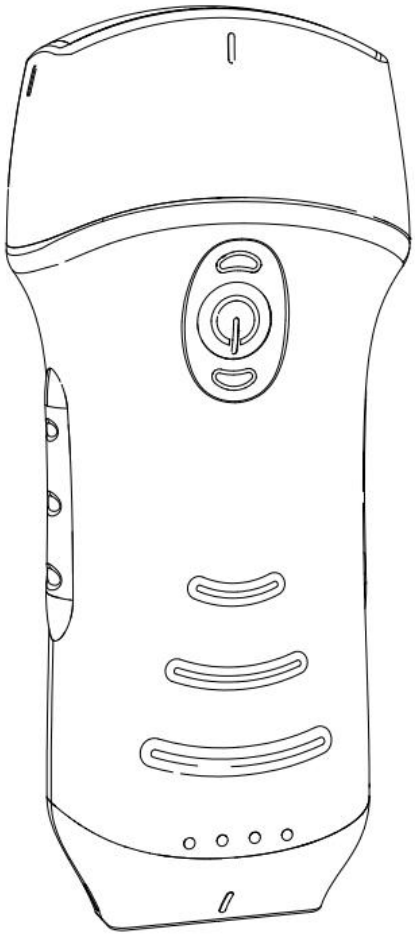
Pocket Ultrasound System

Instruction Manual

(V1.2)



IMPORTANT!

Read and understand this manual before operating the equipment. After reading, keep this manual in an easily accessible place.

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Introduce

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Model: C10

Authorized European Representative:

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CE certificate

CE 1639

This manual describes the operation of the Pocket Ultrasound System. In order to ensure the safe operation of the system, please read and understand the contents of the manual before using the system

This specification is formulated and explained by KONTED.

This manual is published: December 2021, first revised December 2022.

KONTED reserves the right to change the contents of the instruction manual without prior notice

1.Read This First

This manual is intended to assist you with the safe and effective operation of your KONTED product. Before attempting to operate the product, read this manual and strictly observe all warnings and cautions. Pay special attention to the information in the “Safety” section.

The user information for your KONTED product describes the most extensive configuration of the product, with the maximum number of options and accessories. Some functions described may be unavailable on your product's configuration.

Transducers are available only in countries or regions where they are approved. For information specific to your region, contact your local KONTED representative.

any products herein to improve reliability, function, or design. KONTED may make improvements or changes in the products or programs described in this document at any time.

KONTED makes no representation or warranty to the user or any other party with respect to the adequacy of this document for any particular purpose or with respect to its adequacy to produce a particular result. The user's right to recover damages caused by fault or negligence on the part of KONTED shall be limited to the amount paid by the user to KONTED for the provision of this document. In no event shall KONTED be liable for special, collateral, incidental, direct, indirect or consequential damage, losses, costs, charges, claims, demands, or claims for lost profits, data, fees, or expenses of any nature or kind.

Unauthorized copying of this document, in addition to infringing copyright, might reduce the ability of KONTED to provide accurate and current information to users.

Non-KONTED product names may be trademarks of their respective owners.

CAUTION

United States federal law restricts this device to sale by or on the order of a physician.

1.1 Intended Audience

Before you use your user information, you need to be familiar with ultrasound techniques. Sonography training and clinical procedures are not included here.

This document is intended for healthcare professionals who operate and maintain your KONTED product.

1.2 Ultrasound Benefits and Risks

Ultrasound is widely used because it provides many clinical benefits to the patient and has an excellent safety record. Ultrasound imaging has been used for over twenty years and there have been no known long- term negative side effects associated with this technology.

1.2 . 1 Ultrasound Benefits

- Portability
- Cost- effectiveness
- Multiple diagnostic uses
- Immediate results
- Safety record
- Clinical benefit：The clinical benefit of a diagnostic ultrasound device is to help healthcare professionals provide accurate diagnostic information (visualize human tissue/internal structure) that enhances the diagnostic and treatment care pathways of the patient for a variety of diseases and conditions

1 .2.2 Ultrasound Risks

Ultrasonic waves can heat the tissues slightly. It is normal that the probe may feel warm to the touch while charging. If you remove the probe from the charging pad before or immediately after charging is complete , it is recommended that you allow the probeto cool down before use. Since the system limits patient contact temperature and will not scan at or above 43° C(109 ° F) , allowing the probe to cool down before use will optimize scan time performance.

WARNING

Do not use the system for purposes other than those intended and expressly stated by KONTED. Do not misuse the system, and do not use or operate the system incorrectly.

Installation, use, and operation of this product are subject to the law in the jurisdictions in which the product is used. Install, use, and operate the product only in such ways that do not conflict with applicable laws or regulations, which have the force of law.

Use of the product for purposes other than those intended and expressly stated by KONTED, as well as incorrect use or operation, may relieve KONTED or its agents from all or some responsibility for resultant noncompliance, damage, or injury.

WARNING

System users are responsible for image quality and diagnosis. Inspect the data that is being used for the analysis and diagnosis, and ensure that the data is sufficient both spatially and temporally for the measurement approach being used.

CAUTION

The information can be used for basic/focused assessments and adjunctively with other medical data for clinical diagnosis purposes during routine, periodic monitoring, and triage assessments for adult, pediatric.

CAUTION

The information can be used for basic/focused assessments and adjunctively with other medical data for clinical diagnosis purposes during routine, periodic follow-up, and triage information can be used for basic/focused assessments and adjunctively with other medical data for clinical diagnosis purposes during routine, periodic follow-up, and triage.

1.3 Warnings

Before using the system, read these warnings and the “Safety” section.

WARNING

Do not operate this system in the presence of flammable gases or anesthetics. Explosion can result. The system is *not* compliant in AP/APG environments as defined by IEC 60601-1.

WARNING

Medical equipment must be installed and put into

service according to the special electromagnetic compatibility (EMC) guidelines provided in the "Safety" section.

WARNING

The use of portable and mobile radio-frequency (RF) communications equipment can affect the operation of medical equipment

WARNING

System users are responsible for image quality and diagnosis. Inspect the data that is being used for the analysis and diagnosis, and ensure that the data is sufficient both spatially and temporally for the measurement approach being used.

WARNING:

The Pocket Ultrasound System C10 is MR Unsafe. The device presents a projectile hazard.

WARNING

The user and/or patient should report "any serious incident that has occurred in relation to the device"to Beijing Konted and the competent authority of the corresponding Member State.

1.4 Warning Symbols

The system uses various warning symbols. For symbols used on the system, see 3.5 Symbol description.

1.5 Upgrades and Updates

KONTED is committed to innovation and continued improvement. Upgrades may be announced that consist of hardware or software improvements. Updated user information will accompany those upgrades.

1.6 Recycling, Reuse, and Disposal

KONTED is concerned with helping protect the natural environment and helping ensure continued safe and effective use of this system through proper support, maintenance, and training.

KONTED designs and manufactures equipment in compliance with relevant guidelines for environmental protection. As long as the equipment is properly operated and maintained, it presents no risk to the environment. However, the equipment may contain materials that could be harmful to the environment if disposed of incorrectly. Use of such materials is essential for the

implementation of certain functions and for meeting certain statutory and other requirements

WARNING

products should not be discarded at will.

Battery recycling meets local requirements.

-Recycling of waste electrical and electronic products should comply with local laws and regulations.

WARNING

Do not dispose of the device (or any parts of it) with industrial or domestic waste. The system may contain materials such as lead, tungsten, or oil, or other hazardous substances that can cause serious environmental pollution. The device also contains privacy-sensitive information, which should be properly removed (scrubbed). KONTED advises you to contact your KONTED service organization before disposing of this system

1.7 Discarding Batteries

Batteries are internal to the device. The device should be discarded in an environmentally safe manner. Properly dispose of the device according to local regulation.

WARNING

Do not disassemble, puncture, or incinerate batteries. Be careful not to short the battery terminals, because that could result in a fire hazard.

WARNING

Use caution when handling, using, and testing the batteries. Do not short circuit, crush, drop, mutilate, puncture, apply reverse polarity, expose to high temperatures, or disassemble. Misuse or abuse could cause physical injury.

WARNING

If electrolyte leakage occurs, wash your skin with large amounts of water, to prevent skin irritation and inflammation.

2.Safety

Please read this information before using your ultrasound system. It applies to the device, the transducers, and the software. This section covers general safety information only. Safety information that applies only to a specific task is included in the procedure for that task.

The combination of a KONTED transducer, the KONTED MY USG app, and a compatible Android device is considered a medical device. This device is intended for use by, or by the order of, and under the supervision of a licensed physician qualified to direct the use of the device.

Report any serious safety incident that occurs in relation to the ultrasound system to KONTED and to the competent authority of the country in which the user and patient are established.

WARNING

Warnings highlight information vital to the safety of you, the operator, and the patient.

CAUTION

Cautions highlight ways that you could damage the product and consequently void your warranty or service contract or ways that you could lose patient or system data.

2.1 Security classification

According to the type of anti-electric shock:

Internal power supply, where the adapter is Class 1;

According to the degree of anti-electric shock:

Type BF application part;

According to the protection degree of harmful liquid:

The system probe is IP22; the probe head is IP27

According to the degree of safety in the presence of flammable anesthetic gas mixed with air (or oxygen, nitrous oxide two);

According to the working mode: Continuous working equipment.

2.2 Basic Safety

WARNING

Do not use the system for any application until you have read, understood, and know all the safety information, safety procedures, and emergency procedures contained in this "Safety" section. Operating the system without a proper awareness of safe use could lead to fatal or other serious personal injury.

WARNING

If any part of the system is known or suspected to be defective or incorrectly adjusted, do not use the system until it is repaired. Operating the system with defective or incorrectly adjusted components could expose you and the patient to safety hazards.

WARNING

The transducers have small, detachable parts that pose a choking hazard, and the transducer cable is a strangulation hazard. Do not leave children unattended with the system.

WARNING

Do not use the system for any application until you are adequately and properly trained on its safe and effective operation. If you are unsure of your ability to operate the system safely and effectively, do not use it. Operation of the system without proper and adequate training could lead to fatal or other serious personal injury.

WARNING

If any part of the system is known or suspected to be defective or incorrectly adjusted, do not use the system until it is repaired. Operating the system with defective or incorrectly adjusted components could expose you and the patient to safety hazards.

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WARNING

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adequate training could lead to fatal or other serious personal injury.

WARNING

Do not operate the system with patients unless you have an adequate understanding of its capabilities and functions. Using the system without such understanding may compromise the system's effectiveness and the safety of the patient, you, and others.

WARNING

Never attempt to remove, modify, override, or frustrate any safety device on the system. Interfering with safety devices could lead to fatal or other serious personal injury.

WARNING

Use the system only for its intended purposes. Do not misuse the system. Do not use the system with any product that KONTED does not recognize as compatible with the system. Operation of the product for unintended purposes, or with incompatible products, could lead to fatal or other serious injury.

WARNING

Stop use immediately if the system or the transducer appear to be malfunctioning. Contact your KONTED representative immediately.

WARNING

You are responsible for configuring your device in accordance with your institution's security policies. Notifications and alerts from third-party applications may interfere with an exam.

WARNING

Thin needles can bend when entering tissue. Actual position must be verified by identifying the echoes from the needle.

WARNING

Do not perform a needle procedure if the needle is not visible.

WARNING

Reverberation or other tissue artifacts may produce false needle images, which can cause confusion in locating the actual needle image. Ensure that you are not using a false needle image to locate the needle.

Ultrasonic waves can heat the tissues slightly. It is normal that the probe may feel warm to the touch while charging. If you remove the probe from the charging pad before or immediately after charging is complete, it is recommended that you allow the probe to cool down before use. Since the system limits patient contact temperature and will not scan at or above 43°C(109°F), allowing the probe to cool down before use will optimize scan time performance.

2.3 Electrical Safety

The transducer and software, along with a representative device, have been verified as compliant with IEC 60601‑1. The transducers meet Type BF isolated applied part requirements. When the transducer and software are used in conjunction with a device compliant with IEC 60950‑1, the system meets IEC 60601‑1 requirements for internally

powered equipment. (The safety standards met by this system are included in the “Specifications” section.) For maximum safety, observe these warnings and cautions:

WARNING

Devices that are compliant with IEC 60950‑1 have not been evaluated for compliance with the IEC 60601‑1 temperature limits for patient contact. Therefore, only the operator is allowed to handle the device.

WARNING

Do not operate this system in the presence of flammable gases or anesthetics. Explosion can result. The system is not compliant in AP/APG environments as defined by IEC 60601-1.

WARNING

To avoid risk of electrical shock hazards, always inspect the transducer before use. Check the face, housing, and cable before use. Do not use if the face is cracked, chipped, or torn; the housing is damaged; or the cable is abraded.

WARNING

All patient-contact devices, such as transducers, pencil probes, and ECG leads not specifically indicated as defibrillation-proof, must be removed from patient contact before application of a high-voltage defibrillation pulse.

WARNING

Ultrasound equipment in normal operation, as with other medical electronic diagnostic equipment, uses high-frequency electrical

signals that can interfere with pacemaker operation. Though the possibility of interference is slight, be alert to this potential hazard and stop system operation immediately if you note interference with a pacemaker.

WARNING

When using additional peripheral equipment that is to be interconnected by functional connection, the combination is considered to be a medical electrical system. It is your responsibility to comply with IEC 60601‑1 and test the system to those requirements. If you have questions, contact your KONTED representative.

WARNING

Patient-applied parts meet the standard IEC 60601‑1. Applied voltages exceeding the standard, although unlikely, may result in electrical shock to the patient or operator.

WARNING

Connection of optional devices not supplied by KONTED could result in electrical shock. When such optional devices are connected to your ultrasound system, ensure that the total system earth leakage current does not exceed 500 μA.

WARNING

To avoid risk of electrical shock, do not use any transducer that has been immersed beyond the specified cleaning or disinfection level.

WARNING

Electrosurgical units (ESUs) and other devices intentionally introduce radio frequency electromagnetic fields or currents into patients. Because imaging ultrasound frequencies are coincidentally in the radio frequency range, ultrasound transducer circuits are susceptible to radio frequency interference. While an ESU is in use, severe noise interferes with the black- and-white image and completely obliterates the color image.

WARNING

To avoid risk of a burn hazard, do not use transducers with high-frequency surgical equipment. A burn hazard may result from a defect in the high-frequency surgical neutral electrode connection.

WARNING

Using cables, transducers, and accessories other than those specified for use with the system may result in increased emissions from, or decreased immunity of, the system.

CAUTION

Use of the system in the presence of an electromagnetic field can cause momentary degradation of the ultrasound image. When interference is present or intermittent, use caution when continuing to use the system. If interference occurs often, review the environment in which the system is being used to identify possible sources of radiated emissions. These emissions could be from other electrical devices used within the same room or an adjacent room. Communication devices such as cellular phones and pagers can cause these emissions. The existence of radio, TV, or microwave transmission equipment located nearby can

cause emissions. In cases where EMI is causing disturbance, it may be necessary to relocate your system.

CAUTION

For information on electromagnetic emissions and immunity as it applies to the system, see "Electromagnetic Compatibility" on page 84. Ensure that the operating environment of your system meets the conditions specified in the referenced information. Operating the system in an environment that does not meet those conditions may degrade system performance.

2.4 Defibrillators

Observe the following warnings when a defibrillation is required while using the ultrasound system.

WARNING

Before defibrillation, always remove all patient-applied parts from the patient.

WARNING

Before defibrillation, always disconnect invasive transducers that remain in contact with the patient from the system.

WARNING

A disposable transducer cover provides no protective electrical insulation against defibrillation.

WARNING

A small hole in the outer layer of the transducer opens a

conductive path to grounded metal parts of the transducer. The secondary arcing that could occur during defibrillation could cause patient burns. The risk of burns is reduced, but not eliminated, by using an ungrounded defibrillator.

Use defibrillators that do not have grounded patient circuits. To determine whether a defibrillator patient circuit is grounded, see the defibrillator service guide, or consult a biomedical engineer.

2.5 Fire Safety

Fire safety depends on fire prevention, isolating the cause, and extinguishing the fire. If you see evidence of smoke or fire, disconnect system power. Observe the following warnings when using the system.

WARNING

On electrical or chemical fires, use only extinguishers that are specifically labeled for those purposes. Using water or other liquids on an electrical fire can lead to fatal or other serious personal injury. Before attempting to fight a fire, if it is safe to do so, attempt to isolate the product from electrical and other supplies, to reduce the risk of electrical shock.

WARNING

Use of electrical products in an environment for which they were not designed can lead to fire or explosion. Fire regulations for the type of medical area being used should be fully applied, observed, and enforced. Fire extinguishers should be available for both electrical and nonelectrical fires.

2.6 Equipment Protection

Follow these precautions to protect your system:

WARNING

If the system or transducers have been in an environment above 40°C (104°F), allow them to cool to operating temperature before turning on the system or connecting the transducers. Do not allow the transducer to contact the patient if the temperature of the transducer is higher than 43°C (109°F). Allow 25 minutes for the transducer to cool. If the transducers were only briefly exposed to temperatures above 40°C (104°F), then the time required for the devices to return to operating temperature could be less than 25 minutes.

CAUTION

If the system or transducers have been in an environment below 0°C (32°F), allow them to reach operating temperature before turning on the system or connecting the transducers. Allow 20 minutes for the transducers to warm to operating temperature. Otherwise, condensation inside the devices could cause damage. If the transducers were only briefly exposed to temperatures below 0°C (32°F), then the time required for the devices to return to operating temperature could be less than 20 minutes.

CAUTION

In general, only the area of the transducer acoustic window is liquid -tight. Except where specified in specific transducer-cleaning instructions, do not immerse the remainder of a transducer in any liquid.

CAUTION

Do not submerge the transducer connector in solution. The cables and transducer bodies are liquid-tight, but the connectors are not.

CAUTION

Do not use abrasive cleaners, or acetone, MEK, paint thinner, or other strong solvents on the system, peripherals, or transducers

1. **Matters needing attention in clinical examination technology**
   - **This equipment can only be operated by qualified medical personnel.**
   - **This manual does not introduce a clinical examination technique. It is necessary to select the correct inspection techniques according to the professional training knowledge and clinical experience.**
2. **The equipment cannot be checked for a long time.**
3. **Do not use incompatible coupling agents, disinfectants, probe protective cover, probe, puncture rack.**
4. **Sterile gloves must be worn to prevent infection when using ultrasonic probes.**
5. **You must use a sterile ultrasound coupling agent. Use a coupling agent that is in compliance with local regulatory requirements. In addition, it is necessary to properly manage and use the ultrasonic coupling agent to ensure that it does not become a source of infection.**
6. **The probe cover is made of natural rubber and is used with caution for natural rubber allergy.**

7. **For in vivo transducers in a single fault condition, the surface temperature rise shall not exceed 43 ° C.**

CAUTION

In order to prevent abnormal probe function, read the following safety precautions:

1. **After each ultrasonic examination, the ultrasonic coupling agent on the surface of the probe should be thoroughly erased. Otherwise, the ultrasonic coupling agent will be solidified on the probe head, which will affect the quality of the ultrasound image.**
2. **The probe should be cleaned and disinfected before and after each ultrasonic examination Ambient environmental requirements:**

   Please use the ultrasonic probe in the specified environment

   - **Ambient temperature: 0~40°C**
   - **Relative humidity: 30% ~ 85% (No condensation)**
   - **Atmospheric pressure: 70 KPa ~ 106 KPa.**
3. **To prevent damage to the ultrasonic probe, do not expose the probe to the following environment**
   - **Place where the sun shines**
   - **A place where the temperature changes dramatically**
   - **A place filled with dust**
   - **Easy to vibrate place**
   - **Place near the heat source**
4. **Repeated disinfection will lead to the safety and performance of the probe, the performance of the probe should be regularly checked.**

2.7 Product Compatibility

Do not use your system in combination with other products or components, unless KONTED expressly recognizes those other products or components as compatible. For information about such products and components, contact your KONTED representative.

Changes and additions to the system should be made only by KONTED or by third parties expressly authorized by KONTED to do so. Such changes and additions must comply with all applicable laws and regulations that have the force of law within the jurisdictions concerned, and best engineering practices.

WARNING

System changes and additions that are made without the appropriate training or by using unapproved spare parts may void the warranty. As with all complex technical products, maintenance by unqualified persons or using unapproved spare parts carries serious risks of system damage and personal injury.

2.8 Biological Safety

This section contains information about biological safety and a discussion of the prudent use of the system. A list of precautions related to biological safety follows; observe these precautions when using the system.

WARNING

Do not use the system if an error message on the display indicates that a hazardous condition exists. Note the error code, turn off power to the system, and call your customer service representative

WARNING

Do not use a system that exhibits erratic or inconsistent image updating. Discontinuities in the scanning sequence indicate a hardware failure that must be corrected before use

WARNING

Perform ultrasound procedures prudently. Use the ALARA (as low as reasonably achievable) principle.

WARNING

Transducer covers may contain natural rubber latex. Those covers may cause allergic reactions in some individuals. See “FDA Medical Alert on Latex” on page 27.

WARNING

If a sterile transducer cover becomes compromised during an intraoperative application involving a patient with transmissible spongiform encephalopathy, such as Creutzfeldt- Jakob disease, follow the guidelines of the U.S. Centers for Disease Control and this document from the World Health Organization: WHO/CDS/ APH/2000/3, WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies. The transducers for your system cannot be decontaminated using a heat process.

WARNING

If the system becomes contaminated internally with bodily fluids carrying pathogens, you must immediately notify your KONTED service representative. Components inside the system cannot be disinfected. In that case, the system must be disposed of as biohazardous material in accordance with local or federal laws.

WARNING

Select the correct application when starting an exam, and remain in that application throughout the exam. Some applications are for parts of the body that require lower limits for acoustic output.

2.9 FDA Medical Alert on Latex

March 29, 1991, Allergic Reactions to Latex-Containing Medical Devices

Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), the FDA is advising health care professionals to identify their latex sensitive patients and be prepared to treat allergic reactions promptly. Patient reactions to latex have ranged from contact urticaria to systemic anaphylaxis. Latex is a component of many medical devices, including surgical and examination gloves, catheters, intubation tubes, anesthesia masks, and dental dams.

Reports to the FDA of allergic reactions to latex-containing medical devices have increased lately. One brand of latex cuffed enema tips was recently recalled after several patients died as a result of anaphylactoid reactions during barium enema procedures. More reports of latex sensitivity have also been found in the medical literature. Repeated exposure to latex both in medical devices and in other consumer products may be part of the reason that the prevalence of latex sensitivity appears to be increasing. For example, it has been reported that 6% to 7% of surgical personnel and 18% to 40% of spina bifida patients are latex sensitive.

Proteins in the latex itself appear to be the primary source of the allergic reactions. Although it is not now known how much protein is likely to cause severe reactions, the FDA is working with manufacturers of latex-containing medical devices to make protein levels in their products as low as possible.

FDA's recommendations to health professionals in regard to this problem are as follows:

1.When taking general histories of patients, include questions about latex sensitivity. For surgical and radiology patients, spina bifida patients and health care workers, this recommendation is especially important. Questions about itching, rash or wheezing after wearing latex gloves or inflating a toy balloon may be useful. Patients with positive histories should have their charts flagged

2.If latex sensitivity is suspected, consider using devices made with alternative materials, such as plastic. For example, a health professional could wear a non-latex glove over the latex glove if the patient is sensitive. If both the health professional and the patient are sensitive, a latex middle glove could be used. (Latex gloves labeled "Hypoallergenic" may not always prevent adverse reactions.)

3.Whenever latex-containing medical devices are used, especially when the latex comes in contact with mucous membranes, be alert to the possibility of an allergic reaction.

If an allergic reaction does occur and latex is suspected, advise the patient of a possible latex sensitivity and consider an immunologic evaluation.

4.Advise the patient to tell health professionals and emergency personnel about any known latex sensitivity before undergoing medical procedures. Consider advising patients with severe latex sensitivity to wear a medical identification bracelet.

The FDA is asking health professionals to report incidents of adverse reactions to latex or other materials used in medical devices. (See the October 1990 FDA Drug Bulletin.)

To report an incident, contact the FDA Problem Reporting Program, MedWatch, at 1-800-332-1088, or on the Internet:

www.fda.gov/Safety/MedWatch/

For a single copy of a reference list on latex sensitivity, write to: LATEX, FDA, HFZ-220, Rockville, MD 20857.

NOTE

The transducers described in this document do not contain natural rubber latex that contacts humans. Natural rubber latex is not used on any KONTED ultrasound transducer.

2.10 ALARA Education Program

The guiding principle for the use of diagnostic ultrasound is defined by the "as low as reasonably achievable" (ALARA) principle. The decision as to what is reasonable has been left to the judgment and insight of qualified personnel. No set of rules can be formulated that would be sufficiently complete to dictate the correct response to every circumstance. By keeping ultrasound exposure as low as possible, while obtaining diagnostic images, users can minimize ultrasonic bioeffects.

Since the threshold for diagnostic ultrasound bioeffects is undetermined, it is the sonographer's responsibility to control total energy transmitted into the patient. The sonographer must reconcile exposure time with diagnostic image quality. To ensure diagnostic image quality and limit exposure time, an ultrasound system provides controls that can be manipulated during the exam to optimize the results of the exam.

The ability of the user to abide by the ALARA principle is important. Advances in diagnostic ultrasound, not only in the technology but in the applications of that technology, have resulted in the need for more and better information to guide the user. The output display indices are designed to provide that important information.

There are a number of variables which affect the way in which the output display indices can be used to implement the ALARA principle. These variables include index values, body size, location of the bone relative to the focal point, attenuation in the body, and ultrasound exposure time. Exposure time is an especially useful variable, because it is controlled by the user. The ability to limit the index values over time supports the ALARA principle.

2.10.1 Applying ALARA

The system imaging mode used depends upon the information needed. 2D imaging provides anatomical information, while Color imaging provides information about blood flow.

Understanding the nature of the imaging mode being used allows the sonographer to apply the ALARA principle with informed judgment. Additionally, the

transducer frequency, system setup values, scanning techniques, and operator experience allow the sonographer to meet the definition of the ALARA principle.

The decision as to the amount of acoustic output is, in the final analysis, up to the system operator. This decision must be based on the following factors: type of patient, type of exam, patient history, ease or difficulty of obtaining diagnostically useful information, and the potential localized heating of the patient due to transducer surface temperatures. Prudent use of the system occurs when patient exposure is limited to the lowest index reading for the shortest amount of time necessary to achieve acceptable diagnostic results.

Although a high index reading does not mean that a bioeffect is actually occurring, a high index reading should be taken seriously. Every effort should be made to reduce the possible effects of a high index reading. Limiting exposure time is an effective way to accomplish this goal.

There are several system controls that the operator can use to adjust the image quality and limit the acoustic intensity. These controls are related to the techniques that an operator might use to implement ALARA. These controls can be divided into three categories: direct, indirect, and receiver controls.

Acoustic Output Limits

This ultrasound system maintains acoustic output below the appropriate limits for each application, as listed here. The significant difference in magnitude emphasizes the need to select the correct application and remain in that application, so the correct application limits are in use for the appropriate application.

Limits for Non-Ophthalmic Applications

- $I_{spta.3} \leq 720$ mW/cm^2
- MI ≤ 1.9
- TI ≤ 6.0

Direct Controls

Application selection and the output-power control directly affect acoustic intensity. There are different ranges of allowable intensity or output based on your selection. Selecting the correct range of acoustic intensity for the application is one of the first things that occurs in any exam. For example, peripheral vascular intensity levels are not recommended for fetal exams. Some systems automatically select the proper range for a particular application, while others require manual selection. Ultimately, the user has the responsibility for proper clinical use. The ultrasound system provides both automatic (default) settings and manual (user-selectable) settings.

Output power has direct impact on acoustic intensity. Once the application has been established, the power control can be used to increase or decrease the intensity output. The power control allows you to select intensity levels less than the established

maximum. Prudent use dictates that you select the lowest output intensity that is consistent with good image quality.

Indirect Controls

The indirect controls are those that have an indirect effect on acoustic intensity. These controls affect imaging mode, pulse repetition frequency, focus depth, pulse length, and transducer selection.

The choice of imaging mode determines the nature of the ultrasound beam. 2D is a scanning mode; Doppler is a stationary or unscanned mode. A stationary ultrasound beam concentrates energy in a single location. A moving or scanned ultrasound beam disperses the energy over an area and the beam is concentrated on the same area for a fraction of the time as that of an unscanned mode.

Focus of the ultrasound beam affects the image resolution. To maintain or increase resolution at a different focus requires a variation in output over the focal zone. This variation of output is a function of system optimization. Different exams require different focal depths. Setting the focus at the proper depth improves the resolution of the structure of interest.

Transducer selection indirectly affects intensity. Tissue attenuation changes with frequency. The higher the transducer operating frequency, the greater the attenuation of the ultrasonic energy. A higher transducer operating frequency requires more output intensity to scan at a deeper depth. To scan deeper at the same output intensity, a lower transducer frequency is required. Using more gain and output beyond a point, without corresponding increases in image quality, can mean that a lower frequency transducer is needed.

Receiver Controls

Receiver controls are used by the operator to improve image quality. These controls have no effect on output. Receiver controls only affect how the ultrasound echo is received. These controls include gain, time gain compensation (TGC), dynamic range, and image processing. The important thing to remember, relative to output, is that receiver controls should be optimized before output is increased. For example, before increasing output, optimize gain to improve image quality.

2.10.2 An Example of Applying the ALARA Principle

An ultrasound scan of a patient’s liver begins with selecting the appropriate transducer frequency. After selecting the transducer and the application, which are based on patient anatomy, adjustments to output power should be made to ensure that the lowest possible setting is used to acquire an image. After the image is acquired, adjusting the focus of the transducer, and then increasing the receiver gain to produce a uniform representation of the tissue follows. If an adequate image can be obtained with the increase in gain, then a decrease in output should be made. Only after making these adjustments should you increase output to the next level.

Having acquired the 2D display of the liver, Color can be used to localize blood flow. As with the 2D image display, gain and image processing controls must be optimized before increasing output.

In summary: Select the correct transducer frequency and application for the job; start with a low output level; and optimize the image by using focus, receiver gain, and other imaging controls. If the image is not diagnostically useful at this point, then increase output.

Additional Considerations

Ensure that scanning time is kept to a minimum, and ensure that only medically required scanning is performed. Never compromise quality by rushing through an exam. A poor exam may require a follow‐up, which ultimately increases exposure time. Diagnostic ultrasound is an important tool in medicine, and like any tool, it should be used efficiently and effectively.

2.11 Important statement

1. The part or all of the contents of this manual shall not be copied or copied prior to the written permission;
2. It is forbidden to modify the software or hardware of this product;
3. The utility model can provide the doctor with the image and data needed for clinical diagnosis, and the doctor is responsible for the diagnosis process;
4. Quality assurance does not include the following, even within the warranty period:

   (1) Damage or loss caused by improper installation or environmental conditions that do not meet the requirements;

   (2) Damage or loss caused by the supply voltage exceeding the specified range;

   (3) Damage or loss of equipment or components purchased not from KONTED or its authorized distributor or agent;

   (4) There is no damage or loss caused by the use of this instrument in the initial purchase area;

   (5) Damage or loss caused by maintenance of non-authorized personnel of the company;

   (6) Damage or loss caused by force majeure such as fire, earthquake, flood or lightning;

   (7) Damage or loss caused by error or rough use;

   (8) Failure caused by other non product itself

5. FCC Caution:

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

This radio is designed for and classified as “General population/ uncontrolled Use”, the guidelines are based on standards that were developed by independent scientific organizations through periodic and thorough evaluation of scientific studies. The standards include a substantial safety margin designed to assure the safety of all persons regardless of age or health.

Body and limbs operation; this device was tested for typical body and limbs operations kept 0 mm for body worn. To maintain compliance with RF exposure requirements, use accessories that maintain a 0mm for body worn.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 1 5 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

— Reorient or relocate the receiving antenna.

— Increase the separation between the equipment and receiver.

— Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

— Consult the dealer or an experienced radio/ TV technician for help.

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

2.12 Maintenance and repair service

The main warranty period is 1 8 months. The warranty period from the date when the product leave the factory. Within the warranty period, the product can enjoy free customer service; but please note that even in the warranty period, due to the reasons on the page " important statement" caused by the products need maintenance, KONTED will charge maintenance services, you need to pay the cost of maintenance and spare parts costs.

After the expiration of the warranty, KONTED can provide maintenance services. It should be noted that if you do not pay or delay the payment of maintenance costs, US will temporarily suspend maintenance services until you pay.

We hereby declare that you must familiarize yourself with the operating instructions before use and operate and use it in strict accordance with the requirements and methods of operation of the operating instructions . The Company does not assume any responsibility for safety, reliability and performance assurance due to any abnormality caused by operation, use, maintenance and storage in accordance with the requirements of this manual .

Operation taboo:

⚠ **Danger** ※ Do not modify this equipment, including equipment components, software, cables and so on. User modifications may result in security problems or reduced system performance. All modifications must be completed by the personnel approved by KONTED.

2.13 Intellectual Property Statement

This specification and the intellectual property rights of the products are owned by KONTED. No individual or organization may copy, modify or translate any part of this manual without the written consent of KONTED

3 Product overview

3.1 Indications for Use

The Pocket Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), Color Doppler, Combined (B+M), and Pulsed Wave modes.

It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications depending on different configuration of array transducer:

Linear array transducer – Small Parts, Carotid, Peripheral Vessel, Muscular-Skeletal, Pediatric

Convex array transducer- Fetal/Obstetrics, Gynecological, Abdominal, Urology

Phase array transducer - Cardiology

The Pocket Ultrasound System C10 is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.

3.1.1 Intended User

Trained medical personnel which has the professional training knowledge and clinical Experience.

3.1.2 Intended Medical Conditions

This product is intended to be used in professional healthcare facilities.

3.1.3 Intended Patient Population

adult, pediatric

3.2 Contraindication

The Pocket diagnostic ultrasound system is not intended for use with contrast agents.

3.3 Product specifications

3.3.1 Imaging mode

B/M/C/PW **mode**

3.3.2 Power condition

External power adapter

Supply voltage AC : 100 - 240V

Power frequency : 50/60Hz

Output DC: 5V/2A

Internal battery

voltage: 3 .8V

capacity: 2600mAh

3.3.3 Principle of operation

The Pocket Ultrasound System is based on ultrasonic echo imaging, which is a common medical imaging technology to use the transmission speed of ultrasound in different tissues and reflection degree differences, the mechanical ultrasound waves spread through the body, producing an echo where density changes occur. the echoes return to the probe where they are converted back into electrical signals, to get images through computer processing for diagnosis and treatment.

The transducers inside the probe are responsible to emitting and receiving ultrasonic waves. When a pulse with a certain frequency and magnitude onto the transducers, then ultrasonic waves are generated through the inverse piezoelectric effect and transmitted to the human body tissue through the probe. When the ultrasonic wave meets the tissue interface, it will generate echoes, which are scattered in different tissues or blood flow and received by the probe and converted into electrical signals. The receiver amplifies and processes these electrical signals before transmitting them to the processing unit.

Based on the signals received, the processing unit will calculate the intensity and timing of the echoes to form an image.

3 .3 .4 environment condition

	work environment	Storage and transportation environment
ambient temperature	0 °C~ 4 0 °C	0 °C~ + 45 °C
relative humidity	3 0% ~85% (No condensation)	3 0% ~95% (No condensation)
atmospheric pressure	7 0 KPa~ 10 6 KPa	7 0 KPa~ 10 6 KPa

WARNING

Transport:

1. Do not use or store the system outside the specified environmental conditions.

Working:

1. Please ensure that the use of the equipment to master a solid, otherwise, equipment may hurt the patient fall.

2. To ensure that the equipment in a dry environment, the operation of environmental temperature and humidity changes, may lead to liquid condensation in the circuit board, there is the risk of short circuit.

3. Do not operate the unit in an environment with flammable or explosive liquids, vapors or gases such as oxygen or hydrogen. Equipment failure or fan motor sparks may be electronically detonated of these substances.

A. Please ensure that the environment before use, if the detection of flammable substances in the environment, please do not plug in the power or open the system.

B. Use the real-time detection environment to detect flammable substances after the system is turned on. Do not attempt to turn off the device or unplug the power supply. First empty the air in the area and ensure a smooth ventilation and then turn off the power.

4. If the system fails, please do not disassemble the view, please contact the service center or your sales representative.

3.3.5 Diagnostic information

The images provided and the measurement results offered are intended for use by competent users, as a diagnostic tool. They are not to be explicitly regarded as the sole, irrefutable basis for clinical diagnosis. Users are encouraged to study the literature and reach their own professional conclusions regarding the clinical use of the device.

The user should be aware of the product specifications and of the device accuracy and stability limitations. These limitations must be considered before making any decision based on quantitative values. If in doubt, the After sales engineer should be consulted.

Equipment malfunction or incorrect settings can result in measurement errors or failure to detect details in the image. The user must become thoroughly familiar with the operation of the Pocket Ultrasound System C10 to optimize its performance and to recognize possible malfunctions.

3.4 system configuration

The system is mainly composed of probe and application.

3.4.1 Packing list

- (Pocket Ultrasound System)Main unit： 1 set
- Cable: 1 set
- Wireless charger: 1 set
- Black handbag：1 set
- Accessories：None

Apolegamy：

Power adapter

Mobile cart

Custom packing box

A puncture stent

Disposable probe sleeve

IPAD

Couplant

Compatible device： Ultrasonic coupling agent (Note: The product does not include or provide this device.)

3.4.2 Components

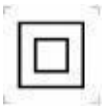
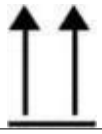
Transducer Type

Transducer model	Type of Transducer	Intended use	Applicable site	Wireless charging
C10	3 in 1 type	Linear array transducer – Small Parts, Carotid, Peripheral Vessel, Muscular-Skeletal, Pediatric Convex array transducer- Fetal/Obstetrics, Gynecological, Abdominal, Urology Phase array transducer - Cardiology	body surface	√

3.5 Symbol description

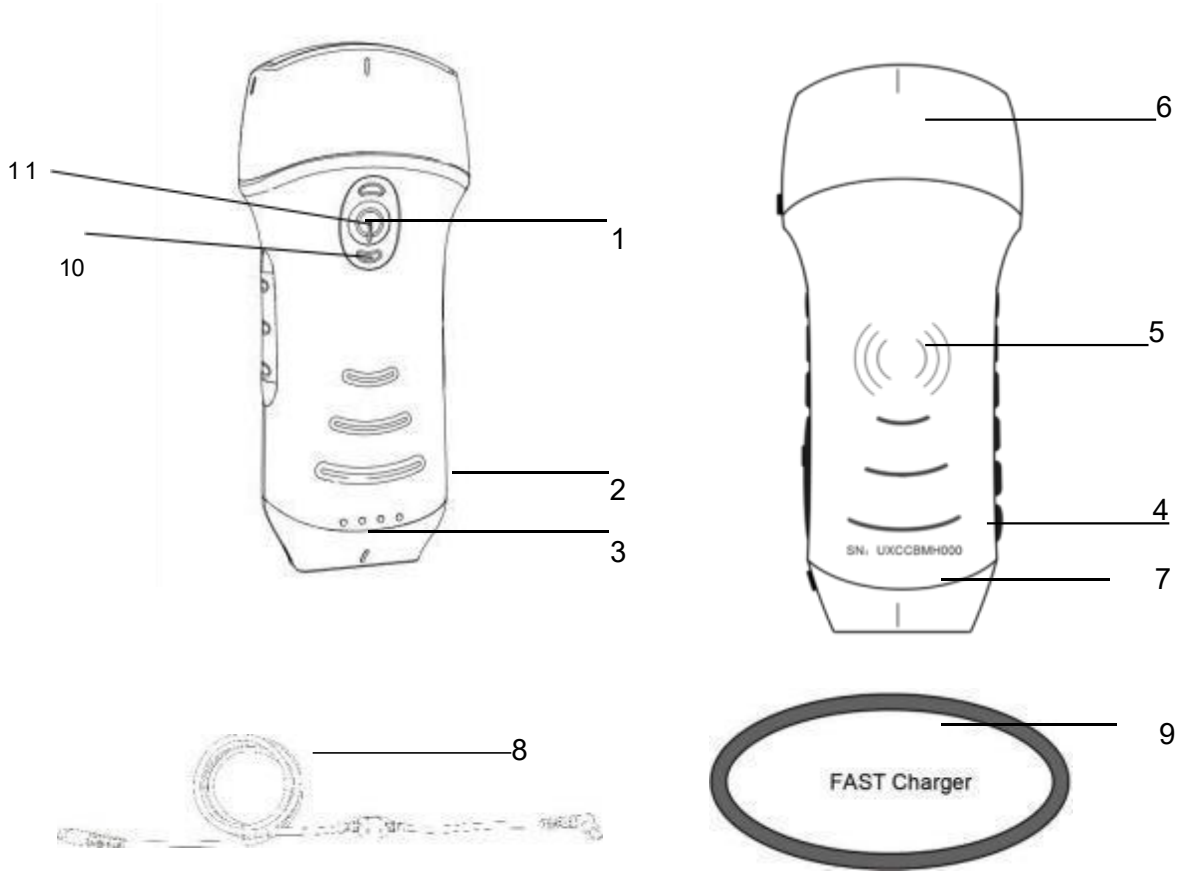
This device uses the following symbol identification, the following list shows its meaning.

Serial number	Symbol	Explain
1		Type BF application part Explain: All ultrasonic probes are part of the BF application.
2		Please refer to the instruction manual for this symbol to avoid accidents
3		Indicates the product serial number
4		Indicates the manufacture.
5	IP22	Prevent the intrusion of solid foreign objects larger than 12 .5 mm in diameter When the appliance is tilted vertically to 1 5 degrees, dripping water will not cause damage to the appliance
6	IP27	Prevent the intrusion of solid foreign objects larger than 12 .5 mm in diameter Prevent the effects of immersion for 30 minutes in water up to 1 meter deep
7		Indicates the date of manufacture.
8		Indicates that the device must be collected separately for disposal. Follow proper disposal procedures.
9	Rx only	Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
10		Indicates the reference or catalog number
1 1		Model number
12		Non-ionizing electromagnetic radiation
13		Country of manufacture

Serial number	Symbol	Explain
14		Importer
15		Distributor
16		Medical device
17		UDI
18		Class II equipment
19		Away from the sunlight
20		Storage temperature limit
21		Upwards
22		Keep dry
23		Storage humidity limit
24		Stacking layer limit
25	CE 1639	Safety mark on behalf of the product has been in line with European standards for safety / health / environmental / health and other standards and directives
26		Indicates that the device must be collected separately for disposal. Follow proper disposal procedures.

27	EC REP	Authorized European Representative: SUNGO Cert GmbH,Add: Harffstr. 47 , 40591 D üsseldorf, Germany
28		Indicates that the user should see the instructions for use for safety information.
29		Do not throw away. Dispose of in accordance with local, state, or federal laws.
30	GMDN	Global Medical Device Nomenclature Code
31		" Be careful" indicates what should be noted. Be sure to read the instructions carefully before using the system.

3.6 Introduction of each component of the system



number	Name	Function
1	Control buttons	Power switch / freeze / Living button
2	USB Type- C port	Charging with USB type- C cable
3	Battery status	Battery charge/ remaining display
4	SN	Serial number; password of this probe' s wifi
5	Wireless charging symbol	Face to wireless charger
6	Convex probe	= Convex probe + Phased probe
7	Linear probe	Linear probe
8	Cable	Charging with USB type- C cable
9	Fast Charger	The wireless charging pad
10	Linear probe indicator lamp	The blue light indicates that the wire Linear probe
11	Convex probe indicator lamp	The green light indicates that the wire Convex probe

3.7 Control panel

Control buttons	Button icon	Key name	Function
		Power switch / freeze / thaw button	1 ） When the probe is not turned on, press the key to open the probe; 2） When the probe is in the open state, hold for 5 seconds to turn off the probe, the indicator become black screen. 3 ） When the probe is in the scanning state, press the key to freeze the screen image; 4 ） In the frozen state, press the button to thaw the screen image, the probe continues to scan the image. 5 ） Press and hold for 3 seconds to switch the scanning mode(Convex array probe/ linear array probe)

Press the button and hold for 3 seconds to switch the scanning mode (Convex array probe ↔ linear array probe)

4 . Basic introduction

4.1 Install software

4.1.1 Android device

Download the Android software from Google Play store . The App name is **MY USG.** The following lists the requirements:

Updates to the App and probe are handled through the Google play.
Keep your mobile device' s operating system and the App updated to ensure you have the most up- to- date version.

The minimum device specifications for MY USG APP:

• Minimum 500 MB of storage space (plus more for patient data storage)

• Color display, minimum 14 cm (5.5 in)

• 1280 x 800 resolution (minimum)

• Touch interface

• Internally mounted speakers

• Date/time configuration

• Android 8.0 or later operating system

• IOS 11.0 or later operating system

• Android phones and tablets with 0x64 ARM based CPU architecture and 64-bit Kernel, Android open GL ES 3.0, and compatibility with Google Play store

• iPad and iPhone devices with iOS 14, 15 or 16

• Wireless or cellular networking capability: Wi-Fi (IEEE 802.11n, 2.4 GHz & 5 G ISM band)

• Audio capability

• Front- and rear-facing cameras

• IEC 60950-1-compliant

• Security requirements

- WPA2

- Data on device must be encrypted and authentication enabled

4.2 Turn on/off the probe

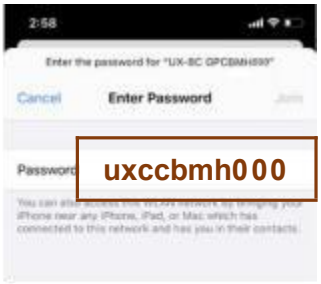
Press the power button  to turn on the probe, the indicator will show the battery icon.

after ultrasonic examination, Press the power button  and hold for 5 seconds to turn off the probe, the indicator become black screen.

4.3 Probe and Terminal connection

4.3.1Wi- Fi connection:

The first time connection between the probe and the smart terminal device need to be entered the Wi- Fi password. After the first time connection, the device will be connected with the probe' s Wi- Fi automatically.



Note:

password is the SN of the probe, but it is the small letter not capital.

Probe SN: uxccbmh000

Step1 :

Turn on the ultrasound transducer and turn on the Wi- Fi on your IOS or Android device.

Step2:

Search the list of networks for the SSID with the suffix "UX-8C *****A000" .

Step3:

Enter the Wi- Fi password, this Wi- Fi password is the serial number of the probe, but it is the small letter not capital.

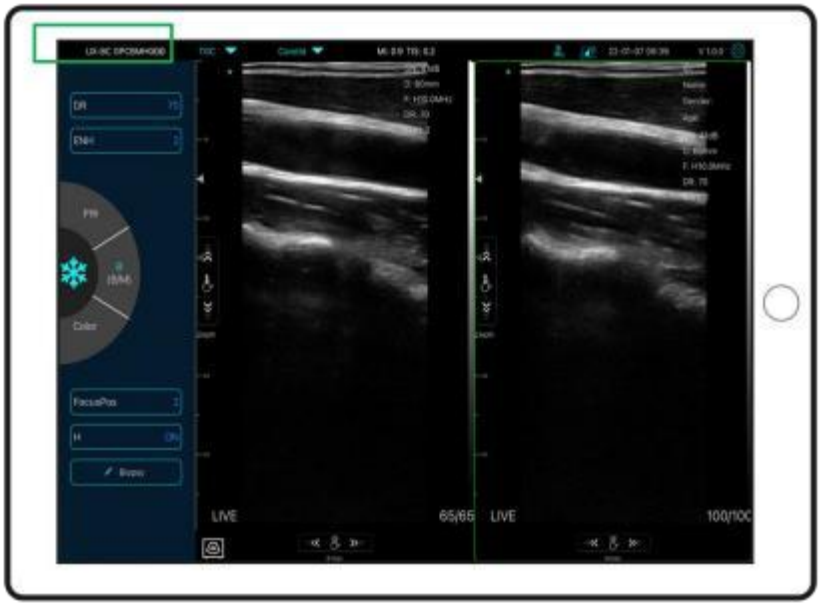
Step4 :

The Wi- Fi name is preceded by a " √ UX- 8 C * * * * * A00 0 " , Indicates the connection is successful

Step5:

To open the MY USG App on your mobile device' s home screen, After successful login,

The " UX- 8 C * * * * * * A0 0 0 " will be represents normal connection displayed on the App interface



Note:

- If you connect the probe to your device successfully, but there is no image on the screen, please try to press the power button again.

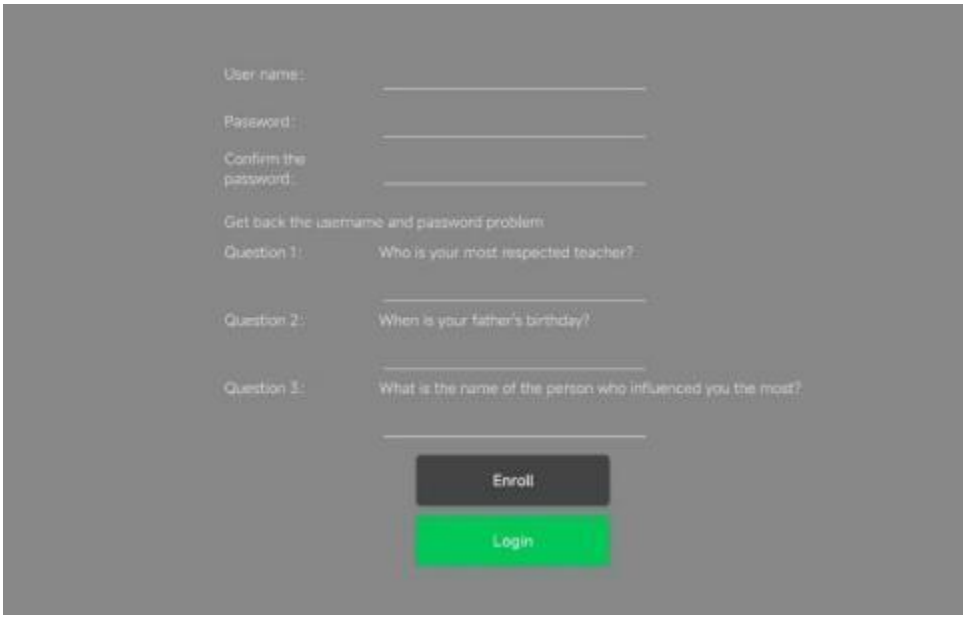
- The password' s letters must be input as small letters, not capital.

- When the probe is connected to mobile device A, if you want to change mobile device B to connect with the probe, please disconnect the probe from the mobile device A firstly. The probe only can be connected to one mobile device at the same time

4 . 4 Users register and log in

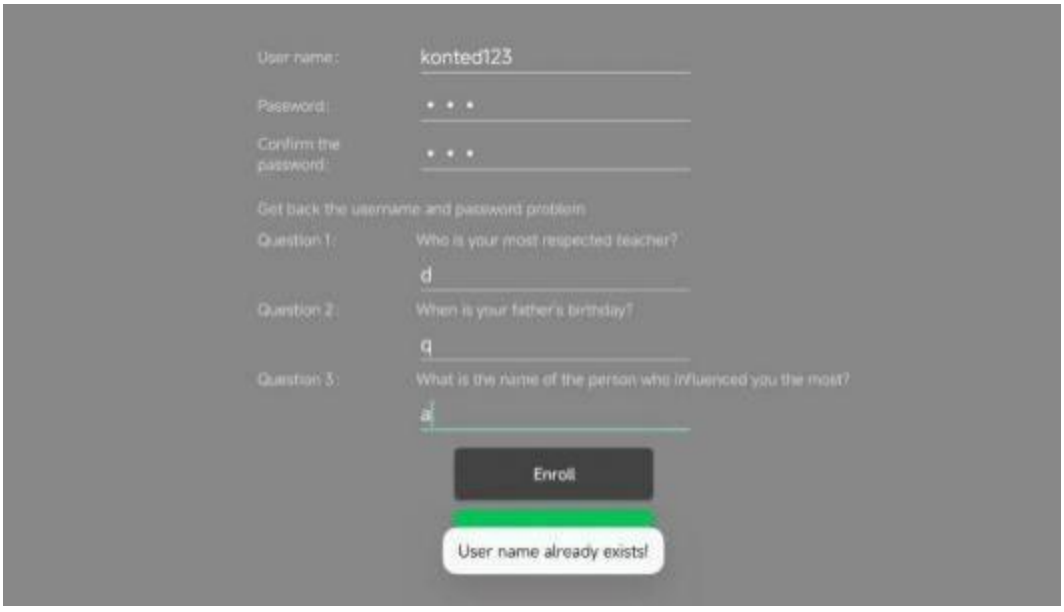
4 . 4 . 1 Users register

The first time you use the software, click “Enroll”. Register according to the interface prompts, the user name " number + letter" composed of no more than 13 bits, the password " number + letter" composed of no more than 13 bits, For Each user, please carefully fill in the following information and questions. The answer to the following question is to forget the password or reset the user registered account, the interface is shown in the figure below.

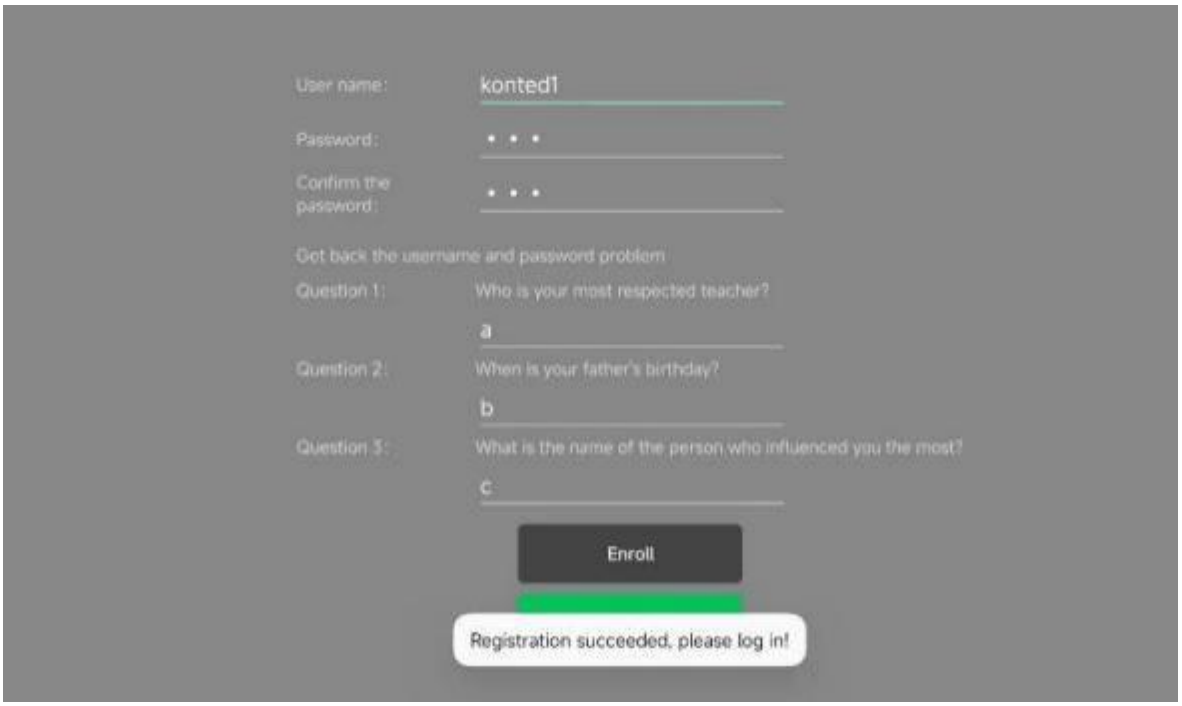


Registration interface

If the user name has been registered during the registration process, the registration will not be successful, the interface will indicate that the user name already exists, please re- register, As shown in the figure below

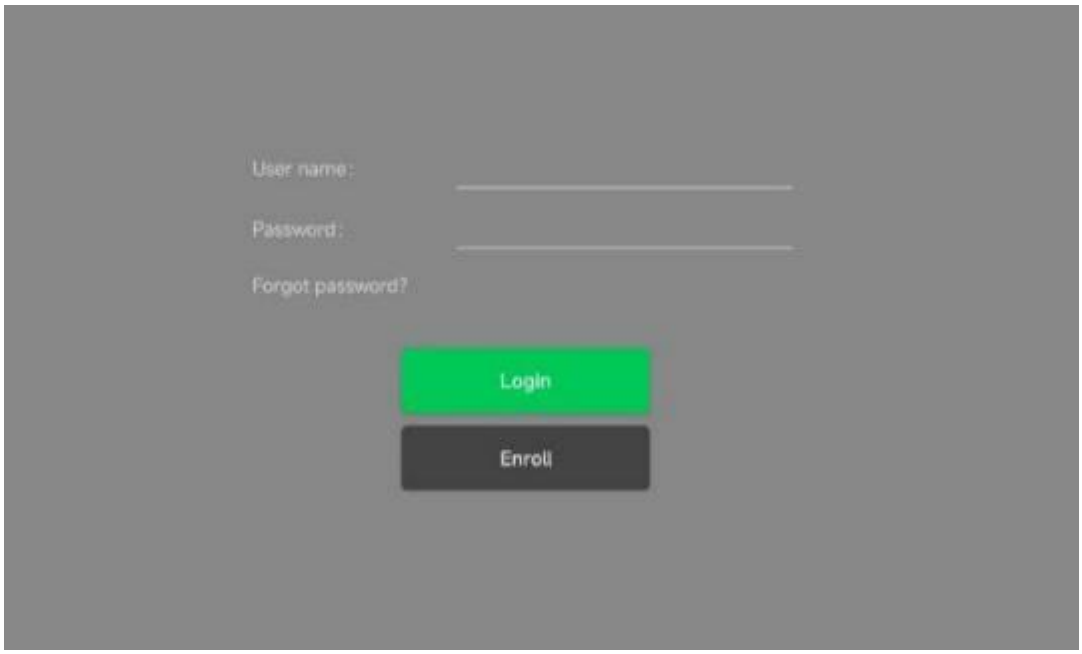


If the user name does not exist, the direct registration is successful, and the interface prompts the registration success, as shown in the figure. Click Login and jump directly to the login interface.



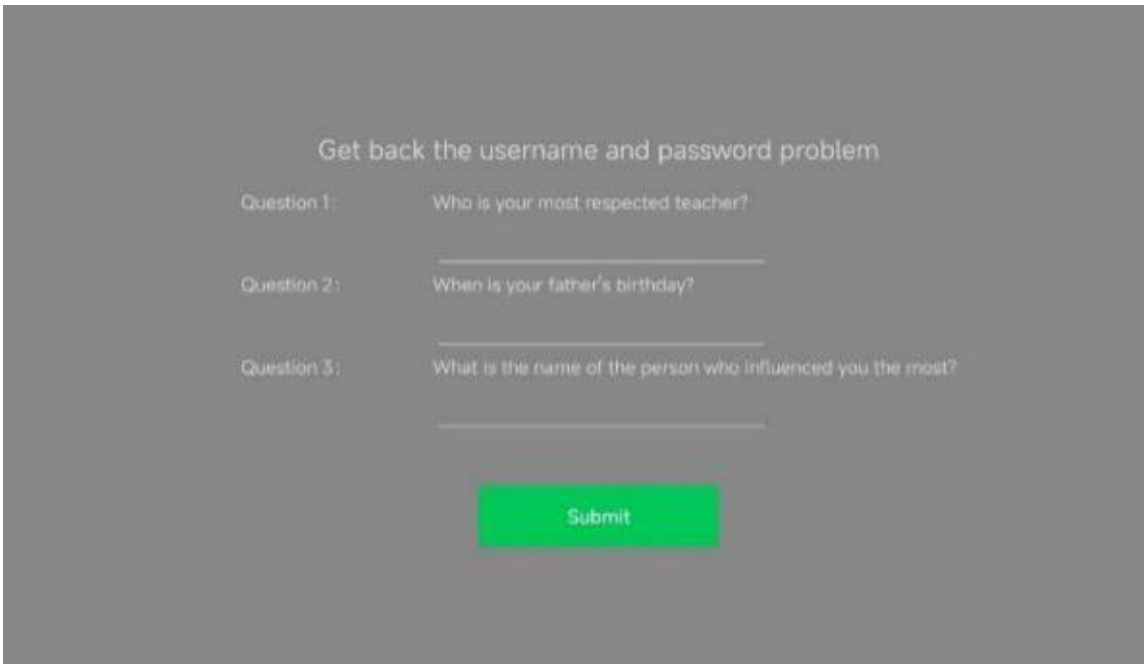
4.4.2 Users login

After registration, enter the registered user name and password for login. The login interface is shown in the figure below



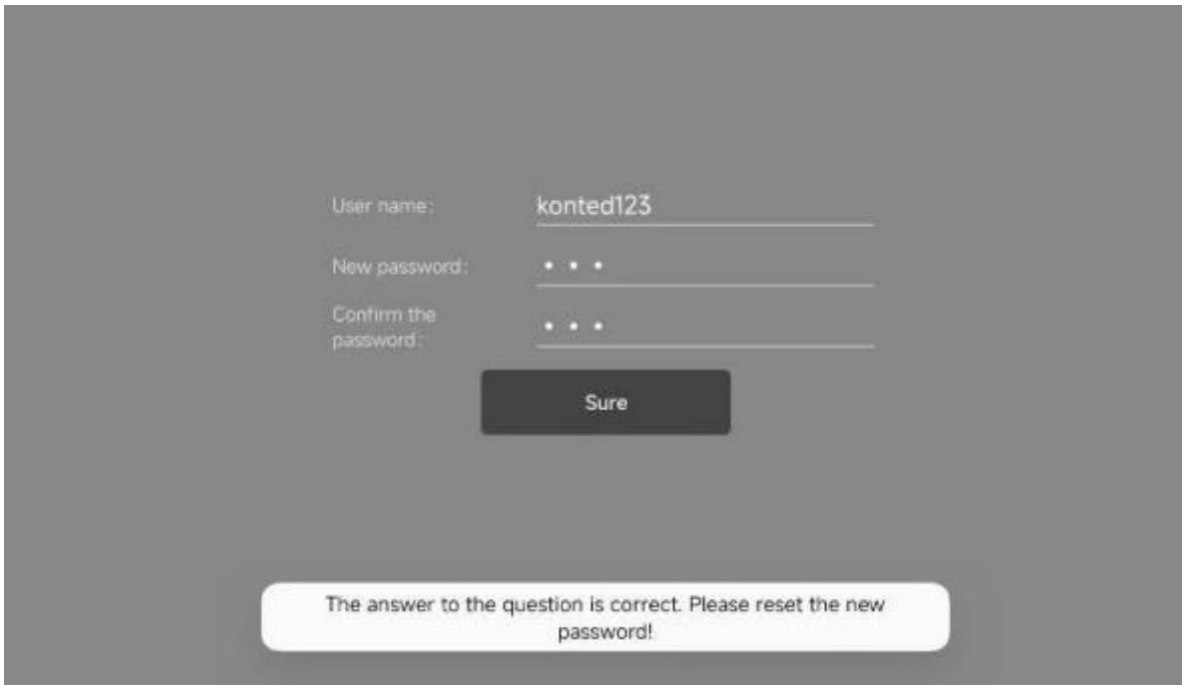
4 .4 .3 Reset the password

When forgetting the password , After entering the username click forget password, the interface jumps to reset the password, through the answer to the question left during registration, you can reset the password， As shown in the figure below

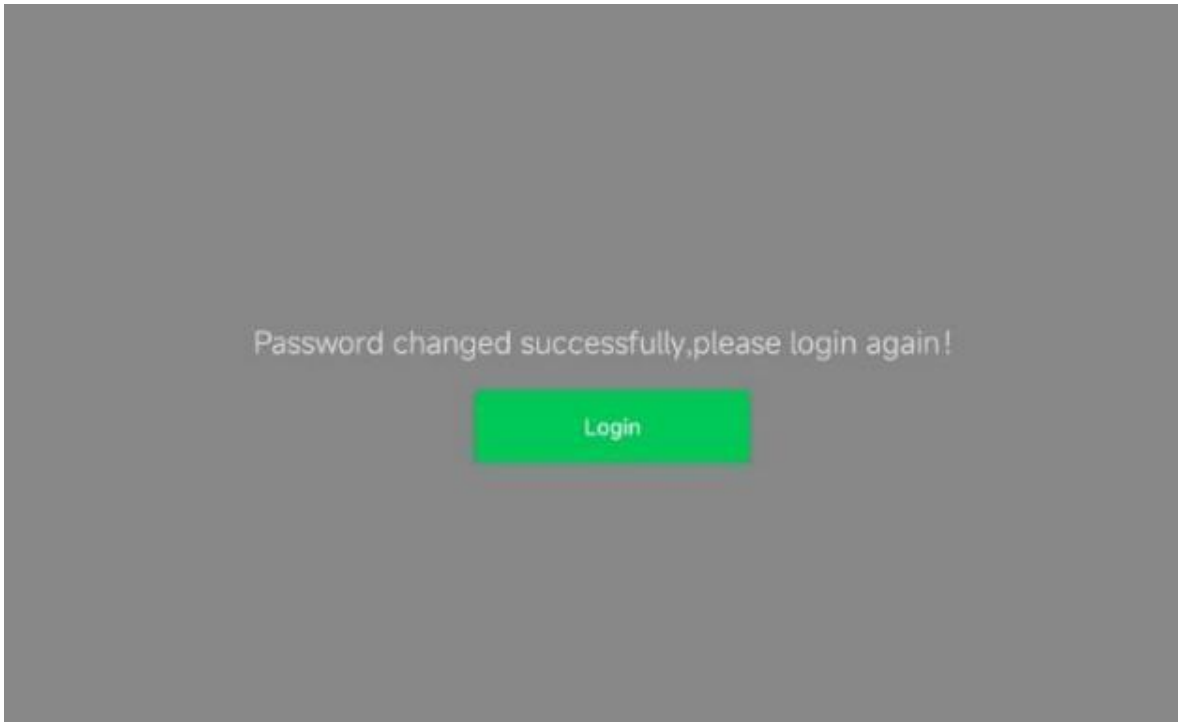


If you enter the answer is incorrect or forget the answer to the question, please contact the manufacturer for help, input the answer a total of five opportunities, input 5 times after the answer is incorrect, the system to protect the security of the data will lock the software, data will be destroyed, in order to prevent data loss, please remember Information at registration, and upload or backup data in time. The interface is shown in the figure below

If you enter the correct answer, the interface will prompt the reset password success, Please enter a new password， The interface is shown in the figure below



After entering the new password, click Sure, and the password will be reset successfully. Please log in again，



4.5 Basic software interface

4.5 . 1 Convex array + Phased array mode:

4.5.2 Linear array mode:

Presets and Transducers

These are the presets for the transducers that are compatible with your ultrasound system.

System Transducers and Supported Presets

5 Detailed operation introduction

5.1 Introduction to all levels of menu

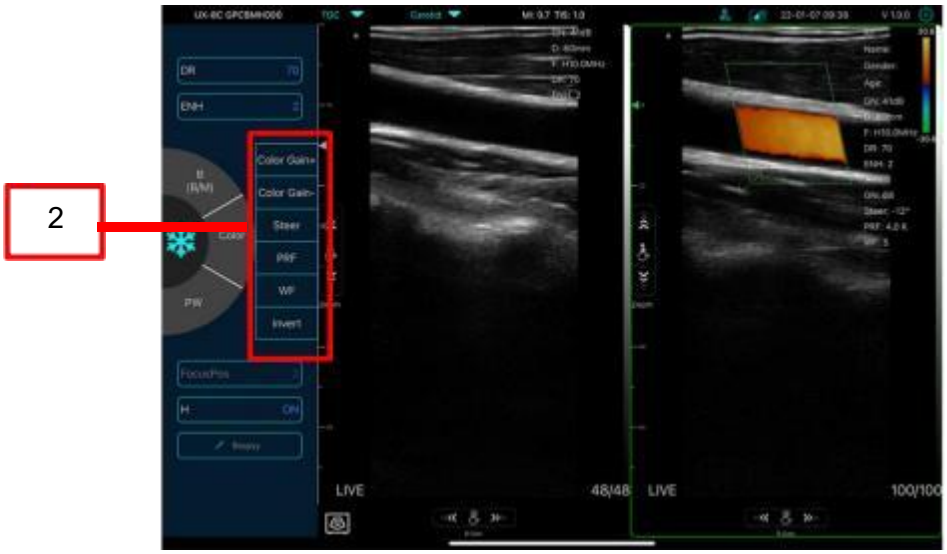
The menu in this system is divided into first level, second level

5.1.1 First level menu

1. Preset button
2. Hidden menu for parameters

5.1.2 Introduction to the second level menu

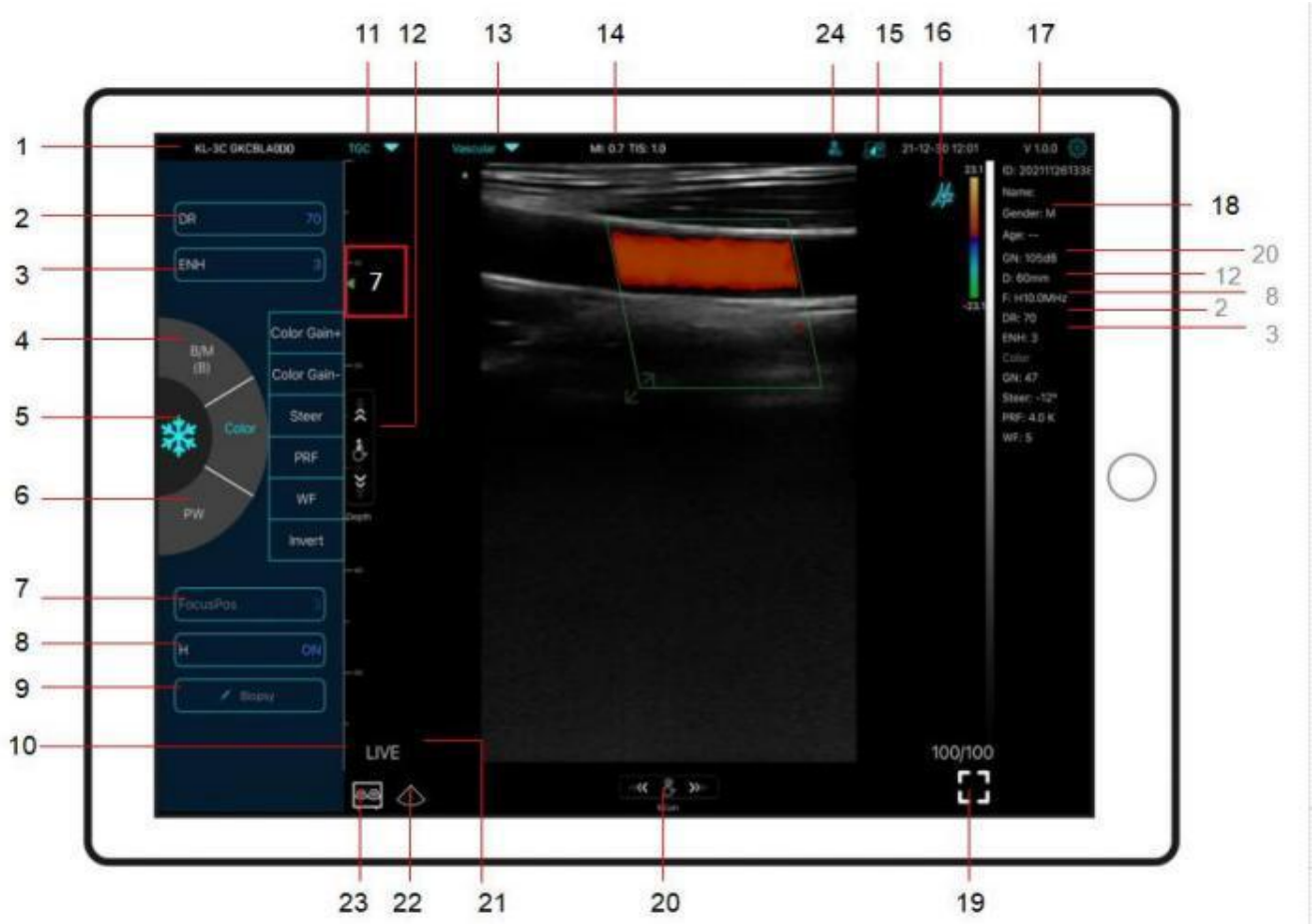
The 2 level menu is controlled by clicking on the corresponding item of the 1 menu. This is the 2 level menu in Color mode.



5.2 Operation Introduction

5.2.1 B mode

Live mode



No	Item Description		
1	Serial number of probe	13	**Preset selection**
2	Dynamic Range (DR)	14	The Thermal Index (TI) , Mechanical Index (MI) , and Hz values
3	**Imaging Enhance (ENH)**	15	DICOM Procedures, uploading images to PACS
4	Mode: B⟺B/ M, Dual click to switch scanning mode	16	Body Mark
5	**Freeze/Live button**	17	APP version number

6 Mode:PW

7 **Focus Position**

8 H: **change scanning frequency(F)**

9 Biopsy Needle Guide line
To invert the image horizontally or vertically. U/D flip, R/L flip

10 Depth Scale display

11 8 TGC: adjust gains of different depth

12 **Depth**: adjust depth by swiping the button (D)

18 Show patient information

19 **Full screen**

20 **B Gain （GN）**

21 Live/freeze display

22 Mid-line

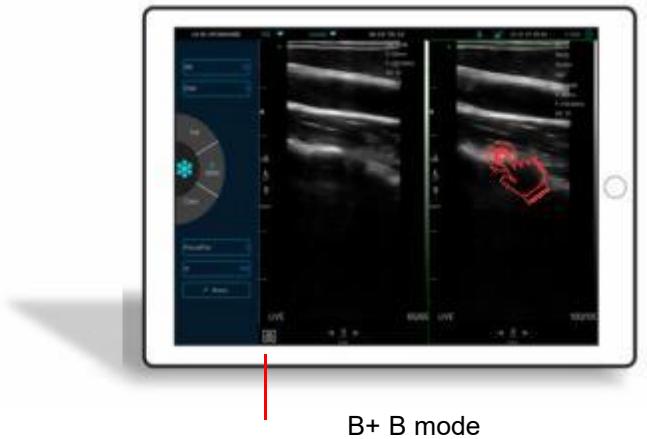
Dual screen display mode
(only available for Apple ipad and android pad device)

24 **New patient & new report**

23 **Dual screen display mode**

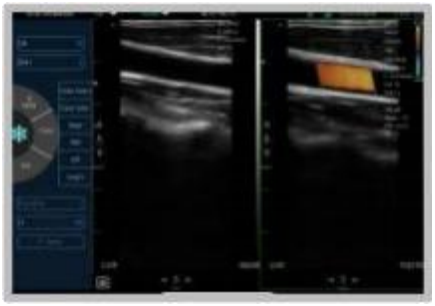
Click  button to switch the dual screen / single screen mode

Click the left/right screens to switch freely, and you can switch B/BM/Color/PW mode at the same time

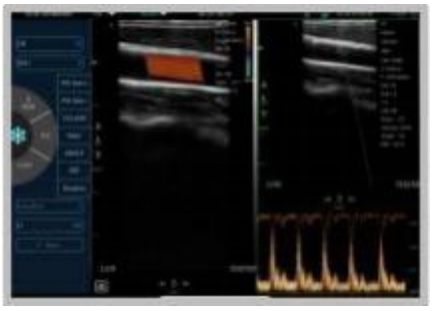


B+ B mode

23



B+Color mode



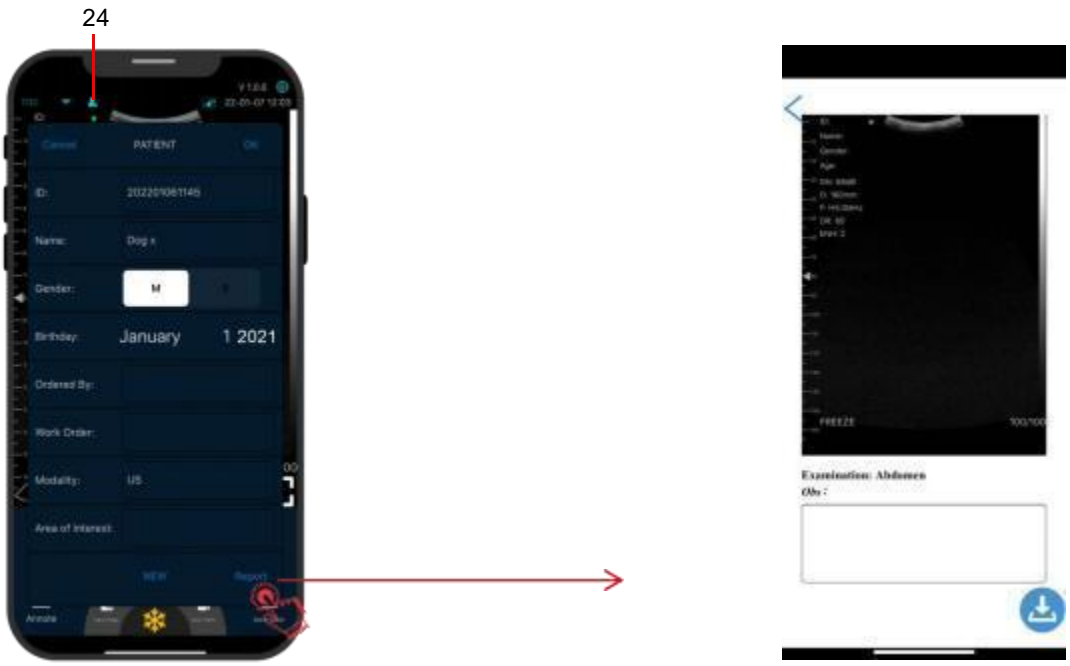
Color+PW mode

24 **New patient & new report**

a. Enter new patient info, click **OK**

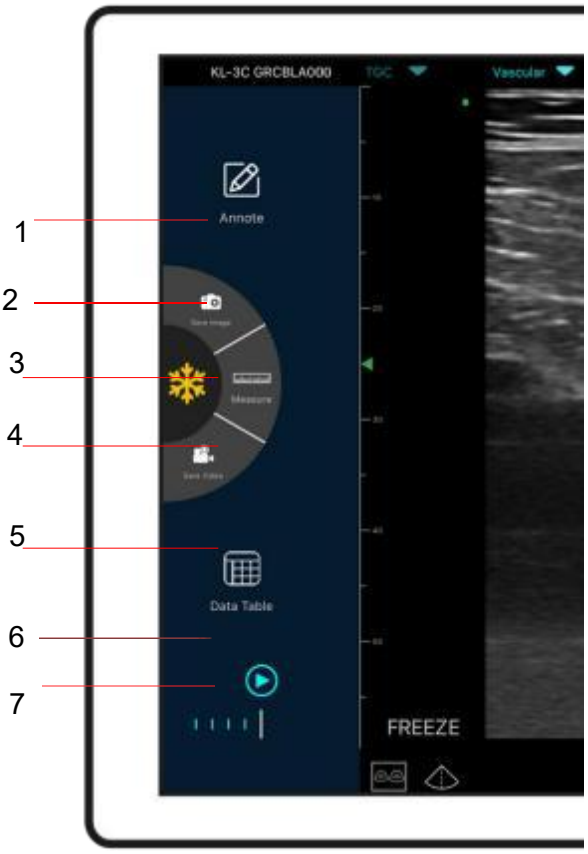
b. Scan now, then Freeze image

c. Edit the report, click  save the report to Data Table 



Freeze mode

1		add annotations on any frozen image
2		Save image, review the image in Date Table
3		Measurements
4		Save video, review the video in Date Table
5		Date Table
6		Auto cine review
7		Manual cine review



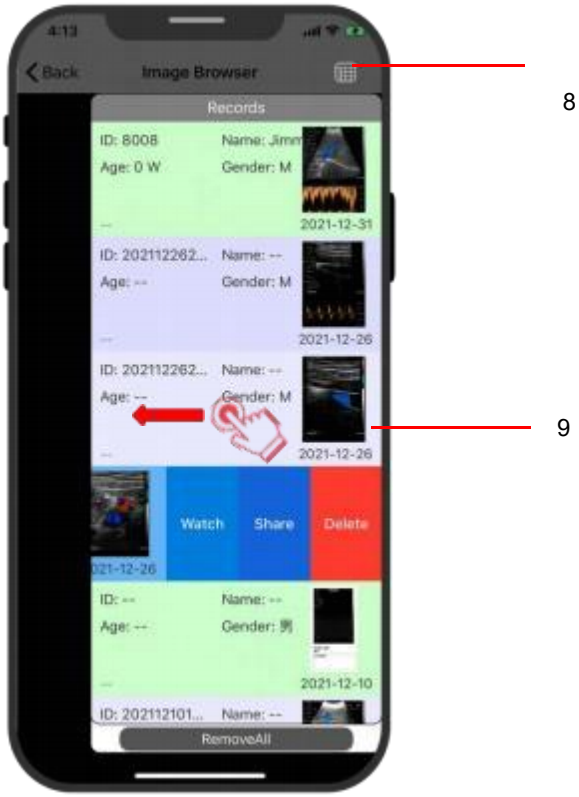


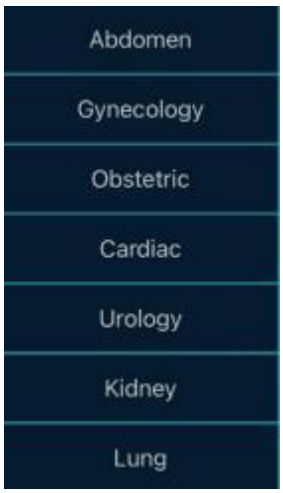
Image Browser
Review image/video/report

Watch	①Click **5 Date Table** ②Click 8 eck record ③ Please swipe to the left to browse the images/videos and report.
Share	Sharing scanned files by other app Printing image/report
Delete	Delete local files The data table can store 500 files

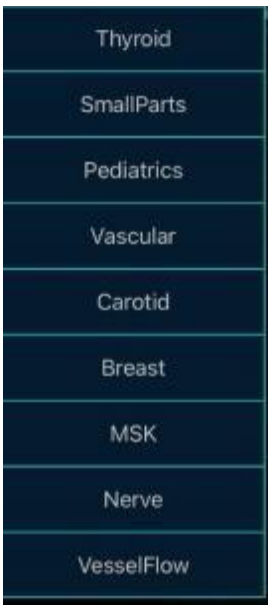
Selecting Exam Present

Tap **No.31 (Abdomen)** to select the present:

Convex probe:



Linear probe:



Switching Between Imaging Mode

Tap **No.22 (Mode)** to select the imaging modes:

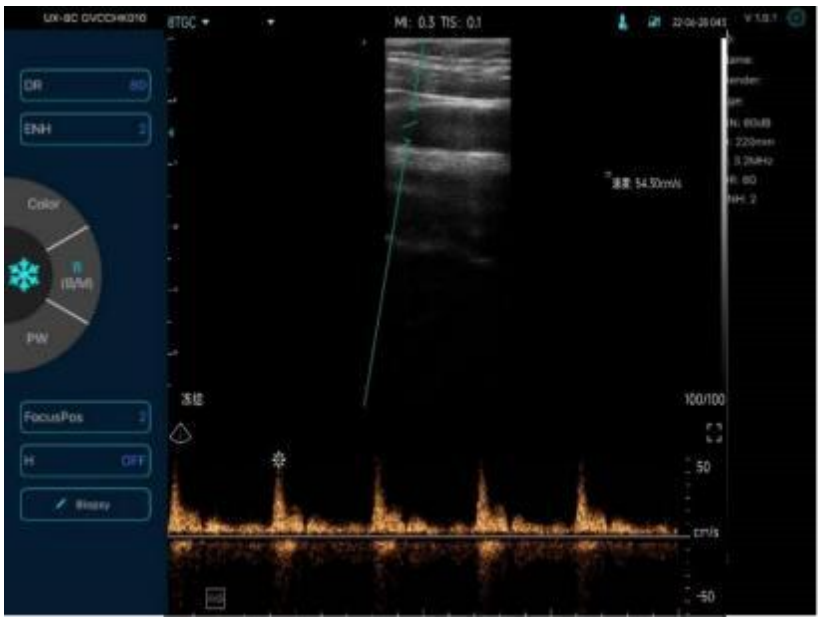
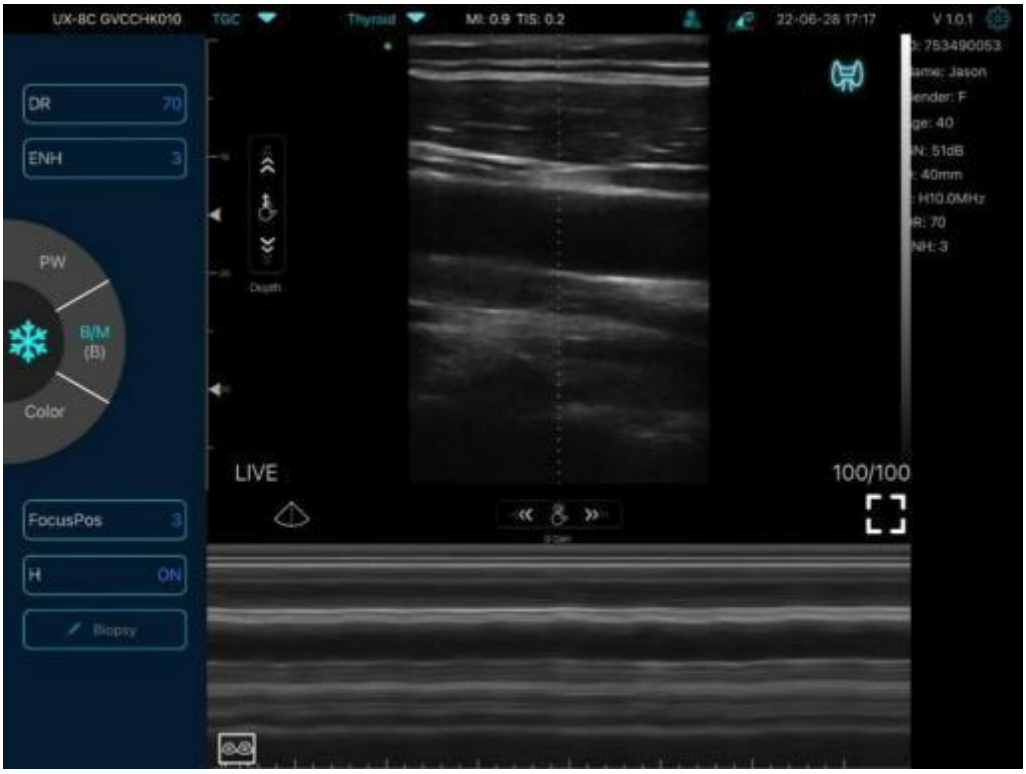


Image Adjustment

Requirement	Available Operations
To modify the brightness	Adjust **No. 10 Gain** Adjust **No. 19 8TGC**
To modify gray scale image effect	Adjust **No.23 Focus Pos** Adjust **No.24 ENH** Adjust **No.25 H** Adjust **No.26 DR**
Zoom	Adjust **No.4 Depth**

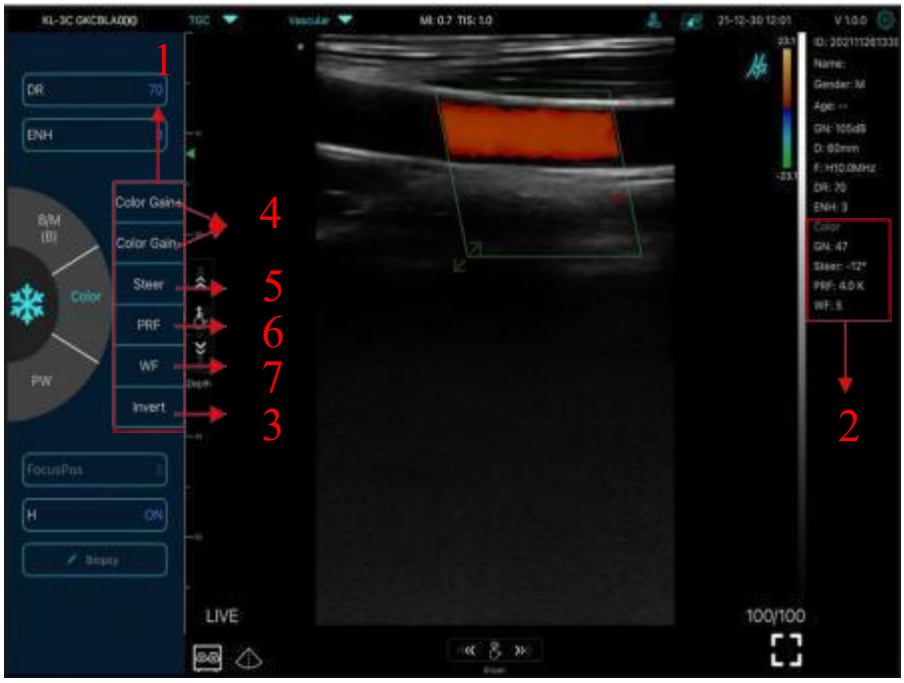
5.2.1 BM mode

In BM mode, click the cursor two times, it will change green,you can adjust the position of the M sampling line by moving the following marks with your finger.



5.2.2 C mode

1). Second menu in color mode,click the buttons, the parameter will be changed
2). Parameters display area in color mode
3) Click this button,this button will be changed to button named”size” ,the***can be adjust the size in this status as below
4) Increase+ or reduce - the color gain
5) Steer: afterglow adjustment
6) PRF:Adjust color pulse repetition frequency
7) WF: adjusting the filtering frequency of a pulse wave or continuous wave Doppler low frequency signal



5 .2 . 3 PW mode

1 .Second menu in PW mode, click the buttons, the parameter will be changed

2. Parameters display area in PW mode

3 .PW gain: Increase+ or reduce - the pulse gain

4 .Steer: afterglow adjustment

5. Angle: real- time scanning state, used to change the spectrum sampling line angle

6 .Sampling volume: change the size of the sampling volume

7 . PRF: Adjust color pulse repetition frequency

5.3 Measurements

5.3.1 General measurements

General measurements refer to general measurements on images of B/ C mode, M mode, PW mode.

To perform a measurement:

1 . Tap  to to freeze the image.

2. Tap  to access the measurement tools.

Mode	Measurement Tools	Available Operations
B/C	Length	Measures the length between two points of interest.
	Area/ Circumference	Measures the distance between two points of interest.
	Trace	Measures the length of a curve on the image
	Distance	
PW	Velocity	Calculate the velocity of the point in Doppler spectrum wave .

3 . To delete a result, tap the result, then tap the "**X**" next to the corresponding numeric measurement display, and then tap Delete Line to confirm.

5.3.2 Measurement Accuracy

You can use the ultrasound system to make measurements on ultrasound images. The measurements are then used with other clinical data to make a diagnosis.

Making a diagnosis based solely on measurements is not recommended. There are numerous factors to consider when using quantified data from any ultrasound imaging system. A careful analysis of those factors indicates that the accuracy of each measurement is highly dependent on image quality. Image quality in turn is highly dependent on system design, operator scanning technique, familiarity with system controls, and, most important, patient echogenicity.

WARNING

System users are responsible for image quality and diagnosis. Inspect the data that is being used for the analysis and diagnosis and ensure that the data is sufficient both spatially and temporally for the measurement approach being used.

Measurement Accuracy Tables

Measurement accuracy – convex array

Measurement	Units	Accuracy	Useful range	Limitation or conditions
Axial Distance	mm	±2% or 2mm whichever is greater	1-50mm	Bmode
Lateral Distance	mm	±2.5% or 3mm whichever is greater	2-40mm	Bmode
Circumference	mm	±15%	10-300mm	Bmode
Area	mm2	±15%	0.04-70cm²	Bmode
Depth	mm	±2% or 2mm whichever is greater	1-50mm	Bmode
Velocity	cm/s	±20%	0-±70cm/s	Doppler mode

Measurement accuracy – linear array

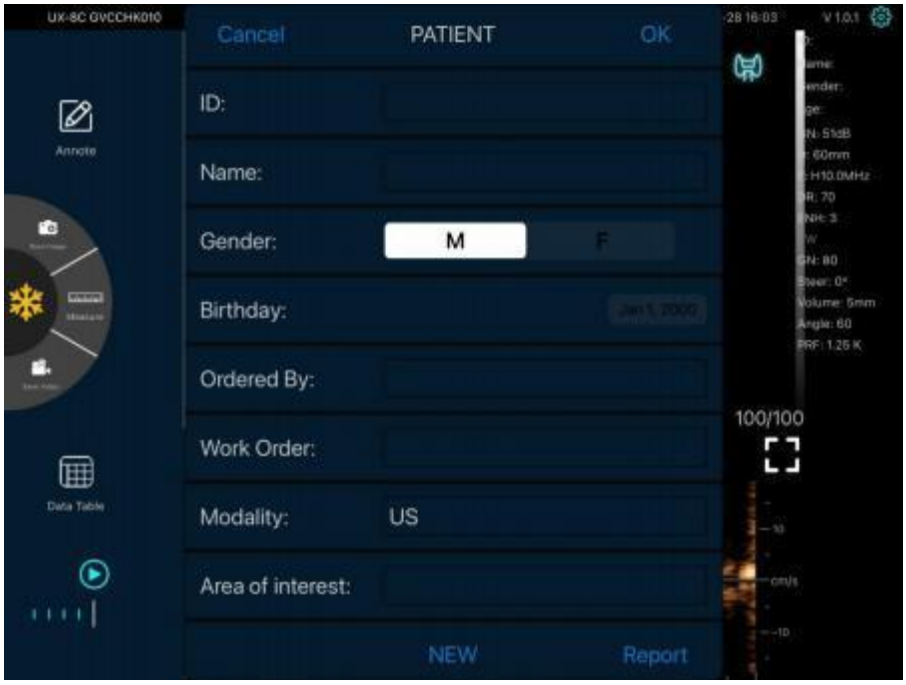
Measurement	Units	Accuracy	Useful range	Limitation or conditions
Axial Distance	mm	±2% or 2mm whichever is greater	1-40mm	Bmode
Lateral Distance	mm	±2.5% or 3mm whichever is greater	2-30mm	Bmode
Circumference	mm	±15%	5-150mm	Bmode
Area	mm2	±15%	0.02-17cm²	Bmode
Depth	mm	±2% or 2mm whichever is greater	1-40mm	Bmode
Velocity	cm/s	±20%	0-±70cm/s	Doppler mode

WARNING

You are solely responsible for custom measurements and calculations and the accuracy of elements entered into the equations.

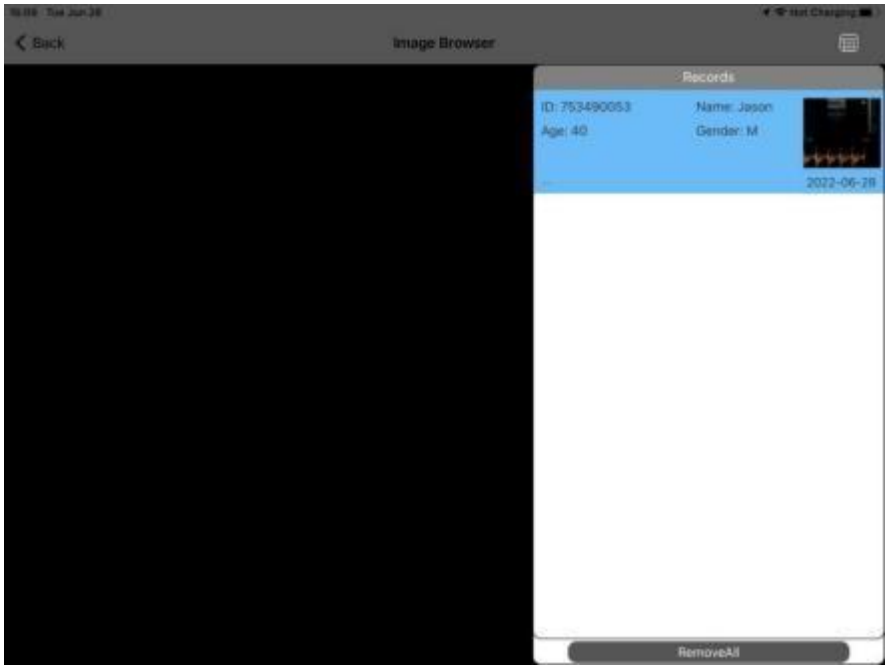
5.4 Patient's information and report

1 . Click "ID" on the patient information enter the patient data input box.



2 . After editing the report, click  to save the report to the  Data Sheet .

Please swipe to the left to browse the pictures/ videos and report.



5.5 DICOM

DICOM is the digital imaging and communication standards. This system support related DICOM functions:

- DICOM Basic function: DICOM connection verify, DICOM storage.
- DICOM work list

5.5.1. Dicom Setting

Step1：

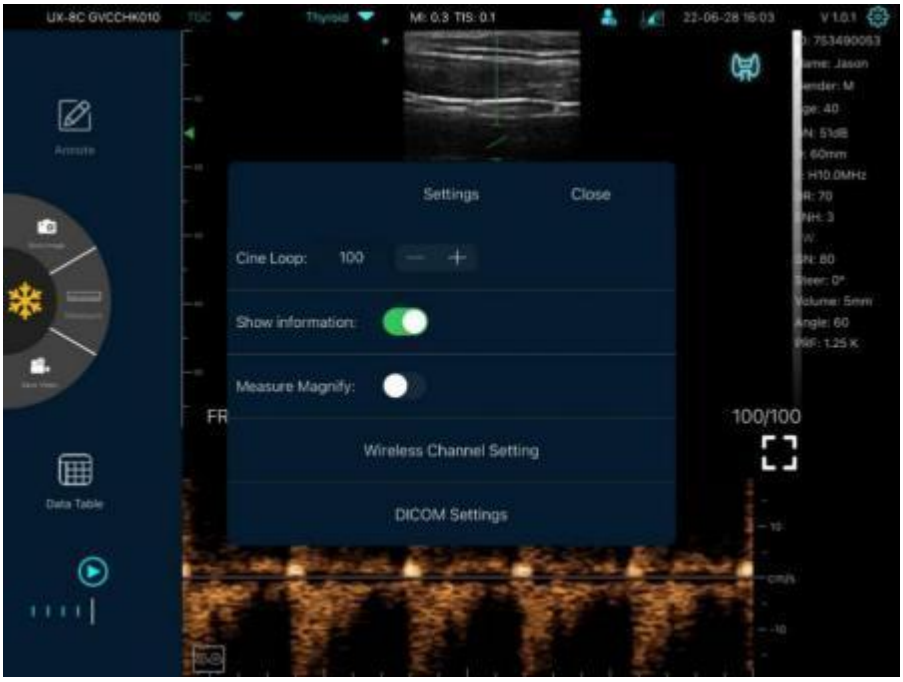
Click setting  , then press Dicom Settings.

Step2：

a. Connect mobile device with Workplace WiFi

b. Fill in the DICOM1 - DICOM2 - Worklist information and tap Ping buttons to test run the Setups .

c. If “ success” messages appear, then the DICOM connection is completed.

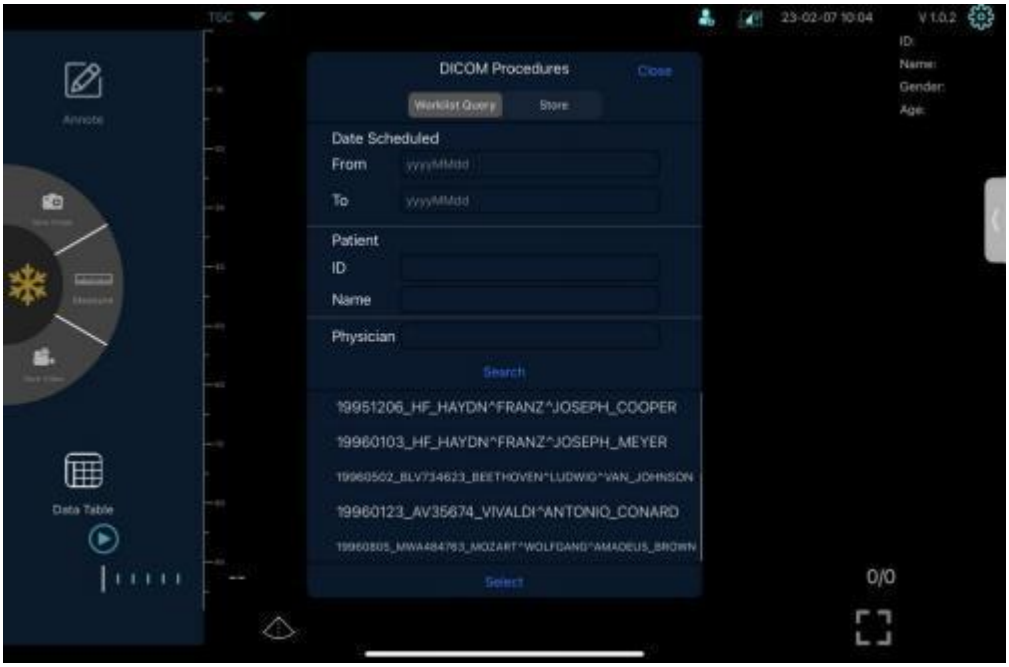


5 .5 .2 . Dicom Procedures

After successfully connect to DICOM Worklist server with ultrasound system .

Click  you can search and query patient records from Worklist server, and then import the desired information to your system .

DICOM Store is used to send image(s) to DICOM store server for store.



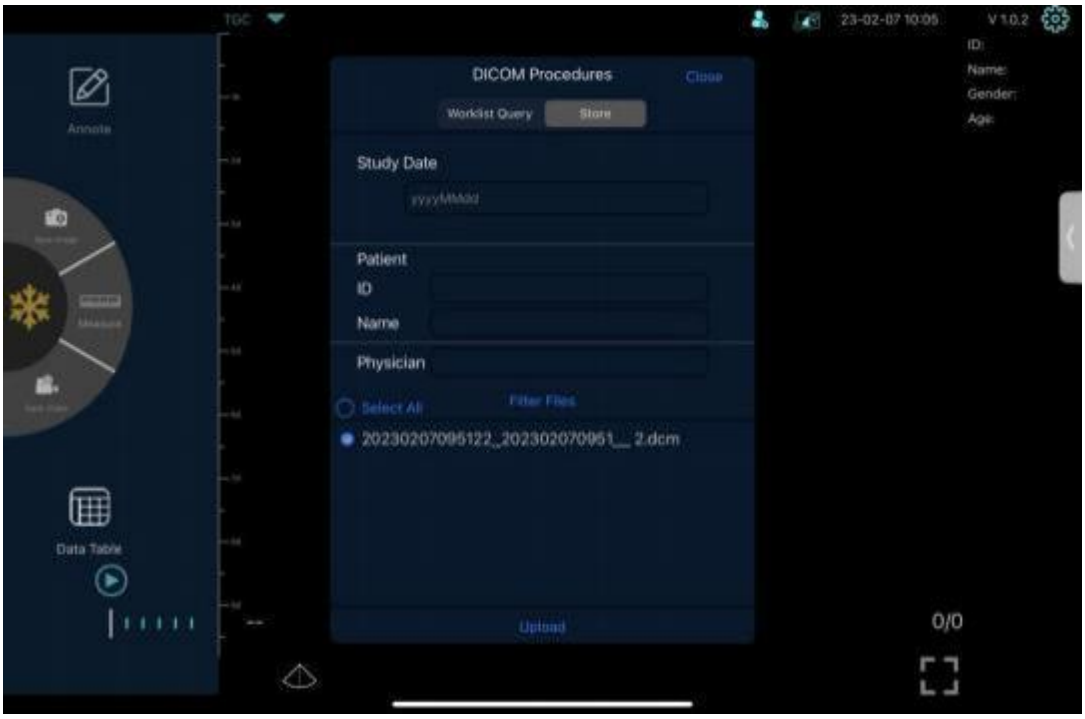
Dicom worklist

- Query patient information: Set query criteria among date Scheduled, Patient ID, Patient Name, physician.
- Click< Search> The scheduled patients, which meet the criteria, are displayed in the lower part of the screen.

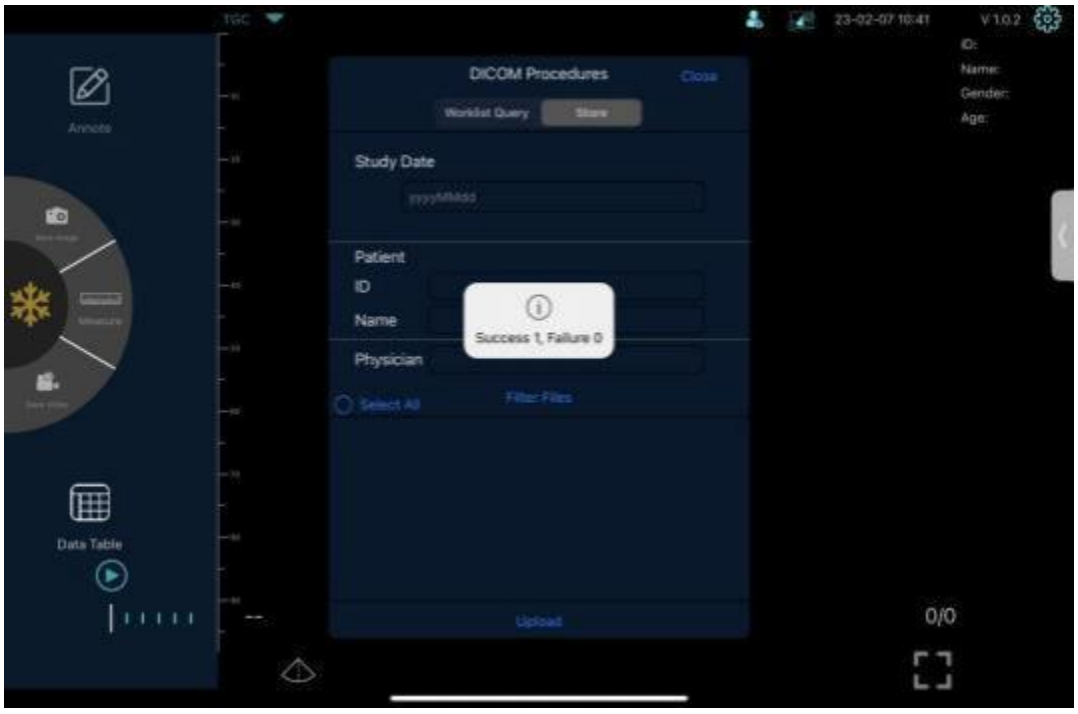
Double-click or select one record, then click “Select” will display some information, and click “Use” to automatically fill in the APP case information form.

Dicom store

You can select a record and click “ upload” it to Dicom store, then the “ upload” is completed.



Successful upload interface is displayed“success” messages appear, To prevent data loss， upload or backup data in time， As shown in the figure below，



6 maintenance and inspect

6.1 Charging the probe

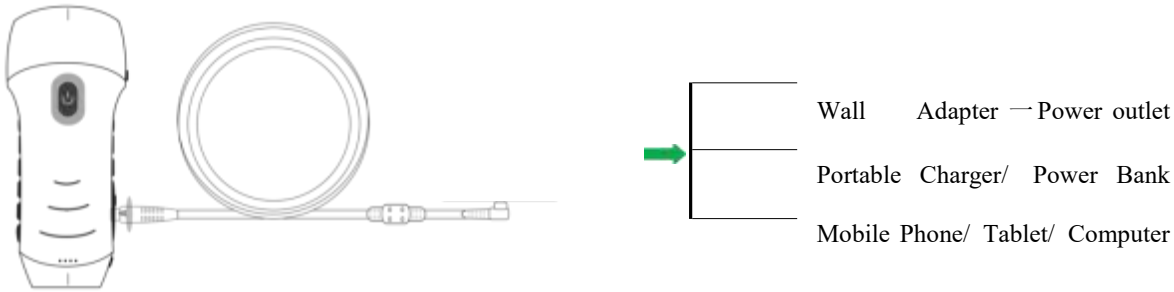
Charge the probe when the battery is low(one cell battery) . When charging, the battery indicator flashes to indicate the current charge level . US suggest the probe should be charged when one cell battery showed. If the 4 - cell battery indicator is on and the battery indicator stops blinking, the battery is fully charged.

6.1.1 Charging by USB cable:

1 . Pull out the rubber plug at the right-side of the probe.

2 . Use our USB Type- C charging cable to connect the probe and wall adapter. (or other USB port that can provide the power supply such as a portable charger) as shown below.

3 . Plug the wall adapter into a power outlet.



Note:

- The probe does not work during charging, and the charging cable has no data transmission

- When you connect the probe to your Mobile phone/Tablet/PC by type- c cable, the probe will be charged automatically.

- The power adapter shall use the European adapter , The standard is as follows

input： 100-240V~50/60Hz 0 .5A max

out put： 13 .6V⎓ 1 .0A

6.1.2 Charging by wireless charging pad:

The probe support wireless charging.

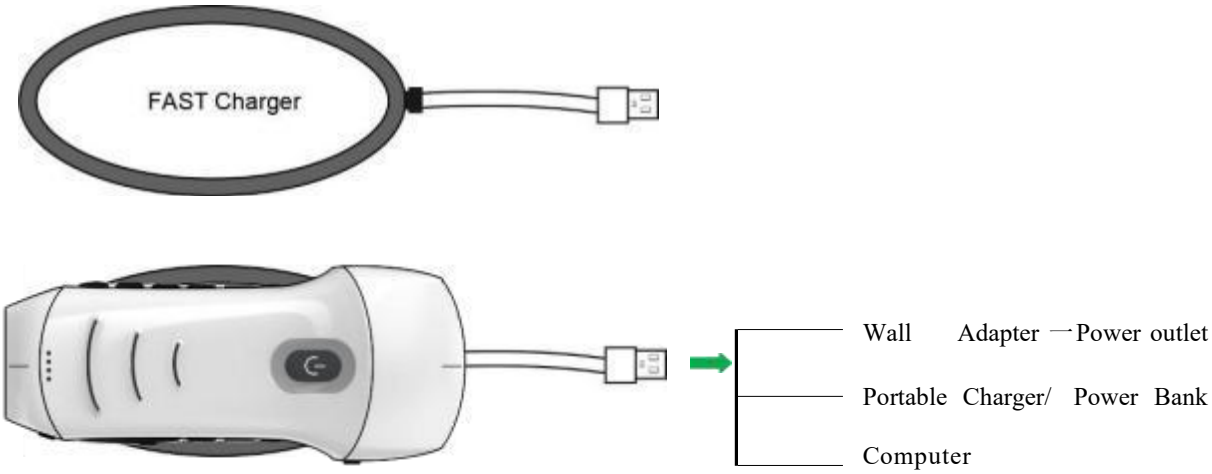
1 . Disconnect the probe from your mobile device.

2 . Connect the Micro USB cable to the wireless charging pad.

3 . Connect the USB end of the cable to the wall adapter.

4 . Plug the wall adapter into a power outlet.

5 . Place the probe onto the white wireless charging pad.



Note:

- When the probe is charged through the wireless charging pad, it cannot work。

- Make sure to place the probe on the charging pad so that it lies flat on the charging pad on a flat surface. Do not hang the charging pad or hang the probe from the charging pad.

- Ensure that the probe is properly placed on the charging pad so that the probe’ s battery indicator flashes blue and the charger indicator light is blue.

CAUTION :

1 If the probe will not power on after charging, it could indicate abattery failure. Contact Support.

2 A non- medical grade power supply must be used outside of the patient environment so that it is at least 1 . 5 meters from the patient .

3 The probe battery should be charged at least monthly to ensure proper functionality.

4 It is normal that the probe may feel warm to the touch while charging. If you remove the probe from the charging pad before or immediately after charging is complete, it is recommended that you allow the probe to cool down before use. Since the system limits patient contact temperature and will not scan at or above 43 °C (109°F) , allowing the probe to cool down before use will optimize scan time performance.

5 If the battery charge is too low (25% or less) , you may not be able to perform a study until the battery is recharged. Keep the battery fully charged whenever possible.

6.2 Replace the battery

The battery of USB& Wi-Fi probe can't be replaced. If the probe cannot be charged or the probe cannot be turned on, please contact us.

6.3 Transducer Maintenance

Inspect the transducer, cable, and lens before each use. Check for cracks or other damage that jeopardizes the integrity of the transducer. Report any transducer damage to your authorized service representative, and discontinue use of the transducer. For all information on transducer cleaning and disinfection, including information on compatible disinfectants, see *Care and Cleaning of Ultrasound Systems and Transducers*, *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers.*

CAUTION

Some ultrasound coupling gels, as well as some solutions for pre-cleaning, disinfecting, and sterilizing can damage a transducer. Before using a gel or solution on a transducer, see "Ultrasound Transmission Gels" on page 77 and *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducer.*You can also contact your authorized service representative. For contact information, see "Introduce" on page 1.

6 .3 . 1 Cleaning the probe

The operation process is as follows:

The following cleaning methods shall be taken immediately after each complete test on the patient to avoid drying of the coupling remaining on the probe, which is not conducive to the cleaning of the probe and to prevent the body and sound head from being corroded by coupling or other reagents .

Before the cleaning or disinfection work begins, the operator should wear professional protective equipment such as goggles and gloves, and check whether the instruments, equipment, materials and environment used meet the requirements in advance.

1. Turn off the power of the ultrasound probe, press and hold the button for more than 3 s until the light goes out. For the specific operation process, please refer to the product instruction manual. At the same time, check whether the waterproof cap of the charging port of the machine is installed and returned. If it is opens, the waterproof cap should be installed and returned.
2. Use clean special wiping paper for ultrasonic instrument (the wiping paper shall be soft non abrasive disposable paper towel) or clean lint free soft cloth to wipe the acoustic head. Gently wipe the paper or soft lint- free cloth along the wide side of the vocal head to the other end (if the wiping force is too large, it may cause the depression of the vocal head and make the machine unusable). The wiping direction should be in accordance with the Repeated wiping is prohibited in the same direction. If the sound head is also stained with coupling or other reagents, it should also be wiped in the same way.
3. During the wiping process, after each wiping from the beginning to the end, fold the special wipe paper for ultrasonic instruments in half, and fold the wipe paper in half

towards the side stained with coupling or other ultrasonic special colloid residues (Fol d the stained side inside the wiping paper) .

4. Ultrasound instrument special wipes or lint-free soft cloth should not be folded in half at most for more than 4 times. If there is still coupling or other ultrasonic special colloids remaining on the ultrasonic probe part after wiping for the 4 th time, you need to replace with new ultrasonic instrument special wipes, and repeat after replacement. The above steps are performed until the coupling remaining in the vocal head is completely wiped.
5. Use ultrasonic special wiping paper or lint free cloth dipped with enzyme containing detergent(the usage of specific cleaners should refer to the usage method of cleaner labels and instructions, and pay attention to whether the use time of detergent is within the warranty period of the product) to clean until there is no visible stain on the acoustic head and the acoustic head and its surroundings have been wiped.
6. Rinse the probe with drinking water or softened filtered water (the water quality of tap water is too hard, there may be residual salt and alkali substances, which will cause different degrees of corrosion to the ultrasonic probe. For specific water quality requirements, please refer to AAMI TIR 34). During the process, keep wiping the vocal head with your hands until all the cleaning agents are rinsed. In principle, the rinsing time should not be less than 30s. During the rinsing process, water should be prevented from splashing on the fuselage. If any liquid enters the fuselage, it will cause irreversible damage to the electronic components of the machine.
7. Use the special wipe paper for ultrasonic instruments or a clean lint- free soft cloth (The same lint free soft cloth used before is no longer used) to wipe the entire body and the vocal head, and wipe the residual water stains on the acoustic head until all the residual water stains on the body are wiped clean.
8. Place the whole machine in the air with humidity ≤ 60 % , temperature ≤ 40 C and ≥ 15 C, fine particles ≤ 3 5 ug/ m³ Ventilation and drying shall be carried out in a ventilated indoor environment, and the drying time should be ≥ 3 0 s. Meanwhile, direct exposure to sunlight shall be avoided.
9. Check whether the whole part of the fuselage is damaged, such as cracks, cracks, cracks or protruding sound head. In case of the above situations,stop using immediately and contact the local dealer or sales representative.

6 .3 .2 Disinfecting the probe

The operation process is as follows:

Before the machine is sterilized, it should be ensured that the cleaning work has been carried out and the cleaning process is correctly followed. Operators should wear protective equipment such as professional goggles and gloves, and check whether the instruments, equipment, materials and environment used meet the requirements in advance

1. Use alcohol disinfectants (For example: The compound double- chain quaternary ammonium salt with free safety content ≤ 2 % is mixed with purified water or softened filtered water. The mixed quaternary ammonium salt

content is 200mg L-1000mg/L, which conforms to the alcohol disinfection solution of double chain quaternary ammonium salt) for spraying and disinfection. Install the mixed disinfectant reagent into a spray pot with spraying function, and use the spray pot to evenly spray the disinfectant on the surface of the ultrasonic probe and around the ultrasonic probe shell. (Quaternary ammonium salts should not be used in combination with soap or anionic surfactants, citrates, iodides, nitrates, potassium permanganate, salicylates, silver salts, tartrates and alkaloids, aluminum, sodium fluorescein, permanganate Hydrogen oxide, kaolin, water- containing lanolin, etc.) Put the machine flat on the workbench for static disinfection, and the static time is 2 min- 5 min.

2. Take a piece of special wiping paper for ultrasonic instrument, and spray it around the central part of the wiping paper for 3 - 5 times with a spray pot equipped with quaternary ammonium salt disinfectant to ensure that the area of the wiping paper containing disinfectant is ≥ 80%. Use wipes sprayed with disinfectant to wipe the machine, and ensure that all surfaces and gaps of the machine body are completely wiped and disinfected.
3. Take a new piece of special wiping paper or clean lint free soft cloth for ultrasonic instrument, wipe the whole body and the acoustic head again, and wipe it from the acoustic head to the body until all the disinfection reagent residues on the body are wiped clean.
4. Check whether there are residual stains or water stains on the body and sound head. If there are still stains or water stains, repeat steps 2 and 3 until the stains on the body and sound head are wiped off. If not, proceed to the next step directly.
5. Place the wiped machine in the air with humidity ≤ 60%, temperature ≤ 40°C and ≥ 15°C, and fine particles ≤ 35ug / m ³ The secondary ventilation and drying shall be carried out in a ventilated indoor environment, and the drying time shall be ≥ 2 min. Meanwhile, direct exposure to sunlight shall be avoided.

6.4 Ultrasound Transmission Gels

For proper transmission of the acoustic beam, use the ultrasound transmission gel supplied by or recommended by KONTED, or another glycol-, glycerol-, or water-based acoustic coupling medium.

CAUTION

Do not use lotion-based products or gels that contain mineral oil. Such products may damage the transducer and void the warranty.

CAUTION

Do not use hand sanitizing gels.

CAUTION

Do not apply the transducer gel until you are ready to perform the procedure. Transducers should not be left soaking in gel.

CAUTION

Gels listed here are recommended because of their chemical compatibility with product materials.

Some recommended gels include:

- Aquasonic 100
- Aquasonic Clear
- Carbogel-ULT
- Scan

6.5 Transducer Storage

Use the appropriate guidelines for storing transducers for transport, and daily and long-term storage.

Storage for Transport

Always use the carrying bag that is provided with your transducer to transport the transducer from one site to another. Follow these guidelines to properly store transducers for transport:

1.Make sure that the transducer is clean and disinfected before placing it in the carrying bag to avoid contaminating the bag

2.Place the transducer in the bag carefully to prevent kinking of the cable.

Daily and Long-Term Storage

Follow these guidelines to protect your transducer:

1.Avoid storing transducers in areas of temperature extremes or in direct sunlight.

2.Store transducers separately from other instruments to avoid inadvertent transducer damage.

3.Before storing transducers, make sure they are thoroughly dry.

6.6 Inspect

Frequently check the probe cable, if found damaged, broken phenomenon, prohibit the use of immediate replacement or repair.

Regularly check the socket, the sound window parts, if found damaged, bubble phenomenon, prohibit the use of immediate replacement or repair.

Every time the main body and head of the probe to clean, disinfect (sterilization), are required to be checked, if found the above, please stop using, immediately replace.

⚠WARNING	**Equipment failure, Users are not allowed to repair without authorization. Product must be sent back to the company**

6.7 Life cycle

According to the manufacturer' s design, production and other related documents, this type of product life is generally 5 years, it depends on using frequency, it is possible to be used 6 - 8 years. constituting the product material over time will gradually aging, continue to

use the products beyond the life of the post, may cause performance degradation and failure rate is significantly high.

⚠WARNING	**The manufacturer will not be held responsible for the risks arising from the continued use of the product life cycle.**

6.8 Transducer Covers

To prevent contamination by blood-borne pathogens, sterile transducer covers are required for needle guidance procedures. KONTED recommends the use of qualified covers.

For procedures for using transducer covers, see the instructions provided with the covers.

WARNING

Latex and talc are commonly used in sheaths marketed to help with infection control during biopsies. Examine the packaging to confirm latex and talc content. Studies have shown that patients can experience allergic reactions with natural rubber latex. See the FDA Medical Alert, March 29, 1991, reprinted in "FDA Medical Alert on Latex" .

WARNING

Sterilized transducers should be used with sterile gel and a sterile transducer cover.

WARNING

Inspect transducer covers before and after use.

WARNING

Do not apply the transducer cover until you are ready to perform the procedure.

WARNING

Sterile transducer covers are disposable and must not be reused.

6.9 Troubleshooting

You should perform system maintenance regularly and as needed. Because the system is a piece of medical equipment, KONTED recommends that only trained personnel service the system.

WARNING

Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.

CAUTION

Follow all instructions provided to avoid damage during cleaning, disinfection, and sterilization. Failure to do so could void your warranty.

WARNING

If the system becomes contaminated internally with bodily fluids containing pathogens, you must immediately notify your KONTED service representative. Components inside the system cannot be disinfected. In that case, the system must be disposed of as biohazardous material in accordance with local or federal laws.

It is important to clean and maintain the ultrasound system and peripherals. Thorough cleaning is important for pieces of peripheral equipment, because they contain electromechanical devices. If exposed to constant and excessive environmental dust and humidity, these devices will suffer in both performance and reliability. It is your responsibility to appropriately clean and disinfect your device in accordance with the device manufacturer's instructions and with your institution's policies for cleaning and disinfecting of medical devices.

Here lists the troubleshooting issues and resolutions.

If you are unable to resolve an issue using Table- 1 , please note the issue and report it to Support for assistance

Table- 1 Troubleshooting

Connection issues	
Display the error password	1 . The SN number of the probe is the wifi password, re- enter the password, The password' s letters must be input as small letters, not capital. 2 . Try to connect to the probe with type- C cable.
The probe can not connected to Mobile phone/ tablet, but can work with laptop	1 . Please change the Wi- Fi channel with your laptop. 2 . Try to connect the probe to your mobile phone again.

The probe can work by Wi- Fi, but can not work with Type- C	1 . The A- end and B- end of the cable can not be inserted reversely. The A- end must be fully inserted into the probe and the B- end must be fully inserted into the smart device. 2 . Try to connect the probe with the other side of the type- C A port interface
Probe issues	
Probe can not be charged by cable	1 . The A- end must be fully inserted into the probe and the B- end must be fully inserted into the smart device. 2 . Charge the probe for 1 h with wireless charger. 3 . If not work, pls contact support!
Can not turn on the probe	1 . Charge the probe for 30 minutes firstly 2 . Try to turn on the probe again 3 . If not work, pls contact support!
Can not turn off the probe	1 . Press and hold the probe' s power Button for 15 - 20 seconds. 2 . Charge the probe
App issues	
App can not turn on App crashes	1 . Delete and re- install the App 2 . Update the App 3 . Try to install the app to other mobile device
App opens but will not scan images	1 . Make sure the probe is connected successfully 2 . Try to press the probe power button 3 . Re- install and update the App 4 . Charge the probe
Black screen or screen no longer updates	1 . Close the App and restart theApp. 2 . Unplug the probe from the mobile platform (mobile device) and reconnect.
Imaging issues	
Image degradation or occurrence of image artifacts	Make sure you are using the appropriate preset and the depth is appropriate for the anatomy being scanned.
Image quality degraded	1 . Make sure you are using enough approved ultrasound gel. If quality does not improve. 2 . If not work, contact Support
Image is nor clear	1 . Adjust the image parameters follow the page- 24 2 . Use enough ultrasound Gel.

7 Electromagnetic Compatibility

1. The product contains RF transmitters:

2. Note: The purchaser or user of the portable color ultrasonic diagnostic instrument should use the portable color ultrasonic diagnostic instrument in the electromagnetic environment specified in Table 1, 2, 3, and 4, otherwise the portable color ultrasonic diagnostic instrument may not work normally.

3. Note: Portable and mobile radio frequency communication equipment may affect the use of this portable color ultrasonic diagnostic instrument. When using this portable color ultrasonic diagnostic instrument normally, please use this device in the recommended electromagnetic environment.

4. The charging cable provided by our company must be used.

5. Warning: In addition to the charging connection cables provided by the company, the use of non-specified charging connection cables may lead to an increase in self- emission or a decrease in immunity.

6. This product is suitable for equipment and system requirements that intentionally receive radio frequency energy for its working purpose, and the receiving bandwidth is 20 M.

7. This product is also suitable for equipment and system requirements that include RF transmitters, and the transmitting frequency is: transmitting frequency: 5 GHz, frequency band: 4.9 GHz~ 5.845GHz, receiving bandwidth 20 M, modulation type: MIMO-OFDM/DSSS/CCK, effective Radiation power: 14dBm.

8. In order to ensure the normal use of the portable color ultrasonic diagnostic instrument and ensure that its emission will not be increased and its immunity will not be reduced, please use the charging connection cable provided by our company.

9. Use of non-specified accessories with the portable color ultrasound system may result in increased emissions or reduced immunity of the equipment or system.

10. Warning: The portable color ultrasonic diagnostic instrument should not be stacked with other devices with the same or similar operating frequency. If it must be stacked, it should be observed to verify that it can operate normally under the configuration it uses.

11. The basic performance is:

    a) Shall not produce waveform noise, image artifacts or distortions, or display incorrect numerical values that could alter diagnostic results

    b) Shall not produce displays of incorrect numerical values related to the diagnostics performed

    c) Shall not produce unintended or excessive ultrasonic output

    d) Do not create unintended or excessive transducer component surface temperature rise

    e) When signal acquisition stops, acoustic output stops.

12. When the portable color ultrasonic diagnostic instrument is in normal use, it may cause electromagnetic interference to other diagnostic or therapeutic equipment. Please keep an appropriate distance from other equipment when using it, and carefully observe the correctness of the data during the use of the equipment.

Table 1 for all devices and systems

Guidance and Manufacturer' s Declaration - Electromagnetic Emissions		
Pocket ultrasound system is expected to be used in the electromagnetic environment specified below,and the purchaser or user should ensure that it is in this electromagnetic environment use:		
launch test	Compliance	Electromagnetic Environment - Guidelines
RF emissions CISPR 11	Not applicable	/
RF emissions CISPR 11	Not applicable	/
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations flicker emissions IEC 61000-3-3	Not applicable	

Table 2 for all devices and systems

Guidance and Manufacturer' s Declaration - Electromagnetic Immunity			
The pocket ultrasound system instrument is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity Test	IEC Test Level Guide	Coincidence Level	Electromagnetic Environment - Guide
Electrostatic Discharge IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±2kV, ±4kV, ±6kV, ±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	The ground shall be wood, concrete or ceramic tile. If the ground is covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient and Burst IEC 61000-4-4	±2kV 100kHz repetition frequency	AC port: ±2kV Patient coupling port: ±1kV 100kHz repetition frequency	The network power supply should have the quality that is used in a typical commercial or hospital environment.
Surges IEC 61000-4-5	Line to line: ±0.5kV, ±1kV Line to ground: ±0.5kV, ±1kV, ±2kV	Line to line: ±0.5kV, ±1kV Line to ground: ±0.5kV, ±1kV, ±2kV	The network power supply should have the quality that is used in a typical commercial or hospital environment.
Voltage Dips and Interruption IEC 61000-4-11	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	The network power supply should have the quality that is used in a typical commercial or hospital environment. If the user of Digital Handheld Probe-type Ultrasound System needs continuous operation during an electric power outage, it is recommended that Digital Handheld Probe-type Ultrasound System uses the uninterruptible power supply or batteries.
	0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0°	0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0°	
	0% UT; 250/300 cycle	0% UT; 250/300 cycle	

Power frequency magnetic field immunity IEC 61000-4-8	30A/m 50Hz or 60Hz	30A/m, 50Hz and 60Hz	In the event of malfunction, it may be necessary to keep Digital Handheld Probe-type Ultrasound System away from the power frequency magnetic field or install a magnetic shield in the field. And the power frequency magnetic field in the expected installation site shall be measured to meet the requirements below the coincidence level.
Note: UT refers to the AC grid voltage before the voltage is applied			

Table 3 For non-life support equipment and systems

Guidance and manufacturer's declaration — electromagnetic immunity			
The pocket ultrasound system instrument is expected to be used in the following electromagnetic environment, and the purchaser or user of the portable color ultrasonic diagnostic instrument should ensure that it is used in this electromagnetic environment:			
Immunity Test	IEC 60601 Test Level Guide	Coincidence Level	Electromagnetic Environment - Guide
Conducted disturbances, induced by RF fields IEC 61000-4-6	3V, 0.15MHz～80MHz 6V, in ISM bands between 0.15MHz and 80MHz 80% AM at 1kHz	3Vrms, 0.15MHz～80MHz 6Vrms, in ISM bands between 0.15MHz and 80MHz 80% AM at 1kHz	Portable and mobile RF communications equipment should not be used closer to any part of the portable color ultrasound system, including cables, than the recommended separation distance. This distance should be calculated using the formula corresponding to the frequency of the transmitter. Recommended isolation distance $d=1.2\sqrt{P}$ 150kHz～80MHz $d=1.2\sqrt{P}$ 80kHz～800MHz $d=2.3\sqrt{P}$ 800MHz～2.7GHz In the formula: P - the maximum output power rating of the transmitter provided by the transmitter manufacturer , in watts (W); d--Recommended isolation distance in Meter (m) as the unit. The field strength of a fixed RF transmitter is determined by the investigation of the electromagnetic fielda and each frequency rangeb should be lower than the coincidence level. Interference may occur near the device marking the following symbol. 
Radiated RF Electromagnetic fields immunity IEC 61000-4-3	3 V/m 80 MHz～2.7 GHz 80% AM at 1kHz	3 V/m 80 MHz～2.7 GHz 80% AM at 1kHz RF Band	
Note1: In the MHz and MHz frequency, the higher frequency band should be used. Note2: These guides may not be appropriate for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects, and the human body.			

aixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts, and television broadcasts, cannot be predicted For the electromagnetic environment of the radio frequency transmitter, the survey of the electromagnetic field should be considered. If the measured field strength in the location where the portable color ultrasonic diagnostic instrument is located is higher than the applicable RF compliance level above , the pocket ultrasound system instrument should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may It is necessary, such as readjusting the direction or position of the portable color ultrasound diagnostic instrument..

b The field strength should be less than V / m over the whole frequency range of KHz to MHz.

Table 4 for nonlife support equipment and systems

Recommended separation distance between portable and mobile RF communication equipment and pocket ultrasound system equipment			
Pocket ultrasound system instrument is intended to be used in an electromagnetic environment where radiated RF disturbances are controlled. According to the maximum output power of the communication equipment, the Pocket ultrasound system purchaser or user of can maintain the portable and mobile RF communication equipment (transmitter) through the following recommended The minimum distance between the pocket ultrasound system instrument is to prevent electromagnetic interference.			
Transmitter maximum rated output power W	Isolation distance corresponding to different frequency of transmitter /m		
	150 KHz～80 MHz $d=1.2\sqrt{P}$	80 MHz～800 MHz $d=1.2\sqrt{P}$	800 MHz～2.7 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 the rated maximum output power of the transmitter not listed in the above table, the recommended isolation distance d, in meters (m) , can be determined by the formula in the corresponding transmitter frequency column, where P is provided by the transmitter manufacturer The maximum output power rating of the transmitter in watts (W). Note 1 : At 80MHz and 800MHz, the formula for the higher frequency band is used. Note 2 : These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

8. Application of Acoustic Power

8.1 Safe Scanning Guidelines

- Ultrasound should only be used for medical diagnosis and only by trained medical personnel.
- Diagnostic ultrasound procedures should be done only by personnel fully trained in the use of the equipment, in the interpretation of the results and images, and in the safe use of ultrasound (including education as to potential hazards).
- Operators should understand the likely influence of the machine controls, the operating mode (e. g. B mode) and probe frequency on thermal and cavitation hazards .
- Select a low setting for each new patient. Output should only be increased during the examination if penetration is still required to achieve a satisfactory result, and after the Gain control has been moved to its maximum value.
- Maintain the shortest examination time necessary to produce a useful diagnostic result.
- Do not hold the probe in a fixed position for any longer than is necessary. The frozen frame and Cine loop capabilities allow images to be reviewed and discussed without exposing the patient to continuous scanning.
- Do not use endo-cavitary probes if there is noticeable self heating of the probe when operating in the air. Although applicable to any probe, take particular care during trans- vaginal exams during the first eight weeks of gestation.
- Take particular care to reduce output and minimize exposure time of an embryo or fetus when the temperature of the mother is already elevated.
- Take particular care to reduce the risk of thermal hazard during diagnostic ultrasound when exposing: an embryo less than eight weeks after gestation; or the head, brain or spine of any fetus or neonate.
- Operators should continually monitor the on- screen thermal index (TI) and mechanical index (MI) values and use control settings that keep these settings as low as possible while still achieving diagnostically useful results. In obstetric examinations, TIS (soft tissue thermal index) should be monitored during scans carried out in the first eight weeks after gestation, and TIB (bone thermal index) thereafter. In applications where the probe is very close to bone (e. g. trans- cranial applications), TIC (cranial bone thermal index) should be monitored.
- MI>0.3 there is a possibility of minor damage to neonatal lung or intestine. If such exposure is necessary, reduce the exposure time as much as possible.
- MI>0.7 there is a risk of cavitations if an ultrasound contrast agent containing gas micro- spheres is being used. There is a theoretical risk of cavitations without the presence of ultrasound contrast agents. The risk increases with MI values above this threshold.
- TI>0.7 the overall exposure time of an embryo or fetus should be restricted in accordance with Table 2-2 below as a reference:
- TI>0.7 the overall exposure time of an embryo or fetus should be restricted in accordance with Table 2-2 below as a reference.

- Non-diagnostic use of ultrasound equipment is not generally recommended. Examples of non-diagnostic uses of ultrasound equipment include repeated scans for operator training, equipment demonstration using normal subjects, and the production of souvenir pictures or videos of a fetus. For equipment of which the safety indices are displayed over their full range of values, the TI should always be less than 0.5 and the MI should always be less than 0.3. Avoid frequent repeated exposure of any subject. Scans in the first trimester of pregnancy should not be carried out for the sole purpose of producing souvenir videos or photographs, nor should their production involve increasing the exposure levels or extending the scan times beyond those needed for clinical purposes.
- Diagnostic ultrasound has the potential for both false positive and false negative results. Misdiagnosis is far more dangerous than any effect that might result from the ultrasound exposure. Therefore, diagnostic ultrasound system should be performed only by those with sufficient training and education.

TI	Maximum exposure time (minutes)
0.7	60
1.0	30
1.5	15
2.0	4
2.5	1

Table 2-2 Maximum recommended exposure times for an embryo or fetus

8.2 Understanding the MI/TI Display

The system output display comprises two basic indices: a mechanical index and a thermal index. The mechanical index is continuously displayed over the range of 0.0 to 1.9, in increments of 0.1.

The thermal index further consists of the following indices: soft tissue (TIS), bone (TIB), and cranial bone (TIC). Only one of these is displayed at any time. Each transducer application has a default selection that is appropriate for that combination. The TIB, TIS, or TIC is continuously displayed over the range of 0.0 to maximum output, based on the transducer and application, in increments of 0.1. For the location of the output display, see “Imaging Display” on page 56.

The application-specific nature of the default setting is also an important factor of index behavior. A default setting is a system control state that is preset by the manufacturer or the operator. The system has default index settings for the transducer application. The default settings are invoked automatically by the ultrasound system when power is turned on, when new patient data is entered into the system database, or when an application change occurs.

The decision as to which of the three thermal indices to display should be based on the following criteria:

Appropriate index for the application: TIS is used for imaging soft tissue, TIB for a focus at or near bone, and TIC for imaging through bone near the surface, as in a cranial exam.

Mitigating factors that might create artificially high or low thermal index readings: location of fluid or bone, or blood flow. For example, is there a highly attenuating tissue path so that the actual potential for local zone heating is less than the thermal index displays?

Scanned modes versus unscanned modes of operation affect the thermal index. For scanned modes, heating tends to be near the surface; for unscanned modes, the potential for heating tends to be deeper in the focal zone.

Always limit ultrasound exposure time. Do not rush the exam. Ensure that the indices are kept to a minimum and that exposure time is limited without compromising diagnostic sensitivity.

The maximum value of acoustic output in any mode should not exceed the limit value of acoustic output (MI limit value is 1.9, $I_{spta.3}$ limit value is 720 mW/cm^2).

8.2.1 Mechanical Index (MI) Display

Mechanical bioeffects are threshold phenomena that occur when a certain level of output is exceeded. The threshold level varies, however, with the type of tissue. The potential for mechanical bioeffects varies with peak rarefactional pressure and ultrasound frequency. The MI accounts for these two factors. The higher the MI value, the greater the likelihood of mechanical bioeffects occurring. There is no specific MI value that means that a mechanical effect is actually occurring. The MI should be used as a guide for implementing the ALARA principle.

The bone thermal index (TIB) informs the user about potential heating at or near the focus after the ultrasound beam has passed through soft tissue or fluid; for example, at or near second- or third-trimester fetal bone.

The cranial bone thermal index (TIC) informs the user about the potential heating of bone at or near the surface; for example, cranial bone.

The soft tissue thermal index (TIS) informs the user about the potential for heating within soft homogeneous tissue.

8.2.2 Thermal Index (TI) Displays

The TI informs the user about the conditions that exist that might lead to an increase in temperature at the surface of the body, within the body tissue, or at the point of focus of the ultrasound beam on bone. That is, the TI informs the user of the potential for temperature rise in body tissue. It is an estimate of temperature increase in body tissue with specific properties. The actual amount of any temperature rise is influenced by factors such as tissue type, vascularity, mode of operation, and others. The TI should be used as a guide for implementing the ALARA principle.

The bone thermal index (TIB) informs the user about potential heating at or near the focus after the ultrasound beam has passed through soft tissue or fluid; for example, at or near second- or third-trimester fetal bone.

The cranial bone thermal index (TIC) informs the user about the potential heating of bone at or near the surface; for example, cranial bone.

The soft tissue thermal index (TIS) informs the user about the potential for heating within soft homogeneous tissue.

8.2.3 Mechanical and Thermal Indices Display Precision and Accuracy

The MI and TI precision is 0.1 unit on the system.

The MI and TI display accuracy estimates for the system are given in Acoustic Output Tables, on your User Information CD. Those accuracy estimates are based on the variability range of transducers and systems, inherent acoustic output modeling errors, and measurement variability, as discussed in this section.

The displayed values should be interpreted as relative information to help the system operator achieve the ALARA principle through prudent use of the system. The values should not be interpreted as actual physical values in interrogated tissue or organs. The initial data that is used to support the output display is derived from laboratory measurements based on the measurement standards in IEC 62359: Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields. The measurements are then put into algorithms for calculating the displayed output values.

Many of the assumptions used in the process of measurement and calculation are conservative in nature. Overestimation of actual in situ intensity exposure, for the vast majority of tissue paths, is built into the measurement and calculation process. For example:

1.The measured water tank values are derated using a conservative, industry standard, attenuation coefficient of 0.3 dB/cm‑MHz.

2.Conservative values for tissue characteristics were selected for use in the TI models. Conservative values for tissue or bone absorption rates, blood perfusion rates, blood heat capacity, and tissue thermal conductivity were selected.

3.Steady State temperature rise is assumed in the industry standard TI models, and the assumption is made that the ultrasound transducer is held steady in one position long enough for steady state to be reached.

A number of factors are considered when estimating the accuracy of the displayed values: hardware variations, estimation algorithm accuracy, and measurement variability. Variability among transducers and systems is a significant factor. Transducer variability results from piezoelectric crystal efficiencies, process-related impedance differences, and sensitive lens-focusing parameter variations. Differences in system pulser voltage control and efficiencies is

also a contributor to variability. There are inherent uncertainties in the algorithms used to estimate acoustic output values over the range of possible system operating conditions and pulser voltages. Inaccuracies in laboratory measurements are related to, among others, differences in hydrophone calibration and performance, positioning, alignment, and digitization tolerances, and variability among test operators.

The conservative assumptions of the output estimation algorithms of linear propagation, at all depths, through a 0.3 dB/cm - MHz attenuative medium is not considered in the accuracy estimate for the display. Neither linear propagation, nor uniform attenuation at the 0.3 dB/ cm - MHz rate, occur in water tank measurements or in most tissue paths in the body. In the body, different tissues and organs have dissimilar attenuation characteristics. In water, there is almost no attenuation. In the body, and in particular, in water tank measurements, nonlinear propagation and saturation losses occur as pulser voltages increase.

Therefore, the display accuracy estimates are based on the variability range of transducers and systems, inherent acoustic output modeling errors, and measurement variability. Display accuracy estimates are not based on errors in, or caused by measuring according to, the IEC 62359 measurement standards, or the effects of nonlinear loss on the measured values.

8.3 Control Effects

Controls Affecting the Indices

As various system controls are adjusted, the TI and MI values may change. This will be most apparent as the output power control is adjusted; but other system controls affect the on‑screen output values

Power

The output power control affects the system acoustic output. Two real‑time output values are on the display: TI and MI. They change as the system responds to power-control adjustments.

In combined modes, such as simultaneous Color and 2D, the individual modes each add to the total TI. One mode will be the dominant contributor to this total. The displayed MI will be from the mode with the largest MI value.

2D Controls

Focus: Changing the focal depth will change MI. Generally, higher MI values will occur when the focal depth is near the natural focus of the transducer.

Zoom: Increasing the zoom magnification by spreading the display may increase frame rate. This action will increase the TI. The number of focal zones may also increase automatically to improve resolution. This action may change the MI, because the peak MI can occur at a different depth.

Color Controls

Color Sector Width: Narrower color sector width will increase color frame rate and the TI will increase. The system may automatically decrease pulser voltage to stay below the system maximum. A decrease in pulser voltage will decrease the MI

Color Sector Depth: Deeper color sector depth may automatically decrease color frame rate or select a new color focal zone or color pulse length. The TI will change due to the combination of these effects. Generally, the TI will decrease with increased color sector depth. MI will correspond to the MI of the dominant pulse type which is a color pulse.

Other Control Effects

2D Depth: An increase in 2D depth will automatically decrease the 2D frame rate. This will decrease the TI. The system may also automatically choose a deeper 2D focal depth. A change of focal depth may change the MI. The MI displayed is that of the zone with the largest MI value.

Application: Acoustic output defaults are set when you select an application. Factory defaults vary with transducer, application, and mode. Defaults have been chosen below the FDA limits for intended use.

Imaging Mode Controls: When a new imaging mode is selected, both the TI and MI may change to default settings. Each mode has a corresponding pulse repetition frequency and maximum intensity point. In combined or simultaneous modes, the TI is the sum of the contribution from the modes enabled, and the displayed MI is the largest of the MI values associated with each mode and focal zone enabled. The system will return to the previously selected state if a mode is turned off and then reselected.

Transducer: Each transducer type has unique specifications for contact area, beam shape, and center frequency. Defaults are initialized when you select a transducer. Factory defaults vary with

transducer, application, and selected mode. Defaults have been chosen below the FDA limits for intended use.

8.4 Related Guidance Documents

For more information about ultrasonic bioeffects and related topics, see the following:

1."Bioeffects and Safety of Diagnostic Ultrasound." AIUM Report, January 28, 1993.

2."American Institute of Ultrasound in Medicine Bioeffects Consensus Report." Journal of Ultrasound in Medicine, Vol. 27, Issue 4, April 2008.

3.Third Edition of the AIUM "Medical Ultrasound Safety" document, 2014. (A copy of this document is provided with each system.)

4."Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." FDA, September 2008.

5.IEC 62359: Ultrasonics - Field Characterization - Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields.

WFUMB. "Symposium on Safety of Ultrasound in Medicine: Conclusions and Recommendations on Thermal and Non - Thermal Mechanisms for Biological Effects of Ultrasound." Ultrasound in Medicine and Biology, 1998: Vol. 24, Supplement 1.

8.5 Acoustic Output and Measurement

Since the initial use of diagnostic ultrasound, the possible human bioeffects from ultrasound exposure have been studied by various scientific and medical institutions. In October 1987, the American Institute of Ultrasound in Medicine (AIUM) ratified a report prepared by its Bioeffects Committee ("Bioeffects Considerations for the Safety of Diagnostic Ultrasound." Journal of

Ultrasound in Medicine, Vol. 7, No. 9 Supplement, September 1988), sometimes referred to as the Stowe Report, which reviewed available data on possible effects of ultrasound exposure.

Another report, “Bioeffects and Safety of Diagnostic Ultrasound,” dated January 28, 1993, provides more-current information.

The acoustic output for this system has been measured and calculated in accordance with IEC 62359: Ultrasonics - Field Characterization - Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields, and the September 2008 FDA document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers."

8.5.1 In Situ, Derated, and Water Value Intensities

All intensity parameters are measured in water. Since water absorbs very little acoustic energy, these water measurements represent a worst case value. Biological tissue does absorb acoustic energy. The true value of the intensity at any point depends on the amount and type of tissue and the frequency of the ultrasound that passes through the tissue. The intensity value in the tissue, In Situ, has been estimated by using the following formula:

***In Situ* = Water [$e^{-0.23alf}$]**

Where:

Variable	Value
In Situ	*In Situ* intensity value
Water	Water value intensity
e	2.7183
a	Attenuation factor
Tissue	a(dB/cm-MHz)
Amniotic Fluid	0.006
Brain	0.53
Heart	0.66
Kidney	0.79
Liver	0.43
Muscle	0.55
l	Skin line to measurement depth (cm)
f	Center frequency of the transducer/system/mode combination (MHz)

Since the ultrasonic path during an examination is likely to pass through varying lengths and types of tissue, it is difficult to estimate the true in situ intensity. An attenuation factor of 0.3 is used for general reporting purposes; therefore, the In Situ value which is commonly reported uses the formula:

In Situ derated = Water $[e^{-0.069lf}]$

Since this value is not the true in situ intensity, the term “derated” is used.

Mathematical derating of water based measurements using the 0.3 dB/cm - MHz coefficient may yield lower acoustic exposure values than would be measured in a homogenous 0.3 dB/ cm - MHz tissue. This is true because nonlinearly propagating acoustic energy waveforms experience more distortion, saturation, and absorption in water than in tissue, where attenuation present all along the tissue path will dampen the buildup of nonlinear effects.

The maximum derated and the maximum water values do not always occur at the same operating conditions; therefore, the reported maximum water and derated values may not be related by the in situ (derated) formula. For example: A multi-zone array transducer that has maximum water value intensities in its deepest zone may have its largest derated intensity in one of its shallowest focal zones.

8.6 Acoustic Measurement Precision and Uncertainty

All table entries have been obtained at the same operating conditions that give rise to the maximum index value in the first column of the tables. Measurement precision and uncertainty for power, pressure, intensity, and center frequency are listed in the following tables.

NOTE

Per ISO/IEC Guide 98-3 (Uncertainty of Measurement - Part 3: Guide to the Expression of Uncertainty in Measurement), measurement precision on the following quantities is determined by making repeated measurements and stating the standard deviation as a percentage.

8.6.1 Acoustic Measurement Precision

Quantity	Precision (Percentage Standard Deviation)
Pr is the underated peak rarefactional pressure measured in megapascals (MPa).	Pr: 5.4%
P is the ultrasonic power in milliwatts (mW).	6.2%
f_{awf} is the center frequency in megahertz (MHz).	<1%
PII.3 is the derated spatial-peak pulse intensity integral in joules per square centimeter (J/cm^2).	PII.3: 3.2%

8.6.2 Acoustic Measurement Uncertainty

Quantity	Measurement Uncertainty (Percentage, 95% Confidence Value)
Pr is the underated peak rarefactional pressure measured in megapascals (MPa).	Pr: ±11.3%
P is the ultrasonic power in milliwatts (mW).	±10%
f_{awf} is the center frequency in megahertz (MHz).	±4.7%
PII.3 is the derated spatial-peak pulse intensity integral in joules per square centimeter (J/cm^2).	PII.3: +18% to -23%

8.7 Acoustic Output Default Tables

Linear array

Preset	Mode	Default TI Label	Default TI	Default MI
Thyroid	2D	TIS	0.2	0.9
	Color Slow Flow	TIS	1.0	0.7
	Color Fast Flow	TIS	1.0	0.7
	M- Mode	TIS	0.2	0.9
	PW	TIS	0.1	0.3
SmallParts	2D	TIS	0.2	0.9
	Color Slow Flow	TIS	1.0	0.7
	Color Fast Flow	TIS	1.0	0.7
	M- Mode	TIS	0.2	0.9
	PW	TIS	0.1	0.3
Pediatrics	2D	TIS	0.2	0.9
	Color Slow Flow	TIS	1.0	0.7
	Color Fast Flow	TIS	1.0	0.7
	M- Mode	TIS	0.2	0.9
	PW	TIS	0.1	0.3
Vascular	2D	TIS	0.2	0.9
	Color Slow Flow	TIS	1.0	0.7
	Color Fast Flow	TIS	1.0	0.7
	M- Mode	TIS	0.2	0.9
	PW	TIS	0.1	0.3
Carotid	2D	TIS	0.2	0.9
	Color Slow Flow	TIS	1.0	0.7
	Color Fast Flow	TIS	1.0	0.7
	M- Mode	TIS	0.2	0.9
	PW	TIS	0.1	0.3
Breast	2D	TIS	0.2	0.9
	Color Slow Flow	TIS	1.0	0.7
	Color Fast Flow	TIS	1.0	0.7
	M- Mode	TIS	0.2	0.9
	PW	TIS	0.1	0.3

MSK	2D	TIB	0.2	0.9
	Color Slow Flow	TIB	1.0	0.7
	Color Fast Flow	TIB	1.0	0.7
	M- Mode	TIB	0.2	0.9
	PW	TIB	0.1	0.3
Nerve	2D	TIS	0.2	0.9
	Color Slow Flow	TIS	1.0	0.7
	Color Fast Flow	TIS	1.0	0.7
	M- Mode	TIS	0.2	0.9
	PW	TIS	0.1	0.3
VesselFlow	2D	TIS	0.2	0.9
	Color Slow Flow	TIS	1.0	0.7
	Color Fast Flow	TIS	1.0	0.7
	M- Mode	TIS	0.2	0.9
	PW	TIS	0.1	0.3

Convex array

Preset	Mode	Default TI Label	Default TI	Default MI
Abdomen	2D	TIS	0.1	0.7
	Color Slow Flow	TIS	1.0	0.9
	Color Fast Flow	TIS	1.0	0.9
	M- Mode	TIS	0.1	0.7
	PW	TIS	0.1	0.6
Kidney	2D	TIS	0.1	0.6
	Color Slow Flow	TIS	1.0	0.9
	Color Fast Flow	TIS	1.0	0.9
	M- Mode	TIS	0.1	0.6
	PW	TIS	0.1	0.6
Lung	2D	TIS	0.1	0.6
	Color Slow Flow	TIS	1.0	0.9
	Color Fast Flow	TIS	1.0	0.9
	M- Mode	TIS	0.1	0.6
	PW	TIS	0.1	0.6

Urinary system	2D	TIS	0.1	0.7
	Color Slow Flow	TIS	1.0	0.9
	Color Fast Flow	TIS	1.0	0.9
	M- Mode	TIS	0.1	0.7
	PW	TIS	0.1	0.6
Gynaecology	2D	TIB	0.1	0.6
	Color Slow Flow	TIB	1.0	0.9
	Color Fast Flow	TIB	1.0	0.9
	M- Mode	TIB	0.1	0.6
	PW	TIB	0.1	0.6
OB	2D	TIB	0.1	0.7
	Color Slow Flow	TIB	1.0	0.9
	Color Fast Flow	TIB	1.0	0.9
	M- Mode	TIB	0.1	0.7
	PW	TIB	0.1	0.6
Cardiac	2D	TIS	0.1	0.7
	Color Slow Flow	TIS	1.0	0.9
	Color Fast Flow	TIS	1.0	0.9
	M- Mode	TIS	0.1	0.7
	PW	TIS	0.1	0.6

8.8 IEC Standardized Acoustic Output Tables

All table entries have been obtained at the same operating conditions that give rise to the maximum index value. Due to the complexities of the system user interface, it may be difficult to exactly replicate the declared condition. For more information, contact KONTED.

8.8.1Definition of Terms Used in Acoustic Output Tables

For descriptions of the symbols used in the tables, see the following:

α: *Acoustic attenuation coefficient* is the coefficient intended to account for ultrasonic attenuation of tissue between the source and a specified point.

B: Real-time B-mode.

C_{MI} : Normalizing coefficient *1 MPa MHz*$^{-1/2}$

D: Static pulsed Doppler mode.

d_{eq} : *Equivalent beam diameter* is the value of the diameter of the acoustic beam at the distance *z*, in

terms of the *equivalent beam area*, and given by $d_{eq}(z) = \sqrt{\frac{4}{\pi} \cdot A_{eq}(z)}$.

f_{awf}: *Acoustic working frequency* is the arithmetic mean of the most widely separated frequencies f_1 and f_2 at which the amplitude of the pressure spectrum of the acoustic signal is 3 dB lower than the peak amplitude.

I_{pa} : *Pulse-average intensity* is the ratio of the *pulse-intensity integral* I_{pi} to the *pulse duration* t_d . $I_{pa,\,\alpha}$: *Attenuated pulse-average intensity* is the value of the acoustic *pulse-average intensity* after attenuation and at a specified point and given by

$$I_{pa,\,\alpha} = I_{pa}(z)\, 10^{(-\alpha z f_{awf}/10)} .$$

I_{pi} or *pii*: *Pulse-intensity integral* is the time integral of the instantaneous intensity at a particular point in an acoustic field integrated over the acoustic pulse waveform.

$I_{pi,\,\alpha}$ or *pii,a*: *Attenuated pulse-intensity integral* is the value of the *pulse-intensity integral* after attenuation, at a specified point, and given by $I_{pi,\,\alpha} = I_{pi}\, 10^{(-\alpha z_{awf}/10)}$.

$I_{spta}(z)$: *Spatial-peak temporal-average intensity* is the maximum value of the *temporal-average intensity* in a specified plane at a specified distance *z* from the transducer.

$I_{spta,\,\alpha}(z)$: *Attenuated spatial-peak temporal-average intensity* is the value of the *spatial-peak temporal- average intensity* after attenuation, at a specified distance *z*, and given by $I_{spta,\,\alpha}(z) = I_{spta}(z)\, 10^{(-\alpha z_{awf}/10)}$.

M: M-mode.

MI: *Mechanical index* is given by $MI \equiv \dfrac{p_{ra}\, f_{awf}^{-1/2}}{C_{MI}}$.

n_{pps}: *Number of pulses per ultrasonic scan line* is the number of acoustic pulses traveling along a particular ultrasonic scan line within one scan frame.

P: *Output power* is the time-average power radiated by an ultrasonic transducer into an approximately free field under specified conditions in a specified medium, preferably water.

P_{1x1} : *Bounded-square output power* is the maximum value of the time average acoustic output power emitted from any 1-cm square region of the active area of the transducer, the 1-cm square region having 1-cm dimensions in the x- and y-directions.

P_{α}: *Attenuated output power* is the value of the acoustic *output power* after attenuation, at a specified distance from the transducer, and given by $P_{\alpha} = P 10^{(-\alpha z_{awf}/10)}$.

p_i : *Pulse-pressure-squared integral* is the time integral of the square of the instantaneous acoustic pressure at a particular point in an acoustic field integrated over the acoustic pulse waveform.

p_r : *Peak-rarefactional acoustic pressure* is the maximum of the modulus of the negative instantaneous acoustic pressure in an acoustic field during an acoustic repetition period.

p_{ra} or $p_{r,\alpha}$: *Attenuated peak-rarefactional acoustic pressure* is the value of the *peak-rarefactional acoustic*

pressure after attenuation, at a specified point, and given by $p_{r,\alpha}(z) = p_r(z)\, 10^{(-\alpha z_{fawf}/20)}$.

prr: *Pulse repetition rate* is the inverse of the time interval between two successive acoustic pulses.

Push: Radiation force imaging mode.

rD: Real-time flow mapping Doppler mode (Color Doppler).

sii: *Scan intensity integral* is the sum over a complete scan frame of the *pulse-intensity integrals* (pii) of the ultrasonic scan lines that make up the scanning components for a scanning mode.

sii,a: *Attenuated scan intensity integral* is the sum over a complete scan frame of the *pulse-intensity integrals* (pii) of the ultrasonic scan lines that make up the scanning components for a scanning mode.

srr: *Scan repetition rate* is the inverse of the time interval between identical points on two successive frames, sectors or scans, applying to automatic scanning systems with a periodic scan sequence only.

TI: *Thermal index* is the ratio of attenuated acoustic power at a specified point to the attenuated acoustic power required to raise the temperature at that point in a specific tissue model by 1°C.

TIB: *Bone thermal index* is the *thermal index* for applications, such as fetal (second and third trimester) or neonatal cephalic (through the fontanelle), in which the ultrasound beam passes through soft tissue, and a focal region is in the immediate vicinity of bone.

TIC: *Cranial-bone thermal index* is the *thermal index* for applications, such as pediatric and adult cranial applications, in which the ultrasound beam passes through bone near the beam entrance into the body.

TIS: *Soft tissue thermal index* is the *thermal index* related to soft tissues.

z: Distance from the source to a specified point.

z_b: Depth for *TIB*.

z_{MI}: Depth for *MI*.

z_{pii}: Depth for *peak pulse-intensity integral*.

$z_{pii,\alpha}$: Depth for *attenuated peak pulse-intensity integral*.

z_{sii} : Depth for *peak sum of pulse-intensity integrals*.

$z_{sii,\alpha}$: Depth for *peak sum of attenuated peak pulse-intensity integrals*.

z_s : Depth for *TIS*.

8.8.2 Acoustic output reporting table

Transducer Model: linear probe

Operating Model: B Mode

Index label		*MI*	*TIS*		*TIB*		*TIC*
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.31	0.15		0.15		N/A
Index component value			0.15	0.15	N/A	0.15	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	0.81					
	P (mW)		4.38		4.38		N/A
	$P_{1 \times 1}$ (mW)		4.38		4.38		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	0.54					
	$z_{pii.\alpha}$ (cm)	0.54					
	f_{awf} (MHz)	7.04	7.04		7.04		N/A
Other information	*prr* (Hz)	4000.00					
	srr (Hz)	17.48					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$ (W/cm^2)	18.18					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$ (mW/cm^2)	11.37					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	23.36					
	p_r at z_{pii} (MPa)	0.92					
Operating control conditions	Focus(mm)	9, 20	9, 20	9, 20	N/A	9, 20	N/A
	Depth(mm)	60	60	60	N/A	60	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.							

Notes: (a) This index is not required for this operating mode. see section of the Output Display Standard

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: linear probe

Operating Model: B+ M Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.31	0. 151		0. 157		N/ A
Index component value			B:0. 15 M: 0 .001	B:0. 15 M: N/ A	N/ A	B:0. 15 M: 0 .007	
A coustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	0.81					
	P (mW)		B: 4 . 38 M:0 . 020		B: 4 . 38 M: 0 . 020		N/ A
	$P_{1 x 1}$ (mW)		B: 4 . 38 M: N/ A		B: 4 . 38 M: N/ A		
	z_s (cm)			N/ A			
	z_b (cm)					1. 14	
	z_{MI} (cm)	0.54					
	$z_{pii.\alpha}$ (cm)	0.54					
	f_{awf} (MHz)	7.04	7.04		7.04		N/ A
Other Information	prr (Hz)	B:4000 .00 M: 17.48					
	srr (Hz)	17.48					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$ (W/cm^2)	18. 18					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$ (mW/cm^2)	11.44					
	I_{spta} at z_{pii} or z_{sii} (mW/ cm^2)	23.45					
	$p_{r.}$ at z_{pii} (MPa)	0.92					
Operating control conditions	Focus(mm)	9, 20	9, 20	9, 20	N/A	9, 20	N/A
	Depth(mm)	60	60	60	N/A	60	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.							

Notes: (a) This index is not required for this operating mode. see section 4 . 1 . 3 . 1 . of the Output Display Standard (NEMA UD-3) .

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: linear probe

Operating Model: B+ C Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.96	0.15		0.15		N/A
Index component value			B:0 .07 C: 0 .08	B:0 .07 C: 0 .08	N/A	B:0 .07 C: 0 .08	
A coustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	2. 16					
	P (mW)		B:2 . 08 C:3 . 28		B:2 .08 C:3 .28		N/A
	$P_{1 \times 1}$ (mW)		B:2 . 08 C:3 . 28		B:2 .08 C:3 .28		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	1. 14					
	$z_{pii.\alpha}$ (cm)	1. 14					
	f_{awf} (MHz)	C: 5 . 08	B: 7 . 04 C: 5 . 08		B: 7 . 04 C:5 . 08		N/A
Other Information	prr (Hz)	C:4000 . 00					
	srr (Hz)	8.33					
	n_{pps}	12					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$ (W/cm^2)	220.70					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$ (mW/cm^2)	163.69					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	243.33					
	$p_{r.}$ at z_{pii} (MPa)	2.64					
Operating control conditions	Focus(mm)	12	12	12	N/A	12	N/A
	Depth(mm)	60	60	60	N/A	60	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.							

Notes: (a) This index is not required for this operating mode. see section 4 . 1 . 3 . 1 . of the Output Display Standard (NEMA UD-3) .

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: linear probe

Operating Model: PW Mode

Index label		*MI*	*TIS*		*TIB*		*TIC*
			At surface	Below surface	At surface	Below surface	
Maximum index value		1.01	0.24		0.82		N/A
Index component value			0.24	N/A	N/A	0.82	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	2.61					
	P (mW)		7.41		7.41		N/A
	P_{1x1} (mW)		N/A		N/A		
	z_s (cm)			N/A			
	z_b (cm)					1.14	
	z_{MI} (cm)	1.14					
	$z_{pii.\alpha}$ (cm)	1.14					
	f_{awf} (MHz)	6.66	6.66		6.66		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)	270.20					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$ (mW/cm^2)	426.00					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	720.00					
	$p_{r.}$ at z_{pii} (MPa)	3.39					
Operating control conditions	Focus(mm)	12	12	N/A	N/A	12	N/A
	Depth(mm)	60	60	N/A	N/A	60	N/A
	Frequency(MHz)	Fixed	Fixed	N/A	N/A	Fixed	N/A
	PRF(kHz)	4.0	4.0	N/A	N/A	4.0	N/A
	SV	1	1	N/A	N/A	1	N/A

NOTE: N/A indicates that there is no corresponding intended use or no data reported.

Transducer Model: convex probe

Operating Model: B Mode

Index label		*MI*	*TIS*		*TIB*		*TIC*
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.97	0.26		0.26		N/ A
Index component value			0.26	0.26	N/ A	0.26	
A coustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	1.62					
	P (mW)		39.78		39.78		N/ A
	P_{1x1} (mW)		19.49		19.49		
	z_s (cm)			N/ A			
	z_b (cm)					N/ A	
	z_{MI} (cm)	4.60					
	$z_{pii.\alpha}$ (cm)	4.60					
	f_{awf} (MHz)	2.80	2.80		2.80		N/ A
Other Information	*prr* (Hz)	3164.56					
	srr (Hz)	11.36					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$ (W/cm^2)	116.50					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$ (mW/cm^2)	2.65					
	I_{spta} at z_{pii} or z_{sii} (mW/ cm^2)	6.26					
	p_r at z_{pii} (MPa)	2.53					
Operating control conditions	Focus(mm)	60	60	60	N/A	60	N/A
	Depth(mm)	160	160	160	N/A	160	N/A
	Frequency(MHz)	3.2	3.2	3.2	N/A	3.2	N/A
NOTE: N/ A indicates that there is no corresponding intended use or no data reported.							

Notes: (a) This index is not required for this operating mode. see section 4 . 1 . 3 . 1 . of the Output Display Standard (NEMA UD-3) .

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: convex probe

Operating Model: B+ M Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.97	0.261		0.264		N/ A
Index component value			B:0 .26 M: N/ A	B:0 .26 M: 0 .001	N/ A	B:0 .26 M:0 .004	
Acoustic P arameters	$p_{r.\alpha}$ at z_{MI} (MPa)	1.62					
	P (mW)		B: 39 .78 M:0 . 14		B: 39 .78 M:0 . 14		N/ A
	P_{1x1} (mW)		B: 19 .49 M: N/A		B: 19 .49 M: N/A		
	z_s (cm)			3.50			
	z_b (cm)					4. 12	
	z_{MI} (cm)	4.60					
	$z_{pii.\alpha}$ (cm)	4.60					
	f_{awf} (MHz)	2.80	2.80		2.80		N/ A
Other Information	prr (Hz)	B:3164 .56 M: 1 1.36					
	srr (Hz)	11.36					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$ (W/cm^2)	116.50					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$ (mW/cm^2)	3.22					
	I_{spta} at z_{pii} or z_{sii} (mW/ cm^2)	7.65					
	p_r at z_{pii} (MPa)	2.53					
Operating control conditions	Focus(mm)	60	60	60	N/A	60	N/A
	Depth(mm)	160	160	160	N/A	160	N/A
	Frequency(MHz)	3.2	3.2	3.2	N/A	3.2	N/A
NOTE: N/ A indicates that there is no corresponding intended use or no data reported.							

Notes: (a) This index is not required for this operating mode. see section 4 . 1 . 3 . 1 . of the Output Display Standard (NEMA UD-3) .

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: convex probe

Operating Model: B+ C Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.97	0.24		0.24		N/A
Index component value			B:0.13 C:0.11	B:0.13 C:0.11	N/A	B:0.13 C:0.11	
A coustic P arameters	$p_{r.\alpha}$ at z_{MI} (MPa)	1.62					
	P (mW)		B: 20.55 C: 19.28		B: 20.55 C: 19.28		N/A
	P_{1x1} (mW)		B: 10.07 C:9.45		B: 10.07 C:9.45		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	4.60					
	$z_{pii.\alpha}$ (cm)	4.60					
	f_{awf} (MHz)	B:2.80	B:2.80 C:2.47		B:2.80 C:2.47		N/A
Other Information	prr (Hz)	1634.64					
	srr (Hz)	5.88					
	n_{pps}	1					
	$I_{pa.\alpha}$ at $z_{pii.\alpha}$ (W/cm^2)	116.50					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$ (mW/cm^2)	20.27					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	46.14					
	$p_{r.}$ at z_{pii} (MPa)	2.53					
Operating control conditions	Focus(mm)	60	60	60	N/A	60	N/A
	Depth(mm)	160	160	160	N/A	160	N/A
	Frequency(MHz)	B:3.2 C: Fixed	B:3.2 C: Fixed	B:3.2 C: Fixed	N/A	B:3.2 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.							

Notes: (a) This index is not required for this operating mode. see section 4.1.3.1. of the Output Display Standard (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: convex probe

Operating Model: PW Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.90	0.46		2.67		N/ A
Index component value			N/ A	0.46	N/ A	2.67	
A coustic Parameters	$p_{r.\alpha}$ at z_{MI} (MPa)	1.42					
	P (mW)		77.89		77.89		N/ A
	P_{1x1} (mW)		N/ A		N/ A		
	z_s (cm)			4 .00			
	z_b (cm)					4 .52	
	z_{MI} (cm)	4.84					
	$z_{pii.\alpha}$ (cm)	4.84					
	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)	87.25					
	$I_{spta.\alpha}$ at $z_{pii.\alpha}$ or $z_{sii.\alpha}$ (mW/cm^2)	510.10					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	720.00					
	p_r at z_{pii} (MPa)	2. 15					
Operating control conditions	Focus(mm)	60	N/A	60	N/A	60	N/A
	Depth(mm)	160	N/ A	160	N/ A	160	N/ A
	Frequency(MHz)	Fixed	N/ A	Fixed	N/ A	Fixed	N/ A
	PRF(kHz)	2.5	N/ A	2.5	N/ A	2.5	N/ A
	SV	1	N/ A	1	N/ A	1	N/ A

NOTE: N/ A indicates that there is no corresponding intended use or no data reported.

Notes: (a) This index is not required for this operating mode. see section 4 . 1 . 3 . 1 . of the Output Display Standard (NEMA UD-3) .

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this mode.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.