



Digital Portable Diagnostic Ultrasound System

User' s Manual

Ver. 1.2-49

- PLEASE READ ALL OF THE INFORMATION IN THE PACKAGE INSERT BEFORE USING THE SPIROMETER.
- IF YOU DO NOT UNDERSTAND THE INSTRUCTIONS, CONSULT MEDITECH, service@meditech.cn
-

Meditech Equipment co., Ltd.

Product information:

Dear customer, thank you for choosing our Digital Portable Diagnostic Ultrasound System. In order to ensure the safe and correct operation of the equipment, please read and understand the entire contents of this manual before using the ultrasonic equipment so that you can familiarize yourself with the device performance and operation. Please place the manual in an easily accessible location.

Product name : Digital Portable Diagnostic Ultrasound System

Product Model : C-Scan

Version : E01

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 **0482**

Product manual :

- A. The system will fully apply quantitative analysis tools which have only been used in research laboratories before into routine clinical examination, so that users can extract more critical diagnostic information through cardiovascular image.
- B. The system uses real, raw data DICOM networking capabilities, enabling users to fully manage data, which can exchange a variety of medical findings, and these data will be open for future quantitative analysis. The user-friendly design and comfortable interface combined with intelligent and efficient software allow the operator to customize the workspace.
- C. The system ergonomic design is simple and comfortable, so that the operator can freely adjust the system monitor and its user interface. High-resolution images can help the physicians to concentrate on the patient.

Advice :

In order to ensure the safe use of this equipment, please comply with the following requirements :

- A. Only qualified medical personnel with a professional qualification certificate can use this system.
- B. Only qualified acoustic images can be used for medical scans for the purpose of medical diagnosis.
- C. The acoustical strengths shown in this manual are below the limits for medical applications.
- D. The formulas and databases in this manual are for reference only.
- E. Although there is no side-effect when using ultrasound diagnosis, it is still advised to avoid the use of unnecessary ultrasound energy on human body.
- F. Do not use the device in the presence of flammable anesthetics. Do not use with a defibrillator.

Statement :

The system provides software upgrades. With the improvement and update in the future, the system may provide new features and performance improvements. At the same time, the software version will also be updated, so the contents of this manual are subject to changes and modifications in the update version without prior notice to the users.

The function and operation interface described in this manual series may be unavailable or look different in your system considering that the product may be slightly customized according to the sales region. Please refer to the actual configuration of the purchased machine.

The Company makes no warranty of any kind with regard to this material, including, but not limited to, implied warranties of fitness for a particular purpose.

For the replaced defective parts and scrapped whole machine, please do not discard as garbage. They should be recycled or discarded according to local laws and regulations, and classified according to environmental protection requirements properly.

Meditech shall be responsible for the performance, reliability and safety of the instrument only if all of the following requirements are met: If it does not comply, it is not within the scope of the Company's responsibility:

- A. Follow the instructions in this manual when operating the device ;
- B. The relevant electrical equipment complies with the national standards and the requirements of this instruction manual ;
- C. Assembly operations, expansion, re-adjustment, modification and repair are carried out by company-approved professionals ;
- D. All components involved in maintenance and all accessories, consumables used are original or company-approved.

Copyright :

- A. The contents of the hardware and related documents of this system are protected by all intellectual property rights
- B. No part of this manual may be copied or reproduced in any form or by any means without prior written consent.
- C. This manual serves only as a reference for operating, servicing and maintaining this system. The company owns the copyright of this non-public publication manual and reserves the right to treat it as confidential information.
- D. Meditech Equipment co., Ltd. has the right of final interpretation of this manual.

Issued Date:

Warranty and maintenance services

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

Consumables: Refers to a disposable consumable that needs to be replaced after each use or a regularly replaced consumable, and the supplies are not warranted.

Warranty period started from the "installation date" filled in the attached "warranty card".

The "warranty card" is the only proof for warranty period calculation. To protect your rights, please fill in the warranty card right after the purchase and return it to the agent or mail back to the service department of the manufacturer.

Please note that the following situations will not be covered by the warranty:

1. The system files are unauthorized modified.
2. The customer does not complete and return the equipment warranty card within 30 days after the purchase acceptance is completed;
3. The serial number of the equipment provided by the customer is not correct (our company validate the warranty by equipment serial number).
4. During the warranty period, after-sales services are free. However, please be aware that, even during the warranty period, we may charge the costs for the maintenance and accessories if the malfunction is caused by the following reasons:
 - Man-made damage ;
 - Improper use ;
 - The grid voltage is outside the product specifications ;
 - Irresistible natural disasters ;
 - Replacement or use of unauthorized parts, accessories, consumables, or maintenance by unauthorized personnel ;
 - Other failure that is not caused by the product itself;

After the expiration of warranty, we can continue to provide maintenance services at your own costs.

If you are unable to pay the fees for the charged repair service in time, we may suspend the service until we receive your payment.

After - sales service units

service@meditech.cn

User Manual framework (Including three parts)

Safety Specifications Volume:

Describes patient safety and operator safety information, and points out the system's compliance standards and safety regulations.

User Manual Main Volume:

Describes the system operating procedures, maintenance checks, basic functions, system daily preparation work and instructions for using the system.

Probe and Consumables Operating volumes:

Describes procedures for cleaning, disinfecting, and maintaining the probe's working and disinfecting procedures and accessories, as well as information on consumables.

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Safety Specifications Volume

Chapter 1 Safety Specifications

This chapter describes important safety measures to be taken before operating the C-SCAN system, and also points out the system's compliance criteria. To ensure the safety of the patient and the operator, please read the following safety regulations before using the unit.



Do not modify this product, including system components, software, cables. User modifications to the device can cause safety problems and system performance degradation. All modifications must be made by our authorized personnel.



- Do not use this unit where water may enter the machine.
- Do not place the liquid above the device. If the conductive liquid permeates into the circuit elements, it may result in a short circuit and cause a fire.
- Never pour any liquid to the machine or let it flow into the machine, otherwise there will be danger of electric shock. If you accidentally spill liquid on the machine, immediately disconnect the power and contact our sales office or dealer.
- Do not operate this equipment in an environment with flammable or explosive liquids, vapors or gases such as oxygen or hydrogen. The

spark generated by equipment failure or the fan motor may electronically detonate these substances.

- Do not place the probe in a chemical (e.g. corrosive, degradable, contaminated) environment to avoid damage to the device / probe due to strong acid or alkali.

Operators should pay attention to the following points to avoid the risk of such explosion :

- If a flammable substance is detected in the environment, do not plug in or turn on the system.
- If a flammable substance is detected after the system has been turned on, do not attempt to turn off the device or unplug the power supply.
- If flammable substances are detected, ventilate the area before closing the unit.
- Connect the power supply and the ground wire according to the correct method in the user manual, otherwise there is danger of electric shock. Do not connect the ground wire to any gas or water pipe, which could lead to risk of explosion.
- Do not use any probes and power adapters other than those supplied by us. Doing so may cause damage to the unit and the probe. In extreme cases, a fire accident may occur.
- Do not open the case. If the case is opened with power on, there is a danger of a short circuit or electric shock.



- Always keep the machine dry and avoid moving the unit from a colder place to a warmer place, otherwise condensation or water droplets may

occur, causing a short circuit hazard.

- Be sure to use the power adapter supplied with this unit.
- If the unit malfunctions, please contact your sales office or agent of UTI Technologies. Do not dispose of this product yourself.

1.1 The text used in this manual



Indicates a particularly hazardous situation which, if not avoided, could result in:

- Severe or fatal injury
- Significant property damage
- Fire



Indicates that a potential situation, if unavoidable, could result in:

- Slight or severe personal injury or life-threatening
- Significant property damage



Indicates a potentially hazardous situation which, if not avoided, could result in :

- Slight personal injury
- property loss
- data lost





Indicates a potential non-compliance situation that could result if unavoidable :

- Abnormal wear and tear of equipment
- Invalid operation

1.2 A description of the safety symbol and the device label

| symbol | Description |
|--------|--|
| | This symbol indicates "power on" |
| | This symbol indicates "Power Off". |
| | This symbol indicates "equipotential". |
| | This symbol indicates a "dangerous voltage". |
| | This symbol usually means security and other important matters. |
| | This symbol indicates the B type application part. |
| | This symbol indicates "AC marking indicates AC power and rated current". |
| | Non - ionizing radiation |
| | Global Medical Devices term |
| | <p>This symbol indicates that the diagnostic system should be appropriately handled in accordance with applicable local, state, or federal laws.</p> <p>In accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive, this symbol also indicates the classification of electrical and electronic equipment.</p> |
| | Atmospheric pressure, transport and storage of atmospheric pressure range from 700 to 1,060 hPa. |

| | |
|---|--|
|  | Relative humidity, relative humidity in the transport range of 30% to 75% (no condensation). |
|  | Ambient temperature, transport and storage Ambient temperature range 5 ° C to 40 ° C (non-condensing). |

1.3 Identify the label

Digital Portable Diagnostic Ultrasound System
MODEL:C-SCAN
INPUT: AC 100V-240V 50Hz
SN:
POWER CONSUMPTION: DC3.8V 2500mAH

 **Meditech Equipment Co., Ltd**
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Probe :

The orange ring indicates a convex array probe and the green one indicates a linear array probe.

All probes have the working frequency indication and a raised edge on the shell to designate the orientation.

The raised edge corresponds to "● ◀" mark on the scanning screen. "● ◀" mark indicates the direction of the scanning probe.

note:

1. *If the probe parameters or specifications change, consult your local authorized representative or refer to the latest instructions.*

1.4 Safety classification

In accordance with the degree of anti-electric shock: Application components for the B-type applications.

According to the degree of protection against harmful liquid into: Host: IPX0 (general equipment); Probe: Waterproof grade IPX7.

Products classified as non-AP / APG based on flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide.

Whether the device has a defibrillation effect of the protection of the application of the discharge part: no application part for the defibrillation discharge protection.

According to the work mode the device is divided into continuous work equipment.

1.5 Patient safety



- Always maintain correct identification of all patient data and verify the accuracy of such data when entering patient names and / or ID numbers. Make sure that all log data and the patient identification provided in the print are correct. Identification errors may result in incorrect diagnostics.
- Make sure the patient information is confidential.
- After disinfection of the accessory, the chemical reagent or gas must be completely removed. Residual chemicals reagent or gases can cause damage to the accessory, as well as damage to the body.



- Do not use the system in the presence of flammable gas (such as anesthetic gas, hydrogen) or flammable liquid (such as ethanol, etc.), otherwise it may cause an explosion.
- Connect the power adapter to a dedicated ground socket on the hospital to ensure that it is adequately earthed.
- There may be a risk of electric shock if any lighting, monitor or visual indicator remains open after the device is turned off.
- Be careful of biohazard when performing inspection procedures. To prevent the spread of the disease.
- The system is not suitable for eye or the examination that may cause the sound beam through the eye.
- The instrument should be used with caution to patients with burns or other external skin damage.
- The device cannot be used for a long time to check the fetus.
- This instrument may cause blurred images if the patient has too much gas in the gastrointestinal tract.
- After examination of each patient, thoroughly clean the probe and reusable accessories and disinfect or sterilize as needed.
- The possibility of system interference with pacemakers is small. However, since this system generates high frequency electrical signals, the operator should be aware of the hazards that this interference may cause.
- There is no risk of burns in normal ultrasound, even when the temperature of the probe surface exceeds the patient's temperature due to the ambient

temperature and inspection mode. To avoid burns, do not expose the probe to the same part of the patient's body for extended periods of time.

In the conditions to meet the diagnosis, try to shorten the inspection time.

- Diagnostic scan is not allowed during device charging.
- Any accessories (such as couplers) used in conjunction with the system must meet the appropriate industry standards and be approved for listing.

1.6 Operator safety

Operator requirements

Only qualified doctors, medical personnel familiar with ultrasound technology or sound spectrum tester may perform the scanning for the patient, unauthorized personnel shall not indiscriminately use the device.



Improper operation of this system may result in the risk of injury to the operator. Only the qualified personnel of our company will be allowed to unpack the equipment and perform the initial system installation. Do not attempt to install the unit yourself.

- Risk of electric shock. Do not attempt to disassemble the system yourself.

Repairs and internal adjustments may only be made by qualified personnel of our company.

- Before cleaning equipment, one should shut down the system to prevent electrical leakage.

- To avoid the operator's hand, wrist or arm fatigue, please note the following :

- 1) Keep the body in a balanced position during the scanning operation.

- 2) During operation, avoid long periods of repetitive operations, regular breaks to relax the muscles.
- 3) Do not force the probe too hard to avoid the operation in an uncomfortable posture caused by the operator hand, wrist or arm fatigue.

1.7 Safety of the Probe



- If the probe falls or collides with the object, do not use the probe until the electrical leakage test confirms that the electrical safety is not impaired.
- Do not immerse the entire probe in the liquid to clean it. Since the probe plug does not have a waterproof function, this may cause an electric shock or malfunction of the probe.
- Using the probe with caution, damage to the probe may increase the risk of electric shock. Always check for cracks or openings on the shell of the probe, whether there are holes inside or around the sound lens, or other damage to allow water to flow into the probe.
- If the contact surface of the probe is scratched, immediately stop using the probe and contact your sales office or dealer. If you use a scratched probe, there is a risk of electric shock.
- Avoid bending or twisting the probe cable so that it will not crack or damage the probe shell, or that the electrical performance of the probe will be affected by the breakage or exposure of the cable.



- Never disinfect the probe with steam, heating or liquid sterilization methods, which will cause permanent damage to the probe.
- Do not connect or disconnect the probe during real-time scanning; the system must be in freeze mode or the system is switched off before connecting or disconnecting the probe.
- Repeated disinfection will lead to the safety of the probe and performance degradation, should regularly check the performance of the probe.

1.8 Electrical Safety



- The ultrasound system must use the matching power adapter.
- When the system is used in conjunction with a high-frequency device (such as a surgical electrode), surgical instrument failure or damage to the probe lens may result in a surgical electrode burned to the patient.
- Remove the probe and heart rate display waveforms from the patient before performing electrical shock defibrillation.
- The system uses high frequency signal. Pacemakers interfere with these signals. Users should be aware of potential hazards and should immediately turn off the equipment if they are found or suspected of interfering with the pacemaker operation.
- All the input / output terminals of this machine can only be connected with

the equipment complying with EN 60601-1. If the equipment is connected with the equipment complying with other relevant national standards, the whole system should meet the requirements of EN 60601-1.

- The components of this equipment and all accessories at the end of their service life cycle in accordance with local environmental laws and regulations to deal with.
- The components of this equipment and all accessories at the end of their service life cycle in accordance with local environmental laws and regulations to deal with.
- All repairs must be made by our company. Therefore, this equipment is not equipped with the corresponding circuit diagram. If the customer has this need, please contact your local distributor or our company.

1.9 EMC

All types of electronic equipment may cause electromagnetic interference to other equipment through air or connecting cables. The term “electromagnetic compatibility (EMC)” means the ability of a device to suppress the effects of electromagnetic interference generated by other devices while not affecting other devices by similar electromagnetic radiation. Radiation or conductive EMC may distort, degrade, or artifact the ultrasound image, making the diagnostic information obscure. The Company does not guarantee that interference will not occur during the installation. Turn the device on and off to determine if the device is generating interference or reactive to interference.

Personnel should attempt to resolve a problem by taking one or more of the following measures:

- Adjust the location or direction of the affected equipment.
- Increase the distance between the equipment and the affected equipment.

- Use a different power supply than the affected equipment to supply the equipment.
- Consult the authorized representative for additional recommendations.

The manufacturer is not responsible for any interference or reaction caused by the use of an interconnected cable other than the recommended cable, or unauthorized alteration or modification of the equipment. Unauthorized changes or modifications may void the user's authority to operate this equipment.



Please install and use the product according to the contents in the manual. If the product is not installed and used according to the instructions in the manual, the safety and electromagnetic compatibility performance will not be expected to decrease. The manufacturer will not bear this risk.



Portable and mobile radio frequency communication equipment may affect the normal use of the product. Equipment standard accessories cable is listed in the following table, if any failure, should contact our company for repair or replacement, or may cause excessive electromagnetic interference.

Product standard accessories cable

| Accessories Cable name | Accessories Model | Cable length (m) | Cable shielding | Manufacturers | Notes |
|---------------------------|----------------------|-----------------------|-----------------|---------------|-------|
| Probe cable | / | 3 | Yes | / | / |
| | | | | | |



In addition to the standard accessories sold by the manufacturer of the product as spare parts for internal components, the use of non-specified accessories may result in an increase in the emission of the product or a reduction in the immunity, and the

manufacturer does not bear this risk.



The product should not be used in close proximity to, or stacked with, other equipment. If it must be used close or stacked, verify that it is functioning properly in its intended configuration.

This product declaration meets the requirements in Table 1-Table 3

Table 1

| Guidance and manufacturer's declaration - electromagnetic emission | | |
|--|------------|---|
| The equipment is intended to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment | | |
| Launch experiment | Conformity | Electromagnetic Environment - Guide |
| Radio frequency emission IEC/CISPR11 : 2010 | 1 | The device uses RF energy only for its internal functions. So its RF emission is very low, and the possibility of interference with electronic devices is very small. |
| Radio frequency emission IEC/CISPR11 : 2010 | A | This equipment is suitable for use in all facilities that are not directly connected to the public low voltage power supply network for domestic and domestic dwellings |
| Harmonic emission IEC61000-3-2 : 2014 | NA | |
| Voltage fluctuation / flicker emission IEC61000-3-3 : 2013 | NA | |

Table 2

| Guidance and manufacturer's declaration - electromagnetic immunity | | | |
|--|--|--|--|
| This equipment is intended for use in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment | | | |
| Immunity test | IEC 60601 Test Level Guide | Coincidence level | Electromagnetic Environment - A Guide |
| Electrostatic discharge IEC 61000-4-2 | ±6 kV Contact discharge ±8 kV Air discharge | ±6 kV Contact discharge ±8 kV Air discharge | The floor should be wood, concrete or tile, if the ground is covered with synthetic material, the relative humidity should be at least 30% |
| Electrical Fast | ±2 kV On the power cord | NA | The network power supply |

| | | | |
|---|---|-----------|---|
| Transient Burst IEC 61000-4-4 | ±1 kV On the input and output lines | | should have the quality that is used in a typical commercial or hospital environment |
| surge IEC 61000-4-5 | ±1 kV Line to line ±2 kV Line to ground | NA | The network power supply should have the quality that is used in a typical commercial or hospital environment |
| Power input line voltage sags, short interruptions and voltage changes IEC 61000-4-11 | <5% 220V for 0.5 weeks (> 95% sag at 220V) 40% 220V for 5 weeks (60% sag on UT) 70% 220V for 25 weeks (30% drop on UT) <5% 220V for 5s (> 95% sag at 220V) | NA | The network power supply should have the quality that is used in a typical commercial or hospital environment. If the user of the all-digital hand-held ultrasonic diagnostic apparatus needs continuous operation during a power outage, it is recommended that the all-digital hand-held ultrasonic diagnostic apparatus be powered by an uninterruptible power supply or battery |
| Power frequency magnetic field (50/60Hz) IEC 61000-4-8 | 3A/m | 50Hz 3A/m | The power frequency magnetic field shall have the characteristics of the power frequency magnetic field level typical of a typical commercial or hospital environment |

Table 3

| Guidance and manufacturer's declaration - electromagnetic immunity | | | |
|---|----------------------|----------------------|--|
| This equipment is intended for use in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment | | | |
| Immunity test | IEC 60601 Test level | Coincidence level | Electromagnetic Environment - A Guide |
| Radio frequency | 3V(Valid values) | 3 V(Valid | Portable and mobile RF communication equipment should not be closer than the recommended separation distance. Any part of a fully digital handheld ultrasonic diagnostic instrument shall include a cable which shall be calculated using the formula |


| | | | |
|--|--|-------------------------------|---|
| <p>conduction IEC 61000-4-6 Radio frequency radiation IEC 61000-4-3</p> | <p>150 kHz ~ 80 MHz 3 V/m 80 MHz ~ 2.5 GHz</p> | <p>values) 3 V/m</p> | <p>corresponding to the frequency of the transmitter. Recommended isolation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz ~ 800 MHz $d=2.3\sqrt{P}$ 800 MHz ~ 2.5 GHz 式中： P —— Maximum transmitter output power, in watts (W), provided by the transmitter manufacturer ; d——Recommended separation distance in meters (m). The field strength of a fixed RF transmitter is determined by survey of the electromagnetic field, and each frequency range b should be lower than the coincidence level. Interference may occur near the device that signs the following symbols </p> |
| <p>Note 1: At 80 MHz and 800 MHz frequencies, the formula for the higher frequency band should be used. Note 2: These guidelines may not be appropriate for all situations. Electromagnetic transmission by the buildings, objects and the body's absorption and reflection.</p> | | | |
| <p>1. Stationary transmitters, such as wireless (cellular / cordless) telephones and terrestrial mobile radio base stations, amateur radio, AM-FM radio, and television broadcasting, are not theoretically predictable. In order to assess the electromagnetic environment of fixed RF transmitters, consideration should be given to the investigation of electromagnetic fields. If the measured all-digital portable diagnostic ultrasound system where the field strength is higher than the RF compliance level, you should observe all-digital handheld ultrasonic diagnostic apparatus to verify its normal operation. If anomalous performance is observed, supplemental measures may be necessary, such as reorienting the orientation or position of the all-digital hand-held ultrasonic diagnostic apparatus. 2. The field strength should be less than 3 V / m over the entire frequency range from 150 kHz to 80 MHz.</p> | | | |

Table 4

| | |
|---|---|
| <p>Recommended separation distance between portable and mobile RF communication equipment and this equipment</p> | |
| <p>This equipment is intended for use in a controlled electromagnetic environment where RF emissions are disturbed. Depending on the maximum output power of the communication device, the purchaser or user of the device may prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communication devices (transmitters) and the device.</p> | |
| <p>Transmitter maximum rated output power</p> | <p>Corresponding to the different frequencies of the transmitter isolation distance/m</p> |

| W | 150 KHz ~ 80 MHz $d=1.2\sqrt{P}$ | 80 MHz ~ 800 MHz $d=1.2\sqrt{P}$ | 800 MHz ~ 2.5 GHz $d=2.3\sqrt{P}$ |
|------|-------------------------------------|-------------------------------------|--------------------------------------|
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters maximum ratings not listed above, the recommended separation distance, d, in meters (m), can be determined using the formula in the corresponding transmitter frequency column, where P is the transmitter provided by the transmitter manufacturer The maximum rated output power in Watts (W).

Note 1: At the 80 MHz and 800 MHz frequency points, the formula for the higher frequency band should be used.

Note 2: These guidelines may not be appropriate for all situations. Electromagnetic transmission by the buildings, objects and the body's absorption and reflection.

1.10 ALARA Principle (As Low As Reasonably Achievable)

Ultrasound should obey the ALARA principle, use the lowest level of energy that does not lead to biological effects, provided that satisfactory diagnostic information is available. Ultrasonic energy depends on the size of the output intensity and exposure time. Different patients and clinical cases require different intensity of ultrasound. Not all inspections can be done by outputting very low energy ultrasound. Very low energy ultrasound will only produce low-quality images or weak Doppler signals, thus affecting the reliability of diagnosis. However, the use of more than actual needs of the acoustic power does not help to improve the quality of information used for the diagnosis, but will increase the risk of biological effects.

When obtaining clinical information, the user should perform the ultrasonic inspection procedure with the lowest output level and irradiation time according to the principle of small size (ALARA) when a satisfactory clinical diagnostic map is available.

1.11 Safety Statements

Although it has been shown that there is no harmful biological effect of the ultrasonic frequency, intensity, and radiation time used during the inspection using this system, we recommend the use of the lowest acoustic output setting in order to produce satisfactory diagnostic information.

See Appendix A for acoustic output data of the system.

1.12 Biological Effects

In recent years, with the rapid development of ultrasonic diagnostic technology, people are increasingly concerned that the application of ultrasound and diagnostic techniques may lead to biological effects in the potential risks. So far, it is generally believed that the diagnosis of ultrasound is safe. There have also been no reports of any human injury caused by ultrasound. In spite of this, we can not arbitrarily believe that all of the ultrasound is absolutely safe. Research has confirmed that high-intensity ultrasound on human tissue is harmful.

User's Manual Main Volume

Chapter 2 System composition and characteristics

2.1 System composition

Digital Portable Diagnostic Ultrasound System contains the host(include display), software, probes, batteries .

The number of elements of the L10-5 probe is 128 elements, the center frequency is 7.5MHz, the length of curvature is 40mm, scanning mode is electronic linear array scanning.

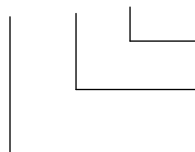
The number of elements of the C5-2 probe is 128 elements, the center frequency is 3.5MHz, the radius of curvature is 60mm, scanning mode is electronic convex array scanning.

2.1.1 Specification of product specification and its division

Model : C-SCAN

Model Description

C-SCAN



Product subclass code: L-linear array/ C-convex array

Product family code

Product Name Code: Digital Portable Diagnostic Ultrasound System

E.g. C-SCANL means Digital Portable Diagnostic Ultrasound System with L-linear array

2.1.2 Performance

Device specifications

- Volume : 165.3 x 85.4 x 19.8 mm
- Probe length : 1150 mm
- Weight : L:550g/C:570g
- Display size : 6 inch LCD

Power specifications

- Power supply : DC3.8V , 2500mA
- Lithium battery capacity : 5400mAh
- Charging conditions : AC/DC power adapter , input : AC100V-240V ,
50/60Hz ; output : DC5V , 2000mA

B model Performance :

B mode

| | | | |
|------------------------------|----------------------------|---|---|
| Probe information | Probe Type | Convex array (type : C5-2) | Linear array (type : L10-5) |
| | Radius of curvature | 60mm | -- |
| | Probe center frequency MHz | 3.5 | 7.5 |
| Image performance indicators | Sound operating frequency | The deviation of the sound operating frequency from the nominal center frequency shall be within $\pm 10\%$, i.e. the frequency range is from 3.15 to 3.85 MHz | The deviation of the sound operating frequency from the nominal center frequency shall be within $\pm 10\%$, i.e. the frequency range is from 6.75 to 8.25 MHz |

| | | | |
|--|--|---|------------------------------|
| | Maximum detection depth (mm) | ≥ 160 | ≥ 50 |
| | Lateral resolution (mm) | ≤ 3 (depth ≤ 80) ≤ 4 ($80 < \text{depth} \leq 130$) | ≤ 2 (depth ≤ 40) |
| | Axial resolution (mm) | ≤ 2 (depth ≤ 80) ≤ 3 ($80 < \text{depth} \leq 130$) | ≤ 1 (depth ≤ 50) |
| | Blind spot (mm) | ≤ 5 | ≤ 3 |
| | Slice thickness (mm) | ≤ 8 | ≤ 5 |
| | Horizontal geometric position accuracy (%) | ≤ 15 | ≤ 10 |
| | Vertical geometric position accuracy (%) | ≤ 10 | ≤ 5 |
| | Area measurement error (%) | Within ± 15 | Within ± 10 |

Color Flow Mode

| | |
|----------------------------|--|
| Repeatability | Color images without overflow Color image and gray-scale map dislocation $< 1/4$ diameter (transient dislocation phenomenon does not count) |
| Flow direction recognition | Can correctly identify the direction, no aliasing |

Working Storage Conditions

- **Working environment**
- **Ambient temperature : 5°C ~ 40°C**
- **Relative humidity : 30%~75% (No condensation)**
- **Atmospheric pressure : 700hPa~1060hPa**
- **Storage environment**
- **Ambient temperature : -10°C ~ 55°C ;**
- **Relative humidity : 30%~95% (No condensation)**
- **Atmospheric pressure : 700hPa ~ 1060hPa**

Functional requirements

- **Touch screen: capacitive touch screen control**
- **Imaging mode: B mode and C mode**
- **Image format : DICOM**
- **Image control: depth adjustable, gain adjustable, color gain adjustable**
- **Information display:**
 - frame rate real-time display**
 - Transmit frequency display**
 - TI-MI display**
 - Patient Information Display**
 - Measurements displayed**
 - Scanning Scenarios display**
- **Doctor Information:**
 - Doctor name**
 - Contact**
 - Name of hospital**
 - Position**

- **Patient Information:**
 - Patient name
 - Gender
 - ID number
 - Medical history
- **Application scenario: General, maternity**
- **Measurement information:**
 - Length
 - Area
 - Arrow
 - Angle
 - Perimeter
 - Text
- **Transmission system: WLAN transmission**
 - Internal storage

Battery life requirements

- **Charging time: not more than 5 hours (charging adapter output: DC5V / 2000mA).**
- **Continuous working time: not less than 1 hour.**

2.2 Intended use

L: The product is suitable for observation and diagnosis of human superficial tissue, small organs, peripheral vascular ultrasound image.

C: The product is suitable for observation and diagnosis of abdominal ultrasound images.

The expected use environment: conventional ultrasound diagnosis, emergency,

screening, field rescue.

Note:

1. *Do not use for fetal gender discrimination.*

2.3 Contraindications

Do not apply to the eye.

2.4 Target population

Target population: Adults, adolescents, pregnant women and fetuses (not used for fetal sex examination).

2.5 Lifetime

This product is designed to be used for a period of five years.

Chapter 3 System Appearance

3.1 System Appearance



Note:

- 1. Volume button:** Control the gain of main interface of scanning, that is, volume "+" is increased, the volume "-" is reduced.
- 2. Freeze / Start button :** Control the freeze / start of the scanning ; press the freeze/start button once can freeze the current scanning interface, press the freeze/start button again can start scanning; press the freeze/start button in other application interface, it can return to the main interface of scanning. Long Press the freeze / start button can turn off the scanning.
- 3. Power:** Long press the power button to turn on / off the device ; Reboot the device (press for 10s) ;

Short press to Sleep / light up the screen.

3.2 Introduction to Parts

Display / touch screen

- 6-inch LCD display, to ensure user comfort and eye fatigue.
- The control panel in the touchscreen contains all the touch buttons of the operating system as well as the alphanumeric keypad.
- The details are described in the operator panel.

Control button

- Convenient and flexible use of the principles of design and layout allows the operator easy, comfortable and efficient use. The control buttons contain quick buttons for use.



















The probe












- Probes are purchased in a medical device production qualification and registration certificate of the manufacturers, each C-SCAN system contain a linear/ convex array probe.

Charging interface

- The charging interface is located below the system, and the USB port charges the system.

Chapter 4 Operation Panel Function Introduction

| icon | name | function | Description | |
|---|------------------------|---|--|------------------|
|  | The initialization key | Initialize the system to scan | Power on the display | |
|  | Freeze key | Freeze the scanned image | The current state is the state of the scan | |
|  | Thaw key | Resume the scanned image | The current state is frozen | |
|  | Image flip key | Flip left / right of the current volume scanned image | The red dot on the left indicates the direction of the probe | |
|  | menu | Menu options | Red Reminds for the diagnosis of unread case files | |
|  | Save key | Save the current image information | Freeze display | |
|  | The Undo key | Undo the last action | | |
|  | Restore key | Restore Undo operation | | |
|  | Single frame mode key | Switch to multiframe mode | | |
|  | Multi-frame mode key | Switch to single frame mode | | |
|  | Slider | Manually drag the slider to view the image in a single frame; multi-frame mode, drag the position of the slider on both sides can be set to start the end of the image interception frame | | |
|  | Play key | Play back the scanned image | | |
|  | Pause key | Pauses playback of the scanned image | | |
|  | Local Scan Log | Mark it for local storage | | Storage type tag |
|  | Cloud scan record | Mark it for Cloud Save | | |
|  | Search key | Save the record search | Search by date and ID | |
|  | Close the search key | The search function is turned off | | |
|  | Clear the search | Search content is cleared | | |

| | | | |
|---|---|--|---|
| | bar | | |
|  | Batch processing keys | Batch processing of saved images | Can be deleted, save, compare and other operations |
|  | Sort key | Storage sort method | The default mode and sort by time |
|  | Show hidden keys | Overlay list can be selected to show or hide | Overwrite Shows or hides |
|  | Emergency key | emergency help | You can send link text messages |
|  | Camera key | Scanned area shooting | Record the current scan image of the scan site, for reference |
|  | Enter key | Confirm the reference image of the scan site | |
|  | Add a key to the teaching pack | Teaching function added | Teaching function-related operations |
|  | Download the teaching package | Teaching function download | |
|  | Instruction Pack Delete key | Remove the instruction pack | |
|  | The current teaching package closes the key | Close the current tutorial package | |
|  | Teaching interface close button | Close the current teaching interface | |

Chapter 5 Storage and Transportation of the System



Do not turn ON the unit's power switch until all system connections and installation preparations have been completed.

5.1 Environment requirement



If you use a device that emits radio waves around your device, this device may malfunction.



Do not operate devices that emit radio waves themselves around the device; for example, portable telephones, radio-controlled toys, and so on.

The person in charge of the device must inform the technician, the patient, and others who may be present around the device to comply fully with the recommendation.



The system has been tested to meet the relevant standards of anti-radio interference, can be used in hospitals, clinics and other medical establishments.

Users need to regularly maintain the operating environment of the system. Ensure the site is ventilated and in good condition. The operating environment should meet the

following conditions:

| | |
|----------------------|---|
| Ambient temperature | 5°C - 40°C |
| Relative humidity | 30% ~ 75% |
| Atmospheric pressure | 700hPa~1060hPa |
| Working Environment | CAUTION: Avoid use in high temperature climates, and malfunction may occur. |

5.2 Power requirements



Operating the equipment in the wrong voltage range will cause equipment damage, we are not responsible for warranty maintenance caused by such situations.



To ensure stable operation of the instrument, the C-SCAN system should use a standard adapter, ensuring that the power supply system is working properly.

The charging power supply system meets the following requirements :

| standard | Metric value |
|----------------|--------------|
| Voltage | 100 - 240V |
| Line frequency | 50HZ |

5.3 Storage and transport conditions

Transport

After the packaging of digital portable diagnostic ultrasound system products can use

the general means of transport, but should prevent severe shock and vibration in the transport, and should be moisture-proof, rain-proof measures.

Storage

Packaged digital portable diagnostic ultrasound system should be stored in a room that meets the conditions in the table below and in a well-ventilated room.

| | |
|----------------------|--------------------------|
| Storage conditions | -10°C-55°C |
| Storage humidity | ≤90% (No condensation) |
| Transport conditions | (-10°~55°) |

5.4 Mobile devices



Avoid the operator's wet hands moving system.

Mobile Device Steps:

- Turn off the system, including turning off the power switch and unplugging the power plug.
- Disconnect all cables between the system and any peripheral devices (not including the board-like peripherals) and the network.
- Place all probes in a safe environment to avoid bumps.
- Make sure that no spare parts are left on the device.
- Mobile devices.

5.5 Transport equipment



Before transporting, make sure the equipment is ready.

Shipping equipment steps:

- Disconnect charged connections and place them in the box.
- Park the vehicle on a flat surface to facilitate loading and unloading.
- Secure the unit so that it does not shake. Place a pad underneath the device and tie it under the strap to prevent it from falling apart or moving.
- The vehicle should be speed limited, and ensure that no debris on the road, so as not to damage the equipment due to vibration.

When transporting this system, the following precautions should be observed:

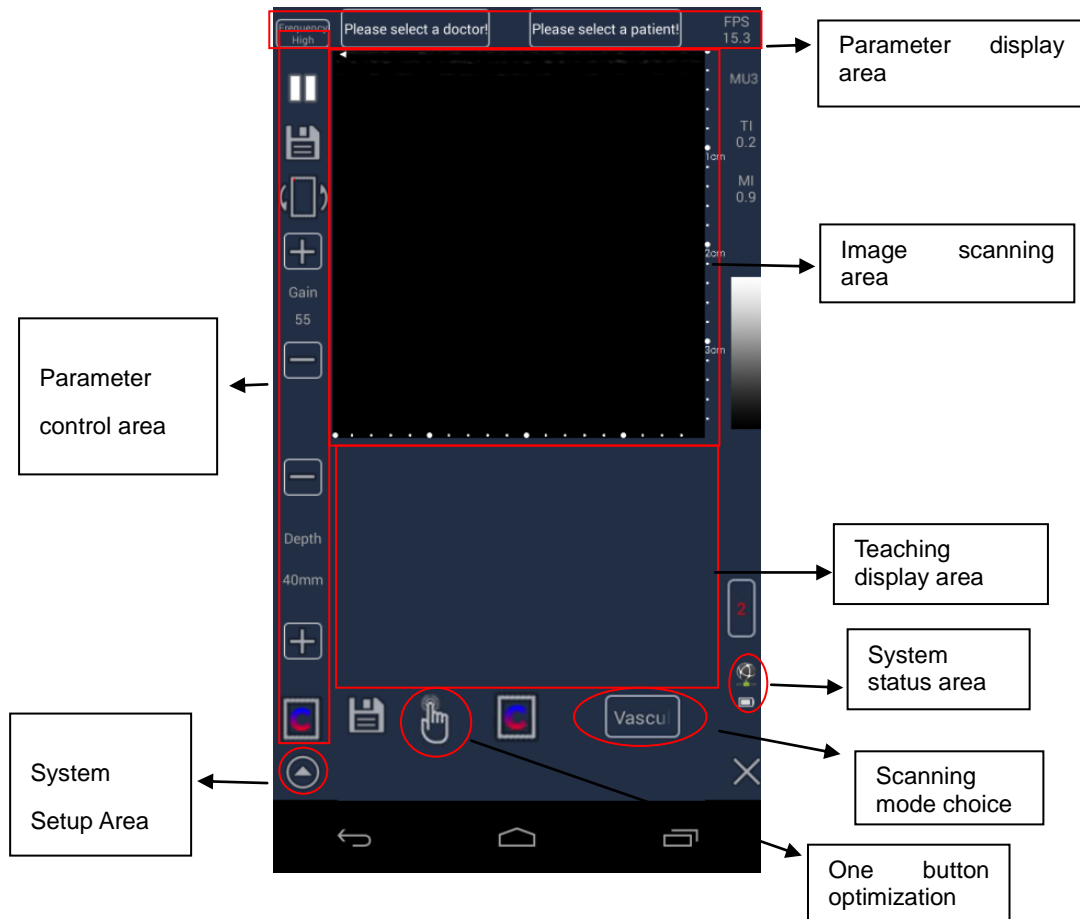
- A. Ensure that the system is powered off.
- B. When passing through the gate post or entering and exiting the elevator, avoid unnecessary vibration of the unit.

When transporting the system using a vehicle, observe the following precautions :

- When moving, disconnect all cables connecting the system and place the probe in the original packaging box.
- For mobile systems, ensure that the probe and the device are secured during movement.

Chapter 6 Basic Screen Layout and Menus

The factory default setting linear/Convex array probe B-mode image settings. Boot interface shown below :



6.1 Parameter display area

The parameter display area mainly displays the current scanning probe frequency, current user ID, current time, patient ID information, TI, MI value.

6.2 Image scanning area

The image area displays the ultrasonic image, the image scale, the gray scale bar and

the direction of the probe marks.

6.3 Parameter control area

The parameter control area shows the image parameters of the currently active application, including depth, gain, and freeze.

6.4 Teaching display area

The teaching display area shows teaching functions in different positions, including physiological anatomy, manipulation practice, and reference for manipulation photos.

6.5 System Setup Area

The system setting area is used to check and set patient archive, biopsy, special, settings and about parameters.

6.6 System status area

System status area is used to show the current system battery power, network connectivity.

6.7 Scanning mode choice

For Convex, the scanning mode choice is general and obstetrics. For Linear the scanning mode choice is small parts, muscle, vascular and superficial (It will change into Transverse and full screen interface .when double checking or pressing return button,it will exit from full screen)

6.8 One button optimization

This button is to calibrate the image effect of black and white to the best condition.

Chapter 7 Turning on / off the system

7.1 Check before starting

Please check before boot:

- The probe line is normal.
- Whether the system is normal.
- Battery power level.

7.2 Turn-on procedure

- Long press the power button.
- Wait for the system to boot.
- Start the display panel control system.

7.3 Check after booting

Checking after the booting

- No abnormal noise, black screen or flashing in the system image area.
- The time and date display is normal.
- Touch the surface of the probe without finding abnormal heating phenomenon
- The indicators on the front panel display normally.

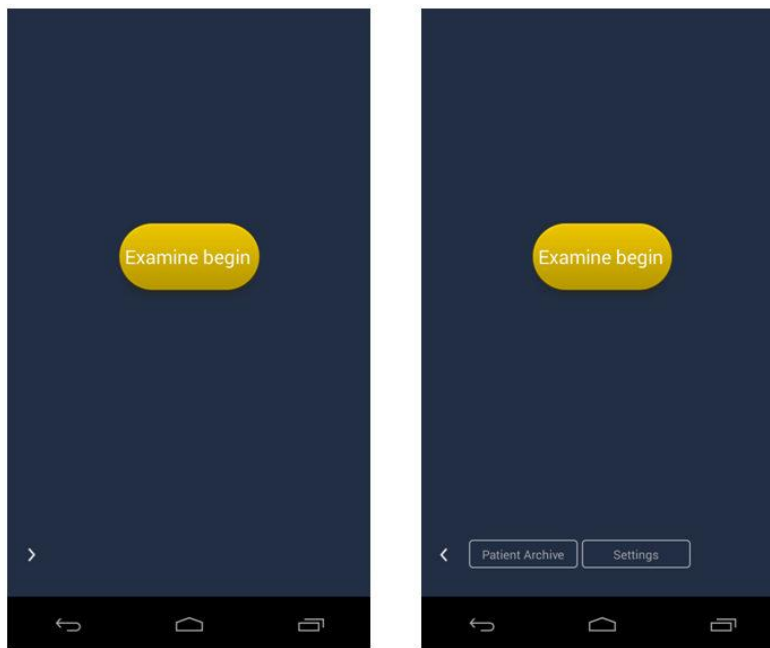


If you use the abnormal heat of the probe, that may burn the patient.

If any abnormality is found, it indicates that the unit is defective. Please immediately shut down and contact the company's sales offices, customer service or agents.

7.4 System Settings

When open the system for the first time, enter into the main interface.



7.4.1

Click System Settings to enter the system settings. Mainly to set the following parameters: set the date and time, WLAN settings, screen brightness and so on.

Time display format is [hour: minute: second]. Manually click on the "Settings" to find the "date and time" click to enter, if the network works normally, select "check automatically determine the date and time" to automatically update to the current date and time, or uncheck the box, manually click the "set time" pop-up box at the hour and minute position, slide up and down to set time.

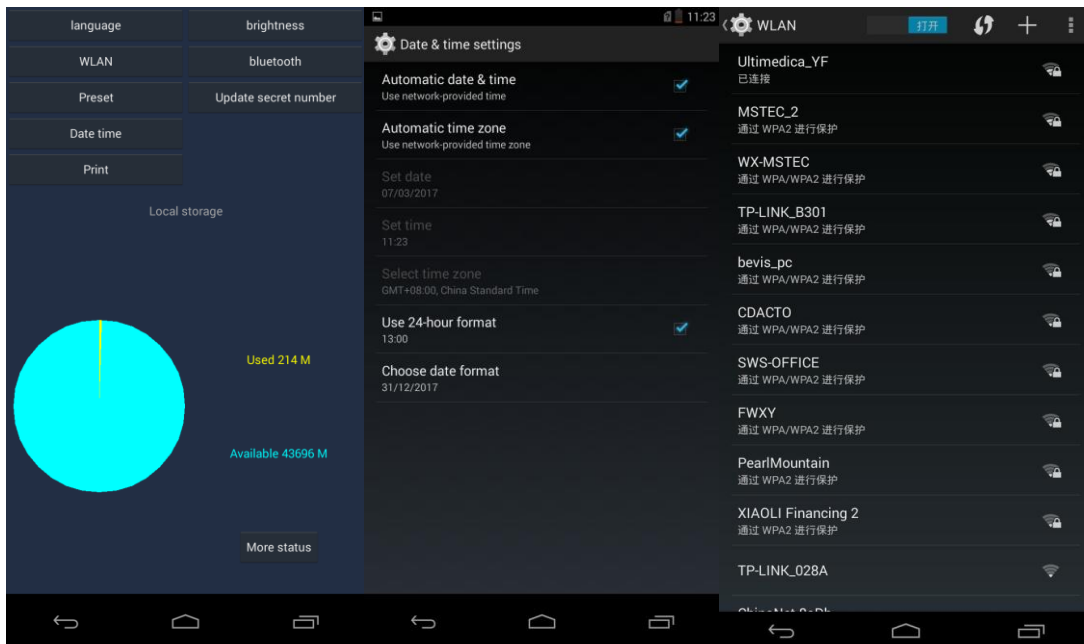
Go to "Settings" in WLAN, and search out a series of network, select a network and enter password to connect. After successful connection, the scanning application can consequently be used with WLAN login.


Enter "Settings", select "Display", click "screen brightness" to adjust the brightness.

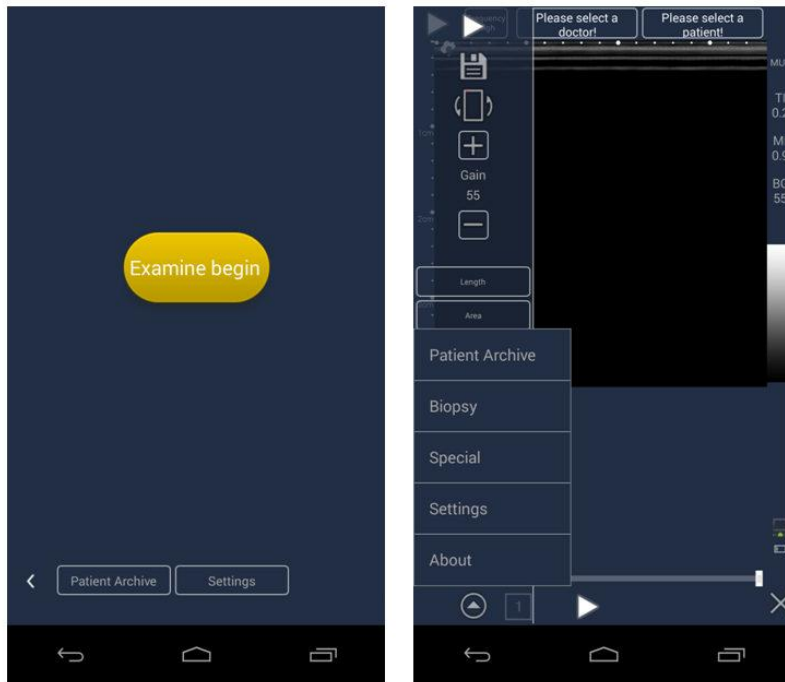
Adjusting the contrast and brightness of the display is one of the important factors in obtaining high-quality images. If these controls are not set correctly, you may need to adjust the gain frequently to achieve the desired image.

You can do the following steps:

- Adjust the contrast and brightness of the display as needed.
- Adjust the gain according to the clinical application and personal vision needs.



Click "Examine begin" or click the home button  or press the freeze start button (Figure 7.4.1) to enter the main interface of scanning.



7.5 Shut down the system

Press and hold the shutdown button to turn off the system.

When the system displays the shutdown screen, it indicates that the system is turned off



Before shutdown, it is recommended to freeze the image and save the useful images in case that the data are damaged or lost during the shutdown.

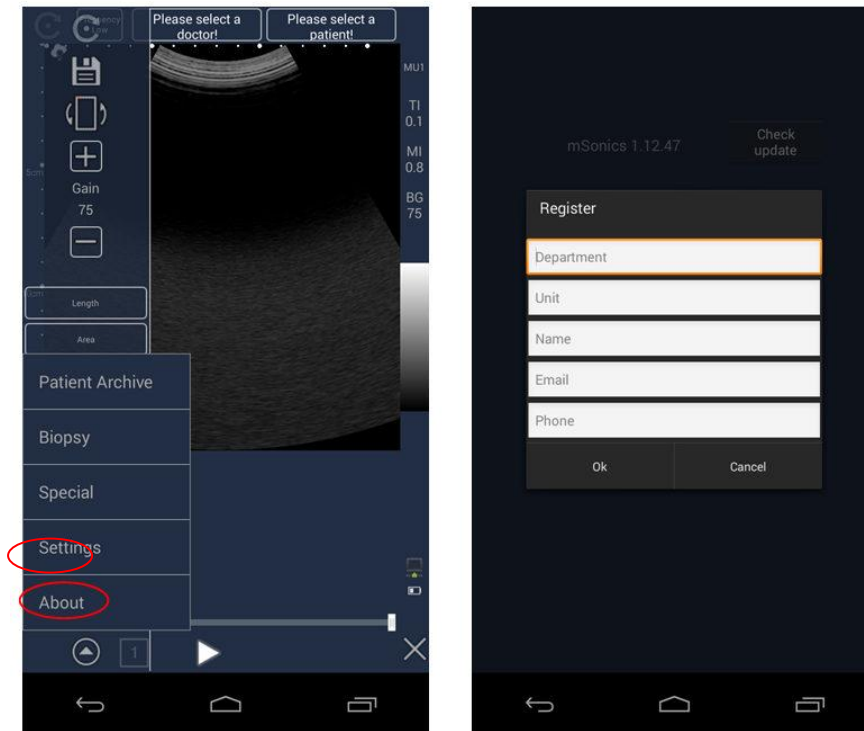


Shutdown process will last for dozens of seconds.

After turning off the system, wait at least 2-3 minutes before turning on the system

again.

7.6 Software Update

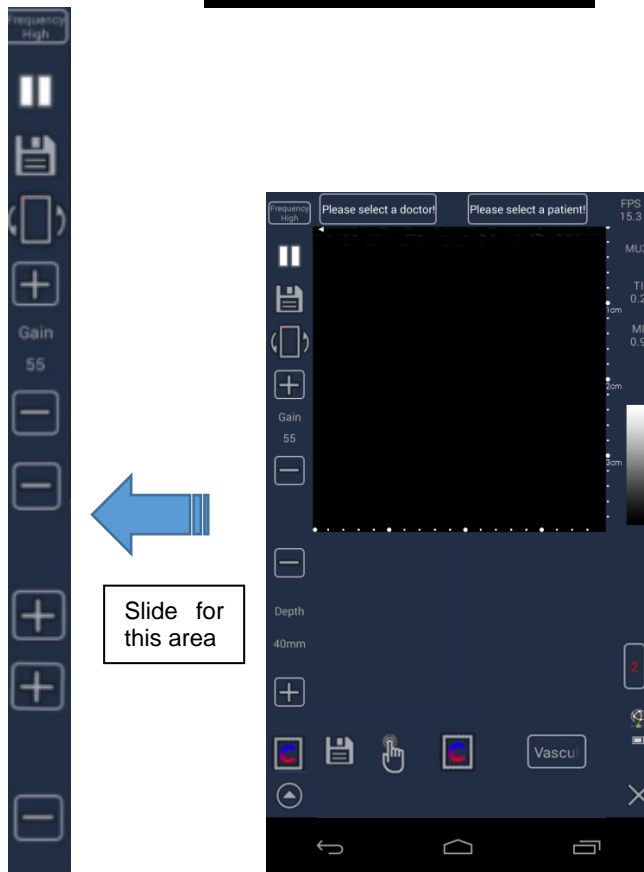
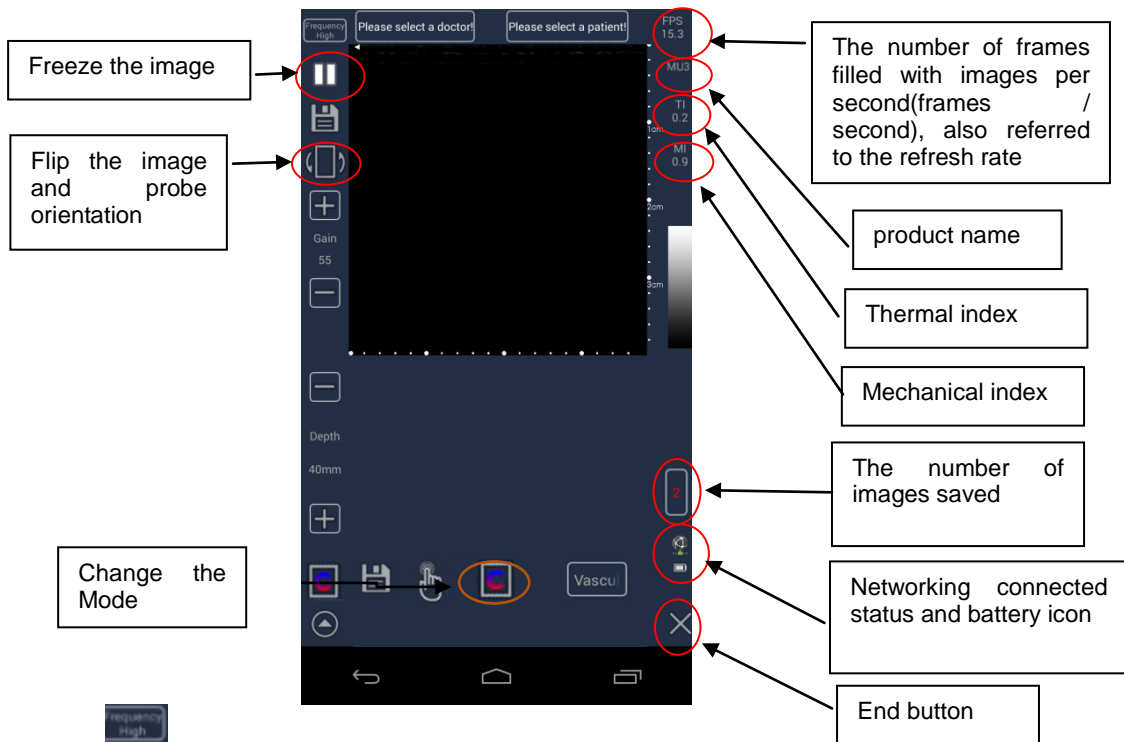


Enter the main scanning interface and unfold the menu, click about, then click check update, fill in the blanks with your information. The update will be initialized.

Chapter 8 Clinical Application Types

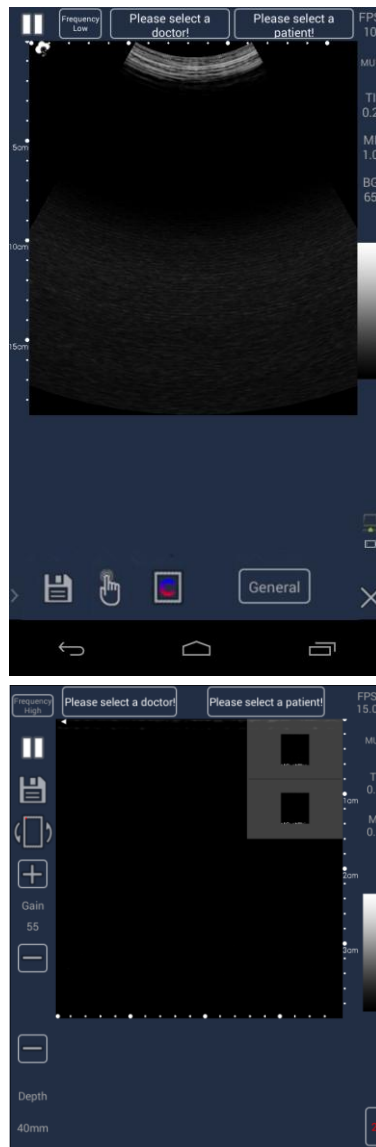
8.1 B mode scanning

Linear: The system has different scanning scenarios, corresponding to different clinical application types. Linear array probe clinical scene: small organs, muscles, blood vessels, superficial.






8.1.1


Convex: The system has different scanning scenarios, corresponding to different clinical application types. The clinical scene of the convex array probe: General, Obstetrics.

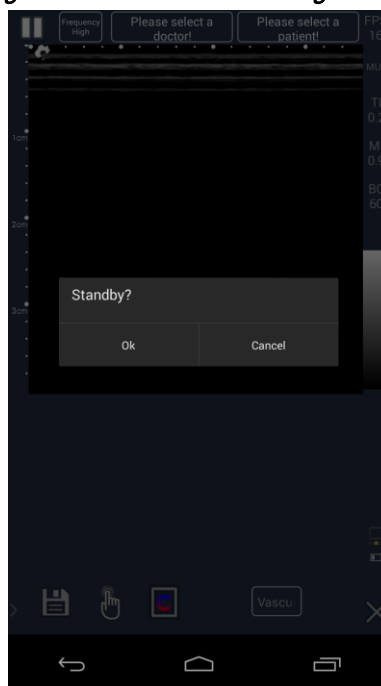


In clinical scanning, for different scanning scenarios, the operator only needs to select the marked area on the bottom of the screen, and the corresponding measurement functions are common in different scenarios.

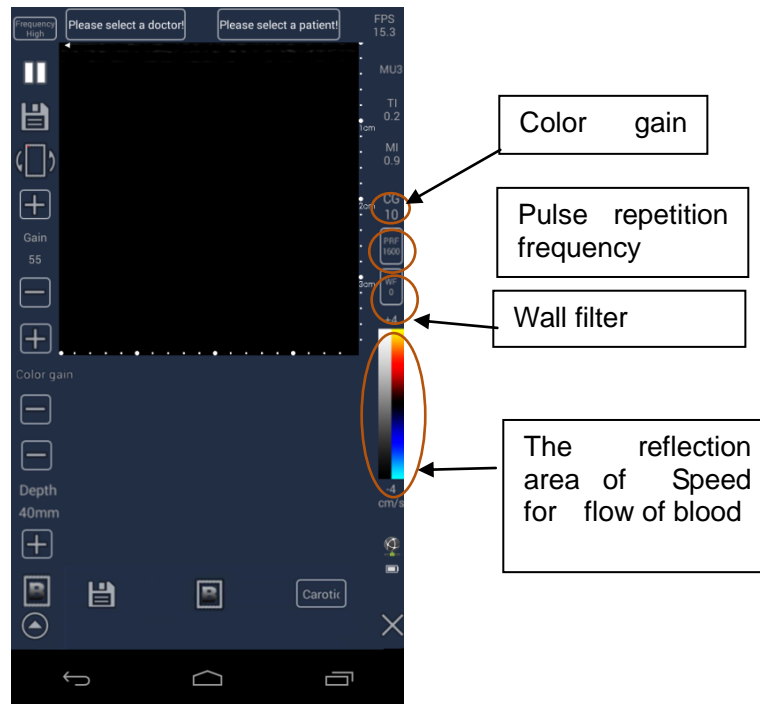
Note:

4. Press "probe frequency" can switch different probe frequencies during the scanning.
5. Press the Save icon  during the scanning can save the still image of the current frame , the red number on the right side shows the number of saved images, click the number can view the image list, clicking the number again, the list is hidden (Figure 8.1.1) .
6. In the interface of scanning, press the "flip" icon  on the left side, you can turn the image from left to right, and corresponding, flip the small triangle that shows the probe orientation.
7. In the interface of B mode scanning, press  to change from B mode into c mode, the real-time scanning mode will change from B mode to c mode(color doppler).
8. In the scanning state, you can adjust the relevant settings through the gain button (B mode, C mode)and color gain(C mode) on the left side and the depth button . You also can set the depth by gesture, sliding in the lower area of the scan area.

9. The left bottom is the menu button , click to pop-up menu options.
10. Press the bottom of the Small Parts, Muscle, Vascular, Superficial can choose the corresponding measurement mode , the default is "Vascular" mode. "Superficial" mode interface displays in a horizontal screen, and it displays a thumbnail image on the right side, Click to view.
11. Click "Please select a doctor" at the top of the screen to enter the doctor information list interface. It can add, select, modify the doctor information, add to the "Scanning Doctor" of the main interface after selecting a doctor.
12. Click "Please select a patient" at the top of the screen to enter the patient information list interface, you can add, select, modify the patient information, add to the "Patient" of the main interface after selecting a patient.
13. Click "X" the end button in the bottom right corner to end the scan and return to the main interface of application.
14. Long Press the Freeze Scanning button to make the scanning standby.




8.2 C mode scanning (for convex and linear)



8.2.1

Note:

In the interface of C mode scanning, press  to change from C mode (Figure 8.2.1) into B mode (Figure 8.1.1). The real-time scanning mode will change from C mode to B mode (color doppler).

Chapter 9 Measurements and application (For both linear and convex)

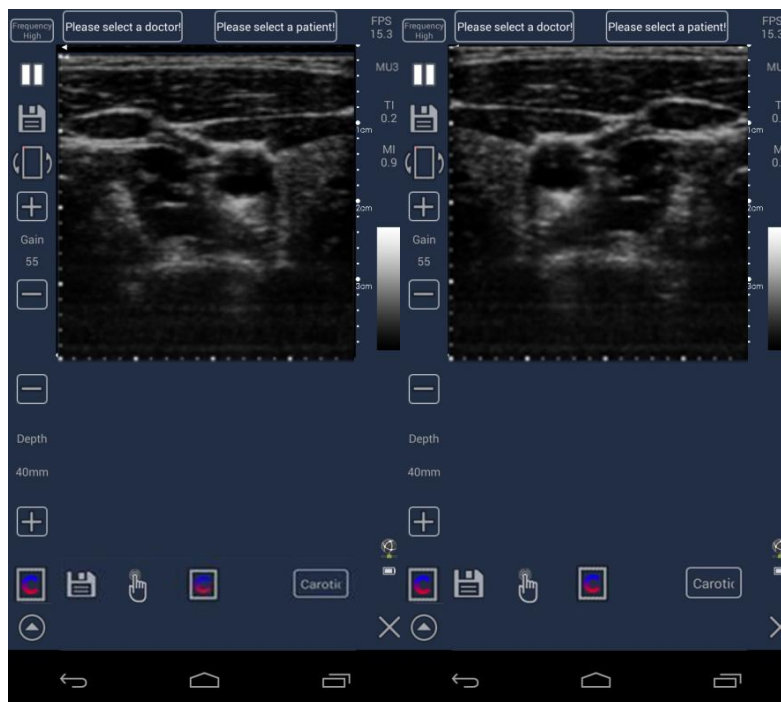
9.1 General scanning

Click the initialization key, the system enters the scanning state, real-time scanning status interface is shown in the left, click the left and right flip key, run the image as shown on the right.

The status of the frozen key is displayed when it is the real-time scanning status. Click the button to enter the frozen state, or press the physical button on the left side of the system.


Adjusting gain in real-time scanning mode: The adjustment range of gain is 0-150dB(convex)/0-120dB(linear), the step is 5, the greater the value, the greater the gain. Press the physical button, you can also adjust the strength of the gain.

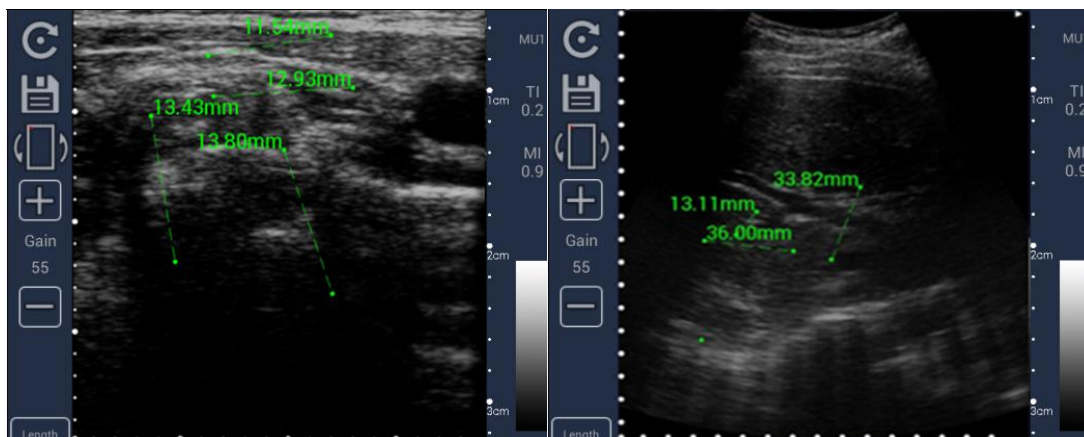
Adjusted depth in real-time scan: The depth can be adjusted in the range of 30-70(Linear) in [mm]/80-180(convex) in (mm).



9.2 Distance measurement

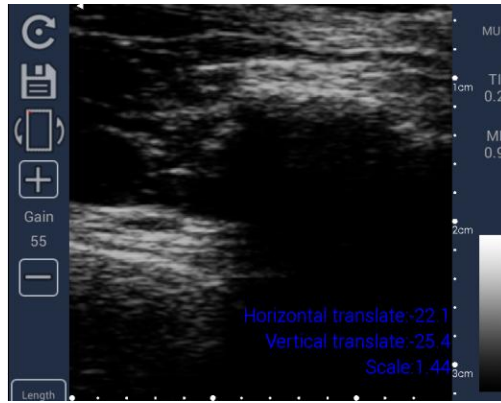
Length measurement: select the "length", the current state is red, the finger touches the screen and trigger a yellow solid dot above the finger, move the finger and the dot will follow until stopping at the specified coordinate point; touch the screen again, another dot will appear and move until stopping at another specified coordinate point to form a measurement line and mark the distance. Maximum 4 length distance lines can be formed.

Undo function: When problems occur during the measurement, the user can undo the operation, when you choose to cancel undo the last measurement, click the undo button .



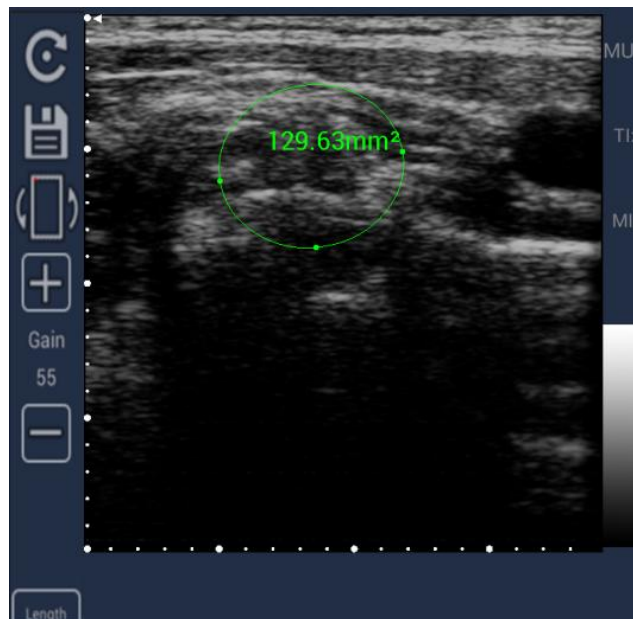
9.3 Enlargement and Translation

The image area receives a two-point touch for the enlarge translation operation. As shown below, the lower right corner will show the magnification and translation of the coordinates. The maximum enlargement is 2 times.



9.4 Area measurement

Select the "area", in order to locate the image area, select 3 points to determine an oval area, then the system automatically identifies the area of this selected region.



9.5 Arrow

Arrow function: select the "arrow", mark on the image, the first touch designates the location of the arrow and the second operation rotates the arrow to determine the direction of the arrow.



9.6 Angle

Arrow function: Select the "angle", determine the First point location with finger, use finger to determine another point, the two point will be connected with a straight line, then determine the third point with finger, this point will be connected with the first point in another straight line. The two line form an angle, and the data will show on the monitor.



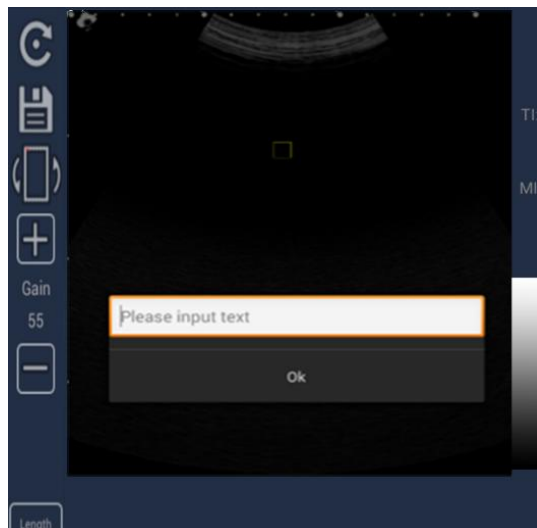
9.7 Perimeter

Select the "area", in order to locate the image area, select 3 points to determine an oval area, then the system automatically identifies the perimeter of this selected region.



9.8 Text

Select the "text", make a point at the scanning interface, it will show an inputting interface. Edit the text you want, after finishing. The text will show on the interface.

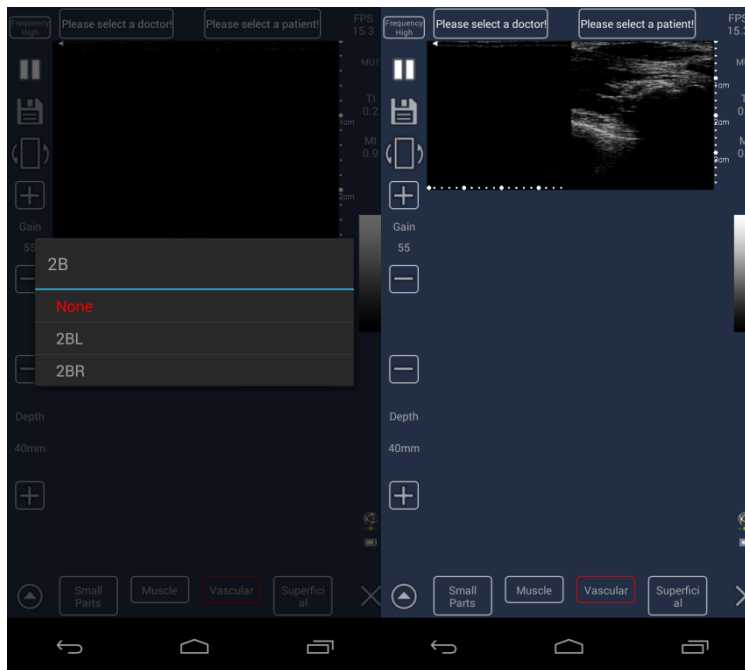


9.9 IMT

Select the "IMT", put the cube at the edge of the carotid, it will automatically measure the thickness of intima.



9.10 Special

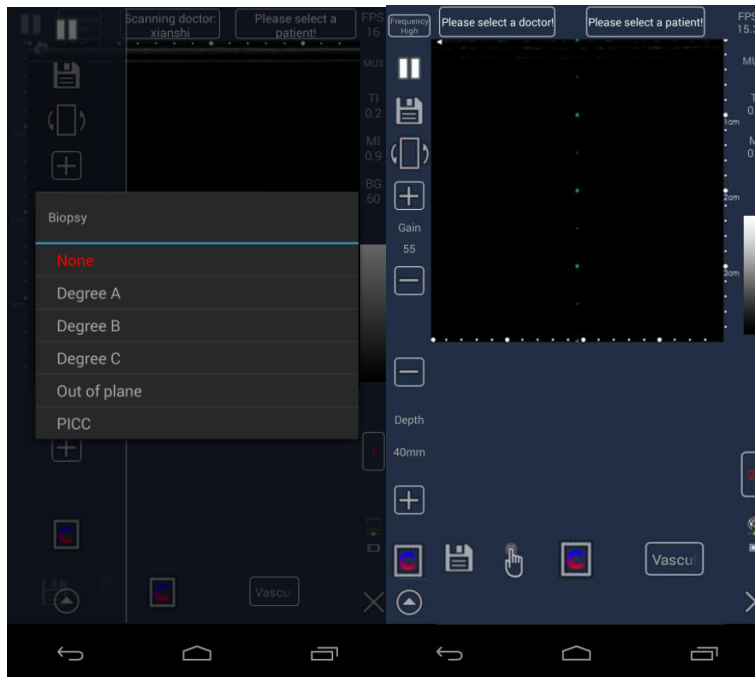


9.9.1

In the scanning interface menu, click "special" option to enter the 2B mode selection interface (Figure 9.9.1) , The default display is None.

Click "2BL" option to enter the 2BL interface (Figure 10.9.2) ; Click the "2BR" option to enter the 2BR interface ; Click the "None" option to return to the main interface of scanning.

9.11 Biopsy

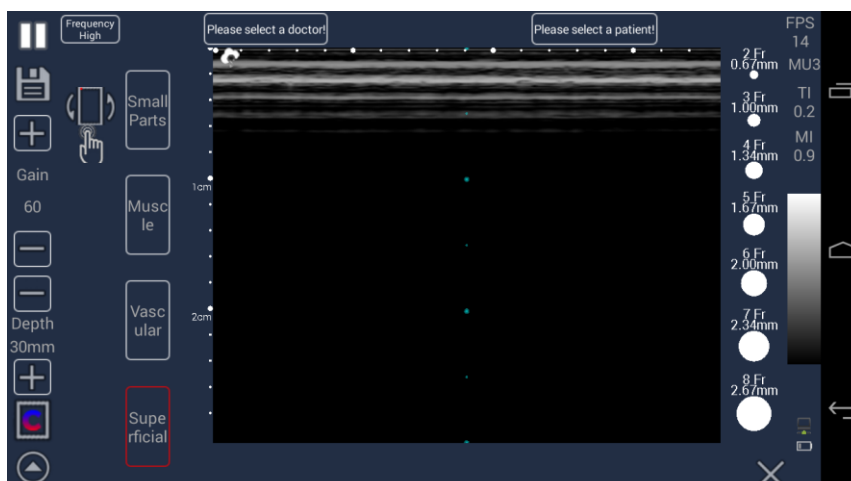


9.10.1

In the scanning interface menu, click biopsy to enter into the biopsy options interface (Figure 9.10.1). The default display is none.

Click "Degree A," "Degree B" and "Degree C" to select different angles.

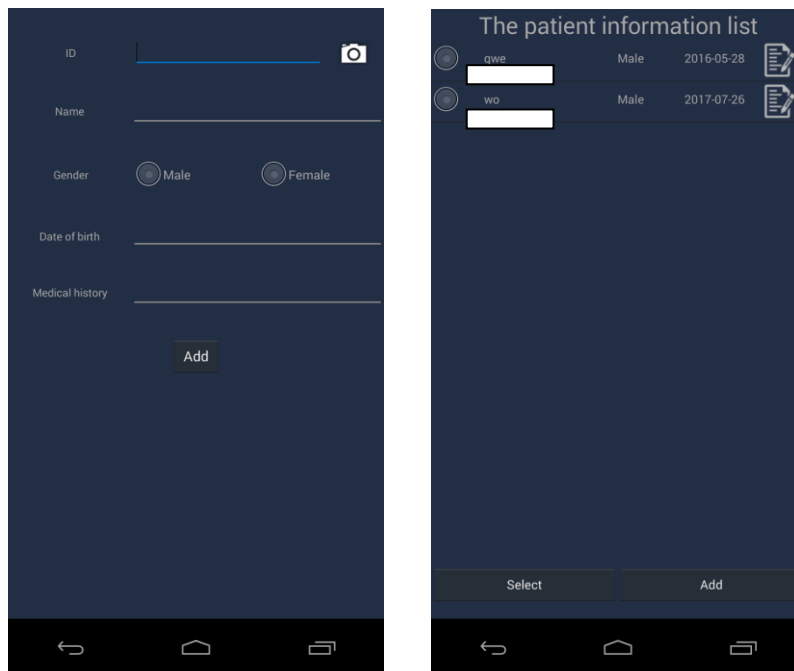
Click "PICC" to jump to the "Superficial" measurement mode interface. The interface will be transverse.



Chapter 10 Instruction and Storage

10.1 Patient Information Maintenance

Click " Please select a patient" in the upper right corner of the scanning interface to enter the patient information list interface .Click the 'Add' button to enter to edit Patient Detail interface (Figure 10.1.1) , Input relevant information of the patient and click the 'Add' button to save the patient information successfully , the added patient is displayed in the patient information list. In case of emergency, in the patient details editing interface click on 'add' can automatically create the patient information, jump to the main interface of scanning.




10.1.1

Click the Scan button  in the Patient Details Editing interface to add by scanning the ID or barcode.

Select a newly added patient, then click 'Select', the patient is selected as the current scanning patient, whose name is displayed in the "Patient" under the scan interface, the patient information is saved in the patient archive, when the scanning image was saved.

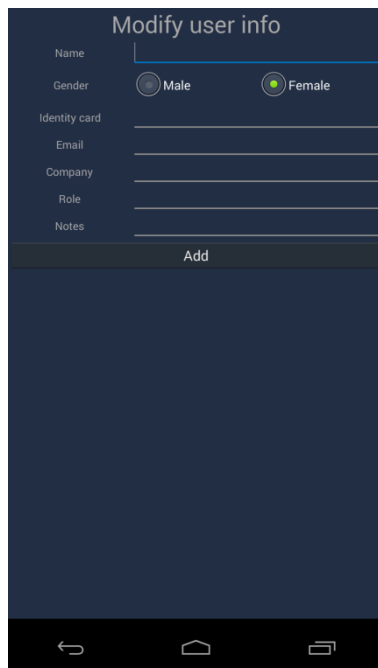
Need to scan another patient, click 'Patient' again to enter the patient information list interface, add a new patient information and select add patient to the 'patient' of main

interface of scanning, and you can directly to scan for another patient.

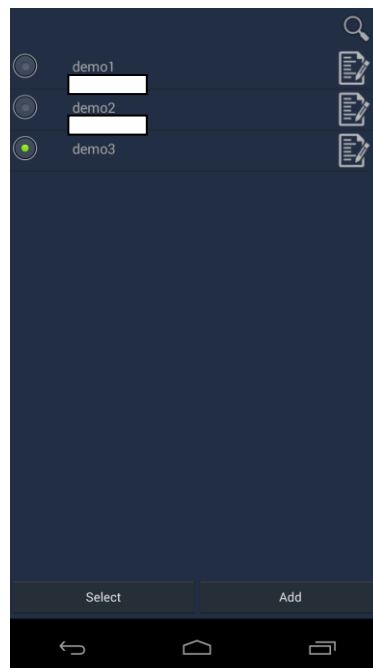
If you want to modify the information of added patient, click the Edit button  to enter the Patient Information Modification interface. You can modify all the information except the ID.

10.2 Doctor Information Maintenance

In the upper left corner of the scanning interface, click "Please select a doctor" to enter the doctor information maintenance interface. Click the "Add" button to enter to edit doctor details interface (Figure 10.2.1). Input the relevant doctor information and click the "Add" button to save the doctor's information. The added doctor is displayed in the doctor information list (Figure 10.2.2).




10.2.1






10.2.2

Select a newly added doctor, then click 'Select', the doctor will be selected as the current scanning doctor, whose name is displayed in the "scanning doctor" under the scanning interface, the doctor name is saved in the patient archive, when the scanning image was saved.

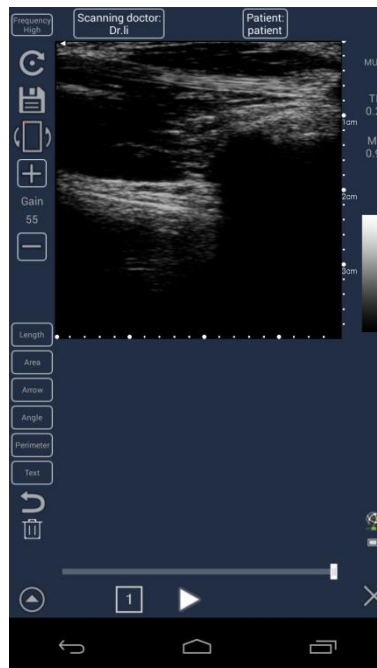
Need to change another scanning doctor, click 'Scanning Doctor' again to enter the doctor information list interface, add a new doctor information and select add the doctor to the main interface of scanning, you can directly view by scanning.

If you need to modify the information, click the edit button  to enter to modify doctor information interface, you can modify all information.

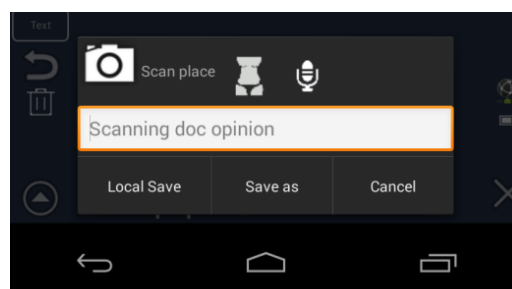
Click the search button , can search a doctor by key words, click the delete button  to clear the contents, and click the arrow button  to close the search bar.

10.3 Image storage

After entering the frozen state, the display interface is shown below. In the frozen state, the real-time scanning parameters are no longer displayed, and display image parameters: save, length, area, arrows, angle, perimeter, text and operation keys.



Save: Click the Save icon to save the currently frozen image. The following dialog box will be displayed to confirm the scan position to assist the diagnosis. This function allows you to save the scanned parts and methods and add scanners' opinions. if no comments, you can directly select "Save to Local", "Save as" and "Save to Cloud(optional with extra cost)".





Click the scan site button to enter camera interface of the scan site. Take photographs and select the satisfactory one, then the photo will be automatically added to the dialog box, the following picture shows the scanning site photos. If you choose to save to the cloud(optional with extra cost), the system will automatically upload images.

Connect the USB wire to export the pics to the computer or other instruments,if you clicked "save as" for storage. The pictures can be automatically exported to the computer or other instruments. you can find the pics in the file: Internal Storage/Meditech.

10.4 Video storage

During real-time scanning, the system will automatically perform the latest 128-frame video caching.



Video playback: when the frozen state, click , you can see the interface as shown below, click , the video can be suspended or playback during the play operation.



The frame rate of the video playback matches the frame rate recorded in real time.

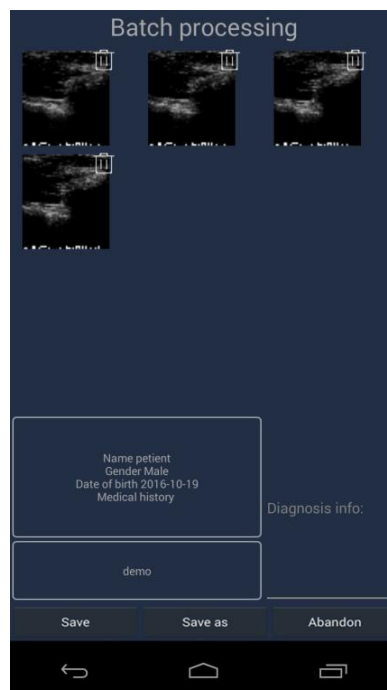
Video storage :

- To play back images: Click the Play button to enter Playback mode. The system will play all the frames from the start frame to the end frame. In the case where the start and end frames are not set, the default is to automatically stop from the start of playback to the end.
- To set the start frame: Click the left white bar button to set the start frame.
- To set the end frame: Click the right-side bar button to set the end frame.
- Store the tag recording, as shown in the green area for the recorded video, click "Save as".



Connect the USB wire to export the videos to the computer or other instruments. The videos can be automatically exported to the computer or other instruments. If the computer or other instruments fail to download the videos, you can find the pics in the file: Internal Storage/Meditech.

10.5 End the examination



After the scanning interface image is saved successfully, press the end examination button  to jump to the examination result interface.

Click the thumbnail image to enter the image details interface ; Click the delete button  in the upper right corner of the screen can delete the current image.

The patient and doctor information is required and the diagnostic content is optional.

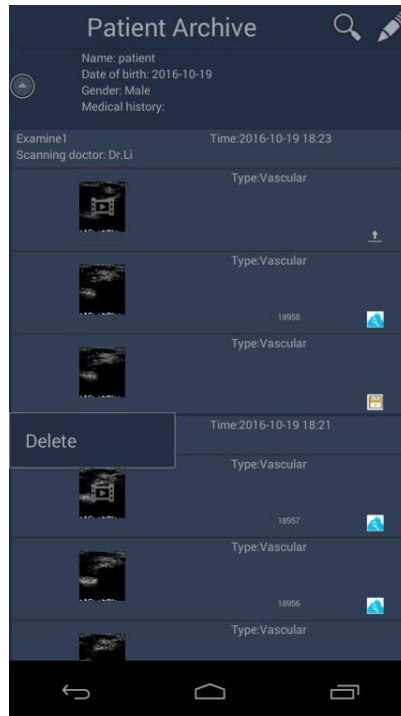
Save : Save the examination results in the local state.

Save as : Save in the external storage Meditech content.




Abandon : Delete the current scanned image.

10.6 Patient Archive




In the scan interface menu, click the case file option, enter the case file area. This area displays all local and cloud DICOM files.



10.6.1

- All scanned images of the same patient are stored in an ID card.
- In the main interface of application, click the unfold icon or click menu options in scanning interface, select the patient archive enter into the patient archive interface. All scanned images of the same patient are saved in the same group.
- The upper-left corner of the list item displays the user description.
- A local icon  in the list item indicates that the image is only saved locally and not synced to the cloud. A cloud (optional with extra cost) icon  indicates that this image is synced to the cloud (optional with extra cost) with a Cloud Unique ID marking (The local image does not have this ID). An upload icon  indicates that the image is uploading from local to

the cloud (optional with extra cost) and it will become a cloud icon (optional with extra cost) after uploading successfully. If there is a medical diagnosis, it will display the time, the doctor information and the diagnosis contents.

- Long press the image list will display the delete option. Clicking delete will delete the image in this device.
- Click the Search button  on the top, it can search by inputting date, cloud unique ID. The date format is similar to 20150804.
- Click Edit button , can pop-up editing menu item, it can delete images in batch in all select model ; "Send" means uploading the local images to the cloud (optional with extra cost) ; "Save as" means saving the image in the external storage Meditech content ; Click  to "Compare" which means selecting two images to compare shown (Figure 10.6.1)

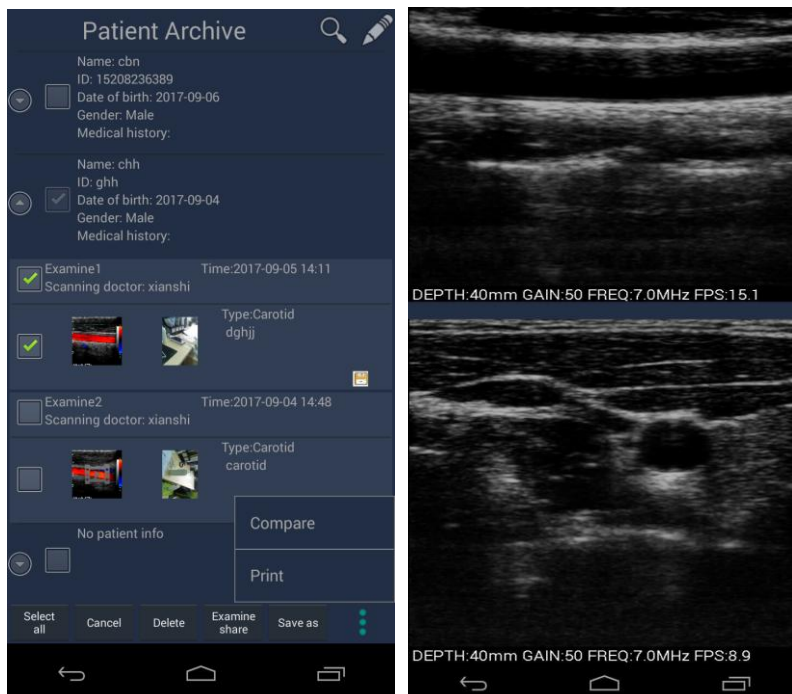
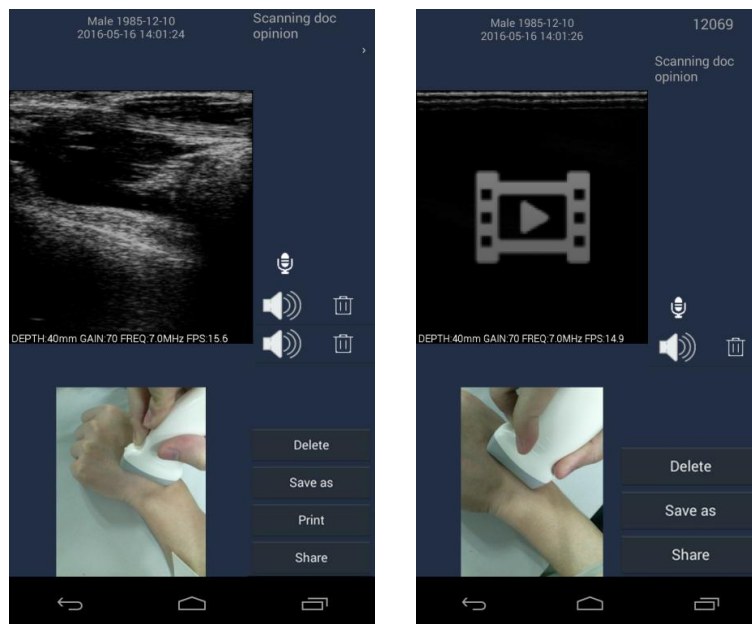


Image Details:

Select a specific image, enter the image area as shown below. This section stores information such as the position of the image scanned, the scanned image, the setting

information of the image, the scanner's opinion, and so on.

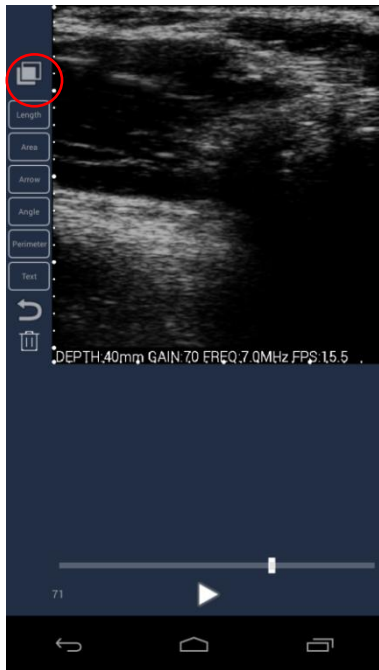


- **Scanning doc opinion** : Click the 'Scanning doc opinion' in the local image detail interface can edit again ,click “Ok” to save successfully. “Scanning doc opinion” in Cloud Image (optional with extra cost)can’t be edited again.
- **Click the Record button** to add voice recording, click the Record button again to end the recording, and the completed recording is displayed below the Recording button. Click the play button to play the recording, and click the Delete button to delete the recording.
- **Delete** : Press the 'Delete' button and the image will be deleted from this device.
- **Save as** : Images are saved in the external storage Meditech content.
- **The same patient images can view by sliding from left to right.**
- **Print:** The result will be printed when Meditech is connected with wifi printer.
- **Share:** QR code w be produced after clicking Share, use a phone to scan it, you can see the picture scanned by Meditech in the phone.(The QR

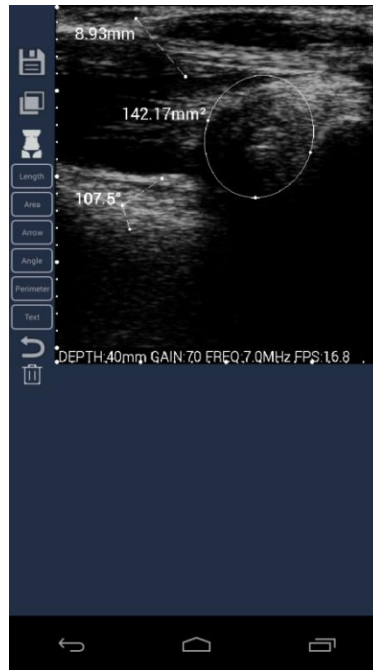
code can show when Meditech is connected with Wifi)

10.7 Image Measure and Play

Click the ' image thumbnail' on the left side of the image detail interface, enter the image measure and play interface.



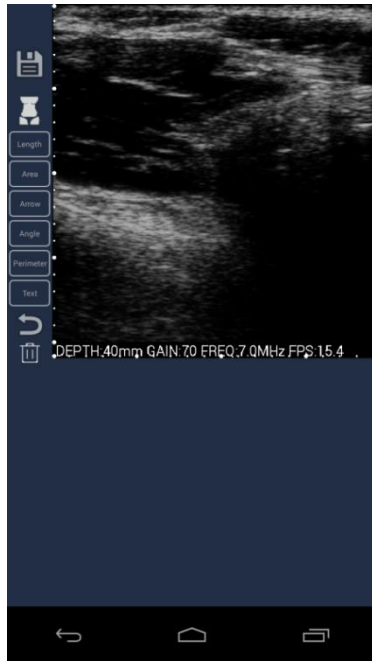
10.7.1



10.7.2

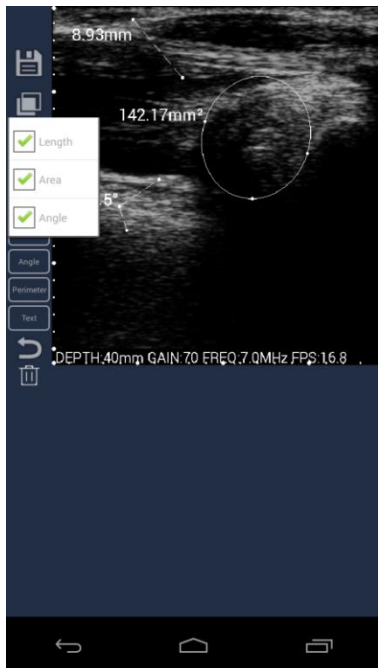
Overlay information :

- In the frozen state, marked "length, area, arrow, angle, perimeter, text", it displays "overlay information" in the image play detail interface after saving the images (Figure 10.7.1).

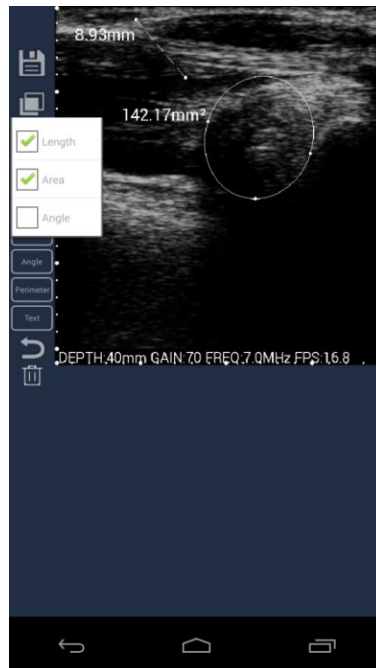


10.7.3








- In the frozen state, if there is no mark "Length, Area, Arrow, Angle, Perimeter, Text" and the logos are not saved, there is no overlay information in the image play detail interface after saving the images.
- Overlay selected button will display on the list, click to enter the overlay list can choose to display, hide the measurement (Length, Area, Arrow, Angle, Perimeter, text) logo (Figure 10.7.4).



10.7.4



10.7.5

- Length, Area, Arrow, Angle, Perimeter, Text : Press 'Length, Area, Arrow, Angle, Perimeter, Text' can make a temporary measurement of the image. click the image by one finger can measurement. The local image can be saved by pressing the Save button . The measurement result of the cloud image can not be saved.
- Undo, Delete : Press the Undo button  to undo the previous operation and press the Delete button  to delete all operations.
- Body mark : Click the Body Marker icon  to mark the current scanning position.
- Drag, enlarge, narrow: it can be dragged, enlarged and narrowed the image by two finger, the translation coefficient and magnification ratio are displayed in the lower right corner .
- Play : At the bottom of the screen is the play button. Press the playback button  can automatically playback, press the pause button  to pause playback.
- Play back single frame images : Drag the slider  manually to view the single frame. This function is not available for still images.
- The depth, frequency, gain and related FPS information settings are displayed at the bottom of the image interface during the scanning.

Probe and consumable operation volumes

Chapter 11 System Maintenance and Care

11.1 System maintenance



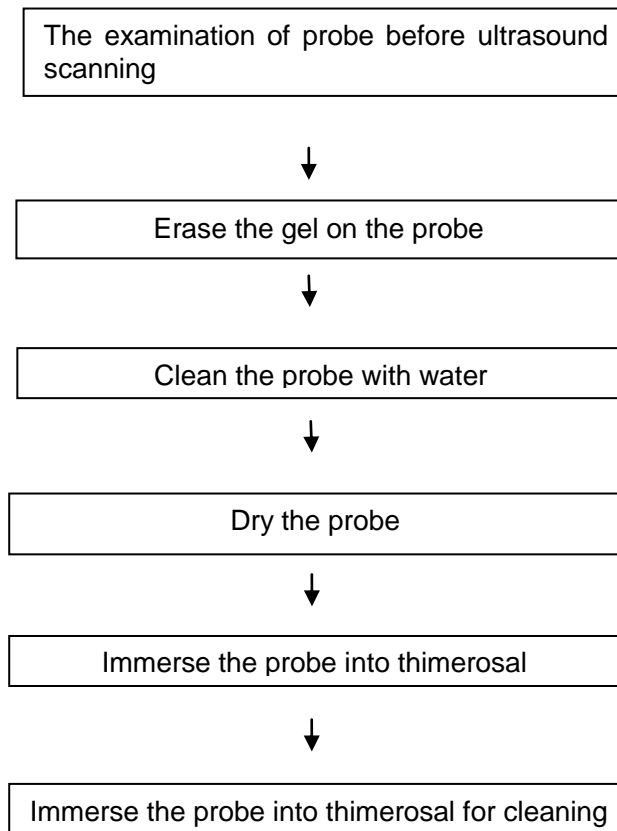
- Equipment should not be frequently turn on and turn off. If you need to reboot after power-off, wait 2 to 3 minutes.
- Please check whether the system is normal frequently if it has been used for some time.
- When the equipment is not in use for a long time, the instrument should be cleaned and packed in the direction indicated by the packing box. The storage environment should be in accordance with the "storage" condition.
- At the end of the day, after cooling, the instrument should be covered with protective cover to prevent dust from entering.
- When the device is prompted "low power level", it should be charged as soon as possible in case the battery voltage drops so low due to excessive discharge that it can't be normally charged and booted.
- Overcharge and over discharge will cause great damage to the lithium battery. Therefore, better charge in accordance with the standard method , in particular, do not carry more than 12 hours of super-long charge.

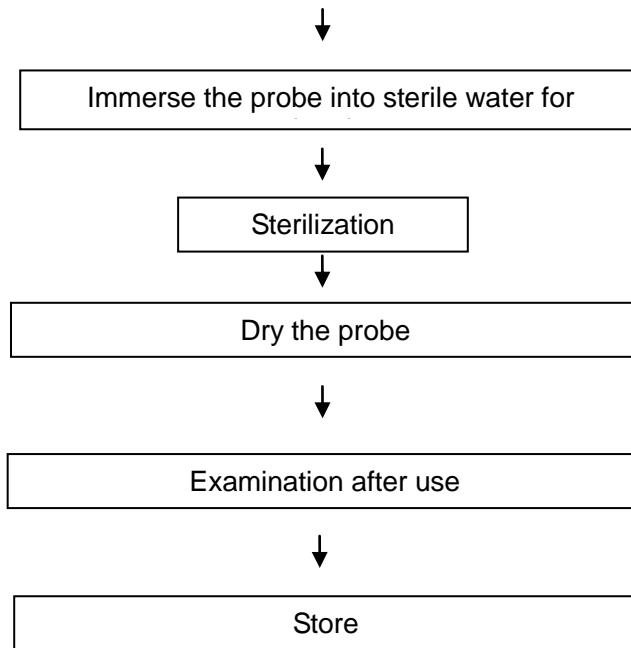
- **Battery treatment should be handled by our company, unauthorized treatment is prohibited to avoid environmental impact.**
- **Regarding to the safety of the battery, the following acts should be strictly prohibited:**
 - **Unauthorized removal of the battery**
 - **The short-circuit of battery positive and negative**
 - **Put the battery in the liquid**
 - **Put the battery in fire**

11.2 Use of the probe

The general procedure for probe operation is described below. Operators should receive specialized training and have some clinical experience.

The flow chart of no puncture operation of the probe:





11.3 Put on probe protective cover

In order to minimize the spread of the disease, it is necessary to take some protective measures. Clinically, the probe sheath is beneficial to prevent infection. It is strongly recommended to use a sterile probe sheath that meets the requirements when performing surgical procedures. The probe sheath has to be used before the cavity-check on the human body. Use a protective cover approved by the market.



- To avoid infection, the probe guard can only be used once during the inspection. Do not use a damaged protective cover.
- The probe sheath is made of natural latex and talc, which may cause allergies to some people.
- Do not use an expired probe cover. Before using the probe sheath, check

whether the probe sheath is out of date.

11.4 Probe maintenance

11.4.1 Precautions

Overview

- If the probe is stored for a long period of time, follow the storage requirements of the label on the box.
- After the probe has been stored for a long time, disinfect the probe again.



- If probe lens, cable, or connector is cracked, ruptured, or damaged, do not use the probe, and contact our technical support for reparation.
- If the probe lens, cable or connector is cracked, ruptured, or damaged, it may endanger the electrical safety of the probe.
- Connector needle cannot bend. If the needle is damaged, do not continue to use and need to repair the probe.
- The user checks the probe by visual inspection and manual operation to ensure that the entire probe surface has no holes, bulging, damaged or sunken parts.
- Do not immerse the probe connector in the liquid, or it may damage the electrical safety of the probe.
- Do not immerse the probe in the disinfectant for the time longer than that

required by the manufacturer during the high sterilization period.

- Should avoid prolonged exposure to the probe in the air and launch sound waves, so as not to damage the probe.



- Do not try to split the probe. Splitting the probe may cause damage to the probe. Failure to do so will void the user's warranty.
- For the probe fallen or collided with items, do not use this probe until the strict leak detection has been passed to confirm that the probe has not been damaged electrically.
- Do not attempt to use an autoclave, ultraviolet rays, γ - rays or gases, steam or heat sterilization method toward the probe, these methods may permanently damage the probe.
- Do not immerse the probe in water or disinfectant liquid, or it may cause electric shock or probe failure.
- Do not drag or bend the probe cable. If carrying the probe with a trolley, make sure that the trolley wheel does not roll the cable.
- Damage to the probe caused by falling or impacting foreign body, as well as extrusion, recoil, winding damage caused by the cable is not covered under warranty.

11.4.2 Clean the probe



- When the probe connected to the system, do not clean or disinfect the probe.
- Do not use gasoline or other organic compound solution to clean the probe.
- If the probe sticks to body fluids, please disinfect and then clean.
- After each ultrasonic examination, completely erase the probe surface of the ultrasonic coupling agent. Otherwise the ultrasound coupling agent will coagulate in the probe acoustic lens and affect the ultrasonic image quality.
- Clean the probe regularly to ensure that the probe is working properly.

Cleaning step

- Make sure that the probe cable is not cracked or ruptured;
- Wipe the dust from the cable with a soft cloth.
- Gently wipe the probe and cable with a soft cloth soaked in an aqueous solution and a mild detergent;
- Use a soft cloth to wipe the coupling agent attached to the probe;
- Wipe the probe and cable with a soft cloth soaked in warm soapy water;
- Wipe the probe and cable with a soft cloth dampened in fresh water until all soap liquid is erased;
- Dry the probe and cable with a dry soft cloth.

11.4.3 Sterilization of the probe

Sterilization of the probe

- The ultrasonic probe can be sterilized with a liquid chemical disinfectant. The degree of disinfection is directly related to the time of exposure to the disinfectant. Increase the contact time has a better disinfection effect.

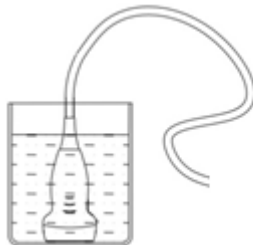
Sterilization step

- Sterile gloves must be worn during disinfection / sterilization to avoid infection ;
- The probe must be cleaned before disinfection / sterilization; it is recommended to disinfect / sterilize the probe using the solution in the table below :

| Operating | Chemical Name | Reagent name | Operating |
|-------------------------|-------------------------|--|--|
| Probe disinfection | Glutaraldehyde (2.4%) | Cidex Glutaraldehyde-based disinfectant | Place the probe in the solution for more than 45 minutes. as the picture shows. |
| The probe sterilization | Glutaraldehyde (2.4%) | Cidex Glutaraldehyde-based disinfectant | The probe is brought to the solution for more than 10 hours. as the picture shows. |

Note:

1. Refer to the manufacturer's instructions for disinfectant concentration, disinfection method and dilution method.
2. Activators are used for glutaraldehyde solutions.
3. Rinse thoroughly with sterile water to remove any residual chemicals from the probe;
4. Wipe the surface of the probe with a sterile cloth or gauze. Do not allow the probe to dry by heating.



Clean the probe cup

- Every day, a soft cloth or brush must be used to clean and clean the probe cover. No residual coupling agent will be left. Otherwise, the ultrasonic coupling agent will coagulate on the probe acoustic lens to affect the ultrasonic image quality. It is recommended to use clean water and pure water, try not to use scrubbing liquid to clean.



- Disinfection and sterilization of the probe may lead to discoloration of the acoustic lens or color fading of the text on the probe label, which is a normal phenomenon.

- Multiple sterilization and sterilization will lead to the decrease of the safety and performance of the probe, so user should minimize the number of disinfection and sterilization.

11.5 Peripheral cleaning

Operating

- Turn off the system, power off the system;
- Moisten the soft cloth with water or alcohol to clean the system and peripherals.



- It is very important to regularly clean the system and some peripherals connected to the equipment. Incorrect maintenance will compromise the stability of the equipment.



- For any malfunction caused by failure to follow the procedure and instructions, no warranty will be served.
- Do not use a scrubbing detergent to clean the main unit.

11.6 Screen cleaning

Operating

- Gently wipe the display surface with a soft, dry cloth;
- If many stains, use clean water or neutral detergent solution to clean and air dry.



- Do not use cleaners or other liquids that come into direct contact with the screen. If you accidentally drop water on the screen, it should be immediately wiped and dried, otherwise it will pollute the screen.

- When cleaning the machine, do not let the liquid flow into the machine, otherwise there will be a risk of failure and electric shock.

11.7 SECURITY INSPECTION

To ensure that the unit is working properly, it is recommended that a maintenance and inspection plan be established and that the machine be inspected periodically. If any abnormality is found, please contact our sales office, customer service department or agent.

If there is no picture or menu without image, please follow the troubleshooting form below. If the problem still can not be eliminated, please contact our sales office, customer service department or agent.

11.8 Troubleshooting

Common troubleshooting reference table 12.1.

Table 12.1 Common Failures, Reasons and Handling

| No. | Failure phenomenon | Method of exclusion |
|-----|--|---|
| 1 | Press the power button to boot, the motor does not vibrate, the display has no signal. | Check whether the battery is intact; Check whether the device has no power or low battery; try charging the device before use; Check whether the power key is intact. |
| 2 | Discontinuous fringe interference and snowflake interference appear on the display. | Environmental inspection, check the machine if there is electromagnetic interference around the space; Check that the power of the unit and the probe are in good contact. |
| 3 | The scanned image on the screen is not clear. | Adjust the brightness of equipment; Whether the coupling agent is applied; Check whether the probe contact of the unit is good. |
| 4 | Image cannot be uploaded after saving. | Check the network connection, check screen wake-up interface drop-down menu or settings to confirm whether the network is normal. |

11.9 List of accessories

Consumable parts are: probe, battery

Replaceable accessories: probe, battery

Key components: probe, battery, motherboard

Replacement of key components: For replacement of key components, please contact the customer service department of our company. Our technician will be responsible for the replacement, and it is strictly forbidden to replace the key components without permission.

11.10 Disposal of the product

When the product reaches the service life or needs to be discarded, please contact the customer service department of Meditech Equipment co., Ltd. for recycling. Our company will dispose of the product in accordance with the relevant laws and regulations.

Appendix A Acoustic Output Data

A.1 Description

Acoustic output

The acoustic output display is located at the top right corner of the system display

Note:

1. *If either MI or TI displays a value greater than 1.0, please follow the ALARA guidelines carefully.*
2. *The sound intensity parameters usually generated by the ultrasonic probe and their meanings are described as follows:*

Mechanical index

The mechanical index can be defined as the peak expansion pressure (MPa) (determined by the tissue attenuation coefficient of 0.3 dB / cm / MHz) divided by the square root (MHz) of the probe center frequency.

Thermal sensitivity

The thermal index (TI) is the ratio of power required to assess soft tissue or bone temperature rise by 1 °C.

Peak expansion pressure

The peak expansion pressure (in MPa) is the temporary peak expansion pressure at the specified point.

Pulse intensity integral

The pulse intensity integral is the instantaneous rate-time integral of any given point and any specified pulse in which the audio pressure or the underwater audio signal is included in a non-zero region. Each pulse is equal to the energy density Joule.

A.2 Maximum probe surface temperature

Subject to Section 42.3 of the standard, the maximum surface temperature data of the probe used in this system are measured in two environments: placing the probe in static air

and contacting the probe to the tissue material of the human body.

| | | |
|------------|--|------------------------------------|
| Probe type | The probe is in contact with the imitated tissue phantom | Placed in static air |
| | Maximum surface temperature (°C) | Maximum surface temperature (°C) |
| L10-5/C5-2 | 38 | 39 |

Test environment: temperature 20-25 °C; relative humidity 50-85%; air pressure 80kPa-106kPa.

A.3 A.3Sound output report form

| Linear array | | |
|--------------|-----|-----|
| Depth mm | MI | TI |
| 40 | 0.9 | 0.2 |
| 50 | 0.8 | 0.2 |
| 60 | 0.7 | 0.2 |

| Convex array | | | | | | |
|--------------|-----|-----|---------|-----------|-----|-----|
| depth | MI | TI | abdomen | Maternity | MI | TI |
| 140 | 1.0 | 0.2 | | | 1.1 | 0.1 |
| 160 | 0.9 | 0.2 | | | 1.0 | 0.1 |
| 180 | 0.8 | 0.1 | | | 0.9 | 0.1 |

A.4 A.4Sound output of published information

Manufacturer : Meditech Equipment co.,Ltd.

Electronic Linear array scanning, hand-held 7.5MHz universal probe

Electronic convex array scanning, 3.5MHz universal probe

| | |
|-----------------------------|----------|
| mode | B |
| p/Mpa | 1.3 |
| Ispta/(mW/cm ²) | 547.9 |
| System Settings | Focus F1 |

| | |
|--|--------------|
| | Output 0dB |
| Lp/mm | 7.8 |
| Wpb6(∥)/mm | 0.4 |
| (⊥)/mm | 1.5 |
| prr/kHz | 13K |
| srr/Hz | — |
| Output beam size/mm | 4 |
| f _{awf} /MHz | 7.58 |
| APF ^a /% | 100 |
| AIF ^b /% | 100 |
| Maximum power ^c /mW | 26 |
| I _{ob} (mW/cm ²) | 0.8 |
| Power on mode | B mode |
| Initial mode | B mode |
| Acoustic output freeze | YES |
| L _{tt} /mm | provide |
| L _{ta} /mm | Contact type |
| Include patterns | — |
| 1) sound boot coefficient; 2) sound initial coefficient; 3) power set every 3dB as a level, can be controlled by the user. | |

Appendix B Type B imaging performance

B type imaging performance indicators

The basic performance of the product is:

- Requirement: The maximum probing depth of the equipment is ≥50mm.
- Test method: according to GB 10152-2009 standard 5.3.2 test method, the results should be consistent with the maximum detection depth requirements.

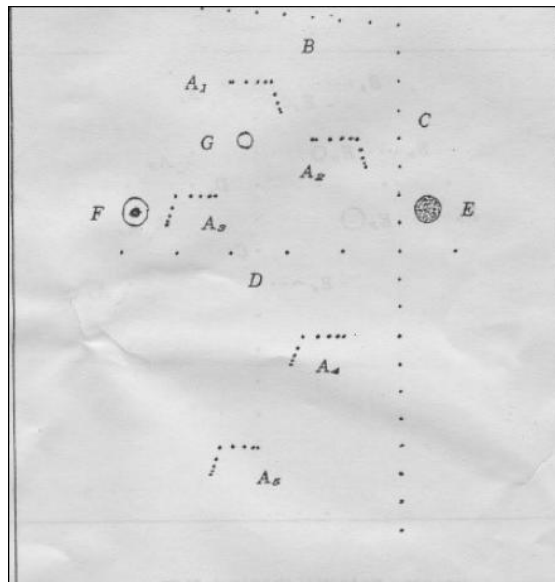
| | |
|------------------------------|-----------------------|
| Probe Type | L10-5 Linear array |
| Probe center frequency (MHz) | 7.5 |

| | |
|--------------------------------------|---|
| Sound operating frequency | Frequency range 3.15 ~ 3.85MHz, the sound frequency and nominal deviation of the center frequency within $\pm 10\%$ |
| Test frequency (MHz) | 7.5 |
| Lateral resolution (mm) | ≤ 2 (depth ≤ 40) |
| Axial resolution (mm) | ≤ 1 (depth ≤ 50) |
| Blind spot (mm) | ≤ 3 |
| The maximum depth of detection (mm) | ≥ 50 |
| Geometric Accuracy(%) | Horizontal ≤ 10 , vertical ≤ 5 |
| Length and area measurement error(%) | ± 10 |
| Slice thickness (mm) | ≤ 3 |

| | |
|-------------------------------------|---|
| Probe Type | C2-5 Convex array |
| Radius of curvature | 60mm |
| Probe center frequency (MHz) | 3.5 |
| Sound operating frequency | Frequency range 3.15 ~ 3.85MHz, the sound frequency and nominal deviation of the center frequency within $\pm 10\%$ |
| Test frequency (MHz) | 3.5 |
| Lateral resolution (mm) | ≤ 3 (depth ≤ 80) |
| Axial resolution (mm) | ≤ 2 (depth ≤ 80) |
| Blind spot (mm) | ≤ 5 |
| The maximum depth of detection (mm) | ≥ 160 |

| | |
|--------------------------------------|---|
| Geometric Accuracy(%) | Horizontal ≤ 15 , vertical ≤ 10 |
| Length and area measurement error(%) | ± 15 |
| Slice thickness (mm) | ≤ 4 |

Appendix C uses ultrasound phantom illustrations



A1---A6: Axis lateral resolution target group

B: Blind target group

C: Longitudinal target group

D: Horizontal target group

E: Imitating Tumor

F: Imitating gallbladder (diameter:10mm)and stone

G: Imitating gallbladder (diameter:6mm)

KS107BD phantom 【Note: KS107BD (L) body membrane donly depth increased, the target group consistent with the KS107BD】

Axis lateral resolution target group: the lateral branch from the acoustic window

30,50,70,120 and 160mm, the parallel distance of the adjacent target line in A1 and A2 is 1,5,4,3,2mm successively, In A3-A6 its 5,4,3,2mm successively, In Longitudinal branch the vertical distance between the center of the adjacent target line is 4,,3,3,1mm respectively.

Blind target group: the distance between the center of the adjacent target line are 10mm, distance to the acoustic window are 10,9,8,7,6,5,4,3 mm, respectively.

Longitudinal target group: a total of 19 with the target line, the distance between two adjacent centers are 10mm.

Horizontal target group: a total of 7 with the target line, the distance between two adjacent centers are 20mm.

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