LELTEK

Leltek Ultrasound Imaging System

for veterinary use only

LU300 Series (LU300C, LU300L, LU300M, LU300PA)

USER MAUNAL REV.A
LK_UI-LU300-01(EN)

Revision History

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I. Using the Leltek Ultrasound Imaging System

A、 About This Manual

	This document contains the following information: ● About the Leltek Ultrasound Imaging System: Describes the product, lists technical specifications, and its intended use. ● A Quick Tour: Shows you how to get started and begin scanning. ● Using the Leltek Ultrasound Imaging System: Introduces you to the features and concepts, helps you set up your system, and explains the tasks you can perform. ● Cleaning & Disinfecting: Explains how to clean and disinfect your System. ● Safety: Outlines important safety standards, principles, and policies to follow when using the product. ● References: Offers information such as product standards, regulatory requirements, terms and conditions, glossary of terms, and acoustic output data.
Target Audience	This document is written for trained medical professionals who operate and maintain user's Leltek Ultrasound Imaging System. It contains instructions and reference material pertaining to the usage and maintenance of the product.

B、 Indications for use

C、 Start Operate LU300

i. To start use the LU300 Series Ultrasound System

1. Ultrasound Probe
2. Ultrasound App
3. User's Tablet/Smart phone/PC

D、 Ultrasound Probe

i. Ultrasound Imaging System Description.

1. FREEZE Button

Stopping the image during the scanning; or re-activating the stopped image.

2. Power Button

Press this button to power on

3. FAN Outlet

For Heat dissipation

4. Wi-Fi Antenna

Power Charging Port

II. SAFETY

A. Contraindications and Warnings

1. Do NOT use the Ultrasound Imaging System to do following situations then result in the produce images with inaccurate results:
   - a Patients who have had surgery, which may have changed the composition of the examining tissue, as this could skew or alter the measured density.
   - b Patients whose bodies contain foreign artifacts (for example, implants), in the examining tissue.
   - c Intra-operative use (e.g., defined as introducing a System into a surgical incision or burr hole).
   - d Ophthalmic use or any use causing the acoustic beam to pass through the eye (LU300L and except).
   - e At the scene of an emergency outside of a professional healthcare facility.
   - f During transportation of a patient to a professional healthcare facility, or between professional healthcare facilities.
   - g Try imaging on an open wound.
   - h Clinically used in secondary areas (including, but not limited to, surgery, rectum, vaginal, etc.). It's should be confirmed that the probe used is approved by the competent authorities' aseptic probe sheath cover.

2. Warnings:
   - a DO NOT immerse the probe into any liquid beyond the immersion level. Never immerse the probe connector into any liquid.
   - b Do NOT use in a patient who would be harmed caused by applying ultrasound.
   - c DO NOT drop the probe or subject them to other types of mechanical shock or impact. Degraded performance or damage such as cracks or chips in the housing may result.
   - d Do NOT modify this device without authorization.
   - e Do NOT use the probe with high frequency surgical equipment. Doing so may damage the equipment.
   - f Do Not use the product close to strong electromagnetic field, electromagnetic wave and magnetic environment. There is possibility of measurement errors or damage to the product.
   - g When the device LU300 is charged with a mobile charging power supply, do NOT use it to work for diagnostic.
   - h 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.
   - i 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.
   - j Do Not charge the battery near a fire or heater.
   - k Never attempt to open a transducer or a transducer connector.
   - l All the contraindications and warning are well concerned by following the regulation of EN ISO 14971:2019 with related report.
   - m MR Unsafe items should not enter the MRI scanner room. Patients with MR Unsafe devices should not be scanned

3. Information security:
   - a When using Ultrasound App, it is the user's responsibility to protect their own security credentials (e.g. passwords) and the patient's persona information (e.g. name and so on).
   - b The confidential information is assured as follows:

c The scanner contains no patient-identifiable information.
d When the scanner connects to a wireless network.
e The data transferred between the smart device and the Leltek Ultrasound App is encrypted.
f Image data contains no patient or user identifiable information and is transmitted in unencrypted form. If you want this data encrypted, connect to a:
g Wi-Fi network where only trusted parties are permitted. The Wi-Fi network encrypts all image data sent from other Wi-Fi networks.
h Wi-Fi Direct network. The Wi-Fi Direct network encrypts all image data, and because no other users are on the Wi-Fi Direct network, the image data is confidential.

4. Network Security:
   a We recommend that user secures this network using WPA (Wi-Fi Protected Access). User will be trained medical professionals (e.g., doctors, nurses, technicians) with previous training in ultrasound. Images produced by the probe are transmitted wirelessly to the user's device (tablet/smart phone/personal computer). ◦
   b As following actions could present new risks to patients, operators, and third parties. It is your organization's responsibility to identify, analyze, evaluate, and control these risks:
   c Changing network configurations.
   d Connecting to additional networks or disconnecting from existing networks.
   e Upgrading to new equipment or updating existing equipment.
   f Using an untrusted wireless access point may allow malware to see your information or perform harmful actions, even to hack communications between the devices. For security purposes, the user is suggested to:
   g Use secure passwords.
   h Use secure wireless equipment using the latest firmware and software, and secure protocols.
   i Lock your smart devices.
   j Integrity of the data transmitted between the smart device and the Ultrasound App is assured as follows:
      1. Authenticated encryption prevents malicious users from intercepting and modifying data.
      2. Integrity checks ensure completion and validity of data received. If any data is incomplete or invalid, it is discarded.
      3. TCP channels used over Wi-Fi ensures that data is delivered correctly. For transmitting image data, a TCP channel is used.

   k This Ultrasound imaging system only one device connection to it at a time. When a smart device directly connects to the system. it disallows other user from connecting, and reduce DoS (Denial of Service) attacks. If the communication is disrupted, the device continues to monitor itself and shuts down after a period of inactivity. The alarm/error message will show up in the Ultrasound App if Wi-Fi connection is weak.

1. Product Safety
   a Please read this information before operating your ultrasound system. It applies to the device, the transducers, and the software. This section covers general safety information that applies only to a specific task and is included in the procedure for that task. Please follow the following requirements:
   b Product Safety
   c Warnings contain information important for the safety of both you the operator, and the patient.
   d Be aware of possible damage to the product that may void your warranty or service contract or lose patient or system data.
   e If a part of the system is known or suspected to be defective or incorrectly adjusted, cease use of the system until repairs are affected. Operating the system with defective or incorrectly adjusted components could expose you and/or the patient to safety hazards.
   f Do not leave children unattended with the system. The transducers pose a choking hazard due to small, detachable parts and the transducer cable is a strangulation hazard.
   g Under no circumstances attempt to remove, modify, override,

or frustrate any safety device on the system. Interfering with safety devices could lead to serious personal injury or death.

h Do not misuse the system - use the system only for its intended purposes. Do not use the system with any product that not designated by manufacturer as compatible with the system. Operation of the product for unintended purposes, or with incompatible products, could lead serious injury or death.

i If the system or the transducer appears to be malfunctioning, immediately cease use and contact your Local representative.

j Responsibility for configuring the device in accordance with an institution's security policies lies with the user. Notifications and alerts from third-party applications may interfere with an exam.

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

l Refrain from using the system with patients without adequate understanding of its capabilities and functions. Using the system without such understanding may compromise the system's effectiveness, as well as the safety of the patient, you, and others.

m Only use this system if you have read, understood, and know all the safety information, safety procedures, and emergency procedures contained in this "Safety" section. Operating the system without proper awareness of safety use could cause fatal or other serious personal injury.

2. Product Compatibility

a Do not use your system in combination with other products or components, unless expressly recognized by the manufacturer as compatible.

b For information about such products and components, contact local representative.

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

3. Electrical Safety

a l 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.

b When using additional peripheral equipment that is to be interconnected by functional connection, the combination which 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 Local representative.

c 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.

4. Battery Safety

a Lithium-ion batteries are also used in medical diagnostic equipment as portable diagnostic equipment; so, cautions indicated information to a user should pay more attention. Please be sure to take to comply with the specifications and the following precautions to use with batteries, did not follow the specifications for the operation caused any accidents, manufacturer will not accept any responsibility.

b Most all instructions for battery using devices give the advice to not let a battery for long periods of unused because can leak and cause damage to electronics; if unused the equipment over one week, it should be charged with the charging power supply of medical products comply with IEC 60601-1 for two MOPP insulation system. The charging power supply should be checked or replaced regularly.

c Do Not charge the battery near a fire or heater.

d If the battery leaks or emits an odor, turn-off the equipment and contact with Local representative.

e If the battery will remain unused for over a month, keep it between-20°C (-4°F) and 20°C (68°F)

f Do Not disassemble the device by yourself. The lithium battery may explode due to a short circuit. Again, if user finds any abnormal behavior of device, please turn-off the equipment and contact with Local representative.

5. Thermal safety

a The operating temperature of the ultrasound probe must remain below 43°C.

b Do not allow the transducer to contact the patient if the temperature of the transducer is higher than 43°C (109°F).

6. Biological Safety

7. Latex

a ultrasound probe does not contain natural rubber latex that contacts animals.

b FDA's recommendations to health professionals concerning latex awareness as follows:

c 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. To the patients with positive histories should mark their charts.

d 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.)

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

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

g 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

B. Acoustic Output and Measurement

1. The system limits patient contact temperature to 43°C (109°F), and acoustic output values to their respective U.S. Food and Drug Administration limits. A power-protection circuit protects against over-current conditions. If the power monitor protection circuit senses an over-current condition, then the drive voltage to the transducer is shut off immediately, preventing overheating of the transducer surface and limiting acoustic output. Validation of the power protection circuit is done under normal system operation.
2. Since the initial use of diagnostic ultrasound, the possible biological effects 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 the “Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment” (Revision 3, AIUM, NEMA, 2004), the “Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment” (Revision 2, AIUM, NEMA, 2004), and the September 2008 FDA document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers."

3. MI & TI & Ultrasound Bioeffects
   a Biological effects of ultrasound are the potential biological consequences due to the interaction between the ultrasound wave and the scanned tissues. Concern about the safety of ultrasound prompted several agencies to devise regulatory limits on the machine output intensities. The visual display of thermal and mechanical indices during ultrasound imaging provides an aid to limit the output of the machine. Sonographic evaluation of the animal body, including potentially sensitive tissues, such as developing fetus and the eye, have been performed on millions of patients without documentation of serious adverse events. However, ultrasound waves have the potential to cause significant biological effects, depending on ultrasound wave characteristics and scanned tissues sensitivity. Physicians and sonographers must be aware of these potential biological effects in assessing the overall safety of the procedure. The biological effects of ultrasound depend on the total energy applied to a given region. Thus, varying duration of exposure to wave emission, intensity and frequency of the ultrasound beam, pulsed or continuous emission modality and acoustic power, may lead to significant biological effects, that are commonly divided in thermal and Mechanical(non-thermal) effects.
   b Acoustic output limit:
      1. ISPTA.3 = 720 mW/cm^2 (50 for ophthalmic) for Track 3; for Track 3 ophthalmic,
      2. TI ≤ 6.0(Max TIS as TIC ≤1)
      3. MI ≤ 1.9 (0.23 for ophthalmic) for track 3;

4. Mechanical Index (MI) (Non-Thermal)
   a Ultrasound energy creates also mechanical forces independent of thermal effects, thereby causing biologic effects that are not related to temperature rise alone, such as cavitation, torque forces, oscillatory shear, radiation, pressure, and microstreaming.
   b The scientific evidence suggests the mechanical bioeffects are threshold phenomena that does occur when a certain level of output is exceeded. The threshold level varies depending on the tissue. The potential for mechanical bioeffects varies with peak rarefactional pressure and ultrasound frequency. The higher MI value reading, the greater the potential. There is no specific MI value, which means that a mechanical effect is occurring in fact. The MI should be used as a guide for implementing the ALARA principle.
   c Mechanical Index Display Accuracy and Precision
      1. It is estimated that 90% of MI values will be within +/–

15% of the displayed value, or +/– 0.14 of the displayed MI value, whichever value is larger. It approximates +/– 1.2 dB. The MI is displayed with a precision of 0.01.

5. Thermal Index (TI)

a The biological effects of ultrasound energy are related primarily to the production of heat. Heat is generated whenever ultrasound energy is absorbed, and the amount of heat produced depends on the intensity of the ultrasound, the time of exposure, and the specific absorption characteristics of the tissue. As much as 70% of the total temperature increase associated with ultrasound occurs within the first minute of exposure [2], but temperature continues to rise as exposure time is prolonged. Minimizing the exposure time is probably the single most important factor for ensuring patient safety from thermal injury [3]. Other important parameters to be considered are:

1. The relative protein content of each tissue, since absorption coefficients of tissues are directly related to protein content; absorption coefficients vary between 1 (skin, tendon, spinal cord) and 10 (bone) dB/cm MHz
2. The perfusion of the tissue, which has a dampening effect on heat generation and physically allows heat to be carried away from the point of energy transfer.
3. Emission modality, since pulsed-wave ultrasound is extremely unlikely to significantly heat tissues.
4. Beam width, since a wider beam width reduces the rate and extent of temperature rise by permitting the energy to be distributed over a larger perfusion territory.

b 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. You can choose to display TIS, TIC, or TIB.

c The App software has real-time display of thermal (TI) and a mechanical (MI) index, according to IEC62359. These two indices are intended to estimate the potential for thermal and mechanical bioeffects induced by ultrasound. Both TI and MI are displayed with increments of 0.01 and the displayed indexes are nominal values.

d The output display indices are calculated with the accuracy described below. The stated display accuracy values are determined relative to the MI and TI models, equations, and measurement methods specified in the "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 2" (NEMA UD3). The TI and MI are relative indicators for the likelihood of tissue thermal rise and mechanical bioeffects, respectively. The accuracy statements listed here are not bound on the deviation of the displayed indices from actual temperature rise or pressure levels in the body. The TI and MI values are determined from measurements in water and derated for tissue attenuation using an assumed homogenous tissue model with attenuation of 0.3 dB/cm/MHz and the sound propagation properties of water. Most tissues attenuate ultrasound at a greater rate. Fluids such as amniotic fluid attenuate less. In addition, the propagation of ultrasound is a nonlinear one in most cases, to different degrees in water and various tissues, with varying resultant effects on actual MI or TI values. The MI is a relative indicator for the likelihood of a mechanical bioeffect, such as cavitation, and its model assumes the presence of nucleation sites needed for cavitation. The TI models assume a blood perfusion length of 1 cm. Tissue

perfusion lengths and rates are dependent on vasculature and blood flow and the thermal properties of the surrounding tissue, which vary greatly. The bone TI derivation assumes all ultrasound energy is absorbed by the impinged bone.

e Thermal Index Display Accuracy and Precision

1. It is estimated that 90% of TI values will be +/– 40% of the displayed TI value or +/– 0.4 of the displayed value, whichever value is larger. It approximates +/–3 dB. The TI is displayed with a precision of 0.01.

f There are three TIs which used for different combinations of soft tissue and bone in the area to be examined. The TI is intending to keep us making aware of condition that cause increased temperature elevations, no matter at surface, within the tissue, or at the point where the ultrasound is focusing on bone.

Thermal index (TI)	Scanned Mode	Un-scanned Mode
Soft Tissue	TIS at Surface	TIS Small Aperture Large Aperture
Bone at Focus	TIS at Surface	TIB
Bone at Surface (Cranial bone)	TIC	TIC

6. Cavitation

a The interaction of ultrasound with gas bubbles or contrast agents causes rapid and potentially large changes in bubble size. This process, termed cavitation, may increase temperature and pressure within the bubble and thereby cause mechanical stress on surrounding tissues, precipitate fluid microbe formation, and generate free radicals [5]. Gas-containing structures (e.g., lungs, intestines) are most susceptible to the effects of acoustic cavitation. Ultrasound wavelength has an important role in bubble formation and growth: short wavelength ultrasound (observed at higher frequencies) does not provide sufficient time for significant bubble growth; therefore, cavitation is less likely under these circumstances compared with long wavelengths. The short half-life of cavitation nuclei prevents most cavitation-related biological effects, unless ultrasound contrast agents are also present. Contrast agents markedly reduce the threshold intensity for cavitation. However, because of the relatively high viscosity of blood and soft tissue, significant cavitation is unlikely, and cavitation has not been shown to occur with the ultrasound exposure commonly used during a diagnostic examination.
Note: *Cavitation depends on:*

1. Frequency
2. Pressure
3. Focused/unfocused beams
4. Pulsed/continuous ultrasound
5. Degree of standing waves
6. Nature and state of material
7. Boundaries

7. Other Effects

a A variety of other physical forces may also be produced by ultrasound energy. Although each of these effects can be demonstrated in vitro, there is no evidence that any of these physical phenomena has a significant biological effect on patients.

b Ensure that scanning time is kept to a minimum and 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.

c B mode 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.

d 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 Intended use.

e 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.

f 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 Intended use.

8. ALARA Principles

a The guiding principle for the use of diagnostic ultrasound is defined by the ALARA (which means that we keep total ultrasound exposure as low as reasonably achievable while optimizing diagnostic information). The decision as to what is reasonable has been left to the judgment and insight of qualified personnel. According to AIUM Medical Ultrasound Safety (Third Edition), there are the following description" With new ultrasound equipment, the on-screen output display (thermal index [TI] and mechanical index [MI]) lets us determine the exposure level in terms of the potential for bio effects. For equipment that does not have an output display, we depend on whatever output information, such as intensity, decibels, or the percentage of power, which the system provides. Because the threshold, if one exists, for diagnostic ultrasound bioeffects is undetermined, it becomes our responsibility to control the total exposure to the patient. Controlling the total exposure depends on the output level and exposure time. The output level required for an examination depends on the patient and the clinical need. Not all diagnostic examinations can be performed at very low levels. In fact, using too low a level may result in poor data and the need to repeat the examination. Using too high a level may not necessarily increase the quality of the information, but it will expose the patient to unneeded ultrasound energy. The use of ALARA is a way of implementing safety assurance. The threshold for diagnostic ultrasound bioeffects is undetermined. Ultimately, the exposure time depends on the person conducting the examination. Primarily, it's our training, education, and experience that determine how quickly we can obtain a useful image and thus the length of the examination and the amount of exposure. So, the question is, "How much time do we need to obtain the desired diagnostic information?" But there are also some other factors that might affect the length of time that any particular tissue is exposed. One is the mode, whether it's a moving or a stationary beam; and another is the choice of transducer. Other factors include the patient's body characteristics, the operator's understanding of the controls on the system and how they affect output levels, and, particularly, whether continuous wave or pulsed Doppler or color flow Doppler is used. To achieve ALARA, we need thorough knowledge of the imaging mode, transducer capabilities, system setup, and operator scanning techniques.

b System capabilities include the following: mode, transducer capabilities, system setup, and scanning techniques. Let's talk about each.

c First, the mode we select, such as M mode, B-mode, or Doppler, depends on what we're looking for. B-mode imaging gives anatomic information, while Doppler and color flow Doppler modes give information about blood flow through vessels. M-mode gives information about how anatomic structures move in time. If one wishes to use 3D/4D ultrasound, one needs to remember that the 3D/4D image sets consist of series of B-mode 2-dimensional (2D) acquisitions, which are then constructed by the computer into 3D/4D representations. Hence, whatever the settings are for B-mode 2D imaging will be what determines the output. Time will be the most important variable because, on the one hand, a 2D sweep will be fast and time limited, but prolonged exposure may result from attempting to obtain the "best" set of images.

Second, transducer capabilities relate to the penetration depth of ultrasound in tissue at the frequency chosen, resolution, and field of view that we can obtain with the selected transducer. Third, system setup and control settings depend on where we start on the output scale and on our knowledge of which combination of controls gets the best results. Fourth, the scanning technique we use is based on our knowledge of anatomy and pathology, of ultrasound physics, and of the equipment's signal-processing features plus our experience with a given scanning modality, such as sector, linear, and so forth. A system's recording and playback features let us reduce the exposure time to just the time necessary to obtain a useful image. Analysis and diagnosis can be performed with recorded images rather than lengthy live imaging sessions. The same can be said about 3D volumes, obtained by an examiner and analyzed by this examiner or someone else, with no exposure to the patient, at the bedside, the reading room, the other side of town, or another country. Without an output display standard, we must rely on that knowledge to estimate a patient's ultrasound exposure. With an output display standard, we have a real-time indication of the exposure in terms of the potential for bioeffects. Either way, we implement ALARA by minimizing the exposure level and duration while being sure to obtain the necessary diagnostic information."

d No set of rules can be formulated that would be sufficiently complete to dictate the correct response to every circumstance. The qualified personnel can adjust to improve image quality and minimize output intensity. There are several variables which affect the way in which the output display indices can be used to implement the ALARA principle. These variables involve:
   1. Index values
   2. Body size
   3. Location of the bone relative to the focal point
   4. Attenuation in the body
   5. Ultrasound exposure time. Exposure time is an especially useful variable, because it is controlled by the users.

9. Applying ALARA
   a The system imaging mode of the operator selected that is depends on the user information needed. Understanding the nature of the imaging mode used, the transducer frequency, system setup values, scanning techniques, and operator experience allow the sonographer to meet the definition of the ALARA principle. The amount of acoustic output is 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, 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. A high index reading does not necessarily indicate the occurrence of a bioeffect; however, it must be taken seriously. It is the operator responsibility to make every effort to reduce the possible effects of a high index reading by limiting exposure time.
   b 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.
10. Using System Controls to Implement ALARA
   a Direct Controls: The system has no direct control for output, therefore the sonographer must control exposure time and scanning technique to implement the ALARA principle. To ensure that acoustic and thermal limits are not exceeded for all imaging modes, the system is designed to automatically adjust output. The system does not exceed a spatial peak temporal average intensity (I SPTA) of 720 mW/cm2for all imaging modes. The equipment's mechanical index (MI) does not exceed values greater than 1.9 and thermal index (TI) does not exceed values greater than 6.0.
   b Indirect Controls: The indirect controls are those that have an

indirect effect on acoustic intensity. These controls affect imaging mode, pulse repetition frequency (PRF), pulse length. The choice of imaging mode determines the nature of the ultrasound beam. 2D is a scanning mode; Doppler is a stationary or un-scanned 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 un-scanned mode.

c 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.

d 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. 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 receiver gain, and other imaging controls.

11. Output Display

a There are two types of indices might be displayed: one is mechanical index (MI) and the other is thermal index (TI). The mechanical index (MI) provides an indication of the risk due to mechanical or nonthermal mechanisms. The thermal index (TI) provides an indication of the risk of harm due to thermal mechanisms. The mechanical index (MI) is continuously displayed over the range of 0.0 to 1.9, in increments of 0.1.

b 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. 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:

c 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.

d 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?

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

f 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.

12. Display Accuracy

a The MI and TI have a precision of 0.01 unit on the system.

b Estimates of the MI and TI display accuracies are shown in the Acoustic Output Tables. Many factors are considered when estimating the accuracy of the displayed values:

c Hardware variations, such as piezoelectric crystal efficiencies, process-related impedance differences, and sensitive lens-focusing parameter variations.

d Estimation algorithm accuracy, including variations in pulser voltage control, operation conditions, and efficiencies.

e Measurement variability, such as inaccuracies in laboratory measurements caused by hydrophone calibration and performance, positioning, alignment, and digitization tolerances, and variability of test operations.

f Controls Affecting the Indices

1. B mode Controls
2. Transducer Frequency
3. Color Controls

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

h 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.

i Measurement Precision and Uncertainty of Acoustic Output Values: The measurement precision of quantities is listed in the table below. They are measured as part of determining MI or TI values. Quantities are listed as one standard deviation, in percentage.

Parameter	Description	Uncertainty
Pulse Intensity Integral (PII)	Energy density (mJoules/cm^2) in an ultrasonic pressure wave. Used in TI, Ispta.0, and Ispta.3 determination.	+/-25.10%
Peak Rarefactional Pressure (Pr)	Largest pressure amplitude (MPa) of the negative pressure half-cycles in an ultrasonic pressure wave. Used in MI determination.	+/-12.55%
Spatial Average	Spatial averaging correction factor	+/-10.00% for intensity, +/-5.00% for pressure
Center Frequency (Fc)	Center frequency (MHz) of an ultrasonic pressure wave. Used in MI determination.	+/-0.012%

III. Technical Features

A. System

1. There are some of the technical aspects of the system as following list:
   - a Receive frequency and/or band and bandwidth of receiving section.
   - b Transmit frequency and/or band, modulation, and ERP
   - c Functions: Image data transmit and control data communications
   - d High performance computing technology of FPGA
   - e unique technology "Ultra Image Block Algorithm" (UIBA) solution for B mode, Color mode, M mode, Power Doppler and PW Doppler block image
   - f High frame rate
   - g High contrast
   - h High resolution
   - i Tissue Harmonic Imaging
   - j Support Image Mode
   - k B mode
   - l Color Doppler
   - m M mode
   - n PW Doppler
   - o Power Doppler
   - p Internal battery continuous use of time
   - q B mode (approx.) 4.5 hours
   - r Color Doppler(approx.) 3.5 hours
   - s M mode(approx.) 4.5 hours
   - t PW Doppler(approx.) 2.5 hours.
   - u Power Doppler(approx.) 3.5 hours

2. Three example compatible adaptor in compliance with IEC 60601-1 for two MOPP insulation system:
   - a Tripp Lite Healthcare Products Group
     Model name: U280-001-W2-HG
   - b Good Opportunity Electronic Co., Ltd.'s
     Model name: Medical Power Adapter 10 W
   - c MEAN WELL ENTERPRISES CO., LTD.
     Model name: GSM12U USB connection

3. Radio Frequency Wireless Technology Description
   - a The 2.4GHz and 5GHz Wireless communication technical aspects of the system as following list

Parameter	Specification	Comment
IEEE 802.11 Level	IEEE 802.11a/b/g/n	802.11b ch 1-11 802.11g ch 1-11 802.11n 20M 802.11a 5150-5250 (UNII-1) 802.11a 5725-5850 (UNII-3)
Wireless Signal Rate	1 - 11 Mbps (IEEE 802.11b) 6 - 54 Mbps (IEEE 802.11g) 6 - 54 Mbps (IEEE 802.11a)	Actual data throughput is lower and is affected by distance from the device and packet error rates network condition, environment factors, etc.
Security Type	WPA2. LU300 works as AP mode connection with SSID selection and password required; only one authenticated connection at a time.	Encryption for improved security and authentication for secured connection.
Redundancy mechanism	CRC	Metadata checking for integrity
Distance between the LU300 and the mobile device	<3 meter; <1 meter if in crowded environment	In most tests See Wi-Fi coexistence testing.
Error rate	<5%	See Wi-Fi coexistence testing.
Data frame rate (regarding data latency and throughput)	8 fps	See Wi-Fi coexistence testing. By default the normal condition frame time is about 0.128s, one sigma is about 0.009s.

B. Clinical measurement range and accuracies

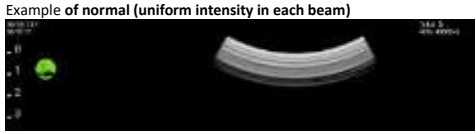
Measurement	Units	Useful Range	Reported Accuracy	Limitations or Conditions	
				Probe	Mode of operations
Distance:					
Vertical	mm	Full screen	Max error. 2.5% Max error. 2.5% Max error. 3.6% Max error. 1.9%	LU300L LU300C LU300M LU300PA	■B
Horizontal	mm	Full screen	Max error. 0.7% Max error. 2.9% Max error. 2.8% Max error. 3.5%	LU300L LU300C LU300M LU300PA	■B
Area:					
Circle	mm^2	Full screen	Max error 3.45% Max error 2.3% Max error. 3.9% Max error. 3.5%	LU300L LU300C LU300M LU300PA	■B
Dead Zone					
Dead Zone	mm^2	-	0 mm 0 mm 0 mm 2 mm	LU300L LU300C LU300M LU300PA	■B
Doppler					
Velocity	mm/s	Full screen	Max error 4.48% Max error 4.1% Max error. 2.8% Max error. 3.6%	LU300L LU300C LU300M LU300PA	■PWD

1. * Perform Traducer Element Check

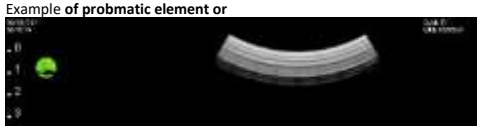
To perform the transducer element test, we added the following function and description to the user manual. The operators can thus check transducer by themselves.

Press the button Advanced Settings in the left menu of the main view . the user can use Transducer Check to determine if the element working as intended. The system transmits and receive by a designed sequence and form the image. The abnormal intensity variations (e.g. dark lines) near the surface shall be considered the possible element failure. Contact the service for guide on further actions needed.

2. Example **of normal (uniform intensity in each beam)**



3. Example **of probmatic element or**



channel failure.

4.

5. Compliance Statement

Leltek products comply with international and national standards and laws. Users are responsible for ensuring that the chosen smart device and scanner are compliant with the law in the jurisdiction where the product is used. Leltek meets all regulatory standards listed in this chapter.

6. Product Classification

The device with transducers: Class IIa/internally powered ME equipment.
Transducers: Type BF applied parts, IP03
Ordinary Equipment/Continuous Operation
Non-AP/APG

7. Electromechanical Safety Standards Met

The transducers and software comply with the requirements of IEC 60601-1 Medical Electrical Equipment, General Requirements for Safety, including all applicable collateral and particular standards, as well as all applicable deviations. System users are responsible for ensuring that the chosen device is compliant with the law in the jurisdiction in which the product is used.

8. System Specifications

Gray shades: 256 in B-Mode
Pressure, humidity, and temperature limits: These limits apply only to the Leltek transducer, not to the Android or iOS device on which the user run the Leltek imaging System app. It is the user's responsibility to select a Leltek-compatible device that meets the needs of the user's clinical environment.
For information about the user's device's environmental specifications, consult the documentation that accompanies users' device.

C. Acoustic Output Tables

1. [LU300L] Acoustic output reporting table

(EN IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: LU300L SN:LT702D-49-00007

Operating Model: B+CF Mode

Index Lebel			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.54	0.61		0.61		N/A
Index component value				B:0.56 CF:0.05	B:0.56 CF:0.05	N/A	B:0.56 CF:0.05	
Associated Parameter	$P_{r.a}$ at Z_{MI}	(MPa)	0.77					
	P	(mW)		B:22.23 CF:2.53		B:22.23 CF:2.53		N/A
	P_{1x1}	(mW)		B:19.85 CF:2.26		B:19.85 CF:2.26		
	Z_S	(cm)			N/A		N/A	
	Z_b	(cm)						
	Z_{MI}	(cm)	0.50					
	$Z_{PII\ \alpha}$	(cm)	0.50					
	f_{awf}	(MHz)	B:5.90	B:5.90 C:4.91		B:5.90 C:4.91		N/A
Other Information	prr	(Hz)	8787.00					
	srr	(Hz)	7.21					
	n_{pps}		1					
	$I_{pa.\alpha}$ at $Z_{PII\ \alpha}$	(W/cm^2)	64.83				-	
	$I_{spta.\alpha}$ at $Z_{PII\ \alpha}$ or $Z_{SII\ \alpha}$	(mW/cm^2)	21.3					
	$I_{spta.}$ at Z_{PII} or Z_{SII}	(mW/cm^2)	49.8				-	
	$P_{r.}$ at Z_{PII}	(MPa)	1.67					
Operating Control Conditions	Display focus	(cm)	4.0	4.0	4.0	N/A	4.0	N/A
	Display depth	(cm)	6.3	6.3	6.3	N/A	6.3	N/A
	Working frequency	(MHz)	B:6.3 CF:5.0	B:6.3 CF:5.0	B:6.3 CF:5.0	N/A	B:6.3 CF:5.0	N/A
	Display focus number		1	1	1	N/A	1	N/A
	PRF	(KHz)	3.57	3.57	3.57	N/A	3.57	N/A

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

(EN IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: LU300L SN:LT702D-49-00007

Operating Model: M Mode

Index Lebel			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.54	0.56		0.56		N/A
Index component value				0.56	0.56	N/A	0.56	
Associated Parameter	$P_{r.a}$ at Z_{MI}	(MPa)	1.30					
	P	(mW)		22.23		22.23		N/A
	P_{1x1}	(mW)		19.85		19.85		
	Z_S	(cm)			N/A		N/A	
	Z_b	(cm)						
	Z_{MI}	(cm)	1.22					
	$Z_{PII\,\alpha}$	(cm)	1.22					
	f_{awf}	(MHz)	5.90	5.90		5.90		N/A
Other Information	prr	(Hz)	8787.00					
	srr	(Hz)	7.21					
	n_{pps}		1.00					
	$I_{pa.\alpha}$ at $Z_{PII\,\alpha}$	(W/cm^2)	64.83				-	
	$I_{spta.\alpha}$ at $Z_{PII\,\alpha}$ or $Z_{SII\,\alpha}$	(mW/cm^2)	11.10					
	$I_{spta.}$ at Z_{PII} or Z_{SII}	(mW/cm^2)	18.20				-	
	$P_{r.}$ at Z_{PII}	(MPa)	1.67					
Operating Control Conditions	Display focus	(cm)	4.00	4.00	4.00	N/A	4.00	N/A
	Display depth	(cm)	6.30	6.30	6.30	N/A	6.30	N/A
	Working frequency	(MHz)	6.30	6.30	6.30	N/A	6.30	N/A
	Display focus number		1.00	1.00	1.00	N/A	1.00	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.								

(EN IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: LU300L SN:LT702D-49-00007

Operating Model: B Mode

Index Lebel			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.54	0.56		0.56		N/A
Index component value				0.56	0.56	N/A	0.56	
Associated Parameter	$P_{r.a}$ at Z_{MI}	(MPa)	1.30					
	P	(mW)		22.23		22.23		N/A
	P_{1x1}	(mW)		19.85		19.85		
	Z_S	(cm)			N/A		N/A	
	Z_b	(cm)						
	Z_{MI}	(cm)	1.22					
	$Z_{PII\ \alpha}$	(cm)	1.22					
	f_{awf}	(MHz)	5.90	5.90		5.90		N/A
Other Information	prr	(Hz)	8787.00					
	srr	(Hz)	7.21					
	n_{pps}		1.00					
	$I_{pa.\alpha}$ at $Z_{PII\ \alpha}$	(W/cm^2)	64.83				-	
	$I_{spta.\alpha}$ at $Z_{PII\ \alpha}$ or $Z_{SII\ \alpha}$	(mW/cm^2)	11.10					
	$I_{spta.}$ at Z_{PII} or Z_{SII}	(mW/cm^2)	18.20				-	
	$P_{r.}$ at Z_{PII}	(MPa)	1.67					
Operating Control Conditions	Display focus	(cm)	4.00	4.00	4.00	N/A	4.00	N/A
	Display depth	(cm)	6.30	6.30	6.30	N/A	6.30	N/A
	Working frequency	(MHz)	6.30	6.30	6.30	N/A	6.30	N/A
	Display focus number		1.00	1.00	1.00	N/A	1.00	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.								

Acoustic output reporting table

(EN IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: LU300L
SN:LT702D-49-00007

Operating Model: PW Mode

Index Lebel			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.67	0.49		1.22		N/A
Index component value				0.49	N/A	N/A	1.22	
Associated Parameter	$P_{r.a}$ at Z_{MI}	(MPa)	1.81					
	P	(mW)		20.82		20.82		N/A
	P_{1x1}	(mW)		N/A		N/A		
	Z_S	(cm)			N/A			
	Z_b	(cm)					1.5	
	Z_{MI}	(cm)	2.34					
	$Z_{PII\ \alpha}$	(cm)	2.34					
	f_{awf}	(MHz)	4.95	4.95		4.95		N/A
Other Information	prr	(Hz)	3570.00					
	srr	(Hz)	N/A					
	n_{pps}		1					
	$I_{pa.\alpha}$ at $Z_{PII\ \alpha}$	(W/cm^2)	125.5				-	
	$I_{spta.\alpha}$ at $Z_{PII\ \alpha}$ or $Z_{SII\ \alpha}$	(mW/cm^2)	441.6					
	$I_{spta.}$ at Z_{PII} or Z_{SII}	(mW/cm^2)	983.6				-	
	$P_{r.}$ at Z_{PII}	(MPa)	2.23					
Operating Control Conditions	Display focus	(cm)	4.0	4.0	N/A	N/A	4.0	N/A
	Display depth	(cm)	6.3	6.3	N/A	N/A	6.3	N/A
	Working frequency	(MHz)	5.0	5.0	N/A	N/A	5.0	N/A
	Display focus number		1.0	1.0	N/A	N/A	1.0	N/A
	PRF	(KHz)	3.57	3.57	N/A	N/A	3.57	N/A

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

1. [LU300C] Acoustic output reporting table

Acoustic output reporting table
(IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: LU710C SN:A20812702
Operating Model: B Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.79	0.70		0.70		N/A
Index component value			0.70	0.70	N/A	0.70	
Acoustic Parameters	$p_{r.3}$ at z_{MI} (MPa)	1.22					
	P (mW)		76.26		76.26		N/A
	P_{1x1} (mW)		60.52		60.52		
	z_1 (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	6.08					
	$z_{pii.3}$ (cm)	6.08					
	f_{awf} (MHz)	2.43	2.43		2.43		N/A
Other Information	prr (Hz)	1790.20					
	srr (Hz)	11.56					
	n_{pps}	2					
	$I_{spta.3}$ at $z_{pii.3}$ (W/cm^2)	68.18					
	$I_{sptb.3}$ at $z_{pii.3}$ or $z_{sii.3}$(mW/cm^2)	9.40					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	21.66					
	p_r at z_{pii} (MPa)	2.04					
Operating control conditions	Focus(cm)	13.5	13.5	13.5	N/A	13.5	N/A
	Depth(cm)	18.9	18.9	18.9	N/A	18.9	N/A
	Working frequency(MHz)	H5.0	H5.0	H5.0	N/A	H5.0	N/A
	THI	On	On	On	N/A	On	N/A

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

Acoustic output reporting table
(IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: LU710C SN:A20812702
Operating Model: B+C/B+PD Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.46	1.06		1.06		N/A
Index component value			B:0.82 C:0.24	B:0.82 C:0.24	N/A	B:0.82 C:0.24	
Acoustic Parameters	$p_{r.3}$ at z_{MI} (MPa)	0.73					
	P (mW)		B:86.22 C:19.52		B:86.22 C:19.52		N/A
	P_{1x1} (mW)		B:68.43 C:15.49		B:68.43 C:15.49		
	z_1 (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	4.55					
	$z_{pii.3}$ (cm)	4.55					
	f_{awf} (MHz)	C:2.53	B:2.53 C:3.26		B:2.53 C:3.26		N/A
Other Information	prr (Hz)	3600.00					
	srr (Hz)	7.79					
	n_{pps}	16					
	$I_{spta.3}$ at $z_{pii.3}$ (W/cm^2)	17.85					
	$I_{sptb.3}$ at $z_{pii.3}$ or $z_{sii.3}$(mW/cm^2)	16.41					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	46.75					
	p_r at z_{pii} (MPa)	1.08					
Operating control conditions	Focus(cm)	13.5	13.5	13.5	N/A	13.5	N/A
	Depth(cm)	18.9	18.9	18.9	N/A	18.9	N/A
	Working frequency(MHz)	B:2.8 C:Fixed	B:2.8 C:Fixed	B:2.8 C:Fixed	N/A	B:2.8 C:Fixed	N/A
	THI	Off	Off	Off	N/A	Off	N/A
	PRF(KHz)	3.6	3.6	3.6	N/A	3.6	N/A

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

Acoustic output reporting table
(IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: LU710C SN:A20812702
Operating Model: M Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.76	0.044		0.086		N/A
Index component value			0.044	N/A	N/A	0.086	
Acoustic Parameters	$p_{r.3}$ at z_{MI} (MPa)	1.23					
	P (mW)		3.53		3.53		N/A
	$P_{1\times1}$ (mW)		N/A		N/A		
	z_1 (cm)			N/A			
	z_b (cm)					5.78	
	z_{MI} (cm)	6.10					
	$z_{pii.3}$ (cm)	6.10					
	f_{awf} (MHz)	2.60	2.60		2.60		N/A
Other information	prr (Hz)	38.15					
	srr (Hz)	N/A					
	n_{pps}	N/A					
	$I_{hpa.3}$ at $z_{Pii.3}$ (W/cm^2)	64.07					
	$I_{spta.3}$ at $z_{Pii.3}$ or $z_{SII.3}$(mW/cm^2)	6.98					
	I_{sptp} at z_{Pii} or z_{SII} (mW/cm^2)	20.86					
	p_r at z_{Pii} (MPa)	2.13					
Operating control conditions	Focus(cm)	13.5	13.5	N/A	N/A	13.5	N/A
	Depth(cm)	18.9	18.9	N/A	N/A	18.9	N/A
	Working frequency(MHz)	Fixed	Fixed	N/A	N/A	Fixed	N/A
	THI	On	On	N/A	N/A	On	N/A

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

Acoustic output reporting table
(IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: LU710C SN:A20812702
Operating Model: PW Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.76	2.24		4.42		N/A
Index component value			2.24	N/A	N/A	4.42	
Acoustic Parameters	$p_{r.3}$ at z_{MI} (MPa)	1.23					
	P (mW)		180.70		180.70		N/A
	$P_{1\times1}$ (mW)		N/A		N/A		
	z_1 (cm)			N/A			
	z_b (cm)					6.58	
	z_{MI} (cm)	6.08					
	$z_{Pii.3}$ (cm)	6.08					
	f_{awf} (MHz)	2.60	2.60		2.60		N/A
Other information	prr (Hz)	4170.00					
	srr (Hz)	N/A					
	n_{pps}	N/A					
	$I_{ta.3}$ at $z_{It.3}$ (W/cm^2)	63.21					
	$I_{spta.3}$ at $z_{Pii.3}$ or $z_{SII.3}$(mW/cm^2)	376.20					
	I_{sptp} at z_{Pii} or z_{SII} (mW/cm^2)	1122.00					
	p_r at z_{Pii} (MPa)	2.12					
Operating control conditions	Focus(cm)	13.5	13.5	N/A	N/A	13.5	N/A
	Depth(cm)	18.9	18.9	N/A	N/A	18.9	N/A
	Working frequency(MHz)	2.6	2.6	N/A	N/A	2.6	N/A
	PRF(KHz)	4.17	4.17	N/A	N/A	4.17	N/A

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

2. [LU300M] Acoustic output reporting table

Acoustic output reporting table
(IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: LU710M SN:C20822603
Operating Model: B Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.37	0.59		0.59		N/A
Index component value			0.59	0.59	N/A	0.59	
Acoustic Parameters	$p_{r.3}$ at z_{MI} (MPa)	0.82					
	P (mW)		25.10		25.10		N/A
	P_{1x1} (mW)		25.10		25.10		
	z_1 (cm)			N/A			
	z_2 (cm)					N/A	
	z_{MI} (cm)	1.54					
	$z_{pii.3}$ (cm)	1.54					
	f_{awf} (MHz)	4.90	4.90		4.90		N/A
Other Information	prr (Hz)	8705.10					
	srr (Hz)	7.79					
	n_{pps}	1					
	$I_{pa.3}$ at $z_{pii.3}$ (W/cm²)	21.39					
	$I_{spta.3}$ at $z_{pii.3}$ or $z_{sii.3}$(mW/cm²)	18.78					
	I_{spta} at z_{pii} or z_{sii} (mW/cm²)	32.56					
	p_r at z_{MI} (MPa)	1.06					
Operating control conditions	Focus(cm)	2.5	2.5	2.5	N/A	2.5	N/A
	Depth(cm)	6.3	6.3	6.3	N/A	6.3	N/A
	Working frequency(MHz)	5.0	5.0	5.0	N/A	5.0	N/A
	THI	Off	Off	Off	N/A	Off	N/A

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

Acoustic output reporting table
(IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: LU710M SN:C20822603
Operating Model: B+C/B+PD Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.33	0.70		0.70		N/A
Index component value			B:0.65 C:0.06	B:0.65 C:0.06	N/A	B:0.65 C:0.06	
Acoustic Parameters	$p_{r.3}$ at z_{MI} (MPa)	0.68					
	P (mW)		B:23.23 C:2.34		B:23.23 C:2.34		N/A
	P_{1x1} (mW)		B:23.23 C:2.34		B:23.23 C:2.34		
	z_1 (cm)			N/A			
	z_2 (cm)					N/A	
	z_{MI} (cm)	1.28					
	$z_{pii.3}$ (cm)	1.28					
	f_{awf} (MHz)	C:4.24	B:5.87 C:4.24		B:5.87 C:4.24		N/A
Other information	prr (Hz)	3500.00					
	srr (Hz)	7.79					
	n_{pps}	16					
	$I_{pa.3}$ at $z_{pii.3}$ (W/cm²)	14.83					
	$I_{spta.3}$ at $z_{pii.3}$ or $z_{sii.3}$(mW/cm²)	19.61					
	I_{spta} at z_{pii} or z_{sii} (mW/cm²)	38.77					
	p_r at z_{MI} (MPa)	0.82					
Operating control conditions	Focus(cm)	2.5	2.5	2.5	N/A	2.5	N/A
	Depth(cm)	6.3	6.3	6.3	N/A	6.3	N/A
	Working frequency(MHz)	B:6.3 C:Fixed	B:6.3 C:Fixed	B:6.3 C:Fixed	N/A	B:6.3 C:Fixed	N/A
	THI	Off	Off	Off	N/A	Off	N/A
	PRF(KHz)	3.5	3.5	3.5	N/A	3.5	N/A

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

Acoustic output reporting table
(IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: LU710M SN:C20822603
Operating Model: M Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.69	0.005		0.013		N/A
Index component value			0.005	N/A	N/A	0.013	
Acoustic Parameters	$p_{r.3}$ at z_{MI} (MPa)	1.52					
	P (mW)		0.22		0.22		N/A
	$P_{1\times1}$ (mW)		N/A		N/A		
	z_1 (cm)			N/A			
	z_b (cm)					2.04	
	z_{MI} (cm)	2.20					
	$z_{pii.3}$ (cm)	2.20					
	f_{awf} (MHz)	4.90	4.90		4.90		N/A
Other Information	prr (Hz)	38.15					
	srr (Hz)	N/A					
	n_{pps}	N/A					
	$I_{spta.3}$ at $z_{pii.3}$ (W/cm²)	110.40					
	$I_{pata.3}$ at $z_{pii.3}$ or $z_{SII.3}$(mW/cm²)	3.20					
	I_{SPTA} at z_{Pii} or z_{SII} (mW/cm²)	6.73					
	p_r at z_{Pii} (MPa)	2.21					
Operating control conditions	Focus(cm)	2.5	2.5	N/A	N/A	2.5	N/A
	Depth(cm)	6.3	6.3	N/A	N/A	6.3	N/A
	Working frequency(MHz)	Fixed	Fixed	N/A	N/A	Fixed	N/A
	THI	Off	Off	N/A	N/A	Off	N/A

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

Acoustic output reporting table
(IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: LU710M SN:C20822603
Operating Model: PW Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.91	0.42		1.76		N/A
Index component value			0.42	N/A	N/A	1.76	
Acoustic Parameters	$p_{r.3}$ at z_{MI} (MPa)	1.87					
	P (mW)		20.70		20.70		N/A
	$P_{1\times1}$ (mW)		N/A		N/A		
	z_1 (cm)			N/A			
	z_b (cm)					1.44	
	z_{MI} (cm)	1.50					
	$z_{pii.3}$ (cm)	1.50					
	f_{awf} (MHz)	4.22	4.22		4.22		N/A
Other Information	prr (Hz)	4170.00					
	srr (Hz)	N/A					
	n_{pps}	N/A					
	$I_{spta.3}$ at $z_{pii.3}$ (W/cm²)	150.10					
	$I_{pata.3}$ at $z_{pii.3}$ or $z_{SII.3}$(mW/cm²)	559.80					
	I_{SPTA} at z_{Pii} or z_{SII} (mW/cm²)	866.80					
	p_r at z_{Pii} (MPa)	2.33					
Operating control conditions	Focus(cm)	2.5	2.5	N/A	N/A	2.5	N/A
	Depth(cm)	6.3	6.3	N/A	N/A	6.3	N/A
	Working frequency(MHz)	4.2	4.2	N/A	N/A	4.2	N/A
	PRF(KHz)	4.17	4.17	N/A	N/A	4.17	N/A

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

3. [LU300PA] Acoustic output reporting table

Acoustic output reporting table
(IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: LU710PA SN:D20852501
Operating Model: B Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.72	0.34		0.34		N/A
Index component value			0.34	0.34	N/A	0.34	
Acoustic Parameters	$p_{r.3}$ at z_{MI} (MPa)	1.02					
	P (mW)		37.20		37.20		N/A
	$P_{1\times1}$ (mW)		35.77		35.77		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	3.93					
	$z_{pii.3}$ (cm)	3.93					
	f_{awf} (MHz)	1.98	1.98		1.98		N/A
Other Information	prr (Hz)	1785.40					
	srr (Hz)	7.79					
	n_{pps}	2					
	$I_{spta.3}$ at $z_{pii.3}$ (W/cm^2)	38.16					
	$I_{sata.3}$ at $z_{pii.3}$ or $z_{sii.3}$(mW/cm^2)	18.92					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	22.95					
	p_r at z_{pii} (MPa)	1.33					
Operating control conditions	Focus(cm)	13.5	13.5	13.5	N/A	13.5	N/A
	Depth(cm)	18.9	18.9	18.9	N/A	18.9	N/A
	Working frequency(MHz)	H3.6	H3.6	H3.6	N/A	H3.6	N/A
	THI	On	On	On	N/A	On	N/A

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

Acoustic output reporting table
(IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: LU710PA SN:D20852501
Operating Model: B+C/B+PD Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.65	0.49		0.49		N/A
Index component value			B:0.24 C:0.25	B:0.24 C:0.25	N/A	B:0.24 C:0.25	
Acoustic Parameters	$p_{r.3}$ at z_{MI} (MPa)	0.88					
	P (mW)		B:29.29 C:21.12		B:29.29 C:21.12		N/A
	$P_{1\times1}$ (mW)		B:28.16 C:20.31		B:28.16 C:20.31		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	3.63					
	$z_{pii.3}$ (cm)	3.63					
	f_{awf} (MHz)	B:1.82	B:1.82 C:2.58		B:1.82 C:2.58		N/A
Other Information	prr (Hz)	3568.60					
	srr (Hz)	7.79					
	n_{pps}	1					
	$I_{spta.3}$ at $z_{pii.3}$ (W/cm^2)	27.90					
	$I_{sata.3}$ at $z_{pii.3}$ or $z_{sii.3}$(mW/cm^2)	46.24					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	67.88					
	p_r at z_{pii} (MPa)	1.10					
Operating control conditions	Focus(cm)	13.5	13.5	13.5	N/A	13.5	N/A
	Depth(cm)	18.9	18.9	18.9	N/A	18.9	N/A
	Working frequency(MHz)	B:1.8 C:Fixed	B:1.8 C:Fixed	B:1.8 C:Fixed	N/A	B:1.8 C:Fixed	N/A
	THI	Off	Off	Off	N/A	Off	N/A
	PRF(KHz)	3.3	3.3	3.3	N/A	3.3	N/A

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

Acoustic output reporting table
(IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: LU710PA SN:D20852501
Operating Model: M Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.39	0.011		0.023		N/A
Index component value			0.011	N/A	N/A	0.023	
Acoustic Parameters	$p_{r.3}$ at z_{MI} (MPa)	0.65					
	P (mW)		0.88		0.88		N/A
	P_{1x1} (mW)		N/A		N/A		
	z_s (cm)			N/A			
	z_b (cm)					3.90	
	z_{MI} (cm)	4.28					
	$z_{PII.3}$ (cm)	4.28					
	f_{awf} (MHz)	2.72	2.72		2.72		N/A
Other Information	prr (Hz)	38.15					
	srr (Hz)	N/A					
	n_{pps}	N/A					
	$I_{spta.3}$ at $z_{PII.3}$ (W/cm^2)	15.42					
	$I_{sptA.3}$ at $z_{PII.3}$ or $z_{SII.3}$(mW/cm^2)	1.60					
	I_{sppa} at z_{PII} or z_{SII} (mW/cm^2)	3.58					
	p_r at z_{PII} (MPa)	0.97					
Operating control conditions	Focus(cm)		13.5	13.5	N/A	N/A	13.5	N/A
	Depth(cm)		18.9	18.9	N/A	N/A	18.9	N/A
	Working frequency(MHz)		Fixed	Fixed	N/A	N/A	Fixed	N/A
	THI		On	On	N/A	N/A	On	N/A

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

Acoustic output reporting table
(IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: LU710PA SN:D20852501
Operating Model: PW Mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.41	0.82		1.47		N/A
Index component value			0.82	N/A	N/A	1.47	
Acoustic Parameters	$p_{r.3}$ at z_{MI} (MPa)	0.72					
	P (mW)		57.00		57.00		N/A
	P_{1x1} (mW)		N/A		N/A		
	z_s (cm)			N/A			
	z_b (cm)					4.15	
	z_{MI} (cm)	4.15					
	$z_{PII.3}$ (cm)	4.15					
	f_{awf} (MHz)	3.03	3.03		3.03		N/A
Other Information	prr (Hz)	4170.00					
	srr (Hz)	N/A					
	n_{pps}	N/A					
	$I_{spta.3}$ at $z_{PII.3}$ (W/cm^2)	19.14					
	$I_{sptA.3}$ at $z_{PII.3}$ or $z_{SII.3}$(mW/cm^2)	97.44					
	I_{sppa} at z_{PII} or z_{SII} (mW/cm^2)	232.40					
	p_r at z_{PII} (MPa)	1.12					
Operating control conditions	Focus(cm)		13.5	13.5	N/A	N/A	13.5	N/A
	Depth(cm)		18.9	18.9	N/A	N/A	18.9	N/A
	Working frequency(MHz)		3.1	3.1	N/A	N/A	3.1	N/A
	PRF(KHz)		4.17	4.17	N/A	N/A	4.17	N/A

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

D. Guidance and Manufacture's Declaration

- LU300 series requires special precautions regarding EMC.
- LU300 series should not be used adjacent to or stacked with other equipment.
- Using the wrong cable and accessories may adversely affect the EMC performance

E. Electromagnetic Emissions

The LU300 Series is intended for use in electromagnetic environments, as specified below. The customer or the user of the LU300 Series should ensure that it is used in such an environment.

Manufacturer's declaration-electromagnetic emissions		
The LU300 Series is intended for use in the electromagnetic environment (for professional healthcare) specified below. The customer or the user of the LU300 Series should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance (for professional healthcare environment)**
RF emissions CISPR 11	Group 1	The LU300 Series uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The LU300 Series is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Manufacturer's declaration-electromagnetic immunity			
The LU300 Series is intended for use in the electromagnetic environment (for professional healthcare) specified below. The customer or the user of the LU300 Series should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for professional healthcare environment)**
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact: ±8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines Not applicable	Mains power quality should be that of a typical professional healthcare environment.
Surge IEC 61000-4-5	± 0.5kV, ±1kV line(s) to line(s) ± 0.5kV, ±1kV,± 2kV line(s) to earth	± 0.5kV, ±1kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical professional healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 25/30 cycles Voltage interruptions: 0 % UT; 250/300 cycle	Voltage dips: 0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 30 cycles Voltage interruptions: 0 % UT; 300 cycle	Mains power quality should be that of a typical professional healthcare environment. If the user of the LU300C, LU300L requires continued operation during power mains interruptions, it is recommended that the LU300C, LU300L be powered from an uninterruptible power supply or a battery.
Power frequency(50 , 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 60 Hz	The LU300C, LU300L power frequency magnetic fields should be at levels characteristic of a typical location in a typical professional healthcare environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

F. Electromagnetic immunity

All LU300 series products are in compliance with the regulation of immunity test, and the detail and declaration as below:

Manufacturer's declaration-electromagnetic immunity			
The LU300 Series is intended for use in the electromagnetic environment (for professional healthcare) specified below. The customer or the user of the LU300 Series should assure that it is used in such and environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for professional healthcare environment)**
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: In ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz e)	**Portable and mobile RF communications equipment should be used no closer to any part of the** LU300 Series including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	**Recommended separation distance:** $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80MHz to 800 MHz $d = 2,3\sqrt{P}$ 800MHz to 2,7 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The LU300Series is intended for use in the electromagnetic environment (for professional healthcare) specified below.

The customer or the user of the LU300 Series should assure that it is used in such an environment.

Recommended separation distance between portable and mobile RF communications equipment and the LU300 Series

The LU300C, LU300L,LU300C,LU300M,LU300PA,LU300E is intended for use in an electromagnetic environment (for professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the LU300 Series can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LU300 Series as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** **m**		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 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 transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for professional
385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT;	Pulse modulation b) 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5 500							
5 785							

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

(a) For some services, only the uplink frequencies are included.
(b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
(c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

G. Federal Communications Commission (FCC) Statement

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 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.

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 of the device.

FCC RF Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Manufacturer's address

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IV. References

A、 Acoustic

i. EN IEC 60601-2-37:2008/AMD1:2015 - Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

ii. AIUM/NEMA UD 2- 2004 2009 NEMA Standards Publication UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3. (Radiology)

iii. AIUM/NEMA UD 3- 2004 2009 NEMA Standards Publication UD 3-2004 (R2009) Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

B、 Biocompatibility

i. EN ISO 10993-1:2009 -Biological evaluation of medical devices - Evaluation and testing within a risk management process

ii. EN ISO 10993-5:2009 -Biological evaluation of medical devices - Tests for in vitro cytotoxicity

iii. ISO 10993-10:2010-Biological evaluation of medical devices. Tests for irritation and skin sensitization

C、 Chemical

i. REACH 02006R1907:2015-03-23 - REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18December2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.

ii. LU300 Ultrasound Imaging System meets the minimum requirements for compliance with the European Union's Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU and its amendments.

D、 Battery

i. UN 38.3 -Lithium Battery Transportation

ii. EN IEC 62133 -Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.

E、 Wireless

i. 2002/96/EC(WEEE)- Directive 2002/96/EC; Waste Electrical and Electronic Equipment Directive

ii. EN 300 328 V2.1.1： 2016 -Wireless Radio Frequency Wideband Transmission);

iii. EN301 489-1& EN301 489-17:2017 03 (Wireless Electromagnetic Compatibility Standard

F、 Waterproof

i. IEC 60529 edition2.2:2013 -Degrees of protection provided by enclosures

G、 Safety and Performance

i. IEC 60601-1:2005+AMD1:2012 / EN 60601-1 :2006+ A1 2013 CSV Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

ii. Evaluation per standard AAMI/ANSI/ES60601-1 and IEC 60601-1-2 were performed for use of the transducers with a specific adaptor (Apple Model A1385) to charge the medical device.

iii. IEC 60601-1-2: 2014 / EN 60601-1-1 :2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Capability - Requirements and tests

iv. EN IEC 60601-2-37 2007 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

v. EN IEC 62304 2006 Medical device software - Software life cycle processes

vi. IEC 62366-1: 2015/EN 62366-1:2015 Medical devices - Application of usability engineering to medical devices

vii. IEC 60601-1-6 / EN 60601-1-6 Usability

viii. ISO 15223-1 2016 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

H、 Quality management

i. ISO 13485 2016 Medical Devices - Quality Management

Systems - Requirements for Regulatory Purposes

I、 Labeling

i. ISO 15223-1:2016 (Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - General requirements)

Symbols

Symbol	ription
	This icon indicates information material or helpful suggestions.
	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings, cautions and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Consult Operators Manual
	Electrical protection. Insulated application with IEC60601-1 (Type BF applied part)
	Wi-Fi. This symbol means wireless communication
	Non-ionizing radiation
	This way up. Indicates this correct upright position of the transport package.
	Manufacturer. Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC,93/42/EEC and 98/79/EC
	Batch Code. Indicates the manufacturer's batch code so that the batch or lot can be identified
	Serial number. It means manufacture’s serial number and the medical device can be identified.
	Model name. It means manufacture’s Model name and the medical device can be identified.

	Fragile and handle carefully. Indicates a medical device that can be broken or damaged if not handled carefully.
	Non-sterile
	Keep dry. It means a medical device which needs to be protected from moisture.
	Indicates medical device that should not be used if the package has been damaged or opened.
	Atmospheric pressure limitation
	Indoor use only. To identify electrical equipment designed primarily for indoor use.
	Requires separate collection for electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE). Directive. When accompanied by or, components of the device may contain lead or mercury, respectively, which must be recycled or disposed of in accordance with local, state federal laws. The backlight lamps in an LCD system monitor contain mercury.
	To identify electrical and electronic equipment that meets the Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU.
	European Conformity. Conforms to European Council Directive 93/42/EEC.
	Recyclable material. To indicate that the marked item or its material is part of a recovery or recycling process.
Rx Only	Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner (USA).
	MR Unsafe an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.

	Medical device Indicates the item is a medical device
	Unique Device Identifier Indicates a carrier that contains Unique Device Identifier information The use of this symbol is optional, but may be used when multiple data carriers are present on the label. If used, this symbol shall be placed adjacent to the Unique Device Identifier carrier. NOTE Used to identify which information is associated with Unique Device Identifier
	Model number To identify the model number or type number of a product This symbol shall be accompanied by the model number or catalogue number of the product, adjacent to the symbol.

A. Label ID

No.	Models	Label Current Version
1	LU300L	
5	LU300C	
6	LU300M	
7	LU300PA	

V. DEVICE MAINTENANCE

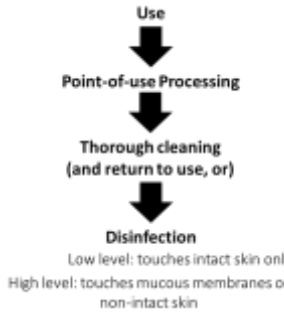
B. WARNING

1. It is your responsibility to appropriately clean and disinfect your compatible smart device in accordance with the device manufacturer's instructions and with your institution's policies for cleaning and disinfecting of medical devices.
2. If the compatible smart device becomes contaminated internally with bodily fluids containing pathogens, you must immediately notify your Manufacturer service representative. Components inside the device cannot be disinfected. In that case, the device must be disposed of as biohazardous material in accordance with local or federal laws.
3. Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.
4. Protective covers are recommended for transrectal and intravaginal procedures; in some regions, the covers are mandatory. Manufacturer recommends the use of qualified covers.

C. Reprocessing Equipment

1. Cleaning & Disinfecting

2. Proper reprocessing instructions is essential to ensure the device performance effective and prevent the microbial transmission or patient infections. The compatible smart device is a not disassembled device. A flowchart of reprocessing is presented below. Each detailed reprocessing step are listed in the following sections.



3. Point-of Use Processing
   - a Items to be used: Single-use paper towel.
   - b Please noted that the abovementioned item must not include any abrasive parts or contain any abrasive cleanser.
   - c Turn off the device.
   - d Use a gentle wiping motion to remove all visible soil or particulate matter from the transducer surface using a clean single-use paper towel.
   - e Visually inspect and confirm all the transducer surface with no visible residual soil or particulate matter. If some debris or contaminants dried on the transducer surface, please follow the cleaning instructions (following Section) to remove it.
   - f Confirm that the compatible smart device shows no cracks or other damages. If appeared, please immediately contact the local distributor or Manufacturer's service representative.
4. Thorough Cleaning
   - a Transducers must be cleaned before each use and it suggested the parts that may be cleaned with isopropyl alcohol are the transducer housing and lens (acoustic window). Inspect all parts of the transducer carefully before each use. Check for cracks or other damage that jeopardizes
   - b the integrity of the transducer. Report any damage to the Manufacturer's agent and discontinue use of the transducer.
   - c Using non-recommended disinfectants, using incorrect solution strengths, or immersing a transducer deeper or longer than recommended can damage or discolor the transducer and voids the transducer warranty.
5. Disinfection
   - a Spaulding classifications are a tool to help reduce cross-contamination and infection by specifying the level of cleaning and disinfecting required for medical equipment. Based on these criteria, the compatible smart device is classified as "non-

critical" or "semi-critical" device, because the device is to scan the skin surface or mucous membranes and do not penetrate it. Therefore, "cleaning" and "low level disinfection" for non-critical and "cleaning" and "high level disinfection" for semi-critical device are required for the next use.

Class	Use	Method	Example
Non-critical	Touches intact skin	Cleaning followed by low-level disinfection.	Convex, Linear, Phase, Microconvex
Semi-critical	Touches mucous membranes or non-intact skin	Cleaning followed by high-level disinfection.	Endocavity

It is important to clean and disinfect the ultrasound probe before and immediately after use. This chapter will guide you through the cleaning and disinfecting process.

When cleaning and disinfecting:

- Follow the procedures in the order they are described in this guide, without skipping steps.
- Use only 70% Isopropyl Alcohol on the device. Other solutions may be incompatible with the system and could damage the scanner.
- Follow the manufacturer's instructions, recommendations, and guidelines for cleaners and disinfectants, as well as your regional regulations.
- Check expiry dates, concentration, and efficacy of the chemicals used.
- Wear the appropriate personal protective equipment (PPE), such as eyewear and gloves, as recommended by the chemical manufacture.
- Repeated use and cleaning over the course of the scanner's life may deteriorate its cleanliness.
- Using incompatible solutions to clean the scanner may damage its surface.
- The scanner and its parts (including accessories) may not withstand the cleaning or disinfecting processes (including repetitive process) specified in this manual and may damage or deteriorate its safety provisions.
- Cleaning or disinfecting the scanner while the battery is charging may cause the battery to short-circuit and overheat, causing an electric shock or burn.
- Cleaning or disinfecting the scanner using **other than** IPA (isopropyl alcohol) may damage it.
- During an emergency where the scanner is used to examine multiple patients in a short period of time, the lack of proper cleaning and disinfecting between patients may spread infections to other patients and users.

- Recommendations for cleaning the ultrasound probe as following step:
- Turn off your devices before cleaning it.
- To be ensured that all the coupling gel and other visible substances from the probe is removed by wiping with a clean paper towel. If necessary, to remove material dried to the surface, the cloth can be moistened with lukewarm water.
- It shall inspect the probe's lens and casing after each use. To check out any damage that would allow liquid to enter the probe. If the user found a probe damage, the probe shall not be placed into any liquid (e.g., for disinfection) and shall not be used until it has been inspected and repaired/replaced by Leltek or a local distributor for service.

Recommendations for disinfecting the ultrasound probe (After cleaning):

- Spray 70% Isopropyl Alcohol onto the surface of probe head.
- Repeat step one for two or three times.
- Wipe out the disinfectant with a clean paper towel.

Model	Photo
LU300L	
LU300C	
LU300M	

Model	Photo
LU300PA