the scope of use recommended in the manual. 2. This commitment does not apply to equipment damage due to accidents, misuse, abuse, falling, and attempts to modify or change any part of the equipment. 3. Surface damage is not included in the free repair or replacement range. 4. Edge Life is not responsible for damage caused by other equipment or unauthorized connection of other equipment. 5. When there is a problem with Edge Life products during the warranty period, please notify Edge Life, stating the equipment model, serial number, date of purchase and the nature of the problem.

Note	1. The maintenance of this product must be carried out by professionals authorized by our company.The device contains no user serviceable parts. Manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair 2. This manual provides instructions for the use of the Ultrasound Scanner. For more information, please contact the local authorized Edge Life distributor. 3. On the premise of meeting the requirements of relevant laws and regulations, it is our responsibility to continuously improve the finished product and enhance the clinical value of the product. The company reserves the right to update the product and no longer explain it to customers separately. We hope to get the understanding of users. Thank you again for your support.

Appendix A Acoustic Output

Ultrasonography is the application of Ultrasound in the human body, the frequencies change between 2.0M-15.0MHz according to the Ultrasound transducer, the Ultrasound has no ionizing in nature.

Caution use statement

- When collect clinical information which are necessary, it is recommended that:(1)avoid high radiation levels, (2)avoid radiation for a long time, 3)as far as possible to avoid unnecessary ultrasonic irradiation in patients.
- ALARA(As Low As Reasonably Achievable)principle : Under the premise of guaranteed access to diagnostic information, as far as possible use low levels of energy which does not cause biological effects. Ultrasound energy depends on the irradiation time and irradiation level, different patient needs different irradiation time and irradiation levels.

MI and TI

The relations between Various of acoustic output parameters (such as Acoustic intensity, Acoustic pressure, etc.) and the final biological effects is still not fully understood now, the current evidence suggests that under certain conditions, there are two basic mechanism that Ultrasound may cause or even damage the organization to biological effects to the thermal and mechanical.

- MI

Select the mechanical index as a data to calculated, the MI represents the indicated value which correlate with the mechanical effect, the index used to estimate the potential mechanical biological effects. The examples of the mechanical effects include Ultrasound pressure waves through the tissue, compressing motion (flow) around the bubbles, and transient cavitation bubbles through the energy released when a crash.

In a typical Ultrasound diagnostic equipment Ultrasound output level irradiation, the current in the human body has not yet reported adverse mechanical biological effects on the development of machinery index, following several observation projects played a role.

—— Gravel machine, mechanical-biological effects of Ultrasound through the same distance from the peak of Acoustic pressure is introduced, although the use of different frequencies, which is sometimes used in diagnostic imaging.

——Testing and observation on the ground outside the human body and other organisms showed the possibility of memory Ultrasound peak Acoustic pressure and frequency ranges of some Ultrasound diagnostic equipment in cavitation.

—— Irradiation of mice is similar to the level of Ultrasound pulsed Ultrasound diagnostic equipment used in (the phenomenon appeared in adult mice, the effect on the fetus has not been found), causing their lungs bleeding.

Laboratory studies of diagnostic Ultrasound radiation on the human body have not been able to draw definitive conclusions, but the results show that enough to cause concern, computing machinery index will arouse the user the possibility of mechanical effects, and it is possible to produce knowledge of the appropriate conditions.

- TI

Because many of the human body may be difficult to foresee Ultrasound scan plane and determine the thermal model, using a simplified model based on the general conditions. Clearly defined three categories of user selectable thermal index, imaging applications foreseeable combinations of different anatomical soft tissue and bone tissue which corresponding to the One or more of each class using the TI model, including the device information based on the transducer aperture size and the beam, or to calculate the imaging mode.

Soft tissue thermal index (TIS) Three soft tissue model based on two models covered in case of non-scan mode small aperture and large aperture, such as Doppler and M mode, another model covering the scan mode, such as color flow and B-mode imaging.

Bone thermal index (TIB), in the non-scan mode using the bone in the model focus area (may occur in fetuses from six months to nine months of the application). Using a soft tissue model in scan mode, as the temperature at the surface is generally higher than or equal to the intersection of the bone tissue.

Skull thermal index (TIC) is located on the bone surface model (adult applications, such as the skull) near the skull model is applicable to non-scanning mode and the scan mode.

- Mechanical index MI / Heat Index Description:

TI and MI values are displayed on the bottom of the screen, the operator during the inspection should monitor these index values, and to ensure access to effective diagnostic information under the premise of the irradiation time acoustic output value is maintained at the lowest possible level.
Under different operating conditions, when a MI value is greater than 1.0, the value will be displayed under the wide range of operating conditions of MI, the display starting point of 0.4, and similarly, when the value exceeds 1.0 TI, TI value is displayed, the display starting point 0.4.

Ultrasound Scanner, display MI values and TIS values under various types of operating conditions.

Note: If the MI and TI display values are more than 1.0, please carefully follow the ALARA principle

Acoustic output control and instructions

- Equipment in line with the average Acoustic power output conforms to milliwatts requirements, and can vary with transducer frequency, size and aggregation points. Ultrasonic attenuation and scattering will pass through or reflecting upon the body tissue.
- Acoustic output control system depends on the operator, the operator shall be qualified under the premise of effective access to diagnostic images to minimize Acoustic output. Control of the acoustic output of an operation control, there are three main types: direct control, indirect control and receiver control.

1） Direct control: In any mode which can't exceed the maximum Acoustic output acoustic output limits (such as MI is limited to 1.9), the following is a direct impact on the control of Ultrasound intensity:

- Focus Depth: With the user to change the depth, the pulse repetition rate will be changed.
- Freeze: start / stop acquiring an image, so the start / stop ultrasonic radiation.
- Location of the focus area: changing the number and location of launch focus area.
- Selection mode key (B, B / M, C, PW) imaging mode may be changed.

2） Indirect control: Acoustic output is controlled mainly caused by image correlation parameters. These controls include mode of operation, and the frequency of the probe, focus, image depth, and the pulse repetition frequency (PRF).

- These controls can affect the imaging mode, the pulse repetition
- Frequency, the depth of focus, the pulse length and probe selection. Selected imaging mode nature of the ultrasonic beam can be determined, B is the scan mode, M is stationary or non scan mode. The stationary Ultrasound beam energy is concentrated in the same area. Moved or scanned ultrasonic beam energy will be distributed in an area, the area of the ultrasonic beam focused at the same time in the same area only non-concentrated fraction of time a scan mode.
- The pulse repetition frequency is within a specific period of time the number of burst of ultrasonic energy. The pulse repetition frequency, the higher the energy of the pulses within a certain time the number of bursts. The following several control affects the pulse repetition frequency: the depth of focus, the display depth of the focus area and the number of fan width.
- Ultrasonic beam focus will affect the clarity of the image. In order to maintain or increase the clarity of the need to change different focus output at the focal area. Output can be changed to optimize the system. Detection of the different needs of different depth of focus. Focus can be set at the correct depth is important to improve the clarity of the structure.
- Pulse length is continuous ultrasonic pulse burst open. The longer the pulse, the time - the greater the average intensity. Time - the greater the average intensity, the greater the likelihood of generating heat and air bubbles. Select the probe will indirectly affect the strength. Tissue attenuation varies with frequency.
- The larger probe operating frequency, the greater the attenuation of ultrasonic energy. The higher the operating frequency of the probe intensity of the need for a larger output in the deeper position of the scanning. To be at the same depth scan output intensity, a low frequency of the probe. Output gain exceeds a certain value, and the image quality is not increased accordingly, it is necessary to use a low-frequency probe.

3) Receiver Control: does not affect the Acoustic output, and therefore, during image optimization, priority should be adjusted to optimize the image receiver controller, followed by the direct control and indirect control regulation.

- Can be used to improve image quality. These controls have no direct effect on the output, but will affect the ultrasonic echo accepted. These controls include receiver gain, TGC, dynamic range and image processing. Before increasing the output can be controlled to optimize the receiver.

- **Acoustic output Description**

- Attenuating acoustic output parameters: In order to measure the acoustic output of the relevant parameters, some means of different depths for the different frequencies and comparing focused Ultrasound system, the method (also known as attenuation) through the water tank as measured in the acoustic output of the Ultrasound waves the effect of the spread of the organization, usually 0.3dB / cm / MHz average Acoustic attenuation values, namely ultrasonic probe launch one centimeter per propagation of ultrasonic intensity attenuation 0.3dB / MHz, calculated as follows:
- Iatten=Iwater×10(-0.3f10×fc×z)
- Wherein Iatten Acoustic intensity is attenuated, Iwater in the tank is measured the Acoustic intensity (at a distance z), fc is the center frequency of the ultrasonic waves (measured in water), z is the distance from

the probe like. The Acoustic pressure level attenuation equation is similar, but the attenuation coefficient is 0.15dB / cm / MHz, half the intensity of the Acoustic, because the Acoustic intensity is proportional to the square of the pressure, so that the Acoustic intensity is twice the coefficient of Acoustic pressure coefficient.

■ Although 0.3dB / cm / MHz than any solid body tissue attenuation systems are much lower, but it can be seen as a case of fetal examination in the early pregnancy test, the ultrasonic probe to reach the fetus from the middle after almost all liquids and the liquid is very small attenuation, thus 0.3dB / cm / MHz attenuation coefficient than the actual checks to be much lower.

■ According to the FDA Track3 requirements, limiting the use of the acoustic output derating (or decay) method, the table below. When using any of the probe in any operating mode, the maximum acoustic output should be within the following limits listed in the table.

Application	Ispta a	Isppa a		MI
Other parts（but the eye ball）	≤720	≤190	or	≤1.9

- Actual MI / TI value and display value differences, these parameters are used as indicators of the Ultrasound thermal effects and mechanical effects of risk, they may increase or decrease the likelihood of thermal effects or mechanical effects prompts the operator to set up a system to more accurately say, these parameters are designed to implement the ALARA principle, when an operator to change some system control, the system will display the changes caused by the change Acoustic output, but the heat index does not mean the body temperature, First, in order to provide a single display index, had to make several assumptions to simplify the problem, one of which is the previously mentioned assumptions attenuation method, for most organizations the actual value of the human body is much smaller (such as muscle or organ tissue scanning generated when the attenuation is much higher than 0.3dB / cm / MHz), the thermal properties of the tissue is also a simplified, and therefore, when the scan hyperperfusion tissue (such as the heart or vascular system), will produce a thermal index was lower than the display multi-thermal effects.
- Mechanical index is used to indicate mechanical (cavitation) the possibility of effects occur, MI depends on the attenuation peak negative pressure and the center frequency, the actual peak negative pressure by the actual attenuation affected, and in turn, the actual cause tissue attenuation between the probe and the focus All solid tissue attenuation is higher than body 0.3dB/ cm / MHz, the actual negative peak value is less than the displayed value will vary with the variation of the scanning site.
- For the above reasons, TI and MI displayed value knowledge to assist the operator in the process of implementing Ultrasound ALARA principle.

Table A-1: D6CL/D5CL LINEAR PROBE (B mode)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.72	1.76		1.76		N/A
Index component value			1.76	1.76	N/A	1.76	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	1.81					
	P (mW)		57.73		57.73		N/A
	P_{1x1} (mW)		57.73		57.73		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	1.52					
	$z_{pii.\alpha}$ (cm)	1.52					
	f_{awf} (MHz)	6.40	6.40		6.40		N/A
Other Information	prr (Hz)	11375.00					
	srr (Hz)	13.99					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$ (W/cm^2)	15.48					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$(mW/cm^2)	6.04					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	10.64					
	p_r at z_{pii} (MPa)	2.52					
Operating control conditions	Focus(mm)	9,20	9,20	9,20	N/A	9,20	N/A
	Depth(mm)	40	40	40	N/A	40	N/A
	Frequency(MHz)	7.5	7.5	7.5	N/A	7.5	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Table A-2: D6CL/D5CL LINEAR PROBE (B/M mode)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.72	1.774		1.776		N/A
Index component value			B:1.76 M:0.014	B:1.76 M:0.008	N/A	B:1.76 M:0.016	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	1.81					
	P (mW)		B:57.73 M:0.45		B:57.73 M:0.45		N/A
	P_{1x1} (mW)		B:57.73 M:0.45		B:57.73 M:0.45		
	z_s (cm)			N/A			
	z_b (cm)					1.52	
	z_{MI} (cm)	1.52					
	$z_{pii.\alpha}$ (cm)	1.52					
	f_{awf} (MHz)	6.40	6.40		6.40		N/A
Other Information	prr (Hz)	B:11375.0 0 M:13.99					
	srr (Hz)	13.99					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$ (W/cm^2)	15.48					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$(mW/cm^2)	6.41					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	11.36					
	p_r at z_{pii} (MPa)	2.52					
Operating control conditions	Focus(mm)	9,20	9,20	9,20	N/A	9,20	N/A
	Depth(mm)	40	40	40	N/A	40	N/A
	Frequency(MHz)	7.5	7.5	7.5	N/A	7.5	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Table A-3: D6CL/D5CL LINEAR PROBE (C mode)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.90	1.24		1.24		N/A
Index component value			B:0.90 C:0.34	B:0.90 C:0.34	N/A	B:0.90 C:0.34	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	2.05					
	P (mW)		B:29.46 C:13.53		B:29.46 C:13.53		N/A
	P_{1x1} (mW)		B:29.46 C:13.53		B:29.46 C:13.53		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	1.60					
	$z_{pii.\alpha}$ (cm)	1.60					
	f_{awf} (MHz)	C:5.21	B:6.40 C:5.21		B:6.40 C:5.21		N/A
Other Information	prr (Hz)	4000.00					
	srr (Hz)	7.14					
	n_{pps}	15					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$ (W/cm^2)	102.20					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$(mW/cm^2)	26.17					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	43.08					
	p_r at z_{pii} (MPa)	2.74					
Operating control conditions	Focus(mm)	20	20	20	N/A	20	N/A
	Depth(mm)	40	40	40	N/A	40	N/A
	Frequency(MHz)	B:7.5 C:Fixed	B:7.5 C:Fixed	B:7.5 C:Fixed	N/A	B:7.5 C:Fixed	N/A
	PRF(kHz)	4.0	4.0	4.0	N/A	4.0	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Table A-4: D6CL/D5CL LINEAR PROBE (PW mode)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.95	0.71		2.66		N/A
Index component value			0.71	0.49	N/A	2.66	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	2.12					
	P (mW)		30.07		30.07		N/A
	P_{1x1} (mW)		30.07		30.07		
	z_s (cm)			N/A			
	z_b (cm)					1.54	
	z_{MI} (cm)	1.54					
	$z_{pii.\alpha}$ (cm)	1.54					
	f_{awf} (MHz)	4.97	4.97		4.97		N/A
Other Information	prr (Hz)	4000.00					
	srr (Hz)	N/A					
	n_{pps}	N/A					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$ (W/cm^2)	159.60					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$(mW/cm^2)	626.10					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	1270.00					
	p_r at z_{pii} (MPa)	3.02					
Operating control conditions	Focus(mm)	20	20	20	N/A	20	N/A
	Depth(mm)	40	40	40	N/A	40	N/A
	Frequency(MHz)	Fixed	Fixed	Fixed	N/A	Fixed	N/A
	PRF(kHz)	4.0	4.0	4.0	N/A	4.0	N/A
	SV	1	1	1	N/A	1	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Table A-5: D6CL/D5CL/D6CE/D5CE CONVEX PROBE (B mode)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		1.01	0.78		0.78		N/A
Index component value			0.78	0.78	N/A	0.78	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	1.75					
	P (mW)		110.65		110.65		N/A
	P_{1x1} (mW)		54.21		54.21		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	4.08					
	$z_{pii.\alpha}$ (cm)	4.08					
	f_{awf} (MHz)	3.02	3.02		3.02		N/A
Other Information	prr (Hz)	3197.60					
	srr (Hz)	12.99					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$ (W/cm^2)	82.59					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$(mW/cm^2)	3.22					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	5.70					
	p_r at z_{pii} (MPa)	2.67					
Operating control conditions	Focus(mm)	60	60	60	N/A	60	N/A
	Depth(mm)	90	90	90	N/A	90	N/A
	Frequency(MHz)	3.5	3.5	3.5	N/A	3.5	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Table A-6: D6CL/D5CL/D6CE/D5CE CONVEX PROBE (B/M mode)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		1.01	0.785		0.793		N/A
Index component value			B:0.78 M:0.005	B:0.78 M:0.005	N/A	B:0.78 M:0.013	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	1.75					
	P (mW)		B:110.65 M:0.86		B:110.65 M:0.86		N/A
	P_{1x1} (mW)		B:54.21 M:0.42		B:54.21 M:0.42		
	z_s (cm)			3.90			
	z_b (cm)					4.08	
	z_{MI} (cm)	4.08					
	$z_{pii.\alpha}$ (cm)	4.08					
	f_{awf} (MHz)	3.02	3.02		3.02		N/A
Other Information	prr (Hz)	B:3197.60 M:12.99					
	srr (Hz)	12.99					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$ (W/cm^2)	82.59					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$(mW/cm^2)	3.82					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	7.10					
	p_r at z_{pii} (MPa)	2.67					
Operating control conditions	Focus(mm)	60	60	60	N/A	60	N/A
	Depth(mm)	90	90	90	N/A	90	N/A
	Frequency(MHz)	3.5	3.5	3.5	N/A	3.5	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Table A-7: D6CL/D5CL/D6CE/D5CE CONVEX PROBE (C mode)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		1.28	1.05		1.05		N/A
Index component value			B:0.40 C:0.65	B:0.40 C:0.65	N/A	B:0.40 C:0.65	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	2.01					
	P (mW)		B:56.82 C:112.71		B:56.82 C:112.71		N/A
	P_{1x1} (mW)		B:27.84 C:55.22		B:27.84 C:55.22		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	4.76					
	$z_{pii.\alpha}$ (cm)	4.76					
	f_{awf} (MHz)	C:2.46	B:3.02 C:2.46		B:3.02 C:2.46		N/A
Other Information	prr (Hz)	2500.00					
	srr (Hz)	6.67					
	n_{pps}	15					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$ (W/cm^2)	94.34					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$(mW/cm^2)	48.71					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	103.60					
	p_r at z_{pii} (MPa)	3.01					
Operating control conditions	Focus(mm)	60	60	60	N/A	60	N/A
	Depth(mm)	90	90	90	N/A	90	N/A
	Frequency(MHz)	B:3.5 C:Fixed	B:3.5 C:Fixed	B:3.5 C:Fixed	N/A	B:3.5 C:Fixed	N/A
	PRF(kHz)	2.5	2.5	2.5	N/A	2.5	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Table A-8: D6CL/D5CL/D6CE/D5CE CONVEX PROBE (PW mode)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		1.04	0.88		4.67		N/A
Index component value			0.65	0.88	N/A	4.67	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	1.64					
	P (mW)		112.80		112.80		N/A
	P_{1x1} (mW)		55.27		55.27		
	z_s (cm)			2.42			
	z_b (cm)					4.38	
	z_{MI} (cm)	5.10					
	$z_{pii.\alpha}$ (cm)	5.10					
	f_{awf} (MHz)	2.49	2.49		2.49		N/A
Other Information	prr (Hz)	2500.00					
	srr (Hz)	N/A					
	n_{pps}	N/A					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$ (W/cm^2)	126.70					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$(mW/cm^2)	702.60					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	1687.00					
	p_r at z_{pii} (MPa)	2.55					
Operating control conditions	Focus(mm)	60	60	60	N/A	60	N/A
	Depth(mm)	90	90	90	N/A	90	N/A
	Frequency(MHz)	Fixed	Fixed	Fixed	N/A	Fixed	N/A
	PRF(kHz)	2.5	2.5	2.5	N/A	2.5	N/A
	SV	1	1	1	N/A	1	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Table A-9: D6CE/D5CE ENDOCAVITY PROBE (B mode)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.64	1.20		1.20		N/A
Index component value			1.20	1.20	N/A	1.20	
Acoustic Parameters	$p_{r.a}$ at z_{MI} (MPa)	1.56					
	P (mW)		42.39		42.39		N/A
	P_{1x1} (mW)		42.39		42.39		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	1.76					
	$z_{pii.a}$ (cm)	1.76					
	f_{awf} (MHz)	5.93	5.93		5.93		N/A
Other Information	prr (Hz)	3628.10					
	srr (Hz)	10.31					
	n_{pps}	1					
	$I_{pa.a}$ at $z_{pii.a}$ (W/cm^2)	45.32					
	$I_{spta.a}$ at $z_{pii.a}$ or $z_{sii.a}$(mW/cm^2)	1.24					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	1.86					
	p_r at z_{pii} (MPa)	2.24					
Operating control conditions	Focus(mm)	10,20	10,20	10,20	N/A	10,20	N/A
	Depth(mm)	30	30	30	N/A	30	N/A
	Frequency(MHz)	6.0	6.0	6.0	N/A	6.0	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Table A-10: D6CE/D5CE ENDOCAVITY PROBE (B/M mode)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.64	1.204		1.205		N/A
Index component value			B:1.20 M:0.004	B:1.20 M:0.002	N/A	B:1.20 M:0.005	
Acoustic Parameters	$p_{r.a}$ at z_{MI} (MPa)	1.56					
	P (mW)		B:42.39 M:0.12		B:42.39 M:0.12		N/A
	P_{1x1} (mW)		B:42.39 M:0.12		B:42.39 M:0.12		
	z_s (cm)			N/A			
	z_b (cm)					1.50	
	z_{MI} (cm)	1.76					
	$z_{pii.a}$ (cm)	1.76					
	f_{awf} (MHz)	5.93	5.93		5.93		N/A
Other Information	prr (Hz)	B:3628.10 M:10.31					
	srr (Hz)	10.31					
	n_{pps}	1					
	$I_{pa.a}$ at $z_{pii.a}$ (W/cm^2)	45.32					
	$I_{spta.a}$ at $z_{pii.a}$ or $z_{sii.a}$(mW/cm^2)	1.42					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	2.22					
	p_r at z_{pii} (MPa)	2.24					
Operating control conditions	Focus(mm)	10,20	10,20	10,20	N/A	10,20	N/A
	Depth(mm)	30	30	30	N/A	30	N/A
	Frequency(MHz)	6.0	6.0	6.0	N/A	6.0	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Table A-11: D6CE/D5CE ENDOCAVITY PROBE (C mode)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.68	1.33		1.33		N/A
Index component value			B:0.57 C:0.76	B:0.57 C:0.76	N/A	B:0.57 C:0.76	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	1.74					
	P (mW)		B:20.01 C:23.94		B:20.01 C:23.94		N/A
	P_{1x1} (mW)		B:20.01 C:23.94		B:20.01 C:23.94		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	1.56					
	$z_{pii.\alpha}$ (cm)	1.56					
	f_{awf} (MHz)	C:6.63	B:5.93 C:6.63		B:5.93 C:6.63		N/A
Other Information	prr (Hz)	4000.00					
	srr (Hz)	7.14					
	n_{pps}	15					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$ (W/cm^2)	65.76					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$(mW/cm^2)	9.41					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	17.13					
	p_r at z_{pii} (MPa)	2.49					
Operating control conditions	Focus(mm)	20	20	20	N/A	20	N/A
	Depth(mm)	30	30	30	N/A	30	N/A
	Frequency(MHz)	B:6.0 C:Fixed	B:6.0 C:Fixed	B:6.0 C:Fixed	N/A	B:6.0 C:Fixed	N/A
	PRF(kHz)	4.0	4.0	4.0	N/A	4.0	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Table A-12: D6CE/D5CE ENDOCAVITY PROBE (PW mode)

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.80	1.10		1.99		N/A
Index component value			1.10	0.70	N/A	1.99	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	2.08					
	P (mW)		34.89		34.89		N/A
	P_{1x1} (mW)		34.89		34.89		
	z_s (cm)			N/A			
	z_b (cm)					1.66	
	z_{MI} (cm)	1.74					
	$z_{pii.\alpha}$ (cm)	1.74					
	f_{awf} (MHz)	6.77	6.77		6.77		N/A
Other Information	prr (Hz)	4000.00					
	srr (Hz)	N/A					
	n_{pps}	N/A					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$ (W/cm^2)	85.71					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$(mW/cm^2)	642.40					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	811.80					
	p_r at z_{pii} (MPa)	2.33					
Operating control conditions	Focus(mm)	20	20	20	N/A	20	N/A
	Depth(mm)	30	30	30	N/A	30	N/A
	Frequency(MHz)	Fixed	Fixed	Fixed	N/A	Fixed	N/A
	PRF(kHz)	4.0	4.0	4.0	N/A	4.0	N/A
	SV	1	1	1	N/A	1	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							